

THE KIDNEY MOONSHOT

By Ryan Murray and Molly O'Neill

The United States was built on bold, audacious plans in which the public and private sectors collaborate to solve complex problems. Our healthcare system is no exception, and the cancer community wrote the book on how to advance the field on behalf of patients.

When President Richard M. Nixon signed the National Cancer Act of 1971, he shared “that a total national commitment means more than government.” Nearly 45 years later, Vice President Joseph R. Biden, Jr., described a Cancer Moonshot to cure cancer through a collaborative, multi-disciplinary coalition of public and private resources. Following the former vice president’s call to action, Congress passed the 21st Century Cures Act in 2016 and allocated \$1.8 billion to the National Institutes of Health (NIH) over seven years dedicated to cancer research in what is referred to as the Beau Biden Cancer Moonshot.

As a direct result of the Obama administration making cancer research a priority, the National Cancer Institute received an additional \$300 million in appropriations for fiscal year (FY) 2017 designated specifically for the Cancer Moonshot, an additional \$300 million for FY 2018, and an additional \$400 million for FY 2019. This three-year \$1 billion was on top of the average annual appropriation for the National Cancer Institute, which during the time was \$5.9 billion.

Kidney disease, often ignored and underfunded in terms of research when compared to other diseases, affects approximately 37 million Americans. More than 700,000 Americans face kidney failure and require dialysis or a transplant to live. Kidney disease was the ninth leading cause of death in 2017. Each year more than 100,000 Americans begin hemodialysis treatment, but tragically there is nearly a 60% mortality rate within five years of treatment—a rate worse than nearly all forms of cancer, which receives 11 times more funding for NIH-supported research than kidney disease.

In addition to poor patient outcomes, there is a tremendous financial cost associated with kidney care. In 2016, the Medicare Program spent approximately \$114 billion to care for people with kidney disease or kidney failure. That represents more than one in five dollars spent by the program. By comparison, the FY 2019 budget for the entire NIH is \$39.1 billion.

For the 37 million Americans with kidney disease, these figures highlight a poor quality of life that is unjustifiable given the financial costs of treatment. Therefore, the current administration has prioritized improving kidney care by creating a version of a kidney moonshot and demanding that the nation support kidney health instead of paying for kidney sickness. The status quo is no longer tolerable, and the kidney community was thrilled to witness President Donald J. Trump sign the Executive Order (EO) on Advancing American Kidney Health (AAKH) on Wednesday,

July 10, 2019. The EO calls for a fundamental shift toward a system of value-based care by incentivizing earlier clinical interventions to delay the progression, or prevent, kidney disease and kidney failure.

For decades, the American Society of Nephrology (ASN) has advocated tirelessly for the priorities highlighted in AAKH, which has three overarching goals:

- Reduce the risk of kidney failure
- Improve access to and quality of person-centered treatment options
- Increase access to kidney transplants

As with the Cancer Moonshot, the kidney community can leverage AAKH to create a variety of opportunities benefiting both patients and kidney health professionals. While at press time Congress was finalizing its appropriations for FY 2020, the House bill provided a substantial increase in funding for the NIH at \$41.1 billion and for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at \$2.1 billion. Appropriations increases will support NIDDK initiatives including the pioneering work that is being conducted by the APOL1 Long-term Kidney Transplantation Outcomes Network (APOLLO) and Kidney Precision Medicine Project (KPMP).

By better educating patients on all treatment options and encouraging home dialysis and preemptive transplant when appropriate, patient outcomes will improve. An increase in the use of telemedicine, new technology that empowers the patient, and the development of an artificial kidney will attract the next generation of clinicians and innovators, helping the specialty reverse its course and ensure a robust workforce pipeline.

AAKH is galvanizing the community behind a singular goal and sparking renewed optimism and hope among kidney health professionals and patients:

For the entire government and president to show this much interest in kidney disease and kidney failure is unprecedented. Having the president sign an Executive Order that increases the recognition of the value, diagnosis, development and use of alternative dialysis therapies, and increasing the number of transplants, signals to the kidney community that they are serious about changing the care of kidney patients.” – Mark E. Rosenberg, MD, FASN, ASN President

The American Association of Kidney Patients (AAKP) “enthusiastically endorses President Donald Trump and his health policy team in their bold and bipartisan efforts to fully empower kidney patient consumers and save kidney patient lives through greater care choice and innovations aimed at preventing and better managing kidney disease.” – Richard A. Knight, MBA, AAKP President

The Executive Order on Advancing American Kidney Health is “a major win in the battle against kidney disease. They have thought about the entire spectrum of kidney disease from better detection to better dialysis therapies and better access to transplantation.” – Holly Kramer, MD, MPH, President of the National Kidney Foundation.

Advancing innovation and reenergizing the nephrology field is a core component of the EO. This is also the overarching mission behind KidneyX, a public-private partnership between ASN and the Department of Health and Human Services. KidneyX is taking a cutting-edge approach to address the lack of funding and ingenuity, and the stagnation in kidney care by accelerating innovation in the development of drugs, devices, biologics, and other therapies. It is also specifically highlighted in the EO as an opportunity to develop an artificial kidney and is actively working on this goal through a series of staged prize competitions.

The initial prize competition sponsored by KidneyX, Redesign Dialysis Phase I, encouraged innovators to conceptualize next-generation dialysis products. Participants were asked to design possible solutions that can replicate normal kidney function and improve patient quality of life. Phase I ignited enthusiasm throughout the nephrology community and received more than double the number of expected submissions. The winning submissions included companies developing advanced nanofiltration for toxin removal, miniaturized wearable dialyzers, real-time infection and clotting sensors, cell-based implantable dialyzers, and regenerative kidneys.

The excitement for Phase I spurred the launch of Redesign Dialysis Phase II, which challenges participants to build prototype solutions, or solution components, that replicate normal kidney functions or improve dialysis access. KidneyX will award up to three winners \$500,000 each in Phase II. Submissions are due by Friday, January 31, 2020, and innovators are encouraged to visit KidneyX.org.

Having experienced stagnation in innovation in kidney care for decades, the kidney community must recognize that this battle cannot be fought alone. AAKH is shining a spotlight on kidney disease. There has been an increase in news coverage on the plight of kidney care, and a public awareness campaign (called for in the EO) will also raise the profile of kidney health. The current focus on kidney disease, failure, and health provides an opportunity to attract creative minds in the fight against kidney disease, not just the next generation of clinicians and researchers but innovators from diverse disciplines.

With the kidney community uniting, and the full support of the federal government, ASN is optimistic about the innovation on the horizon for patients and about the future of the specialty. ■

Ryan Murray is ASN research advocacy specialist and Molly O'Neill is ASN KidneyX coordinator.

Time on Dialysis

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hood of becoming pregnant than those on hemodialysis. The duration of dialysis appeared to play a role as well: compared with women on dialysis for less than 1 year, women on dialysis for 1 to 3 years had a 21% lower likelihood of pregnancy, and women on dialysis for more than 3 years had a 33% lower likelihood of pregnancy.

“For patients undergoing dialysis, the study findings increase the awareness regarding incidence of pregnancy

and factors associated with it,” Shah said. “This information will help them in shared decision-making regarding management of their reproductive health.”

Shah noted that the racial/ethnic differences uncovered in the analysis should be a focus of future research. “The real reasons for these differences remain unknown,” she said. “We were also not able to determine the differences in unintentional and intentional pregnancies and whether level of education was associated with likelihood of pregnancy.”

An unknown pregnancy outcome in 31% of the women is an important limitation of the study, said Giordina Piccoli, MD, of the University of Torino, Italy.

“The study basically says that pregnancies are much more frequent on dialysis than previously thought, and this, from my optimistic point of view, may be a good message; however, when we dissect the paper, we find that pregnancies more often occur in poor and Hispanic or black women, and we may suppose that these pregnancies are not the positive result of improved care, but the current disaster of lack of attention,” Piccoli said. “In this line, I have been almost shocked . . . to see that, according to the data only about one-third of the babies survived. This paper conveys a fundamental message: pay more attention to women on dialysis and pay more attention to their pregnancies.” ■