

# Policy Update

## ASN, AAKP Join Forces to Advance Living Donor Protection Act

Kidney transplantation is the optimal renal replacement therapy for the majority of people with kidney failure—yet the nearly 110,000 Americans on the kidney wait list face significant barriers to receiving a transplant. The Living Donor Protection Act aims to eliminate some of these barriers and increase transplantation by strengthening and protecting the rights

of living organ donors.

A top priority for the ASN Public Policy Board, the Living Donor Protection Act was introduced in the US Senate as S. 2584 by Senators Mark Kirk (R-IL) and Kirsten Gillibrand (D-NY), and in the US House of Representatives as H.R. 4616 by Representatives Jerrold Nadler (D-NY) and Michael Burgess, MD (R-TX).

Building Congressional support and co-sponsorship for this important legislation will be the focus of ASN's annual Kidney Health Advocacy Day on Thursday, April 21, 2016.

In partnership with the American Association of Kidney Patients (AAKP), ASN Kidney Health Advocacy Day will bring nearly 50 patient and health profes-

sionals from around the country to Washington, DC, to meet with their members of Congress and ask for their support for the Living Donor Protection Act. The introduction of this bill and the April advocacy effort build on Kidney Community Advocacy Day 2015, when ASN convened 16 kidney patient and health professional organizations in Washington,

### VELTASSA™ (patiromer) for Oral Suspension

Brief Summary of Prescribing Information. Please see Full Prescribing Information for complete product information.

#### WARNING: BINDING TO OTHER ORAL MEDICATIONS

VELTASSA binds to many orally administered medications, which could decrease their absorption and reduce their effectiveness. Administer other oral medications at least 6 hours before or 6 hours after VELTASSA. Choose VELTASSA or the other oral medication if adequate dosing separation is not possible [see Warnings and Precautions and Drug Interactions].

#### INDICATION AND LIMITATION OF USE

VELTASSA is indicated for the treatment of hyperkalemia.

**Limitation of Use:** VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action

#### CONTRAINDICATIONS

VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components [see Adverse Reactions].

#### WARNINGS AND PRECAUTIONS

**Binding to Other Orally Administered Medications** VELTASSA binds many orally administered medications, which could decrease their gastrointestinal absorption and lead to reduced efficacy. Administer other oral medications at least 6 hours before or 6 hours after VELTASSA. Choose VELTASSA or the other oral medication if adequate dosing separation is not possible [see Drug Interactions].

**Worsening of Gastrointestinal Motility** Avoid use of VELTASSA in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because VELTASSA may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies.

**Hypomagnesemia** VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA [see Adverse Reactions]. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels on VELTASSA.

#### ADVERSE REACTIONS

The following adverse reaction is discussed in greater detail elsewhere in the label:

- Hypomagnesemia [see Warnings and Precautions]

**Clinical Trials Experience** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of VELTASSA cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice. In the safety and efficacy clinical trials, 666 adult patients received at least one dose of VELTASSA, including 219 exposed for at least 6 months and 149 exposed for at least one year. Table 1 provides a summary of the most common adverse reactions (occurring in  $\geq 2\%$  of patients) in patients treated with VELTASSA in these clinical trials. Most adverse reactions were mild to moderate. Constipation generally resolved during the course of treatment.

**Table 1: Adverse Reactions Reported in  $\geq 2\%$  of Patients**

Adverse Reactions	Patients treated with VELTASSA (N=666)
Constipation	7.2%
Hypomagnesemia	5.3%
Diarrhea	4.8%
Nausea	2.3%
Abdominal discomfort	2.0%
Flatulence	2.0%

During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of VELTASSA were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%). Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated with VELTASSA in clinical trials. Reactions have included edema of the lips.

**Laboratory Abnormalities** Approximately 4.7% of patients in clinical trials developed hypokalemia with a serum potassium value  $< 3.5$  mEq/L. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value  $< 1.4$  mg/dL.

#### DRUG INTERACTIONS

No formal drug interaction studies have been conducted in humans.

In *in vitro* binding studies, VELTASSA was shown to bind about half of the oral medications that were tested. Binding of VELTASSA to other oral medications could cause decreased gastrointestinal absorption and loss of efficacy when taken close to the time VELTASSA is administered. Administer other oral medications at least 6 hours before or 6 hours after VELTASSA. Monitor for clinical response and/or blood levels where possible.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

##### Risk Summary

VELTASSA is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

##### Lactation

##### Risk Summary

VELTASSA is not absorbed systemically by the mother, so breastfeeding is not expected to result in risk to the infant.

**Pediatric Use** Safety and efficacy in pediatric patients have not been established.

**Geriatric Use** Of the 666 patients treated with VELTASSA in clinical studies, 59.8% were age 65 and over, and 19.8% were age 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. Patients age 65 and older reported more gastrointestinal adverse reactions than younger patients.

**Renal Impairment** Of the 666 patients treated with VELTASSA in clinical studies, 93% had chronic kidney disease (CKD). No special dosing adjustments are needed for patients with renal impairment.

#### OVERDOSAGE

Doses of VELTASSA in excess of 50.4 grams per day have not been tested. Excessive doses of VELTASSA may result in hypokalemia. Restore serum potassium if hypokalemia occurs.

#### PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

**Drug Interactions** Advise patients who are taking other oral medication to separate the dosing of VELTASSA by at least 6 hours (before or after) [see Drug Interactions].

**Dosing Recommendations** Inform patients to take VELTASSA as directed with food and adhere to their prescribed diets. Instruct patients to prepare each dose separately using the preparation instructions provided in the FDA-approved patient labeling (Medication Guide). Inform patients that VELTASSA should not be heated (e.g., microwaved) or added to heated foods or liquids and should not be taken in its dry form.

#### Manufactured for:

Relypsa, Inc.  
Redwood City, CA 94063  
Version 01; October 2015

DC, to urge members of Congress to introduce the Living Donor Protection Act. ASN and AAKP will now work collaboratively with other stakeholders in the kidney and transplant community to advance and ultimately enact the bill.

The Living Donor Protection Act would eliminate barriers and safeguard the rights of living donors in three ways:

- **Prohibiting discrimination against living donors** No laws currently exist that prohibit life, disability, or long term care insurance companies from denying or limiting coverage to people who have donated an organ. A 2007 study demonstrated that more than 10% of living donors encountered challenges in obtaining or paying for insurance post-donation owing to these discriminatory policies.

- **Providing job security to living donors during recovery** Four to six weeks are typically required for recovery from living organ donation, so job security can be a serious concern for potential living donors. The Living Donor Protection Act would clarify that living donors can utilize protections under the Family and Medical Leave Act to ensure that their employer cannot penalize them for time spent away from work recovering from the donation surgery. Although this provision would not reimburse donors for lost wages, it would provide job security and re-assurance that employment will be waiting upon recovery.

- **Updates educational materials** The US Department of Health and

Human Services (HHS) plays an integral role in educating kidney patients and their families about all types of donation and the treatment options available. If the Living Donor Protection Act is enacted, HHS would be called upon to update its materials regarding living donation to reflect these new protections and encourage more Americans to consider becoming living donors.

The Living Donor Protection Act would also help save Medicare money. ASN Public Policy Board member Kevin F. Erickson, MD, conducted an analysis that concluded that by increasing living donation by just 10%, the Living Donor Protection Act could save Medicare \$560 million to \$1.2 billion over 10 years.

“Organ donation saves Medicare mil-

lions of dollars every year,” said Rep. Nadler. “It cuts health care costs as much as two-thirds by reducing the need for dialysis and other expensive medical interventions to treat chronic illnesses. Yet, after taking this heroic step to save a life, living organ donors may unfortunately face discrimination when they try to take medical leave or buy insurance. Our bill would address that injustice.”

“This bill will cut costs and make it easier for healthy people to donate living organs without fear of losing their jobs or their paychecks,” commented Sen. Kirk. ●

*Kidney News* readers can learn more and join ASN in advocating for this important legislation by visiting ASN’s Legislative Action Center or visiting the ASN Advocacy and Public Policy website.

## President’s 2017 Budget Cuts VA Kidney Research

By Grant Olan

The Department of Veterans Affairs (VA) helps fund more than 3400 investigators around the country who conduct cutting-edge veteran-focused research in many areas, including kidney disease. More than 3000 veterans are diagnosed with kidney failure each year, and 30,000 veterans are on dialysis.

The list of VA investigator contributions to research during the agency’s 90-year history is lengthy and includes the first long-term successful kidney transplant. The VA research program was a big winner in the 2016 budget deal, which increased its funding by \$42 million, a 7.1% increase. In his 2017 budget proposal, President Barack Obama is again asking

Congress for an increase of \$30 million, 5% over the 2016 budget.

None of that funding would go to kidney research. In fact, the President’s budget proposal cuts kidney research funding in 2017 by more than \$500,000, because the budget would invest an additional \$65 million in the Million Veteran Program (MVP) in 2017. MVP will be the world’s largest genomic database, with the goal of studying how genes affect veterans’ health. To date, the VA has collected DNA samples from nearly 500,000 veteran volunteers. Most of the \$65 million would be used for sequencing those DNA samples.

Since the President’s requested \$30 million increase for the VA research pro-

gram in 2017 would only fund half of the \$65 million increase for MVP, the budget proposal cuts funding for kidney research and most other research areas to pay for the balance. ASN President Raymond C. Harris, MD, FASN, strongly denounced the proposal.

“While MVP is a worthy and noble initiative, investigator-initiated grants for kidney research and other VA research priorities shouldn’t be sacrificed to pay for it,” Dr. Harris said. “Too many veterans have kidney disease. We need better therapies for treating them, and the President’s 2017 budget request would evaporate the 2016 budget gains.”

Instead, the Friends of VA Medical

Care and Health Research (FOVA) advocacy coalition is asking for the \$30 million increase *plus* an additional \$65 million for MVP so it does not come at the expense of other important veteran research like kidney disease. ASN serves on the executive committee of FOVA, which represents 80 academic institutions, patient organizations and medical professional associations, and veterans service organizations. ●

**Have questions about kidney research funding or the federal budget? Email Grant at [golan@asn-online.org](mailto:golan@asn-online.org). Your question could be the basis for the next *Kidney News* policy article.**

## Correction: *Kidney News* regrets an error in the March Detective Nephron column in which text was incorrectly repeated on the first page. The corrected text appears here.

*Nice Glom (the new medical student) enters the room along with L.O. Henle to present a case.*

**Nephron** What do you have for me today Henle?

*Henle looks at Glom*

**Glom** I have a 65-year-old man with a serum sodium concentration of 112 mEq/L.

**Nephron** Hyponatremia! My favorite electrolyte disorder. What is the first question you need to ask?

**Henle** Whether the patient has symptoms?

**Nephron** Exactly. Given the severity of this hyponatremia, we need to know if we need to treat immediately with hypertonic

saline to avoid life-threatening cerebral edema. Severe symptoms such as seizures and coma indicate significant cerebral edema and require the use of NaCl 3% 100 mL IV bolus, which you could repeat twice if symptoms persist. Moderate symptoms such as confusion indicate a lesser degree of cerebral edema but still significant enough to be dangerous and also require the use of NaCl 3% but in slow infusion. Remember, severely symptomatic or moderately symptomatic hyponatremia are medical emergencies and need to be treated with hypertonic saline.

**Henle** I interviewed the patient and did a full neurological exam. The patient is asymptomatic.

**Nephron**

*(upset)* That is not entirely true, is it? Evidence has emerged over the last several years suggesting that all hyponatremias are symptomatic to a degree. Even mild chronic hyponatremia in the range of 125 to 135 mEq/L is not only associated with increased mortality but also increased morbidity in the form of subtle attention deficits, gait disturbances, falls, fractures, and osteoporosis.

**Glom**

I did not know that.

**Nephron**

*(smiling)* Are you familiar with the concept of regulatory volume decrease or RVD?

**Henle & Glom**

*(looking at each other)* No.