



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

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