

THE AMERICAN SOCIETY OF NEPHROLOGY

UNITED STATES SENATE COMMITTEE ON APPROPRIATIONS

WRITTEN TESTIMONY IN SUPPORT OF INCREASED FEDERAL INVESTMENTS TO SPUR INNOVATIVE KIDNEY DISEASE TREATMENTS

April 23, 2014

The American Society of Nephrology (ASN) is the world's largest kidney health professional organization in the world. Representing nearly 15,000 scientists, physicians, nurses, and other healthcare professionals in more than 110 countries, ASN leads the fight against kidney disease. Kidney disease is the eighth leading cause of death in the United States. It is a silent killer that destroys lives and families, placing a staggering burden on public health, resources, and society. Most of the more than 20 million Americans with kidney disease do not know they have it until late in the disease's progression, as kidney disease does not exhibit symptoms in the early stages. As such, they are at high risk to progress to kidney failure.

Today, the nearly 450,000 Americans whose kidney disease has progressed to complete kidney failure rely on the Medicare End-Stage Renal Disease (ESRD) Program for lifesaving dialysis. The ESRD Program is the only federal health entitlement program that provides coverage regardless of age. Caring for people with kidney failure costs Medicare nearly \$35 billion annually. Patients with ESRD account for less than 1% of the Medicare population but their care constitutes 7% of the program's budget. Again, all Americans, regardless of age, income, or eligibility for any other federal program, qualify for coverage under the Medicare ESRD Program.

This automatic eligibility for Medicare distinguishes kidney disease from any other aspect of federal health-related spending. When it comes to the ESRD Program, the federal government is already "all in" and essentially shouldering nearly 100% of the cost of dialysis for every American with kidney failure. We must work together to innovate, to continually improve care, to help the millions of kidney patients become more productive citizens, and to contain the costs of the program. We must incentivize the development of therapies that give the ESRD Program greater value for the taxpayers' contribution in terms of lower expenditures on care and better outcomes for patients.

That is why kidney research supported by the National Institutes of Health (NIH), Department of Veterans Affairs (VA) research program, Agency for Healthcare Research and Quality (AHRQ), and Department of Defense (DOD) research program, is so essential. A better understanding of how to prevent kidney disease and improve care is the best way to reduce the burden of kidney disease.

Research supported by these agencies and programs has led to innovative changes in care that improved patients' lives. But since the inception of the ESRD program, there

have been no revolutionary or fundamental advances in improving the clinical outcomes of Americans on dialysis or in increasing the cost-effectiveness of this therapy. Dialysis and kidney care have not advanced at the same pace as treatments for other life-threatening chronic illnesses, despite the significant annual cost to Medicare of providing this lifesaving care.

Most people with kidney failure rely on thrice-weekly, in-center dialysis—a draining and time-consuming process. Half of the patients who start dialysis die within three years, and nearly 6,000 people die waiting for a kidney transplant annually. Meanwhile, federal investments in research have led to remarkable advances in treatments and survival rates of other chronic illnesses that allow afflicted Americans to live normal and full lives.

Granted, there have been some, albeit, incremental therapeutic advances in kidney care. Dialysis machines have become smaller, computerized, and more portable so that some patients can dialyze at home. However, patients still endure getting stuck with needles and having their blood filtered for an average of 12 hours a week. This reality is in stark contrast to dramatic advances for other diseases. We have developed insulin pumps that automatically deliver accurate insulin doses, implantable defibrillators that shock a heart back to function, and robotic surgery to minimize hospital stays and pain after gallbladder and prostate surgery, to name just a few.

History proves that federal investments in research are the best way to catalyze innovation that improves patients' lives and brings much-needed alternative therapies. These advances in biotechnology—insulin pumps, arrhythmia detectors, and robotic instruments for surgery—have all improved quality of life for patients with diabetes, heart disease, and cancer.

Yet kidney research has been underfunded compared to other diseases and the public health burden. At approximately \$650 million per year, total federal funding for kidney research is equivalent to less than 1% of the total \$77 billion cost to Medicare for the care of patients with kidney disease. Increased federal investments in kidney research are needed to improve care and keep people off of dialysis, which would result in significant savings to Medicare.

Beyond bolstering traditional funding streams for NIH, VA, AHRQ, and DOD kidney research, federal prize competitions are another great mechanism for spurring scientific and technological breakthroughs. While prize competitions are not a replacement to the traditional investigator-initiated model, they may complement the model and help fill gaps where innovation is limited—such as kidney care.

ASN is working on a number of fronts to promote innovation in the kidney space, to better prevent kidney failure that requires dialysis in the first place, and to make dialysis a more effective, efficient process for those who do progress to kidney failure. For example, ASN partnered with the Food and Drug Administration (FDA) to establish the Kidney Health Initiative in September 2012.

The Kidney Health Initiative has 65 members, from ASN and the FDA to other health professional organizations and patient groups, to biotechnology, pharmaceutical, and medical device companies, to dialysis providers and startups. The goal of the Kidney Health Initiative is to provide a platform to increase innovation in drugs, devices, biologics, and food safety to improve the lives of millions of people with kidney disease. It is clear from the number of partners in this initiative that the interest in improving kidney care is broad.

ASN believes federal investments in medical research—through both increased funding for NIH, VA, AHRQ, and DOD kidney research, as well as through strategic opportunities in prize competitions in diseases where innovation has been particularly absent, are powerful and important tools to spur development of kidney therapies that are more efficient and cost-effective than current options and would improve the lives of hundreds of thousands of Americans saved by the Medicare ESRD Program as well as the millions of Americans at risk for kidney failure.

Thank you for the opportunity to provide testimony. Should you have any questions or wish to discuss kidney research, prize competitions, or ASN in more detail, please contact ASN Manager of Policy and Government Affairs Rachel N. Meyer at (202) 640-4659 or rmeyer@asn-online.org.

ABOUT ASN

The American Society of Nephrology (ASN) is a 501(c)(3) non-profit, tax-exempt organization that leads the fight against kidney disease by educating the society's nearly 15,000 physicians, other healthcare professionals, and scientists sharing new knowledge, advancing research, and advocating the highest quality care for patients. For more information, visit ASN's website at www.asn-online.org.