May 30, 2014

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: *21st Century Cures: A Call to Action* White Paper

Dear Chairman Upton and Congresswoman DeGette:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Energy and Commerce Committee with comments on the 21st Century Cures initiative and the *21st Century Cures: A Call to Action* white paper. The Alliance shares the Committee's goal to "accelerate the discovery, development, and delivery of promising new treatments to patients" and looks forward to working with the Committee throughout its process to help to identify policies to accomplish this goal for home dialysis patients.

The Alliance is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

As you may know, today more than 600,000 Americans are living with end-stage renal disease (ESRD), a ten-fold increase compared to 1980.[1] This number will likely continue to increase, as an estimated 26 million people in the United States have chronic kidney disease and are at risk for kidney failure. Due to the limited number of kidneys available for transplantation, the vast

[1] U.S. Renal Data System. 2013 USRDS Annual data Report: Volume 2, "Atlas of End-Stage Renal Disease in the United States." Washington, D.C.: National Institute of Diabetes and Digestive and Kidney Diseases, May 2014. Web.

majority of ESRD patients, approximately 70 percent, depend on dialysis to replace kidney function.[2]

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. For instance, because HHD offers more frequent and/or lasting dialysis sessions, studies demonstrate individuals have a quicker recovery time after treatment[3] and have an increased opportunity for rehabilitation.[4] PD patients experience fewer negative side effects, such as nausea, and dietary restrictions than in-center patients.[5] However, today, only 10% of U.S. dialysis patients receive treatment at home, with less than 2% of patients receiving HHD.[6]

Congress' stated intent in the creation of the End Stage Renal Disease (ESRD) benefit was that "the maximum practicable number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."[7] The Alliance believes that the work the Committee is embarking on to align policies with technological advances in order to ensure patients have access to new treatments, new applications and new products in a timely manner could help the kidney community to fully realize this goal. While research is underway to look at ways to prevent ESRD and improve treatments (including creating an artificial kidney), greater investment in these concepts is needed to bring them to light faster.

Many innovations are a long way off from benefitting those who have or who are moving towards kidney failure today. One way to have a more immediate improvement in options for treating kidney failure is to focus on improving upon existing options for home dialysis. We have a shared interest in improving patient outcomes and experiences, and the Alliance believes that the discovery, development and delivery of new interventions for dialysis patients is critical and should include innovations in home dialysis, which can provide meaningful clinical and quality of life benefits to those living with ESRD.

One way to achieve this goal is to include the patient perspective in the development of new technologies. The Food and Drug Administration (FDA) has started this process with a workshop

---

[2] The Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy, Chapter 6, "Outpatient Dialysis Services". Washington, DC: MedPAC, March, 2014. Web. http://www.medpac.gov/documents/Mar12_EntireReport.pdf

[3] Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.

[4] Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22-28. Web. 12 Apr 2012 http://www.aami.org/publications/HH/Home.Blagg.pdf.

[5] "A Brief Overview of Peritoneal Dialysis." DaVita, Inc., Web. 16 Jul 2012. http://www.davita.com/treatment-options/home-peritoneal-dialysis/what-is-peritoneal-disease-/a-brief-overview-of-peritoneal-dialysis/t/5483.

[6] U S Renal Data System, USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

[7] Section 1881(c)(6) of the Social Security Act.

held in September of last year titled, *The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes*.[8] The Alliance attended and provided input at the event. We strongly support FDA's efforts to incorporate the patient perspective in the approval process and encourage the Committee to prioritize this type of engagement when considering ways to accelerate treatments and cures to patients.

The FDA, though, has not yet articulated its next steps to realize the full potential of this effort or the timing for such activities. We recommend that the Committee reach out to the FDA to solicit next steps and request an action plan on how they plan to incorporate patient preference into the medical device regulatory process on existing and future device approval applications. We are also aware that the broader kidney community is involved in ongoing discussions with the FDA on this topic through the Kidney Health Initiative (KHI). We encourage the Committee to consider this FDA-KHI initiative ("Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease") and ways to support its activity, as well as similar efforts to incorporate the patient perspective in FDA processes as part of the Committee's work on 21st Century Cures. The home dialysis patient community is eager to offer its perspective and to be a constructive part of the FDA approval process.

The Alliance applauds the Committee for its work on this initiative and the inclusive nature of its approach to understanding how to accelerate cures for Americans living with serious chronic illnesses like ESRD. We look forward to being an active participant in this ongoing discussion. Thank you for the opportunity to provide these comments.

Sincerely,

Stephanie Silverman
Executive Director

[8] http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm361864.htm

Signing Alliance Members

American Association of Kidney Patients

American Kidney Fund

American Nephrology Nurses Association

American Society of Nephrology

American Society of Pediatric Nephrology

Baxter

Cleveland Clinic

DaVita HealthCare Partners Inc.

Dialysis Clinic, Inc.

Dialysis Patient Citizens

Fresenius Medical Care

Greenfield Health Systems

Home Dialysis Plus

Home Dialyzors United

Hortense and Louis Rubin Dialysis Center, Inc.

Medical Education Institute

National Kidney Foundation

National Renal Administrators Association

Northwest Kidney Centers

NxStage Medical

Renal Physicians Association

Renal Support Network

Satellite Healthcare

Southwest Kidney Institute

TNT Moborg International Ltd.