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Dear Members of the Obama Transition Team focused on the National Institutes of Health (NIH):

On behalf of the American Society of Nephrology-ASN—the world’s largest organization dedicated to the study, prevention, and treatment of kidney disease—thank you for the opportunity to provide insight on how the Obama Administration can enhance the research efforts of NIH.

Sustained Research Support

First and foremost, ASN encourages President-elect Barack Obama and Secretary-designate Thomas Daschle to support sustained and robust research funding for NIH. Since the doubling of the NIH budget between 1998 and 2003, NIH has failed to receive the funds necessary to sustain the momentum achieved by the doubling; once inflation is taken into account, the budget has declined each year since 2003. The cut in spending power limits the amount of research undertaken in US academic medical centers and research institutes, stifles innovation, and discourages a new generation of investigators from entering the research pipeline. ASN hopes President-elect Obama maintains his campaign promise to double federal funding for medical research at NIH over the next ten years.

In addition, ASN urges the new administration and Congress to consider the long-term trajectory of medical research when developing the federal budget. The process of researching, developing, and approving a new treatment may take up to two decades. An influx of funding one year will not yield automatic results in the next. In assessing whether NIH is effectively leveraging its financial input into medical discovery, and in turn, whether funding increases are necessary, President-elect Obama and Congress should consider the context in which the federal dollars are being spent.

In addition to identifying new methods of treatment and prevention to improve the long-term health of the nation, NIH research is an effective mechanism for revitalizing state and local economies, creating new jobs, and spurring private business. ASN encourages President-elect Obama to consider increasing NIH funding under an economic stimulus package. According to NIH, each funded research grant creates approximately seven jobs, which lead to a total of 350,000 jobs and over \$18 billion in wages in fiscal year 2007 alone.

Health Care Reform

ASN urges President-elect Obama to include support for medical research in any legislation addressing health care reform. In discussions with House and Senate staff, ASN has learned that health care reform will likely include programs that improve prevention and wellness. These efforts to improve health before disease strikes are incredibly important and will hopefully increase life expectancy and worker productivity as well as reduce the number of people stricken by disease, thereby limiting health care costs.

However, it is important to recognize that we know how to screen for disease because medical research identified which patients are at highest risk and what tools are needed to assess the earliest signs of disease. For example, while early kidney disease does not present obvious symptoms, researchers learned that a few simple tests—a blood test to estimate the level of remaining kidney function and a urine analysis to measure protein levels—can catch the disease in its early stages. Research also taught us that healthy diets and increased exercise limit the risks for heart disease, diabetes, and kidney disease, thereby halting the progression of disease.

Meanwhile, NIH is poised to uncover new medical responses that improve patient care, reduce medical errors, and stave off disease. Additional research in genomics will allow physicians to personalize treatments to individual patients to improve outcomes. Comparative effectiveness research will identify which drugs and biologics are most successful for various patient groups. If we are to be effective in true health care reform that improves health outcomes and mechanisms of care, the administration and Congress must provide the necessary support for medical research.

Support for the Next Generation of Investigators

ASN encourages the new administration and NIH to support the next generation of investigators. Restricted budgets have pitted experienced and junior investigators against one another for funding, thus limiting the amount of support available for the next generation of investigators. NIH should support junior investigators via enhanced mentorship (and

revitalized K award programs that reward and track mentorship), greater flexibility for investigators with family responsibilities, and additional support for first-time R01 recipients.

ASN believes that specific attention should be paid to encourage young physician-scientists to enter, and remain in, the research pathway. The percent of physicians engaged in research is declining and the loss of this unique group of investigators will likely have a deleterious effect on the translation of research into effective treatments and forms of prevention. ASN recommends expanding the loan repayment program to include physician-scientists engaged in all forms of disease-oriented research; exorbitant medical school debt often deters physicians from entering the research pathway. In addition, ASN suggests that NIH reconsider its US citizenship/permanent resident requirements for NIH training and mentored awards to physician-scientists. Current regulations limit access to an outstanding pool of physician-scientists trained outside of the US who could make positive contributions to our national research programs.

Health Care Disparities

NIH should take the lead on funding research that addresses why health and health care disparities exist as well as identifies treatments that benefit underrepresented populations. Health disparities are still rampant—African Americans with chronic kidney disease (CKD) are four times more likely to progress to kidney failure than Caucasians. When kidney transplantation is an option, African American patients also have substantially reduced graft survival rates than Caucasian patients and, sad to say, there is virtually no research into the cause. NIH should increase funding for research in health care disparities with increased attention on the role of biologic and non-biologic factors in creating disparities. NIH should also increase its support for underrepresented minority (URM) investigators. By improving diversity, NIH may also expand the workforce of disparities researchers as URM investigators are more likely to pursue such a pathway.

Research in Chronic Diseases

ASN urges NIH to place priority on research that addresses chronic disease and comorbidities. Chronic diseases are currently the leading causes of death in the United States, comprising 70% of all deaths, or 1.7 million lives, and accounting for 75% of the nation's \$2.4 trillion dollar health care costs. Patients are often stricken with numerous, interrelated diseases at once. More than 80,000 patients die annually from CKD, making the disease a leading cause of death in the United States. Yet, patients with diabetes and hypertension are at the highest risk for developing kidney disease. NIH needs to ensure that research studying one disease considers the various diseases that are associated with a diagnosis and contribute in an important way to the complications and outcomes of the disease. Particularly as NIH considers ways to resolve the obesity epidemic, it must consider how kidney disease, heart disease, and diabetes fit into the paradigm.

Clinical Research Infrastructure

ASN encourages NIH to support necessary infrastructure for disease-specific registries as well as multi-center clinical trials networks to better allow investigators to bridge the gap from the bench to the bedside. While academic institutions and NIH invigorate their clinical research enterprises, the rarity of many diseases and the interrelationship among disorders limits the number of patients available for each unique clinical trial. No single research center has sufficient prevalent study subjects or sustainable research infrastructure to recruit enough subjects for meaningful research. These deficiencies are amplified in the study of pediatric disease because of the greater rarity of disease and an exacerbated concern about patient protection in clinical trials. For example, CKD research has been limited due to a lack of effective infrastructure, resulting in many small, underpowered studies, but limited introduction of novel treatments. The value of kidney disease research will be enhanced with mechanisms that improve design and infrastructure to support meaningful trials and patient-based research.

Again, thank you for the opportunity to comment on the ways in which President-elect Obama, Secretary-designate Daschle, and the next NIH Director can enhance the research efforts at NIH. To discuss this letter in more detail, or if ASN can be of any assistance in the transition, please contact ASN Director of Policy and Public Affairs Paul C. Smedberg at (202) 416-0646 or psmedberg@asn-online.org.

Sincerely,



Thomas Coffman, MD
President