

August 16, 2015

Francis S. Collins, MD, PhD  
Director, National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Collins:

On behalf of the American Society of Nephrology (ASN) and the more than 15,000 nephrologists, scientists, and other healthcare professionals the society represents, thank you for the opportunity to provide comments on the proposed National Institutes of Health (NIH) framework for developing an agency-wide five-year strategic plan. ASN is pleased to offer the following comments for your consideration.

Kidney diseases affect more than 20 million Americans, are the 9<sup>th</sup> leading cause of death in the United States, and are potent risk factors that independently associate with many of the leading additional causes of mortality, including heart disease, diabetes, hypertension, and stroke. Kidney diseases are also one of the most economically costly conditions in the United States.

As NIH considers its strategic planning for the next few years, ASN suggests that the agency emphasize developing budget requests for Congress that distribute research funding based on 1) the federal cost of care, 2) disease burden, including disproportionate burden on under-represented minorities, and 3) opportunities to improve overall public health and the federal cost of care.

Currently, NIH investments in kidney research (\$585 million) are less than 1% of total Medicare costs for patients with kidney diseases (\$80 billion). In fact, costs of care for patients with kidney failure alone—the only health condition for which Medicare automatically provides coverage regardless of age or disability—are more than NIH's entire budget (\$35 billion vs. \$30 billion annually). Despite the medical and economic burden of kidney diseases, NIH invests less per patient in kidney research than many other diseases (see Table 1).

ASN recommends that NIH take into account the cost of care to the federal government as it considers disease funding allocation in the new strategic plan. Besides examining the cost of various diseases as a percent of the Medicare budget versus population affected, NIH may also consider examining the most costly chronic disease dyads and triads as identified in the "Chronic Conditions among Medicare Beneficiaries Chartbook" online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook.html>.

Clinical advances in kidney care in the past 25 years have been sporadic, paling in comparison to the consistent advances made in other diseases such as HIV and cancer therapies that have improved treatment and patient outcomes. It is not an exaggeration to note that patients with kidney failure are treated much the same way today as they were when Medicare began universal coverage of dialysis treatment in 1972. Most patients still require multiple dialysis

sessions a week—three treatments for three to four hours at a time—which are often both emotionally draining and physically exhausting and, while life sustaining, fail to optimize quality of life for our patients.

Patients on dialysis have other doctor visits in between treatments for their comorbidities and are frequently admitted to the hospital. As a result, only 1 in 5 dialysis patients work, and many receive Social Security Disability Insurance benefits. On top of that, outcomes for patients with ESRD are grim. Fifty percent of patients with kidney failure die within three years of initiating dialysis, and most people who are wait-listed for a kidney transplant, the optimal therapy for most of patients, die before receiving a donor organ.

Furthermore, kidney diseases disproportionately affects African Americans, Hispanics, and other under-represented minority populations compared to Caucasians. For example, African Americans make up approximately 13% of the United States population but account for 32% of Americans with kidney failure. Hispanics and Native Americans are twice as likely as Caucasians to develop kidney failure.

The above facts underscore ASN's recommendation that the disease burden is an important element that should influence how NIH allocates funding in its new strategic plan. Moreover, ASN suggests that NIH also consider prioritizing funding to study diseases with a disproportionate burden on racial/ethnic minority populations; investing in science to explain the causes of these disparities, and to develop targeted therapies to treat and prevent them, should be a national research priority.

Better and more cost-efficient treatments and therapies are desperately needed to slow or prevent progression of kidney diseases and improve care for all patients with kidney diseases. The good news is that in recent years there have been a number of exciting scientific discoveries in the kidney field that present opportunities to improve overall public health and have the potential to lead to a new generation of effective therapeutics.

One such example is the discovery of risk alleles in the APOL1 gene that are strongly associated with non-diabetic kidney diseases among African-Americans, a racial group at much greater risk for progressive kidney failure than Caucasians and other minorities. Improved understanding of the genetic origins of diseases opens the door to broadly-applicable, revolutionary therapies that provide hope at a population level. ASN encourages NIH to prioritize funding in a way that enables investigators to capitalize on scientific discoveries to produce new therapies in these and other areas that are likely to advance overall public health.

**In summary, ASN believes NIH should allocate funding based on disease burden, opportunities for improving overall public health, and the federal cost of care. These guiding principles and goals should be incorporated within the framework and subsequent strategic plan.**

Increases in the NIH budget have not kept pace with inflation and the agency has lost nearly 25% of its purchasing power since 2003. Moreover, there is no reason to believe the current trend is likely to change anytime soon given the federal government's long-term fiscal outlook. The consequences are well-known: grant application success rates are near record lows and the average age a first-time investigator is awarded her or his first research project grant is at a record high.

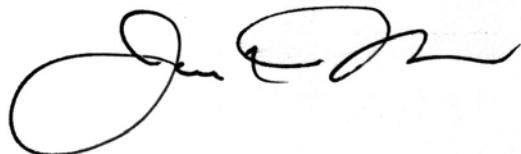
Cuts to NIH salary caps and efforts by NIH to spread funding further have forced universities and hospitals to absorb research costs, which many are not in a position to bear given current fiscal challenges. As a consequence, a number of universities and hospitals are restricting research grant applications and/or are shutting down research labs forcing promising young researchers (including those receiving NIH training awards) and highly productive senior investigators to leave research altogether. Researchers are ending their careers as a result, moving to industry where research may become proprietary, or moving overseas to pursue their work in countries where the research funding outlook is brighter.

Perhaps the greatest tragedy is the discouraging effect the funding crisis has had on young scientists who see their mentors and other leaders in their fields being forced to end productive research programs. These young scientists may not even try to open the door to a research career. This reluctance to plunge into research will compromise America's position as the global leader in research and the development of innovative treatments and cures for patients. ASN encourages NIH to ensure future funding strategies both support young investigators and create sustainable research career path opportunities in the long-term.

The current budget and funding challenges compel NIH to take a broad and systematic approach to evaluate how to improve the current funding structure. There is no better time to do this than at the start of the strategic planning process which will guide NIH into a future that all of us hope will be brighter and more promising for young scientists, patients with kidney diseases, and the health of all Americans.

Thank you very much for your consideration of ASN's recommendations. For questions about this letter, the burden of kidney diseases, or ASN, please feel free to contact me at (206) 744-4932 or [himmej@u.washington.edu](mailto:himmej@u.washington.edu).

Sincerely,



Jonathan Himmelfarb, MD, FASN  
President

**Table 1: NIH Research Funding by Disease<sup>1</sup>**

Disease (Prevalence)	2014 NIH Budget	Spending per Patient
<b>HIV/AIDS</b> (1 million)	\$2,978,000,000	\$2,978
<b>Cancer</b> (14 million)	\$7,957,000,000	\$568
<b>Heart Disease</b> (27 million)	\$1,645,000,000	\$61
<b>Kidney Diseases</b> (20 million)	\$585,000,000	\$29

<sup>1</sup> [http://report.nih.gov/categorical\\_spending.aspx](http://report.nih.gov/categorical_spending.aspx)