

**Written Testimony – House Space, Science and Technology Committee
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Chairman Smith, Ranking Member Johnson, and Members of the Committee, my name is Dr. Sharon Moe, and I am the President of the American Society of Nephrology, better known as ASN. I'm a nephrologist, or kidney doctor, in Indianapolis, Indiana and Professor of Medicine, and the Director of the Division of Nephrology in the Department of Medicine at the Indiana University School of Medicine. I thank the committee for calling this hearing to discuss the role of prize competitions in promoting innovation, and I appreciate the opportunity to testify before you today.

With nearly 15,000 physicians, scientists, 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 remain unaware of its presence; these patients are at high risk to progress to kidney failure that requires dialysis or transplantation.

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 or disability. 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 care from any other aspect of health-related spending in the federal government. When it comes to the ESRD program, you are 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.

When the ESRD Program began in 1972, innovative changes in care improved our patients' lives. But over the last 25 years, there have been too few advances in improving the clinical outcomes of Americans with kidney failure and increasing the cost-effectiveness of kidney care. Dialysis and kidney care have not advanced at the same pace as treatments for other life-threatening chronic illness, despite the significant annual cost of providing this lifesaving care. Most people with kidney failure rely on thrice-weekly, in-center dialysis—a time-consuming process that often fails to restore patients to full-time careers.

Dialysis, while keeping patients alive, does not come close to replacing normal kidney function. Patients on dialysis do not regain their healthier lives. The federal government pays \$35 billion a year on dialysis care. Don't patients and taxpayers deserve progress in treatment that parallel advances in other diseases? That's why a prize competition in

kidney innovation is so critical to raise the stakes for innovative technologies to be developed, and that's why I'm testifying today.

A prize competition is what is needed to drive the health sector to innovate and reduce dependency on the current form of dialysis provided by the ESRD program. If Congress signals to the private sector that you want alternatives to the forms of dialysis currently covered by the ESRD program, then I believe companies, investors, and inventors will produce life-changing and cost-saving technologies. The knowledge is available to invent alternatives such as a bioengineered kidney or other technologies that don't simply make different machines, but instead revolutionize kidney replacement therapy altogether.

My patients are constantly asking for an alternative to dialysis as the thought of being hooked up to a machine three times a week is terrifying. I have a 48-year-old patient who epitomizes the need for innovation in kidney care. My patient has kidney damage that was the result of radiation therapy for his now-cured cancer. His kidney disease has slowly progressed and, as soon as he was eligible, we placed him on the transplant wait list along with 99,970 other Americans. My patient did everything he could to slow the progression of the disease: he took his medications, kept all his appointments, and even participated in every possible clinical research study I suggested. But, his kidney disease still progressed to kidney failure.

My 48-year-old patient is deathly afraid of needles, and when he finally started dialysis, he had to take medications to tolerate getting stuck with large needles three times a week. He tried dialyzing at night so he could keep working full time, but he felt too sick to function at work and had to go on disability. Twice he was called for a transplant, and both times something was wrong with the kidney and he did not get a transplant. He is now dialyzing in a unit closer to his home under the care of another physician.

A few weeks ago, he sent me an email that said, "I can't take it anymore. I feel bad all the time. I can't work. I thought dialysis was a bridge to transplant, and it seems like the transplant will never happen. I would like to stop dialysis. Will you be my doctor while I die?"

He went from working full time to contemplating death as a better option than dialysis. Surely we can do better. I am frustrated that I have no other options for this patient and that the options I do have for him have not significantly advanced since I became a nephrologist.

Since I started caring for patients with kidney disease 25 years ago, the therapeutic developments have been minimal, especially compared to the dramatic therapeutic advances for other chronic diseases. For example, 25 years ago, patients with abnormal heartbeats were at risk of dying suddenly. Now we have technologies to test specific parts of the heart to understand where the abnormal beats come from. We also have the technologies to fix these abnormalities and small devices placed on the heart called implantable defibrillators that sense abnormal heartbeats and deliver a lifesaving shock .

25 years ago, patients with prostate cancer had major abdominal surgeries requiring long hospital-based recovery stays. They were often left with impaired sexual and

urinary function. Now, surgeons perform robotic surgery, leaving just with three small holes in the belly and a patient who can return home complication-free in two days.

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.

In the last 25 years, we have made the dialysis machines smaller and computerized, and we have made the tubes and dialyzers better. The smaller machines have made them more portable so that dialysis can be done at home, but these changes are incremental. Patients still get stuck with two needles, and have their blood run through a filter. This basic dialysis technique has not changed in 25 years. Our kidneys function 24/7; most patients get dialysis 12 hours a week in outpatient centers.

What has changed is that more and more patients need dialysis, increasing the costs of the ESRD program to the federal government. It is time for you to make the statement that we need innovation in kidney care. That is what a prize competition could do for patients, taxpayers, and health professionals, including the 15,000 ASN members.

I feel strongly that current scientific knowledge in the understanding of the kidney is at a level that makes such life-altering innovation a real possibility. I firmly believe American ingenuity is ready and willing to take this basic knowledge and turn it into a transformative, cost-saving technology that offers real hope for a better life to patients suffering through the current consequences of dialysis. Together, we can offer hope to the 20 million Americans with kidney disease who fear dialysis is in their future.

A prize competition that helps harness the power of the private sector can spur the scientific and technological breakthroughs to deliver improved technology for kidney replacement therapy. The legislative language in the FIRST Act (HR 4168) would pave the way for such an incentive, as well as other important scientific prize competitions, by providing the guidance that federal agencies need to make the competitions a reality.

Currently, the encouragement to innovate in dialysis therapies is limited, because we think of dialysis as saving lives. While obviously a laudable accomplishment, we need to recognize that the quality of these lives is poor and thus alternative therapies are needed. In part, innovation is limited due to the lack of competition among payers in the dialysis market. The recent implementation of a fully bundled payment for dialysis care has also exacerbated the absence of market forces driving innovation.

My patients don't feel good on dialysis and want an alternative. But, it is challenging for such patients to advocate for innovation and for the development of better therapies. They cannot miss the lifesaving—but time-consuming and exhausting—dialysis treatments. They are often sicker than patients with other chronic diseases, making it hard to advocate for more research and innovation. This challenge is another reality that highlights how a prize competition could uniquely fill a gap to spur much-needed innovation in kidney care.

Historically, dialysis was thought of as a bridge to kidney transplantation. However, the increase in the number of patients with kidney disease without an increase in the number of available organs has left patients waiting for a transplant for years, often feeling miserable, like my 48-year-old patient. In fact, most patients die on dialysis

waiting for an available kidney. We need to transform dialysis, or prevent the need for dialysis, so that patients can return to healthier and more productive lives. This reality is a prime challenge for a prize competition to help tackle: by drawing a broader, more diverse group of inventors, scientists, and investors beyond the traditional kidney community to innovate and help find alternatives to dialysis, we can work together to dramatically increase the likelihood of real innovation in kidney replacement therapy. Such advancements have been a long time coming.

Beyond its robust support for the prize competition provisions in the FIRST Act, 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 Association in September 2012 to establish the Kidney Health Initiative.

The Kidney Health Initiative has 65 members, from ASN and 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 that a prize competition is another powerful lever that could significantly spur development of a novel kidney replacement therapy that is more efficient and cost-effective than current therapies and makes patients feel better. Such a competition could help mobilize the private sector to facilitate meaningful innovation to address one of the costliest challenges our government faces today—and to 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.

I appreciate the opportunity to testify and welcome any questions you might have.