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Testimony of John P. Butler
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Thank you Chairman Buchanan, Ranking Member Doggett, and Members of the Health Subcommittee for holding this important hearing on "Improving Kidney Health Through Better Prevention and Innovative Treatment." My name is John Butler, and I am the President and Chief Executive Officer of Akebia Therapeutics, a biotechnology company based in Massachusetts that is dedicated to developing innovative treatments for patients with kidney disease. Thank you for the opportunity to testify today on this very timely topic.

To quote a former Director of the Centers for Disease Control and Prevention (CDC), Dr. Robert Redfield, in a recent article, "Chronic disease is the central public health challenge of our time, and kidney disease sits squarely in the middle." Kidney disease affects more than 37 million Americans and has tremendous consequences to the clinical outcomes of patients and cost to the nation's health care system. In fact, the numbers are staggering.

Each year, the Medicare program alone spends about $150 billion for beneficiaries with chronic kidney disease and kidney failure. Most patients are unaware they have the disease, despite the fact that it can be detected through routine lab testing. All too often, patients' first interaction with the disease is in the hospital emergency room, when they are put on life-saving dialysis and then face five-year survival rates that are well below 50% -- worse than most cancers. The more than 500,000 Americans who progress to kidney failure spend at least 12 hours a week receiving maintenance dialysis. Yet, the protocols for dialysis care have remained largely unchanged since its introduction over 50 years ago.

Although innovation in many areas of science has been transformative, there has been little innovation in dialysis, prompting nephrologists to call dialysis a profound "innovation desert." My fellow panelist, Dr. Suzanne Watnick, a preeminent American nephrologist, used this phrase in a recent article in *Health Affairs* on her assessment of what is wrong in dialysis care in the U.S. As Dr. Watnick has articulated, rather than a lack of scientific imagination, it is largely the delivery system – including incentives and disincentives created by Medicare payment policy-- that has led to stagnant care for dialysis patients.

In 1972, Congress established a unique federal entitlement allowing every individual with end stage renal disease (ESRD) to become Medicare eligible, regardless of age,

disability or income. The legislation marked the first time that individuals were allowed to enroll in Medicare based on a specific medical condition. Since enactment of the legislation, Medicare has become the primary source of coverage for almost 80% of all dialysis care.

Congress has enacted a number of changes over the years, most notably the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which took effect in 2011. MIPPA created a bundled payment system that provides a flat, capitated payment for each dialysis session, currently about $280, which includes staffing, dialysis equipment, laboratory tests, drugs and other overhead costs. Although the bundled payment has sharply constrained costs, it has resulted in cost shifting to other parts of Medicare, such as increased hospitalization of patients, and reduced access to care.

A significant deficiency of MIPPA is the lack of a mechanism in the system to pay for the adoption of new technology. A flat "base rate" per dialysis session is merely updated by price proxies annually, minus a "productivity adjustment," resulting in static payment that has failed to even keep up with general medical inflation incurred by providers, much less to allow financial "headroom" to modernize care. Having no sustained payment for better drugs, equipment, devices and diagnostics, providers have initiated little change in how patients are managed.

Furthermore, the original cost inputs into the calculation of the base rate date back to 2007 – reflecting the dialysis cost paradigm from 20 years ago. It is no wonder that many in the kidney community who once viewed the 1972 Medicare eligibility as a "unique" benefit, now view the ESRD system that has evolved from that special entitlement as a unique disadvantage.

TDAPA and Post-TDAPA Challenges

The Centers for Medicare & Medicaid Services (CMS) tried to address the statutory deficiencies of MIPPA by creating a Transitional Drug Add-on Payment Adjustment (TDAPA) in 2020 to provide payment at the "average selling price" (ASP) for innovative drugs on top of the base rate, but only for two years. While well intended, the limited duration of the TDAPA period creates obstacles for the adoption of innovative therapies in dialysis settings. Two years is not sufficient time for dialysis providers to assess the value of a new treatment option for their patients, conduct pilots in their facilities, evaluate real-world impact, establish new protocols, engage in contracts, and educate clinical staff.

In addition, physicians are generally unwilling to prescribe a new drug, if they are concerned that patients will lose access once the TDAPA period ends, due to limitations in the dialysis facility's prescribing list or formulary. Dialysis organizations exercise significant control over prescribing of dialysis-related drugs and face their own financial pressures to allocate costs and resources.

Physicians affiliated with these organizations rarely have any discretion over what drugs are included on their facility's formulary. In addition, patients have little to no voice in this aspect of their care. CMS has previously asserted in rulemaking that "Nephrologists and ESRD patients make decisions about which drugs and biological products best serve the patients' needs".[1] This is, unfortunately, not the reality for dialysis patients or the nephrologists who provide them care.

In addition, CMS finalized in CY 2025 rulemaking a post-TDAPA reduced add-on that is unworkable and perverse. Based on the most recently available Medicare claims data, CMS takes total utilization of a new drug over a 12-month period. This number is multiplied by the current average sales price (ASP) for the drug and then divided by the total number of Medicare dialysis sessions nationwide. The result of this calculation is then discounted by 35%. The agency provides the reduced add-on to the base rate for each dialysis session, regardless of whether the new drug is utilized or not. After three years, no additional or sustained funding is provided.

The methodology for determining the amount and allocation of payments both dramatically underpays a facility that might want to provide the drug, while directing Medicare dollars to dialysis organizations that do not. This is because the post-TDAPA add-on is allocated by CMS to providers based on their respective number of Medicare fee-for-service dialysis sessions and not aligned with their patients' actual TDAPA drug utilization.

While building the cost of certain commoditized products that are common to all dialysis sessions into the base rate makes logical and economic sense, using the same process for payment of innovative new drugs during the post-TDAPA period, where implementation can vary widely across providers, does not.

This also creates a potential moral hazard where a financial benefit can be obtained by providers by denying access to these innovative products and "free-riding" on other provider's adoption to increase their revenues. The current structure actually creates a barrier to adoption and an incentive to reduce access post-TDAPA, by rewarding providers that choose to restrict patient access to the innovative products.

Experience to Date

There have been only four innovative dialysis drugs approved by the Food and Drug Administration (FDA) and granted TDAPA by CMS since its inception. The first two drugs reached less than 1% of dialysis patients during their TDAPA periods, despite significant unmet need in their therapeutic areas.

[1]Vol. 89 Federal Register 89084, November 12, 2024, p. 89124

Korsuva (difelikefalin) is the first and only FDA-approved therapy for CKD-associated pruritus, a condition that affects approximately 35 percent[2] of ESRD patients. Korsuva received breakthrough status from the FDA, which is awarded to investigational products that demonstrate significant improvement over existing therapies for serious or life-threatening conditions. The condition is characterized by intense and relentless itching, skin lacerations, scarring and infections, all of which diminish patient quality of life. The cost to the Medicare system of treating infections and hospitalizations related to pruritus can be significant.

During its TDAPA period, nephrologists were unwilling to prescribe Korsuva, knowing they would have to take patients off the product after its two-year TDAPA, which ended on March 31, 2024. Even physicians who served as principal investigators in the clinical trials and had directly observed the drug's efficacy, felt it would be "unethical" to provide relief for patients during the drug's TDAPA period, if forced to withdraw treatment due to lack of payment in the post-TDAPA period.

Now in that post-TDAPA period, dialysis organizations are unwilling to make Korsuva available because of the inadequate Medicare reimbursement under CMS' flawed post-TDAPA policy. CMS pays $0.11 per dialysis session for a product that costs facilities about $27 per session. This means a typical dialysis facility would have to receive that $0.11 from 250 patients to have the resources to support a single patient with Korsuva, when an average facility census is 60-80 patients. Although the product continues to be available for purchase under an agreement with another company, Cara Therapeutics, the developer of Korsuva, ceased operating as an independent company.

Jesduvroq (daprodustat), the second TDAPA drug, was a first-in-class drug to treat anemia in dialysis patients. GSK, the developer of Jesduvroq, removed the drug from the U.S. market at the end of 2024 – before even finishing the product's TDAPA period, likely recognizing that the bundle's reimbursement is inadequate to support continued patient access. GSK has abandoned further dialysis research.

The failure of the first two TDAPA drugs to reach the patients for whom they were developed demonstrates that TDAPA has not achieved its intent. Without changes, access to the two current TDAPA drugs could be compromised as well. Not only could patients lose potential clinical benefits, but the Medicare system could lose significant savings from reduced hospitalizations and other downstream costs associated with the availability and use of these two treatment options.

DefenCath® (taurolidine) is the first and only antimicrobial catheter-lock solution approved by the FDA under the Limited Population Pathway for Antibacterial and

[2] Sukul N, Karaboyas A, Csomor PA, Schaufler T, Wen W, Menzaghi F, Rayner HC, Hasegawa T, Al Salmi I, Al-Ghamdi SMG, Guebre-Egziabher F, Ureña-Torres PA, Pisoni RL. Self-reported Pruritus and Clinical, Dialysis-Related, and Patient-Reported Outcomes in Hemodialysis Patients. Kidney Med. 2020 Nov 21;3(1):42-53.e1. doi: 10.1016/j.xkme.2020.08.011. PMID: 33604539; PMCID: PMC7873756.)

Antifungal Drugs, and is also designated as a Qualified Infectious Disease Product. This important innovation is indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter. CRBSIs occur at a startling rate in the first several months of dialysis and mortality rates are 25%. These life-threatening infections are a major driver of mortality and hospitalization among dialysis patients.

Clinical studies have demonstrated a clinically and statistically significant reduction of 71% in CRBSIs using DefenCath[3]. Providers have shown CorMedix real world data which far exceeds these results in actual practice, as well as captured data on the meaningful reduction in downstream hospitalizations. These results, when applied to the billions of dollars spent by Medicare on treating CRBSIs and subsequent hospitalization, could improve clinical outcomes and generate significant Medicare cost savings.

VAFSEO® (vadadustat), Akebia's product, is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least three months. The unique mechanism of action (MOA) was built on Nobel Prize-winning science in 2019. This novel drug provides an important alternative to pre-existing erythropoiesis-stimulating agents (ESAs). As an oral anemia treatment, it provides a significant practical advantage for patients on home dialysis making it important to the goal of expanding home modalities, as well as offering simple titration and fewer dose modifications for patients choosing any dialysis modality.[4]

The clinical evidence and early data generated since launch of VAFSEO shows significant potential value for patients with ESRD and the Medicare program. A post-hoc analysis of the pivotal Phase 3 INNO$_2$VATE trial in patients undergoing dialysis showed a statistically significant reduction in the composite endpoint risk of death and hospitalization with VAFSEO compared to darbepoetin alfa (an ESA).[5] In addition, a cost comparison analysis of the data showed VAFSEO has significant impact on the cost of hospitalization versus darbepoetin – about an 8% reduction in hospitalization rate, a 16% reduction in hospital days, and a 15% reduction in Medicare hospitalization costs. Nearly $2 billion in annual savings to Medicare could be achieved if all eligible beneficiaries received VAFSEO versus standard of care.[6]

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[3] LOCK IT-100, Agarwal, Anil K.1, a; Roy-Chaudhury, Prabir2; Mounts, Phoebe3; Hurlburt, Elizabeth3; Pfaffle, Antony3; Poggio, Eugene C.4. Taurolidine/Heparin Lock Solution and Catheter-Related Bloodstream Infection in Hemodialysis: A Randomized, Double-Blind, Active-Control, Phase 3 Study. Clinical Journal of the American Society of Nephrology ():10.2215/CJN.0000000000000278, September 06, 2023. | DOI: 10.2215/CJN.0000000000000278

[4] Vafseo's Full Prescribing Information, including BOXED WARNING and Medication Guide, is available at www.vafseo.com/pdf/prescribing-information.pdf.

[5] Chertow G, et al. Poster Presented at: American Society of Nephrology (ASN) Kidney Week 2025; November 5-9, 2025; Houston, TX.

[6] Luo W, et al. Poster Presented at: Annual Dialysis Conference 2026; February 26-March 1, 2026; Kansas City, MO.

DefenCath and VAFSEO are continuing to demonstrate potential for significantly improved health outcomes for dialysis patients, and both are currently receiving TDAPA, which will expire during the year. The short duration of only two years has not been sufficient, however, to facilitate provider utilization and patient access broadly. The structure of the post-TDAPA add-on payment may disincentivize dialysis providers to maintain patient access to these drugs, despite very positive clinical results.

Further, the lack of sustainable reimbursement has chilled investment in new research and development for ESRD patients. Investors, both public and private, look to invest in companies and products where the reimbursement path is clear after successful clinical trial development. There are many options for them other than products covered by the ESRD PPS and TDAPA. Until this changes, dialysis patients will continue to be left behind in this era of unprecedented innovation in medical care.

Legislative Solution

Given the urgency of dialysis patients losing access to new innovative products in real time due to the lack of sustained funding, Akebia urges the Subcommittee to act on important legislation that was introduced by two of its members, Congresswomen Carol Miller (R-WV) and Terri Sewell (D-AL). As long-term champions for kidney patients, their legislation, H.R. 6214, the Kidney Care Access Protection Act (KCAPA), would take concrete steps to address the lack of access to innovation as well as improve screening, prevention and disease education.

While this legislation is not a complete solution to the serious innovation challenges facing dialysis care, it represents a critical and practical step that would improve patient access to new therapies today while Congress continues to examine longer-term reforms.

Section 101 would establish a sustainable pathway for new drugs and devices in the ESRD PPS bundle. First, it would extend the TDAPA adjustments from two to three years, aligning it with drug pass-through systems in other parts of Medicare. Three years of separate payment would provide the time necessary for physician and provider adoption of a novel drug, and allow for collection of robust data upon which to accurately establish the post-TDAPA add-on amount.

Medicare allows three years for a drug to receive a pass-through payment under the Outpatient Hospital Prospective Payment System (OPPS) as well as under the Inpatient Hospital Prospective Payment System (IPPS) through the New Technology Add-on Payment (NTAP) adjustment.

Second, it would calculate the post-TDAPA add-on based only on patient treatments where the drug is actually used, and likewise, pay the add-on only for patients where the drug is actually used. We believe that by changing the distribution of the same

pool of expenditures by targeting payment to a product's actual use, patients would get needed therapies with little to no impact on overall Medicare spending, and that it would be administratively simple to implement.

Dialysis patients would benefit immediately from these two modifications, and they would also stabilize the ESRD program and help achieve the goals of the Administration's "Advancing American Kidney Health" initiative. In 2019, the Department of Health and Human Services (HHS) committed to the goals of providing more treatment options for patients, increasing efforts to prevent kidney disease, and encouraging transplantation. The initiative recognized that there has been little innovation in the treatment of kidney disease in comparison to other diseases. Aligning the ESRD payment system with a meaningful, sustained reimbursement pathway for innovative therapies would help further the goals of improving health and quality of life.

I have worked in the field of kidney disease for over 35 years, and firmly believe that we can, and must, do more to improve the lives of these patients. I am grateful for the opportunity to share my thoughts with the Subcommittee and appreciate your attention to these important issues. Akebia looks forward to working with the Subcommittee on policies to expand prevention, encourage innovation, and ensure that breakthrough therapies reach the dialysis chair where they can improve, and save, lives.