President Proposes Modest 2016 Budget Increases for NIH and NIDDK

By Grant Olan

On February 2, 2015, President Barack Obama released his proposed federal budget for Fiscal Year 2016 (October 1, 2015, to September 30, 2016), the starting point of the congressional budget-making process.

In his State of the Union address, the president made the case that the US has turned the corner on the economy and is now in a stable position. As such, the president is now asking Congress to make investments in government services—including research—that have been underfunded since Congress instituted deficit reduction measures earlier in the decade.

The president is specifically calling on Congress to raise the 2016 spending caps for defense and non-defense programs and to pay for the increases by cutting spending for inefficient government programs and reforming the tax code. As federal budget experts in Washington, DC, continue to observe, since all discretionary programs (defense and non-defense combined) constitute less than one-third of total federal spending, these programs are not the driver of U.S. debt.

Nonetheless, due to the deficit reduction measures, funding for discretionary programs as a percentage of the GDP is at a near record low and annual budgets for federal research agencies have not kept pace with increases in inflation. As a result, the National Institutes of Health's (NIH) purchasing power is shrinking, grant application success rates are at record lows, and the average age a first-time investigator gets their first research project grant (nearly 45 years of age) is a record high.

ASN is especially concerned about the funding environment for kidney research, which has been underfunded compared to other areas of research. And the trend continues: in his budget proposal, the president is requesting a 2.95% increase in the overall NIH budget, but just a 2.59% increase for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—the largest funder of kidney research in the world (Table 1).

"Considering that Medicare spends more on the cost of care for patients with end stage renal disease than the entire NIH budget ($35 billion vs. $30 billion in 2014), ASN believes more investments are needed in kidney research to slow or prevent the progression of kidney disease and develop better therapies to improve patient care and health, which could yield significant saving to Medicare, the federal government, and taxpayers," ASN Research Advocacy Chair Frank "Chip" Brosius said. "Total federal investments in kidney research are less than 1% of what it spends on the total cost of kidney care (about $650 million vs. $80 billion)."

"ASN is working with the research advocacy community (including Friends of NIDDK) in urging the president and Congress to raise the spending levels for discretionary programs and ensure parity between increases for defense and non-defense programs," continued ASN Public Policy Board Chair John R. Sedor, MD, FASN. "The society is specifically calling on Congress to provide NIH $32 billion and NIDDK $2.066 billion in 2016, as well as provide NIDDK an additional $150 million per year over the next 10 years on top of the current funding level for kidney research to spur innovation in this field, which has lagged far behind other areas."

Congress is currently working on a budget resolution instructing the House and Senate Appropriations Committees how much they can allocate for discretionary programs for 2016. Follow ASNAdvocacy on Twitter or check back here for updates.

Table 1
NIH and NIDDK Funding

	2015 Actual	President's 2016 Budget Request	% Change Over 2015 Actual
	Millions of Dollars		
NIH	$29,446	$29,446	2.95%
NIDDK	$1,889	$1,889	2.59%

	2015 Actual	ASN's 2016 Budget Requests	% Change Over 2015 Actual
	Millions of Dollars		
NIH	$29,446	$32,000	8.67%
NIDDK	$1,889	$2,066	9.37%

Industry Spotlight

New Drug for Type 1 and 2 Diabetes

The US Food and Drug Administration has approved Sanofi's new diabetes drug formulation Toujeo (insulin glargine injection, 300 U/mL). The drug, which may be used by patients with either type 1 or type 2 diabetes, is a once-daily long-acting basal insulin.

The new drug is a triple dose of the insulin glargine found in Sanofi's existing diabetes drug Lantus (100 U/mL). Designed to release insulin more slowly, Tuojeo was better at modulating nighttime hypoglycemia than Lantus, according to results from the EDITION clinical trial program. The EDITION trial evaluated the efficacy and safety of Toujeo compared to Lantus in more than 3500 adults with type 1 or type 2 diabetes, all with uncontrolled diabetes on their current therapy,

Toujeo is expected to be available in the United States in early April. In February, Lantus was to lose its patent protection. Analysts say that Sanofi, however, may have to work very hard to persuade Lantus users to make the switch to Toujeo.

Toujeo's clinical advantages are not found on US labeling, according to Fierce Biotech analyst Tim Anderson. Europe's different labeling rules allow the advantages to be noted.

In addition, Novo Nordisk's long-acting diabetes drug Tresiba is approved for use in Europe, creating a crowded marketplace for big diabetes drug companies, Reuters noted. While the FDA rejected a Novo bid for approval in February 2013 with a directive for more testing, Novo said it would submit interim results with an eye toward a potential launch in 2016.

Rockwell Wins Approval for Triferic

Rockwell Medical has won drug approval by the US Food and Drug Administration (FDA) for a new anemia drug, Triferic (soluble ferric pyrophosphate or SFP).

The results from two phase 3 clinical studies demonstrated that Triferic was effective in maintaining "hemoglobin during the treatment period in iron-replete patients with hemodialysis-dependent chronic kidney disease in the studies as conducted," according to FDA documents.

The drug could reduce the need for erythropoiesis-stimulating agents (ESAs). Motley Fool financial website highlighted data that showed a reduction of 30 to 37 percent in the need for ESAs when Triferic was used. "The impact of this on dialysis providers is enormous," Motley Fool wrote, and estimated that a 35 percent reduction in the $2 billion spent on ESAs annually would be about $700 million in savings.

Several industry analysts expect Triferic to change the way iron replacement therapy is given in dialysis patients. Triferic so far is the only iron replacement therapy that can be delivered through the dialysate solution. Triferic also is slowly infused and taken up by the body in a manner similar to dietary absorption, Seeking Alpha noted, qualities that may be bad news for earlier FDA-approved intravenous iron products for the treatment of iron deficiency anemia that require patient monitoring after administration.