

Welcome to the December Edition of the KHI Patient and Family Partnership Council Newsletter

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Welcome

Welcome to the third edition of our newsletter. 2018 is almost over and it's been an important transition year for kidney research and patient advocacy. After more than 50 years of very little change in the prevention or treatment of kidney disease, this year ends with some optimism.

The Kidney Innovation Accelerator, best known as KidneyX, was announced in late 2017 by the Department of Health and Human Services and will award \$2.6 M in public / private funding for innovative research. Word spread over the year sparking interest in new solutions among kidney research centers, drug makers and medical device manufacturers.



Richard Fissel, Editor

The Kidney Precision Medicine Project (KPMP) led by the National Institutes of Diabetes and Digestive and Kidney Disease (NIDDK) aims to apply some of the same technology which improved treatments for cancer and cardiovascular disease to kidney disorders. Patients are playing an increasingly important role by advising researchers on the outcomes which mean the most to them.

In October I had the privilege of attending ASN Kidney Week, the largest annual conference of kidney researchers worldwide. Patients were better represented than ever and their views were of genuine importance to those attending. The Kidney Health Initiative (KHI) itself brings together key stakeholder organizations able to make a difference in the kidney space. With the ongoing inclusion of the patient voice, positive change is on the horizon.

At year's end the KHI Patient and Family Partnership Council (PFPC) will be losing two valued members as they rotate off the council: Roberta (Bobbi) Wager and Terry Litchfield brought tremendous knowledge and professional experience to our council. In January 2019, the KHI PFPC will welcome new members Mary Baliker and Patrick O. Gee. Both are kidney patients with experience in patient engagement and a professional background in medicine and clinical trials.

Read on for articles covering inaugural patient presentations at ASN Kidney Week 2018, a call for workgroups for upcoming KHI projects, and links to articles recently published by PFPC members. In future newsletters we will address several matters including the critical issue of patient participation in clinical trials, possibly the most powerful way patients can make a difference and even ease their own symptoms in the process.

On behalf of the entire KHI PFPC, thank you for your continued support. We wish you all happiness for the holidays and the new year and look forward to connecting with you in 2019.

Best regards,
Richard Fissel

Community News

Reflections on ASN Kidney Week & Celeste Castillo Lee Lectureship

by Richard Fissel

Kidney Week 2018 brought more enthusiasm for patient advice and participation in kidney research than ever. Many panels made up of physicians and researchers also included patients: KHI PFPC member Terry Litchfield spoke on championing a multidisciplinary patient centered approach to developing alternative therapies to vascular access: "Patient Perspectives on Vascular Access: Has Anyone Asked Me?".

Additional presentations at Kidney Week included a special session titled "Developing Therapies That Matter Most to Patients: A Patient-Centered Approach to Innovation" including the Celeste Castillo Lee Memorial Lectureship. Moderation was provided by Jonathan Himmelfarb, MD, FASN and Uptal D. Patel, MD for the following session presentations:

- Designing Innovative Alternatives to RRT: Patients as Partners - The Celeste Castillo Lee Memorial Lectureship; Presented by: David M. White (KHI PFPC Chair)

- Precision Medicine: Developing Meaningful Therapies for Patients Through Collaboration in Research; Presented by: Nichole M. Jefferson (KHI PFPC Member and current President of Home Dialyzors United)
- Patient-Centered Clinical Trials: Defining Outcomes That Matter Most to Patients; Presented by: Allison Tong, PhD, MPH (SONG Initiative)
- A Better Way: Hemodialysis Patient Perspective on Optimal Weight and Holistic Fluid Management; Presented by: Caroline Wilkie (KHI PFPC member)

All the patient presentations focused on subjects to which I personally related after nearly four years of in-center dialysis and a transplant less than a year ago. We've been there and understand what is most important from the patient perspective. Our opinions are being heard and respected which strengthens the value of patient guided research going forward.

Earlier in this missive I discussed funding from KidneyX and other resources that will help make a difference in future research. The dollars are still limited and participation by patients at each stage of new product development from concept to design to finished product will better leverage those funds. Patients are natural partners in kidney research and new product development.

US FDA Patient Advisory Committee Meeting

by Staff

On November 15, 2018 the FDA Patient Engagement Advisory Committee held a public meeting centered around the topic "Connected and Empowered Patients: e-Platforms Potentially Expanding the Definition of Scientific Evidence." The function of the Committee is to provide advice to the Commissioner, or designate, on complex issues relating to medical devices, the regulation of devices, and their use by patients.

This meeting served to ensure that patient perspectives are continuously included as the FDA moves forward with medical device deliberations. Additionally the meeting provided a platform to discuss potential health information collection methods and ways to leverage such information.

More information on the meeting can be found [here](#).

What's Important To Us

2018 KHI Patient Focused Project Highlights

by Staff

KHI completed its workgroup application process for recently endorsed project: "Developing Measures for Muscle Cramping". This project is set to begin in 2019 and is related to three current or completed KHI projects:

1. Prioritizing Symptoms of ESRD Patients for Developing Therapeutic Interventions
2. Development of a Roadmap for Innovation in RRT
3. Fostering Innovation in Fluid Management

Members are urged to look for KHI's next Call for Workgroups in early 2019 that is focused on patient-reported outcomes (PRO) for vascular access. This project expands

on KHI's efforts to support the development of patient centered devices.

In keeping with patient focused projects, the KHI project workgroup involved with "Overcoming Barriers to Drug Development in Children with CKD" launched the pilot phase of Kidney-PATCH (Pediatric Accelerator Trial Clearing House).

Kidney-PATCH aims to:

- Enable *feasibility assessment* in terms of the available patient populations through data sharing and access to CKD pediatric registries
- Facilitate *centralized coordination* with the various pediatric kidney clinical trial networks and other stakeholder organization in US and Europe
- Assist with *identification of expertise* that can provide consultation on pediatric study planning

The KHI PFPC thanks KHI workgroups and KHI members for their hard work and commitment to enhance the lives of people living with kidney diseases.

Events & Announcements

Throughout 2018, several KHI PFPC members have written articles that have been published in Clinical Journal of the American Society of Nephrology and the Journal of the American Society of Nephrology. KHI's mission involves greater understanding of patient safety implications of new and existing therapies and medical products. It is with inclusion of the patient voice and perspective that the mission will be achieved.



Kevin J. Fowler

- [The New HHS Kidney Innovation Accelerator](#)
- [Innovation in Transplantation: Accountability, Collaboration, and the Value of the Patient Voice](#)



Terry Litchfield

- [Clinical Trial End Points for Hemodialysis Vascular Access](#)



Caroline Wilkie

- [Symptom Prioritization among Adults Receiving In-Center Hemodialysis](#)

KHI PFPC Member Spotlight



Roberta (Bobbi) Wager

[Learn More](#)



Terry Litchfield

[Learn More](#)

As our three-year term on the KHI PFPC comes to an end in 2018, words cannot express how grateful we are to have played a role advising KHI stakeholders on policy initiatives based on the patient and care provider's perspective. Despite diverse experiences dealing with kidney disease, we are united in the goal of having patient voices heard in the development of drugs and devices to prevent kidney disease and improve treatment for existing patients.

We look forward to seeing new KHI PFPC members add unique perspectives and continue to promote appropriate solutions; lifting the voice of the patient so all can hear it.

We are grateful to ASN Co-Chair for KHI, Prabir Roy-Chaudhury, MD, PhD, and KHI Project Director Melissa West, for their guidance, direction and understanding in enabling the KHI PFPC to reach its goals and truly make a difference. Thanks also to KHI PFPC Chair, Dave White, for his leadership and keeping our group on track. But most of all, our thanks goes to Celeste Castillo Lee for her vision that the patient voice be heard to guide future kidney research and innovation. God bless you!

About the PFPC

Patients and their care partners are at the center of the [KHI mission](#). The KHI PFPC is a tangible representation of that commitment.

By providing a channel for patients to get involved in advising and making recommendations on the priorities and projects of KHI, patients can influence innovation in the kidney community and ensure the patient voice is heard in the development of clinical trials, treatments, drugs and devices.

Learn more and get involved [here](#).

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