

Changes Under Consideration for Technical Expert Panels

The Senate Committee on Homeland Security and Governmental Affairs is reviewing a report and considering action to modify and expand requirements for federal advisory committees through the Federal Advisory Committee Act Amendments of 2017, H.R. 70.

At any given time, ASN members serve on multiple technical expert panels

(TEPs) providing professional guidance to policymakers in the federal government, particularly the Department of Health and Human Services (HHS). TEPs and other federal advisory groups help inform public policy, and Congress has deemed it appropriate to require public transparency of advisory committee membership and activities.

However, TEPs are among the groups whose activities could be affected by the

bill's amendments to the Federal Advisory Committee Act (FACA).

FACA defines a federal advisory committee as any term-limited committee, board, commission, council, conference, panel, task force, or similar group that dispenses objective advice and recommendations to officers and agencies of the executive branch, including TEPs commonly used by the Centers for Medicare & Medicaid Services.

In 1970, Congress conducted hearings that revealed the ways in which advisory committees were being used by agencies to cherry-pick industry leaders to advise on policy in secret. In addition, agencies did not have a standard set of requirements for advisory committee operations, resulting in uncontrolled costs, missing reports on activities, and duplication of roles between multiple committees.

As a result, Congress passed FACA in 1972 to give uniform guidance to agencies on how to operate advisory committees and report on their activities.

The current bill requires that appointments to federal advisory committees be made without regard to political affiliation or political activity, unless required by federal statute.

The head of a federal agency making an appointment to an advisory committee must give interested persons an opportunity to suggest potential committee members by including a request for comments in the Federal Register and providing a mechanism for interested persons to comment through the agency's official website. The agency must consider any comments submitted in making selections of advisory committee members.

The proposed bill requires that any individual appointed to an advisory committee who is not a full-time or permanent part-time officer or employee of the federal government shall be designated as:

- (1) a special government employee if the individual is providing advice based on the individual's expertise or experience, or
- (2) a representative if representing the views of an entity outside of the federal government.

Advisory requirements

The bill specifies that an agency may not designate committee members as representatives to avoid making them subject to federal ethics rules and requirements.

Also, a designated ethics official of each agency shall review the designation of each member of an advisory committee to determine whether such member's designation is appropriate and may re-designate members if appropriate.

The bill gives the Government Accountability Office the authority to review, and report on, compliance by agencies with FACA, including whether agencies are appropriately appointing advisory committee members as either special government employees or representatives.

The American Society of Nephrology (ASN) is monitoring this situation and any possible implications for ASN members. ■

VELTASSA® (patiomer) for Oral Suspension

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

INDICATION AND USAGE

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

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

In clinical studies, VELTASSA decreased systemic exposure of some coadministered oral medications. 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 3 hours before or 3 hours after VELTASSA.

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

Drug Interactions Advise patients who are taking other oral medication to separate the dosing of VELTASSA by at least 3 hours (before or after) [see *Drug Interactions*].

Dosing Recommendations Inform patients to take VELTASSA as directed with food and adhere to their prescribed diets. 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 04: November 2016

References: 1. Weir MR, Bakris GL, Bushinsky DA, et al; for OPAL-HK Investigators. Patiomer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med.* 2015;372(3):211-221. 2. Data on file as of December 2017. Relypsa, Inc.

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