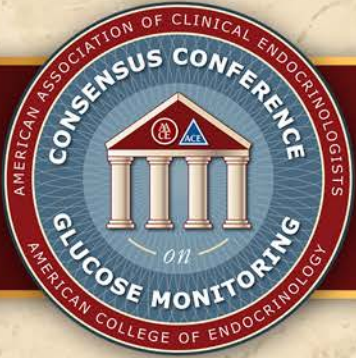


# AACE/ACE CONSENSUS CONFERENCE ON GLUCOSE MONITORING

SEPTEMBER 28–29, 2014

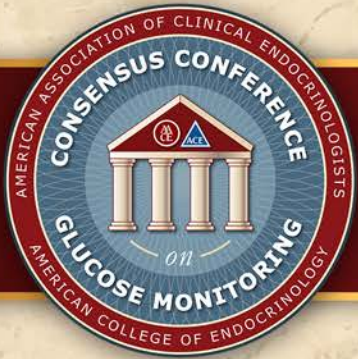
HYATT REGENCY WASHINGTON ON CAPITOL HILL  
WASHINGTON, DC



# Pillars

Pillars of support to create a comprehensive evidence base:

1. Medical/Scientific/Professional/Educational Societies
2. Patients/Lay Organizations
3. Government/Regulatory/Payers/Employers
4. Industry



# Medical/Scientific/Professional/ Educational Societies

**Dr. Yehuda Handelsman**

**Dr. Eric Orzeck**

**Dr. Richard Bergenstal**

**Mrs. JoJo Dantone**

**Mrs. Helena Duncan**

**Mrs. Marion Franz**

**Dr. Guido Freckmann**

**Dr. Barry Ginsberg**

**Dr. Louis Haenel**

**Dr. Irl Hirsch**

**Dr. David Klonoff**

**Dr. Aaron Kowalski**

**Ms. Betty Krauss**

Pillar Co-Moderator

Pillar Co-Moderator

Park Nicollet International Diabetes  
Center

Diabetes Care and Education Group

College of American Pathologists

Academy of Nutrition and Dietetics

IDT

Diabetes Technology Consultants

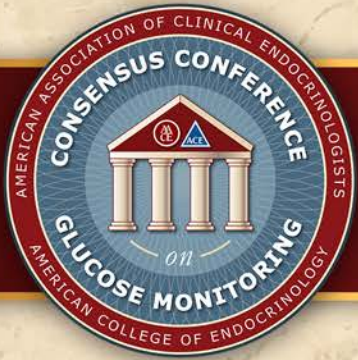
American Osteopathic Association

University of Washington

Diabetes Technology Society

JDRF

Diabetes Care and Education Group



# Medical/Scientific/Professional/ Educational Societies (cont.)

**Dr. David Marrero**

Diabetes Translational Research  
Center, Indiana University

**Ms. Molly McElwee-Malloy**

American Association of Diabetes  
Educators

**Dr. Gerardo Moreno**

American Geriatrics Society

**Dr. Jerry Penso**

American Medical Group Association

**Dr. Gary Puckrein**

National Minority Quality Forum

**Dr. Robert Ratner**

American College of Physicians &

American Diabetes Association

**Dr. David Sacks**

American Association for Clinical  
Chemistry

Dr. Mitchel Scott

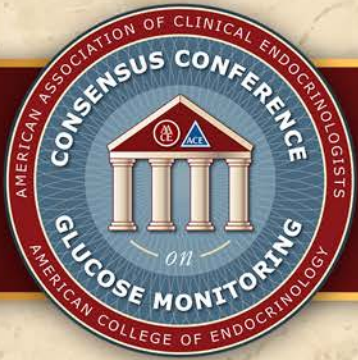
Chemical Chemistry, Washington  
University

**Dr. Krishnaswami Vijayaraghavan**

American College of Cardiology

**Ms. Phyllis Zimmer**

Nurse Practitioner Healthcare  
Foundation



# Patients/Lay Organizations

**Dr. Bill Law**

**Dr. Pauline Camacho**

**Mrs. Kelly Close**

**Mr. Bennet Dunlap**

**Mr. Larry Ellingson**

**Mr. Larry Smith**

**Mr. Manny Hernandez**

**Mr. Jeff Hitchcock**

**Ms. Cynthia Rice**

Pillar Co-Moderator

Pillar Co-Moderator

diaTribe.org

Strip Safely

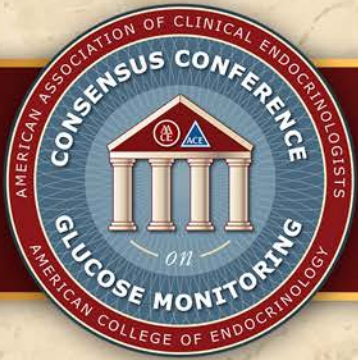
National Diabetes Leadership Council

National Diabetes Leadership Council

Diabetes Hands Foundation

Children with Diabetes

JDRF



# Government/Regulatory/Payers/ Employers

**Dr. Jonathan Leffert**

**Dr. Howard Lando**

**Dr. Pamela Allweiss**

**Dr. Guillermo Arreaza**

**Dr. Sanford Cohen**

**Dr. Alberto Gutierrez**

**Dr. Kimberly Jinnett**

**Dr. David Knowlton**

**Dr. Courtney Lias**

**Dr. Todd Prewitt**

**Dr. William Rogers**

**Dr. Kenneth Snow**

Pillar Co-Moderator

Pillar Co-Moderator

Centers for Disease Control

National Institute of Diabetes,  
Digestive and Kidney Diseases

United Healthcare

Food & Drug Administration

Integrated Benefits Institute

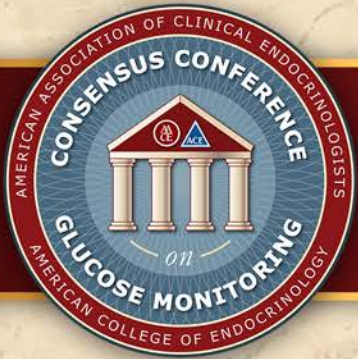
New Jersey Healthcare Quality  
Institute

Food & Drug Administration

Humana

Centers for Medicare and Medicaid  
Services

Aetna



# Industry

**Dr. Daniel Einhorn**

**Dr. Timothy Bailey**

**Mr. Chris Arapoff**

**Dr. Alan Cariski**

**Dr. Nathan Carrington**

**Mr. Jacob Drapkin**

**Dr. Claudia Graham**

**Dr. Brian Levy**

**Dr. Robert Morin**

**Mr. Markus Ott**

**Dr. David Price**

**Ms. Melissa Dobson Schooley**

**Mr. Steve Scott**

**Mr. Bruce Taylor**

**Mr. Duncan Williams**

**Dr. Ramakrishna Venugopal**

Pillar Co-Moderator

Pillar Co-Moderator

Medtronic Diabetes

LifeScan, Inc.

Roche Diabetes Care

J & J Diabetes Solutions Companies

Dexcom, Inc.

J & J Diabetes Solutions Companies

Bayer HealthCare, LLC

Bayer HealthCare, LLC

Dexcom

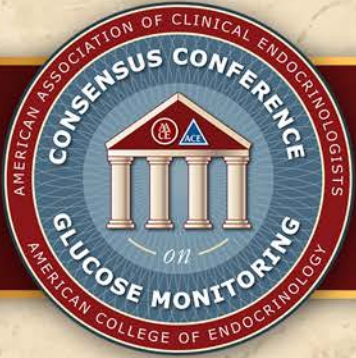
Medtronic

Abbott Diabetes Care

Roche Diagnostics Diabetes Care

Abbott Diabetes Care

Animas Corporation

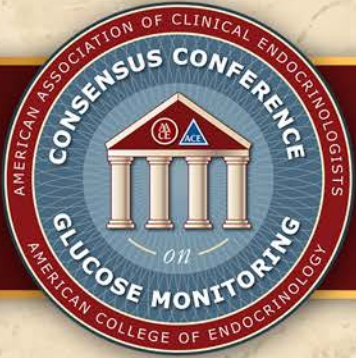


# Question 1

What data support glucose monitoring (as distinct from glycemic control) as a means to prevent diabetic macro- and microvascular complications?

- A. Does frequency of glucose monitoring correlate with better outcomes?
- B. Which patients benefit the most from rigorous glucose monitoring?
- C. Does strip accuracy and/or CGM accuracy correlate with better outcomes?

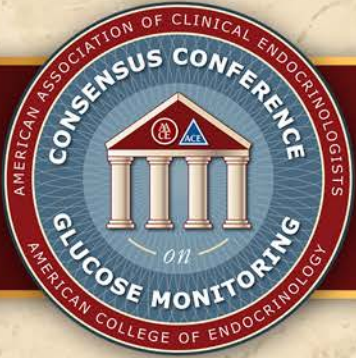




## Question 2

Can the FDA improve post-approval surveillance of strip/meter/CGM quality?

- A. Does sub-standard glycemic monitoring technology harm patients? If so, what data exist to support such a claim? Are all manufacturers required to report this data to the FDA?
- B. What is the current state of affairs at the FDA in post-marketing meter and CGM surveillance?
- C. What enforcement options are available to the FDA and how are they implemented?

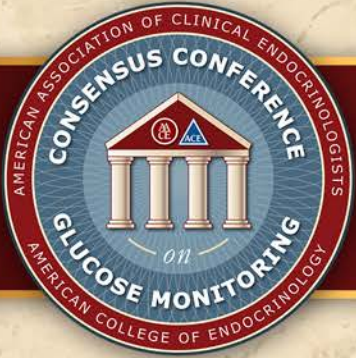


# Question 3

Does current private insurance and Medicare policies balance the need to provide patient access to high quality care and effective glucose monitoring and, if not, what policy changes are needed with respect to:

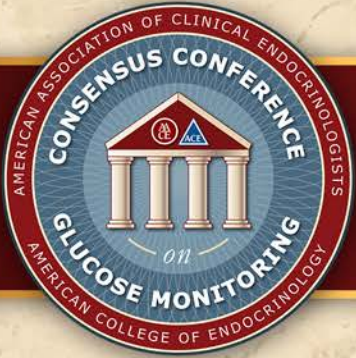
## A. Patient Access to BGMS supplies

- i. Competitive Bidding Program (medical necessity attestation and other paperwork requirements for physicians' offices *vs.* potential fraud and abuse, access to blood glucose test strips that are accurate and reproducible)
- ii. Limiting single strip brand/meter type



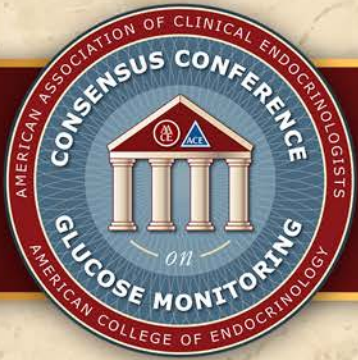
## Cont. Question 3

- B. Patient access to CGM technology (access by appropriate patients)
- C. Limited or lack of coverage for sensor-augmented insulin pump therapy and emerging semi-automated CGM/pump combinations (e.g., threshold suspend systems)?



# Question 4

What is the most effective way for the key stakeholders (physicians, allied health care professionals, patients, professional associations, educators, investigators, payors, industry, employers, health care systems, regulators) to achieve equitable, evidence-based, cost-effective regulation of glucose (blood, continuous) monitoring technology?

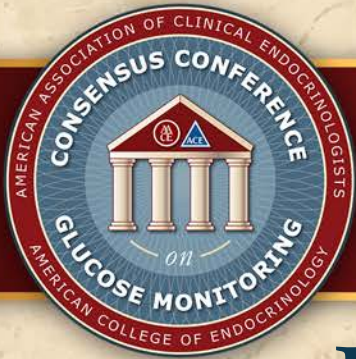


# Pillar Breakout Sessions



8:30 am 12:00 pm

*Constituencies within each Pillar  
examine data and discuss  
answers to the four questions.*



# Pillar Breakout Sessions

## Pillar Co-Moderators and Rooms

Medical/Scientific/Professional/  
Educational Societies

Dr. Yehuda Handelsman

Dr. Eric Orzeck,  
**Columbia C**

Government/Regulatory/  
Payors/Employers

Dr. Howard Lando

Dr. Jonathan Leffert  
**Bunker Hill**

Patients/Lay Organizations

Dr. Pauline Camacho

Dr. Bill Law, Jr.

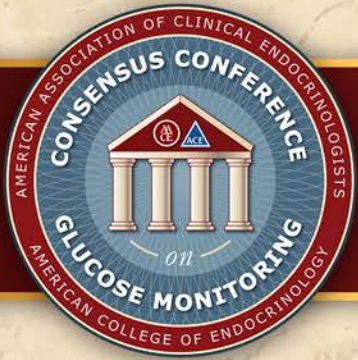
**Lexington**

Industry

Dr. Timothy Bailey

Dr. Daniel Einhorn

**Conrad**

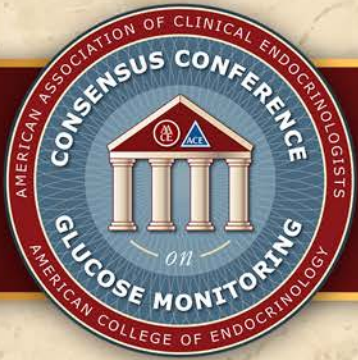


# Lunch Break



12:00 pm 1:30 pm  
Regency B

- *Lunch and networking*
- *Pillar Co-Moderators  
developing pillar summaries  
for presentation at Pillar  
Forum*

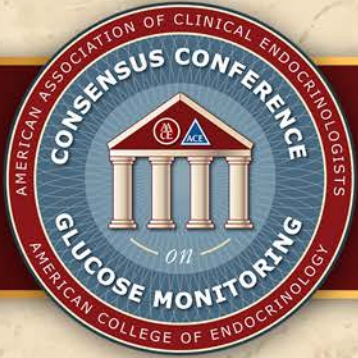


# Pillar Forum



1:30 pm 4:30 pm  
*Pillar Breakout Sessions*  
*Summaries and Q & A*





# Pillar Forum



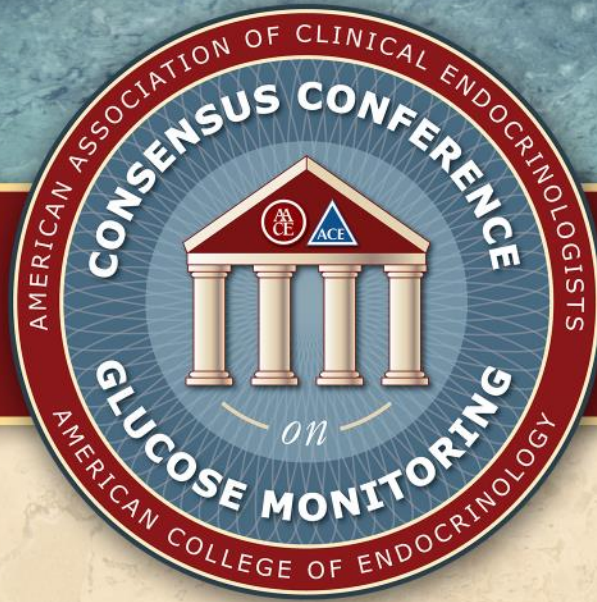
**Conclusion & Adjourn**

4:30 pm 4:45 pm

**Writing Committee**

**Convenes**

5:00 pm



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