

For Immediate Release

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The Kidney Health Initiative Attending White House Organ Summit

Washington, DC (June 13, 2016) — The Kidney Health Initiative (KHI) is pleased to support President Barack Obama's call to action through its attendance at the White House Organ Summit on Monday, June 13. This Summit will examine ways to improve the outcomes for individuals waiting for organ transplants and support living donors in addition to improving kidney patient care options and access to transplantation.

KHI, a public-private partnership established by the U.S. Food and Drug Administration and the American Society of Nephrology (ASN), is composed of more than 75 member organizations that represent all major stakeholders in the field of kidney disease, including patient and health professional organizations, pharmaceutical companies, device manufacturers, dialysis providers, research institutions, and federal agencies.

KHI will initiate the development of a roadmap that will describe scientific, technical, and regulatory milestones needed to achieve the goal of creating a bio-artificial or bioengineered alternative to dialysis as renal replacement therapy. The roadmap will also consider challenges, provide "state of the art" expectations for entrepreneurs and other technology developers, and spur innovation in producing functioning kidney replacements by engaging stakeholders, identifying research priorities to alleviate critical knowledge gaps, and advancing the science of alternatives to dialysis.

KHI will invite a diverse group of stakeholders to participate in the development of the roadmap. These stakeholders include scientific, engineering, and clinical expertise from NIH, professional medical societies, academic institutions, industry researchers, regulatory expertise from FDA, in particular the Center for Biological Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH), prospective payers, and patients as the end users of any new device that is developed.

According to Dr. Prabir Roy-Chaudhury MD, PhD, a Professor of Medicine at the University of Arizona and the ASN co-chair of the Kidney Health Initiative; "we appreciate the clinical need; we understand the biology, and in many cases we can develop the technologies needed to develop an innovative, effective and durable bioengineered alternative to dialysis. What is sometimes lacking, however, is a clear and well defined pathway and metrics, to achieve this goal. I truly believe that this "roadmap" will allow for an integrated, multi-disciplinary and patient-centric approach to this problem, with the active participation of all the involved stakeholders; so that we can provide better care to patients with kidney disease".

Established in 2012, the Kidney Health Initiative (KHI) is a public-private partnership between ASN and the U.S. Food and Drug Administration to advance kidney health issues through a collaboration of patients, health care professionals, scientists, and industry.

For more information on KHI, please visit <https://www.kidneyhealthinitiate.org>.

Since 1966, the American Society of Nephrology (ASN) has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients. ASN has nearly 16,000 members representing 112 countries. For more information, please visit www.asn-online.org or contact us at 202-640-4660.

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