ASN Discusses ESA Label Changes with FDA

When the Food and Drug Administration (FDA) changed the label on erythropoiesis-stimulating agents (ESAs) in July, ASN raised concerns about the modifications to the label in a letter to the administration. In this letter, ASN emphasized that health-care and disease and variable follow up. How low is it safe to let hemoglobin levels go? And would exceeding 11 g/dL generate risk, and is it necessarily the case in the event of an adverse event?

Given the confusion and alarm among the nephrology community regarding the changes, ASN was pleased that FDA suggested an in-person meeting to discuss the already-published label—a rare move for the agency. ASN Public Policy Board chair Tom Hostetter, MD, and Public Policy Board member Wolfgang Winkelmaier, MD, ScD, FASN, represented the society at the FDA, along with ASN Manager of Policy and Government Affairs Rachel Shaffer. The key points ASN’s contingent emphasized centered on the agency’s assertion that hemoglobin levels above 11 g/dL have conclusively been proven to increase risk of adverse events.

ASN emphasized that since adverse events were consistently observed in randomized groups targeting only hemoglobin concentrations >13 g/dL, no scientific data are currently available that would either justify dropping the previous hemoglobin target of 10–12 g/dL, or substantiate the statement of risk at 11g/dL (Table 1).

Debt Committee Urged to Protect Kidney Disease Funding

The Joint Committee on Deficit Reduction, or the “super committee” is without question the most talked-about—and feared and revered—entity in Washington, DC, this fall. Tasked by the Budget Control Act of 2011 with developing a plan by November 23rd to trim at least $1.2 trillion from the national debt over the next decade, the super committee’s job is daunting. However, the committee possesses no short age of options to meet that $1.2 trillion goal: everything is “on the table” for reductions. ASN is leading the way in making sure that funding affecting kidney patients and physicians is not among the reduced.

ASN identified the funding streams pertinent to kidney disease most likely to be eliminated by the committee’s search for programs to trim, and together with the American Society of Pediatric Nephrology (ASPNI) and the Renal Physicians Association (RPA) and with input from the super committee outlined the vital importance of their preservation for patient care, job preservation, and economic stability. “It’s critical that the survivors of the possible elimination of these programs, especially at this time,” said ASN Public Policy Board chair Thomas H. Hostetter, MD. “Our letter emphasizes that it’s not just a few, or even just doctors and patients, who benefit—it is every American whose job, community or local economy is affected by these issues.”

Discretionary workforce programs are considered to be among the most vulnerable. In the letter, ASN emphasized that decreasing federal support for physician training would result in a host of unintended consequences for patients and the nation’s healthcare workforce. The society urged the super committee to avoid any cuts to physician training programs, as this would increase the problem of Americans’ access to care, worsen the physician shortage already recognized by Congress, and endanger thousands of jobs. According to the economic consulting firm Tripp Umbach, cuts to graduate medical education at the nation’s largest teaching hospitals alone would trigger the elimination of over 3,700 jobs and the loss of $10 billion to the U.S. economy.

Similarly, ASN highlighted the crucial role the research activities funded through the National Institutes of Health (NIH), Agency for Healthcare Research and Quality, and the Veterans’ Administration play in maintaining the health of the U.S. population and the nation’s economy. Research provides enabling important medical discoveries, according to a 2010 study, investment in the NIH led to the creation of 487,900 new jobs and produced more than $68 billion in new therapeutic activity.

The letter also urged the super committee to account for the needs of ESRD patients, the most vulnerable of all Medicare patient populations, by maintaining funding for ESRD care at current levels and not subjecting ESRD care to possible payment reductions. It further encouraged the super committee to consider incorporating the “Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant” provision for famotidine into its recommendations to Congress, noting that this bipartisan legislation would save lives and protect Medicare’s investment in kidney transplants. ASN, ASPN, and RPA also advocated that at this juncture in particular, repeal and replacement of the flawed sustainable growth rate (SGR) formula would be the most appropriate step forward in the effort to preserve Medicare beneficiary access to care.

Looking Ahead

Should the bipartisan group fail to reach agreement on a plan to reduce the deficit, or if Congress fails to enact the committee’s recommendations, sequestration is automatically triggered. Spending cuts to the tune of 50 percent would be applied to all defense, non-defense discretionary, and mandatory spending. Exemptions exist for certain programs, including Social Security, Medicare, military retirement, unemployment insurance, and income programs. An across-the-board 2 percent cut to Medicare would go into effect. And as doubt grows regarding the committee’s ability to reach a bipartisan consensus, the 2 percent cap is increasingly looking like a bright spot for the patients and physicians affected by the Medicare program.

For programs other than Medicare, failure to achieve a plan that Congress can agree upon would potentially be devastating. The good news is that several members of the super committee, including Rep. Max Baucus (D-MT) and Rep. Chris Van Hollen (D-MD)—whose constituent the NIH in Bethesda, MD—have voiced their continued support for the NIH. “It would be very short-sighted to make cuts to NIH because the history has [sic] that the discoveries that they’ve come up with have helped to reduce costs because they’ve developed treatments to various diseases, so I’m very hopeful that we’ll be able to prove that very important national investment,” said Rep. Van Hollen in a recent interview.

Finally, it is significant that if the super committee is unable to develop a plan that Congress supports, the actual automatic cuts would not be implemented until January 2013. Conceivably, Congress would still have another year to devise a different plan or otherwise prevent the automatic cuts—something it has proven adept at pulling off before. For the time being, ASN will continue to urge the committee to reach agreement, while protecting certain key health training, research, and patient care programs. Join ASN in advocating for sensible protections for these programs by visiting ASN’s Legislative Action Center at http://capwiz.com/asn/home.

Policy Update
By Rachel Shaffer

Table 1
Available evidence from randomized controlled trials showing adverse cardiovascular outcomes in patients with CKD

<table>
<thead>
<tr>
<th>Target hemoglobin (g/dL)</th>
<th>Achieved hemoglobin (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>NHT</td>
<td>10</td>
</tr>
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<td>CHOIR</td>
<td>11.3</td>
</tr>
<tr>
<td>TREAT</td>
<td>&gt;9</td>
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* Not a hemoglobin target, but a threshold group; placebo group with darbepoetin rescue below a hemoglobin concentration of 9 g/dL. Adapted from Sem in Dial

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