



# Kidney Health Initiative

## Second Annual Stakeholders Meeting

June 11-12, 2014 • Hyatt Regency Bethesda

### Agenda

*Program Subject to Change*

#### Wednesday, June 11

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6:00 PM **Registration Opens**

6:15 PM **Dinner Reception**

7:30 PM - 9:00 PM **“Innovation, Incentives, and Interactions between Approval and Access”**

Keynote Lecture

*Mark B. McClellan, MD, PhD*

*Senior fellow and Director of the Health Care Innovation and Value Initiative, Brookings Institution  
Former FDA Commissioner and CMS Administrator*

Panel Discussion

Moderator: Patrick Archdeacon, MD (*KHI Co-chair*), *KHI Member: FDA*

Paul Conway, *KHI Member: American Association of Kidney Patients*

Louis B. Jacques, MD, *Senior VP and Chief Clinical Officer, ADVI  
Former Director of the Coverage and Analysis Group (CAG) within the Center for Clinical Standards  
and Quality (CCSQ) at the Centers for Medicare and Medicaid Services (CMS)*

Mahesh Krishnan, MD, MPH, MBA, FASN, *KHI Member: DaVita Healthcare Partners*

Prabir Roy-Chaudhury, MD, PhD, FASN (*KHI Co-Chair*), *KHI Member: American Society of Nephrology*

Murray Sheldon, MD, *Associate Director of Technology and Innovation, Center for Devices and  
Radiologic Health, FDA*

#### Thursday, June 12

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8:30 AM **Registration Opens/Continental Breakfast**

9:00 AM - **Welcome Remarks**

9:15 AM Patrick Archdeacon, MD (*KHI Co-chair*), *KHI Member: FDA*

Prabir Roy-Chaudhury, MD, PhD, FASN (*KHI Co-chair*), *KHI Member: ASN*

9:15 AM - **Overcoming Barriers to Innovation in Kidney Health—Forging a Platform for the Future**

9:45 AM Moderator: Peter G. Linde, MD, FASN (*Workgroup Chair*), *KHI Member: Abbvie*

Ronald J. Falk, MD FASN, *KHI Member: ASN*

Jula K. Inrig, MD, FASN, *KHI Member: Quintiles*

Celeste Castillo Lee, *KHI Member: Vasculitis Foundation*

James A. Sloand, MD, FASN, *KHI Member: Baxter International, Inc.*

Updated 6/8/2014

9:45 AM -  
10:15 AM

**KHI's Pilot Projects: Lessons Learned**

Moderator: Reshma Kewalramani, MD, FASN *KHI Member: Amgen*

**Pharmacokinetics in Patients Receiving CRRT**

Stuart Goldstein, MD, (Workgroup Member), *KHI Member: American Society for Pediatric Nephrology*  
Thomas D. Nolin, PhD, PharmD, FASN (Workgroup Co-chair), *KHI Member: ASN*

**Clinical Trial Endpoints: Outcome Measures in Lupus Nephritis**

Ronald J. Falk, MD, *KHI Member: ASN*

Laura Straub (Workgroup Member), *Strategic Review & Planning Manager, Immune Tolerance Network (Workgroup Member)*

10:15 AM -  
10:45 AM

**Breakout #1: Kidney Health Initiative: Current Projects**

**1. Clinical Trial Endpoints: Dialysis Vascular Access**

*Monnie Wasse, MD, MPH, FASN (Workgroup Co-chair), KHI Member: American Society of Diagnostic and Interventional Nephrology & ASN*  
*Surendra Shenoy, MD, PhD (Workgroup Co-chair), KHI Member: Vascular Access Society of the Americas*

**2. Data Standards: Diabetic Nephropathy**

*Jula Inrig, MD, KHI Member: Quintiles Global Clinical Research Organization*

**3. Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease**

*Dolph Chianchiano, JD, MPH (Workgroup Co-chair), KHI Member: National Kidney Foundation*  
*Carolyn Y. Neuland, PhD, KHI Member: FDA*

10:45AM –  
11:45AM

**Breakout #2: KHI Project Pipeline - Presentation and Discussion of KHI Members' Project Proposals**

Attendees will select one of the following options

**1. Gerontology in Nephrology: An Unmet Clinical Need**

*Markus Bitzer, MD, KHI Member: ASN*

- A. Designing Studies to Evaluate Supportive Care vs. Dialysis for Frail Older Adults with Advanced Kidney Disease
- B. Enhancing the Relevance of ESRD Prevention Trials for Older Adults

**2. Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease**

*Stephen Ash, MD, KHI Member: ASDIN*

*Douglas Silverstein, MD, KHI Member: FDA*

**3. Aligning Existing Voices | KHI Kidney Patient Voices Project**

*Celeste Lee, KHI Member: Vasculitis Foundation*

*Sam Pederson, KHI Member: AAKP*

11:45 AM –  
12:30 PM

**Networking Lunch**

12:30 PM-  
1:30 PM

**Breakout #3: KHI Project Pipeline - Presentation and Discussion of KHI Members' Project Proposals**

Attendees will select one of the following options

- 1. Facilitating the Development of Novel and Effective Therapies for Acute Kidney Injury: A Time for Change**
  - A. Clinical Trial Endpoints for Acute Kidney Injury (AKI)  
Stuart Goldstein, MD, *KHI Member: ASPN*
  - B. Definition of a Pathway for the Development of Drugs that Can Prevent or Treat Acute Kidney Injury  
Jerome Rossert, MD, PhD, *KHI Member: Thrasos Innovation*
- 2. Vascular Access Data Collection in the Dialysis Unit: Moving Towards a Real Time Registry**  
Paul Kravitz, *KHI Member: NxStage, Inc.*
- 3. Workshop to Determine Priorities for Drug Safety Evaluation Across the Spectrum of CKD**  
Wendy St. Peter, PharmD, FASN, *KHI Member: American College of Clinical Pharmacists, Practice and Research Nephrology (ACCP PRN)*
- 4. Enhancing Quality of Life for Patients Undergoing Maintenance Dialysis: Exploring the Role of Patient- Reported Outcomes for Drug Approval**  
Sharon M. Moe, MD, FASN, *KHI Member: ASN*

1:30 PM-  
2:30 PM

**Breakout #4: KHI Project Pipeline - Presentation and Discussion of KHI Members' Project Proposals**

Attendees will select one of the following options

- 1. Barriers to Clinical Trials – Increasing the Number of Nephrology Investigators to Facilitate the Formation of CKD Consortia and Centers of Excellence in Clinical Research**  
Barbara Gillespie, MD, *KHI Member: Quintiles Global Clinical Research Organization*
- 2. Advancing Technologies to Facilitate Remote Management of Patient Self-Care in Renal Replacement Therapy**  
James A. Sloand, MD, FASN, *KHI Member: Baxter International, Inc.*
- 3. Initiatives to Support Patient Engagement and Public Awareness**
  - A. Educational Video to Increase Kidney Patient Participation in Clinical Studies  
Angela Connelly, *KHI Member: PKD Foundation*
  - B. Unified Kidney Fact Sheet  
Lori Hartwell, *KHI Member: Renal Support Network*

2:30 PM-  
3:00 PM

**Wrap-up and Next Steps**

Patrick Archdeacon, MD (*KHI Co-chair*), *KHI Member: FDA*

Prabir Roy-Chaudhury, MD, PhD, FASN (*KHI Co-chair*), *KHI Member: ASN*

## Hyatt Regency Bethesda

One Bethesda Metro Center (7400 Wisconsin Ave)  
Bethesda, Maryland, USA, 20814