**Annual Stakeholders Meeting**  
**September 6-7, 2023**  
**Grand Hyatt Washington**  
**Washington, DC**  

“Defining the Next Decade of Kidney Innovation”

**Wednesday, September 6, 2023**

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| 1:00 PM | Pre-Workshops – *Spots are limited*  
**APOL1 Kidney Disease: A Roadmap from Community Awareness and Screening to Clinical Trial Participation**  
Join the launch of KHI’s APOL1 Kidney Disease Roadmap to the kidney community. This workshop aims to gather your thoughts and experiences to inform how KHI can further engage community-based organizations. Registered workshop participants will receive an early copy of the roadmap.  
*Registration is required*  

**SGLT2 Inhibitors: Conducting Pediatric Clinical Trials**  
In July 2023, together with KHI member, Nephcure, and key stakeholders from the United States and Europe, a workshop was organized to discuss the need for clinical trials of SGLT2 inhibitors in pediatric chronic kidney disease. This session will highlight the key conclusions of the workshop and will solicit input from the community on how to foster awareness of the need for clinical trials of SGLT2 inhibitors in the pediatric nephrology community and patient populations.  
*Registration is required*  

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| 3:00 PM | Pre-Meeting Networking  
*Join us for light refreshments and informal networking to highlight KHI projects, members, the Board of Directors, and staff.* |
| 5:00 PM | Welcome and Opening Comments  
**Uptal D. Patel, MD**  
Chair  
**Kidney Health Initiative** |
| 5:15 PM | Reflection on Current and Future Priorities for the FDA Commissioner  
**Robert M. Califf, MD**  
Commissioner  
**US Food and Drug Administration (FDA)** |

*Program subject to change. Visit the KHI website for updates.*
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5:45 PM  A Patient Advocacy Group's Impact on Clinical Trial Infrastructure: The Cystic Fibrosis Foundation's Therapeutics Development Network  
John P. Clancy, MD  
Senior Vice President of Clinical Research  
Cystic Fibrosis Foundation

6:15 PM  Dinner

6:45 PM  Celebrating 10 Years of the Kidney Health Initiative  
Prabir Roy- Chaudhury, MD, PhD, FASN, Moderator  
Reshma Kewalramani, MD, FASN  
Barbara S. Gillespie, MD, FASN  
Brigitte Schiller, MD, FASN

7:30 PM  Dessert Reception and Networking

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Thursday, September 7, 2023

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8:00 AM  Breakfast

8:30 AM  Current and Future Priorities for the FDA CDRH Director  
Jeffrey Shuren, MD, JD  
Director  
Center for Devices and Radiological Health (CDRH)

8:45 AM  From Napkin Sketch into Patient Hands: Innovative Device Development  
Brigitte Schiller, MD, FASN, Moderator  
Dawn Edwards  
Sarah Lee  
Paul Komenda, MD  
Manisha Dadhania, MBA

10:00 AM  Break

10:30 AM  Current and Future Priorities for FDA CBER Director  
Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research (CBER)

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10:45 AM  Cell and Gene Therapy...What Can the Kidney Community Learn from Others?
Reshma Kewalramani, MD, FASN, Moderator
Keziah Lukombo (Fireside chat with Moderator Barbara S. Gillespie, MD, FASN)
Jeremy Duffield, MD, PhD, FRCP
Celia Witten, MD, PhD

12:00 PM  Lunch and Networking

1:00 PM  Utilizing Patient Advisory Boards to Accelerate Innovation
KHI Patient and Family Partnership Council
Patrick O. Gee, Sr., PhD

1:30 PM  From Predictive Analytics to Personalized Care: Unleashing the Power of Data to Accelerate Clinical Drug Development
Amit Sharma, MD, FASN, Moderator
Ravindra L. Mehta, MBBS, MD, FASN
Lesley Ann Inker, MD, MS
Robert A. Star, MD
Aliza M. Thompson, MD, MS
Curtis Warfield, MS

3:00 PM  Closing Comments and Next Steps
Uptal D. Patel, MD

The KHI Board of Directors would like to thank the Program Committee Co-Chairs:

Barbara S. Gillespie, MD, FASN
Reshma Kewalramani, MD, FASN
Brigitte Schiller, MD, FASN

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