

FDA PUBLIC MEETING  
CLINICAL ACCURACY REQUIREMENTS FOR  
POINT OF CARE BLOOD GLUCOSE METERS  
March 16, 2010

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1 DR. HARPER: Good morning everyone. My  
2 name is Courtney Harper and I'm the director of the  
3 Division of Chemistry and Toxicology Devices at the  
4 Food and Drug Administration, and I'd like to welcome  
5 you all to our public meeting on blood glucose meters.  
6 We're very excited to have you all here, and we really  
7 think that this is a great opportunity for us at FDA  
8 to hear from stakeholders about this important topic,  
9 blood glucose meters and their use in the lay-user  
10 population, and also in health care facilities and  
11 settings.

12 So I hope you all are looking forward to the  
13 next two days as much as I am. I'm going to give a  
14 few logistics, and then I'm going to introduce Dr.  
15 Jeff Shuren, our Center Director, who is going to  
16 officially open this meeting.

17 So a couple of housekeeping items. For  
18 lunches on today and tomorrow, lunch is on your own.  
19 The hotel actually offers a buffet and other menu  
20 items, but we've also provided in your packet some  
21 information about some of the local lunch areas that  
22 you can find nearby, within walking distance or

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1 driving distance.

2 We will be strictly adhering to the start  
3 times of the sessions, so please be prompt in  
4 returning to your seats. I believe there's a bell  
5 that may significant the start of each session. And  
6 we ask that you turn off all cell phones to be  
7 courteous to those around you.

8 So before I review the format for today, I  
9 am going to remind you that transcripts of this  
10 meeting can actually be obtained approximately ten  
11 days after the meeting, and the instructions for  
12 obtaining those transcripts are actually located in  
13 the FR notice, which can be linked through this public  
14 meetings website. So you can go on line and find out  
15 how to get transcripts of the meeting if you're  
16 interested. We ask that you actually contact speakers  
17 individually if you would like copies of their  
18 presentations, to ask them if they're willing to share  
19 them.

20 So the format of this meeting, we actually  
21 have three sessions; two sessions are today. The  
22 first session is on the clinical accuracy requirements

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1 for blood glucose meters, and the second session is on  
2 glucose meter interferences and limitations. And  
3 tomorrow we will be talking about tight glycemic  
4 control in health care facilities, and also a couple  
5 of topics on user error and liability.

6 For each of these sessions the moderators  
7 will be introducing the topic. If there is time at  
8 the end of each presentation, we'll take a few  
9 questions. Then there will be presentations from the  
10 speakers in that area, and following that there will  
11 be a panel discussion by panelists. The panels will  
12 consist of the speakers from that session, and in some  
13 cases a few other selected experts.

14 Our moderators will lead the panel  
15 discussions. The moderators may have some questions  
16 for the panel that they want the panel to address, but  
17 we would also really encourage audience participation  
18 in that portion of the program. We would really like  
19 people to come up to the microphones that are set up  
20 in the aisles, and address some questions to the panel  
21 that you would like discussed. Also, if you have any  
22 comments or points of view, we would be very happy to

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1 hear from you on those.

2           The microphones are set up in the aisles, as  
3 I said. We ask a couple of things, though; first,  
4 that you identify yourself prior to asking a question  
5 or giving a brief comment, and second, that you limit  
6 your comments to a minute or less so that they can be  
7 brief. So questions to the panel or brief comments or  
8 a point of view are quite welcome.

9           So now it's my great pleasure to introduce  
10 Dr. Shuren. Dr. Shuren became the Director of The  
11 Center for Devices and Radiological Health in January  
12 of 2010. Before that he was our acting Center Director  
13 since September. Our Center is responsible for  
14 assuring the safety, effectiveness and quality of  
15 medical devices, assuring the safety and quality of  
16 radiation-emitting products, such as cell phones and  
17 microwaves, and for fostering device innovation, which  
18 is why we're here today.

19           Dr. Shuren received his Bachelor of Science  
20 and Medical Doctorate Degrees from Northwestern  
21 University under its Honors Program in Medical  
22 Education. He completed his Medical Internship at

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1 Beth Israel Hospital in Boston, his Neurology  
2 Residency at Tufts New England Medical Center, and a  
3 Fellowship in Behavioral Neurology and Neuropsychology  
4 at the University of Florida. He received his J. D.  
5 from the University of Michigan. He has  
6 held various policy positions and planning positions  
7 within the FDA from 1998 to 2009, including Acting  
8 Deputy Commissioner for Policy, Planning and Budget,  
9 Associate Commissioner for Policy and Planning,  
10 Special Counselor to the Principal Deputy  
11 Commissioner, Assistant Commissioner for Policy and  
12 Medical Officer in the Office of Policy.

13 Dr. Shuren has served in the leadership role  
14 at FDA, or on behalf of the Agency, on numerous  
15 initiatives, just to name a few, including the  
16 reauthorization of The Medical Device User Fee Act,  
17 the creation of the Sentinel Initiative and the  
18 development of FDA's Pandemic Influenza Preparedness  
19 Strategic Plan. So we're in good hands, and I would  
20 really like you to join me in welcoming Dr. Shuren.

21 DR. SHUREN: Thank you, Courtney. Good  
22 morning. Can everyone hear me in the back? Good. I

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1 ask because I'm known to mumble, and this actually got  
2 me in trouble the other week. So I don't know if  
3 you've ever been out to our White Oak facilities, but  
4 if you go, particularly the conference rooms on the  
5 ground floor, they have glass windows. And just about  
6 ten days ago I had this professor come in, an elderly  
7 gentleman, very nice, and he started talking and I  
8 started to answer his questions. He goes, well, I  
9 can't hear you, I'm a little hard of hearing. So I  
10 speak up. I really can't hear you. So the next thing  
11 I know, I'm talking very loudly. After the meeting  
12 some people came up to me and said, why were you  
13 yelling at that old man? So I want to make sure I get  
14 it right.

15 Well, thank you for joining us, either in  
16 person or on webcast, for today's meeting on the  
17 clinical accuracy of blood glucose meters. If you're  
18 viewing via the web and would like to comment on  
19 anything that you see or hear today, I encourage you  
20 to submit written comments to the docket, which will  
21 remain open until April 20.

22 Diabetes affects individuals of all ages,

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1 from infants to the elderly. There are currently at  
2 least 24 million Americans with either Type I or Type  
3 II diabetes, and likely many more cases that have yet  
4 to be diagnosed. Over the past 20 years, the number of  
5 people diagnosed with diabetes has increased from 30  
6 million to 250 million worldwide. And the prevalence  
7 of the disease, if it continues to increase, is  
8 estimated to be, in 2025, as many as 350 million  
9 diabetics worldwide. The numbers are staggering.

10 Without proper management, diabetes can have  
11 devastating consequences. Let me quickly run through  
12 some statistics. Diabetes increases the risk of  
13 cardiovascular disease by up to a factor of four. It  
14 accounts for thousands of emergency room visits each  
15 year, and is the leading cause of kidney failure and  
16 adult onset blindness. Additionally, complications  
17 for diabetes can lead to more than 80,000 amputations  
18 each year.

19 The importance of blood glucose meetings in  
20 the management of control of diabetes is  
21 unquestionable. Thirty percent of those diagnosed with  
22 diabetes require insulin, and are likely to use blood



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1 glucose meters. These devices are used by patients  
2 themselves for self- monitoring, and also by health  
3 care providers in a variety of clinical settings such  
4 as hospitals, emergency response units, nursing homes  
5 and physicians' offices.

6           We're here today to discuss issues related  
7 to point- of-care use of blood glucose meters. FDA  
8 receives approximately 12,000 adverse event reports  
9 associated with blood glucose meters each year. Many  
10 reports highlight issues related to the analytical and  
11 physiological limitations of these devices to the lay  
12 users, whether at home or in the clinical setting,  
13 influence the performance of these devices, and to the  
14 way performance may vary under different conditions of  
15 use. This workshop will focus on three important  
16 topics related to blood glucose meters performance.

17           Session 1 will focus on the clinical need  
18 for accuracy in blood glucose meters, and the reality  
19 of what point-of-care meters are capable of achieving.  
20 To evaluate pre-market submissions of blood glucose  
21 meters, FDA currently applies the principles outlined  
22 in our own guidance on glucose meters, and ISO 15197

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1 Standard. Some in the clinical and patient  
2 communities have questioned whether the current FDA  
3 recognized accuracy standards for blood glucose meters  
4 are acceptable, and have challenged FDA to require  
5 tighter performance requirements. Others believe the  
6 current analytical performance of glucose meters is  
7 adequate, and that there is no evidence to support the  
8 need for higher standards.

9 We are interested in hearing about what the  
10 appropriate analytical and clinical accuracy  
11 requirements for blood glucose meters should be. This  
12 discussion is very timely, since we are currently  
13 updating our guidance and the ISO Standard is going  
14 through revision.

15 Session 2 will focus on medications and  
16 other substances that interfere with the technologies  
17 blood glucose meters employ. Performance of blood  
18 glucose meters may be affected by administered drugs,  
19 common physiological conditions such as diabetic  
20 ketoacidosis and user interface issues. For example,  
21 administration of therapies containing maltose, which  
22 are commonly prescribed to patients in the hospital,

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1 have resulted in falsely elevated glucose readings. We  
2 are interested in hearing about analytical  
3 interferences and physiological limitations, an issue  
4 that is not unique to blood glucose meters, but rather  
5 one that the majority of point-of-care technologies  
6 face.

7           The third and final session, to take place  
8 tomorrow, will focus on the use of blood glucose  
9 meters for tight glycemic control in clinical  
10 settings. Despite the fact that these devices have  
11 not been approved for this use, glucose meters are  
12 increasingly being used to achieve tight glycemic  
13 control. Over the past three decades, blood glucose  
14 meters have become smaller, faster and more accurate,  
15 and they now allow for better glycemic control than in  
16 the past. However, there is no consensus that blood  
17 glucose meters currently on the market are accurate  
18 enough to be used in this way. We're interested in  
19 hearing about the benefits and risks of using glucose  
20 meters to achieve and maintain tight glycemic control.

21           We've assembled an impressive and  
22 distinguished list of speakers for this meeting. They

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1 will provide a basic framework from which to begin our  
2 discussions. The roughly 400 participants and  
3 attendants at this workshop, you, form an equally  
4 impressive group. You represent health care  
5 providers, diabetic educators, professional  
6 organizations, and perhaps most importantly, the  
7 people who use these meters every day, either for  
8 self- monitoring or for clinical care. I encourage  
9 you to engage in the discussions today and tomorrow,  
10 share your questions, as they might shed further light  
11 at the issues at hand, and please also share your  
12 ideas for solving the problems we will be discussing  
13 today and tomorrow.

14 I'll conclude by leaving you with two  
15 critical questions that we want you to keep in mind  
16 and address during this workshop. First, how should  
17 the FDA address and balance the clinical needs of  
18 diabetics and the technological limitations that are  
19 inherent to fast and relatively simple blood glucose  
20 meters. Second, what steps should the FDA take to  
21 improve the quality of point-of-care blood glucose  
22 meters, and what are the responsibilities of industry,

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1 the health care professional community and consumers,  
2 to assure that point-of-care blood glucose meters are  
3 safe and used safely.

4 Thank you very much for joining us today and  
5 tomorrow, and I look forward to a very lively dialog.

6 DR. HARPER: Thank you, Jeff. I'd like to  
7 now introduce Dr. Bill Clarke. Dr. Clarke is the  
8 Robert Blizzard Professor of Pediatrics and Chief of  
9 Pediatric Endocrine Division at the University of  
10 Virginia School of Medicine, in Charlottesville,  
11 Virginia. He is the author of over 130 Journal  
12 articles, has served on several editorial boards, and  
13 has been associate editor of Growth, Genetics and  
14 Hormones for the past 15 years.

15 Dr. Clarke is a graduate of Duke University  
16 and Vanderbilt University School of Medicine, and did  
17 his pediatric and endocrine training at Washington  
18 University in St. Louis, Missouri. He is board  
19 certified in Pediatrics and Pediatric Oncology.

20 You all are familiar with Dr. Clarke's error  
21 grid, which has been useful in the evaluation of the  
22 performance of glucose meters. His research

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1 interests involve understanding glucose counter-  
2 regulation and devising methods for improving glucose  
3 control in children with Type I diabetes, including  
4 recent contributions regarding the accuracy of  
5 continuous glucose sensors and the artificial  
6 pancreas. Dr. Clarke has been honored by the American  
7 Diabetes Association for his work and outstanding  
8 contributions to diabetes in youth, and has been  
9 listed in Best Doctors in America. Welcome, Dr.  
10 Clarke.

11 DR. CLARKE: Thank you. I'm always a little  
12 bit technologically impaired. Well, I was given ten  
13 minutes to be the moderator, so I am going to take my  
14 ten minutes but no longer.

15 I do have some questions and some comments  
16 that I think are important for us to think about this  
17 morning as we talk about clinical accuracy  
18 requirements for blood glucose meters, the first of  
19 which is what we mean by accuracy standards for  
20 glucose monitors. This is the current FDA  
21 requirements for blood glucose monitors, for self-  
22 blood glucose monitor accuracy, and I think that we're

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1 going to be spending a lot of time talking about ISO  
2 criteria, and maybe even some time talking about the  
3 error grid analysis and strictly clinical accuracy of  
4 the systems a little bit later.

5           Now, from my standpoint, clinical accuracy  
6 means that the information that is presented to one  
7 can result in a clinically accurate treatment  
8 decision. And those decisions may be different in  
9 different situations, and I think we're going to talk  
10 about that over the course of the next couple of days.  
11 Specifically, self-blood glucose monitors were  
12 developed for patients and for health care  
13 professionals to guide clinical decisions. And there  
14 are a lot of us who were around at the time when they  
15 were developed, so that people didn't have to collect  
16 urine samples to make clinical decisions. With these  
17 systems, I think it's important to point out that we  
18 conducted a 10-year diabetes control and complications  
19 trial, which is the largest clinical trial ever, and  
20 we got very, very significant results. So they can  
21 really, really help us, even in their current form.

22           The other important factor is, I am unaware

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1 of any superiority studies with one meter versus  
2 another. Do people have less hypoglycemia on one  
3 system than another, more DKA, do they have better  
4 hemoglobin A1Cs?

5 Fourth, here, it's very important that the  
6 ADA has said that they are not acceptable for  
7 diagnosing diabetes, and the FDA will tell you that  
8 their use is really not approved in intensive care  
9 units.

10 So, where are the problems and what are the  
11 problems that we're kind of looking for? I think it's  
12 going to be a little bit of a challenge for us to look  
13 at this, but here are some reasons I think of for  
14 concerns regarding accuracy: Hypoglycemia, it's still  
15 the barrier to normal blood sugar levels. Glycemic  
16 variability causes oxidative stress. Failure to  
17 achieve hemoglobin A1C targets. Cognitive dysfunction,  
18 which is now reported in people with frequent low  
19 blood glucose and frequent high blood glucose.  
20 Depression, which is rampant in the diabetic  
21 population. And new uses, such as in the intensive  
22 care unit. Krouwer and Cembrowski, and I saw Dr.



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1 Cembrowski here just a few minutes ago. I didn't  
2 speak to him, but they talk about total error, and  
3 this is part of the presentation you're going to hear  
4 later. But if you look at total error, or total  
5 accuracy, which is the way I changed it, notice that  
6 analytical, clinical and statistical really only form  
7 a small portion of the accuracy, and I think that's  
8 because there are limitations. And those limitations  
9 may be particularly in the area of interpretation and  
10 response.

11 A paper in diabetes care last month, with an  
12 internet survey of people with Type I diabetes,  
13 demonstrated that over 50 percent of people omitted  
14 insulin, and over 30 percent intentionally omitted  
15 insulin. Peter Chase at the Barbara Davis Center has  
16 shown that if you omit one injection a week, it's  
17 approximately a .5 increase in the hemoglobin A1C  
18 level.

19 So what are we trying to really achieve  
20 here? Dr. Breton's going to tell us about some  
21 simulation studies later, and insulin delivery. If  
22 you're talking about giving a dose of five units or

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1 less, well, we know that the accuracy of that is at  
2 least plus or minus one unit, that's 20 percent. For  
3 children that's a big deal, because that may be what  
4 their insulin dose is prior to a meal. And then there  
5 are all kinds of health care professional factors that  
6 I'm not going even begin to talk about.

7 I like to always show the error grid. I  
8 think most of you are familiar with it, but I want to  
9 also show you how it can be modified when one changes  
10 the target range. So here you see the target range is  
11 70 to 180. Here is the target range of 80 to 110,  
12 which is what's commonly being talked about for  
13 intensive care unit purposes. And notice that what  
14 happens is, that when you scrunch that target range,  
15 you increase the errors by a significant amount.

16 Pardon my drawings, but the computer program  
17 for doing error grid was down, so I can guarantee you  
18 that this is accurate. I'm not a good colorer and  
19 actually, my junior faculty associate pleaded with me  
20 to be allowed to make these on his computer, and I  
21 told him, no, he needed to go do his research.

22 Anyway, the original error grid is on the

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1 left. Here on the right is what happens to the error  
2 grid when you say, well, we're only going to have plus  
3 or minus 5 percent be considered accurate. So you  
4 really, really squeeze down that accurate range and  
5 increase again your other errors, and perhaps your  
6 benign errors as well. If you do both, squeeze down  
7 the zone A or the accuracy to plus or minus 5 percent,  
8 and move the target to 80 to 120, what you see is that  
9 there's a very narrow window in which you can be  
10 clinically accurate, and lots of overtreatment. Either  
11 too much insulin or not, decisions that could be made,  
12 at least based on what we have right now.

13           Finally, I think we need to talk about how  
14 we will evaluate a change in meter accuracy. Will  
15 superiority be our goal, or will equivalency -- I  
16 apologize for the spelling -- be tolerated, and poor  
17 spelling can be certainly tolerated. At the current  
18 moment, I think there's only one decision that can be  
19 made using a blood glucose monitor, and that is, my  
20 blood sugar is low and I need to eat something now.  
21 And any other decision is going to be based on what  
22 the previous glucose is, and so maybe we really need

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1 to be talking about continuous systems and trends and  
2 rates of fall and direction of change, in order to  
3 make an intelligent clinical decision.

4 Well that's my last slide. I hope that I've  
5 given you some things to think about over the next day  
6 or so, and we will move on to our first speaker, who  
7 is Patricia Bernhardt. Ms. Bernhardt is a scientific  
8 reviewer here at FDA, and she is involved in pre-  
9 market clearance and approval, and has been since  
10 1997. And so she is going to present for us the FDA  
11 perspective on evaluation of point-of-care blood  
12 glucose meters. And would somebody like to clear  
13 that, and we'll escape this, maybe, and go to your  
14 talk.

15 MS. BERNHARDT: Thank you, Dr. Clarke, and  
16 good morning, everyone. Blood glucose monitoring  
17 systems are used by diabetics in the United States  
18 every day. They have been around for more than three  
19 decades, and during that time they have become  
20 smaller, faster, easier to use and more accurate. They  
21 are used not only by diabetic patients, but also by  
22 health care providers in a variety of settings such as

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1 hospitals, nursing homes, emergency response units and  
2 in physicians' offices.

3           Before I talk about FDA's evaluation of blood  
4 glucose monitoring systems, I'm going to provide a  
5 brief overview of the medical device regulations.  
6 Congress gave FDA the authority to regulate medical  
7 devices under the 1976 Medical Device Amendments to  
8 the Federal Food, Drug and Cosmetic Act. So, how are  
9 medical devices regulated?

10           They're regulated by intended use, they're  
11 risk-based by intended use in to three  
12 classifications: Class 1, which is low risk; Class 2,  
13 which are moderate risk; and Class 3, which are high  
14 risk.

15           Now, how do blood glucose monitoring systems  
16 fit into this picture? Blood glucose monitoring  
17 systems are in a category of medical devices called in  
18 vitro diagnostic devices, or IVDs. By definition, an  
19 IVD is a reagent instrument or system intended for use  
20 in the diagnosis of a disease or other conditions,  
21 including a determination of the state of health, in  
22 order to cure, mitigate, treat or prevent disease, or

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1 its sequellae in man. They are for use in the  
2 collection, preparation and examination of specimens  
3 from the human body. IVDs are used in clinical  
4 laboratories, point-of-care sites such as operating  
5 rooms, emergency room, nursing units, nursing homes,  
6 and by patients at home.

7           FDA regulates IVDs by their intended use and  
8 the risk of an incorrect result. For example, a high-  
9 risk IVD could be an HIV test, where the risk of a  
10 false negative result could expose others to the  
11 disease. All IVDs must establish adequate analytical  
12 and clinical performance, and IVDs have their own  
13 unique labeling regulations, which require that  
14 certain information such as intended use, limitations  
15 and performance are in the product labeling.

16           So blood glucose monitoring systems as IVDs  
17 are Class 2 devices that have a moderate risk. They  
18 require FDA clearance. They must be substantially  
19 equivalent to a predicate device, which means that  
20 they must be at least as good as, but do not have to  
21 be better than, a device that is already on the market  
22 with a similar intended use. FDA evaluates the

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1 intended use performance and labeling of glucose  
2 meters. So a typical intended use for glucose meter  
3 is that they are for the quantitative measurement of  
4 glucose and whole blood by lay users at home, or by  
5 health care professionals in clinical settings, to  
6 assist in the ongoing evaluation and management of  
7 individuals with diabetes. They are for monitoring,  
8 not for diagnosing or screening. And currently there  
9 is no distinction between the performance requirements  
10 for over-the-counter and professional use glucose  
11 meters. So when a glucose meter is cleared for over-  
12 the-counter use, it can also be used in professional  
13 settings.

14           The components of a blood glucose monitoring  
15 system typically include a meter, test strips, quality  
16 control solutions and sometimes lancing devices,  
17 lancets and alcohol wipes. Although sometimes more  
18 than one meter from a single manufacturer can use the  
19 same test strip, FDA considers each meter and test  
20 strip, when used together, to be a separate system,  
21 and each system requires its own performance and is  
22 evaluated separately.

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1           There are different samples types that can  
2 be used with glucose meters, and each sample type  
3 requires FDA review and clearance. All meters  
4 typically use capillary whole blood from finger  
5 sticks, but in addition, some use arterial, venous or  
6 neonatal blood. Also capillary blood from sites other  
7 than the finger, such as the forearm, upper arm, palm,  
8 thigh or calf, is sometimes used. This is known as  
9 alternative site testing, or AST.

10           Glucose measurements from alternative sites  
11 can differ significantly from measurements from the  
12 finger at certain times, and require specific  
13 instructions for use that define the appropriate times  
14 when alternative site testing can and cannot be used.  
15 There are a variety of guidances, guidelines and  
16 standards that FDA currently uses in the evaluation of  
17 blood glucose monitoring systems. This list shows  
18 some of these documents. The documents provide  
19 recommendations for the types of information and data  
20 to be evaluated for glucose monitors, and are used by  
21 industry to prepare FDA submissions, and by FDA when  
22 reviewing the submissions.



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1           To evaluate the performance of glucose  
2 meters, FDA looks at factors. To evaluate the  
3 precision of a blood glucose monitor, we look at  
4 repeatability and intermediate precision. We evaluate  
5 glucose concentration spread across the measuring  
6 range, and determine the variation and repeated  
7 results over time. One way to evaluate accuracy is  
8 with method comparison. Method comparison studies are  
9 conducted to demonstrate how well results compare to a  
10 reference method. A reference method, such as the  
11 YSI, is defined as one that is well validated for  
12 precision and trueness, and is traceable to a  
13 recognized glucose standard, such as the National  
14 Institute of Standards and Technology standard  
15 reference material.

16           Method comparison studies are conducted on a  
17 minimum of 100 capillary samples that span the  
18 measuring range of the device. Because it's hard to  
19 find samples with glucose concentrations at the  
20 extreme low and high ends of the measuring range, a  
21 small number can be spiked or altered to achieve those  
22 levels.

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1           The results of the method comparison study  
2 are evaluated with a variety of statistical  
3 presentations to determine system accuracy. The term,  
4 system accuracy, means how well the results agree with  
5 truth. And total system accuracy includes elements of  
6 imprecision and interferences as well. The current  
7 FDA minimal acceptable system accuracy, and accuracy  
8 in the hands of lay users, is that 95 percent of  
9 individual glucose results shall fall within plus or  
10 minus 15 milligrams of the results of the reference  
11 measurement at glucose concentrations less than 75,  
12 and 95 percent of individual results shall fall within  
13 plus or minus 20 percent at glucose concentrations of  
14 greater than or equal to 75. This criteria is the  
15 current recommended ISO 15197, standard criteria for  
16 system accuracy.

17           Now to see how well the device performance  
18 meets the minimum acceptable criteria, the data from  
19 the meter is presented in two tables that show the  
20 number and percent of results that are within 15, 10  
21 and 5 milligrams per deciliter of the reference  
22 results for samples with concentrations less than 75,

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1 and within plus or minus 20, 15, 10 and 5 percent of  
2 reference results for samples with concentrations  
3 greater than or equal to 75. This format is  
4 recommended by ISO 15197. A minimum of 95 percent of  
5 the results must meet the minimum acceptable criteria  
6 for both less than 75, and greater than or equal to  
7 75.

8           It's interesting to note that in a recent  
9 internal evaluation of glucose meters cleared in the  
10 last two years, we saw that approximately 72 percent  
11 of them would meet a plus or minus 10 milligrams per  
12 deciliter for concentrations less than 75, and  
13 approximately 50 percent would meet plus or minus 15  
14 percent at concentration greater than or equal to 75.

15           In addition to method comparison, we  
16 evaluate performance in the hands of lay users. We  
17 look at studies conducted with a minimum of 100  
18 participants. The participants collect and measure  
19 their own finger stick samples, using only the  
20 instructions for use that will be provided with the  
21 marketed device. A health care professional also  
22 obtains samples from the participants at the same time

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1 to run on the reference device. A statistical  
2 comparison is made between the lay user results and  
3 the reference, and the results are presented in the  
4 ISO recommended tabular format that I just showed you.  
5 In addition, FDA evaluates the results from  
6 questionnaires given to the study participants to  
7 assess the readability of the labeling, and the ease  
8 of use of the device.

9           When a claim is made for alternative site  
10 testing, FDA also evaluates data from studies where  
11 lay users obtain and run their own samples from each  
12 alternative site being claimed. The subject should be  
13 in a steady state condition, which means times when  
14 their blood glucose is stable, and results from each  
15 site are compared to a sample obtained by a health  
16 care professional at the same time, and tested on a  
17 reference method. This data from each site must meet  
18 the minimum acceptable accuracy criteria, and is also  
19 presented in the ISO recommended tabular format.

20           Other sample types that we evaluate are  
21 venous and arterial when claims are made for those  
22 matrices. Data from study comparing the results from

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1 each matrix to a reference are evaluated. The samples  
2 are collected in the appropriate anticoagulant, and  
3 they span the measuring range. For neonatal claims,  
4 as mentioned on the slide that showed the guidance  
5 documents that we use, there is an FDA guidance that  
6 provides recommendations on the study, design and data  
7 collection for neonatal studies. The critical glucose  
8 range for these samples is 10 to 15 milligrams per  
9 deciliter, which hematocrits between 45 to 65 percent,  
10 so extra attention is paid to samples with those  
11 values.

12           FDA also evaluates linearity which refers to  
13 the ability of the device to provide results directly  
14 proportional to the true concentration across the  
15 measuring range. In other words, how well the device  
16 results compared to true results conformed to a  
17 straight line. We evaluate multiple replicates of  
18 multiple points across the entire claimed reportable  
19 range. We look at the line of regression and the  
20 different plots as recommended in Clinical Laboratory  
21 Standards Institute's guidelines on the evaluation of  
22 linearity of quantitative measurement procedures.

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1           Now all IVDs have some interference from  
2 certain compounds, and blood glucose monitors are no  
3 exception. When we evaluate interference with glucose  
4 meters, we identify the substances that interfere and  
5 define the extent of the interference. There are  
6 common endogenous and exogenous substances that can  
7 interfere with glucose meters. Endogenous refers to  
8 substances naturally found in the patient's blood,  
9 such as cholesterol or bilirubin, and exogenous refers  
10 to substances such as drugs.

11           We evaluate endogenous and exogenous  
12 substances that have been known to interfere with  
13 glucose methodology. The endogenous substances, such  
14 as cholesterol, are evaluated at the highest levels at  
15 which they are known to occur in patients' blood. The  
16 exogenous substances, such as acetaminophen, are  
17 evaluated at therapeutic levels and at the highest  
18 levels at which toxic doses may occur. Samples are  
19 evaluated at clinically relative decision points, and  
20 the calculated bias, or difference, of the sample  
21 containing the interferent to the reference should not  
22 be greater than plus or minus 10 percent.

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1           For hematocrit, we evaluate samples with  
2 glucose concentrations that span the measuring range  
3 at hematocrit levels that span the claimed range. We  
4 compare individual results of each hematocrit and  
5 glucose combination to results of a sample at the same  
6 glucose concentration with a normal hematocrit, and  
7 also to a reference value. The calculated bias should  
8 not be greater than plus or minus 15 percent for  
9 hematocrit interference.

10           Other factors that we evaluate are  
11 environmental effects such as temperature, humidity  
12 and altitude, and we also look at conformance to the  
13 International Electrical Commission Standards for  
14 medical electrical equipment. We also look at  
15 electromagnetic compatibility, and we look at  
16 software.

17           And lastly, FDA evaluates the labeling of  
18 blood glucose meters. The term labeling refers to all  
19 printed material that will be provided with the  
20 marketed device. This includes user manuals, test  
21 strip inserts, quality control solutions inserts,  
22 quick reference guides, if applicable, and also box

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1 and container labels. As mentioned earlier, IVDs have  
2 their own labeling regulation, so when we evaluate  
3 glucose meter labeling, we make sure it contain the  
4 required elements, such as intended use, instruction  
5 for use and performance, as mentioned earlier. And  
6 since most glucose meters are for over-the-counter  
7 use, we evaluate the readability assessments of the  
8 labeling to ensure that it is written at no higher  
9 than eighth grade level.

10           So in summary, I have talked about many  
11 individual factors that can affect blood glucose  
12 meters. However, another factor that I haven't  
13 touched upon is user error. User error, intentionally  
14 or unintentionally, is misuse of the device, or when a  
15 user does not follow the instructions for use, or  
16 disregards the limitations and warnings in the  
17 labeling. This will be discussed in a separate  
18 session tomorrow. But the factors that I have  
19 discussed, and their effects on blood glucose  
20 monitoring systems, are those that can occur when the  
21 device is being used as intended, with the limitations  
22 heeded and the instructions appropriately followed.



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1 And while we evaluate each of these factors  
2 individually, and determine the individual acceptable  
3 limits where appropriate, it is important to realized  
4 that the user experiences the cumulative effect of  
5 these factors. Thank you for your attention, and I  
6 think we have time for any questions.

7 DR. CLARKE: If you have any questions for  
8 Ms. Bernhardt, she is the FDA person who is speaking  
9 this morning, so please come forward and state your  
10 name and ask your question. (Pause) You had your  
11 chance. Okay.

12 The next speaker for this morning is Dr.  
13 Mitchell Scott, who is Professor of Pathology and  
14 Immunology at Washington University School of  
15 Medicine, and he is going to talk to us about  
16 analytical performance of blood glucose meters, and  
17 give us a state-of-the-art presentation. Dr. Scott.

18 DR. SCOTT: Well, first, I'd like to thank  
19 Courtney and Arlene for inviting me, and what I would  
20 like to do today is, first, figure out the computer.

21 I'll try to sort of give us a historical  
22 perspective on glucose meter evaluations. Now there's

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1 no shortage of glucose meter evaluations in the  
2 literature, and if I stood here for 20 minutes, and  
3 went through 20 different glucose meter evaluation  
4 studies, I'm pretty sure everyone out here would be  
5 asleep by the end of it. So I'm just going to give a  
6 few representative examples, and then present some  
7 suggestions about, or actually go through the  
8 allowable error criteria that are there now. I'll talk  
9 about some data from my own institution, which is a  
10 1,200 bed academic center, and then make some  
11 suggestions about maybe where we should start the  
12 discussion in terms of allowable error criteria.

13           So I think some of these things have already  
14 been stated this morning, the meters are getting  
15 smaller, there's over 30 of them listed on the ADA  
16 Website for home use, there's five manufacturers for  
17 hospital use. It's a growing market, and it actually  
18 accounts for, according to a Frost and Sullivan  
19 report, 30 percent of all laboratory revenue, in vitro  
20 diagnostics laboratory revenue. So it's significant.

21           Recent improvement in meters, no wipe  
22 strips, sample volume detection. Most importantly

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1 from a hospital perspective is data storage and  
2 capture. It's only been five or six years that we've  
3 actually been able to capture the data from our  
4 glucose meters at our institution. Prior to that they  
5 were performed, they sometimes got written in the  
6 nursing notes, but we had no other way of capturing  
7 the data until five or six years ago. Alternate site  
8 testing was mentioned. There's a time lag issue in  
9 terms of alternate sites, and I'm not really going to  
10 discuss that because we aren't using this in the  
11 hospital at this point in time.

12 Interferences, more this afternoon: the  
13 hematocrit effect, anemia, higher glucose. Keep that  
14 in mind when you think of these meters being used in a  
15 critical care setting. Anemia is very common in  
16 intensive care units. Reducing agents, the effects  
17 vary by method; I'll show you just a few figures. But  
18 some newer meters correct for hematocrit and reducing  
19 agents. And I think the theme that I'm going to try  
20 to present through this talk this morning is that  
21 meters are getting better, and I think they can beat  
22 current criteria that are out there.

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1           So here's an example of the hematocrit  
2 effect, significant differences, particularly in  
3 hematocrits that you'll actually see in an intensive  
4 care setting, and if it's falsely elevated, is that  
5 going to cause overdosing of insulin? PO2 effect.  
6 Glucose-oxidase methods are affected, glucose  
7 dehydrogenase methods are not. Here's a glucose-  
8 oxidase method that takes it into account, and is not  
9 affected by PO2. So they're out there.

10           The maltose for the GDH methods has already  
11 been mentioned, as has user-induced errors. Now in  
12 this study, this was users actually performing self-  
13 monitoring following the package insert. And what  
14 they did in this study, it's somewhat contrived, I  
15 agree, but they had a mechanical flicker, that after  
16 the sample was applied to the strip, this little  
17 spring would hit the strip, and this is what happened  
18 to the results. So this was a sort of a reproducible  
19 way to induce user error. So you can see that just  
20 flicking the strip a little bit can greatly alter the  
21 values.

22           Okay. My main interest is the use of meters

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1 in hospital setting, so I have to mention tight  
2 glycemic control. Today, most critical areas have  
3 protocols to keep glucose below now 130 until NICE  
4 sugar was generally below 110. This requires frequent  
5 and rapid glucose values, resulting in IV insulin  
6 adjustment.

7           Now what kind of an impact has TGC had on  
8 the use of glucose meters in hospitals? In 2000,  
9 before TGC became standard care, we used about 250,000  
10 strips a year. Last year we used 550,000 strips at  
11 our institution, and almost half of those are in  
12 critical care settings. These meters are being used in  
13 intensive care units to the tune of 250,000 times a  
14 year at our institution alone.

15           So the original Van den Berghe study is  
16 blood gas instruments in arterial blood, the second  
17 use, the Hemo- Q, but very few of the TGC studies out  
18 there even tell you what method was used to measure  
19 glucose. The meta- analysis that was published in  
20 JAMA, in August of 2008, looked at 27 studies. Only  
21 ten of those studies, when I actually looked at the  
22 original papers, tell you how the glucose was

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1 measured. Two of those were the Van den Berghe  
2 studies, that didn't use glucose meters, eight used  
3 meters, and seventeen, you have no clue, it does not  
4 say how glucose was measured. In the NICE-SUGAR paper  
5 you can't tell; it says, glucose was obtained by  
6 meters or blood gas analyzers, that's it. Again, I  
7 just want to point this again as the interference.  
8 Here's some meters are greatly affected with low  
9 hematocrits, and anemia is common in intensive care  
10 settings.

11                   What about sample type? This is a study  
12 from Mayo, with 20 patients in the CCU, and they  
13 looked at the first five hourly samples after they  
14 began IV insulin. They looked at arterial, venous and  
15 capillary samples compared to the main lab. Now I'm  
16 not going to show the capillary data; it actually  
17 matched very well to the main laboratory. But  
18 arterial samples, the difference between the main lab  
19 and arterial blood gas values ranged from a positive  
20 35 or so to a negative 5, but the average difference  
21 was a positive 15. Is that going to lead to over-  
22 usage of insulin if arterial samples are used?

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1           How about venous samples? The same mean  
2 bias, but tremendously more scattered, using a venous  
3 sample. And again, the TGC studies that are out there  
4 do not usually say what type of sample was used. And  
5 I know in our critical care settings, it's all three,  
6 it's finger stick, its arterial and its venous.

7           So, after the JAMA meta-analysis we started  
8 thinking about this and wrote an editorial in Clin  
9 Chem, asking the question of whether or not these  
10 things are up to the task of use in critical care  
11 settings. Pointing out the fact that they are not to  
12 be used for diagnosis, so should they be used to make  
13 dosing decisions with what is a very dangerous drug?

14           Okay, accuracy and reproducibility. Where  
15 have we been, where are we now? We've seen these  
16 already, so I'm not going to spend a whole lot of time  
17 here. Main laboratory is 10 percent or 6, and these  
18 are the other criteria with the ADA, of course, being  
19 less than 5 percent, which all know really no meter  
20 can achieve. What I really want to point out here is  
21 the requirements of all of these criteria, that 95  
22 percent of the values fulfill these criteria.

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1           What about the other 5 percent? Okay, we do  
2 600,000 a year at our institution, and let's just do a  
3 comparison study using one dear of data from my  
4 institution, okay. 600,000, that means 570,000 glucose  
5 values have to be within 20 percent. 30,000 can be  
6 anywhere. So I think we really need to think about  
7 this 5 percent of the values just sort of being  
8 unclassified.

9           Okay, let's just review a few representative  
10 studies, saying we'll start with some older ones. This  
11 was 2,000 values performed by nurses, published in  
12 2001 but it was really data from the 90s. And if you  
13 look here, you'll see that 25, 15 percent of the  
14 values are not within 15 percent. So pretty poor  
15 performance in the 90s.

16           This is a more recent CDC study performed by  
17 Mary Kimberly and Gary Myers here in the front row, at  
18 CDC. A single medical technologist operator looked at  
19 five meters to see ranged from 6 to 11 percent, even  
20 more important, up to 32 percent bias between meters.  
21 And their conclusion was that standardization was  
22 necessary for meters and they needed to match the main



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1 laboratory much better than they currently did.

2           This study came from the NIH, was  
3 commissioned by the FDA of four common meters, and the  
4 data was a little bit better, CVs in the one to nine  
5 percent range; again, health care operators, not self-  
6 users. The worse CVs, as expected, were at lower  
7 glucose values, but still, eight or nine percent,  
8 that's not too bad below 60. But again, there were  
9 significant biases to the laboratory reference method,  
10 so between negative 12 and positive 12 per cent bias,  
11 so up to 24 percent.

12           Now let's take that study and look at the  
13 various criteria. Okay. All four of these meters  
14 would not have done very well with the ADA criteria,  
15 92 percent of the values would have failed with meter  
16 A, 42 percent with meter C. Meter B, C and D all  
17 would have done quite well with the current FDA and  
18 ISO criteria, and very well with the Clarke error  
19 grid, including meter A, which was miserable by any of  
20 the criteria up above.

21           So, which criteria should we be using? I  
22 don't have an answer; I'm going to end with a

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1 suggestion. Let's look at CAP data. There is where  
2 we are today. See these between methods, and this is  
3 all hospital meters with five manufacturers  
4 represented here. With exception of a few, where the  
5 end is very small, the CVs with very large ends is not  
6 that bad any more. I mean, it's not main laboratory  
7 CV. If you look at this same report from the main  
8 laboratory it's between 1 and 2 percent, but a lot  
9 of 3 percent CVs between all laboratories using the  
10 same method.

11 Now for CAP data it's a little unfair, I  
12 think, to compare mean values per system, because of  
13 matrix effects. So I think the 78 to 124 difference  
14 between meters is probably partially due to matrix  
15 effects. But let's look at the low and high value  
16 within a system. Here's a meter used at 4,000  
17 institutions, and the lowest value was 83, the highest  
18 was 116. That's within a system, so there is still  
19 spread within a system. But overall, I think the CVs  
20 are reasonable.

21 Okay, what about Barnes Jewish Hospital at  
22 Washington University Medical Center? We've got about

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1 200 meters out on the floors, over 2,000 certified  
2 operators. We do 1,400 of these strips a day, and  
3 this is our QC data, very similar to the CAP. I  
4 think, you know, 200 meters, 4,000 QC points a month,  
5 CVs in the 9 to 6 percent range. That's how we do in  
6 our institution. I actually distributed a sample to 40  
7 different sites, same patient sample, and the range of  
8 values was 153 to 210 in a 95 percent confidence  
9 interval of 139 to 195. So there is still some, with  
10 the system that we're current using at Barnes,  
11 considerable spread.

12           Now this data from our institution I think  
13 is particularly telling. I get a report on a monthly  
14 basis of all meter values that are repeated within 15  
15 minutes. The reason for this report is actually a  
16 billing compliance issue. We can't bill for duplicate  
17 testing. So I saw it, not from a compliance billing  
18 opportunity, but let's see what kind of repeat values  
19 we're actually seeing. And this number is between .8  
20 and 1.2 percent of all of our glucose values every  
21 month. This just happens to be November, 2009. So we  
22 did about 40,000 or so that month. 357 were repeated

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1 within 15 minutes. The median repeat time is 3.5  
2 minutes.

3           So these are not values being repeated  
4 because they just gave insulin or they just gave  
5 orange juice and they want to see what happens. These  
6 are values being repeated because the operator didn't  
7 believe the number. The mean absolute difference  
8 between repeat values is 84, in November. That number  
9 I've seen as high as 125. These are clearly being  
10 repeated because they didn't believe the first value.  
11 What about values that are performed and never  
12 repeated, because they're close enough. I have no  
13 idea of that number, but I think there's a hint in  
14 these repeat values here.

15           Okay, let's go back to some comparison  
16 studies and look at some more recent ones, published  
17 last year. This is a newer meter. All the CVs in  
18 this evaluation using venous arterial whole blood and  
19 aqueous Qz material were less than 5 percent. No  
20 effects from hematocrits or reducing substances, this  
21 is one of the newer meters that corrects for that.  
22 Very good bias values.

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1           If you put it on an error grid, that is what  
2 that particular study looked like, fairly impressive.  
3 This tells me that probably some of the newer meters  
4 are able to pull off tighter performance criteria than  
5 what's currently out there.

6           Here's another study of a new meter. Again,  
7 very good precision and very small bias, you see, plus  
8 or minus 10 or so versus the laboratory method.

9           Okay, so what criteria should we use? I  
10 think the outcome studies to determine that are  
11 probably not going to happen. It's going to involve  
12 randomizing patients to a meter versus a main  
13 laboratory or a blood gas analyzer, and the end's  
14 going to have to be tremendously large to detect a  
15 difference, I believe.

16           But, how about biologic variability? Callum  
17 Fraser is a very strong proponent of using biologic  
18 variability. And for glucose, total allowable error  
19 should be less than 8 percent. Well, now, what's the  
20 biologic variability in a critical care setting? I  
21 have no idea, I don't think anybody does. But, is  
22 this a place to start?

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1           So, what I'd like to end with is this is a  
2 discussion point and a place to start. 10 percent, or  
3 10 milligrams, I think the newer meters can probably  
4 do that. And then let's develop a new error grid for  
5 critical care settings, and George Cembrowski and Jon  
6 Krouwer are big proponents of doing this, and I think  
7 you can. I don't have the crayon skills of Dr.  
8 Clarke, so I didn't actually draw a new error grid. So  
9 95 percent within 10 percent, or 10, would be like  
10 zone A, 99 percent of the values within 15 percent, or  
11 12, zone B, and then nothing exceeding 20 or 15, or  
12 very few. But I think what this does it accounts for  
13 all the values, and you don't have this 5 percent sort  
14 of random numbers out there that can be anywhere,  
15 according to the current criteria.

16           So, what about -- can new meters do this?  
17 Well, I don't know. Here's another study in 2009.  
18 This is the current ISO criteria, and I just drew in  
19 here the 10 percent, maybe not. But I think it's a  
20 point to start discussions and see where we end up.

21           So with that, I believe the newer meters  
22 appear to be getting better, the comparison studies

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1 seem to suggest better in precision, less bias, less  
2 effects from interferences. I think they can clearly  
3 do better than the current ISO/CLSI criteria.

4           Can they meet a 10 to 15 percent allowable  
5 error? I think time will tell, and the FDA  
6 presentation before me showed that half of them, at  
7 least, probably can. But, in the overall analytical  
8 performance criteria, you've got to always consider  
9 more than just precision and bias. You've got think  
10 about interferences, particularly in critical care  
11 settings, sample types, user errors. These all go  
12 into the evaluation of a meter and have to be  
13 considered.

14           I believe the patients receiving a dangerous  
15 drug should have the best analytic method available,  
16 and, quite frankly, there are alternatives to meters  
17 in critical care settings, blood gas analyzers, a few  
18 meters that are approved for diagnosis. They probably  
19 cost more, but they're out there. So with that I'll  
20 be glad to take questions.

21           DR. CLARKE:       Questions?

22           DR. GINSBERG:   Dr. Barry Ginsberg, Wyckoff,

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1 N.J. You sought to raise an interesting question,  
2 which I'm going to raise in my talk as well, which is  
3 that of outliers. And it's interesting, because when  
4 you look at the clinical data from virtually every  
5 meter out there, which is done on 100 or 200 or 500  
6 patients, you don't see outliers. When they give  
7 their ranges on Clarke or the Consensus error grid,  
8 its 97, 98, 99 percent A, and 2, 3 or 4 percent B, no  
9 Cs, no Ds, no Es.

10           When you look at data from the manufacturers  
11 when they're not doing 100, 200 or 300, but in the  
12 laboratory they're doing 5,000, 10,000, 15,000, 50,000  
13 numbers, you start to see that outliers are real. I'll  
14 show you some data on that. That depends upon the  
15 company, but somewhere between .03 and .1 percent of  
16 data is out in that range, is which is more than 100  
17 or 200 milligrams away. And it's real, and it's  
18 something that I think we need to start thinking  
19 about.

20           DR. SCOTT: Yes, I mean that's exactly why I  
21 presented the duplicate data from our own institution,  
22 where almost 1 percent are being repeated, and of



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1 those, probably right, .2, .3 percent show greater  
2 than 150, 200, I mean, they go as high as a 450  
3 difference between values.

4 DR. ELAHI: Dariush Elahi, Baltimore. Could  
5 you make a comment? When you spoke about  
6 repeatability, you were speaking of a second sample  
7 within 15 minutes, I assume.

8 DR. SCOTT: Correct.

9 DR. ELAHI: Could make a comment about the  
10 repeatability of this exact same sample within a  
11 minute of duplicate reading or triplicate reading.  
12 What are your thoughts about that? How close should  
13 that be?

14 I took a blood sample, I don't believe it.  
15 Maybe I made a mistake, I'm going to do it again. Now  
16 I have a 40 milligrams difference. Should I take a  
17 new sample? Should I run the third time?

18 DR. SCOTT: The problem is these decisions  
19 are being made by the patient caregivers.

20 DR. ELAHI: I'm asking your opinion.

21 DR. SCOTT: Oh, my opinion? I think if it  
22 was carefully performed, they're probably going to

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1 come within 5 or 6 percent of each other, which is  
2 what our quality control, what the studies show as  
3 current imprecision of glucose meters. What we're  
4 seeing with our values that are repeated, in my  
5 opinion are user errors, not an error by the device  
6 itself. But something was done incorrectly by the  
7 user.

8 DR. GINSBERG: I disagree with that. Again,  
9 using some data, in 1993 we tested about 1,000 strips,  
10 having the patients test their own meter against a  
11 reference. And we found that the average error was  
12 about 13 percent. And it turned out that at that time,  
13 if a health care professional did it, they had an  
14 average error of about 7 percent. So in the early  
15 90s, strips, required a lot of attention to how the  
16 user did it, and professionals were much better than  
17 patients.

18 We repeated that study in 1996, and what we  
19 found was that the professionals were still about 7  
20 percent, a little bit better, meters and strips had  
21 gotten a little bit better but not a lot, in the hands  
22 of people who were very careful about how they did it.

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1 The difference was at that point, that patients were  
2 substantially more accurate than professionals, that  
3 patient's were about a half percent better than the  
4 professionals were at that, because they actually do  
5 it more often. And I think, the outliers I talked  
6 about were done in the laboratory by highly  
7 experienced professionals. I think there are some,  
8 whenever you produce large numbers of anything you're  
9 going to have some outliers.

10 DR. SOLDI: Monnett Soldo. I'm from  
11 California. My question is, it seems that there are  
12 two issues here, one is whether or not meters can meet  
13 the accuracy of the ISO or any other standard in any  
14 environment, and the other is in an ICU environment.

15 And for one, with all the data that is being  
16 presented, I personally am having trouble  
17 distinguishing between these two. I can't tell when  
18 you present data, and when any of the panelists  
19 present data, whether it's for an ICU setting with  
20 significant interferences, or whether it's just what  
21 the manufacturer did. So, to the extent possible, if  
22 we can distinguish between what data is being

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1 presented that's relevant to an ICU setting, or point-  
2 of-care setting, I think that would be helpful.

3 DR. SCOTT: The only two studies, one I said  
4 the Mayo study was clearly from a CCU, the evaluation  
5 of the newer meter strip in 2009, that was also from a  
6 critical care setting and I failed to say that. The  
7 others were performed in the laboratory or by users.

8 MS. MANN: Hi, Elizabeth Mann. I'm from the  
9 Army Burn Center. We tested five different meters,  
10 four of the currently available meters, and then the  
11 new 4- channel meter. I personally did all the  
12 glucose measurements myself. I'm a nurse, throughout  
13 our ICUs within our hospital, Burn, Trauma, Surgical  
14 and Medical ICUs.

15 The error in normal patients who have  
16 hematocrits between 18 and 25 percent, generally,  
17 after the ABARE study, where we definitely titrate to  
18 a very low level, I think this point about was it done  
19 in the ICU versus non- ICU is extremely relevant,  
20 especially with the data that you presented here.

21 I would just like to say that we did develop  
22 a correction factor for that hematocrit. It's a

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1 simple math formula and we applied it to each of those  
2 meters, and we were able to achieve less than 5  
3 percent error in real patients. And then we did the  
4 4-channel glucometer and it was no different in our  
5 labs. So I would agree with you that, yes, the  
6 technology is there with the new meter, but even more  
7 so, the technology is actually available in the  
8 current meters if they're corrected. And when you  
9 correct, you actually capture occult hypoglycemia, and  
10 we found that we reduced our hypoglycemia rate within  
11 our unit by just treating the proper number with  
12 insulin.

13 DR. SCOTT: I believe there to be some  
14 practical issues, unless you could actually get the  
15 meter to do it.

16 MS. MANN: Well, that's the best thing.  
17 Right now we use the computer and the nurses enter the  
18 glucometer value into a computer, so it is an extra  
19 step, but we felt like, for safety's sake, when these  
20 glucometers all had errors more than 15 percent, some  
21 over 20 percent, it was simply not safe to do tight  
22 glycemic control without some sort of correction until

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1 we got the 4-channel glucometer.

2 DR. SCOTT: We've got over 2,000 operators,  
3 and trying to get sort of a manual step conversion  
4 like that, I think it would be very difficult, really.

5 MS. MANN: As a nurse, just to follow along  
6 with the user error, I do agree. When we're busy, and  
7 we're doing tight glycemic control in this day and  
8 age, and we're doing a measurement every hour, the  
9 strips sit for a long time, there's not appropriate  
10 draw out of the A-line or the central line. So I  
11 agree, it really is user error rather than  
12 repeatability on a device.

13 DR. CLARKE: Thank you, and we will proceed.  
14 Our next speaker this morning also comes to us by way  
15 of Washington University. Dr. David Sacks is  
16 Associate Professor of Pathology at Harvard, and  
17 Director of the Clinical Chemistry Division at  
18 Brigham and Women's Hospital. He did his medical  
19 training in Cape Town, South Africa, and Residency in  
20 internal medicine at Georgetown, and Clinical  
21 Pathology at Washington University School of Medicine.  
22 He is a Fellow of the Royal College of Pathologists,

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1 and is currently chair of the National Glycohemoglobin  
2 Standardization Program Steering Committee. And he is  
3 going to talk to us this morning about the clinical  
4 perspective, and the clinical need for tighter  
5 performance requirements. Dr. Sacks.

6 DR. SACKS: Thank you for the introduction,  
7 and I'd also like to thank Courtney and Arlene for  
8 inviting me to speak here today. So if I can get this  
9 thing to work. So just an overview of my talk. I'm  
10 going to talk about, since I'm doing the clinical  
11 perspective, I'm going to give a little background on  
12 the clinical aspects, the need for near normal  
13 glycemia, then I'm going to divide the clinical use of  
14 meters into two groups, self- monitoring of blood  
15 glucose and tight glyceemic control in ICUs.

16 And so I thought, being the first clinical  
17 speaker, I should give a little bit of context. Now  
18 this has been touched on before but this is a map of  
19 the world, showing the prevalence of diabetes in the  
20 year 2000, which are the red bars, and the blue bars  
21 are the predicted prevalence in 2030. And you can  
22 see, in the United States there's a predicted increase

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1 of 70 percent. But the most dramatic increases are in  
2 Asia, India and South America, where the increases are  
3 up to 150 percent or more.

4 And, of course, the major complications of  
5 diabetes, which is the reason why people with diabetes  
6 are treated, are microvascular complications,  
7 retinopathy, neuropathy, nephropathy, and then, of  
8 course, the macrovascular complications. So I'd just  
9 like to emphasize the Diabetes Control and  
10 Complications Trial, because that was the major study  
11 that looked at the role of self- monitoring in  
12 diabetes, and they had 1,441 patients, all with Type I  
13 diabetes. And they were randomized to either  
14 intensive or conventional insulin therapy. And the  
15 goals of the intensive therapy were evaluated by the  
16 patients performing self-monitoring four times a day,  
17 and also monthly hemoglobin A1Cs. And the patients  
18 were followed for a mean of 6.5 years.

19 And the outcomes of the study were very  
20 dramatic. The patients on conventional control, this  
21 is the glucose, capillary glucose, during a single day  
22 at different times of the day. The conventional



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1 control is the top line, the intensive control is the  
2 lower line, and you can see there was a marked  
3 reduction in glucose values at all times of the day in  
4 the intensively controlled patients.

5           And if one looks at the development of  
6 complications, the conventionally controlled group are  
7 the blue bars, the intensive control the red bars, all  
8 the microvascular complications, retinopathy,  
9 nephropathy and neuropathy, were significantly lower  
10 in patients on the intensive control. Macrovascular  
11 complications were not decreased at the time the study  
12 ended in 1993, but subsequent follow-up has shown a 50  
13 percent reduction in myocardial infarction in the  
14 intensively treated group.

15           So what are the recommendations for portable  
16 meter use? Well, they're used by patients at home,  
17 work and school, and also in acute and chronic care  
18 facilities, including ICUs and in physician offices.

19           So I am going to talk first about self-  
20 monitoring of blood glucose. And like Dr. Scott, I'm  
21 going to pick a few representative studies again, just  
22 to illustrate points. So self-monitoring is

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1 recommended for the following reasons:

2           To determine the insulin doses at meals, and  
3 the recommendation by the ADA is this should be  
4 performed at least three times daily if people are on  
5 multiple insulin injections. And there is evidence in  
6 the literature that glycemic control is worse if this  
7 is done less than three times a day.

8           To determine the insulin dose in pregnant  
9 women with diabetes.

10           To determine whether patients are achieving  
11 glycemic controls.

12           And the last one, which is really important,  
13 is detection and avoidance of hypoglycemia, and  
14 actually there is a very large body of literature on  
15 the fear of hypoglycemia. This is the factor that's  
16 most limiting for tight glycemic control.

17           So that raises the question of does meter  
18 performance meet clinical needs? So let's have a look  
19 at this. So hypoglycemia, the risk increases  
20 dramatically with therapy directed at near  
21 normoglycemia. Patients in the intensively treated  
22 group in the DCCT had three times the rate of severe

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1 hypoglycemia. As I mentioned, near normoglycemia  
2 reduces the risk of chronic complications, so this is  
3 the goal.

4 Another important factor to consider is that  
5 many patients with Type I, and even with longstanding  
6 Type II diabetes, have hypoglycemia unawareness, so  
7 they lose the symptoms of hypoglycemia. And self-  
8 monitoring is the only defense when the symptoms are  
9 lost, because the patients don't know they're  
10 hypoglycemic. And severe hypoglycemia is associated  
11 with mortality, dementia and harm to self, or others,  
12 for example, if the subject has an episode while  
13 driving.

14 So there are a lot of books about  
15 hypoglycemia. If one looks at the internet you can  
16 find the recipe to conquering hypoglycemia. You can  
17 even find hypoglycemia for dummies. But the important  
18 question is, can meters reliably detect hypoglycemia,  
19 since this is one of the major uses for people with  
20 diabetes. Say, if one uses the current ISO/CLSI  
21 criteria, and you imagine that an individual has a  
22 true glucose of 50, if one does the calculation the

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1 acceptable limits, the results, are 35 to 65  
2 milligrams per deciliter. So 35 would be severe  
3 hypoglycemia, 65 would be, you don't have to do  
4 anything.

5           And of courses, as was emphasized in the  
6 previous talk, 5 percent of values may be outside of  
7 these ranges. The problem is, the patient may not know  
8 which values are wrong. So if the patient ends up  
9 with a value that's outside the limits, they may not  
10 know, particularly if there is hypoglycemia  
11 unawareness. So I would argue that these results  
12 cannot reliably detect hypoglycemia. And you may end  
13 up with severe hypoglycemia, requiring help from  
14 another individual, and again, somebody may actually  
15 have to call 911.

16           Let's look at meter use in practice.  
17 Accuracy criteria are exclusively for analytical  
18 performance, as has been mentioned before.

19           I think one of the advantages of being the  
20 third or fourth speaker is that there is limited  
21 overlap with what's gone before. The last speaker, I  
22 don't know if they're going to be able to say

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1 anything, because probably everything they need to say  
2 will have been said before. So I apologize for some  
3 repetition. But it helps, you know. People doze off,  
4 you know, you wake up. For those of you who stay awake  
5 all the time, I'm sorry.

6 But in practice, the accuracy criteria did  
7 not consider pre- or post-analytical error, and very  
8 importantly, the evaluation is usually performed by  
9 highly trained medical technologists under optimal  
10 conditions. And the ISO specifications, I would  
11 argue, do not inform the condition of how the meters  
12 actually perform in the patients' hands.

13 So as it's been mentioned, current meters  
14 have performance superior to prior generations, you  
15 know, the technological advances by the manufacturers  
16 have been remarkable, they decrease operator error.  
17 But the evidence in the literature shows that  
18 performance by patients is inferior to medical  
19 technologists.

20 I'm just going to give one representative  
21 example of this study from Norway, by Sandberg. And  
22 they looked at five different meter types, and the CVs

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1 for patients among these five meters ranged from 7 to  
2 as high as 20 percent, and the medical technologists  
3 had CVs of 2.5 to 5.9 percent. So there's a huge  
4 difference in the hands of patients who were  
5 performing self-monitoring anyway. These were people  
6 who were doing self-monitoring.

7           And this is an example of one of those  
8 meters, this is from the same study, what's shown in  
9 the vertical axis is the percent deviation from the  
10 laboratory method, the horizontal axis is the  
11 concentration of glucose in the lab method. The left  
12 panel is patients, the right is technologists, and you  
13 can see a huge difference. This meter seems to have a  
14 positive bias, even in the hands of the medical  
15 technologists, but there's a very tight precision when  
16 it's done by technologist.

17           And one of the interesting findings in the  
18 study, which was published in 2002, is that patients  
19 failed to meet ISO criteria. None of the five meters  
20 in the patients hands met ISO criteria in this study.  
21 Two of them met ISO criteria in the technologists'  
22 hands, but none in the patients' hands.

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1           How accurate does a glucose measurement need  
2 to be? Well, this has been addressed a little bit  
3 before. Several criteria have been proposed for  
4 analytical goals. There is expert opinion, there's  
5 opinion of clinicians -- I don't know what the  
6 difference is between 1 and 2 -- it implies that  
7 clinicians are not experts, state-of-the-art,  
8 regulation, biological variation. But there is no  
9 consensus regarding this.

10           But what's missing from this is what do  
11 patients think? So for most, analytes were measured  
12 in the lab, it's done in the clinical lab. But self-  
13 monitoring of glucose is different because this is  
14 actually done by patients themselves. So what do  
15 patients think? How accurate do patients think that  
16 the meters need to be?

17           So there was a very nice study which looked  
18 at 201 patients with Type I diabetes. And these  
19 people, on average, had been doing self-monitoring for  
20 ten years, and there was a means of 11 measurements a  
21 week, which is less than the recommendation, but  
22 still, people who had been doing this for a long time.

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1 And each individual completed a questionnaire, there  
2 were nine questions. And the patients said that they  
3 reacted to critical differences, which is the  
4 difference between two consecutive results, of 22 to  
5 30 percent. So that's quite a big difference with  
6 four patients reacted.

7           And this shows you, from that study, the  
8 vertical axis is the imprecision, the horizontal axis  
9 is the bias, and the critical difference of 22 percent  
10 is plotted here, and 30 percent is plotted there. So  
11 based on the results of the study, the calculations,  
12 the analytical CV of 6.4 to 9.7 percent is needed for  
13 patient-derived criteria. However, this excludes  
14 hypoglycemia. And the patients were very afraid of  
15 hypoglycemia. And for hypoglycemia, they wanted a CV  
16 of 3.1 percent, which is incredibly low, but this is  
17 what patients say they need. And based on the study, a  
18 CV of less than 5 percent and a bias of less than 5  
19 percent are required to meet the expectations of 75  
20 percent of these patients. Again, this excludes  
21 hypoglycemia. So patients expect their meters to  
22 perform very well.



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1           Now in 1987, the ADA recommended a total  
2 error of less than 10 percent for 100 percent of  
3 results, and in 1996, in response to the DCCT, the ADA  
4 modified this to total analytical error of less than 5  
5 percent. And as has been mentioned, the other  
6 recommendations, CLSI or ISO, 95 percent of results,  
7 and this has been discussed in some detail, but I'm  
8 going to discuss it again. So, as was suggested by  
9 Dr. Scott, I think we need an addendum to meet a  
10 performance criteria, because 5 percent are excluded  
11 from accuracy criteria. And these values can be  
12 essentially anything. So, if you do the calculation,  
13 if a patient does self-monitoring of blood glucose  
14 four times a day, you'd expect one result to be  
15 outside the analytical limit every five days. The  
16 problem is the patient won't know which this one  
17 result is, which is outside. So that's very, very  
18 frequent. So I think we need to define criteria that  
19 include these 5 percent of values.

20           Okay, so now I'm going to talk about tight  
21 glycemic control. I like this picture, which was put  
22 in a News and Views article I wrote by the editors of

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1 Nature.

2           So does meter performance meet the clinical  
3 needs in tight glycemic control? Nobody can see this  
4 of course, you're not supposed to. This is from that  
5 JAMA meta- analysis. So there're lots and lots and  
6 lots of studies, so how does one pick a study to  
7 evaluate this? And I thought I would pick the NICE-  
8 SUGAR because that's the study that seems to have  
9 influenced practice the most since the original paper  
10 by Greet Van den Berghe.

11           See, if you're from South Africa you can  
12 pronounce the name properly. I think it's close;  
13 there's somebody here from Belgium that could correct  
14 me.

15           But it was also the biggest study. And for  
16 those of you who don't know, it's a multinational  
17 study designed to test the hypothesis that intensive  
18 glucose control reduces mortality in 90 days, a very  
19 large study, 6,104 adults, who were admitted either to  
20 the medical or the surgical ICU at one of 42 hospitals  
21 in Australia, New Zealand or Canada. And within 24  
22 hours of admission, the patients who were expected to

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1 require more than three days, at least three days of  
2 critical care, were randomized either to intensive or  
3 conventional glucose control. And they had quite  
4 tight criteria. They target glucose ranges where  
5 intensive control was 81 to 108, and the conventional  
6 control was less than 180 milligrams per deciliter.

7           So what were the results of the study? Well,  
8 if you compare the intensive and the conventional  
9 treatments, there was a significantly lower mean  
10 glucose in the intensively treated group, 115, versus  
11 144 in the conventional group. There was a  
12 statistically significant increase in mortality in the  
13 intensively treated patients, 27.5 percent, versus  
14 24.9 in the conventional group. And a remarkable  
15 increase in severe hypoglycemia, which is defined as  
16 less than or equal to 40 milligrams per deciliter, 6.8  
17 percent in intensive, and 0.5 percent in the  
18 conventional group.

19           Now this is hypoglycemia that was detected.  
20 So as Mitch mentioned earlier, it's impossible to  
21 obtain details concerning how glucose was analyzed in  
22 this NICE- SUGAR study. So this has changed clinical

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1 practice, but we don't even know how they measured  
2 glucose.

3           What did they say? They said glucose  
4 measurements were performed on arterial blood whenever  
5 possible -- I don't know what that means -- using  
6 point-of-care or arterial blood gas analyzers, or  
7 laboratory analyzers in routine use at each center. I  
8 mean, this is just absolutely useless information.  
9 There's just no way to know how glucose was measured.  
10 And this has changed clinical practice.

11           So let's look at the study in a little more  
12 detail. So, one of the potential problems is that the  
13 different glucose values produced by diverse methods  
14 and samples will lead to different insulin doses, and  
15 potentially wide variations in true glucose  
16 concentrations, right, because the results they're  
17 getting may not be the true glucose concentration,  
18 which is what we really need to know.

19           So I did some analysis of this study. Now  
20 if you look at CAP proficiency testing dotted for 17  
21 meters, the bias is up to 41 percent. So let's think  
22 about that for a little bit. So if the true glucose

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1 is 144, which is the mean of the conventionally  
2 treated patients in the NICE-SUGAR study, a bias of 41  
3 percent is 59 milligrams per deciliter. So if you  
4 take that value, the difference in the mean glucose  
5 between intensive and conventional groups in NICE-  
6 SUGAR was 29 milligrams per deciliter, so the bias can  
7 be twice the difference in the mean glucose between  
8 these two groups. That's just bias.

9           So if you think about this, if a meter is  
10 high bias, what does it mean? The results will be  
11 higher than the patient's actual glucose, and the  
12 patient will receive too much insulin and will develop  
13 hypoglycemia, which may not be detected in these  
14 patients because many of them are unconscious. And we  
15 have no way of knowing whether these people are  
16 hypoglycemic if you use a meter that has high bias.

17           Let's do a little more analysis of the  
18 study. So let's say the patient has a true glucose of  
19 95, that's right in the middle of the target goal for  
20 the intensively treated patients. So the acceptable  
21 range for the meter, based on current ISO/CLSI  
22 criteria, is 76 to 114 milligrams per deciliter. So

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1 the meter will give you this result. Anywhere is  
2 acceptable between 76 and 114. This is excluding any  
3 of the conditions that occur in patients in ICUs.  
4 Remember, 5 percent of values could be outside this  
5 range, and when you're doing hundreds of thousands of  
6 these, a lot are going to be outside the range. Now  
7 these values, 76 to 114, exceed the range for the  
8 intensive control target of 81 to 108 milligrams per  
9 deciliter. So I'm not sure that anybody in this study  
10 knew what the actual glucose was.

11           So, I'm going to summarize now. Measurement  
12 of blood glucose concentrations has a very important  
13 role in patient management, obviously. Accurate  
14 identification of hyperglycemia is absolutely  
15 essentially for people with diabetes who are doing  
16 self-monitoring, and certainly patients in intensive  
17 care units on tight glycemc control protocols do.  
18 Current performance criteria for glucose meters, I  
19 would argue, are inadequate for clinical needs. And  
20 based on biological variability, the recommended  
21 accuracy criteria for meters would be a minimum of  
22 plus or minus 15 percent, desirable would be plus or

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1 minus 10 percent, and optimum would be plus or minus 5  
2 percent, clearly not achievable with the current  
3 generation of meters.

4           And I'd just like to end with a potential  
5 new problems with meters that has come up recently,  
6 that people would not have thought of before, and this  
7 is somebody on an airplane that goes beep-beep-beep  
8 and he says, sorry, it's just my glucose monitor.  
9 Thank you very much.

10           DR. CLARKE: Go ahead, please.

11           MR. ERVIN: Ken Ervin from California. Dr.  
12 Sacks, given the known differences in the way CAP  
13 proficiency samples behave with respect to glucose  
14 meters, do you think that's an appropriate way to  
15 evaluate bias of glucose meters with old whole  
16 samples?

17           DR. SACKS: Look, clearly, I mean one of the  
18 problems with a CAP proficiency testing for glucose  
19 meters is that it's not whole blood. I'm actually on  
20 the CAP Committee, Chemistry Committee, and every few  
21 years I raise the point of can we do whole blood, and  
22 we have not been able to do that. So clearly, some of

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1 the bias is exaggerated in that study, as you point  
2 out, because of matrix effects among the different  
3 meters, which was mentioned earlier by Dr. Scott.

4 DR. CLARKE: Other questions? Well, I have  
5 a question. Would you suggest that our criteria for  
6 testing meters and looking at their accuracy should  
7 include a specific percentage of numbers in the  
8 hypoglycemic range? In other words, we see lots of  
9 data presented on new meters, but very few of the data  
10 points are less than 70 milligrams per deciliter,  
11 whereas when we're out in the real world, what we see  
12 is 8, 9, 10 percent of our patients' glucose numbers  
13 are actually in that range.

14 DR. SACKS: Right. Now I think that's a  
15 very good point that you make, and I think that since  
16 the hypoglycemic range is so critical to patient  
17 decision making, I think it's very important that the  
18 meters perform as accurately as possible in that  
19 range, and they should be evaluated for that.

20 DR. CLARKE: Go ahead, please.

21 DR. SIMMONS: Dr. David Simmons, Tarrytown,  
22 NY. Professor Sacks, we had this conversation at the



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1 ISO meeting in February, and I'm still struggling a  
2 little bit with how we can take a study where you led,  
3 NICE-SUGAR, led by telling us we have no idea what  
4 samples were used or what analytic method was used,  
5 take the results of that study and then very elegant  
6 analysis of what the potential modeling may have been,  
7 but use that as a strong argument to say that hand-  
8 held meters, which might be used for home care, or  
9 might be used in the study, but we don't know whether  
10 they were used in this study, use that as a compelling  
11 story for why hand- held meters might not have the  
12 analytic strength to be used in intensive care units.

13           So my concerns are, one, we haven't  
14 separated out home use from intensive care unit use;  
15 and two, we have no idea whether the study cited, with  
16 the problematic outcome, had any use of the meters  
17 where you used the modeling from a 41 percent bias,  
18 which I don't think that the current standards would  
19 accept, would provide inadequate results. So I think  
20 that I'm seeing a lot of mixing of different results  
21 to come to the conclusions.

22           DR. SACKS: I'm sorry you were confused. I

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1 thought I made it very clear with the difference  
2 between -- the first half of my talk was on self-  
3 monitoring, and the second half was on tight glycemc  
4 control.

5           And what I was trying to point out in the  
6 analysis of the NICE-SUGAR study is, as you indicated,  
7 clearly not only glucose meters that were used in the  
8 study. But I'm just pointing out the limitations of  
9 the glucose meters as currently accepted for ISO  
10 criteria could not be used properly in a study of that  
11 nature because of the large variation in acceptable  
12 criteria for meter accuracy.

13           DR. SIMMONS: But I just think, to be  
14 completely transparent, we should de-link the results  
15 of NICE-SUGAR from those criteria, because we don't  
16 know what analytic methods were used. And then the  
17 other is there are other issues with NICE-SUGAR,  
18 including attribution of morbidity and mortality in  
19 the time windows applied. So although the analysis  
20 may be very interesting, I think we need to de-link  
21 that from the outcome in NICE-SUGAR, to be completely  
22 transparent.

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1 DR. SACKS: I'm not sure that some of the,  
2 that you can actually do that, because it's quite  
3 possible that some of the patients in NICE-SUGAR, some  
4 of the worst outcomes, may be due to undetected  
5 hypoglycemia. And there's no way to know whether  
6 that's true or not.

7 MR. COMBS: Art Combs, St. Louis. I'm  
8 actually an ICU director. ICU patients have nothing  
9 to do with ambulatory patients. I was interested in  
10 this a number of years ago and I just looked at the  
11 laboratory printout and found that more than 50  
12 percent of all of my admissions had at least one  
13 abnormal ionized calcium. More than 80 percent had at  
14 least one abnormality serum phosphorous. These are  
15 things you never see in an ambulatory person. So  
16 that's one point I wanted to make.

17 The second I wanted to make is that we heard  
18 at the beginning, from the regulatory perspective,  
19 that this is all about intended use. I would ask the  
20 panel what in home care is intended for the intensive  
21 care unit, and the answer is nothing. And the  
22 standards for the way we measure blood pressure in

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1 home care, or the way we measure temperature in home  
2 care, or the way we measure anything in home care, has  
3 nothing to do with the intensive care unit.

4 I would submit to you that in the intensive  
5 care unit, there currently are no adequate  
6 technologies to test the hypothesis of the benefits of  
7 tight glyceic control. With that conclusion, I agree  
8 100 percent. But to suggest that every ambulatory  
9 diabetic should be walking around with an instrument  
10 qualified for the care of the critically ill is  
11 preposterous. I don't think we need standards for  
12 home care that were established in the intensive care  
13 unit. We need to divide these, we need to talk about  
14 them completely separately, and we need to understand,  
15 in my opinion, ironically, the FDA's point of view,  
16 which is what is the intended us. Thank you.

17 DR. SACKS: Those are clearly very valid  
18 points, and I'm not for a femtosecond suggesting that  
19 everybody who dies in these ICU and tight glyceic  
20 control protocols is due to hypoglycemia. These  
21 people are really, really sick, as was made evident.  
22 So one of the suggestions that comes up from -- and

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1 the other point, of course, is that everybody in this  
2 room knows is that glucose meters are not FDA approved  
3 for use in tight glycemic control protocols in ICUs.  
4 But having said that, people are using them, and they  
5 are used very, very, very widely, and not just in this  
6 country.

7 I mean, so one of the possibilities from  
8 your argument is that there can be two different  
9 criteria, one for meters in ICUs, and one for meters  
10 in home use. And that's something that is a topic for  
11 extensive discussion, and could certainly be addressed  
12 by the FDA and other people.

13 DR. CLARKE: Final question.

14 MR. COMBS: May I just offer a minor  
15 rebuttal now?

16 DR. CLARKE: What's a -- I'm not sure what a  
17 minor rebuttal is. The term, minor ...

18 MR. COMBS: Let me call it a clarification.  
19 It's my opinion, and this is an opinion, that the  
20 migration of hand-held glucose meters into the  
21 intensive care unit was, as many things in medicine,  
22 the result of a lot of perverse incentives. Some of

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1 them actually, however, are legitimate. The  
2 turnaround time of laboratories may not be enough to  
3 meet the needs of the care of critically ill patients.  
4 In some cases there is point-of-care meters testing,  
5 in some cases there are satellite laboratories, in  
6 other places there really is only a central  
7 laboratory, and the turnaround time is simply  
8 unacceptable. And so the nurses wanted to have  
9 something at the bedside.

10           Secondly, there was the convenience and the  
11 cost factor. It is easier to put a meter at each  
12 bedside than it is to install, qualify, staff, et  
13 cetera, a satellite laboratory, and so that is another  
14 reason.

15           And the third is a very important thing, and  
16 I want to echo the comments of the nurse who spoke  
17 earlier. No one has any idea what a burden this is.  
18 Let's say, soup to nuts, from obtaining a blood  
19 sample, purging the arterial line, getting the strip,  
20 measuring the number, writing it down, re-purging the  
21 lines, establishing everything, takes five minutes. My  
22 nurses work 12 hours. Twelve times five is 60. That is

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1 one hour out of an entire nursing shift, one hour,  
2 devoted to a single task.

3 I would submit that intensive care patients  
4 are a good deal more complex than that. So I believe  
5 that cost, convenience, turnaround time and immediacy  
6 or immediate availability of results are the things  
7 that drove hand-held meters to the bedside. But they  
8 don't belong there. They belong in the hands of  
9 ambulatory diabetics who are not on a continuous  
10 insulin drip, and who are not a priori critically ill.

11 DR. SACKS: So I have no rebuttal to your  
12 rebuttal because I agree with you.

13 DR. CLARKE: We are going to take a break  
14 until eleven o'clock, and you can enjoy your coffee  
15 and whatever in the foyer. Please take your seats so  
16 that we can keep on time. (Meeting recessed.)

17 SECOND SESSION

18 DR. CLARKE: The first speaker for the  
19 second session here is here -- ah, yes, oh, you were  
20 hiding behind there, Marc -- Dr. Marc Breton, who is  
21 in -- at the University of Virginia, has a PhD in  
22 Systems Engineering, and has specialized in the

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1 application of engineering to medicine and has done  
2 human testing of autonomic or -- automatic, excuse me,  
3 insulin control systems and simulation of glucose  
4 insulin dynamics in man. And he's going to talk to us  
5 about clinical perspectives, self-monitoring of blood  
6 glucose inaccuracy, and clinical consequences in Type  
7 I using an in silico model. Dr. Breton?

8 DR. BRETON: Good morning. So I'm put in  
9 the slightly odd position of being an engineer  
10 addressing a mainly clinical panel and talking about  
11 clinical consequences, but I'm going to try to make as  
12 much sense as I can.

13 So, the quick background, which has been  
14 talked about at length by now, is most -- all Type I  
15 diabetics, and consequent number of Type II diabetics,  
16 who use insulin, face a challenge of trying to attain  
17 tight glucose control and avoid hypoglycemia at the  
18 same time. And they are trying to attain that tight  
19 glucose control for the reasons that were discussed  
20 previously and the consequences of not having a tight  
21 glucose control.

22 And the issue with working towards that



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1 tight glucose control, that target, as low as possible  
2 is that you need a very good information, a very  
3 accurate information, about the status of the system  
4 to control it. And in that particular case, you need  
5 very good information about the glucose level of a  
6 particular patient.

7           Now, the only means for diabetic patients to  
8 have regular, frequent information about their glucose  
9 levels is the glucose meters. Now, Dr. Clark, on my  
10 right, in the review article stated the following  
11 sentence, which basically say that accuracy should  
12 only be seen in terms of clinical consequences, and  
13 that pure engineering study of the devices, though  
14 interesting, were mostly irrelevant to the patients  
15 themselves, and I tend to agree with that particular  
16 statement.

17           There were several studies along the last  
18 ten years, we'll say, that looked at particular errors  
19 of glucose meters and their clinical consequences. The  
20 first one that I wanted to cite was by Raine, et al.  
21 in 2008, and they studied the effect of miscoding  
22 meters. And they had a series of automatically coding

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1 meters and non- automatically that were either coded  
2 or miscoded. And he looked at the consequences in  
3 terms of glucose excursions and insulin dosing and  
4 detected that the risk for hypoglycemia in miscoding  
5 meters, so creating a bias, was about ten percent  
6 higher.

7           There were very few clinical studies of the  
8 effect of accuracy, mainly because to design such a  
9 study is extremely intricate, and in some cases  
10 unethical. It's difficult to send a patient out in  
11 the field and then intentionally miscode or bias his  
12 or her meter by a hundred points.

13           So to circumvent that particular hurdle,  
14 what Burnt, Burns and Boyd did a few years ago, and  
15 what -- in a landmark article for us was that they  
16 used simulation, or a mathematical model of a human --  
17 of the glucose response of a human being to study more  
18 thoroughly the effect of inaccuracies in meters. And  
19 the work that I'm going to present here is really in  
20 line with Dr. Bruns' work.

21           Now, the first thing I need to talk to you  
22 about, and I will try to be as short as I can, is

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1 simulation, and the tool that I basically use in the  
2 study of this image inaccuracy. So what you're seeing  
3 here has absolutely nothing to do with diabetes,  
4 obviously. And the one thing that is interesting  
5 about these three pictures -- it was more interesting  
6 than last year -- until last year, the plane that  
7 you're seeing on the screen had never flew. And the  
8 Boeing 787 was entirely designed based on simulations,  
9 mathematical modeling, and such engineering tools.

10           So I present that slide to basically show  
11 you that simulation is not, by any stretch of the  
12 imagination, a new idea. It's a tool that has been  
13 used over the last decades by engineers to design and  
14 to test the validity of different systems.

15           Now, why do you need to create such a  
16 simulation in man and to apply it to diabetes? Well,  
17 first you need mathematical models that are based on  
18 clinical knowledge. And so some understanding of the  
19 physiology that will allow you to create mathematical  
20 models. You need to accumulate data targeting a  
21 specific subsystem of that physiology to understand  
22 how the different fluxes interact. You need to

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1 identify the physiological processes and the fluxes  
2 that I just talked about. Finally, you create in  
3 silico subjects, and based on these in silico  
4 subjects, in silico standing in for a computer, you  
5 assess the intra-subject variability and create in  
6 silico populations.

7           Finally, you implement it in a software, and  
8 you absolutely need to validate it against in vivo  
9 data, and in vivo data that you did not use to create  
10 the simulation environment in the first place. And  
11 that, basically, allows you to have a software that  
12 will give you the opportunity to run what we call in  
13 silico experiments. The advantage of in silico  
14 experiments versus in vivo experiments is not only do  
15 you go incredibly faster, a fraction of a second to  
16 simulate several days of diabetes treatment, but you  
17 can test situations that would put the human at risk,  
18 knowing that in a computer, the risk is also  
19 mitigated.

20           Now, what you start with is that  
21 mathematical models based on understanding of the  
22 physiology. That work was started probably 30 years

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1 ago, if not 40 years ago, by Dr. Cobelli in Padova in  
2 Italy, and his assistant, Kadava(ph) Amann. They had  
3 two publications in 2006 and 2007 presenting the  
4 mathematical models that we worked on. And then Dr.  
5 Kovatchev(ph) and myself took these models one extra  
6 step, and developed them to specifically address Type  
7 I diabetes. And you can see that you basically had  
8 mathematical models of the liver, the glucose system,  
9 muscle adipose tissues, insulin delivery. In Type II  
10 or normal subjects, you would have insulin secretion  
11 also. And, of course, the gastrointestinal tract to  
12 simulate meals.

13           You attach simulate measurements to these  
14 mathematical models. These allow you to measure the  
15 glucose of these patients. You can, of course,  
16 simulate the YSR(ph) of Beckman, or you can simulate  
17 an SMBG, which is exactly what we're going to do  
18 today.

19           We can also simulate a continuous monitor,  
20 which has allowed us to do closed-loop trials in  
21 simulation environments. You devise a treatment,  
22 obviously, and then you administer the treatment

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1 through a simulated pump or a simulated multiple daily  
2 injection or even IV injection in the types of -- in  
3 the case of simulating ICU studies.

4           You need to accumulate data, and we  
5 accumulate -- well, we got access to 350 healthy Type  
6           I, Type II, and pre-diabetic patients across  
7 numerous universities and studies. For all these  
8 patients, they had one characteristic in common: all  
9 these experiments were done with triple tracers, and  
10 this gave us access to the fluxes of glucose and not  
11 only its concentration, so we actually know what's  
12 coming out of the liver, what's coming from the meal,  
13 which is used in the tissues, what's excreted. And  
14 using all these fluxes, we can actually identify a  
15 patient, and it corresponds to our good-old  
16 mathematical problem of the holes in the bathtub.

17           Now, the bathtub in this case is that  
18 particularly ugly depiction of -- you can, for  
19 example, recognize here the concentration of glucose  
20 in plasma. These are the insulin states. Insulin is  
21 administered subcutaneously in that case, makes its  
22 way to the plasma. Plasma and insulin influence the

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1 different musage(ph) of glucose.

2           And what's even more ugly is the  
3 mathematical equations that correspond to that  
4 figures. I'm showing that first to justify my PhD,  
5 and second to show you that a patient is --  
6 corresponds to 26 independent barometers. And I'm not  
7 trying to throw 26 to impress you. What I'm trying to  
8 convey is that it's absolutely impossible, even  
9 knowing perfectly the patient, to guess in advance how  
10 a patient is going to react to a meal or to a bolus of  
11 insulin. So we do not have any foreknowledge when we  
12 simulate of what's going to happen. We set the  
13 scenario. The patient is going to eat 60 grams of  
14 carbohydrates at one hour and take a bolus of three  
15 units at the same time. But we really don't know what  
16 the -- how glucose is going to evolve in the next six  
17 hours. We have to actually run the software to figure  
18 it out.

19           Once you've created an insilico subject, you  
20 get to create an in silico population, and that's  
21 basically to have as -- about 100 subjects, in our  
22 case, that span all the variability that is observed

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1 in vivo. And that basically allows us to have very  
2 different subjects, the same way you observe them in  
3 your clinics.

4 We finally validated with external datasets  
5 both from hyperinsulemic clamp and from the direct net  
6 study. We also did some validation using basal rates  
7 and carbohydrate ratios and different measures of  
8 insulin sensitivity. And I have to thank Dr.  
9 Buckingham and Dr. Clarke for sharing their -- the  
10 data of their patient in these particular case that  
11 allow us to verify that the patients that were present  
12 in that simulator had characteristics that  
13 corresponded to what's observed in vivo.

14 Finally, that simulator was accepted in  
15 January 2008 by the FDA to replace pre-clinical  
16 studies in closed loop trials. And so it means that  
17 it was at least good enough to replace animal trials,  
18 and it has been at the foundation of all of our  
19 investigational device exemption for such studies  
20 since.

21 The current in silico population is made of  
22 300 patients -- 100 children, 100 teenagers, and 100



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1 adults, all Type I. They can be admitted to the CRC.  
2 They can be tested in different ways to extract  
3 information about them, and of course you can submit  
4 any scenarios composed of any combination of meals,  
5 carbohydrate intake of any form, and insulin injection  
6 of any form. And that's the demographic  
7 characteristic of the population. All right.

8           Now, enough about the tool. Let's talk a  
9 little bit about the study that we did. So we used  
10 this simulator to study the effect of how tight that  
11 ISO standard that we've been hearing about, what's the  
12 effect of its amplitude on glucose control. And so  
13 the only thing that I've done here is reproduced that  
14 ISO standard, you can see that, of 275 milligram per  
15 deciliter. You have a fixed error, and after 75  
16 milligram per deciliter, you have a relative error. In  
17 this case, it was 20 percent plus/minus 15. I wanted  
18 to emphasize with another figure that what we're  
19 talking about is the famous 95 percent, and not all  
20 the points have to be in there. And so the color-  
21 coded graph that is on the right here, the more red  
22 you are, the more data points you're going to see. The

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1 more blue you are, the less data points you're going  
2 to see, but you're still going to see data points in  
3 the blue area.

4           The first study we did was to look at the  
5 detection of hypoglycemia based on different levels of  
6 sensor accuracy. And so that's been shown to be a  
7 very important feature to Type I diabetic patients, is  
8 that fear of hypoglycemia is what generally limits  
9 their capability of controlling their (inaudible)  
10 their glucose.

11           Now, if you take the actual sensor -- well,  
12 the actual ISO standards of 20 percent, you can see  
13 that first, if your true sugar is 70, there is a 50  
14 percent chance of detecting or not. So that basically  
15 means that what we're studying are unbiased sensors.  
16 We're only looking at the spread as defined by the ISO  
17 standard.

18           Now, when you go down in true plasma  
19 glucose, of course, your probability of missing the  
20 hypoglycemic event diminishes, and you can see that  
21 about -- if the true glucose is about 60, you have  
22 about a 10 percent chance of missing it. When it's

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1 about 50, you barely have a one percent chance of  
2 missing the event, and that was demonstrated in a talk  
3 earlier.

4 Now, if your accuracy becomes better, so if  
5 you move from 20 to 15 to 10 and to 5, you can see  
6 that your probability of missing a hypoglycemic event  
7 is reduced dramatically. And I'm going to be  
8 particularly interested in the .60, and you can see  
9 that if your true plasma glucose is 60 milligrams per  
10 deciliter, with a five percent errors -- of course, if  
11 you have a perfect sensor, you're not going to miss  
12 the hypoglycemic event. At a five percent accuracy  
13 level, there is almost no chance of missing that  
14 event, either. It's .001 or something like that.

15 At ten percent, you have about one percent  
16 chance of missing a hypoglycemic event, which is  
17 reasonable. And you can see that between ten and 15,  
18 something happened that actually makes that risk of  
19 missing an event increase quite dramatically. And the  
20 difference between 10 percent accuracy and 20 percent  
21 accuracy is actually a factor 10.

22 Now, we also looked, in a second study, at

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1 what the effect of accuracy is on one very simple  
2 treatment, treatment of hyperglycemia. So we used the  
3 previously described simulator and the previously  
4 described model of SMBG noise, or SMBG error. Each in  
5 silico patient starts the experiments stable at 200  
6 milligrams per deciliter, and for each of these  
7 patients we designed a perfect bolus that would bring  
8 the patient down to 100 within four hours. And so  
9 basically you measure glucose at times zero, that  
10 measure is perfect, and you have the perfect bolus  
11 that will bring the patient down to 100.

12           And then we repeated that experiment with  
13 actual measure designed with the SMBG error model and  
14 looked at what was happening. Now, of course if you  
15 measure lower, you're going to treat a little lower  
16 and you're not going to achieve your target. If you  
17 measure higher, you're going to actually see that you  
18 go lower than your target, and you might actually get  
19 into hypoglycemia.

20           Now, this presented the result that we have  
21 from this experiment, and you can see that at five  
22 percent error, I mean the minimum that we saw was

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1 about 90. The maximum that we saw at about 110. So  
2 by all practical measures, they achieved perfect  
3 treatment of hyperglycemia. And you can see how the  
4 capacity of treating hyperglycemia deteriorates with  
5 increased errors, SMBG errors. At 15 percent, you  
6 actually start seeing occurrence of hypoglycemia. At  
7 20 percent, you see both hypoglycemia and for some  
8 subjects, they did not even reach the 140 milligram  
9 per deciliter limit. So they probably have to treat  
10 further down the line.

11 And these results are presented in bar  
12 graph. You can see that the risk of hypoglycemia is  
13 zero percent up to 10 percent of error, and then rises  
14 to 3.5, and then 5.5 percent.

15 We also looked at glucose variability, and  
16 this time we actually simulated a meal. So we measure  
17 at the beginning of a meal for the meal bolus, and we  
18 also have a measure two hours later. The meal bolus  
19 was intentionally underestimated so that we would be  
20 high two hours later. And then the patient treats  
21 from the point there are two hours later.

22 If you under-measure at times zero right

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1 before the meal, you're probably going to under-bolus.  
2 You're going to get a little higher. Let's say you  
3 over-measure at two hours later, you're going to over-  
4 treat, and then this time probably end up lower than  
5 you initially intended. The results that are  
6 presented here are -- it's called the control  
7 variability grid. On the X axis is the lower points  
8 that you attained. On the Y axis is the highest  
9 points that you attained. So basically, if I was an  
10 absolutely perfect control, I would be somewhere  
11 around this in the A zone. You will note the  
12 similarity with the Clare Error Grid. Anywhere around  
13 that arc is proper treatment in the D zone, and then  
14 these are the error zones of danger. For example, if  
15 you're in the E zone, not only do you go over 300  
16 milligram per deciliter after your meal, but you went  
17 hypoglycemic afterwards.

18           So you take, basically your glucose curves.  
19 You obtain the maximum to minimum. Take these two  
20 numbers, and that gives you a point on the grid. And  
21 you can see the difference between white and black.  
22 White is almost no noise; black is a lot of noise. You

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1 can see that when you had an inaccurate sensor, you  
2 start dealing with dangerous situations.

3           Finally, we studied the long-term effect of  
4 SMBG accuracy, and so it's -- it was a similar  
5 simulation, but with three meals a day for ten days  
6 for each patient. And what we observed first in a  
7 nominal -- we fixed the risk of hyperglycemia for each  
8 patient at 15 percent, which is basically one day out  
9 of -- one day every week where they would experience a  
10 hypoglycemic event.

11           And when we augmented the sensor errors, we  
12 actually observed that these hypoglycemic events  
13 became more frequent. And so we estimated that each  
14 patient had their own -- their own aversion for  
15 hypoglycemia, and so we dialed back in all the traces  
16 for each patient to their original nominal aversion of  
17 hypoglycemia, which is the 50 percent I just talked  
18 about, and that dial back in, we transform into HbA1c  
19 using the ADA formula. And that basically shows that  
20 at nominal level, it's exactly at 15 percent. Five  
21 percent error, you had no more hypoglycemia. And then  
22 10 percent, 15 percent, 20 percent, you can see a

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1 linear increase. In transforming into HbA1c, you can  
2 see a moderate increase from nominal to 20 percent, of  
3 about .4 percent of HbA1c.

4 So in conclusion, in silico experiments  
5 allow for fast and inexpensive study of clinical  
6 consequences. We've shown that SMBG accuracy has  
7 dramatic consequences in terms of hypoglycemia  
8 detection. We've shown that it has also very  
9 important consequences in terms of treatment of  
10 hypoglycemia. It also augments glucose variability,  
11 due to the treatment of the meal. And it had a  
12 moderate effect in HbA1c over a long term period.

13 I would like to end up with very wise words,  
14 which is that all models are wrong, but some of them  
15 are useful.

16 (Applause) I would like ....

17 DR. GINSBERG: Ginsberg, New Jersey. Marc,  
18 very nice study.

19 When you do a model of merits, it's  
20 important that you consider all the system merits.  
21 When you modeled it, what did you use as the error for  
22 carb counting, for error in the constants, and error



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1 for the absorption of insulin?

2 DR. BRETON: So what I really -- so there's  
3 different answers for the different parts of your  
4 question.

5 So first, the error in carb counting, I was  
6 not necessarily interested in that. What I wanted to  
7 see was the sole effect of an error of glucose  
8 measurement. So of course I can induce some error of  
9 carb counting, but that would have induced errors in  
10 my -- in my results that would not have been caused by  
11 the SMBG. So there was no errors in carb counting.

12 Now, for the difference in insulin  
13 absorption, as you very well know, each of our  
14 subjects has a specific insulin absorption, and it's  
15 not going to change during the course of the day. What  
16 we are simulating, the observed variability, is not  
17 within one subject, but by having different subjects  
18 with very different characteristics. And so even  
19 though our subjects keep the same insulin absorption  
20 throughout the day, Subject Number 2 is going to have  
21 a very different insulin absorption than Subject  
22 Number 1, and that's how we account for that

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1 variability.

2 DR. GINSBERG: Okay. I'll present some of  
3 that in my talk. But when you put in all the errors,  
4 would you find, for a patient with Type I, based upon  
5 a meal dosing, that the error in glucose is about four  
6 to six percent of the total error in the system?  
7 Doubling the error in glucose goes to almost nothing.

8 DR. BRETON: It's not surprising. As Dr.  
9 Clarke was telling me earlier before this talk, if a  
10 patient forgets -- correct me if I'm wrong -- if the  
11 patient forgets one insulin shot in one week, their  
12 HbA1c is probably going to rise by the equivalent  
13 amount of what I showed today.

14 DR. CLARKE: One final quick question.

15 DR. BRETON: Okay.

16 DR. HARPER: I'd like to remind people with  
17 questions to please state your affiliation, as well.

18 MR. HUANG: Okay.

19 DR. CLARKE: Even if you've asked before.

20 MR. HUANG: Dijia Huang with Bayer Diabetes  
21 Care from Indiana. It's just a quick comment.

22 And I feel generally people use simulations

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1 for two purposes. One is to identify the trend, such  
2 as the percentage that we miss the hypo event versus  
3 the accuracy of the meter. The second application is  
4 to read exact number, such as, under what accuracy of  
5 the meter - - meter accuracy and what's the exact  
6 percentage of a missed hypoglycemic event?

7           And personally, I feel for the first  
8 application, for the trend, simulation is an excellent  
9 tool. But then when we go to -- when we go beyond  
10 this trend, go to the -- to read an exact number, to  
11 reach the conclusion, use the exact number, then I  
12 think it becomes weak. My concern is, such as the  
13 differential equation you showed, and in it, minor  
14 adjustment on those constants could shift the curve  
15 left and right and make the -- make us get different  
16 readings.

17           Just my short comments.

18           MARC BRETON: I'm going to have to both --  
19 which is interesting -- both agree absolutely with you  
20 and disagree. First, let's go on with the perfectly  
21 agree. Simulations is a limited tool, and it had -- it  
22 is designed for specific goals, and generally it

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1 shouldn't be used outside of these goals. You will  
2 note also that I only claim to replace pre-clinical  
3 data. At no point in this talk will I ever claim to  
4 replace clinical studies.

5           The place where I disagree with you is  
6 you're saying any shift of these constants in the  
7 equations would shift the curve left or right. Well,  
8 you're right if I was using only one set of such  
9 parameters. Now, this particular simulator has the  
10 advantage of having a 300 subject population, in which  
11 we claim we actually represent the variability.  
12 Actually, we represent more than the variability that  
13 is observed in vivo. So that particular shift that  
14 you're talking about, we actually see it here, and we  
15 account for it. And the result that I present to you,  
16 of course, averages over all these subjects.

17           MR. HUANG: Thank you.

18           DR. CLARKE: Thank you, Marc.

19           (Applause) Our next speaker this morning is  
20 Dr. Stephen Brotman, who is vice-president of payment  
21 and Healthcare Delivery Policy at AdvaMed. Dr.  
22 Brotman, like Dr. Shuren, has both an M.D. and a J.D.,

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1 and he's Board- certified in pathology and has worked  
2 as a senior regulatory and research attorney at Wyeth,  
3 which is now Pfizer this week, and who knows what next  
4 week.

5 And Dr. Brotman's going to talk about  
6 tighter performance criteria for blood glucose meters  
7 and whether or not they're needed.

8 DR. BROTMAN: Thank you. Good morning, good  
9 afternoon maybe. My name is Steve Brotman, and I'm  
10 currently a senior vice president at AdvaMed, which is  
11 the Advance Medical Technology Association. I'll be  
12 discussing this morning the industry perspective on  
13 tighter accuracy requirements for blood glucose  
14 meters.

15 This is an incredibly important issue for  
16 which industry has been engaged for years in  
17 development of the standard and ongoing advances in  
18 technology to bring the latest innovations in blood  
19 glucose meters to patients. We thank FDA for the  
20 opportunity to speak today at this meeting.

21 Just a little bit of background about our  
22 organization. AdvaMed is the world's largest

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1 association representing manufacturers of medical  
2 devices, diagnostic products, and medical information  
3 systems. Our member companies produce the medical  
4 devices, diagnostic products, and health information  
5 systems that transform - - they're transforming  
6 healthcare through early disease detection, less  
7 invasive procedures, and more effective treatments.

8           The medical technology industry is strongly  
9 committed to designing and manufacturing blood glucose  
10 meters that meet the needs of individuals with  
11 diabetes. We share the goal of improving meter  
12 accuracy.

13           Meter accuracy includes not only analytical  
14 performance, but the key areas impacting blood glucose  
15 meter accuracy include use error and interferences.  
16 The industry has made tremendous strides in  
17 improvements in both reducing use error and reducing  
18 the impact of interferences. Both are incredibly  
19 important aspects of use of blood glucose meters by  
20 self-testers.

21           The standard currently governing blood  
22 glucose meters for self-testing, ISO 15197, itself

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1 recognizes the importance of usability improvement.  
2 Specifically, it notes that the goals for performance  
3 criteria should be weighed against the capabilities of  
4 current self- monitoring devices. Furthermore, the  
5 standard notes that care should be taken implementing  
6 performance requirements that cause manufacturers to  
7 focus design improvements on analytical performance at  
8 the expense of other important attributes, such as  
9 greater convenience and greater compliance. Thus, the  
10 standard acknowledges the careful balance of these  
11 factors and the minimum acceptable device performance  
12 for glucose meters for self-testing. The standard  
13 supports performance improvements beyond analytical  
14 performance, such as advances that reduce dependence  
15 on user technology, otherwise referred to as patient  
16 usability.

17           Industry has made major advances through  
18 usability improvements since the approval of ISO  
19 15197. These address ergonomic and human factors that  
20 are incredibly important to patients who are self-  
21 testing. Manufacturers also integrate overall  
22 usability engineering in device design. There has

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1 never been an array of usability -- there have been an  
2 array of usability improvements. Such features will,  
3 of course, vary per meter. No single blood glucose  
4 meter will meet the needs of all patients.

5           While I'm not going to go into detail on  
6 each and all the various usability improvements, it  
7 should be noted that there are numerous improvements  
8 for which we have outlined. This gives a sense of the  
9 types of advances made by industry which contribute to  
10 the overall improved device performance. Among  
11 others, they include faster test times; smaller blood  
12 samples for decreased comfort (sic), and I just want  
13 to mention under that, patient discomfort was, in  
14 fact, a focus of the discussion in October 2001 FDA  
15 panel, where the panel encouraged FDA to approve blood  
16 glucose monitors with alternate site testing labeling  
17 instructions. Although alternative site testing may  
18 introduce more inaccuracy in precision, the panel  
19 cited that reducing pain would improve overall patient  
20 compliance with their testing program.

21           If we look at additional usability  
22 improvements, they also include overall increased



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1 robustness, such as cleaning solutions and hardware  
2 testing, enhanced meter displays, such as larger  
3 readouts, back lighting, and universal symbols. They  
4 include ergonomic design, such as buttons and meter  
5 size, including smaller meters for more discreet  
6 testing.

7           Another usability improvement would be non-  
8 changeable unit of measure by the user. And in some  
9 cases, no coding or calibration or timing is needed.

10           Other usability improvements include wider  
11 temperature range; improved range and stability for  
12 longer use life and decrease susceptibility to  
13 exposure; biosensor in addition to photometric  
14 technology; plasma- referenced results; integrated  
15 meter and lancing devices; improved voice simulators  
16 for the visually impaired; flagging test results, for  
17 example, meal markers; innovative software to organize  
18 meter data; and in some cases, no individual test  
19 strip for lancet handling, to reduce use error and to  
20 increase the ease of use.

21           And the list goes on. I will not go through  
22 all the improvements, but they are quite significant

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1 and certainly have impacted increased compliance and  
2 frequency of patient testing.

3           Just a word about additional usability  
4 improvements which are listed here. I'm not going to  
5 go into these, but it's evident there are clearly many  
6 options available, reflecting significant technology  
7 advances over the years.

8           Most of these usability improvements are  
9 actually beyond the current standard. They are not  
10 required under ISO 15197. They are the result of  
11 manufacturers' commitment to constant innovation to  
12 meet the needs of the self-tester. It should be noted  
13 that beyond the usability improvements, there are  
14 other significant improvements, including advances  
15 that have reduced susceptibility to interference, such  
16 as hematocrit. All of the advances are part of  
17 industry's efforts to support technology innovations  
18 that improve health care and lead to better outcomes.

19           So the question comes, where are we today?  
20 Well, multiple clinical studies have shown that home  
21 blood glucose meters meeting the current standard for  
22 accuracy, which is ISO 15197, are associated with

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1 improved glycemic control and produce positive  
2 clinical outcomes in such large randomized clinical  
3 trials, such as DCCT, the Diabetes Control and  
4 Complications Trial, which looked at the effect on  
5 insulin-dependent diabetes mellitus.

6           Furthermore, the current standard has been  
7 shown to produce clinically acceptable results. This  
8 was illustrated in consensus error grid analysis which  
9 has been constructed as an unbiased tool to analyze  
10 the clinical significance of blood glucose self-test  
11 measurement errors.

12           According to the consensus error grid  
13 analysis, 96 percent of the results fall within the  
14 range indicating no effect on clinical action, and the  
15 remainder fall in a range indicating altered clinical  
16 action with little or no effect on clinical outcome.  
17 Error consensus grid is a tool, we think, that is  
18 strongly considered an important tool for objective  
19 outcome assessment for blood glucose devices for self-  
20 testing.

21           We also believe that the impact of criteria  
22 changes on current meters should be considered in any

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1 change to accuracy. This is important, because some  
2 improvements will be difficult to sustain. Potential  
3 negative impact may be increased test time, increased  
4 sample size; narrow operational conditions, such as  
5 temperature or relative humidity; potential bulkier  
6 meter; and impact on usability and how overall user-  
7 friendly a meter may be. Cost is also a factor for  
8 patients in terms of affordable meters that meet the  
9 needs for self-testing.

10           It is important to recognize that the  
11 current accuracy criteria in the ISO standard is  
12 specific to self-monitoring use, not professional use.  
13 Industry fully supports efforts to develop increased  
14 accuracy requirements for blood glucose meters used in  
15 hospitals and long-term facilities. A standard is  
16 being completed to address this issue as we speak  
17 through the Clinical Laboratories Standards  
18 Institutes, CLSI, through updating of POCT(12),  
19 otherwise referred to as point of care blood glucose  
20 testing in acute and chronic care facilities. FDA,  
21 industry, and key representatives of the clinician  
22 community are all engaged in this effort. The

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1 political consequence of an inaccurate glucose result  
2 in these particular settings, which include immediate  
3 treatment decisions and generally increase  
4 susceptibility of the hospitalized patient merit  
5 specific guideline development for meters used in  
6 those settings.

7           We fully support those efforts. We also  
8 acknowledge that tight glycemic control is an  
9 important issue for hospitalized patients and the  
10 clinicians who are treating them. Importantly, we  
11 note that the current standard, which is for home use,  
12 was never intended for patients on tight glycemic  
13 control in the hospital setting. It will be addressed  
14 in POCT(12) and we fully support these efforts to  
15 address this in POCT(12).

16           As previously discussed, there has been a  
17 number of recent advances and evolution in blood  
18 glucose meter innovation by industry, contributing to  
19 an enhanced overall device performance. As part of  
20 that commitment to blood glucose meter innovation,  
21 industry is actively participating to update ISO  
22 15197. In addition to other revisions to further

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1 improve the standard, industry strong supports  
2 revising the accuracy standard in section 7 of ISO  
3 15197 for system accuracy of more than or equal to 95  
4 percent of the individual glucose results to be within  
5 plus or minus 15 milligrams per deciliter from the  
6 reference glucose values, and within plus or minus 15  
7 percent. At present, the current standard is plus or  
8 minus 20 percent.

9           There is also recognition by the standard  
10 review working group that the standards for hospital  
11 is CLSI POCT(12), and not ISO 15197. In addition,  
12 industry is actively engaged in discussing how to best  
13 deal with interfering factors in the standard.  
14 Industry is strong supportive of all these efforts,  
15 which we expect to culminate in a newly updated  
16 standard of great importance to the blood glucose  
17 meter industry and the patients using these innovative  
18 technologies.

19           Industry has also been proactively engaged,  
20 as mentioned, in an update of POCT(12). It should be  
21 noted that the document that the document is near  
22 completion and will set out the latest guidelines for

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1 blood glucose monitors in the hospital setting,  
2 including considerations of overall accuracy and tight  
3 glycemic control in that setting.

4           We also believe there are other mechanisms  
5 to support appropriate use of standards. FDA could  
6 formally adopt the ISO standard into FDA guidance to  
7 support enforcements for use of standards for self-  
8 testing only. But we continue to encourage that  
9 usability and analytical performance should be  
10 carefully weighed to assure meters that meet patients'  
11 needs.

12           Thank you for the opportunity to present  
13 today. Industry looks forward to ongoing work with FDA  
14 and the global standards community in systemic review  
15 of ISO 15197, as well as the completion of POCT(12) to  
16 support blood glucose meter innovation and the needs  
17 of users. I'll take any questions.

18                           (Applause)

19           DR. CLARKE: I have one question. I guess  
20 maybe I'm -- I'm inferring, from what you've said,  
21 that industry is trying to separate or would like to  
22 perhaps separate out home use by patients from

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1 intensive care use. And if that is so and they would  
2 like to have an ISO standard to improve the home use,  
3 but not necessarily the ICU use, I'm sure that  
4 industry wouldn't want to forego those 250,000 blood  
5 tests that are done in the ICU at Barnes Hospital  
6 every year, or -- I mean, I'm -- I don't get that --  
7 seems like that's a disconnect.

8 DR. BROTMAN: Well, I -- I see your concern,  
9 and I think the best way to address it is that there  
10 are members in Panel 2 from the blood glucose working  
11 group that have been talking about this for quite some  
12 time in quite some detail. And I think it's probably  
13 better addressed during that panel, if you wouldn't  
14 mind.

15 Yes, ma'am?

16 MS. RUTHERFORD: My name is Diane  
17 Rutherford, with Kenbuck(ph) Consulting in Dallas,  
18 Texas. And as a representative of industry, I thought  
19 this might be better suited for you.

20 We're talking about increasing the  
21 capabilities, the accuracy of the monitoring devices.  
22 How does that affect the accuracy of the dosing



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1 instruments? Your syringe dose tolerances are pretty  
2 wide, from my experience in industry. And is it fair  
3 to make the monitors more accurate and not make the  
4 dosing requirements more accurate, as well?

5 DR. BROTMAN: Well, I -- I think that that's  
6 a valid point for discussion. I think that's a  
7 discussion that's probably an ongoing discussion, and  
8 it's probably something that is continuing at this  
9 time. Again, I think that's something that could be  
10 addressed, and probably has been addressed, by the  
11 blood glucose working group, and you may want to pose  
12 that question.

13 DR. CLARKE: One further question? It's a  
14 long way down front.

15 MS. SOLDI: Sorry.

16 DR. CLARKE: It's okay.

17 MS. SOLDI: Monnett Soldo from OptiScan in  
18 California. We are not participants in the industry  
19 group that you mentioned, as a small startup. I was  
20 wondering if you could share with everybody, since you  
21 said the new proposed CLSI standard is near  
22 completion, what exactly that standard would be?

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1 DR. BROTMAN: Again, I think in terms of all  
2 the details that have been worked through and  
3 considered, the members of the working group would be  
4 the best members to be able to address something like  
5 that.

6 MS. SOLDI: Okay. I was thinking at the  
7 level of, you know, we're talking plus or minus 15 --  
8 plus or minus 15 percent. Can you summarize at that  
9 level?

10 DR. BROTMAN: Again, ask me specifically  
11 your question? The POCT(12)?

12 MS. SOLDI: Yeah.

13 DR. BROTMAN: I think that's a question  
14 that's probably best aimed at the working group, if  
15 you wouldn't mind.

16 DR. CLARKE: Other questions? Thank you  
17 very much.

18 DR. BROTMAN: Thank you.

19 DR. CLARKE: I'm going to just wing it,  
20 Barry.

21 Our next speaker is Dr. Barry Ginsberg, who  
22 is the CEO of Diabetes Technology Consultants. Dr.

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1 Ginsberg is former vice president of WorldWide Medical  
2 Affairs for the Diabetes Division of Becht &  
3 Dickinson, where he led the diabetes program there for  
4 about 17 years. He is a former professor of internal  
5 medicine at the University of Iowa. He has done his  
6 training at Beth Israel Hospital, as well as at the  
7 diabetes branch at the NIH.

8 He has been a consultant to the  
9 technological aspects of diabetes for a number of  
10 years, and he's going to talk to us today on Industry

11 Perspective: Tighter Performance Criteria  
12 are Achievable and Appropriate.

13 DR. GINSBERG: Thank you, Bill.

14 I actually had tried to make it easier for  
15 Bill by actually putting a small CV up in here, but  
16 .....

17 Let me talk a little about my conflict,  
18 first. I'm a consulting medical director for  
19 Agamatrix, which is a blood glucose monitoring  
20 company, as well as a speaker for Bayer and a  
21 consultant to the Juvenile Diabetes Research  
22 Foundation on the Artificial Pancreas Project.

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1 Indirectly, I work for companies who've worked for  
2 Roche and for LifeScan.

3           Let me talk a little about the industry  
4 perspective, tighter performance control -- criteria  
5 are achievable and appropriate. I think I'm the first  
6 speaker up here today who has an academic, a clinical,  
7 and an industry background. And all three of those go  
8 into my opinions today, which are solely my own.

9           As an overview, we'll produce some  
10 background. We'll talk about measurements of  
11 inaccuracy, necessary accuracy, and a little bit of  
12 outliers, and something about the sources of error.  
13 I'll talk a little about the current technology, where  
14 the accuracy is, and methods to improve it. I'll talk  
15 about testing and reporting, whether the testing ought  
16 to be done by the companies themselves internally or  
17 externally by a notified body like company, and  
18 whether testing should be done initially or  
19 periodically. And then finally, since this is a  
20 consumer product, what we ought to do about consumer  
21 labeling. And I think I can do that all in 20  
22 minutes.

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1 All right. When we talk about accuracy,  
2 we're really talking about accuracy and precision, and  
3 you really need both. A device which looks like this  
4 in terms of its accuracy, when you average out that  
5 accuracy, it's actually perfectly accurate, even  
6 though none of the individual values are even close to  
7 being accurate. So average accuracy by itself doesn't  
8 necessarily help us.

9 Similarly, average precision, by itself,  
10 doesn't help, because that's pretty tight and precise  
11 but nowhere near the value that we're interested in.  
12 And it's only when you consider both accuracy and  
13 precision that you get values which are right at your  
14 target. We'd like that with one number. And the  
15 number that comes closest to that is the number that's  
16 been given a couple of different names today, or mean,  
17 absolute, relative error, mean average deviation,  
18 relative average deviation, and so on.

19 And what it really does is, you just look at  
20 accuracy. What you're looking at here, if this is  
21 plus ten, this is minus ten, that's plus ten, that's  
22 minus ten. When you average those all out, that comes

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1 out to zero error. When you do this, you take the  
2 absolute value. So a plus ten becomes a plus ten, a  
3 minus ten becomes a plus ten, plus ten and minus ten  
4 again -- the average error here is ten percent. And  
5 so that single value, you're taking the absolute  
6 value, gives you an error which is useful in this. We  
7 also need to consider bias.

8           Now, we've talked a lot about ISO 15197.  
9 It's an international standard. It contains both  
10 clinical and laboratory standards, as well as other  
11 parts. Most importantly, it contains the study design  
12 of how this study should be done. We've talked about  
13 values, that 95 percent of the values should be within  
14 20 percent of the reference value for values greater  
15 than 75, and 15 milligrams per deciliter for values  
16 less than 75. And shown on a graph, that's sort of  
17 what this looks like.

18           Within the ISO, there's also an extended ISO  
19 standard, which is not required for approval, but is  
20 suggested it be done as well. And the extent that ISO  
21 looks at accuracy of not only 95 percent -- 20  
22 percent, but at 15 percent, 10 percent, and 5 percent,

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1 and that's shown in the graph here in the orange,  
2 yellow, light green, and dark green.

3           More importantly, when you ask the question  
4 of, what do these do in terms of hypoglycemia? Because  
5 I believe that glucose monitoring is most useful at a  
6 patient level. Let me point out here, I am only  
7 talking about self-glucose monitoring here. I am not  
8 talking about hospital use of meters in any part of  
9 this talk. It's really useful in two respects for the  
10 patient. One is it's useful in helping them select  
11 the dose of insulin appropriate at a meal, and  
12 secondly, it's helpful in letting them know when  
13 they're becoming hyperglycemic. And we'll talk about  
14 those two separately.

15           But when you look at the ISO standard and  
16 ask, So if the actual blood glucose is 70, at the  
17 various ISO standards, what is my 95 percent  
18 confidence limits on what I'm going to see? And so at  
19 the ISO standard of 20 percent, that 70 is somewhere  
20 between 55 and 85. Well, if I'm 70 and the meter's  
21 telling me 85, I'm not sure I'm getting the  
22 appropriate information.

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1           At 15 percent, it goes up to 81; at 10  
2 percent, 78; and at 5 percent, it's down to 74. So  
3 the more accuracy here is actually probably pretty  
4 important.

5           ON the other hand, when you consider the  
6 effect of blood glucose in terms of selecting an  
7 insulin dose, I think it becomes pretty unimportant.  
8 Let's consider all the errors that go into selecting  
9 an insulin dose. So I'm sitting down to a meal, and  
10 the first thing I'm going to do is count my  
11 carbohydrates. Well, how much of an error is there  
12 when I figure out how much food is in that meal? Well,  
13 it turns out the likely number is 15 to 20 percent.  
14 Some people are significantly less accurate than that  
15 and may have numbers up to 25, even 35 percent.

16           So I now have a number, I'm going to eat 60  
17 grams of carbohydrate. Well, I'm going to take that  
18 and divide that by my carbs to insulin ratio, which is  
19 ten, saying I need six units of insulin. How much  
20 error is that constant? Because it turns out that  
21 most patients are given a number when they develop  
22 diabetes, and no one ever changes that number again.



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1 They have that number for the rest of their life. The  
2 likely error there is at least ten percent, and maybe  
3 as high as 25 percent.

4           And then finally, I actually get my  
5 calculation, I need six units of insulin, and I inject  
6 it. How much error is there in that six units of  
7 insulin being absorbed? And again, it depends on the  
8 kind of insulin. For a rapid-acting insulin like  
9 lispro, it turns out that's about 20 percent. For a  
10 less-rapid acting insulin, like regular insulin, it  
11 turns out that's about 35 percent.

12           Now, when you have a series of errors --  
13 engineers like to stack them -- but it turns out the  
14 correct thing to do is to take the square root of the  
15 sum of the squares. And when you do that, you find  
16 out that the total error here is about 27 percent,  
17 which gives you a 95 percent confidence in the error  
18 of plus or minus almost 70 percent. And likely error  
19 here is 46 percent, with a 95 percent confidence limit  
20 on that of plus or minus 115 percent.

21           Now, it turns out -- I didn't put blood  
22 glucose monitoring in here, because it turns out that

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1 if you take blood glucose monitoring and change the  
2 error, the average error, from five percent to ten  
3 percent, you barely change that number. You increase  
4 it by one to three percent. Well, at three percent at  
5 27 percent, I increase my error by only ten percent.  
6 And here, even less.

7           So it turns out that blood glucose  
8 monitoring error, in terms of selecting a meal, is  
9 actually probably relatively unimportant. ON the  
10 other hand, as you look at Number 4, blood glucose  
11 monitoring error when I select -- when I want to know  
12 if I'm hypoglycemic, is actually pretty important.

13           Now, based upon that, and this is only  
14 personal opinion, what I would suggest is how much  
15 accuracy you need depends upon who you are. If I'm a  
16 patient with Type II Diabetes on diet or non-  
17 hypoglycemic oral agents, I don't need to know about  
18 hypoglycemia. I'm never going to become hypoglycemic.  
19 There's nothing there to make me hypoglycemic. And so  
20 the current standard of 20 percent is actually fine.

21           If I'm a patient with Type II Diabetes on  
22 insulin or an oral agent that does cause hypoglycemia,

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1 which is becoming rarer and rarer, then I probably  
2 need a little more accuracy, and 15 percent is  
3 probably appropriate for me.

4           If I am a patient with Type I Diabetes who  
5 is now running my blood glucose an average of 80 or 90  
6 or maybe 100, now accuracy in terms of hypoglycemia  
7 becomes very important for me, and an average accuracy  
8 of ten percent would actually be very helpful to me. I  
9 might comment here that laboratory accuracy at two  
10 percent would put me up here.

11           Just an interesting point as an aside here.  
12 When you start to consider the accuracy of these  
13 meters, you start to consider how you're going to test  
14 them. If I have an average meter with ten percent --  
15 95 percent confidence limits or a four percent average  
16 in accuracy, I can't test that with a laboratory  
17 instrument. Because laboratory instruments have two  
18 and a half to three percent inaccuracy. That means  
19 the error in my testing instrument is going to be 30  
20 to 40 percent of my total error. Then when I get down  
21 to this, I'm going to have to start going to GCMS spec  
22 or another really tight reference value, which is

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1 going to be very hard to do.

2 Now, we talked a little about error grids.

3 And what I've shown here is something I consider very

4 important in terms of outliers. This is not real

5 data, because the real data it's based upon is owned

6 by a company that I couldn't -- I actually didn't have

7 a chance to ask them to use the data. So this is data

8 that I've made up, but it does reflect real data. So

9 it's for illustrative purpose only.

10 And here you have 5,000 samples on a

11 consensus error grid. It looks pretty good, except

12 there are five values there, or about .1 percent,

13 which are not so good. It's a value of 290, which is

14 showing up as 525; a value of 230, showing as 475; a

15 value of 205, showing up as 350. At .1 percent, the

16 average patient with Type I Diabetes will get at least

17 one of these a year, and probably more. And if they

18 don't -- if they believe this, that's going to lead to

19 serious hypoglycemia when they take that insulin for

20 that.

21 So I think outliers are important. I don't

22 know what to do about them, but right now we're doing

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1 nothing about them. We're not even talking about  
2 them. I think it's important that we start talking  
3 about them.

4           Now, where are the sources of error that's  
5 we're going to deal with? Well, the first is  
6 intrinsic sources. Manufacturing variation -- there  
7 are small variations in the size of the well or the  
8 size of the silkscreen-printed electrodes. There are  
9 differences in how well the enzyme is laid down in  
10 that well or print screen. There is the age of the  
11 strip, and mediator oxidation, all of which add to  
12 intrinsic error of the strip.

13           This physical location -- temperature can  
14 affect this, and altitude can affect this. There are  
15 interfering substances, and I won't go into these in  
16 detail, because they have been before -- intrinsic  
17 urate triglycerides for some oxygen, for glucose  
18 oxidase, ascorbate, acetaminophen, L-Dopa,  
19 Enflazamide, and for glucose, the hydrogenous PQQ  
20 maltose, icodextrin, and xylose.

21           And then finally, there are patient factors.  
22 From a medical point of view, there's hematocrit. From

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1 an educational point of view, there's technique,  
2 coding, and hand-washing, all of which add to the  
3 errors that we're dealing with.

4           Now, this is a paper by Freckmann from  
5 Diabetes Therapeutics and Technology in December. And  
6 God bless him, he actually took a whole bunch of  
7 meters and tested them all in the lab, and actually  
8 found that for the most part, they were pretty  
9 accurate. That you can see all of them met the 20  
10 percent standard, many of them met the 15 percent  
11 standard. As you go down to the ten and five, fewer  
12 and fewer of them did.

13           If you look at data from FDA submissions or  
14 in package inserts, you find data here, and this is  
15 from nine companies which we could get this from, and  
16 you can see that for the most part, they all met the  
17 20 percent. A number of them met the 15 percent; some  
18 ten, and some five. Some of these are clinical and  
19 some of these are laboratory, but Company E, actually,  
20 I know is clinical. And they did pretty well. They  
21 can meet a 15 percent standard. They can almost meet  
22 a ten percent standard. The question you could ask is,

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1 do you need that? We'll get back to that in a second.

2 Now, there are methods to improve this.

3 Hematocrit can be measured by AC impedance or by

4 dynamic electrochemistry. Temperature and altitude

5 can be met by thermistors, and again, dynamic

6 electrochemistry. Manufacturing variation, QC,

7 interference by multiple electrodes or dynamic

8 electrochemistry. Coding, by no coding meters, either

9 by code selection or coding on the strip. And

10 finally, aging -- some of the meters actually, they

11 use cartridges, print the age on the cartridge, and

12 the meter won't work if the strip is too old. So

13 there are approaches which will get us more accurate

14 as we go further along.

15 Now, a number of years ago, I made a

16 statement you can trust device manufacturers in

17 clinical trials. If it's EU certified, you can ask

18 the notified body testing, and you can pass it. I've

19 seen some data recently which makes me a little less

20 confident about manufacturing testing, particularly

21 from some of the smaller manufacturers, and I sort of

22 wonder about that. So I'm going to ask the question,

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1 Is it appropriate now to go beyond internal testing by  
2 the manufacturers and go to a system closer to Europe,  
3 where you have notified bodies or other groups that  
4 actually do the testing for you, so you can be sure  
5 that when you publish the results of your accuracy,  
6 it's the same for everybody?

7           Blood glucose meters have become consumer  
8 products. When companies advertise on blood glucose  
9 monitors, they talk about size. They talk about  
10 shape, they talk about color. They talk about  
11 convenience. Those are consumer features. Some of  
12 them are talking about accuracy, but for the most  
13 part, we're talking about consumer products, in which  
14 consumers are making decisions about the device they  
15 choose. And for a consumer product, information is  
16 king. You need to create informed consumers, and the  
17 consumer needs to have standardized, accurate  
18 information.

19           Because of that, I think we ought to go to  
20 external testing. It's a standard protocol with  
21 clinical testing of random lots, not specific lots. A  
22 standardized analysis of the data in order to produce



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1 standardized labeling. And put the label right on the  
2 strip container, saying exactly how accurate how you  
3 are in a method that anyone can understand. As a  
4 matter of fact, at a fifth grade reading level -- as a  
5 matter of fact, if we come up with a better number,  
6 something akin to a batting average, I think that will  
7 be even better.

8 I put this in gold because I don't know  
9 whether we ought to have -- we ought to develop a  
10 standard protocol for outlier analysis, but I don't  
11 know what to do with it after you get that.

12 Clinical testing ought to be periodic. It  
13 ought to be every six to 12 months so we know that the  
14 accuracy of the initial test is continuing. It ought  
15 to be done on random lots. I think reasonable  
16 failures don't require a corrected -- they require  
17 correction, they don't require recall. And outlier  
18 testing ought to be continuous, but outlier testing  
19 requires so many strips. You need 10, 20, 30, 50,000  
20 strips to test for outliers. I think that has to be  
21 done by the manufacturer.

22 So my recommendation is, then, our accuracy,

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1 the substantial majority of users, which is those  
2 patients with Type II Diabetes on diet or non-  
3 hypoglycemic oral agents, don't require more accuracy  
4 than we have today. And if we get -- if we demand more  
5 accurate devices, we're going to lose other consumer  
6 features and/or make them more expensive. So I think  
7 we ought to keep the current ISO standard as the  
8 minimal acceptable clinical accuracy, although it  
9 ought to be done with random lots.

10 I think we ought to be labeling devices with  
11 what the true accuracy is. The strip container should  
12 be labeled with the mean average rule of error, and  
13 the ISO errors, and maybe, although I'm not sure,  
14 labeled as group-appropriate. This is appropriate for  
15 Type II's on oral agents; this is appropriate for Type  
16 I's on insulin, et cetera.

17 Testing ought to be done initially with  
18 random lots, external control at a notified body-like  
19 device, and periodic testing of random lots and better  
20 testing of outliers.

21 Labeling -- I just put a hypothetical label  
22 here -- should show, develop a standard label, sort of

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1 like nutrition labeling, or Energy Star labeling. I  
2 mean, all other consumer products have this. Why  
3 shouldn't this consumer product have it? So develop a  
4 standard label so you can look at it and know exactly  
5 where the average error is going to be, where the  
6 extended ISO error is going to be. Put in MARE, or  
7 even better, a batting average. Put in extended ISO  
8 data, and question about intended consumers.

9           So in summary, then, I think blood glucose  
10 monitoring is currently accurate enough for a  
11 substantial majority of patients. Now let me say,  
12 this is not strips. Those patients do not use the  
13 majority of the strips, but it is the majority of  
14 patients.

15           Better accuracy is achievable, but not  
16 necessary for everybody. Since it's a consumer  
17 product, better labeling is essential. We ought to do  
18 that with external testing with a standard protocol  
19 and periodic testing. And a standard label, like a  
20 nutrition label.

21           With that, I'll stop, and ask if there are  
22 any questions.

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1 (Applause)

2 DR. CLARKE: Are there questions for Dr.  
3 Ginsberg? I have a question.

4 DR. GINSBERG: Okay.

5 DR. CLARKE: You talked about labeling, and  
6 you talked about pitching it at a fifth grade level,  
7 which I think is really a good idea. But it seemed to  
8 me like the labeling that you were talking putting on  
9 the strip bottle could not be interpreted by somebody  
10 with a fifth grade or an eighth grade education.

11 DR. GINSBERG: I'm not sure that -- I'm not  
12 sure that's true. If you present a booklet to go  
13 along with this -- when you go to Consumer Reports and  
14 look at their red circles, black circles, and half  
15 circles, they don't explain to you what it means. And  
16 it's not that hard to say a MARE, the lower the number  
17 it is, the more accurate it is; that for the ISO  
18 standards, the higher the number it is the better it  
19 is. And that for different groups, you may require  
20 different amounts. And we have to agree on what that  
21 is, but I think that could be done.

22 DR. CLARKE: Go ahead, please.

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1 MR. BASHAN: Eran Bashan from Michigan. I  
2 actually think that your data suggests that we're much  
3 better positioned than we think, because you know,  
4 even if you look among insulin testers, 60 percent of  
5 the folks on insulin use either long-acting insulin or  
6 premixed biphasic insulin. And their dose doesn't  
7 actually depend on the glucose level. And if you look  
8 at, you know, your major concern, the outliers, there  
9 are roughly ten billion tests done in the U.S. every  
10 year. If you think that one percent of them are  
11 extremely inaccurate, that's 100 million tests per  
12 year.

13 DR. GINSBERG: Point one percent.

14 MR. BASHAN: If you look -- .1 percent, ten  
15 million. If you look at, you know, mortality from  
16 diabetes, that's two orders of magnitude less than  
17 that. So you can actually claim that 99.95 percent of  
18 the tests done today are extremely safe.

19 DR. GINSBERG: But there are 50,000 serious  
20 hypoglycemic events per year.

21 MR. BASHAN: I know. But that suggests,  
22 given the amount of measurements, that the real

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1 accuracy that you have today is much better than the  
2 ones actually reported.

3 DR. GINSBERG: Thank you.

4 DR. WHITE: I'm Neil White. I'm a pediatric  
5 endocrinologist from Washington University in St.  
6 Louis. I think that education of the consumer is  
7 really important, and you've made -- you've made that  
8 point. And we talk about error in here, I think some  
9 of us in the audience are learning a lot about error  
10 in the measurements. But I don't think our patients,  
11 especially the mothers of our children with diabetes,  
12 understand error at all. They expect the number to be  
13 a number; okay? They don't see -- they call us when  
14 they do two measurements in rapid succession and one  
15 is 120 and one is 135, okay, which we all know is  
16 within the error of a test. But they don't understand  
17 that. There's a huge opportunity for education for  
18 the consumers understanding what these strips are  
19 capable of doing and what the results mean.

20 DR. GINSBERG: I agree. As long as Neil is  
21 up and reminding me, actually, let me actually point  
22 out in terms of accuracy that a number of people have

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1 talked about the DCCT. The average error of the  
2 meters in DCCT was between 13 and 15 percent in the  
3 hands of patients, significantly higher than we're  
4 talking about today, by a factor of three.

5 DR. CLARKE: Other questions? Thank you.

6 (Applause) We are going to break now for  
7 lunch until 1:30. At that time, we will reassemble  
8 here, and a larger, expanded panel will be present for  
9 you to question. So while you're having lunch, ask  
10 your friends, or you're not-friends, what they thought  
11 of this morning's presentations and what questions  
12 they had, and let's make sure our questions are  
13 answered at 1:30. Thank you.

14 SESSION 1 PANEL DISCUSSION

15 DR. CLARKE: Please take your seats. We are  
16 ready to begin this afternoon's session. We are about  
17 to have a panel discussion, and the panel includes all  
18 of the speakers from this morning, plus some  
19 additional distinguished individuals, including Ellen  
20 Ullman, who is a diabetes advocate and Vice President  
21 of Children with Diabetes, and works closely with  
22 Kelly Close and Closer Concerns and is a parent. And

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1 so she is really the Type I Diabetes advocate here,  
2 and we're going to all want to hear from her.

3 Dr. David Klonoff, who is sitting to her  
4 left, but to my right, who is Clinical Professor of  
5 Medicine at UC San Francisco, the founder of the  
6 Diabetes Technology Center, the Editor-in-Chief of the  
7 Journal of Diabetes Science & Technology, and the  
8 Medical Director of the Mills-Peninsula Diabetes  
9 Research Institute, in his spare time.

10 And next to him is Dr. Alberto Gutierrez,  
11 who is the Office director or Director of the Office  
12 of In Vitro Diagnostics at the FDA.

13 And this is going to be an exciting time. I  
14 would stress to the people here, when a question is  
15 asked to you, make sure you push your microphone until  
16 the red light comes on, and when you're finished  
17 talking, make sure you turn it off, because otherwise  
18 people will hear what you say.

19 (Laughter) And it could be embarrassing.

20 And at -- at this time, I'd like to invite  
21 people to come to the microphone, and you may ask any  
22 question that you wish. Don't be shy. There was



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1 someone who stood in line a long time and didn't get  
2 to ask a question.

3           Okay. I'm going to start out with a  
4 question for Ms. Ullman. Because you've been through  
5 this business of testing blood glucose a lot in a  
6 child, and because I'm a pediatrician I can empathize  
7 with that. And I guess I'm wondering, do you feel  
8 that you needed a blood glucose monitor for your son  
9 which was significantly more accurate than you had?  
10 And -- here's the second part of the question -- would  
11 you be willing to give up something in order to have  
12 more accuracy? And that giving up might mean taking  
13 longer to get a test result, giving a -- maybe having  
14 a larger drop of blood, or something else?

15           MS. ULLMAN: Oh, absolutely. We needed --  
16 my son was one when he was diagnosed. He's now 22, so  
17 we've done 21 years of blood glucose testing. And  
18 when you have a little child, you know, one year old,  
19 and you see a 360 on a meter because -- for whatever  
20 reason, you're going to dose. And if that 360 was  
21 really a 240, your child's going to be hypo, we're  
22 going to be getting out the gluca gun, and yeah, we

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1 would sacrifice several of the convenience factors.  
2 Not that I want to bring back the hanging drop of  
3 blood, but yeah, I mean, what's another 20 seconds  
4 versus five seconds? Absolutely, accuracy is the most  
5 important.

6 And that's really what I heard across the  
7 board. I'll talk about the survey tomorrow, but across  
8 the board, parents want accuracy, first and foremost.

9 DR. HARPER: Ellen, do you believe that  
10 parents of Type I diabetic children, or some Type I  
11 diabetics that you've talked to, do you believe they  
12 realize that the blood glucose meters have some  
13 inherent inaccuracy? Or do you -- do you think  
14 they're aware of that or not?

15 MS. ULLMAN: Well, in the survey, and I  
16 don't remember the statistics exactly, but it was  
17 approximately -- at least 40 percent thought it was 15  
18 percent or less, within 15 percent. And this was a  
19 fairly sophisticated group, because they all took it  
20 online, so they were all Googling, and they could  
21 certainly look up to see that it was 20 percent. So,  
22 yeah, I don't think -- I think there are a lot of

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1 people that have no idea, and I do think we need  
2 labeling.

3 DR. CLARKE: Questions?

4 MS. BOWMAN: My name is Cynthia Bowman. I'm  
5 from Long Island Jewish Medical Center. And I was  
6 just wondering how you would tie in -- I mean, I  
7 realize the total testing process is pre-analytic and  
8 analytic and post-analytic. And you know, you have to  
9 equate glucose monitoring with wave testing. And the  
10 definition is -- you know, the fundamental definition  
11 is it's so simple that you won't make a mistake. And  
12 if you do make a mistake, it doesn't matter. It was  
13 part of the, you know, fundamental definition of wave  
14 testing.

15 But how much do you think that actually  
16 contributes? I mean, do you think that still  
17 contributes to some sort of devaluing of it? As many  
18 fail-safes as you put in, et cetera, do you think  
19 that, especially in the hospital setting, that people  
20 take it as seriously as they should? Do you think that  
21 that actually gets in the way of taking it seriously?

22 For anybody.

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1 DR. HARPER: You know, I'll leave the  
2 clinical comments to the clinicians, but I would like  
3 to comment that Carol Benson tomorrow will be giving a  
4 talk on sort of the difference between CLIA  
5 requirements -- she's not going to go into it a lot,  
6 but I'll mention that anything that's cleared over the  
7 counter is actually automatically waived. So the  
8 evaluation that goes into a device that actually gets  
9 evaluated for being simple and having those fail-safe  
10 processes isn't actually implemented for all over-the-  
11 counter reviews. So that is something that perhaps is  
12 not in place necessarily for all over-the- counter  
13 product reviews, including -- including this.

14 Now, that doesn't mean we don't assess any  
15 user factors or the ability of users to use these  
16 devices. But it definitely is a place where if people  
17 are assuming that these devices have gone through that  
18 type of evaluation, that actually isn't true.

19 MS. BOWMAN: I mean, in that grueling  
20 hospital environment, one of the things we find is a  
21 resistance to proper technique. I mean, these are  
22 supposed to be easy. Plus, you know, in their defense,

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1 they're very busy. They're doing many other things, et  
2 cetera, et cetera. But you know, doing the QC, paying  
3 attention time after time to the technique, et cetera,  
4 et cetera, is sometimes devalued. And, you know, I  
5 realize it's not just the meter that you're looking at  
6 here when you're looking at accuracy. You're looking  
7 at the whole process.

8 DR. SCOTT: I'll take a shot at that, and  
9 also maybe try to get a discussion amongst the panel  
10 members here, because I don't think there's a single  
11 shy person up here, so ....

12 The total testing process is really more  
13 than just the meter. I was talking with Gary Tobin,  
14 who heads our diabetes clinics in St. Louis, just last  
15 week. And he believes that errors in the meters are  
16 just a small component of the total number of errors  
17 that are made in the intensive care units. There's  
18 errors in dosing; there's errors in timing. But --  
19 and I think Dr. Ginsberg made this point -- the errors  
20 of the meters are a small part. But it's sort of like  
21 Toyota, you know. They've got a brake problem and  
22 they've got an acceleration problem. And to say,

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1 well, we're going to ignore the brake problem, because  
2 the acceleration problem is bigger. Fix what we can,  
3 I mean one step at a time. And meters are certainly  
4 one of those steps that I think we can fix.

5 I'm tossing that out to Barry.

6 DR. GINSBERG: Actually, probably the  
7 biggest error in glucose monitoring is one that I  
8 don't think I had on my slides, although I may have,  
9 in the home setting. And probably the biggest single  
10 error is hand-washing. That, you know, all the meters  
11 say wash your hands before you do a test. Well, it  
12 turns out nobody does. We actually studied that, and  
13 at least four out of five patients did not wash their  
14 hands, including our director of blood glucose  
15 monitoring marketing, who had diabetes, and didn't  
16 wash his hands before he did it. I came in one day,  
17 and our head of a lab was bashing me as I walked in  
18 the door, that "your meter is so inaccurate." You  
19 know, "I don't have diabetes, and I'm getting a  
20 reading of 300." Well, it turns out she had just  
21 eaten a banana, and the banana was on her hands. We  
22 had to wash her hands, the blood glucose was back down

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1 to 80.

2                   Then if you have Chips A'hoy on your hands,  
3 that will raise your blood glucose by 200 to 300  
4 points. That's as bad as talking about with the  
5 icodextrins(ph), that hand-washing is a critical  
6 factor in these things. There's probably nothing you  
7 can do -- nothing you can do in the meter to protect  
8 against that. And part of it is that the drop of  
9 blood that you take now is so small. For those of you  
10 who don't -- I assume you all know this, but if you  
11 don't, the average meter is now running .3 to .5  
12 microliters. If you were to look at that on a piece  
13 of paper, that's a decimal point. That's the dot at  
14 the end of the period is how much blood you need to  
15 run one of those things.

16                   Well, it doesn't take very much glucose to  
17 raise that drop of blood by a lot, and that's a big  
18 error. And I'm not suggesting in the least that we  
19 don't need better accuracy of meters. What I'm  
20 suggesting is that not everybody needs better accuracy  
21 of meters. And a better accuracy of meters means that  
22 you have to give up something, that you have to go

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1 back to a hanging drop, or you have to go to a bigger  
2 meter, or you have to go to longer times. That's a  
3 consumer products issue.

4           And some people, you'll need to go to  
5 hanging drops. And some people who don't like to go to  
6 bigger meters, and some people don't care. What's  
7 appropriate is to make people understand -- help  
8 people to understand what they need and how they get  
9 it, and then give them the information they need to  
10 make that decision properly.

11           DR. HARPER: So I have maybe something to  
12 add to that, because I agree that certainly user  
13 errors and perhaps of unawareness of the things that  
14 might impact a glucose result definitely do contribute  
15 to error. But what I'd like to point out is that that  
16 error is actually not captured in the numbers that we  
17 were talking about earlier today in terms of the  
18 requirements. So that error is above and beyond the  
19 data that FDA, for example, sees when they're clearing  
20 or approving a glucose device.

21           So the studies that we see are performed in  
22 the laboratory, or they're performed in cases where



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1 maybe a layuser comes in. And they probably make sure  
2 they wash their hands.

3 DR. GINSBERG: Absolutely.

4 DR. HARPER: So -- so although we may not be  
5 able to address every single source of error, we can  
6 certainly try to increase education and awareness.  
7 Like Mitch said, we actually -- I'd like to see if we  
8 could focus on the types of error that perhaps we can  
9 address, because the error that you're referring to is  
10 on top of the 20 percent. So what you're seeing is  
11 that, you know, you have the 20 percent error inherent  
12 in the system, in an ideal situation, plus any added  
13 error based on use.

14 MR. TORJMAN: Marc Torjman, Cooper  
15 University Hospital. I think you've probably answered  
16 my question. But what I was wondering is whether there  
17 are requirements for the manufacturers to actually  
18 alert the patient when a glucose value is -- is out of  
19 range, and how you define this out of range is an open  
20 question, I guess. But does the agency require that,  
21 so that a patient who is at home at least has some  
22 idea that they need to repeat the measurement, as

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1 opposed to the -- in the hospital setting, where the  
2 clinicians tend to make those decisions and send a  
3 blood sample to the laboratory to make sure that they  
4 have an accurate value? That's not the case with the  
5 home use.

6 DR. HARPER: Yes, that's definitely a  
7 challenge. So the home user does not have another  
8 method to rely on to check a value, and I think in  
9 most cases, a false result may be unidentifiable to  
10 the patient.

11 Probably the only way a patient might be  
12 able to determine when a meter is not working, and  
13 this is if it's a systemic problem, is if they do the  
14 recommended control material testing. We've heard,  
15 though, that a lot of patients may not do that as  
16 often as perhaps is recommended. So if, you know, a  
17 reduced amount of control material testing is done,  
18 then they may not catch any inherent problems with  
19 their meter. And also if it's a sporadic issue. If  
20 it's not hand washing, if it's a sample application  
21 issue, if it's something like that that's specific to  
22 that one test strip, then I think that there is a

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1 problem that the patients at home wouldn't be able to  
2 identify.

3 DR. GINSBERG: Let me raise a question.  
4 We're dealing with two separate items, and we're  
5 dealing with them together, which is probably  
6 inappropriate.

7 When we talk about a blood glucose which is  
8 really 240 but measures out 360, there we're talking  
9 about an outlier. And outliers occur at .1 percent or  
10 less, so one in a thousand strips will be there. I  
11 mean, they happen, and I think we ought to be paying  
12 more attention to them, but they're not that common.

13 When we talk about a 20 percent error, which  
14 we're saying 95 percent of the values would be that,  
15 and we do the ISO testing, the other five percent are  
16 not out at 400. They're at 21 percent, 22 percent --  
17 they're not way out there. They're pretty close.

18 On 240, a 20 percent error is 48. So you're  
19 looking at 200 to 280. That's a big difference, but  
20 in terms of insulin dose, that's only one unit for  
21 most people. And that the absorption change in  
22 insulin, if you give somebody six units, the

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1 variability of giving to the same patient in the same  
2 place with the same syringe or same pen or same pump  
3 at exactly the same time of day is 20 to 35 percent.  
4 So they're going to be one and a half to two units off  
5 just because the insulin's so variable.

6 MR. TORJMAN: Thank you.

7 MS. ULLMAN: And I would add that one unit  
8 in a two- year-old is huge.

9 DR. GINSBERG: I'm sorry, I agree with that,  
10 because a unit -- she was only taking two units. But  
11 in a two- year-old, 40 wouldn't be a unit. Forty  
12 would be a quarter of a unit.

13 MS. ALLBRIGHT: Hi, I'm Ann Allbright. I'm  
14 the Director of the Division of Diabetes at the CDC.  
15 I'm going to ask the panel a question that I hope will  
16 spark some discussion. From the public health  
17 perspective, meter accuracy is absolutely critical for  
18 patients who are testing for their management, and  
19 certainly for hospital use. But there is another end  
20 of the spectrum, and that is really the screening  
21 arena. And it's very controversial, and those of us  
22 in public health deal with this every day.

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1           So comments from the panel about not  
2 diagnosis of diabetes, but screening, and where it's  
3 used. And there's actually a reasonable amount of  
4 evidence that suggests that people are much more  
5 responsive for follow- up if their screening  
6 conversation involves a blood measure of some sort, as  
7 opposed to paper and pencil risk test.

8           So I'd be interested in the panel's comments  
9 on that, particularly as we're now moving into the  
10 arena of needing to identify people with pre-diabetes,  
11 get them into having conversations, and now developing  
12 a national prevention program.

13           So, eager to hear the panel's comments on  
14 screening using monitoring.

15           MS. BERNHARDT: Well, currently, the FDA  
16 does not clear meters for screening or diagnosis.  
17 We're well aware that they're used in that manner,  
18 especially like at health fairs and stuff, but just  
19 informationally, they are not cleared for that use.

20           DR. CLARKE: If I may say something as a  
21 pediatrician who -- whose parents and grandparents --  
22 who has parents and grandparents who are forever

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1 screening their children and their grandchildren, and  
2 calling at all hours of the night with blood sugars  
3 that are 150 and 160 or 40, and these are in children  
4 who don't have diabetes. And this necessitates quite  
5 a large workup, because they are either -- their local  
6 physician will not see those children. They are sent  
7 immediately to the medical center with the diagnosis  
8 of diabetes, which they most of the time do not have.

9           So that I think that if we had something  
10 that was more accurate in terms of screening, I think  
11 that would be a tremendous asset, but it would need to  
12 be in every system, it wouldn't need to -- you know,  
13 because it's grandmother's meter that is usually the  
14 impetus for the patient to come to the hospital the  
15 next day.

16           DR. GINSBERG: I'm going to disagree again.  
17 If you had a more accurate meter and you took it from  
18 20 percent down to 10 percent, what that would mean is  
19 for an average value of 120, instead of being 120 plus  
20 or minus 24, it would be 120 minus 12. So you'd go  
21 from 144 to 132. That's not going to make a big  
22 difference in your phone calls.

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1           And as to Ann's question, I think that's --  
2 it's a very interesting question, that when you look  
3 at impairing glucose tolerance, which I think is one  
4 of the major risk factors that you're looking for, an  
5 hour after a meal, you're looking for a blood glucose  
6 value of 200 or more. And so if you take the 20  
7 percent accuracy where we are now, that would say that  
8 if you're looking for 200, your 95 percent confidence  
9 limit is 160 to 240. The upper side is no problem, you  
10 still have over 200, you still have impaired glucose  
11 tolerance.

12           The problem is, what happens if you're low?  
13 Well, I would actually say, you know, if somebody two  
14 hours after a meal has a glucose value of 160, they're  
15 still somebody you want to look at. So I think while  
16 they're not as accurate as you'd like for this, I  
17 think they still meet the needs.

18           DR. KLONOFF: I'd like to comment on this  
19 discussion and where I see this is going. I feel that  
20 the group has already accomplished a lot. When this  
21 meeting was announced about three or four months ago,  
22 my sense was that there were many people who thought

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1 this meeting could be very confrontational and that  
2 perhaps the FDA would be making demands of industry  
3 that it would be very difficult to achieve. Perhaps  
4 industry would be refusing to budge on the products  
5 that they're producing.

6 In fact, I'm seeing this as very collegial,  
7 and for the most part, it seems as if the two groups  
8 are coming together very well. Plus the medical and  
9 academic communities, everybody seems to agree that we  
10 need in general lower standards for accuracy, go down  
11 from 20 to around 15. That's the number that keeps  
12 coming up.

13 And what I think is happening is that when  
14 the FDA is setting standards, these are regulatory  
15 standards. A regulatory standard means this is  
16 something that's achievable. When doctors make  
17 requests or standards, we tend to talk about what's  
18 needed. Those are clinical standards. We can say  
19 we're like the ADA, we want five percent accuracy or  
20 we want zero percent errors, we want absolutely  
21 perfect meters. We can say this, because this is what  
22 we want in our hearts. But that's not necessarily



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1 achievable, either in terms of the technology or in  
2 terms of making it economically viable. I mean, for  
3 enough money, you probably could get a device that's  
4 extremely accurate, but the cost would be impossible.

5           So what I think we're seeing here is a very  
6 healthy process. I see that industry is responding to  
7 the -- the sense that they're hearing from FDA, from  
8 what they're hearing from the clinical and the medical  
9 community, that something has to be done. The  
10 standards have to become at a lower number. And there  
11 are some issues that still have to be resolved, such  
12 as do hospital use meters need the same standards as  
13 outpatient use meters? That's probably going to be  
14 discussed some here.

15           The kind of process that we're seeing  
16 reminds me of how standards are set in other  
17 industries. I'll give you an example. I'm from  
18 California, and almost every hospital in California  
19 now is being replaced because of the seismic act of  
20 earthquakes. And we realized in California in the  
21 '70s after the San Fernando earthquake that we needed  
22 some hospital seismic security activities, and the

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1 Hospital Seismic Security Act was passed right around  
2 the time that blood glucose monitoring came to the  
3 forefront. And as blood glucose monitor standards  
4 have been getting tighter over the years, so has  
5 hospital seismic security.

6           And what happens is that about every ten to  
7 20 years, it's announced that every hospital is going  
8 to have to withstand an even greater earthquake, or  
9 they have to shut down. So essentially, all the  
10 hospitals get rebuilt. We've just seen the most  
11 expensive hospital in the history of California built,  
12 which is the Ronald Reagan UCLA Medical Center. That  
13 cost over a billion dollars. What'll happen in  
14 another 20 years is the earthquake requirements are  
15 going to get even stiffer, and even modern hospitals  
16 like Ronald Reagan, my own hospital, Mills-Peninsula,  
17 and many others are going to be deemed behind the  
18 times.

19           This is just a natural evolution as the  
20 technology improves, and it's going to happen with  
21 blood glucose monitoring. But what I really have  
22 enjoyed about the meeting so far is seeing that people

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1 really are getting together. We see the need. We're  
2 not going to get to zero percent today, just like  
3 we're not going to get to a medical center in  
4 California that will withstand every possible  
5 earthquake. But it's a gradual process, and every  
6 once in a while things get tighter and tighter. That's  
7 what's happening with blood glucose monitoring.

8           So I wanted to really commend what I think  
9 must e a lot of really good behind-the-scenes work by  
10 FDA people and by industry people and AdvaMed to get  
11 to this collegial point. Because it didn't  
12 automatically seem like it was going to happen, but it  
13 is happening. So, thanks to everybody.

14           MS. RUTHERFORD: Diane Rutherford again with  
15 Ken Block Consulting in Dallas.

16           What I brought up earlier was the dose  
17 accuracy issue with syringes. What you had said the  
18 difference between one unit and two on a child, is  
19 very significant. But if I recall correctly, the  
20 tolerance on one unit could -- you could be giving two  
21 and still meet the syringe requirements. So I would  
22 think that would still be a concern on some level.

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1           Also, you guys are talking about re-testing  
2 high values, it seems to be. And basically, it sounds  
3 like if you get a value you like, you accept it. If  
4 you get a value you don't like, you're going to re-  
5 test and see if it's really the right number. So how  
6 many of the numbers that we like are actually  
7 accurate?

8           DR. CLARKE: That's an exceedingly important  
9 question, and who would like to answer that?

10           MR. CEMBROWSKI: Hi. George Cembrowski,  
11 University of Alberta. The test is as good as the  
12 drop of blood that is derived from the patient. I'm  
13 wondering if someone has done any theoretic  
14 calculations as to how well we can measure this drop  
15 of blood as the volumes get smaller and smaller and  
16 the analytic time decreases, as well. I think we're  
17 hitting a wall, and I'm thinking that there are all  
18 kinds of reasons for bad results. A hypertensive  
19 patient in Alberta winters, the drop of blood is  
20 mercilessly evaporating once it comes out of the  
21 patient; the nurse might not be all that good at  
22 moving that drop of blood to the instrument. I'm

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1 wondering if, especially in the ICU, whether we can  
2 even achieve 100 percent of the time, a CV of five  
3 percent measuring a drop of blood. And I'm wondering  
4 -- Dr. Ginsberg is probably the numbers guy. Could  
5 you throw some numbers around?

6 DR. GINSBERG: I actually think that a drop  
7 of blood is probably a bad way to measure blood in an  
8 ICU. That you have patients who may be hypotensive;  
9 they may be over-hydrated, they may be under-hydrated,  
10 and all of those add a lot to the inaccuracy of a drop  
11 of blood in ICU. I think a venous and arterial is  
12 probably a much better way to do it in ICU.

13 Unfortunately, not all meters are calibrated  
14 appropriately for venous/arterial blood. As we've  
15 talked about today, a number of the meters are very  
16 oxygen-sensitive. All the glucose oxidase meters,  
17 all the oxidase biocenters are, or should be, oxygen-  
18 sensitive. If the oxygen is high, the reading is going  
19 to be low. If the oxygen is low, the reading is high.  
20 They are calibrated to capillary blood, but capillary  
21 blood is a bad way -- I think a bad way to go in the  
22 ICU.

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1           That said, I'm not a hospital expert. I  
2 haven't done anything in the hospital for over 20  
3 years.

4           MS. HARPER: So, if there -- if there were a  
5 need for, and it sounds like there is, obviously,  
6 because these products have migrated into the ICU and  
7 other hospital settings even though they're not --  
8 they're tested or intended for those facilities. Since  
9 there is a need there, what type of -- you know, we're  
10 talking a lot about requirements. We've heard a lot  
11 about, you know, that maybe ten percent accuracy might  
12 be a minimum needed for that type of environment. But  
13 how do you design a study -- I'd like to hear from  
14 some of the -- the clinical people -- how do you  
15 design a study to demonstrate that in that population  
16 in the ICU, that you have a device that performs  
17 adequately?

18           DR. SCOTT: They are difficult studies to  
19 do. I mean, your outcomes are going to be fairly rare  
20 events. I mean, look at NICE-SUGER. They had a three  
21 percent difference in mortality, and it took 6,000  
22 patients to determine that. But, I mean, ideally what

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1 you would do is randomize patients in units to current  
2 meters versus something that is far more accurate, and  
3 track outcomes.

4 But I think the end required for that study  
5 is going to be quite large.

6 DR. HARPER: So that's definitely true for  
7 clinical determinations of benefit or perhaps  
8 accuracy. But I'm also interested in hearing how you  
9 believe that, you know, because I agree that perhaps  
10 capillary blood might not be appropriate in some very  
11 sick patients, or things like that. Analytically, how  
12 would you determine for the range of types of patients  
13 that might be seen in hospitals just what type of  
14 analytical study? Because right now we do, as Pat  
15 pointed out, you know, we have 100 patients, and they  
16 do 100 capillary samples, and that's the performance.  
17 Is that enough for something in the ICU, or not?  
18 That's ....

19 DR. SCOTT: I think the closest that  
20 addressed that was a study that Brad Carrone (ph) did  
21 at Mayo, where they simultaneously drew all three  
22 types of samples and then sent a venous sample to the

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1 main laboratory. And I presented those findings, or  
2 actually the capillary, which surprised me, because I  
3 tend to agree with what -- who was it, was it George  
4 that said that finger-sticks may not be the ideal  
5 sample in intensive care units. But that was a  
6 reasonably well designed study, in my opinion. And I  
7 think it's going to be very meter-dependent. That was  
8 done with one of the newer meters.

9 DR. KLONOFF: One feature of a study that  
10 was suggested earlier is that you make sure that there  
11 are enough data points in the hypoglycemic range.  
12 That's what we did when we had our continuous glucose  
13 monitoring performance guidelines through CLSI. We  
14 ended up stipulating that there has to be some  
15 hypoglycemic points. Otherwise, you get this, you  
16 know, 180 to 240 syndrome, and you can certainly look  
17 just fine on the error grid, and you don't even look  
18 too bad on the analytic. But you have to have some  
19 hypoglycemic points.

20 DR. GINSBERG: The other point in terms of  
21 ICU patients is, the hundred patients that you do for  
22 a supplementary blood glucose study is because the



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1 assumption, with some reason behind it, is that out in  
2 -- at home, that most patients are fairly healthy and  
3 are similar, although you do ask that you have a wide  
4 variety of races involved.

5           When you go to the ICU, I think a hundred  
6 patients in insufficient. I think you need to start  
7 categorizing by kind of patient, and look at the  
8 various kinds of patients you're going to have in  
9 terms of hypotensive, under-hydrated, over-hydrated,  
10 and so on, as well as a wide variety of blood glucose  
11 .... So I'd be surprised if a hundred was enough.

12           MR. MELKER: Richard Melker, University of  
13 Florida College of Medicine. I could change the tone  
14 of the meeting, but -- (laughter from audience) --  
15 I've elected not to. But number one, the first thing  
16 I'd like to say is that everybody talks about meter  
17 accuracy. It's really the test strips that are the  
18 issue. It's not the meters. The meters are very  
19 accurate. It's the test strips that deteriorate over  
20 time. So the first comment I'd like to make is,  
21 nobody's mentioned glucose control solutions, which,  
22 if you go into the MARE databases, the reason that all

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1 the manufacturers use when a patient gets an  
2 inaccurate reading and gives themselves an  
3 inappropriate dose of insulin. I -- I've done a lot  
4 of studies on myself, since I'm a Type I diabetic, and  
5 so I have to consent myself for studies, which is fun.  
6 But I'll actually run my glucose up and down on  
7 purpose in order to test glucose meters. And so I'd  
8 like to ask Dr. Ginsberg, if I open a vial of test  
9 strips and I test the first time and the number is  
10 175, and I immediately take another drop of blood and  
11 put another strip in the same meter and it's 200, and  
12 then I immediately take out another strip and I put in  
13 the meter, it's 225 -- if I had taken any one of those  
14 individually and tried to calculate that it was plus  
15 or minus 20 percent, you realize how confusing it  
16 becomes to the patient when they only did one of those  
17 three. I'd like to say that the middle one was the  
18 average of the three, but you don't know that if you  
19 only take one, and one of them is 175 and one is 225.

20           The last thing I want to say is what you  
21 said about hand washing, which I think is really  
22 interesting. Because if you wash your hands and you

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1 don't dry them really well, you get low glucose  
2 readings, because you have water on your hands. So  
3 not washing your hands is a problem, and washing your  
4 hands and not drying -- which takes a fair amount of  
5 time to do properly -- is a problem.

6           The other problem with not drying your hands  
7 completely is if you open the vial and you take a  
8 glucose test strip out while your hands are wet, you  
9 can ruin all the other test strips in that vial.  
10 Nobody teaches patients about any of these issues, so  
11 have at any of them.

12           MS. HARPER: Well, I personally really  
13 appreciate those comments, because these are things  
14 that, you know -- we always struggle with labeling.  
15 We heard some really good comments today that may help  
16 us with that, including this one. Labeling isn't,  
17 obviously, the -- the be-all, end-all, and it  
18 certainly isn't the answer to all. But the more input  
19 we can get on how we can help to develop clearer  
20 labeling for patients and educational materials, the  
21 better, because this is certainly something that adds  
22 to the problem.

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1 DR. CLARKE: And take it from someone who  
2 one night was testing a continuous glucose sensor, and  
3 it was -- the alarm went off to put in the glucose  
4 reading, and we were just finishing up dessert. And  
5 it was this wonderful English, what is it, you know,  
6 trifle, that's right. And I licked my finger, and got  
7 a glucose of 222 and nearly passed out, and wondered  
8 what in the world I was going to do next. Yeah,  
9 washing your hands is really an important thing to do.

10 DR. CARISKI: Alan Cariski, LifeScan OPS  
11 California. I think this is an issue that's been  
12 addressed tangentially, but I just wanted to make it a  
13 little clearer and get some comment from the panel.  
14 It's true that the accuracy standards are plus/minus  
15 20 percent, plus/minus 15, but that's for populations,  
16 whereas the precision is closer to five or six  
17 percent, so that the variability that any individual  
18 patient will see is generally going to be a lot less  
19 than plus/minus 20 percent, because the things that  
20 affect the accuracy of the strip are going to be  
21 pretty constant to that patient -- the hematocrit, the  
22 uric acid, et cetera, et cetera. I was wondering if

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1 the panel agrees or disagrees. Thank you.

2 DR. HARPER: Well, for some of that, it  
3 depends on if you're comparing two results or not. I  
4 mean, if the patient has a hematocrit, it may actually  
5 affect the true value. I mean, it may actually affect  
6 the reading.

7 MR. MELKER: (Inaudible, off-mike) the next  
8 glucose is going to be off by the same amount?

9 DR. HARPER: Right. But your comment that -  
10 - you're commenting that this may not be a problem  
11 with 20 percent total error in an individual patient,  
12 and I'm saying it's possible it could be that or more  
13 if they have a high or low hematocrit. So it could  
14 actually -- or an interfering substance, or something  
15 like that. So, it's -- imprecision is certainly part  
16 of it, and certainly where there are not other issues,  
17 it is part of the total error. But it isn't  
18 necessarily the only part of the total error that  
19 might lead somebody to treat on a number that isn't  
20 really the true number.

21 DR. CLARKE: Next?

22 MAJOR MANN: Major Mann again from the Army

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1 Burn Center. One thing that really concerned us when  
2 we discovered the hematocrit effect on our point of  
3 care glucometer was when we approached the lab, and we  
4 use CLIA -- or we use CLIP, rather than CLIA,  
5 actually, in the military -- they said, well, the  
6 meters meet all of our standards. And we looked at  
7 the fine print, and they were supposed to test the  
8 meters on normal subjects. And our subjects, our burn  
9 patients, actually have a hematocrit of 24 percent.  
10 And so that is below the meter accuracy that's on the  
11 label of our glucometer. So there's a big disconnect  
12 in the providers understanding the variability within  
13 these meters, as well as the meters that we tested  
14 that said that they have an accuracy to 20 percent  
15 hematocrit. Frankly, that wasn't true, either, in our  
16 data that we collected.

17           So I guess one of my concerns would be that  
18 there would be a requirement within the hospital,  
19 within an ICU, to test the device that you're going to  
20 use on the patients you intend to use it, not on  
21 normal controls.

22           And furthermore, as I had mentioned before,

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1 I think a study that you can do -- an outcome study  
2 clearly is not feasible to do any kind of morbidity or  
3 mortality. But it's very simple to do an outcome study  
4 on rates of hypoglycemia using different meters. And  
5 that's exactly what we did, and we found that once we  
6 changed to the corrected value, we stopped having  
7 occult hypoglycemia, and this means the matched blood  
8 that we sent to the lab was hypoglycemic, but the  
9 point of care device was clearly in a normal range.

10 So I think that's a very easy study to do to  
11 test meter performance in a variety of subjects.

12 Thank you.

13 DR. GINSBERG: Let me actually comment on  
14 that.

15 Hematocrit is actually much more complicated  
16 than that. Part of it is that no meter is a pure  
17 whole blood glucose meter, and no meter is a pure  
18 plasma meter. They are all somewhere in between. And  
19 so based upon an average hematocrit, they then put in  
20 a correction factor to bring you to a plasma value.  
21 And if the hematocrit's not correct, then that  
22 correction factor needs to be corrected. Many meters

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1 have a correction factor within that, if they can  
2 measure the hematocrit.

3           But it also turns out that hematocrit --  
4 that the change in the volume of red blood cells can  
5 also affect the reading in other ways. For example,  
6 the surface area of the electrode is a critical factor  
7 in terms of current flow, which is the determinant of  
8 -- of the blood glucose. The higher number of red  
9 cells you have, the more red cells clog up, because  
10 the red cells don't pass that current -- clog up that  
11 electrode, and you have to correct for that as well.

12           And for at least some companies I've seen,  
13 the error in hematocrit can be huge. Not four or -  
14 when you correct plasma to glucose, that's a 12  
15 percent correction at a hematocrit of 40. The  
16 correction can be up to 50 percent, depending on the  
17 particular meter, that meter/strip combination that  
18 you're using.

19           So I applaud that you're correcting for the  
20 correction from whole blood to plasma and changing the  
21 hematocrit in that, but the correction is actually  
22 more - - and you're doing something, but the



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1 correction is actually more complicated than that.

2 MAJOR MANN: If you're looking at a similar  
3 patient population that all tend to be anemic,  
4 wouldn't the normal correction sort of be consistent  
5 across that population?

6 DR. GINSBERG: Yes.

7 MAJOR MANN: You wouldn't use the same  
8 correction factor for a neonatal population as you  
9 would for an anemic adult population --

10 DR. GINSBERG: Right.

11 MAJOR MANN: -- for example, so that you are  
12 precise and maybe not accurate, but --

13 DR. GINSBERG: Yeah. I -- I'm sorry. If  
14 you were correcting using empirical data, I agree.  
15 That's even better.

16 MAJOR MANN: Right.

17 DR. GINSBERG: I assumed you were correcting  
18 just based upon taking the 12 percent for hematocrits.

19 MAJOR MANN: We -- we actually take the  
20 daily hematocrit. It is automatically extracted from  
21 our patient care record in the electronic medical  
22 database, and the formula is embedded in our

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1 electronic medical record. So when the nurse enters  
2 the glucometer value, it automatically retrieves the  
3 most recent hematocrit value and matches to that most  
4 updated value. And we feel like a 24-hour or 12-hour  
5 hematocrit is pretty fine in a non-bleeding patient.  
6 And we again have had a decrease in the rate of  
7 hypoglycemia that's measurable compared to a unit that  
8 didn't correct, and their rate of hypoglycemia  
9 actually went up.

10 So that's just a different type of study to  
11 think about.

12 DR. KLONOFF: I'd like to comment.

13 First, I think what you're doing does make  
14 sense in a specific group of patients. Second is we  
15 need to see more modeling data like what Marc did with  
16 Boris Kobichev. If we're going to find out what are  
17 the -- what are the clinical consequences of error,  
18 then either we do a study which basically, as Dr.  
19 Scott said, is impossible -- it's unethical, we're  
20 never going to do that -- or we get some modeling  
21 data.

22 Modeling data is so useful. You can find

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1 out what's the frequency of hypoglycemia, what's the  
2 frequency of different combinations, complications.  
3 The modeling studies do require assumptions. Even  
4 with all the equations, they're assumptions. And I  
5 think that it would be very nice if others in this  
6 room were to try to do a study similar to what Marc  
7 and Boris did. Their study is the first of its kind  
8 that's gone beyond looking at what happens to the  
9 insulin dose with inaccuracy, but actually what then  
10 goes on to happen to the blood glucose level. So it's  
11 a pioneering, very important study.

12 But the basic idea of modeling what happens,  
13 others could do it, too. And I think that if we see  
14 more of this type of information brought forward,  
15 we'll all have a better idea. Because we're saying,  
16 well, we'd like more accuracy, but I think it's still  
17 very difficult for all of us to get a handle on how  
18 much accuracy do we really need, let alone what's it  
19 going to cost. So let's see some more modeling  
20 studies.

21 MR. SOUTHERLAND: Phil Southerland, Team  
22 Type I. I've got a few comments which I hope will

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1 maybe spark also some discussion.

2 I've had Type I since I was seven months  
3 old, so almost 28 years now. So Ellen, I can relate  
4 to what your son's going through. But in the first 25  
5 years, I checked my blood sugar about 118,000 times,  
6 which means at .01 percent of outliers, I've had 118  
7 outliers, and then guess what? I've lived through  
8 them.

9 But, you know, we've come a long way in that  
10 time. My mom used to squeeze the urine out of my  
11 diaper to get it onto a test strip to find out where  
12 my blood sugar was four hours before, you know, where  
13 I actually was. So here we are talking about a small  
14 differential of percentages, but I do agree, David, to  
15 what you said. We can keep moving the needle forward,  
16 which is going to make the control better.

17 Also in the last three years, and using  
18 continuous glucose modeling technology, I've checked  
19 my blood sugar 109,000 times. Averaging the fact that  
20 I pressed the button about a hundred times a day to  
21 figure out not only where I am, but the trend in where  
22 it's going. And if you look at the average person who

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1 checks two times a day, going on the basic math,  
2 that's .04 percent of the day that they know where the  
3 blood sugar is. You know, they have no idea what the  
4 trend's going, what direction it's going, and that  
5 creates a huge margin for user error and the effect  
6 that it might have.

7           So can we, you know, start pushing for the  
8 Type I community who's on insulin using CGM, because  
9 that takes so much of the user out of it the majority  
10 of the time? And I do agree, there is still user  
11 error. Last Friday in advance of coming to this  
12 meeting, I checked with three different meters. One  
13 of them said 69; one of them said 150; another said  
14 213, all at the same time. So I checked again. Then  
15 another one said 78; one said 108; one said 113. And  
16 the third time, they were all around 102. You know,  
17 it's --

18           UNIDENTIFIED: Wash your hands?

19           MR. SOUTHERLAND: I did wash my hands before  
20 that third test.

21           (Laughter) But, you know, that user error,  
22 if I went on that first 213 and gave three units of

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1 insulin like I normally would, I'd have been in for  
2 big trouble if I wouldn't have checked my blood sugar  
3 45 minutes later like I always do after I give  
4 insulin. So, I mean, where is -- where's the curve,  
5 where do we need to go? Can we make this, you know,  
6 five percent a little bit better?

7           The ICU, I've been in the hospital, and they  
8 said, we're going to check your blood sugar every six  
9 hours, and we're going to give you a shot of regular  
10 insulin every six hours. You know, we're talking  
11 about five percent in the meters, when I'm going to  
12 use regular insulin, which I haven't used in ten  
13 years? Where's the margin of error in that one?

14           DR. HARPER: Yes.

15           MR. SOUTHERLAND: Where do we draw the  
16 lines?

17           DR. HARPER: Those are all good comments,  
18 and I'd like to say, we are talking to -- not only do  
19 we work with the glucose meter manufacturers, but we  
20 also work with the CGM manufacturer community to try  
21 and get them accurate enough so that people could  
22 possibly in the future use them.

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1           But I think you raise a good point about  
2 standardization, and that came up earlier in one of  
3 the talks. So I would like to hear perhaps from some  
4 of the other panel members on whether there's a need  
5 for increased standardization or not, given that at  
6 least at home, single meters are used, and generally  
7 multiple different types of meters are not used. Or  
8 are they?

9           DR. KLONOFF: Phil, the problem that I think  
10 happened to you that day was your 213 was one of these  
11 five percent outliers that was really bad. And this  
12 seems to be an area that people are now starting to  
13 discuss. It's only in the last year or so that I'm  
14 hearing much talk about it. And if -- I think  
15 something should be done to address that five percent  
16 group. And it has to either be -- at the most extreme  
17 would be to eliminate it completely and say 100  
18 percent have to be within range, or something that may  
19 be more achievable is to just analyze that five  
20 percent and say how it has to be distributed.  
21 Currently, the worst of that five percent can be as  
22 bad as you can imagine. But if something was done to

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1 tighten those up, those you would just never see a  
2 number like that again.

3 MR. SOUTHERLAND: And thank you, everyone in  
4 the room, for all the work you're doing. You're  
5 making all of our lives better. Appreciate it.

6 DR. BRETON: There was one -- one more thing  
7 that I wanted to add, in that Phil is pointing at an  
8 application of SMBG that we've barely discussed. And  
9 they're used to calibrate the continuous meters. And  
10 all right, you know, an error of ten or 15 percent  
11 might not make a huge difference in your insulin dose,  
12 especially if you have error in what's absorbed or  
13 what's actually injected.

14 But an error of ten percent will have a  
15 dramatic effect on the calibration algorithm of a  
16 continuous meter. And that effect won't be apparent  
17 when you calibrate; it will be apparent at your next  
18 meal excursion. And now you're not talking about ten  
19 percent error any more. You're probably talking about  
20 50 to 100 percent error. And if you ever were to, by  
21 all means use a CGM to treat or even take another SMBG  
22 at that time and that happened to be erroneous, too,



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1 you can be in actually serious trouble.

2           So there is also clinical consequences of  
3 SMBGs that are not directly linked to your insulin  
4 dosing at the time of SMBG.

5

6           DR. GINSBERG: I'm going to take that,  
7 actually, as another chance to suggest what I'm  
8 suggesting, and that is, there are different segments.  
9 For that segment that is looking to calibrate their  
10 glucose meter, to calibrate their continuous monitor,  
11 they may want five percent inaccuracy, or five  
12 percent/95 percent confidence limits on inaccuracy.  
13 That's not the suggest that everybody has to have  
14 that. And a suggestion that there are different needs  
15 for the device, and that we ought to publish what the  
16 accuracy is people can select the meter appropriate  
17 for -- system appropriate for their needs.

18           DR. HARPER: But part of the -- part of the  
19 thing we struggle with there is how do we get data  
20 good enough to actually demonstrate the accuracy?  
21 Because I think what we struggle with not only in  
22 blood glucose meters, but in any of the devices we

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1 regulate, is that we get the data we get. That's what  
2 goes in the label. And in the field, we may or may  
3 not see that same performance. So what -- what we  
4 would like to hear from people, either today or, you  
5 know, you can send in comments or give us a call or  
6 whatever, what we actually want to know is if you have  
7 ideas on how we can actually tell people how they  
8 work, for real, in the real use environments.

9 MR. BALTUR(ph): I'd like to make a comment  
10 about ICUs and the intensive insulin therapy. The  
11 nurse who runs this usually makes the decision based  
12 on the current evaluation and the one that would  
13 probably make six hours or two hours or whatever the  
14 interval was. Some of us think that a continuous  
15 glucose monitor will be ideal for intensive IV insulin  
16 therapy in a ICU, provided you had a reliable machine.  
17 And we tested the continuous glucose monitor which is  
18 interstitial, and that's not good enough, because the  
19 delay is so bad. And I know there are some companies,  
20 and I tried to get a hold of them, that have a meter  
21 that you can place in the vein, and then you really  
22 have -- there is no nursing, there is a continuous

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1 monitor; you can look at its trend, and you can make  
2 very nice decision.

3 Can you tell us what the status of those  
4 kind of instruments are today?

5 DR. HARPER: There are some blood gas  
6 analyzers there are indwelling currently, and I  
7 believe there is one system that was, I believe,  
8 cleared in the '90s that is capable of making frequent  
9 measurements of blood glucose meters. But in terms of  
10 continuous monitoring, I think, you know, we have also  
11 heard about some companies that have some products in  
12 development, but none of those have been recently  
13 cleared.

14 MS. PINKOS: Arleen Pinkos from Baltimore.  
15 We have heard 15 percent over and over again, and  
16 there does seem to be some kind of agreement or  
17 comfort level with that. So my question is a couple.  
18 Is 15 percent good enough for -- I would like to hear  
19 from all of -- at least the clinicians on whether 15  
20 percent is good enough. And also not just the 15  
21 percent, but how many milligrams per deciliter should  
22 it be below 75 milligrams per deciliter?

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1           And after you've answered that, I'd just be  
2 curious to know how you would apply those to home  
3 settings versus clinical settings. Are they the same?  
4 Should they be different? But is 15 percent good  
5 enough? What about the low range, too?

6           DR. GINSBERG: I think it depends upon who  
7 you are. I think if you're calibrating a continuous  
8 glucose monitor, 15 percent is not good enough. I  
9 think if you're an intensive insulin therapy patient,  
10 keeping your blood glucose in the 80, 85 range most of  
11 the time, I think 15 percent is not good enough. I  
12 think if you're a Type II on insulin, sure, 15  
13 percent's plenty good. If you're a Type II not on  
14 insulin, I think you don't even need 15 percent, so  
15 it's certainly good enough for them.

16           I think a reasonable number below 75 is to  
17 use the same standard that you use for 20 percent --  
18 that basically you take the value at 75 and just bring  
19 it down. And at 15 percent, the value at 75 is 12.25  
20 or 12, and you just bring that down from there.

21           DR. CLARKE: Let me say that I have a little  
22 problem with that 15 under 75, and I think that if --

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1 I think that 10 under 75 would be much more  
2 acceptable, especially in children. And -- yeah, and  
3 I also think that, now, I agree with your other  
4 comments. I think that if you're going to put  
5 labeling on glucose strips, that it really needs to  
6 say specifically, under 75 this product will read  
7 this. Above 75, it will read that. Because those are  
8 the standards -- those are the ISO standards that  
9 you're using, and to just tell somebody that it's  
10 accurate within -- this many times within this percent  
11 of accuracy really doesn't tell them anything that  
12 they can use.

13 MR. BRETON: I would like to add one more  
14 thing towards that Bill was saying, which is that for  
15 hypoglycemia detection, so for values in the low  
16 range, 15 percent still gives you the opportunity to  
17 miss hypoglycemic events in quite large numbers. Ten  
18 percent seemed that you were actually starting to  
19 reduce the number of mis-events, and in quite a  
20 dramatic way.

21 Now, if you're at 150 milligrams per  
22 deciliter, the difference between ten and 15 percent

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1 is probably not that great.

2 Another comment that I wanted to make is  
3 that I'm wondering where that fixed rate of error  
4 below 75 milligrams per deciliter came from. Because  
5 it seems to me that even though it's technically  
6 challenging, I understand that, I want to be much more  
7 precise. At 50, even, I want to be at 75. And the  
8 relative nature of the error that we have higher than  
9 75 seems to still have some relevance below. And so  
10 I'm pretty sure that people might have comments about  
11 that.

12 DR. CLARKE: Anybody else on the panel want  
13 to take that?

14 MS. PINKOS: Can I just have one follow-up  
15 for Barry? You said 15 percent is probably not good  
16 enough for those patient populations. What is?

17 DR. GINSBERG: Oh, for that patient  
18 population, Marc and I are actually talking about the  
19 same problem. And that is the problem of knowing when  
20 you're hypoglycemic. If you remember his graph of how  
21 often you would miss hypoglycemia at various error  
22 levels, what he said is at five percent you won't miss

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1 it at all. At ten percent, you'd miss it at one  
2 percent. At 15 percent, you'd miss it at five  
3 percent, and at 20 percent, I think you'd miss it at  
4 ten percent.

5 And so the big cutoff there, it'd be nice to  
6 get down to five percent. That's really quite  
7 challenging. I think ten percent would be acceptable.

8 DR. CLARKE: Neil?

9 MR. WHITE: Neil White, St. Louis. And I --  
10 I'll say in many ways, I agree with Barry. That's  
11 probably pretty unusual. But -- (laughter) -- we need  
12 -- we probably need different standards for different  
13 things. But I just want to point out -- maybe this is  
14 repetitious of what others have alluded to -- if we're  
15 ever going to move in the direction of a closed loop,  
16 and if we're going to count on blood glucose meters as  
17 the standard by which we calibrate the sensor, we  
18 can't tolerate large levels of error on both devices  
19 in a device that's going to be making decisions  
20 independent of our own human input.

21 DR. BRETON: To further that comment, so we  
22 -- at UVa, we have a few trials going on about

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1 artificial pancreas and closed loop. And what we've  
2 noticed is that a CGM calibrated with a YSI, for  
3 example, is tremendously more accurate than a CGM  
4 that's calibrated even with a good meter value. And  
5 by -- I mean, you're always have the problem of the  
6 delay, of course, and it's still slightly different in  
7 plasma or glucose, what you're measuring. But a  
8 perfect calibration makes all the difference with the  
9 use of a CGM in a closed loop system. And so I really  
10 want to emphasize the need for accuracy when we talk  
11 about calibration, and not necessarily insulin dosing.

12 DR. HARPER: So I have a question, actually,  
13 for Steve and Barry, so our industry panel.

14 DR. GINSBERG: May I?

15 DR. HARPER: Sure.

16 DR. GINSBERG: It's critical to realize that  
17 the YSI is not a perfect instrument. The YSI actually  
18 has about a two and a half percent error, meaning the  
19 95 percent confidence limit on that is plus or minus  
20 eight percent. So that when we talk about a  
21 calibration device, what we're saying is we need  
22 something between five and ten percent, which I think



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1 everyone would agree with. And we're not that far. If  
2 you look at the very best meters out there, they're  
3 now getting 75 percent of their values within five  
4 percent.

5 DR. BRETON: All right. I might want to  
6 just qualify a little bit what I said. When I said we  
7 calibrated with YSI, what we do is we have duplicates,  
8 and actually four total membranes. So that eight  
9 percent is dramatically reduced with that type of  
10 setting.

11 DR. HARPER: So, I have a question for our  
12 industry panel members, so Steve and Barry. We talk a  
13 lot about sort of, oh, what would the ideal, you know,  
14 level be. We hear a lot about 15; now we're starting  
15 to hear about in the hypoglycemic ranges, getting down  
16 to ten or even ten percent, I heard.

17 From an industry point of view, we'd like to  
18 hear some discussion about the barriers to achieving  
19 better accuracy. So what would need to happen, from a  
20 manufacturing point of view, or a development point of  
21 view, to enable meters to become more reliably  
22 accurate to the point where we're discussing?

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1 DR. BROTMAN: That's obviously a very  
2 important question. And, you know, it's --  
3 manufacturers really look at designing these things  
4 and trying to meet the users' needs all the time. And,  
5 you know, you reach a certain level sometimes where  
6 you have tradeoffs between accuracy. Accuracy is made  
7 up of accurate results sometimes, and you're also  
8 looking at user -- end user errors and interferences,  
9 and so forth.

10 So it's a delicate balance between that  
11 situation. And if you're looking for consistency  
12 across the board, as you, you know, as you get closer  
13 and closer to ten percent, there may be devices now  
14 that are measuring ten percent. There may be -- as  
15 you get closer and closer to that non-tolerant level  
16 of having any errors, you're looking at, you know, how  
17 much these improvements can be sustained across the  
18 board. And I think that's a hard thing to do at a  
19 certain point. So you get down and you get down, and  
20 --

21 DR. HARPER: Yeah. So what's hard about it?  
22 I think we're trying to understand what actually needs

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1 to happen. Are there -- are there any ways that  
2 scientists can help --

3 DR. BROTMAN: Well, I --

4 DR. HARPER: -- or any ways that we can  
5 actually help?

6 DR. BROTMAN: Right. I mean, I think you're  
7 also looking at all the other things that have been  
8 brought up today. You have a lot of interferences,  
9 and you have a lot of use type of situations. So  
10 your, you know, your hematocrit, your humidity,  
11 everything else that -- that's in there contributes to  
12 this process also.

13 DR. KLONOFF: Courtney, one thing, it  
14 strikes me that we've been hearing about the  
15 tradeoffs, that there are many nice features of  
16 monitors, so it's not -- even if the accuracy hasn't  
17 improved that much, there's a lot of nice features.  
18 And some of them, I think, could be sacrificed if it  
19 would lead to more accurate blood glucose readings.

20 For example, in the hospital, you're not  
21 worried about, does the consumer like the product?  
22 Does he find it easy to use? Because it's not even

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1 the consumer, it's the nurse, and the consumer doesn't  
2 really notice what's going on. Or the same thing with  
3 a long-term facility.

4           So if a company is going to have a second  
5 line of meters, let's say the standard accuracy and  
6 the greater accuracy, to me the first thing they would  
7 do is get rid of some of the features that are nice  
8 for being less accurate, but aren't necessary. For  
9 example, in some cases, have a longer measuring time;  
10 in some cases, have a larger drop of blood; in some  
11 cases, require a type of coding system -- require it,  
12 which is very clunky and difficult to do, but the  
13 patient doesn't have to worry about it, the nurse is  
14 going to do it.

15           So I think that some of the ability to  
16 create a more accurate monitor has to already be there  
17 if certain populations are willing to forego those  
18 nice features. And I think those populations will.  
19 I'll be even the CGM user, knowing how important it is  
20 to have an accurate calibrating device, would be  
21 willing to give up some of those features, too. And  
22 the majority of patients would never have to face

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1 that. They could get by with the standard accuracy.

2 DR. GINSBERG: Let me talk about the company  
3 I know best, which uses something called dynamic  
4 electrochemistry. And what that means is the  
5 following. What they do first is they bring -- what a  
6 normal meter does, is it brings the voltage up to,  
7 let's say, .3 volts, and then measures the current  
8 over time as a way of measuring blood glucose.

9 What this system does is it brings the  
10 voltage up to .01 volts, or some number like that. And  
11 from that, you measure nothing except the well size.  
12 So if there are any changes in the manufacturing of  
13 the well, you immediately pick that up.

14 Then it goes up a little higher and does  
15 some tricks to pick up the hematocrit. Then it  
16 notices the slope of the current as it's changing its  
17 voltage, from which it can pick up the oxygen  
18 concentration and the altitude.

19 Then it goes up to a voltage just a little  
20 bit below, where it'll pick up glucose, and picks up  
21 all the interference. Then it goes up and picks up  
22 the glucose and uses software to get rid of all the

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1 others. And by doing this, they took an original  
2 strip, a Korean strip, which had by itself an  
3 inaccuracy of 11 percent, and brought that down to a  
4 little over five. And they believe, at least, when  
5 they designed their strip themselves, that they can  
6 get their inaccuracy down to about two.

7 DR. CLARKE: We have time for one comment.  
8 Go ahead.

9 MR. COMBS: Art Combs from St. Louis. A few  
10 years ago, they closed the major east-west road in St.  
11 Louis, and so that road right next to the university  
12 got a lot of extra traffic. And it always had a 30  
13 mile an hour speed limit, and nobody ever paid  
14 attention to it. But now with the extra volume, they  
15 put up a new sign, and the new sign said, "30 miles an  
16 hour no tolerance." And they started giving out  
17 tickets for people driving 34 in a 30. Now people  
18 drive 30 miles an hour on the street. I think if you  
19 walk into a classroom and say, Passing is 65, but  
20 starting next week, passing's going to be 75, all the  
21 same people are going to fail, and now more people are  
22 going to fail.

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1           My suggestion would not be to lower the  
2 standard. My suggestion would be to enforce the  
3 standard you have, and enforce it in the user  
4 environment. I know that any of the large strips  
5 companies can perform a clinical trial, and under the  
6 right conditions hit that Clarke A space 95 percent of  
7 the time. But that's not what's going on in people's  
8 kitchens.

9           So why don't we enforce the standard, rather  
10 than change it? I think that speaks to the outlier  
11 question, particularly.

12           The second thing I wanted to say is, no  
13 monitor, in my view, is worth anything unless it's a  
14 safety monitor. If your blood sugar is dangerously  
15 low, that's an emergency, and everybody needs to be  
16 able to detect that with a certain accuracy. If your  
17 blood sugar is 300 or 360, it's not an issue from a  
18 treatment point of view, and no one's life is in  
19 danger. The 20 percent standard is adequate.

20           So we seem to be in this meeting looking for  
21 a one size fits all. We need a standard across the  
22 entire dynamic range of glucose, and we need a

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1 standard that's from the entire dynamic range of  
2 patient experience from their own kitchen to being  
3 profoundly ill in an intensive care unit, and I don't  
4 think that's the case.

5           The last point I wanted to make: I think  
6 that from an FDA point of view, and I certainly can't  
7 speak for them, but two things have been lost. One  
8 is, what is the intended use? And the second is, what  
9 is the indication for use? There are many diabetics,  
10 and I suspect the young man who was up here earlier  
11 wears an insulin pump. This is a \$5,000 device. It's  
12 very precise. It's programmable, it's complex. Not  
13 every diabetic gets it. Some people get a \$5,000  
14 device, some people get a bag of 100 syringes for  
15 \$9.99 and a multi-use vial of insulin. The same thing  
16 should be true of meters. That's why I don't believe  
17 you can use the same thing in the intensive care unit  
18 as you can in your kitchen.

19           But why don't we view standards, instead of  
20 saying, Gee, it's 20, should we lower it to 15? Let's  
21 start with, Why don't we enforce the one we have now  
22 so we don't have outlier problems? Why don't we make



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1 sure it's always a safety monitor, at the very least,  
2 in the hypoglycemic range? And why don't we start  
3 thinking about indications for use? If I'm an  
4 ambulatory or otherwise well Type II diabetic in my  
5 kitchen, do I need an ICU monitor? And should I have  
6 the same standard?

7 Thank you.

8 DR. CLARKE: Thank you for your comment.

9 We're going to have to stop now. I want to  
10 thank all of the panel members for your participation,  
11 and the audience for your participation, as well.

12 (Applause)

13 DR. HARPER: So first, I'd like to extend  
14 warm thanks to Dr. Clarke, who did a wonderful job  
15 moderating Session Number 1. I think we had a lot of  
16 good discussion, and I know I can certainly speak for  
17 myself that I heard a lot of interesting insights that  
18 I think will be very helpful to us.

19 So while the Session 1 panelists are coming  
20 to their seats, I'd like to introduce the moderator  
21 for Session 2. Dr. Gary Myers is the Chief of the  
22 Clinical Chemistry Branch in the Division of

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1 Laboratory Sciences at the Center for Disease Control  
2 and Prevention. In his more than 30-year career at  
3 CDC, he has focused on improving lab measurements of  
4 biochemical markers used to assess chronic disease  
5 risk, with particular emphasis on cardiovascular  
6 disease and diabetes.

7 Dr. Myers is a member of the American  
8 Diabetes Association's Insulin Standardization Working  
9 Group, and in 2007, Dr. Myers served as president of  
10 the American Association for Clinical Chemistry. He  
11 has authored or co-authored more than 80 peer reviewed  
12 publications and chapters.

13 Please join me in welcoming Dr. Myers.

14 (Applause)

15 DR. MYERS: Thank you, Courtney.

16 Okay. It was a pleasure to be here, and I  
17 want to thank Courtney and the FDA for asking me to  
18 moderate this session.

19 Our session today is, the second session is  
20 Blood Glucose Meter Performance, Interferences, and  
21 Limitations. And you've heard from Dr. Scott and Dr.  
22 Ginsberg when they were talking about total error, the

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1 idea that total error is not just bias and  
2 imprecision, but there are other things as far as the  
3 pre-analytical and post-analytical that goes into  
4 considerations of performance for blood glucose  
5 meters.

6           So meter performance is limited by a variety  
7 of environmental, physiologic, and operator factors.  
8 And in my brief introduction, I'm going to list a few  
9 of these things. You've heard some of them already  
10 described. We're going to refocus on these in this  
11 session, so our speakers will have an opportunity to  
12 go in a little bit more detail.

13           What I've listed here, and I'm not going to  
14 go into any kind of detail, but just list these --  
15 there are possible factors, interferences, that have  
16 been investigated and reported in the published  
17 literature. And there are environmental factors. We've  
18 heard about exposure of test strips -- exposure to  
19 air, exposure to light. The use of generic strips --  
20 that may not have been evaluated on different meters,  
21 but are also available. Age of strips -- we did an  
22 evaluation of meter performance at the CDC some years

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1 ago, and we found that on getting strips from the  
2 pharmacy, if you had strips that were early in their  
3 shelf life versus those that are towards of their  
4 shelf life, we found a significant difference in the  
5 performance of those strips. Reuse of strips --  
6 altitude has an effect on the performance; humidity  
7 and temperature, again, having the strips exposed to  
8 various humidity and temperatures. Specimen  
9 preservatives -- volume of the sample, are you under-  
10 dosed or over-dosing the sample? And animal blood --  
11 not in the measurement of animal blood, but in the use  
12 of animal blood in the preparation of control and  
13 survey materials. Maybe not as prevalent now as it  
14 used to be, but there was a time that animal blood was  
15 used to prepare control materials and survey  
16 materials. That may still be going on. And we know,  
17 we've heard from Dr. Scott, the problem of matrix  
18 effects when survey materials do not simulate patient  
19 samples, so that's a big concern when evaluating the  
20 performance of meters.

21 Patient-specific variables: extremes in  
22 hydration. Is the person hydrated or over-hydrated?

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1 Hypotension, prandial state. We've heard a lot about  
2 hematocrit, and we're going to hear some more from one  
3 of our speakers. Hemodialysis, hemolysis, extremes in  
4 pH. Cases of severe acidosis, like diabetic  
5 ketoacidosis, as an example. Hypoglycemia -- you've  
6 heard a lot about hypoglycemia from Dr. Sacks. Blood  
7 sources -- differences in arterial versus capillary,  
8 versus venous blood. The specimen matrix --  
9 differences between whether you're measuring it as  
10 plasma or whole blood.

11           And then the issue of substances and  
12 conditions.

13           Acetaminophen, which at therapeutic drug  
14 levels certainly causes interferences. Ascorbic acid,  
15 dopamine, fluorescein IV's, mannitol, salicylate. We  
16 all know about the therapeutic products with non-  
17 glucose sugars:

18           maltase, galactase, and xylose with GDH and  
19 PTQ test strips. And we're going to hear a little bit  
20 more about that in some detail in just a minute from  
21 Dr. Harper.

22           So as we go forward in this session, just

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1 some issues and questions to consider. And some of  
2 these we've already heard discussed and brought up in  
3 the previous session. But again, focusing on  
4 inferences and limitations, some things to consider.

5 First of all, the investigation of  
6 interference effects is the responsibility of  
7 instrument manufacturers. This really has to be done  
8 by the manufacturers before it's put on the market.

9 The information provided is often too vague  
10 and to be of little value, and some manufacturers may  
11 take exception with this, but this is some of the  
12 general feelings that have been published in the  
13 literature by people that have done studies: There is  
14 no specific single criterion that exists for  
15 delineating the presence of significant interference.  
16 What do we mean in the product insert, what is a  
17 significant interference? There's no consistent  
18 definition of that.

19 Guidelines have been established for  
20 evaluating of interference effects, and we've heard  
21 some of those. There is the CLSI EP7. IFCC has a  
22 guideline. Several individual groups, individuals

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1 have published in the literature different processes  
2 for approaching how we evaluate interferences and  
3 limitations for glucose monitors.

4           There is no current consensus exists among  
5 manufacturers about the most appropriate way to  
6 publish guidelines on how a interfering substance is  
7 affecting a particular method. We've heard from Dr.  
8 Ginsberg the idea of standardizing. And I'm all for  
9 standardization, and so we do need to look at how we  
10 can standardize the information that's provided to the  
11 end user.

12           And some other issues and questions: Should  
13 there be a standardized procedure for evaluating  
14 interferences? Yes, I think there should be. How  
15 aware of these factors and interferences are the end  
16 users, and has such an awareness survey been done? Do  
17 we really know how aware the end users are, whether  
18 they be in the ICU or whether they be the home users?  
19 Are package inserts enough? Are they adequate in the  
20 information that is provided to the end user?  
21 Certainly is more public education needed? And I think  
22 we'll all agree that yes, there is more education

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1 needed.

2 Sources of information for the end user:

3 again, package inserts and instructions, are  
4 they adequate? Probably not. Where can the public get  
5 information about their blood glucose meter? Well,  
6 some of them go to the pharmacist to ask the  
7 pharmacist at their local pharmacy. These individuals  
8 are not trained necessarily, and aren't staying on top  
9 of the information, but this may be a source where  
10 many of the end users go to ask for information. If  
11 it's a hospital staff, obviously, they have their  
12 clinical chemist in their central laboratory that they  
13 can get information.

14 And the place where most people nowadays go  
15 get information, the Internet. And what websites are  
16 available? One website, and example, is the ACC's Lab  
17 Tests On Line, which provides end users with  
18 information about the glucose test and what the test  
19 means and what the limitations of those tests are. So  
20 there are websites that are available, but we need to  
21 look and see if these websites can be improved.

22 So this gives you a little bit of a



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1 background, what I'd like for you to consider as we  
2 hear and talk more now in this session about  
3 interferences and limitations for blood glucose  
4 determinations.

5           So with that introduction, I'll introduce  
6 our first speaker in this session, and that's Dr.  
7 Courtney Harper. And as you know, she is the current  
8 Chief of the Division of Chemistry and Toxicology and  
9 Devices. And Courtney's going to talk about the FDA  
10 perspective, public health notification, potentially  
11 fatal errors with the GDH PQQ glucose monitoring  
12 technology.

13           DR. HARPER: Thank you, Gary.

14           So, today I'm going to talk to you a little  
15 bit about interfering substances. And I'm also going  
16 to talk to you about how FDA sort of tries to detect  
17 problems with devices. So this morning we heard about  
18 some inherent problems with devices. I'm going to  
19 talk a little bit from a different perspective about  
20 those problems, first of all how FDA collects that  
21 type of information, and second of all how FDA and  
22 others react to it. And what I hope to gain out of

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1 this is by using one particular example, later on this  
2 afternoon I'd really like to hear input from the panel  
3 and also any of you in the audience about how can FDA  
4 and others better send messages and collect  
5 information about the problems with products.

6           So first, I'd just like to reemphasize.  
7 We've been talking today about a lot of issues with  
8 glucose meters. We keep talking about how they need to  
9 be more accurate, they don't do well enough in the  
10 ICU, or they do do well enough at home, or whatever  
11 we're talking about. But these particular devices,  
12 these types of devices, have been very beneficial. And  
13 we've heard a little bit about this, too. So let's  
14 keep in mind the context here, which is that without  
15 self-monitoring of blood glucose, diabetic patients  
16 would be worse off than they are today. So even  
17 without our current performance, I think we need to  
18 recognize that these are good products to have out  
19 there, and they have revolutionized the treatment and  
20 monitoring of patients with diabetes.

21           Most of you probably know the majority of  
22 glucose meters that are used at home use two different

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1 types of methodologies. One methodology is the  
2 glucose oxidase method. You've heard some about that  
3 today. This is the one that's more oxygen sensitive.

4           The other type of methodology is a glucose  
5 dehydrogenase enzyme, and this particular enzyme can  
6 use three different types of mediators: PQQ, FAD, and  
7 NAD. And those actually have some separate types of  
8 interferences.

9           These types of technologies are used, as you  
10 all know and we've discussed, at different places.  
11 They're used at home by lay users. They're used in  
12 healthcare settings, and those settings vary quite a  
13 bit, from hospitals and ICU units all the way to  
14 emergency response units and also long-term care  
15 facilities and nursing homes. And perhaps each of  
16 these facilities and each of these use settings has a  
17 lot of different issues, as we also discussed today.

18           So hopefully the majority of the time,  
19 things go well, and these devices are used well and  
20 the majority of the time people get accurate results,  
21 or accurate enough results to use for dosing insulin  
22 or any other treatment choices they may make. But

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1 sometimes things go wrong, and sometimes we have  
2 adverse events as a result of incorrect test results  
3 or the use of medical products. And FDA actually  
4 collects adverse event data from our medical device  
5 reporting system.

6           The medical device reporting system has a  
7 method for users, laboratories, and clinicians to  
8 actually report to FDA any problems they may have been  
9 with any medical devices. So if you take glucose as  
10 an example, if a lay user realizes somehow that they  
11 have an inaccurate measurement on their glucose meter,  
12 they can actually report that to the manufacturer, who  
13 then can report it to FDA. Or you can actually report  
14 to FDA directly. At the end of the talk, I'll  
15 actually have a link so anybody who wants to can  
16 actually report adverse events to FDA, and we  
17 encourage that they do so.

18           And when we get that data, FDA tries analyze  
19 it for trends. We look to see whether or not there's  
20 a trend of a problem, or we look to see whether or not  
21 there's a problem that's sticking out as something  
22 that needs to be addressed, or perhaps something

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1 that's showing that things are going well or things  
2 like that. We can do that with greater or lesser  
3 success depending somewhat on product type and also  
4 the type of reports that we get.

5           So the medical device reporting is actually  
6 sometimes difficult to analyze, and difficult to find  
7 those trends. And this is particularly true for over-  
8 the-counter devices. So you have to keep in mind that  
9 blood glucose meters are used -- there are billions of  
10 test strips sold per year. So the denominator is  
11 huge, and the number of tests that are performed is  
12 huge. And we know that events are underreported, but  
13 they're also underreported in specific populations.  
14 They're underreported by lay users. They're probably  
15 more likely to be reported when there's a problem  
16 noticed at the hospital. And we know that overall  
17 they're underreported, and that even when there is a  
18 device result, either it's unrecognized that the  
19 incorrect result happened, or it's not reported to  
20 FDA. So the actual reporting of blood glucose meter  
21 adverse event data is actually a little bit misleading  
22 for us.

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1           Another issue is that the data fields that  
2 we receive is often descriptive. So what happens is,  
3 depending on the reporter, sometimes there's more or  
4 less information about the event that's included. And  
5 this actually really limits the ability for us to do  
6 electronic analysis of large datasets. So we know  
7 there are some cases where you can search for a  
8 particular word, but if it was entered with an  
9 incorrect spelling or if it was entered with a  
10 different word or a synonym for something that's not  
11 often used, sometimes it's very difficult to group  
12 similar or like issues together.

13           So these are some limitations of the  
14 database. Now, it stands out for glucose meters,  
15 because if you have a product where perhaps there's  
16 only three or four of these devices implanted into  
17 patients in the U.S., you're going to be able to look  
18 at very closely every single adverse event report that  
19 comes to you, so you'll be able to read them  
20 individually. You can do a very good analysis. We  
21 get more than 12,000 reports on glucose meters per  
22 year, and so it's actually not feasible for FDA

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1 analysts to read every single report and somehow group  
2 them or analyze them and call and contact every single  
3 reporter. So that's where some of the limitations of  
4 the database come through.

5           Now, the fact is we get these 12,000 reports  
6 a year, but also keep in mind that that's almost a  
7 little bit good, because we do have billions of tests  
8 performed per year.

9           Now, here's an idea of what I mean by how  
10 it's difficult sometimes to group some of the device  
11 reports. So we did a little bit of an analysis of the  
12 database, where we actually pulled out all of the  
13 glucose serious injury reports from 2004 to 2008. And  
14 I will point out that probably we would get different  
15 numbers if we used different search terms, so this is  
16 another limitation of our database. So for this  
17 particular search, we pulled out 12,672 serious  
18 injuries.

19           Now, each of these injuries is described in  
20 different ways. So here I've shown you the top 11  
21 injury codes that came out of this search, and you can  
22 tell that the numbers don't add up to 100 percent,

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1 because sometimes these things are overlapping. Also,  
2 the terminology that's inherent in the FDA database is  
3 confusing, because they have blood glucose low and  
4 hypoglycemia as separate events, and sometimes things  
5 are reported in both, and sometimes things are  
6 reported in one. So it very much makes the job of FDA  
7 in terms of looking for these trends difficult. So  
8 we're actually actively working on trying to improve  
9 some of the data analysis and reporting techniques for  
10 glucose meters over time to see if we can get some  
11 better data to try and make sure that if there are  
12 trends or events, that we can pick up on them.

13           What's a little easier to look at is the  
14 death data, because fortunately, there is a manageable  
15 number of deaths reported to FDA. These are also  
16 underreported, but like I said, given the volume of  
17 testing, 100 deaths since 1992 is actually not good in  
18 that you don't want any deaths, but it's better than  
19 having 12,000. So we actually did look at all 100  
20 deaths between 1992 and 2009 in a single analysis, and  
21 we tried to classify them. And as you can see,  
22 because of the database, the majority -- or not the



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1 majority, but the largest category that we had to put  
2 things in was "unknown cause." And that is actually a  
3 feature of our reporting database, where you might  
4 read the description of the event and you can actually  
5 not attribute any cause to the death that occurred. So  
6 you don't know whether it was associated with the  
7 meter or not, or you don't know what happened with the  
8 meter to make that happen.

9           Meter malfunctions would be 11. An example  
10 of this would be meters that inadvertently switched  
11 from milligrams per deciliter to millimoles per liter.  
12 If somebody might take an action on a number for  
13 millimoles per liter, thinking it's milligrams per  
14 deciliter, they may actually make an incorrect  
15 treatment choice.

16           False high results and diabetic ketoacidosis  
17 were also high numbers. And there were 13 deaths from  
18 the issue of maltose interference for glucose  
19 dehydrogenase PQQ meters.

20           And so I'm going to take this example to  
21 walk you through a case where we have identified an  
22 issue over time and the way FDA has gone about trying

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1 to address this issue, because later on, if you have  
2 an input on how FDA can better do this to actually  
3 help put out the message, we'd really like to hear it.  
4 So I'd like to use this as an example.

5           So the particular issue with glucose  
6 dehydrogenase PQQ is the following. So glucose PQQ --  
7 in the interests of time, I'm not going to try and  
8 pronounce PQQ for you, but there it is on the screen.  
9 This is a type of technology that's been around for a  
10 very long time. It's been marketed for over 20 years.  
11 This technology is non- selective for glucose, and  
12 that means that it also detects other sugars, such as  
13 maltose, xylose, or galactose. And these meters were  
14 actually already around when certain drug products  
15 were approved by FDA that contain these sugars as  
16 components. And when that happened, sometimes when  
17 patients were treated with these drugs, the meters  
18 actually detected those sugars as glucose, to some  
19 extent, and so although the meter is actually giving a  
20 correct reading of the sugar that it's seeing in the  
21 blood, all of it isn't glucose. So taking an action  
22 on that number can be inappropriate clinically. And

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1 there have been deaths and serious injuries associated  
2 with this, and also severe hypoglycemic events.

3 Now, both the devices and the drug are  
4 labeled against this use, so there's clear labeling on  
5 the devices and clear labeling on these drugs, as  
6 well, to say that these two products shouldn't be used  
7 together because of this interaction. But as I'll  
8 show you in a minute, some of that hasn't been  
9 effective.

10 So the types of drugs -- I'll list them more  
11 completely later. But a lot of them are IB drugs,  
12 because that's where you get enough exposure to these  
13 sugars to actually cause the issue with the reading.  
14 So Extraneal would be a peritoneal dialysis solution  
15 that's been involved in some of these issues, and also  
16 some IB immunoglobulin solutions that use maltose as a  
17 stabilizer.

18 So FDA actually recognized this problem  
19 several years ago and has taken several actions over  
20 the last several years. So in 2005, we released a  
21 MedWatch Safety Alert on this issue. In 2006 we did  
22 another Patient Safety News to try and reach out to

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1 healthcare providers to describe this problem. In  
2 2008 we published two articles, one out of the Center  
3 for Drugs and another out of the Center of Biologics  
4 on this particular issue, describing deaths that may  
5 occur, and also another Patient Safety News on the  
6 topic. And last spring, in 2009, the Center for Drugs  
7 actually updated the package insert for the Extraneal  
8 drug product to include a back- box warning against  
9 using GDH-PQQ test strips on these patients.

10           Regardless, from 1997 to 2009, FDA has  
11 received 13 total deaths reported to FDA associated  
12 with this glucose test strip. We've actually seen a  
13 few other cases in the literature that weren't  
14 reported to FDA, as well. These deaths all occurred  
15 in healthcare facilities, and six of the 13 deaths  
16 have occurred since 2008. So this told us that even  
17 though we've been doing sort of outreach efforts for  
18 the last several years, these deaths continue to  
19 happen at some rate, so it really gives us a signal  
20 that some of our outreach efforts are not being  
21 effective enough.

22           Ten of these 13 patients reported were on

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1 Extraneal, the drug that received the black box  
2 warning, and three of the 13 patients were receiving  
3 other maltose- containing substances, like these IV  
4 immunoglobulins.

5           So as you can see, we have a problem. These  
6 previous actions that we've taken are not having an  
7 effect on deaths, and we are actually continuing to  
8 see deaths. It's almost as if when an alert goes out,  
9 there's some period of awareness and then there's a  
10 little bit of a decline in awareness, perhaps because  
11 of turnover of workers in healthcare facilities.

12           And the other part of this problem is that  
13 this is an issue that doesn't actually affect the  
14 majority of patients using these devices. So this is  
15 a very -- this is a pretty small minority of patients  
16 that are on these devices. But when this happens,  
17 it's devastating for that patient, so it is a very  
18 serious problem when it happens.

19           So FDA, we thought that additional action  
20 was warranted, but what we were worried about, because  
21 this affects a small minority of patients and because  
22 testing for blood glucose in diabetic patients is so

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1 important, we really struggled with how to balance the  
2 message, to make sure that people continued to test  
3 and did not misunderstand the message and believed  
4 that there was a problem that applied to them, when  
5 really we wanted to reach a very small population of  
6 patients and the healthcare providers who treated  
7 them.

8           So how do we balance a safety warning and,  
9 you know, getting the message out that patients, you  
10 know, really need to keep testing? So the  
11 communication of complex issues is definitely  
12 something that we really work on and try to do well,  
13 and I think sometimes we succeed and sometimes we  
14 don't.

15           So this time we actually decided on a  
16 stronger message, hoping that it would get a little  
17 bit more attention in the healthcare facilities, and  
18 also some ongoing other actions. So FDA published in  
19 August of 2009 a public health notification on this  
20 issue. And the point was to try and raise the level  
21 of the recommendation to attempt to increase awareness  
22 about the problem. And this public health

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1 notification was aimed at healthcare providers and  
2 healthcare facilities. And it described the nature of  
3 the problem in detail in the public health  
4 notification, and the link was on the previous slide.  
5 And it described that this issue, when it's  
6 unrecognized and when these test strips are used on  
7 patients that have these drugs in their system, may  
8 lead to inappropriate insulin dosing that could lead  
9 to serious injuries, such as severe hypoglycemia or  
10 perhaps leading to coma and also death. And also, it  
11 can lead to unrecognized hypoglycemia. And it can  
12 occur anywhere, so although these -- all the deaths  
13 have occurred in healthcare facilities, it is possible  
14 for some of these drugs, which are outpatient drugs,  
15 that it could happen at home.

16           We also tried to describe that this is not a  
17 problem with other types of technologies. It does not  
18 affect glucose oxidase test strips. It doesn't affect  
19 the other two glucose dehydrogenase test strips, which  
20 aren't maltose-sensitive. So the GDH-NAD and GDH-FAD  
21 have a much lower sensitivity to maltose, galactose,  
22 and xylose. And it also doesn't affect laboratory-

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1 based methods, so usually those methods use  
2 hexokinase, which is a little bit more sensitive.

3           So the recommendations that we gave to  
4 healthcare facilities were these. We actually  
5 recommended that healthcare facilities avoid, in  
6 general, the use of glucose dehydrogenase PQQ test  
7 strips in their facilities. For those facilities who  
8 continue to use, or in the meantime before they  
9 switched over, GDH-PQQ test strips, we recommended  
10 that they never use them on patients receiving these  
11 particular drugs or products and/or on patients from  
12 whom they couldn't get that information, so patients  
13 who were perhaps unresponsive when they entered the  
14 hospital. And we recommended that only laboratory-  
15 based assays be used on these patients.

16           We also recommended that not only hospitals  
17 determine whether patients are receiving these upon  
18 admission, but also periodically through their stay;  
19 that hospitals increase efforts to educate staff about  
20 this issue; that they consider using drug action  
21 alerts in their hospital information systems, and that  
22 they periodically verify glucose meter results on any



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1 meter with laboratory-based methods. And the public  
2 health notification also lists the particular drugs.

3 As I mentioned already, Extraneal and some  
4 IV immunoglobulins -- Orenzia, Adept adhesion  
5 reduction solution, Bexxar(ph). And also we included  
6 a bullet saying any product containing or metabolizing  
7 into maltose, galactose or xylose.

8 We have had some questions on this, because  
9 it is a little bit vague. And the reason it's vague  
10 is that there are some products out there where the  
11 content of maltose or these sugars isn't known, or  
12 there could be compounding within hospitals using some  
13 of these products.

14 So what happened in some of these cases is  
15 that you have an issue where a test or result on one  
16 of these strips and the patient who receives some of  
17 these drugs might be three to 15 times higher than the  
18 lab result. For example, one patient where the blood  
19 glucose result on the meter was 200, the lab result at  
20 the same time was 19. And when those patients are  
21 treated with insulin, it drives them even lower, and  
22 that's where the deaths have occurred.

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1           So at the same time we released the public  
2 health notification, we also released an advice for  
3 patients. This is a publication that accompanies the  
4 public health notification and is intended for lay  
5 users. And it held similar, but separate  
6 recommendations for these lay users, because we were  
7 trying to balance the message to make sure that people  
8 could find out whether they were affected or not and  
9 what they should do in the meantime.

10           So we recommended that diabetic patients who  
11 any of those blood products should never use test  
12 systems that use GDH-PQQ test strips, and that they  
13 contact their healthcare provider if they aren't sure  
14 if they have those particular types of technologies or  
15 are on those drugs, or if their results don't reflect  
16 the way they feel.

17           We went on to make general recommendations  
18 for all diabetic patients that they continue testing;  
19 that they not change test strips that were intended to  
20 use for their meter; that they try and find out or  
21 understand the type of technology they're using, the  
22 drugs they're on; and to make sure that they know that

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1 any meters and strips that don't use this technology  
2 are okay for them.

3           And in the meantime, we're still working  
4 with manufacturers to address some of these issues.  
5 And we're also monitoring the adverse event reports to  
6 see if this problem keeps occurring. In the meantime,  
7 like I said, we encourage all facilities and users to  
8 report problems of this type or any type to us so that  
9 we can continue to do this type of trend analysis.

10           Because here's an example that I've given,  
11 where you have an interference that's known. So this  
12 is something that a lot of people in this room  
13 probably already know about. This interference is  
14 predictable. If you're on one of these drugs, you  
15 know that this is going to happen. And it's  
16 preventable, because if you know it's going to happen,  
17 then you can certainly avoid it.

18           But the problem is that the awareness has  
19 been too low, and it continues to be too low. So  
20 we're trying to figure out what is the right balance  
21 of how much is enough to do in this case.

22           So our challenges that I'll leave you with

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1 are that past communications have not had a lasting  
2 effect, so we would like to hear from you all about  
3 potential other ways that we can do outreach and  
4 education on issues like this or whether other actions  
5 are necessary to mitigate the risk of this type of  
6 problem. And what more can we, the healthcare  
7 industry, and the medical device industry do to  
8 prevent some unnecessary deaths due to known  
9 interferences like this and like other interferences?

10 So I thank you for your attention, and I  
11 look forward to the discussion. Thanks.

12 (Applause)

13 DR. CLARKE: We have time for one question.

14 MR. KIECHLE: I'll be quick. It's Fritz  
15 Kiechle, clinical pathologist from Memorial Healthcare  
16 System in Hollywood, Florida. Excellent presentation.  
17 This sort of represents a never event, and it's  
18 clearly a patient's safety issue. But it's one that a  
19 hospital is perfectly capable of tackling if done  
20 carefully and with diligence and surveillance.

21 And the way we've handled it, and I've dealt  
22 with this problem in two different hospitals -- we

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1 handled it the same way both places. Those items that  
2 contain maltose, for the most part, the interfering  
3 substance, are in the pharmacy. The pharmacy has a  
4 committee, has a formulary, which controls the  
5 substances they carry in the pharmacy. And they have  
6 a Pharmacy and Therapeutics Committee that makes those  
7 decisions. The first thing we did was go to the P&T  
8 Committee, as it's known, and asked them to remove  
9 these maltose-containing substances from their  
10 formulary and find substitutes. If that couldn't be  
11 done or there was an exception where there might be a  
12 physician who insists on using one of these compounds,  
13 we would then send the compound with a note from the  
14 pharmacy reiterating that we will not use this  
15 particular glucose meter for these patients while  
16 they're taking this substance. And we also get a  
17 phone call to the point of care coordinator the minute  
18 the drug is shipped to the floor. That person goes up  
19 and re-instills with the actual nursing staff that are  
20 taking care of the patient that they should not be  
21 using the glucose meter.

22 And that really has worked quite well, and

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1 as far as I know, we've had absolutely no problems.

2 DR. HARPER: I'm really glad to hear that. I  
3 mean, that sounds like your hospital has taken this  
4 problem seriously and tried to address it. And that  
5 sounds like it will be effective when you are actually  
6 the ones administering the drug. Some of the reports  
7 have actually been cases where a patient had had the  
8 drug outside of the healthcare facility in which they  
9 are being treated, and they actually then arrived at  
10 the healthcare facility and in some cases told the  
11 nurse or nurse practitioner that they shouldn't use  
12 that meter. And unfortunately, there wasn't enough  
13 education of the person running the test to know that  
14 maybe they should believe the patient. So it actually  
15 can be quite tragic.

16 But I'm glad to hear that there's a lot of  
17 risk mitigation procedures being put in place.

18 MS. SKEENS: Can I just clarify? This is  
19 Lisa Skeens from Baxter Healthcare. And I just want  
20 to point out that for Extraneal, where this a very  
21 serious issue, as you've pointed out, that maltose  
22 actually stays in your body for two weeks after a

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1 patient is administered. It's not prescribed by the  
2 pharmacy, so that actually would not mitigate this  
3 risk for Extraneal patients. So it's, as you  
4 mentioned, very important to have other types of  
5 education involved, because it's not your typical  
6 situation, and Extraneal is a chronic use product. So  
7 again, a patient may be administered not receiving the  
8 product in the hospital, but have this serious issue.

9 DR. HARPER: Right. Thank you.

10 DR. CLARKE: Okay. Thank you again.

11 It's time for our break. We'll take a 15-  
12 minute break. We'll reconvene at 3:20 or when you  
13 hear the bell ringers in the crowd.

14 (BREAK)

15 DR. MYERS: If I could ask everyone to take  
16 your seats, we'll continue with our second session.

17 Okay. I want to welcome you back to the  
18 continuation of our second session, Blood Glucose  
19 Meter Performance, Interferences and Limitations. Our  
20 second speaker today is Ken Ervin. And Ken obtained  
21 his bachelor's and master's degree with a focus on  
22 analytical chemistry from the University of California

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1 at Riverside. He's held positions with R&D with Syva  
2 Corporation, Abbott Diagnostics, and SmithKline  
3 Instruments. In 1983 he joined the startup company of  
4 LifeScan as an R&D director, and there he participated  
5 in the development of Glucoscan, One Touch, and  
6 SureStep blood glucose monitor systems. And he took  
7 early retirement in 2004 and has been consulting  
8 primarily with startup companies in the blood glucose  
9 field.

10 His talk today is going to be Analytical  
11 Interferences and Physiological Limitations of Blood  
12 Glucose Meters. Ken?

13 MR. ERVIN: Thank you, Dr. Myers. As you  
14 may have gathered from that introduction, I've spent a  
15 good part of my career within the glucose monitoring  
16 area, and as such, I have observed evolution of the  
17 product over this time frame.

18 Initially, the biggest place to hit accuracy  
19 was with user error. And a lot of the early products  
20 attempted to do that. We ended up with what were  
21 called second generation products, where we did away  
22 with that wiping and blotting business, and that was



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1 the major source of user error.

2 But we've also seen evolution in the  
3 technology itself to provide a more convenient,  
4 faster, and cheaper product. And we are also seeing  
5 evolution of the technology to produce more accurate  
6 results and to deal with some of the lingering  
7 problems. One of these is the area of analytical  
8 interferences and physiologic limitations.

9 There's a plethora of information out there  
10 on this topic. And if you're really interested in it,  
11 I think two reviews in particular by Wahl and Duncan  
12 are particularly useful, in that they're pretty  
13 comprehensive and pretty informative. There's also a  
14 number of original articles. I've just got partial  
15 lists here in both categories. There's no shortage of  
16 information.

17 We've already heard about package inserts  
18 several times today. And generally, these things are  
19 captured in the section that's typically called  
20 procedural limitations. And they're bucketed into  
21 several different categories: things that are  
22 considered to be sample- related, that is, the sample

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1 hematocrit; po2; whether or not the patient's in DKA  
2 or HHNK. There's a category for endogenous compounds,  
3 sort of naturally occurring substances which, should  
4 they become elevated, could possibly create a problem;  
5 exogenous compounds -- we just heard a bit about  
6 maltose, but there are others; and of course the  
7 environmental considerations.

8           Now, one of the things we were talking about  
9 a little while ago was accuracy. One of the main  
10 differences between blood glucose monitors and  
11 laboratory instruments is -- I know this coming from a  
12 laboratory instrument background -- they do everything  
13 they can to control things like temperature and the  
14 environment that the test is being done in. Blood  
15 glucose monitors probably could do that, but as we've  
16 heard earlier, the cost of the devices would probably  
17 go up exponentially. It takes a lot of power and a lot  
18 of work to do that.

19           So what they've done is to sort of confine  
20 the use range in terms of temperature or in terms of  
21 humidity. Altitude is essentially a po2 problem.

22           One theme that I'd like to carry through

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1 today is that each manufacturer, in producing their  
2 product, has some design goals that they're going to  
3 go after, and that those design goals to some extent,  
4 and also the effort to achieve a proprietary position,  
5 they're going to pick some set of technologies to put  
6 into their system and give them a competitive device.  
7 The choices of those technologies in essence leads to  
8 some of these interferences and these limitations.

9           However -- I'll go back to the point I  
10 wanted to make earlier -- technology is evolving, and  
11 you are seeing products in the marketplace now that  
12 are dealing with some of these, and dealing with them  
13 quite effectively.

14           This is just a partial list of some design  
15 goals that a blood glucose manufacturer might  
16 consider. The obvious ones, accuracy and precision,  
17 specificity, et cetera. I've asterisked some very  
18 important ones from their perspective, though. The  
19 product has to be stable. That is, the test strips  
20 have to be stable at room temperature. We've already  
21 heard some discussion this afternoon about the impact  
22 of using fresh and late-dated strips.

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1           The test has to be rapid. Now, we're  
2 talking in the order of five seconds now for many  
3 products that are available to the consumer. That  
4 basically -- and the environment where we're dealing  
5 with it in the home, in particular, means that you're  
6 going to use whole blood. You don't have time to deal  
7 with plasma or serum. So the use of a whole blood  
8 sample is a key piece of the design goal.

9           And then the second -- or the third item  
10 here I've asterisked is, it has to be very easy to  
11 use. If these products are going to be used even by  
12 nurses in the hospital, they've got to be easy,  
13 because they don't have time to pay attention to a lot  
14 of technical detail.

15           Another item I'm going to mention here,  
16 because it relates to accuracy, is you've got to  
17 develop some sort of calibration strategy. And  
18 historically, the calibration codes have actually been  
19 windows. It could be two, three, four percent that a  
20 particular cal code would represent. And so one of  
21 the areas that manufacturers obviously are trying to  
22 work is how they can actually pull these calibration

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1 codes into tighter and tighter ranges.

2           So in order to meet these design goals and  
3 specifications, they choose particular technologies,  
4 both for the device and for its method of production.  
5 The other thing that's worth remembering is that blood  
6 glucose measurement is based on combining  
7 technologies. For example, you have to have a method  
8 of getting your sample into the device. And  
9 currently, most methods are using some sort of  
10 capillary action. There are some that are using, for  
11 example, blood drops on a membrane, but for the most  
12 part, everybody's headed toward some sort of capillary  
13 approach.

14           You have to have a method to identify  
15 glucose, and you want to do this without question.  
16 This is the reason for the GDH-PQQ problem in the  
17 maltose. It's referred to as specificity, and in  
18 fact, there are three enzymes that have been used in  
19 blood glucose monitoring devices. All of them are  
20 fairly common in the laboratory, and they've all been  
21 used in blood glucose monitoring devices, as well.

22           And finally, you need to have a method to

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1 quantify the glucose. Essentially right not, it's  
2 either a photometric, colorimetric assay or an  
3 electrochemical assay. You also have a method of  
4 calibration, which I mentioned a moment ago, and this  
5 not only relates to sort of the samples that you have  
6 to use, the reference system that you're going to use,  
7 the width of your cal code space -- a number of  
8 important variables. And in recent years you've seen  
9 more effort in the area of assessing whether or not a  
10 test was done correctly. Is there something that  
11 could have gone wrong? Was the temperature incorrect?  
12 Instrument manufacturers have been trying to evolve  
13 their technology to identify these conditions, and  
14 even more recently now, if they've identified a  
15 significant contributor, can they correct the results  
16 for that?

17           So interferences result in two areas. One,  
18 from the analyte specificity or some effect on the  
19 reaction that follows, either a sample influence or an  
20 environmental influence on the measurement reaction.  
21 I've said the enzymes that are being used are glucose  
22 oxidase, glucose dehydrogenase, and hexokinase.

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1 Glucose oxidase in the original products was  
2 exclusively used. All of the original blood glucose  
3 monitoring products used that, for two reasons. One,  
4 it's very stable at room temperature, and secondly, it  
5 was very specific. It could easily be formulated into  
6 a test strip. And then thirdly, it was easily coupled  
7 to a colorimetric indicator system, of which there  
8 were many, and you had your blood glucose monitoring  
9 device.

10           GDH has historically been most used with the  
11 HemoCue system -- I mean, that's the one that's been  
12 out there the longest using GDH. That enzyme is  
13 particularly insensitive to interferences. However,  
14 it does have a tradeoff, in that it's not particularly  
15 stable, and therefore their cuvettes have to be  
16 refrigerated.

17           There was one product from Bayer, called the  
18 Encore, that actually used a hexokinase G6 PDH system,  
19 affording it great specificity. And I'll talk a  
20 little bit more about it later on when we're talking  
21 about po2.

22           We've heard a lot already about endogenous

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1 substances and exogenous substances, but what I really  
2 wanted to talk a little bit about today is not what  
3 they were and how much effect they have, but rather,  
4 how does that happen? Let me take ascorbate as an  
5 example.

6           In a colorimetric system using glucose  
7 oxidase, where we produce hydrogen peroxide as an  
8 intermediate product, and then a final colored  
9 product, ascorbate has the property that it can either  
10 reduce the peroxide or the colored product and  
11 actually produce a low result. In some electrochemical  
12 systems, it can be read independently of the glucose  
13 reaction and produce a positive bias to the result.  
14 Fortunately, the electrochemical systems are now  
15 beginning to incorporate, as Dr. Ginsberg has  
16 mentioned, schemes to identify the occurrence of this  
17 background current and to eliminate it from the  
18 glucose calculation.

19           When we talk about patients with DKA or  
20 HHNK, I don't think I've seen very much about a pH  
21 problem with glucose test strips. That's not to say I  
22 don't think they've happened, but generally the test



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1 strips are highly buffered so that pH shifts in DKA  
2 are not going to be much of an issue. On the other  
3 hand, viscosity of the sample -- remembering that  
4 these samples tend to be dehydrated, and as such,  
5 there's very little water left in them -- they tend to  
6 be hyperosmolar. And these can have flow effects in a  
7 system, particularly in capillary systems.

8           Back in my days at LifeScan, we had an HHFK  
9 sample that I put on top of a test strip. It took  
10 over 30 seconds to penetrate into that test strip when  
11 a really high hematocrit sample might take only three  
12 to four seconds. There was so little water in that  
13 sample that it wouldn't penetrate the strip. When it  
14 did, it produced a very low result. So these kinds of  
15 samples can have what I call flow effects on your  
16 glucose monitor. They don't happen very often, but  
17 that's why they're in the labeling.

18           Environmental influences -- I mentioned  
19 earlier that laboratory instruments are trying to  
20 control everything. Glucose monitors just try to  
21 control by defining a range in which they work. The  
22 altitude thing is basically a po2 problem.

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1           When we go to looking at physiological  
2 limitations, we basically have three choices of  
3 samples, or after talking with Jeff DuBois earlier, I  
4 probably should have said "specimen" here --  
5 capillary, venous, or arterial. This presents us with  
6 three or four different difficulties. One is that the  
7 actual concentrations of glucose can be different in  
8 the three, and that's well understood. We've also  
9 heard today reiterated several times that hypotensive  
10 patients, other conditions creating profusion  
11 problems, and I ran across a patient once where  
12 Reynaud's Syndrome actually created a big difference  
13 between the vein of puncture and the capillary result.  
14 We've heard already today about the alternate site  
15 time lag and the po2 differences.

16           Okay. What I wanted to do today, and since  
17 I'm beginning to run out of time I'm going to have to  
18 hustle along here, I was going to cover two examples,  
19 hematocrit and the po2 problem. These reactions on  
20 the screen, the upper one is that typical glucose  
21 oxidase reaction where oxygen is used. And this is  
22 where the po2 effect comes from. In systems where

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1 oxygen cannot get to the sample, or where the sample  
2 itself varies a great deal in its concentration, you  
3 can create an effect that is the result of  
4 competition. So for example, in an electrochemical  
5 system, where they use mediators, because they're more  
6 efficient in turning over the current, the - - this  
7 reaction will be in competition with the glucose plus  
8 oxygen reaction. And we get a competition now such  
9 that in the case of venous blood, you're going to get  
10 higher results, because there's less oxygen present in  
11 the sample. More of the glucose can go the mediator  
12 pathway, and so you tend to get higher results.  
13 Arterial tends to read lower, because you have a lot  
14 more oxygen present. By the way, this is all relative  
15 to being calibrated with capillary blood, so you have  
16 more oxygen, or in the case of highly oxygenated  
17 venous samples. You can take a venous sample and mix  
18 it with air for a while, you'll get the same effect.  
19 So we have a competition going on there that drives  
20 this  $po_2$  effect.

21           The second-generation products had a similar  
22 difficulty if their reaction site was somehow occluded

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1 from exposure to the atmosphere. Products like One  
2 Touch and SureStep, where the membrane surface is open  
3 to the atmosphere, they didn't have much of an issue.  
4 But other products, where they use a window, you no  
5 longer could get oxygen in there, and so you ended up  
6 with this po2 competition problem.

7 I mentioned the Bayer product earlier,  
8 hexaconagesic (ph) PDH. They went with this system  
9 ostensibly to get away from the po2 effect, but they  
10 also had some stability issues, as well.

11 The GDH PQQ system was introduced to  
12 alleviate this po2 effect. Doesn't involve oxygen, so  
13 there's no competition. And this particular enzyme  
14 happened to be relatively stable at room temperature,  
15 so it had that attribute. However, that particular  
16 enzyme has demonstrated less specificity for glucose,  
17 as we've heard, and recognizing other glucose-  
18 containing sugars. And hence the problem.

19 In terms of the evolution, people have been  
20 working on trying to develop GDH enzymes that, again,  
21 use the NAD or FAD co-factor. And these are, through  
22 their genetic engineering, becoming more specific and

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1 more stable, and you're seeing some of these in  
2 products now.

3           The other condition I wanted to talk about  
4 was -- that we've heard a lot about today is  
5 hematocrit. One of the problems here is that because  
6 we were dealing with so much confusion between  
7 understanding the difference between whole blood and a  
8 plasma result, a lot of the manufacturers moved over  
9 to reporting plasma-equivalent results. These systems  
10 have to be calibrated at normal hematocrit, but we  
11 know that the hematocrit ranges can vary  
12 substantially, five-fold, or nearly five-fold. So  
13 applying that calibration to samples that are  
14 significantly different than normal is a source of  
15 error.

16           In this illustration, what I'd like to show,  
17 the blue line is what you would expect just on the  
18 basis of physiology. In other words, if you take a  
19 whole blood sample and plasma from that same sample  
20 and look at the glucose content, as you go down  
21 towards a sample with a hematocrit of 20, you're going  
22 to have basically about a six percent bias. If you go

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1 to higher hematocrits, you've going to have a six  
2 percent negative bias. That's just the physiology of  
3 that sample.

4 And as Dr. Ginsberg mentioned earlier,  
5 hematocrit is a more complex issue, and he already  
6 alluded to the business of red blood cells and how  
7 they may impact the measurement itself.

8 The yellow line illustrates a product which  
9 has minimal what I'd call method effect related to the  
10 technology, the green line representing a product  
11 which has increased or greater effect as a result of  
12 its technology. And some products are really  
13 sensitive, to the extent that as you approach higher  
14 hematocrits, they just nosedive, and that's  
15 illustrated here by the red line.

16 And as he was suggesting, hematocrit does  
17 influence the access of plasma or the diffusion of  
18 glucose through that sample in the test device,  
19 suppressing results. So you would expect, then, that  
20 when you're really trying to turn over reactions  
21 quickly, like at higher glucose, the effect is going  
22 to be greater. And in fact, that's observed. If you

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1 look at some of the labeling and products a while ago,  
2 the -- they actually had two different hematocrit  
3 ranges, one for lower glucoses and one for higher  
4 glucoses, the higher glucoses being somewhat  
5 compressed.

6           The good news is, and several companies are  
7 doing this now, it can be measured, and it can be  
8 corrected. One question I have there is, is there a  
9 price? Now that you're making two measurements, is  
10 there a price you pay in terms of imprecision?

11           So in conclusion, limitations and  
12 interferences are related to the particular  
13 technologies. The goals of a BGM system to me make it  
14 unlikely they'll ever completely match a lab-based  
15 system, but they'll get close. They can get close.  
16 And the evolution of these devices is a demonstration  
17 of trying to achieve this balance between a high  
18 degree of performance with a rapid, versatile, easy-  
19 to-use system.

20           And of course, the last conclusion is when  
21 we're talking about hematocrit, we've got an automatic  
22 plus or minus six percent.

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1 Thank you.

2 (Applause)

3 DR. MYERS: We have time for some questions.

4 Ken, I have a question for you. How many  
5 different bases of calibration for the instruments are  
6 you aware of, as far as methodology calibration?

7 MR. ERVIN: Oh, one of the reference bases  
8 early on was YSI, because it dealt very easily with  
9 whole blood samples. So a lot of the instrument  
10 manufacturers used YSI initially.

11 Also initially, all of the testing was  
12 intended to be done on capillary blood, because these  
13 were intended for users at home. As we moved to  
14 trying to improve accuracy and the versatility of the  
15 product, you started seeing other reference systems  
16 utilized. For example, one company I know used a  
17 deproteinized hexokinase as their reference system.

18 If you're asking the question about the  
19 calibration codes themselves, I don't have  
20 information. A lot of it's proprietary. But there  
21 are very different schemes in the way people approach  
22 calibration of their devices. Some will use equations



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1 built into the system to actually describe the  
2 behavior versus whether it's a current or a  
3 photometric measurement. Others will make sure that  
4 their product behaves in a linear fashion, and then  
5 they just assign a cal code that normalizes their  
6 result to their reference value.

7 I'm not sure if that completely answers your  
8 question, but ....

9 DR. MYERS: Well, I guess the question is,  
10 some are, as you say, calibrated to the YSI, and some  
11 are actually calibrated directly to mass spec. So is  
12 there an issue among meter variability because of how  
13 the variation in what the calibration point is?

14 MR. ERVIN: I hope I didn't say GC mass  
15 spec. I don't believe any of the manufacturers are  
16 using that as their routine method for calibration.  
17 When you're in a manufacturing situation, and I'm sure  
18 they're going to address this themselves, but when  
19 you're in a manufacturing situation, you've got to  
20 have something that is feasible for routine day-in and  
21 day-out operation. And I'm not privy to what all of  
22 the different manufacturers are using as their

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1 reference systems. For example, Nova probably is  
2 using something very different.

3 But initially, and it's evolved from that,  
4 but initially everybody pretty much was using YSI,  
5 because of its convenience in dealing with whole blood  
6 samples.

7 DR. MYERS: Thank you.

8 Okay. Our next speakers will be two  
9 individuals representing the industry's perspective.  
10 And I'll go ahead and introduce them both at the same  
11 time.

12 First of all is Dr. Alan Cariski. And Dr.  
13 Cariski received his bachelor's degree from John  
14 Hopkins University, his medical degree from the  
15 University of Rochester School of Medicine and  
16 Dentistry, and his law degree from the University of  
17 Maryland School of Law. Dr. Cariski has over 30 years  
18 of experience in the healthcare industry, having  
19 practiced medicine as a board-certified internist and  
20 endocrinologist before transitioning to industry in  
21 1991. Since 2001, he has been Vice President of  
22 Worldwide Medical Affairs and Medical Safety Officer

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1 at LifeScan.

2                   And our other individual is Mike Fliss, and  
3 he has a BS degree in mechanical engineering from  
4 Marquette University. His industry leadership  
5 experience includes serving as Co-chair of AdvaMed's  
6 Blood Glucose Working Group since 2007, and he has  
7 held a variety of key regulatory roles during his 23  
8 years at Roche Diagnostics working with product  
9 developers to optimize product design characteristics,  
10 product risk assessments, clinical trial designs, and  
11 instructions for use in promotional materials to  
12 facilitate prompt registration processes.

13                   Gentlemen?

14                   DR. CARISKI: Thank you very much, Dr.  
15 Myers.

16                   Why don't you manufacturers make glucose  
17 meters more accurate? That's a question a well-known  
18 endocrinologist asked me at the Diabetes Post-Graduate  
19 course in San Francisco that was held recently. And  
20 as luck would have it, I didn't have this slide set  
21 with me. But I have it today, and I'd like to spend  
22 the next few minutes answering that question for you

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1 as best I can.

2 So the glucose manufacturers as a whole are  
3 committed to designing and manufacturing glucose  
4 meters to meet the needs of individuals with diabetes.

5 And industry shares a goal of advancing  
6 meter technologies and improving accuracy through  
7 innovations in meter systems that accomplish these  
8 three things:

9 Reduce use error. And I think it's  
10 important that most people today have used the term  
11 "use error" rather than "user error," because the term  
12 "use error" recognizes that it's not only the user,  
13 per se, but it may be the way in which the product was  
14 designed, so that any user might encounter problems.  
15 So I think use error is an important term.

16 Also, the manufacturers try to reduce the  
17 impact of interference and improve the overall quality  
18 of testing for patients.

19 And finally, both the glucose standard for  
20 consumer meters, that 15197, and industry recognize  
21 the role of design to improve not only analytical  
22 performance, but also the usability of the instruments

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1 to increase patient compliance with glucose monitoring  
2 regimens.

3           It's instructive to compare the meter to the  
4 other technologies that are available, and to some  
5 extent, Ken and some of the other speakers have done  
6 that. The so-called definitive method uses isotape-  
7 labeled glucose dilution mass spectrometry with gas  
8 chromatography. And while this is something you might  
9 think that no home should do without, I think you have  
10 to concede that it's not something you're going to  
11 take on the road with you. The method requires  
12 meticulous and time-consuming serum sample  
13 preparation.

14           The same thing is true for the reference  
15 method. It's time-consuming, requires serum or plasma.  
16 And finally, the typical diagnostic laboratory method  
17 also uses prepared serum or plasma, and the  
18 environment is very precisely controlled, both the  
19 environment in which the device sits and also the  
20 environment within the device itself in terms of pH  
21 reaction initiation, et cetera.

22           The meter, on the other hand, uses capillary

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1 whole blood, a point that Ken just emphasized. And it  
2 emphasizes ease of use. It has to be portable; it  
3 uses small volumes, people want fast testing. And it  
4 has to be used in a variety of environments. The lab,  
5 it has, of course, a controlled environment. There  
6 are restrictions on where meters can be used, but  
7 they're fairly broad in terms of temperature, altitude  
8 -- most will work up to 10,000 feet -- and most have a  
9 fairly broad range of relative humidity.

10           And of course, these tests are performed by  
11 lay users, not by trained laboratory technicians. And  
12 when you think about it, we're really asking lay  
13 people to perform a laboratory test; okay? And we're  
14 trying to make it as simple as possible and still be  
15 accurate.

16           So the next few slides will compare and  
17 contrast the lab instrument to the glucose meter. So,  
18 as I mentioned, the lab has definitive reference  
19 methods. The glucose meter can at best say that it's  
20 ultimately traceable to the definitive or reference  
21 method.

22           There are standard reference materials to

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1 test the lab instrument. These don't exist for  
2 glucose meters.

3           The hematocrit effect we discussed. In  
4 glucose meters, the hematocrit effect is mitigated by  
5 measurement, but not necessarily entirely, and also by  
6 the use of algorithms.

7           Finally, there are some fairly accurate  
8 devices that use whole blood, but they eliminate the  
9 hematocrit effect through membranes, and the membranes  
10 also protect the enzymes and sensor from interfering  
11 compounds. SMBG technology, at least what's available  
12 today, doesn't have these advantages. And the  
13 presence of multiple interference provide a  
14 considerable technical challenge.

15           Again, laboratory instruments tend to cost  
16 more than \$10,000. A typical glucose meter is less  
17 than \$100. Lab instruments require maintenance;  
18 glucose meters don't. Plasma versus blood -- giving of  
19 plasma equivalent. Trained technician versus a lay  
20 person -- the lab instruments are typically calibrated  
21 many times daily. Glucose meters cannot be calibrated  
22 by the user. The controlled versus the uncontrolled

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1 environment I've alluded to. And in the lab, controls  
2 are run frequently. Control solution is available for  
3 users to test the integrity of their system. Many  
4 people don't use it, or use it sparingly. And if they  
5 detect a problem, unlike the lab, there's nothing they  
6 can do, at least with the product they have.

7           A laboratory instrument is large and  
8 stationary, susceptible to shock. The meters, you  
9 know, are brought everywhere. They have shock  
10 testing. They're very tolerant to shock. Most lab  
11 equipment requires at least five milliliters of blood.  
12 I expressed it as microliters just to contrast with  
13 the glucose meter, which requires less than a  
14 microliter. And the meters requiring the smallest  
15 samples today require just .3 microliters.

16           A typical lab instrument takes at least 60  
17 seconds to give a result. The glucose meter, less  
18 than 10 seconds, and the majority of meters today take  
19 less than five seconds, or no more than five seconds  
20 to give a result.

21           The inaccuracy of a lab is generally in the  
22 range of plus or minus four percent. Studies have



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1 shown some are as high as plus or minus ten percent,  
2 but I think in general it's closer to the lower level.  
3 As Dr. Ginsberg mentioned, in general the meter can be  
4 much more than two times as accurate as the laboratory  
5 instrument on which its accuracy as being based.

6           So this is a slide which, by the way, took  
7 me hours to produce.

8           (Laughter) But it shows the -- the basic  
9 reaction, and I'll just go over it briefly, as Ken has  
10 spoken about it a little bit. So glucose is converted  
11 by an enzyme with more or less specificity. There's  
12 sometimes co- factors. And that enzyme is an oxidizer.  
13 It produces electrons. The electrons often are passed  
14 on to a mediator, and the mediator captures and  
15 transports the electrons to a test strip electrode or  
16 a test strip indicator. The meter reads a current,  
17 which is proportional to the glucose, or a colorless  
18 dye precursor is converted to a dye, which is read  
19 photometrically, and the changing color is  
20 proportional, again, to the glucose concentration.

21           So that's the basic principle. Of course,  
22 there are various things that can interfere. We've

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1 already mentioned things like inadequate washing, that  
2 milking the site can dilute the glucose. Various  
3 enzymes have interference. Courtney spoke at some  
4 length about GDH PQQ. The mediators are sensitive to  
5 substances such ascorbic acid, or Vitamin C. The  
6 electrodes are sensitive to a variety of endogenous  
7 compounds, such as uric acid. And despite all this,  
8 the enzyme mediator actions have to be fast to yield a  
9 fast test time.

10           So there are a number of sources of  
11 inaccuracy. Some are analytical and some non-  
12 analytical. So interference, we've talked about  
13 endogenous interference. The one that presents the  
14 greatest issue is hematocrit. And then there are  
15 exogenous compounds, such as acetaminophen, the  
16 environment, temperature, relative humidity, altitude.

17           Misuse can be exposing test strips to high  
18 temperature and relative humidity. It's very hard for  
19 manufacturers to prevent a test strip that's been  
20 misused to be -- for a patient to use that test strip.  
21 All you can do is label.

22           And industry carefully considers all these

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1 factors and the customer requirements, for example,  
2 hospital versus consumer, in providing devices that  
3 deliver maximum medical benefit.

4           Another important thing to remember is that  
5 the accuracy and precision testing of individual test  
6 strips is destructive. So any individual test strip  
7 has not been tested; okay? The lot has been tested.  
8 And the release criteria rest on sampling and  
9 statistical modeling. But to my knowledge, no  
10 manufacturer has a technique today that allows him or  
11 her or it to say that any given test strip meets  
12 specifications. It's a statistical statement.

13           Patents -- one of the reasons for the  
14 existence of patents is to provide blocking of other  
15 manufacturers from using your technologies. There are  
16 variabilities in raw materials that are not always  
17 understood, and small variations may have a  
18 substantial impact. It's incredibly difficult to  
19 tease out which ones to address to try to make the  
20 test strips work uniform and to extract whatever  
21 remaining variability in an individual test strip that  
22 is that remains.

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1           And manufacturers are committed to meeting  
2 these challenges in ways that address patient needs as  
3 to cost, convenience, accuracy and precision, and data  
4 analysis.

5           So the challenge to industry is to  
6 manufacture high volumes of glucose meters and test  
7 strips. And in 2009 on a worldwide basis, individuals  
8 tested 17 to 18 billion times annually, which works  
9 out to 47 to 49 million tests a day. And the  
10 corresponding figures in the U.S. were 6.2 billion  
11 tests annually and 17 million tests daily. So that's  
12 a lot of product with which to maintain quality  
13 control. And any given manufacturer may make several  
14 billion test strips a year.

15           And I'll give the floor to Mike.

16           DR. MYERS: Thank you, Alan.

17           MR. FLISS: Whereas Alan is a medical  
18 doctor, I'm a little bit of a process geek, and it's  
19 my role to help my company register products. And I'm  
20 a big fan of national and international standards,  
21 because they create a roadmap. They're built upon  
22 consensus of industry, health authorities, and the

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1 diabetes community. So they lay out -- if a  
2 manufacturer follows these requirements or the roadmap  
3 for developing a product, manufacturing a product,  
4 evaluating a product, and then presenting that data to  
5 the health authorities, they're like to receive a  
6 quick and favorable outcome to their registration, and  
7 that's helpful to the public that is served by the  
8 products.

9 Let me push through a few of these.

10 We've already heard today that there's an  
11 interest in addressing the performance characteristics  
12 of hospital systems differently than self-testing  
13 products. And industry supports that view, that not  
14 only from the perspective of accuracy, but also in the  
15 identification of potential interferences and  
16 limitations of procedure. We're working in conjunction  
17 with the ISO standard group, as well as the CLSI  
18 working group. And I wanted to clarify something that  
19 may have been said this morning. Neither one of these  
20 activities is close to bearing fruit at this point.  
21 The working groups are still gathering ideas and  
22 putting together their first drafts of the documents.

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1 The CLSI committee, I believe, has two documents that  
2 they're working on. The ISO group is trying to revise  
3 the self-test blood glucose document that was created  
4 in 2003. So there is still quite a bit of an  
5 opportunity to have your voices heard. And the people  
6 who are involved in these groups, several of them are  
7 here with us today. In fact, Dr. David Sacks, who  
8 spoke this morning, is the chair of the CLSI committee  
9 that is examining what to put in this point of care  
10 document for glucose testing.

11 At a recent ISO meeting held in Washington,  
12 D.C., in January, we considered interferences and  
13 thought it might be best if we could create a master  
14 list of all the compounds that manufacturers should  
15 consider for self- testing and what concentrations  
16 those compounds should be evaluated at. And now the  
17 work -- it's a homework assignment a couple of the  
18 individuals accepted -- to put together a straw man  
19 proposal that could be shared with the other members  
20 of the ISO team. And that first document is going to  
21 be addressing self-testing.

22 From what we heard this morning, that

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1 hospitals would have different requirements than self-  
2 testing, we'd like to see that perhaps the CLSI group,  
3 when they see what the ISO group creates for self-  
4 testing, can look at that and see, could a similar  
5 document be created for glucose tests that are  
6 performed in a hospital setting? And that document  
7 would, it would seem -- need to have a mechanism to be  
8 periodically updated. If we find that it's difficult  
9 to do that within standards, we might defer to a local  
10 health authority who has the ability to occasionally  
11 issue guidance documents, and in that guidance  
12 document perhaps as attachment, we could have this  
13 list of potential interfering compounds and the  
14 concentrations at which they should be tested.

15           What ideally -- if you can imagine, if there  
16 are over 20 companies that are competing to offer  
17 blood glucose monitoring devices, and as Dr. Cariski  
18 mentioned, there are almost 18 billion strips that are  
19 used over the world in a year. But only about a third  
20 of those are used in the United States. The other two  
21 are used globally. If 20 companies come up with 20  
22 different ways of evaluating hematocrit, and all of

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1 the interested health authorities around the world  
2 have a different way of looking for data from  
3 hematocrit, that is chaos. So if possible, within the  
4 next version of the international standard, we would  
5 like to see if we could address similar, as you see  
6 today, that there's a section that refers to accuracy  
7 studies; another section about user performance  
8 evaluation -- let's introduce another section that  
9 refers to how to evaluate potential interferences and  
10 how to present them to the health authorities so that  
11 they can make quick and informed decisions.

12           There was some mention by Dr. Ginsberg of  
13 reexamining how labeling should be laid out so that  
14 it's more helpful to our users, and I think that's an  
15 initiative that we all support. And I was reminded  
16 that back in 2001, FDA published a really nice  
17 guidance document for patient labeling. Now, it  
18 really goes into what you could say in a package  
19 insert. And what it -- if you're familiar with the  
20 reagents that come into the laboratory, they all  
21 follow a standardized format. That format is actually  
22 in the regulations. But for a self- testing product,



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1 you're given some amount of latitude to try to take  
2 your content, your text, and write it in such a way  
3 that the self-tester would understand. So we're  
4 allowed to deviate from the -- the format of the  
5 centralized lab, and the companies are actually  
6 deviating from each other, as well.

7           So if you wanted to compare two products  
8 side by side by pulling out the package inserts from  
9 two different manufacturers, you might have a little  
10 bit of difficulty finding the similar claims. And  
11 this is something that perhaps we could work together  
12 through consensus as to the best way to lay out the  
13 package inserts so that people can get the information  
14 they need. And then Dr. Ginsberg's idea from this  
15 morning of let's perhaps get more information out at  
16 the point of purchase, perhaps on the carton label or  
17 on the vial label. Just as an idea, we know on the  
18 back of the carton label today, we have the range and  
19 composition table, which isn't very helpful to our lay  
20 public. So that's space that could be available to  
21 convey to the user what are some of the key  
22 limitations and procedure of that particular product,

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1 and if there's a way to characterize accuracy with a  
2 number or small display.

3           So what we would like to conclude is that it  
4 is somewhat challenging to create many millions of  
5 these devices when we have to perform the tests with  
6 whole blood samples. We're aware that there's a need  
7 to evaluate several potential interferences, and we  
8 wish to work with the consensus developing  
9 organizations, both domestically and internationally,  
10 to create lists of potential interferences that should  
11 be examined and how they should be examined so that  
12 whether -- whatever product you're buying from  
13 whatever company, you can be confident that they all  
14 evaluated their product in a consistent manner.

15           As was mentioned earlier, it is challenging  
16 for these products, because they're used in a wide  
17 variety of settings. There's a potential the user  
18 might misuse the product beyond the manufacturer's  
19 instructions. And we have constraints for size, the  
20 meter sample, and the test time in order to make the  
21 product appealing so that people will reliably perform  
22 their tests and comply with their monitoring program.

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1           So one of the key pieces we've been asked,  
2 how do we make our decisions as to the final design of  
3 our product? And we really try to take into  
4 consideration the requirements that have been  
5 expressed by our customers. And then we co-optimize  
6 across all these potential decisions we can make to  
7 design the product which is best-suited for that  
8 particular part of the marketplace.

9           Perhaps for the consumer channel, we might  
10 want to emphasize having a broad operating temperature  
11 claim so that we're confident that if there is a  
12 parent who wants to run a glucose test on a soccer  
13 field in Georgia in August, they're going to get a  
14 quantified test result, rather than an error message.

15           But we might take that same product and look  
16 at it a little differently in design technology, just  
17 a little different so that when it's being used in the  
18 healthcare facility, where we could perhaps narrow the  
19 operating temperature, and we could optimize one of  
20 the other characteristics of the product.

21           I hope you've found these remarks helpful.  
22 Thank you.

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1 (Applause)

2 DR. MYERS: Thank you. Do we have any  
3 questions for either Dr. Cariski or Mr. Fliss? Yes?

4 MS. ULLMAN: Ellen Ullman, patient advocate.

5 I wanted to know with respect to the  
6 temperature of the strips, because now a lot of people  
7 through managed care are getting their strips  
8 delivered through mail order pharmacy, spending at  
9 least a week in transportation in dark brown UPS  
10 trucks in south Florida, so it's been now exposed to,  
11 I don't know, 140 degrees, who knows. Are they still  
12 accurate, those strips?

13 DR. CARISKI: You know, the supply chain and  
14 the way strips are transported is taken into account  
15 in the way the strips are made and the expiration  
16 dates. But what isn't taken into account is the  
17 notion that somebody can leave the vial in the baking  
18 sun for weeks on end, okay. But those elements of the  
19 supply chain are taken into account.

20 MS. ULLMAN: So up to how many days is that

21 --

22 DR. CARISKI: I couldn't tell you, because

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1 it's going to vary on temperature and humidity and the  
2 product, and there are all kinds of variables. I will  
3 say this: in case there's ever any doubt, the best  
4 thing to do would be to run a control solution test,  
5 and that'll tell you the system's working or not.

6 MS. ULLMAN: Okay. Thank you.

7 DR. CARISKI: Sure.

8 MR. SCHLEIS: Tom Schleis with Octapharma.  
9 We're one of the manufacturers of immune globulin that  
10 has maltose in it, and we've worked with the FDA very  
11 closely to make our customers and our patients aware  
12 of this interference. And I published a peer-reviewed  
13 article regarding the interference of maltose,  
14 icodextrin, galactose, and xylose with blood glucose  
15 monitoring systems. And we've heard about maltose and  
16 icodextrin. But the other thing I learned when I was  
17 doing the research for this article is about galactose  
18 and xylose. And galactose and xylose are naturally  
19 occurring. You can find them in fruits, vegetables,  
20 herbs, and dairy products. Whether or not ingestion  
21 of these foods can result in a high enough level to  
22 cause the interference, we really don't know. It's

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1 not been studied. But what's more worrisome is that  
2 they are heavily marketed in health food stores for a  
3 whole wide range of unsubstantiated claims. They're  
4 purported to prevent and cure cancer, cure multiple  
5 sclerosis, cure bacterial and viral infections, boost  
6 the immune system, improve the functioning of the  
7 liver and intestinal tract -- and that's the short  
8 list.

9           And they are promoted in very high doses,  
10 doses high enough to cause this interference. And  
11 they're also specifically noted to be safe for use in  
12 diabetic patients, because they don't increase glucose  
13 levels -- serum glucose levels. So this is another  
14 area where we really don't know if patients are  
15 experiencing hypoglycemia and potentially deaths as a  
16 result of these two sugars.

17           And when I saw the number of 13 deaths with  
18 maltose and icodextrin-containing solutions, that's 13  
19 deaths that we know of. And as was mentioned, many of  
20 these -- more of these cases of adverse incidents are  
21 unreported, so that number is, I think we can safely  
22 say, is quite a bit higher.

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1           And I have a problem just looking at this as  
2 a statistic. To me, this is 13 deaths. This is 13  
3 families that lost a loved one because of an  
4 interference that was completely avoidable. And I  
5 really have to ask the question, why do we allow these  
6 glucometers to still remain on the market? These  
7 patients did not die from maltose. They did not die  
8 from icodextrin. They died because the glucometer  
9 gave a false reading. And we have safe alternatives.  
10 We continue to do as much education as possible, but I  
11 guarantee there will be more deaths, and I have a real  
12 problem with that.

13           DR. HARPER: Well, we definitely appreciate  
14 your comments. And I agree that we may not know the  
15 extent of the problem, so any information that you may  
16 have discovered about some other potential issues, we  
17 would be happy to hear.

18           We are talking to manufacturers and others  
19 to try and figure out what is the best way to move  
20 forward to be sure that products are available for  
21 people who are safe. And so any input we get on that  
22 is actually very much appreciated.

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1 MR. SCHLEIS: Thank you.

2 DR. MYERS: Before we take the next  
3 question, we're scheduled now for our open panel  
4 discussion. So I just want to indicate that we're  
5 open for any questions to any of the panel members at  
6 this time.

7 MS. SKEENS: Hi. Lisa Skeens, Baxter  
8 Healthcare, and I appreciate the comments from the  
9 person before me and agree with that.

10 I want to now move on to what can we to  
11 further mitigate the interference issue, whether it's  
12 icodextrin or other drug products that are now. For  
13 Extraneal or icodextrin, we have a global risk  
14 management program that is in place to ensure that we  
15 are educating clinicians and our patients about this  
16 risk. And we've done verification of that training.  
17 We also provide patient med guides; we provide  
18 hospital admission kits to educate them about how to  
19 advocate for themselves when they are going into a  
20 hospital; and this will shortly be approved as a  
21 REMS (ph) through Cedar.

22 And so part of the question is, if you are a



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1 manufacturer who has an interfering enzyme and  
2 provides falsely elevated readings when used with  
3 something like icodextrin, you know, what are the  
4 device companies to mitigate the risk, to educate  
5 their end users, such as hospitals, where we're seeing  
6 the biggest issue? It's actually trained healthcare  
7 professionals where we're seeing the significant  
8 issues around the world.

9           So what can device manufacturers do, or what  
10 can FDA do to require risk management programs of  
11 device manufacturers to further reduce the risk, to  
12 educate clinicians about the risk? And it seems like  
13 there should be parity between what we're doing on the  
14 drug side and what we're doing on the device side.  
15 Other things I know, other ministries of health, have  
16 done are required stickers in the hospital. So  
17 actually a sticker on the point of care monitors that  
18 reminds the nurse that if this person is on peritoneal  
19 dialysis, that they should not be using the point of  
20 care monitors, that they should be using the  
21 analytical hospital labs.

22           So are there other -- I want to throw out

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1 those ideas and really ask both industry and FDA to  
2 comment on that. Thank you.

3 DR. MYERS: Thank you.

4 DR. HARPER: I'll just go briefly, Mike,  
5 first, because our recommendations are in the public  
6 health notification. And just to reiterate, our first  
7 recommendation is that health care facilities avoid  
8 using these particular test strips in their facility  
9 at all, and if they do use them, we did recommend a  
10 series of steps that we believe would be risk  
11 mitigation steps to help increase awareness of this.

12 So we have attempted to do that. The  
13 question does remain open on how effective has that  
14 been. I don't think we have enough time yet to  
15 understand how effective that communication has been  
16 yet, but we are following it.

17 MR. FLISS: On behalf of industry, it is our  
18 goal to provide safe, reliable, and accurate product,  
19 and we think that we're doing so. When we become  
20 aware of an issue, we have -- the best solution is to  
21 do something through design. But you also, if you're  
22 unable to do that for a period of time, you try to

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1 address it through labeling, through an education  
2 campaign.

3           In the case of maltose, you're seeing the  
4 companies get the message out over the course of  
5 several years, and keep having the message out. And  
6 then through design, in addition to having the  
7 stickers on the device, some of the meters now have  
8 been changed so that there is a software prompt that  
9 comes up for the operator to make sure to ask  
10 themselves, "Is this a patient who might be on therapy  
11 that would raise their maltose level?" So that's a  
12 design solution for the short term.

13           MR. CEMBROWSKI: Cembrowski, University of  
14 Alberta. A point for Dr. Cariski. You could get out  
15 of your box a little bit. There are different boxes  
16 for measuring blood glucose. Probably the best one to  
17 compare to any point of care method is the blood gas  
18 glucose. It gives you whole blood. It's as good as -  
19 - as good as or better than a laboratory method, and  
20 you can use it in your evaluations or even sort of  
21 post-marketing, and this would be a good idea for FDA.  
22 There are a lot of patients in ICUs who have their

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1 bloods drawn both with capillary specimens that are  
2 run on point of care instruments and then they also  
3 have their arterial bloods run on blood gas glucoses.  
4 And it's amazing what you can find. And I think you  
5 could be able to discover many, many interesting  
6 outliers that you could use to develop better systems.

7 DR. CARISKI: Well, thank you for your  
8 suggestion. I know that people from R&D are here  
9 listening to the meeting. I know that we use as our  
10 reference the YSI, which is supposed to be a, you  
11 know, reasonably accurate instrument and measures  
12 capillary samples so that we're comparing, you know,  
13 apples to apples rather than, you know, a capillary to  
14 arterial. But thank you for your point.

15 MS. SOLDI: Hi. Monnett Soldo again from  
16 OptiScan.

17 You know, we in our company, use a different  
18 technology, so perhaps it's not a fair question, but  
19 I'm going to ask anyway. Where we put the bar for our  
20 own performance is that we meet the ISO standard even  
21 in the presence of all the interference that one  
22 would find in the ICU. And so I'm a little bit

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1 confused in this discussion how we're distinguishing  
2 between, there's the ISO standard and then there's  
3 interferences, and we're going to just basically try  
4 to label against them, which obviously has  
5 effectiveness problems; right?

6           So I would challenge the other industry  
7 representatives on two counts. Number one, can we  
8 meet the ISO standard as currently stated in an ICU  
9 setting, including all the interferences that are  
10 currently present in that environment, number one? And  
11 number two, is it possible to introduce, using maybe  
12 this dynamic electrochemistry or whatever was  
13 mentioned before, some sort of a no-read criteria to  
14 detect outliers and report them as outliers, and give  
15 no reading whatsoever rather than a fundamentally  
16 wrong reading?

17           It would seem to me that the technology  
18 possible today ought to support both of those, so I'd  
19 like to hear your thoughts.

20           DR. CARISKI: Well, I've looked around and  
21 nobody else looks like they're prepared to answer, so  
22 I'll do the best that I can.

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1           First of all, I think this meeting has --  
2 one thing it's done has clearly distinguished between  
3 meters for consumers and meters for hospitals. And  
4 the ISO standard, by its very statement, addresses  
5 consumer meters. It has nothing to do with hospital  
6 meters, and by default, it came to be used for meters  
7 that are used in hospitals. And as has been noted,  
8 CLSI is working on POCT(12) to address standards for  
9 hospital meters, and that's a separate issue.

10           For consumer meters, I tried to point out  
11 how difficult it is for manufacturers with current  
12 technologies to eliminate all interferences. And when  
13 you start stacking interferences, it becomes a real  
14 problem. So a meter might do okay with the crit, and  
15 then you add some uric acid, and it's okay. But then  
16 when you start adding, you know, acetaminophen and the  
17 patient has high lipids and a high bilirubin, and --  
18 which, you know, some people do when they're  
19 outpatients -- it becomes really problematic.

20           I don't know enough about the technology  
21 that Dr. Ginsberg mentioned to say to what extent it  
22 can successfully address these things, but also there

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1 may be patents involved that prevent other  
2 manufacturers from using it. All I can say is that  
3 every manufacturer, I think it's fair to say, wants to  
4 make the best, most accurate product that they can  
5 that the patient can use, and we're all working  
6 towards that end.

7 DR. HARPER: I would actually like to press  
8 on this issue a little bit more, because I think this  
9 is something we're interested in. Not -- not simply  
10 for the current ISO standard or some other standard,  
11 but if there were to be standards developed, no matter  
12 whether it's a standard for lay use or a standard for  
13 hospital use, do you believe -- anyone on the panel --  
14 do you believe that interference should be a part of  
15 this concept of total system accuracy, or a total  
16 allowable error concept? Because, you know, what is  
17 encompassed in that total allowable error in terms of  
18 the intended use of the device?

19 So I'd like to hear from you all about your  
20 opinions on the inclusion of interference in that.

21 MR. FLISS: Well, the challenge is when  
22 you're trying to stack potential errors to evaluate

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1 what their total might be. What we do is, before we  
2 market any new product, we bring our product out to  
3 the marketplace, to hospitals, physician offices, and  
4 we conduct method comparison studies where we gather  
5 samples from patients, measure them on the  
6 investigative device as well as on our reference  
7 method, and we're also recording what concentrations  
8 of potential interferences are in that sample to see,  
9 if we do find that there's a flyer, was it caused by  
10 the presence of one of the compounds that we suspect  
11 is an interferent for that particular assay?

12 DR. HARPER: So do you think interference  
13 should be included in the total allowable error? Is  
14 that what you're saying?

15 MR. FLISS: Well, actually I think you find  
16 that by looking at the regression equation that comes  
17 out of the method comparison study. Because the  
18 sample isn't contrived or controlled. It in theory  
19 has whatever interfering compounds the patient is  
20 carrying with them or her at that given time.

21 DR. HARPER: Yeah. I mean, I think we're  
22 not aware, and perhaps you have this data and we



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1 haven't seen it or aren't aware -- I don't think we're  
2 aware at FDA when the data we get, that it actually  
3 would, you know, be a broad enough selection of  
4 patients to actually get an idea of the range of  
5 interferences that are possible. And that's  
6 especially true for, I'd say, hospital use and the  
7 types of sick patients. We already talked about that  
8 this morning. But even in the lay environment, the  
9 sort of ranges of interferences you'd see. So we are  
10 interested in feedback from people, you know, to the  
11 docket or any other way on how interferences can be  
12 assessed, and also which products -- and we're working  
13 on this as well with some other groups -- which  
14 products are actually most important to look at where  
15 you might be more likely to see it more often than  
16 sporadically. Because if you have a sporadic  
17 interference that's significant, you might want to  
18 look at that. If you have a constant sort of  
19 interference that's likely, you also want to make sure  
20 you look at that. And I don't know how much current  
21 study designs actually evaluate that.

22 MR. ERVIN: I would like to suggest that

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1 interferences usually aren't sporadic; that an  
2 interference is going to be a relatively systemic  
3 effect. Witness ascorbate as an example.

4           And another thing I would like to suggest is  
5 that rather than including it, necessarily, in total  
6 error, eliminate them. I think we should be trying to  
7 develop technologies -- and there are pieces of them  
8 out there -- that manufacturers can use to ultimately  
9 eliminate the effect of interferences. Maltose is a  
10 good example. There are other enzymes available. You  
11 can get away from it, but -- from a manufacturer's  
12 perspective, that's not an easy thing to do, but it's  
13 really where we should be headed.

14           DR. HARPER: Yeah, I mean by sporadic, I had  
15 meant, you know, people -- some people are on a drug  
16 and some people aren't. Some people may be on  
17 acetaminophen, some people may not.

18           But that's an interesting point of view, I  
19 think, is to eliminate it. And I think we would all  
20 like to see that happen.

21           But another question I had relative to this  
22 question of interferences is how best to communicate

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1 this information to lay users? I tell you one thing  
2 we struggle with sometimes is if there is a certain  
3 level of interference in a laboratory or a hospital  
4 environment, we may be able to label against it.  
5 Sometimes more effectively than others, obviously,  
6 with the PQQ issue shows that sometimes not -- not  
7 terribly effective. But in the lay population, you  
8 may have interferences that are not identifiable by  
9 the patient. So they may not know that they have a  
10 high level of triglycerides; they may not know that  
11 they have some sort of high level of an endogenous  
12 compound. They may be able to avoid acetaminophen if  
13 they read it. But so any suggestions, as well, on how  
14 best to communicate information about interferences to  
15 the lay public would also be helpful.

16 MR. FLISS: We're also interested in  
17 pursuing that line of thought. We were recently  
18 considering ascorbic acid as being something of  
19 interest that shows up in some of the tests for  
20 package inserts. But how would someone from the lay  
21 public figure out what that means to them? Do they  
22 realize that we're talking about Vitamin C, and how

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1 many glasses of orange juice or how many vitamins they  
2 can take before they reach a point that they should be  
3 concerned? So making a limitation statement that's  
4 very scientific in nature isn't easily used by the lay  
5 public. So I was hoping that this would be the type  
6 of subject that we could address perhaps within this  
7 consensus organization, whether it be CLSI, or if it's  
8 a lay product, it'd be the ISO organization.

9 DR. CARISKI: I want to make one comment,  
10 and that is that there has to be some limit to the  
11 consideration of interferences in terms of total  
12 error, because by definition, they're interfering  
13 substances. We don't test every substance known to  
14 man. We test only certain substances, because we know  
15 they have a propensity to interfere with the  
16 technology. And sure, ultimately we would like to  
17 have a technology that eliminates any interference  
18 whatsoever, but right now, to my knowledge, for the  
19 test strips that isn't the case.

20 One thing that patients can do is they can  
21 check their blood sugar against the lab. And there  
22 are instructions in all the inserts telling them how

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1 to do that, and it will give them some idea as to how  
2 accurate it is for them. So whereas they may not know  
3 their lipid level or their -- how much acetaminophen  
4 or ascorbic acid they have, they can see whether  
5 they're close to the lab or not.

6 DR. HARPER: I will comment that at FDA, we  
7 tend to believe that all sources of error should be  
8 included in an allowable error measurement. So we  
9 would be interested in actually identifying the  
10 interferences and being sure that a particular patient  
11 is likely to be within that error range, even with the  
12 presence of interferences.

13 MS. PINKOS: Arleen Pinkos, FDA. My  
14 expectations for this session were to hear the  
15 barriers, and for the barriers to be described  
16 specifically enough that we could start working on the  
17 solutions towards them. We've already heard that  
18 there are some other technologies that can eliminate a  
19 lot of the interferences and can get more accurate  
20 results. Can we ever get closer to the performance  
21 that we need in terms of eliminating all the  
22 interferences and physiological limitations with this

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1 technology, or do we really need to be looking at a  
2 different technology? Is it achievable or not, and if  
3 it really is, I've heard cost is a factor. But I  
4 mean, is there anything that's specific that anybody  
5 can do to help remove those limitations?

6 MR. ERVIN: Well, I think that there are at  
7 least two companies out there that are demonstrating  
8 that you can do this, and publishing a lot on the  
9 topic. So like with all things, sometimes it takes  
10 considerable energy to move a huge, massive business.  
11 I mean you're talking here multiple billions of tests  
12 and lots of different products. The companies that  
13 can come up with a innovative technology that has a  
14 proprietary position and can go and develop tools to  
15 do this, they're working on it. They're doing it.  
16 Other companies have a lot invested in where they're  
17 at at the moment, and they have to move forward, too.  
18 But it's a little bit more difficult for them.

19 MS. PINKOS: Just a follow-up. Are the  
20 companies that you're referring to things like HemoCue  
21 and i-STAT, or are there a simple, inexpensive device  
22 that people could use at home that are starting to

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1 overcome the physiological limitations and  
2 interferences? I guess my question is, is it possible  
3 for these home use types of meters -- the pure, simple  
4 point of care analyzers that we're used to thinking of  
5 at the home use -- are we ever going to, with that  
6 technology, be able to overcome the limitations, or do  
7 we really -- do we need a new technology like some of  
8 these other devices and the blood gas analyzer?

9 MR. ERVIN: I don't know if we can get this  
10 technology into the home use situation. Sitting  
11 behind you is Jeff Dubois, who probably could address  
12 that more easily. But I don't see any long-term  
13 barrier to it. As with most things, you -- once you  
14 scale up things and you get your technology made rock-  
15 solid and less costly to manufacture, yeah, you can  
16 spread it out into other environments. And I think  
17 that's possible with some of these products. In fact,  
18 I know some of them are actually targeting the home  
19 use market now. So it's possible.

20 DR. KLONOFF: David Klonoff, Mills-Peninsula  
21 Health Services. One suggestion was made that if  
22 there's interference, that the meter should provide no

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1 information, should just be blocked. That ties in  
2 with one of the accuracy topics, that we were trying  
3 to figure out how to deal with outliers. But I didn't  
4 hear anybody this morning talk about how to deal with  
5 non-readings, what happens if there's no reading at  
6 all? That should be a form of an outlier. I think  
7 that should be taken into account.

8 MS. BOWMAN: Cynthia Bowman, Long Island  
9 Jewish Medical Center. I know this is a conference  
10 concerning glucometers, but I'm just going to say as  
11 far as interference goes, it's not so easy in the  
12 central lab on the main analyzers, too. And if any of  
13 you have ever tried to confirm your interferences --  
14 you know, confirm the manufacturer's claims? Sometimes  
15 you wish you hadn't tried, because it is really  
16 confusing. And for somebody who's been on a three-  
17 year odyssey right now to try to figure out what's  
18 going on because you have -- you put rules in and, you  
19 know, middle ware and auto verification and all that  
20 sort of stuff. And I'm aware of peers who've gone the  
21 same road that I have, that it varies over time. You  
22 try to set very conservative limits.



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1           But the other thing, too, and there's  
2 literature about one person's lipemia is not the same  
3 as another person's lipemia, different particle size -  
4 - I suspect the same thing is true for hemolysis and  
5 icterus also. And so I can tell you that, you know, I  
6 give the device manufacturers their due -- it's not  
7 easy. And I think it probably cuts across all sorts  
8 of instruments, and the interferent we fear is the one  
9 we're not aware of.

10           DR. SACKS: Sacks from Boston. One of the  
11 points that came up in several slides in this last  
12 session as one of the limitations of the technology  
13 was the time. It's not clear to me why this is  
14 necessary. I can understand why patients would want  
15 small meters that they can put in their purse or  
16 pocket, why they'd want small volume of blood. But  
17 why a test needs to be done in ten seconds or five  
18 seconds versus 45 seconds is not clear to me if people  
19 are only doing it four times a day. Would  
20 manufacturers care to respond to that?

21           DR. CARISKI: I know that -- I don't have  
22 the specific data. I know it's been looked at in

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1 terms of patient preferences. And clearly the  
2 preference is for shorter, because, you know, it's  
3 like anything else. We used to have, you know, a  
4 modem that worked at 400 or 1600 or whatever, and now  
5 it's -- and you wonder how we ever lived with it  
6 before.

7           And as meters became faster and faster, that  
8 was what people expected. I think if a manufacturer  
9 were to come out with a meter now that took a minute,  
10 let's say, but was more accurate, I'm not sure how  
11 many people would -- would embrace it. All I know is  
12 the marketing says that most people want faster and,  
13 you know, smaller.

14           MR. FLISS: As people are living more active  
15 lives, they desire to be able to discreetly perform  
16 their tests. And being able to get a result quickly is  
17 attractive to many people.

18           DR. SACKS: I understand those points, but I  
19 remain unconvinced that a 30-second difference in the  
20 timing that could significantly improve the accuracy  
21 of a meter and avoid hypoglycemia is beneficial to  
22 patient care.

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1 DR. CARISKI: The other -- thank you.

2 DR. WHITE: Neil White, pediatric  
3 endocrinologist from St. Louis. I think if -- the  
4 patients don't understand the importance or the lack  
5 of accuracy that we're talking about here, and if you  
6 tried to market a meter now that took a minute next to  
7 a meter that took five seconds, they're not going to  
8 go for the minute. I can tell you that. They --  
9 every time the meter gets shorter, they say, Oh, I'm  
10 going to get this one, because it only takes three  
11 seconds or whatever.

12 Now, if we can really demonstrate an  
13 importance in certain patient populations where the  
14 accuracy is a key component that they will understand  
15 that accuracy as important, then they might be willing  
16 to sacrifice the speed for the accuracy if there was a  
17 reason that they needed -- that we can convince them  
18 that they needed that accuracy. But at this point in  
19 time, they don't know -- they're not convinced of  
20 that. They're not even convinced that there's an  
21 error at all.

22 MS. KOLLER: Beth Koller from --

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1 DR. CARISKI: I'd like to add one thing, if  
2 I may. I know that for some technologies, more time  
3 doesn't make a difference. So it may be a matter of  
4 going to a whole new technology. It's not like if you  
5 have a strip today and you said, Okay, instead of  
6 running the test five seconds, we'll run it 30  
7 seconds. It'll be more accurate. It won't  
8 necessarily be true, because the strip may have been  
9 optimized for the five-second result, okay. So it's a  
10 little complicated, is what I'm trying to say.

11 MS. KOLLER: Beth Koller from CMS.

12 I'd like to make an inquiry about what is  
13 and is not in the label, and how the label changes.  
14 And if you would comment on how this relates to drugs,  
15 where I think people have a better understanding of  
16 what a label means.

17 It's my understanding that a label can be --  
18 can be more transient for devices than it is for --  
19 for drugs, that there can be -- that manufacturers can  
20 insert the label -- can change the labels without  
21 agreement with the FDA. And it's also been our  
22 experience that it's difficult to actually find the

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1 most current label for a device, and this has some  
2 implications for us at our agency.

3           And in addition, because many devices are  
4 approved - - not approved, they're cleared through the  
5 510(k) process, if you could comment on that. And  
6 what kinds of drift in the data might occur when  
7 you're using not a single predicate, where there can  
8 be multiple predicates.

9           Thank you.

10           DR. HARPER: Sure. So Beth has pointed out  
11 some -- definitely some differences between drug  
12 labels and device labels. So for those of you who  
13 aren't aware, when a drug is approved, the labeling is  
14 available on line, and it actually cannot be modified  
15 without interaction with FDA and FDA approval of that  
16 modified labeling.

17           For Class 2 devices like glucose meters,  
18 that isn't true. FDA looks at what we would consider  
19 draft labeling. And so some of the information on the  
20 labeling, or the way that's stated, could possibly be  
21 modified by the manufacturer without a submission to  
22 FDA or FDA review.

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1           Now, there are some limitations on that.  
2 They cannot change claims or add additional claims to  
3 the labeling that would be outside of the clearance  
4 they received. But they can certainly modify the  
5 labeling sufficiently.

6           And also you're right that there is right  
7 now, because of this a little bit, there isn't  
8 consistently any sort of resource to obtain device  
9 labeling. There's definitely discussions, especially  
10 for over-the-counter products, of trying to get that  
11 to happen, but those discussions are in the early  
12 stages. And it's difficult where there is a draft  
13 labeling involved, in terms of figuring out how to  
14 keep that current. So that is definitely one of the  
15 challenges there.

16           In terms of the potential problem with  
17 performance drift because of the nature of the 510(k)  
18 program, it certainly is possible. For those of you  
19 who are less familiar, FDA has -- and for Class 2  
20 devices, it's actually a performance between devices.  
21 So if one device compares to another device, and that  
22 device compares to another device, and that compares

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1 to another device, there is a possibility sometimes  
2 for performance drift from the original device. And  
3 this sometimes creates a situation where devices  
4 aren't comparable.

5           We try to minimize that as much as we can. I  
6 think it's very clear that these devices aren't always  
7 completely comparable to each other. But at least for  
8 blood glucose meters, we do look at them in  
9 relationship to a reference method that's -- we try  
10 to keep a little bit more traceable. So we try to  
11 minimize that a little bit by comparing the  
12 performance to the reference, rather than to another  
13 blood glucose meter. It may not be ideal, but it  
14 certainly is something to keep in mind.

15           MR. FLISS: If I may add a remark? There is  
16 a certain limitation to that freedom to change  
17 labeling, like Dr. Harper mentioned. We're not  
18 allowed to expand the intended use or indication for  
19 use of the product, and we're not allowed to remove a  
20 warning, precaution, or limitation without seeking  
21 concurrence from the FDA before that labeling is  
22 changed.

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1 DR. MYERS: Yeah, and I have one other  
2 comment.

3 With the 510(k), using the predicate device  
4 comparison, what would it take to change that to do it  
5 -- make it a standards-based comparison, rather than a  
6 predicate comparison?

7 DR. HARPER: We do have, or have exercised,  
8 some leeway there, in that in 2003, FDA actually did  
9 recognize the ISO standard. And that standard was  
10 actually better than what we had been using before.  
11 And so there are devices that are not cleared because  
12 they don't meet that standard.

13 So there is some way for us to do that, and  
14 certainly right now many of you may be aware that the  
15 Center for Devices is actually looking into the 510(k)  
16 program in general. And part of that evaluation is  
17 looking at the scientific standards and where they  
18 should be looked at or evaluated. So I think if we  
19 have, especially clinical and scientific reasons  
20 behind meeting certain types of data, I think that  
21 where we have justification, we could do it for  
22 patient safety.



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1 MR. NEUMANN: Glenn Neumann, New World  
2 Regulatory Solutions.

3 Something that struck me early on today was  
4 how much the user can impact the accuracy of the test.  
5 And it seems to me we have -- we know about human  
6 factors. I don't think we know enough. We have flex  
7 study menu; I don't think it's big enough. So perhaps  
8 if we could put more effort into preventing user error  
9 through flex studies and better technology, even -- if  
10 we could take or eliminate or reduce, seriously  
11 reduce, the user error, we could take a big bite out  
12 of this total error, it would seem to me.

13 So for example, I've typed how many millions  
14 of words into my computer in my lifetime. I still  
15 make typos. I still make the same typos over and  
16 over. Microsoft Word is smart enough to correct some  
17 of them for me. But if we could do something with  
18 these meters that would see and detect user error, and  
19 if we do more flex studies to really know what goes  
20 on, you now, maybe what Courtney needs is a million  
21 data points, a thousand users doing a thousand  
22 repetitions. The young man who was here did over

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1 100,000. He got a 76 and a 210 on the same day.

2 There's got to be something going on there. So I think  
3 if we focus on that, that's something we can do right  
4 now. It could help out.

5 MR. FLISS: Thank you. I know you're  
6 hearing a lot about standards today, but I've got a  
7 couple more to share with you.

8 IEC has published a document that has the  
9 number 62366, and it describes a usability engineering  
10 program that a company might consider while designing  
11 a product. Another standard is ISO 14971, which is  
12 risk management for medical devices. And there was an  
13 annex added to that a couple years ago to address in  
14 vitro diagnostic products.

15 So the designers of blood glucose meters are  
16 aware of these standards and have adapted our  
17 development, manufacturing, verification and  
18 validation activities to comply with those standards.  
19 So an example of how a system might be changed because  
20 of usability engineering -- many devices now have come  
21 out with under-dose detection. So although the size  
22 of the sample is much smaller than it used to be, but

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1 still if the user places a sample on the strip that is  
2 too small to conduct the test, the meter now is smart  
3 enough to notice that and default to an error message  
4 rather than giving a biased test result.

5 DR. SCOTT: Mitch Scott from St. Louis.

6 One thing I'm hearing now that I think  
7 everyone is buying into is that we need to have  
8 different performance criteria in different settings.  
9 The three of you from industry just said you support  
10 that.

11 The issue today, though, is that it doesn't  
12 exist. The technology, the interferences, is pretty  
13 much spread across home use and hospital use meters;  
14 correct? Okay? That leaves you to a hypothetical  
15 question that I think gets to the crux of the matter,  
16 and I'd like to hear your opinions on the answer. You  
17 have two choices. You tell those of us in a hospital,  
18 "Keep using what you're using. We'll get you a better  
19 meter in three or five years." The other alternative  
20 is stop using what you're using, and go use a blood  
21 gas analyzer or an i-STAT.

22 That's the two answers you've got, if

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1 everyone's in agreement with this, and I --

2 MR. ERVIN: In the hospital.

3 DR. SCOTT: -- in the hospital. In the  
4 hospital.

5 DR. CARISKI: Isn't that a question the  
6 hospital can answer -- isn't that a question the  
7 hospital can answer for itself?

8 DR. SCOTT: You're absolutely correct. But  
9 we're going to have a lot of pressure on cost.

10 UNIDENTIFIED: He would answer in a  
11 different way than his hospital.

12 (Laughter)

13 DR. SCOTT: Yes. If I had my 'druthers, we  
14 would switch to a more accurate method, but I think  
15 we'll run into issues with cost.

16 MR. FLISS: I think your question is  
17 complicated for us to answer, because we haven't  
18 really yet considered how accurate, precise a device  
19 needs to be in order to address your need to implement  
20 a tight glycemic control, so -- and our devices aren't  
21 on label indicated for tight glycemic control  
22 programs. They're monitoring devices. They were

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1 created when we thought that our self-testers were  
2 interested in being between 80 and 180, and I believe  
3 it was mentioned earlier today that the hospital  
4 protocol has historically been to try to keep the  
5 patient below 180 milligrams per deciliter. So that's  
6 what we're providing today.

7 DR. SCOTT: Okay. So, does anybody want to  
8 tell me what to do?

9 (Laughter)

10 MR. WHITE: I have a question which is a  
11 little bit off the subject, and I'm sorry. I wanted  
12 to ask somebody in response to something that Mr.  
13 Ervin said, and I don't know if you'll be able to  
14 answer this or not, but maybe somebody here in the  
15 front row can help me answer this. You talked about  
16 the po2 and the difference between arterial and venous  
17 blood. When we are doing physiologic studies in a  
18 clinical research center environment, we are often  
19 trying to keep blood glucoses at a steady level, such  
20 as by a clamp. We often arterialize the blood because  
21 we think that the venous blood is different than the  
22 arterial blood. Is that an analytic difference, or is

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1 that a physiologic difference of actual blood sugar?

2 MR. ERVIN: And the process for  
3 arterializing involves?

4 MR. WHITE: Warming -- warming the hand.

5 MR. ERVIN: Okay. You're going to have the  
6 temperature effect on the equilibrium. I'm going to  
7 say that that's probably an analytical effect.

8 UNIDENTIFIED: Think so? (Inaudible, off  
9 mike) It's different than what I've always been  
10 taught, yeah.

11 DR. GINSBERG: When you arterialize the  
12 blood, what you basically do is you create AV shunts,  
13 so that you basically bypass the capillaries, and the  
14 arterial blood is now picked up in the veins. And  
15 when you do that, you do two things. One, you do  
16 increase the oxygen. Well, they don't think you  
17 increase the oxygen in the arterialized blood much  
18 above 80 or 85 milligrams -- milliliters of mercury.  
19 So you're not going to create a major oxygen problem,  
20 I don't think. I've never checked it, but I don't  
21 think you're going to create that.

22 What you are going to do, though, is there's

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1 another factor. And that is, the blood glucose is not  
2 the same in the arteries, the capillaries, and the  
3 veins. And part of that is because there's some  
4 glucose extracted by the muscles and other things as  
5 you go along there. And when you arterialize it --  
6 and for that reason, arterial and capillary blood are  
7 actually pretty close. Venous blood is lower,  
8 particularly in a time around a meal. So that if you  
9 measure glucose in the veins about -- within an hour  
10 to two hours after a meal, it will be one to two  
11 millimolar. So 18 to 36 milligrams per deciliter  
12 lower than capillary blood, which is very similar to  
13 arterializing. But because arterializing capillary is  
14 similar, and I don't think there's an oxygen problem  
15 on arterialized blood, although I don't know that,  
16 it'd be worth checking -- I think that arterialized  
17 blood would be very similar to capillary blood in  
18 terms of the number you get.

19 MR. WHITE: (Off mike) What you're saying is  
20 what I've always been taught, but you (inaudible).

21 MR. ERVIN: I probably misunderstood the  
22 point you were trying to make. If in fact the oxygen

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1 levels in that arterialized venous blood is in the  
2 order of 80 to 90 milligrams -- I'm sorry, millimeters  
3 pressure, then that's very -- very, very close to  
4 capillary level. So you're not going to see a po2  
5 effect with these po2 sensitive methods in that  
6 application.

7 MR. STR Hi. Anders Strfrom HemoCue Sweden.

8 A question for FDA. Considering the two  
9 sessions today talking about accuracy and precision,  
10 combined with this interference discussion we're  
11 having, is the result of this that we need to have  
12 different requirements for different type of patient  
13 settings and so on? So it's not only about home use  
14 and hospital use, but it's about neonatals, about  
15 different type of ICU settings, about different type  
16 of home patients, being that -- using a lot of -- I  
17 don't know the English word, but substances you buy in  
18 the drugstore and so on?

19 DR. HARPER: So I think that part of -- part  
20 of the reason that we hosted this meeting is actually  
21 to hear from this community of people about maybe what  
22 steps we might need to take. Because, you know, we



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1 definitely heard the point of view that perhaps there  
2 needs to be some enforcement of FDA's point of view  
3 about intended use population. So, you know, right  
4 now these meters are being used off-label as part of  
5 the practice of medicine in hospitals, and we're  
6 hearing some people have feedback that perhaps they're  
7 not safe.

8           We've also heard today, though, that some  
9 people are using them in their hospitals and need  
10 them. So we'll have to create the right balance, and  
11 we're interested from hearing all stakeholders on  
12 that. But that is exactly the question that we're  
13 trying to address, is how do we make these safe for  
14 all patients on which they're used?

15           DR. BRETON: It just tends to be just home  
16 use versus hospital use, and that means maybe not the  
17 only two options.

18           DR. HARPER: Yeah, I mean, quite frankly,  
19 even though these meters come in for over-the-counter  
20 clearance right now, when they are claiming healthcare  
21 provider use in populations such as neonates, we  
22 already actually ask special questions for those. So

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1 I think it wouldn't be outside of our realm of comfort  
2 to be sure that if there are populations that need to  
3 be addressed, we would want to address them.

4 MR. DUBOIS: Jeff DuBois. I'm with Nova  
5 Biomedical, Waltham, Massachusetts. And Ken used my  
6 name, and indicated that there may be some technology.  
7 So in answer to Arleen's question, there is some  
8 technology that does address the issue of accuracy and  
9 precision. Barry referred to it this morning.

10 But that's not why I'm up here. Gary has  
11 been involved with a program through NKDEP where we  
12 looked at an analyte that's problematic in the  
13 laboratory. That's creatinine. And there's an  
14 initiative that's global to standardize creatinine  
15 measurements so that we can report an EGFR and  
16 properly assess the patient's glomerular filtration  
17 rates and assess their stage in chronic kidney  
18 disease.

19 What we haven't done with glucose, and what  
20 we need to do, and having been responsible for the  
21 Area Committee for Point of Care Testing of CLSI, is  
22 to have an initiative where we standardize glucose

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1 testing. There was some reference to IDMS  
2 traceability. And there are informed or notarized  
3 bodies in Europe that take some different methods than  
4 we do here in the United States, and there's  
5 traceability.

6 So what we need to move toward in the United  
7 States and overseas is harmonization of this approach  
8 with glucose. And once we begin to do that --  
9 industry, practitioners, and the regulatory bodies --  
10 then we will improve the accuracy and precision of  
11 devices.

12 DR. MYERS: Yeah. A comment on that. One  
13 of the things that we've looked at at CDC in the past  
14 is looking at that very issue of having a  
15 standardization program for blood glucose meters. And  
16 the issue is -- one of the challenges that we have is  
17 that unlike for creatinine, we don't have good  
18 reference materials that really simulate what the  
19 blood glucose meters are actually measuring.

20 And that's part of the challenge that we're  
21 facing: how do you come up with a whole blood glucose  
22 reference material that's easily stable, that can be

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1 used to establish traceability? So there are  
2 challenges involved in coming up with a program that  
3 standardizes blood glucose meters. Not laboratory  
4 instruments, but blood glucose meters.

5 MR. DUBOIS: But Gary, there are issues with  
6 the central lab method. I attended a chronic disease  
7 conference, and David was the speaker there, along  
8 with a fellow from UCLA, Davidson. And their  
9 justification for using hemoglobin A1C for diagnosis  
10 of diabetes is there's too much variability in plasma  
11 glucose from central lab analyzers. So we've got a  
12 problem, and we need to begin to work at it as a  
13 community. So I don't see glucose apart from central  
14 lab or apart from self-monitoring, or at the bedside.  
15 Glucose is glucose, and we really need to give  
16 accurate and precise glucose measurements to our  
17 clinicians so they can make appropriate decisions  
18 about the use of a lethal drug, insulin.

19 MS. PINKOS: Hi. Arleen Pinkos, FDA. I  
20 have two questions, and I'd really appreciate hearing  
21 an answer to both of them.

22 The first is, we've already heard this

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1 morning that there are some technologies in point of  
2 care meters that are meeting a much stricter  
3 performance criteria, or performance cutoff, closer to  
4 ten percent. What can be done to get some of the  
5 other manufacturers to pull their quality up? Is that  
6 something that can be done when incentives might be  
7 provided?

8           And secondly, the way FDA operates, once a  
9 product is on the market, and maybe in five years or  
10 seven years, it still doesn't meet the current  
11 requirement, should there be something in place, like  
12 a sunset law, that says, you know, here's the new  
13 performance criteria. If you still haven't met it in  
14 five years or whatever that time might be -- is that a  
15 reasonable approach? Or should they all be left on  
16 the market indefinitely?

17           MR. ERVIN: I'll try and answer the first  
18 question. The second one, I'm probably going to leave  
19 to either industry or to Dr. Harper here.

20           I would be surprised if every manufacturer  
21 is not already trying to get to that plus or minus ten  
22 percent. I know that there are programs in development

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1 that have that as their target, and so I think it's on  
2 the near horizon. And that's about all I could say on  
3 that is that there are -- it is an important goal of  
4 all of these companies, to get there.

5 DR. HARPER: I don't know if I can address  
6 your second question or not, Arleen.

7 MS. PINKOS: No, I really wanted to hear  
8 from --

9 DR. HARPER: Right.

10 MS. PINKOS: -- from Mike and Alan, from  
11 industry, like do you think that's a reasonable  
12 approach to have some type of sunset law on -- one  
13 people. When the performance requirements go up --  
14 let's say it's raised to 15 or 10 percent now, then in  
15 another five years or whatever, it's raised again --  
16 what, if any, action do you think should be taken on  
17 all those products that were cleared a while ago and  
18 they're not anywhere near that -- that criteria?  
19 What's -- what's your opinion on that?

20 MR. FLISS: My sense is that individuals,  
21 when they grow accustomed to using a particular test  
22 system, it becomes part of their daily live, and they

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1 would like to continue to use that system if they have  
2 found that it's safe and effective for managing their  
3 particular health. And although the 510(k) may have  
4 cleared three years ago, if it's a reliable product  
5 for that individual, I think industry would like to  
6 continue to provide test strips and controls so that  
7 they can continue to operate that meter.

8 DR. CARISKI: I think also it should be  
9 based on risk, as best one can assess it. And for  
10 example, you know, it may be that one wants to look at  
11 different risk categories. So for example, as Dr.  
12 Ginsberg suggested, the standard for someone who's a  
13 Type II on orals or diet, and the oral isn't anything  
14 that will produce hypoglycemia, the current standard  
15 may be okay. And if it turns out that the meters  
16 meeting the tighter standard are a lot more expensive  
17 in terms of the meter itself and/or the test strips,  
18 it may not be appropriate to require people who don't  
19 need that kind of accuracy to get a more accurate  
20 meter. But it may be appropriate to label the -- but  
21 to, you know, make that distinction in the labeling as  
22 to who the intended user is.

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1           Again, it's a question of health risk. I  
2 mean, I don't think anybody today would remove all the  
3 meters from the market on the grounds that they're not  
4 as accurate as we would like. They're certainly doing  
5 an adequate job. You know, it could be better, but  
6 they're certainly better than nothing. So to just  
7 like say, you know, in X number of years if the  
8 standard is stricter, we should remove all the old  
9 meters, I'm not so sure I would agree with that.  
10 Partly for the economic reasons and, as Mike said,  
11 when people get accustomed to --

12           MS. PINKOS: That is what they do in Europe,  
13 though, right? With the IVD directive you have a  
14 certain grace period and then if you don't need it any  
15 more, you're -- you have to come off the market?

16           DR. CARISKI: That's true.

17           MS. PINKOS: Do I understand?

18           DR. CARISKI: It's not like it's not been  
19 tried. You're just asking our opinion. I'm giving you  
20 our opinion. You didn't ask what's done worldwide.  
21 Thank you.

22           DR. MYERS: This will have to be our last



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1 question.

2 MR. WHITE: Yeah. I'm sorry to be up here  
3 again. I guess I just like to hear myself speak. But  
4 I just wanted to make a comment that I don't think had  
5 been made earlier until just a minute ago, when Dr.  
6 Harper made another setting in which we really have to  
7 be very careful is our very vulnerable population of  
8 the neonatal intensive care unit, where sugars tend to  
9 run on the low side anyway, so the accuracy is poor.  
10 And they have all -- many of the different  
11 interference factors, such as different hemoglobins  
12 and many medications and low oxygens and high PCO2's.  
13 And I think we have to really think of that as a  
14 population which we don't know if we're getting any  
15 good numbers or not.

16 DR. MYERS: Well, that concludes our  
17 afternoon session. I'm going to turn the microphone  
18 over to Dr. Harper for closing remarks. Before I do,  
19 I want to thank all of our afternoon speakers.

20 (Applause)

21 DR. HARPER: So I really want to thank  
22 everyone for a wonderful day. As I said in the

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1 opening of this particular session, I'm really happy  
2 with the -- the information that I've heard with the  
3 discussions that we've had so far, and I'm really  
4 looking forward to tomorrow.

5           So as a reminder, we start again tomorrow at  
6 9:00 a.m. And everyone who's here today, you still  
7 will need to sign in again tomorrow, as you did this  
8 morning.

9           We have a really exciting day tomorrow.  
10 While today we talked about accuracy standards in  
11 general and some of the issues with meter performances  
12 and interferences, tomorrow morning we're going to  
13 focus on the issue of tight glycemic control in  
14 hospitals and the advantages and disadvantages of  
15 that, and have probably a little bit more discussion  
16 on some of the requirements that might be required for  
17 that, or the advantages and disadvantages, and  
18 hopefully with an emphasis on patient safety.

19           And then also we are going to hear from a  
20 patient representative on the issues that are  
21 important to patients when they choose and use blood  
22 glucose meters, and also from a point of care risk

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1 manager about the issues that are -- that are  
2 important to them.

3           Opening the day, we'll actually hear about  
4 liability issues, potential liability issues on the  
5 use of blood glucose meters.

6           So I hope that you're as excited about  
7 tomorrow as I am, and I will adjourn the meeting for  
8 the day, and see you tomorrow.

9           Thank you.

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