

# Kidney News

An Official Publication of the  
American Society of Nephrology

## San Diego Sights and Sounds Are Sure to Satisfy Meeting-goers



*With panoramic views of both the city and sparkling San Diego Bay, the convention center is a short walk from the vibrant Gaslamp Quarter, a hub for dining, shopping, and entertainment.*

Welcome to San Diego, where you'll experience a laid-back and friendly feel—a wonderful atmosphere for exploring the city and surrounding areas. Abundant in beautiful, world-renowned beaches, breathtaking vistas, and fun things to do, San Diego

has something for everyone.

Boasting some of the best weather in the country year-round, San Diego is a great place for fun in the sun. The city transitions to the wet season in October, but overall it is sunny and warm, with an average high of 75 degrees. Evenings can be cool, with an average low of 63

degrees, so wear a light sweater.

If you want to tour art galleries and boutiques, or enjoy turn-of-the-century Victorian architecture, take a walk through **The Gaslamp Quarter**, across from the convention center. The Gaslamp Quarter hosts its annual **Monster Bash** on Halloween weekend—an outdoor music festival featuring live bands and a huge costume contest.

Also near the convention center is **Seaport Village**, a great area to watch passing ships on the bay, fly a kite, window shop, enjoy free music and entertainment, or grab a bite to eat at one of 17 restaurants.

### If animals are your thing. . .

. . . then San Diego is the place to be.

Time in San Diego isn't complete without a trip to the **San Diego Zoo**. One of the country's top-rated zoos, the San Diego Zoo features both familiar and exotic animals like tree kangaroos and komodo dragons. It also hosts a botanical garden with more than 6500 plant species. Animals are more active during the early morning and afternoon, so go early if you can. Consider purchasing a bus tour with your entry

ticket to catch some of the sites you might miss around the hilly parts of the zoo.

If you don't get to see enough animals at the zoo and have a bit more time, take in the **San Diego Wild Animal Park**, only a 45-minute drive from downtown. Meander through 1800 acres of land and gardens and observe species mingling much as they do in their native Asia and Africa. Take the 30-minute Journey into Africa to get a close-up view of animals in the wild, or try feeding the colorful birds at Lori-keet Landing. If you want more hands-on time with tame animals, check out Nairobi Village.

For aquatic animals, visit **SeaWorld**, a medium-sized park that's easy to walk. Featuring penguins, feeding sharks, and touchable bat rays, SeaWorld provides animal exhibits and interactions as well as rides and shows.

### Theme parks and culture

San Diego features theme parks and cultural offerings for almost every taste.

For beachfront amusement, **Belmont Park** offers rides, a wave pool,

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## Scientific Sessions

### 32 THURSDAY

Breeding and Building Molecules for Whole-Animal and Clinical Imaging  
*State-of-the-Art Lecture:* Roger Tsien  
John P Peters Award: William E. Mitch  
The Steven C. Hebert Memorial Symposium: Thick Ascending Limb Function and Dysfunction  
Christopher R. Blagg Endowed Lectureship: Bernard Lo

### 34 FRIDAY

Genetic Associations in Complex Human Diseases  
*State-of-the-Art Lecture:* Kári Stefánsson  
Young Investigator Award and Address: Matthias Kretzler  
Robert G. Narins Award: Burton D. Rose  
Robert W. Schrier Endowed Lectureship: Thomas Kleyman

### 36 SATURDAY

Genetic Insights into the Innate Immune System  
*State-of-the-Art Lecture:* Bruce Beutler  
Homer W. Smith Award: René Jan Maria Bindels  
Barry M. Brenner Endowed Lectureship: Oliver Smithies  
Jack W. Coburn Endowed Lectureship: L. Darryl Quarles

### 39 SUNDAY

Signal Transduction Mechanisms in the Kidney  
*State-of-the-Art Lecture:* Tony Pawson  
Belding H. Scribner Award and Address: James E. Cimino

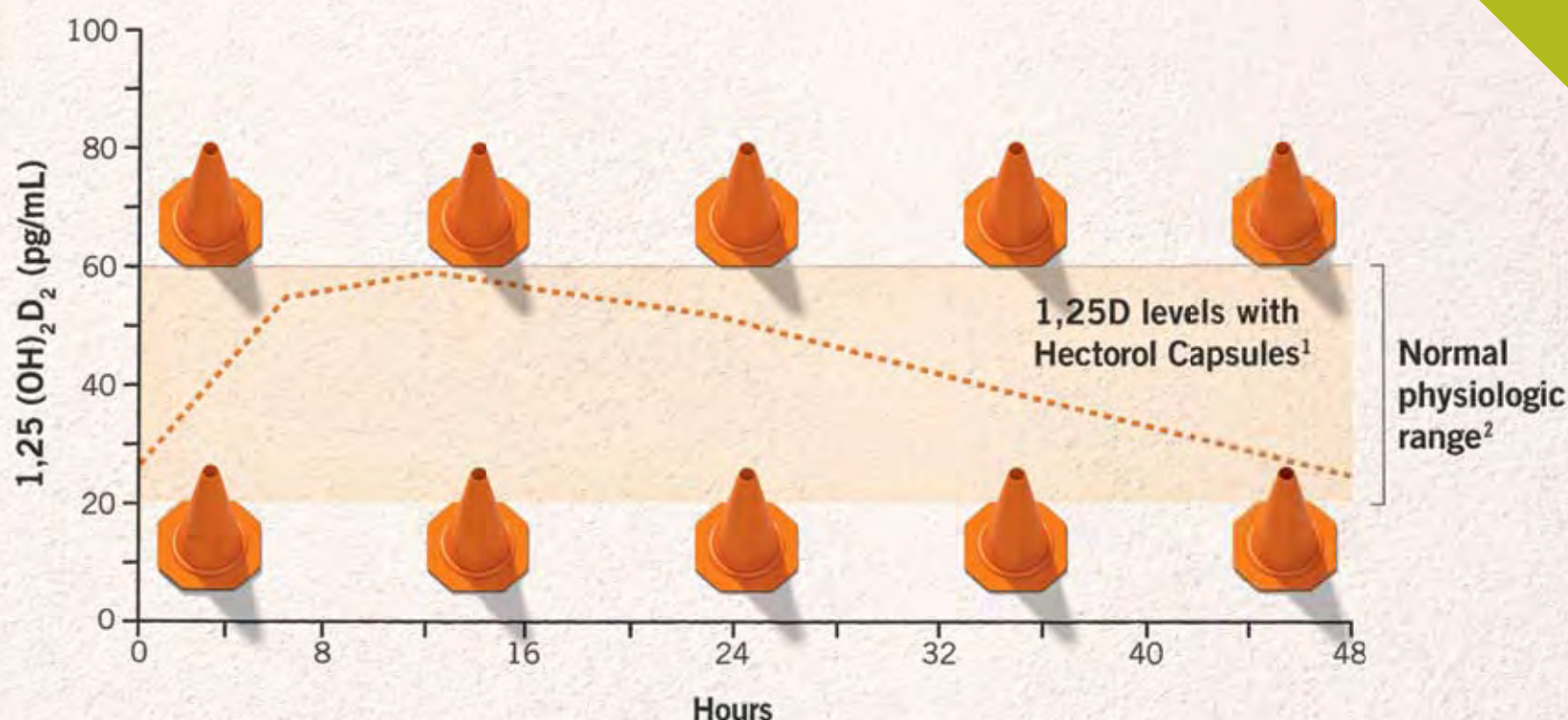




**1 mcg Now  
Available**



## Hectorol® keeps vitamin D where it's meant to be.



**Only Hectorol is clinically proven to maintain consistent serum concentrations of vitamin D hormone.<sup>1,2</sup>**

Hectorol provides effective iPTH reduction to KDOQI\* targets for your CKD Stage 3 and 4 patients while serum calcium and phosphorus are maintained within normal range.<sup>3,4</sup>

  
**HECTOROL®**  
(doxercalciferol capsules)

**Consistent D-livery**

**Important Treatment Considerations:** Hectorol is indicated for the treatment of secondary hyperparathyroidism in patients with Stage 3 or Stage 4 Chronic Kidney Disease (capsules) and in patients with Chronic Kidney Disease on dialysis (capsules and injection). • Hectorol is contraindicated in patients with a tendency toward hypercalcemia or evidence of vitamin D toxicity. • Overdosage of any form of vitamin D is dangerous. • Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis drugs. • Chronic hypercalcemia can lead to generalized vascular and soft tissue calcification. • Pharmacologic doses of vitamin D and its derivatives should be withheld during Hectorol treatment to avoid possible additive effects and hypercalcemia. • Magnesium-containing antacids and Hectorol should not be administered concomitantly. • Adverse effects of Hectorol treatment are: hypercalcemia, hyperphosphatemia, hypercalciuria, and oversuppression of iPTH. • Adverse events reported by ≥5% of the Hectorol-treated predialysis patients included: infection, chest pain, constipation, dyspepsia, anemia, dehydration, depression, hypertonia, insomnia, paresthesia, increased cough, dyspnea, and rhinitis. • Adverse events reported by ≥5% of the Hectorol-treated dialysis patients included: headache, malaise, bradycardia, nausea/vomiting, edema, dizziness, dyspnea, and pruritus.

Please see brief summary of Prescribing Information following this advertisement. For more information, call 1-800-847-0069 or visit [www.hectorol.com](http://www.hectorol.com).

\* KDOQI: Kidney Disease Outcomes Quality Initiative

References: 1. Upton RA, Knutson JC, Bishop CW, LeVan LW. Pharmacokinetics of doxercalciferol, a new vitamin D analogue that lowers parathyroid hormone. *Nephrol Dial Transplant*. 2003;18:750-758. 2. Bailie GR, Johnson CA. Comparative review of the pharmacokinetics of vitamin D analogues. *Semin Dial*. 2002;15:352-357. 3. Coburn JW, Maung HM, Elangovan L, et al. Doxercalciferol safely suppresses PTH levels in patients with secondary hyperparathyroidism associated with chronic kidney disease stages 3 and 4. *Am J Kidney Dis*. 2004;43:877-890. 4. National Kidney Foundation. KDOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis*. 2003;42 (suppl 3):S1-S201.

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# Balboa Park

Just minutes from downtown San Diego, **Balboa Park** is a great area to spend some time visiting its 15 major museums, renowned *performing arts* venues, lush gardens, and the *San Diego Zoo*. Balboa Park is the country's largest urban cultural park and also offers year-round museum exhibitions, plays, musicals, concerts, and classes. Take a guided tour of the Park, or grab your bike or hiking shoes to tour the Park by trail. (Download a trail map from the Park's website.) Stop for a game of tennis, golf, or lawn bowling. Stroll through the shopping areas, or check out the *Spanish*

*Village Art Center*, which features daily, local art demonstrations of contemporary fine arts and crafts.

If you're looking for a little free entertainment, visit the **Spreckels Organ Pavilion** in Balboa Park, one of world's largest outdoor pipe organs and a San Diego landmark since 1914. Hear organists play traditional favorites, waltzes, and show tunes on enormous 32-foot pipes.

When hunger sets in, grab a bite to eat at one of the many restaurants or outdoor eating areas. If you want more in your dining experience, make a reser-

vation at *The Prado*, an award-winning, full-service restaurant with charming indoor and outdoor dining, located in the National Historic Landmark *House of Hospitality*.

Take a look at the Park's website (www.balboapark.org) before you visit, and upon entrance into the park, stop at the Visitors Center in the House of Hospitality. Admittance is free to the Park grounds, *Botanical building*, outdoor gardens, and some attractions. Admission fees vary at other cultural attractions. Whatever you decide to see and do, Balboa Park will not disappoint. ●



Balboa Park's reflecting pool offers the tranquility of still water, and is home to water lilies, lotus, goldfish, and koi.

## San Diego Sights

*Continued from page 1*



One of the most beautiful beaches in Southern California, La Jolla Cove is tucked between sandstone cliffs.

glow-in-the-dark mini golf, shopping, and dining. **Knott's Soak City** provides more than 20 rides and interactive water play areas.

**Legoland** is a 128-acre interactive theme park with more than 50 rides, shows, and attractions. Test your paleontology skills at Dino Island, or sail your own boat through pirate-infested waters at Pirate Shores.

Searching for culture? Step into **Balboa Park** (see sidebar), and visit one of the 15 museums, including art, history, science, aerospace, and automotive. Take a ride on the carousel or miniature train, or enjoy an outdoor organ concert or presentation in one of the several theaters. Meander through the park's renowned 1200 acres of lush landscaping and gardens, including the award-winning Rose Garden, the Japanese Friendship Garden, or the Alcazar Garden. You can get around the park easily with the free tram. A good starting point is the Visitors Center, where you can purchase a Balboa Park Passport that provides entrance to most of the park's attractions.

To learn about America's longest serving aircraft carrier, climb aboard the **USS Midway Museum**, a floating city at sea. Tour the Navy ship and learn how aircraft land and take off from an aircraft carrier. Spend the day exploring the collection of 25 restored aircraft and more than 60 exhibits, including the crew's sleeping quarters, engine room,

*Continued on page 51*

## HECTOROL<sup>®</sup> doxercalciferol capsules

## HECTOROL<sup>®</sup> doxercalciferol injection

See package insert for full prescribing information.

### BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

#### INDICATIONS AND USAGE

##### Hectorol Capsules

**Dialysis Patients:** Hectorol is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

**Pre-Dialysis Patients:** Hectorol is indicated for the treatment of secondary hyperparathyroidism in patients with Stage 3 or Stage 4 chronic kidney disease.

##### Hectorol Injection

Hectorol is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

#### DOSE AND ADMINISTRATION

##### Hectorol Capsules

##### Adult Administration:

The optimal dose of Hectorol must be carefully determined for each patient. The following table provides the current recommended therapeutic target levels for iPTH in patients with chronic kidney disease.

Table 1: Target Range of Intact Plasma PTH by Stage of CKD		
CKD Stage	GFR (mL/min/1.73m <sup>2</sup> )	Target "Intact" PTH (pg/mL)
3	30 - 59	35 - 70
4	15 - 29	70 - 110
5	< 15 (or dialysis)	150 - 300

From Table 15 of National Kidney Foundation, *K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease*. Am J Kidney Dis 42:S1-S202, 2003 (suppl 3).

**Dialysis:** The recommended initial dose of Hectorol is 10 mcg administered three times weekly at dialysis (approximately every other day). The initial dose should be adjusted, as needed, in order to lower blood iPTH into the range of 150 to 300 pg/mL. The dose may be increased at 8-week intervals by 2.5 mcg if iPTH is not lowered by 50% and fails to reach the target range. The maximum recommended dose of Hectorol is 20 mcg administered three times a week at dialysis for a total of 60 mcg per week. Drug administration should be suspended if iPTH falls below 100 pg/mL and restarted one week later at a dose that is at least 2.5 mcg lower than the last administered dose. During titration, iPTH, serum calcium, and serum phosphorus levels should be obtained weekly. If hypercalcemia, hyperphosphatemia, or a serum calcium times serum phosphorus product greater than 55 mg/dL<sup>2</sup> is noted, the dose of Hectorol should be decreased or suspended and/or the dose of phosphate binders should be appropriately adjusted. If suspended, the drug should be restarted at a dose that is at least 2.5 mcg lower.

Dosing must be individualized and based on iPTH levels with monitoring of serum calcium and serum phosphorus levels. The following is a suggested approach in dialysis titration:

Table 2: Hectorol Capsules Dialysis Dosing Recommendations	
iPTH Level	Initial Dosing
	Hectorol <sup>®</sup> Dose
> 400 pg/mL	10 mcg three times per week at dialysis
iPTH Level	Dose Titration
	Hectorol <sup>®</sup> Dose
Above 300 pg/mL	Increase by 2.5 mcg at eight-week intervals as necessary
150 - 300 pg/mL	Maintain
< 100 pg/mL	Suspend for one week, then resume at a dose that is at least 2.5 mcg lower

**Pre-dialysis:** The recommended initial dose of Hectorol is 1 mcg administered once daily. The initial dose should be adjusted, as needed, in order to lower blood iPTH to within target ranges (see table below). The dose may be increased at 2-week intervals by 0.5 mcg to achieve the target range of iPTH. The maximum recommended dose of Hectorol is 3.5 mcg administered once per day.

Serum levels of calcium and phosphorus and plasma levels of iPTH should be monitored at least every two weeks for 3 months after initiation of Hectorol therapy or following dose adjustments in Hectorol therapy, then monthly for 3 months, and every 3 months thereafter. If hypercalcemia, hyperphosphatemia, or a serum calcium times phosphorus product greater than 55 mg/dL<sup>2</sup> is noted, the dose of Hectorol should be decreased or suspended and/or the dose of phosphate binders should be appropriately adjusted. If suspended, the drug should be restarted at a dose that is at least 0.5 mcg lower.

Dosing must be individualized and based on iPTH levels with monitoring of serum calcium and serum phosphorus levels. The following is a suggested approach in dialysis titration:

Table 3: Hectorol Capsules Pre-dialysis Dosing Recommendations	
iPTH Level	Initial Dosing
	Hectorol <sup>®</sup> Dose
> 70 pg/mL (Stage 3)	1 mcg once per day
> 110 pg/mL (Stage 4)	
iPTH Level	Dose Titration
	Hectorol <sup>®</sup> Dose
Above 70 pg/mL (Stage 3)	Increase by 0.5 mcg at two-week intervals as necessary
110 pg/mL (Stage 4)	
35 - 70 pg/mL (Stage 3)	Maintain
70 - 110 pg/mL (Stage 4)	
< 35 pg/mL (Stage 3)	Suspend for one week, then resume at a dose that is at least 0.5 mcg lower
< 70 pg/mL (Stage 4)	

##### Hectorol Injection

##### Adult Administration:

For intravenous use only. The optimal dose of Hectorol must be carefully determined for each patient.

The recommended initial dose of Hectorol is 4 mcg administered intravenously as a bolus dose three times weekly at the end of dialysis (approximately every other day). The initial dose should be adjusted, as needed, in order to lower blood iPTH into the range of 150 to 300 pg/mL. The dose may be increased at 8-week intervals by 1 to 2 mcg if iPTH is not lowered by 50% and fails to reach the target range. Dosages higher than 16 mcg weekly have not been studied. Drug administration should be suspended if iPTH falls below 100 pg/mL and restarted one week later at a dose that is at least 1 mcg lower than the last administered dose. During titration, iPTH, serum calcium, and serum phosphorus levels should be obtained weekly. If hypercalcemia, hyperphosphatemia, or a serum calcium times phosphorus product greater than 55 mg/dL<sup>2</sup> is noted, the dose of Hectorol should be decreased or suspended and/or the dose of phosphate binders should be appropriately adjusted. If suspended, the drug should be restarted at a dose that is at least 1 mcg lower.

Dosing must be individualized and based on iPTH levels with monitoring of serum calcium and serum phosphorus levels. The table below presents a suggested approach in dialysis titration.

Table 4: Hectorol Injection Initial Dosing	
iPTH Level	Initial Dosing
	Hectorol <sup>®</sup> Dose
>400 pg/mL	4 mcg three times per week at the end of dialysis, or approximately every other day
iPTH Level	Dose Titration
	Hectorol <sup>®</sup> Dose
Decreased by <50% and above 300 pg/mL	Increase by 1 to 2 mcg at eight-week intervals as necessary
Decreased by >50% and above 300 pg/mL	Maintain
150 - 300 pg/mL	Maintain
<100 pg/mL	Suspend for one week, then resume at a dose that is at least 1 mcg lower

Discard unused portion.

#### CONTRAINDICATIONS

Hectorol should not be given to patients with a tendency towards hypercalcemia or current evidence of vitamin D toxicity.

#### WARNINGS

Overdosage of any form of vitamin D, including Hectorol, is dangerous (see **OVERDOSAGE**). Progressive hypercalcemia due to overdosage of vitamin D and its metabolites may be so severe as to require emergency attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis drugs. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. The serum calcium times serum phosphorus (Ca X P) product should be maintained at < 55 mg/dL<sup>2</sup> in patients with chronic kidney disease. Radiographic evaluation of suspect anatomical regions must be done in the early detection of this condition.

Since doxercalciferol is a precursor for 1α,25-(OH)<sub>2</sub>D<sub>3</sub>, a potent metabolite of vitamin D, pharmacologic doses of vitamin D and its derivatives should be withheld during Hectorol treatment to avoid possible additive effects and hypercalcemia.

Oral calcium-based or other aluminum-containing phosphate binders and a low phosphate diet should be used to control serum phosphorus levels in patients with chronic kidney disease. Uncontrolled serum phosphorus exacerbates secondary hyperparathyroidism and can lessen the effectiveness of Hectorol in reducing blood PTH levels. If hypercalcemia occurs after initiating Hectorol therapy, the dose of Hectorol and/or calcium-containing phosphate binders should be decreased. If hyperphosphatemia occurs after initiating Hectorol, the dose of Hectorol should be decreased and/or the dose of phosphate binders increased. (See dosing recommendations for Hectorol under **DOSE AND ADMINISTRATION** section.)

Magnesium-containing antacids and Hectorol should not be used concomitantly in patients on chronic renal dialysis because such use may lead to the development of hypermagnesemia.

#### PRECAUTIONS

##### General

Active vitamin D sterols should not be used as initial treatment of nutritional vitamin D deficiency (as defined by low 25-hydroxy vitamin D). Patients should be checked and treated for nutritional vitamin D deficiency prior to initiating treatment with Hectorol.

The principal adverse effects of treatment with Hectorol are hypercalcemia, hyperphosphatemia, hypercalcemia, and oversuppression of iPTH (PTH less than 150 pg/mL). Prolonged hypercalcemia can lead to calcification of soft tissues, including the heart and arteries, and hyperphosphatemia can exacerbate hyperparathyroidism. Hypercalcemia can accelerate the onset of renal failure through nephrocalcinosis. Oversuppression of PTH may lead to adynamic bone syndrome. All of these potential adverse effects should be managed by regular patient monitoring and appropriate dosage adjustments. During treatment with Hectorol, patients usually require dose titration, as well as adjustment in co-therapy (i.e., dietary phosphate binders) in order to maximize PTH suppression while maintaining serum calcium and phosphorus within prescribed ranges.

**Dialysis (Capsules):** In four adequate and well-controlled studies, the incidence of hypercalcemia and hyperphosphatemia increased during therapy with Hectorol. The observed increases during Hectorol treatment, although occurring at a low rate, underscore the importance of regular safety monitoring of serum calcium and phosphorus levels throughout treatment. Patients with higher pre-treatment serum levels of calcium (> 10.5 mg/dL) or phosphorus (> 6.3 mg/dL) were more likely to experience hypercalcemia or hyperphosphatemia. Therefore, Hectorol should not be given to patients with a recent history of hypercalcemia or hyperphosphatemia, or evidence of vitamin D toxicity.

**Dialysis (Injection):** In two open-label, single-arm, multi-centered studies, the incidence of hypercalcemia and hyperphosphatemia increased during therapy with Hectorol Injection (see **Adverse Reactions** section). The observed increases during Hectorol treatment underscore the importance of regular safety monitoring of serum calcium and phosphorus levels throughout treatment. Patients with higher pre-treatment serum levels of calcium (> 10.5 mg/dL) or phosphorus (> 6.3 mg/dL) were more likely to experience hypercalcemia or hyperphosphatemia. Therefore, Hectorol should not be given to patients with a recent history of hypercalcemia or hyperphosphatemia, or evidence of vitamin D toxicity.

Table 5: Incidence Rates of Hypercalcemia and Hyperphosphatemia in Two Phase 3 Studies with Hectorol <sup>®</sup> Injection					
Study	Hypercalcemia (per 100 patient weeks)		Hyperphosphatemia (per 100 patient weeks)		
	Washout (Off Treatment)	Open-Label (Treatment)	Washout (Off Treatment)	Open-Label (Treatment)	
Study C	0.9	0.9	0.9	2.4	
Study D	0.3	1.0	1.2	3.7	

**Pre-dialysis:** In two clinical studies, the incidences of hypercalcemia and hyperphosphatemia during therapy with Hectorol were similar to placebo therapy, and no episodes of hypercalcemia were observed. The baseline median 25-(OH) vitamin D levels of patients enrolled in these studies was 17.2 ng/mL. Ninety-three percent of patients had 25-(OH) vitamin D levels less than 30 ng/mL; 28% had 25-(OH) vitamin D levels ≥ 20 to < 30 ng/mL; 28% had levels > 10 to < 20 ng/mL; 7% had levels > 5 to < 10 ng/mL; and 2% had levels < 5 ng/mL. The incidences of hypercalcemia, hyperphosphatemia, and hypercalcemia in patients treated with Hectorol for hyperparathyroidism related to pre-dialysis renal insufficiency has not been fully studied when 25-(OH) vitamin D levels are greater than or equal to 30 ng/mL.

#### Information for the Patient

The patient, spouse, or guardian should be informed about compliance with dosage instructions, adherence to instructions about diet, calcium supplementation, and avoidance of the use of nonprescription drugs without prior approval from their physician. Patients should also be carefully informed about the symptoms of hypercalcemia (see **ADVERSE REACTIONS** section).

Patients' total combined elemental calcium intake (dietary and phosphate binder) should not exceed 2 g daily.

#### Laboratory Tests

Serum or plasma iPTH and serum calcium, phosphorus, and alkaline phosphatase should be determined periodically. In the early phase of treatment for dialysis patients, iPTH, serum calcium, and serum phosphorus should be determined prior to initiation of Hectorol treatment and weekly thereafter. For pre-dialysis patients, serum levels of calcium and phosphorus and plasma levels of iPTH should be monitored at least every two weeks for 3 months after initiation of Hectorol therapy or following dose-adjustments in Hectorol therapy, then monthly for 3 months, and every 3 months thereafter.

#### Drug Interactions

Specific drug interaction studies have not been conducted. Cholestyramine has been reported to reduce intestinal absorption of fat-soluble vitamins; therefore, it may impair intestinal absorption of doxercalciferol. Magnesium-containing antacids and Hectorol should not be used concomitantly because such use may lead to the development of hypermagnesemia (see **WARNINGS**). The use of mineral oil or other substances that may affect absorption of fat may influence the absorption and availability of Hectorol. Although not examined specifically, enzyme inducers (such as glutethimide and phenobarbital) may affect the 25-hydroxylation of Hectorol and may necessitate dosage adjustments. Cyclochrome P450 inhibitors (such as ketoconazole and erythromycin) may inhibit the 25-hydroxylation of Hectorol. Hence, formation of the active Hectorol moiety may be hindered.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential of doxercalciferol have not been conducted. No evidence of genetic toxicity was observed in an *in vitro* bacterial mutagenicity assay (Ames test) or a mouse lymphoma gene mutation assay. Doxercalciferol caused structural chromosomal aberrations in an *in vitro* human lymphocyte clastogenicity assay with metabolic activation. However, doxercalciferol was negative for *in vivo* mouse micronucleus clastogenicity assay. Doxercalciferol had no effect on male or female fertility in rats at oral doses up to 2.5 mcg/kg/day (approximately 3 times the maximum recommended human dose of 60 mcg/week based on mcg/m<sup>2</sup> body surface area).

#### Use in Pregnancy

##### Pregnancy Category B

Reproduction studies in rats and rabbits, at doses up to 20 mcg/kg/day and 0.1 mcg/kg/day (approximately 25 times and less than the maximum recommended human dose of 60 mcg/week based on mcg/m<sup>2</sup> body surface area, respectively) have revealed no teratogenic or fetotoxic effects due to doxercalciferol. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

#### Nursing Mothers

It is not known whether doxercalciferol is excreted in human milk. Because other vitamin D derivatives are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from doxercalciferol, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

#### Pediatric Use

Safety and efficacy of Hectorol in pediatric patients have not been established.

#### Geriatric Use

Of the 138 patients treated with Hectorol Capsules in Two Phase 3 clinical studies, 30 patients were 65 years or over. In these studies, no overall differences in efficacy or safety were observed between patients 65 years or older and younger patients.

#### Hepatic Insufficiency

Patients with hepatic insufficiency may not metabolize Hectorol appropriately; the drug should be used with caution in patients with impaired hepatic function. More frequent monitoring of iPTH, calcium, and phosphorus levels should be done in such individuals.

#### ADVERSE REACTIONS

**Dialysis (Capsules):** Hectorol has been evaluated for safety in clinical studies in 165 patients with chronic kidney disease on hemodialysis. In two placebo-controlled, double-blind, multicenter studies, discontinuation of therapy due to any adverse event occurred in 2.9% of 138 patients treated with Hectorol for four to six months (dosage titrated to achieve target iPTH levels, see **CLINICAL PHARMACOLOGY/Clinical Studies**) and in 3.3% of 61 patients treated with placebo for two months. Adverse events occurring in the Hectorol group at a frequency of 2% or greater and more frequently than in the placebo group are presented in the following table:

Table 6: Adverse Events Reported by ≥ 2% of Hectorol <sup>®</sup> Treated Patients and More Frequently Than Placebo During the Double-blind Phase of Two Clinical Studies		
Adverse Event	Hectorol <sup>®</sup> (n=61) %	Placebo (n=61) %
<b>Body as a Whole</b>		
Abscess	3.3	0.0
Headache	27.9	18.0
Malaise	27.9	19.7
<b>Cardiovascular System</b>		
Bradycardia	6.6	4.9
<b>Digestive System</b>		
Anorexia	4.9	3.3
Constipation	3.3	3.3
Dyspepsia	4.9	1.6
Nausea/Vomiting	21.3	19.7
<b>Musculoskeletal System</b>		
Arthralgia	4.9	0.0
<b>Metabolic and Nutritional</b>		
Edema	34.4	21.3
Weight increase	4.9	0.0
<b>Nervous System</b>		
Dizziness	11.5	9.8
Sleep disorder	3.3	0.0
<b>Respiratory System</b>		
Dyspnea	11.5	6.6
<b>Skin</b>		
Pruritus	8.2	6.6

A patient who reported the same medical term more than once was counted only once for that medical term.

**Dialysis (Injection):** Hectorol Injection has been evaluated for safety in 70 patients with chronic renal disease on hemodialysis (who had been treated previously with oral Hectorol) from two 12-week, open-label, single-arm, multi-centered studies. (Dosage titrated to achieve target plasma iPTH levels, see **CLINICAL PHARMACOLOGY/Clinical Studies**.)

**Pre-dialysis:** Hectorol has been evaluated for safety in clinical studies in 55 patients (27 active and 28 placebo) with chronic kidney disease, Stages 3 or 4. In two placebo-controlled, double-blind, multicenter studies, discontinuation of therapy due to any adverse event occurred in one (1.7%) of 27 patients treated with Hectorol for 24 weeks (dosage titrated to achieve target iPTH levels, see **CLINICAL PHARMACOLOGY/Clinical Studies**) and in three (10.7%) of 28 patients treated with placebo for 24 weeks. Adverse events occurring in the Hectorol group at a frequency of 5% or greater and more frequently than in the placebo group are as follows: **Body as a Whole** – Infection, Chest Pain; **Digestive System** – Constipation, Dyspepsia; **Hematologic and Lymphatic** – Anemia; **Metabolic and Nutritional** – Dehydration; **Nervous System** – Depression, Hypertonia, Insomnia, Paresthesia, **Respiratory System** – Cough increased, Dyspnea, Rhinitis.

Potential adverse effects of Hectorol are, in general, similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms of vitamin D intoxication associated with hypercalcemia include:

#### Early

Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, metallic taste, and anorexia.

#### Late

Arrhythmia, polydipsia, anorexia, weight loss, nocturia, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated blood urea nitrogen (BUN), albuminuria, hypercholesterolemia, elevated serum aspartate transaminase (AST) and alanine transaminase (ALT), ectopic calcification, hypertension, cardiac arrhythmias, sensory disturbances, dehydration, apathy, arrested growth, urinary tract infections, and, rarely, overt psychosis.

#### OVERDOSAGE

Administration of Hectorol to patients in excess doses can cause hypercalcemia, hypercalcemia, hyperphosphatemia, and oversuppression of PTH secretion leading in certain cases to adynamic bone disease. High intake of calcium and phosphate concomitant with Hectorol may lead to similar abnormalities. High levels of calcium in the dialysate bath may contribute to hypercalcemia.

#### Treatment of Hypercalcemia and Overdosage

General treatment of hypercalcemia (greater than 1 mg/dL above the upper limit of the normal range in dialysis patients; > 10.7 mg/dL in pre-dialysis patients) consists of immediate suspension of Hectorol therapy, institution of a low calcium diet, and withdrawal of calcium supplements. Serum calcium levels should be determined at least weekly until normocalcemia ensues. Hypercalcemia usually resolves in 2 to 7 days. When serum calcium levels have returned to within normal limits, Hectorol therapy may be reinstated at a dose that is lower (at least 2.5 mcg in dialysis patients and 0.5 mcg in pre-dialysis patients) than prior therapy. In dialysis patients, serum calcium levels should be obtained weekly after all dosage changes and during subsequent dosage titration. Persistent or markedly elevated serum calcium levels may be corrected by dialysis against a reduced calcium or calcium-free dialysate.

#### Treatment of Accidental Overdosage of Doxercalciferol

The treatment of acute accidental overdosage of Hectorol should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low calcium diet are also indicated in accidental overdosage. If persistent and markedly elevated serum calcium levels occur, treatment with standard medical care should be followed, as needed. Based on similarities between Hectorol and its active metabolite, 1α,25-(OH)<sub>2</sub>D<sub>3</sub>, it is expected that Hectorol is not removed from the blood by dialysis.

#### How Supplied

##### Hectorol Capsules

0.5 mcg doxercalciferol in soft gelatin, salmon, oval capsules, imprinted g; foil induction sealed bottles of 50.

1 mcg doxercalciferol in soft gelatin, peach, oval capsules, imprinted g; foil induction sealed bottles of 50.

2.5 mcg doxercalciferol in soft gelatin, butter yellow, oval capsules, imprinted g; foil induction sealed bottles of 50.

##### Hectorol Injection

Hectorol (doxercalciferol injection) is supplied in single-use 2 mL amber glass vials; the closure consists of a fluorocarbon-coated chlorobutyl stopper, with an aluminum seal and a yellow plastic flip off cap.

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## ASN in Review

# ASN in 2009: Directions and Advances

### Educational Programs

#### Renal Week

The members of the Program Committee (chaired by Raymond C. Harris, MD, FASN) and the Postgraduate Education Committee (chaired by Mark E. Rosenberg, MD, who is also ASN Renal Week Education Director) developed clinical and basic science symposia as well as clinical nephrology conferences that address key issues in kidney biology and disease.

Four featured topics will be highlighted at this year's meeting: epithelial transport and cell biology; renal immunology and transplantation; glomerular structure and function; and kidney development and stem cells. Each day's program provides a number of choices

designed to appeal to a broad spectrum of clinical and scientific interests.

A vital part of the education at Renal Week 2009 is available in the ASN Scientific Exposition. The exposition enhances the understanding of the latest advancements in pharmaceuticals, devices, imaging, and services that are needed to help provide high quality patient care. ASN provides an unparalleled international venue for the demonstration of products and services supporting kidney care. The ASN Scientific Exposition is also the venue for the display of well over 3000 basic, clinical, and educational research posters during the course of the annual meeting.

ASN has consolidated participant resources into "ASN Services." ASN

Services will be located in the exposition hall and will include the cyber center; general Renal Week information; information about continuing medical education (CME) credits and maintenance of certification (MOC) points; ASN membership support; Career Center; and ASN publication material including *CJASN*, *JASN*, *ASN Kidney News*, and *NephSAP*.

The newest addition to the ASN Renal Week exposition hall is the exhibitor spotlight. ASN has built a special theater in the hall to spotlight some of the advances in nephrology practices, products, services, and technologies during 30-minute presentations.

ASN has moved toward producing less waste. Continuing a practice started last year, the Clinical Nephrol-

ogy Conferences (CNC) syllabus will produce an electronic, online-only publication. This year, the traditional "Abstract Issue" of *JASN* will only be available in an electronic edition. These changes will afford attendees easy access to these valuable educational resources, any time and any place, and support a "greener" Renal Week.

#### Renal WeekEnds

ASN held six Renal WeekEnds in 2009. Under the leadership of Renal WeekEnds Education Director Jerry Yee, MD, FASN, these meetings provided an exceptional review of key topics presented during Renal Week 2008 in Philadelphia. Locations included Chicago, Dallas, Miami, New York, San Francisco, and Washington, DC.



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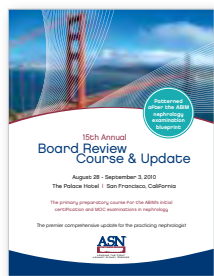
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New this year: an Acute Kidney Injury session, a “Meet-the-Professor” pre-dinner reception providing attendees a chance to spend one-on-one time with faculty, and the ability to download lectures from the program after the conclusion of the six meetings.

In 2010, ASN will hold Renal WeekEnds in six cities (Atlanta, Chicago, Dallas, Los Angeles, New York, and Washington, DC) and produce an online version of the program.

### Annual Board Review Course & Update (BRCU)



After a national search, ASN selected John M. Burkart, MD, and Mark A. Pohl, MD, as BRCU Co-Education Directors, succeeding Patrick

T. Murray, MD, FASN. New in 2009, BRCU topic sections and time allocations were redesigned after the American Board of Internal Medicine (ABIM) nephrology examination blueprint. Lectures, interactive case discussions, and panel Q&A sessions were integral parts of the 2009 program. Relevant physiology and pathophysiology blended with clinical discussions to prepare participants for ABIM examinations.

For the first time, ASN will offer to its members an online version of BRCU, scheduled to launch in January 2010. This web-based product is a valuable resource for those unable to attend the BRCU live activity. The online program includes presentations from the meeting, audio recordings of the lectures, and the option to complete the practice final exam. This program is offered for CME credit.

### Communications and Publications

#### Journal of the American Society of Nephrology



The leading kidney journal in the world, the *Journal of the American Society of Nephrology* (JASN) is the highest-ranked journal in urology

and nephrology, according to the latest Thomson/ISI impact factor ratings. The JASN impact factor increased to 7.505. Led by Editor-in-Chief Eric G. Neilson, MD, JASN averages

144,897 monthly website visitors viewing 330,270 page titles.

Under Dr. Neilson's leadership, JASN continues to forge new ground with innovative approaches to content and journal design, enhanced quality and readability, and new features including Brief Reviews, Occasional Observations, JASN Debates, Science in Renal Medicine, Pathophysiology of the Renal Biopsy, and Clinical Commentaries.

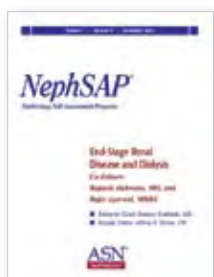
#### Clinical Journal of the American Society of Nephrology

Led by Editor-in-Chief William M. Bennett, MD, the *Clinical Journal of the American Society of Nephrology* (CJASN) continued its rapid ascent as the primary resource for breaking clinical nephrology studies, nearly doubling its impact factor from 2.236 to 4.361—a 95 percent increase. Despite its recent entry in the market, CJASN already ranks seventh in urology and nephrology.

CJASN transitioned to a monthly publishing schedule in January. Also, for the second year in a row, CJASN increased original manuscript submissions by 35 percent.

New features include the “Hall of Fame” series, which highlights the seminal contributions of nephrologists, and “Biology of Renal Disease: Laboratory to Clinic,” which debuted in July with an article on microRNAs. This series updates clinicians on advances in basic science with a focus on transition of research findings to the clinic setting.

#### Nephrology Self-Assessment Program



The *Nephrology Self-Assessment Program* (NephSAP) continues to provide ASN members with CME credits and MOC points through print

and online formats. New in 2009, the program is available in a podcast format (Audio NephSAP). With 15,000 online visits and 5500 subscribers (and counting) to its podcast during the first six months of 2009, NephSAP's page is the second most popular on the Society's website. Editor-in-Chief Stanley Goldfarb, MD, FASN, and Editor Jeffrey S. Berns, MD, FASN, also added interventional nephrology, renal pharmacology, and primary care medicine for the nephrologist to the list of topics published on a two-year schedule.

#### ASN Kidney News



the premier news publication for kidney specialists with Pascale H. Lane, MD, FASN, as its Editor-in-Chief. Published every other month, the society's newsmagazine analyzes research findings, policy changes, and emerging trends in industry, medicine, and training that impact practitioners in kidney health and disease. Issues examined include new conditions for coverage of dialysis, a proposed system for allocating kidneys for transplantation, factors driving students toward (or away from) careers in nephrology, and the impact the changing workforce will have on patient care and the advancement of the field.

ASN Kidney News Podcasts debuted in May 2009, and their online home is currently the most popular page on the ASN website, with over 30,500 downloads in the first three months. The ASN Kidney News Podcast will evolve in 2010 with content created from the newsmagazine, JASN, CJASN, the ASN Public Policy Board, and the general medical community.

The Indian edition of ASN Kidney News debuted in July; the publication compiles articles from previous editions of ASN Kidney News for nephrologists and other medical professionals in India.

ASN Kidney News will begin monthly publication in 2010. Online material to supplement the printed magazine will continue to evolve through the coming year, including a website and discussion forums.

#### Kidney Daily

ASN Kidney Daily—an exclusive service to the Society's members that compiles breaking news from journals, newspapers, and other sources into a daily email—continues to be popular among members, with a daily open rate (percentage of members who read the briefing daily) that exceeds the industry average for comparable news briefings. Among ASN members, 25–30 percent consistently read *Kidney Daily*.

#### Press Promotion

During the past year, ASN communications staff members improved press promotion efforts to better identify studies that promote important clinical and research findings and address public interests in compelling ways. In addition, ASN highlighted its signal achievements, such as developing the first geriatric nephrology curriculum

and initiating the ASN podcast program.

In advance of Renal Week, staff members worked with program committee members and other ASN leaders to identify newsworthy items, cutting-edge advances in nephrology, and an expanded list of experts to speak to the media.

### Policy

Since 2006, ASN has significantly expanded its work representing the Society's members on the most important issues in kidney care, research, and education. This year, ASN has focused on reforming health care, implementing the kidney care provisions in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, increasing research funding, and expanding educational programs for nephrology fellows and other ASN members.

#### Reforming Health Care

To help improve care for patients with kidney disease, ASN monitors all current health care legislation. Such legislation addresses comparative-effectiveness research and proposed policies specific to kidney care: follow-on biologics (biosimilars), immunosuppressive drug coverage, and bundling for end stage renal disease (ESRD). The ASN Public Policy Board developed an ASN ESRD/Health Care Reform Task Force to support appropriate legislation for kidney disease patients and providers, with special focus on ESRD.

Like ESRD bundling, the patient-centered medical home (PCMH) concept has received substantial attention from lawmakers. ASN formed a PCMH Task Force to study the issue and generated a report that included four in-depth case study scenarios involving renal patients (published in JASN in April 2009). Additionally, Thomas D. DuBose, Jr., MD, FASN, Chair of the Society's PCMH Task Force, participates in the American College of Physicians' Council of Subspecialty Societies PCMH workgroup.

#### Implementing MIPPA

Since the U.S. Congress approved MIPPA in 2008, ASN and other renal organizations, including the Kidney Care Partners (KCP), have worked to develop recommendations for implementing MIPPA provisions on ESRD. ASN staff and leaders serve on two KCP committees that oversee policy and implementation for payment and quality issues.

First, the KCP Payment Committee addresses MIPPA payment issues related to the scope of services, items in

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## ASN in Review

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the ESRD bundle, and how to establish the unit of payment. Second, the KCP Quality Committee maintains responsibility for all MIPPA quality issues, such as identifying appropriate measures for the law's ESRD quality program. KCP Payment and Quality Committees collaborate to address application of mandated "quality incentive" payment reductions.

In March 2009, KCP approved its first recommendation on new Medicare prospective payment system (PPS) elements for an expanded bundle. Such recommendations will enable the nephrology community to respond quickly to a proposed rule from the Centers for Medicare and Medicaid Services (CMS) on MIPPA, or a potential standalone ESRD bundled payment rule.

ASN met with CMS earlier this year to discuss potential education benefits and other ESRD-related issues and

participated in a stakeholders' meeting on the topic convened by the Agency for Healthcare Research and Quality (AHRQ) in December 2008. At the AHRQ meeting, participants examined ESRD education issues: criteria for diagnosis of stage IV chronic kidney disease (CKD), appropriate modalities to include in educational sessions (such as frequency and duration), existing programs, resources, and best practices.

### Increasing Research Funding

ASN in 2009 advocated to Congress to increase National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) funding commensurate with the growth of the National Institutes of Health (NIH). The Society also advocated to boost funding for basic research on the major causes of kidney disease, particularly diabetes, hypertension, aging, and obesity. ASN informed legislators about key studies

aimed at improving mortality statistics in patients with kidney disease, including those treated for failure by dialysis.

Additionally, ASN recommended expanding loan-repayment programs for physician-scientists, promoted more funding for health disparities research and increased support for underrepresented minority investigators. The Society provided key information to legislators about disease-specific registries and clinical trial networks that might bridge the gap from bench to bedside. Similarly, ASN supported funding of the AHRQ comparative effectiveness research program, which received substantial resources under the economic stimulus package.

ASN advocated for \$65 million in funding for the VA Medical and Prosthetic research program, to keep pace with inflation, support new programs for soldiers returning from Iraq and Afghanistan, advance genomic research, and maintain investigation into chronic disease and aging population health. Moreover, the Society recommended that Congress set aside \$145 million for VA infrastructure improvements (long placed on hold due to internal competition for funds).

In March 2009, more than 20 members of ASN, its policy board, and staff traveled to Washington, DC, to commemorate World Kidney Day. Participants encouraged congressional representatives to support sustained NIH funding for kidney disease. Following World Kidney Day, Public Policy Board Chair Jonathan Himmelfarb, MD, FASN; ASN President Thomas Coffman, MD, FASN; and other leaders met with representatives from NIDDK; the National Heart, Lung, and Blood Institute (NHLBI); and the National Institute on Aging (NIA) to discuss the institutes' focus on kidney disease and its associated co-morbidities.

As a result of these efforts, NHLBI representatives will consider the relationship between kidney disease and cardiovascular disease when designing clinical trials and discuss a future conference on the interrelationship between the two diseases. In August, NIA and NIDDK released two funding opportunity announcements (FOAs) on "Renal Function and Chronic Kidney Disease (CKD) in Aging." The FOAs request research applications in "both animal models and in humans, addressing the etiology, pathophysiology, risk factors, consequences, prevention, or treatment of CKD in older patients."

ASN organized a working group to revise the Society's 2005 Renal Research Report for 2009. Led by John

R. Sedor, MD, the group worked with ASN advisory groups, who unanimously voiced support for developing new disease biomarkers, imaging technologies, and a robust clinical trials infrastructure for management of kidney diseases. The working group summarized essential long-term research priorities for NIDDK, including development of cross-disciplinary and multicenter groups that collect data on new patient cohorts for comparative effectiveness and outcomes studies, and recommended that NIDDK optimize data-mining strategies.

### Expanding Educational Programs

Leading the effort to increase ASN's involvement with nephrology training, Donald E. Kohan, MD, PhD, FASN, this year became the first ASN Education Director for Fellowship Training. Dr. Kohan brought great energy to the position, and the Training Program Directors (TPDs) worked together to improve their programs and the education of nephrology fellows.

In May 2009, TPDs held a retreat in Chicago and shared insights on how to "survive" a site visit by the Accreditation Council for Graduate Medical Education (ACGME). A course for new TPDs included presentations on financing fellowship positions and how (and where) to file online reports.

ASN launched the In-Training Examination (ITE) for Nephrology Fellows. A task force led by Mitchell H. Rosner, MD, worked with the National Board of Medical Examiners to create a multiple choice test modeled after the ABIM's certifying exam in nephrology. In April, 693 fellows completed the online ITE. Results show that participants gained tremendous insight into which subject areas they should focus on in the future. The exam will again take place April 8 and 9, 2010.

ASN also launched the first ever Online Curriculum in Geriatric Nephrology. Hosted on the ASN website, this curriculum presents 38 chapters covering all aspects of kidney disease in the elderly and is based on the six core competencies put forth by ACGME. It was supported by a grant from the Association of Specialty Professors.

In the spring of 2009, ASN conducted a survey of its fellow membership. Fellows provided information about their background and training and shared insights regarding the Society resources they find most useful. Among those fellows who responded, 92.6 percent were "very satisfied" or "somewhat satisfied" with the services

*Continued on page 8*

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### BRIEF SUMMARY OF PRESCRIBING INFORMATION

**CONTRAINDICATIONS:** Patients with hypercalcemia. **INDICATIONS AND USAGE:** For the control of hyperphosphatemia in end-stage renal failure. **WARNINGS:** Patients with end-stage renal failure may develop hypercalcemia when given calcium with meals. No other calcium supplements should be given concurrently with PhosLo. Progressive hypercalcemia due to overdose of PhosLo may be severe as to require emergency measures. Chronic hypercalcemia may lead to vascular calcification, and other soft-tissue calcification. The serum calcium level should be monitored twice weekly during the early dose adjustment period. The serum calcium times phosphate (Ca x P) product should not be allowed to exceed 66. Radiographic evaluation of suspect anatomical region may be helpful in early detection of soft-tissue calcification.

**PRECAUTIONS:** Excessive dosage induces hypercalcemia; therefore, early in the treatment during dosage adjustment serum calcium should be determined twice weekly. Should hypercalcemia develop, the dosage should be reduced or the treatment discontinued immediately depending on the severity of hypercalcemia. Do not give to patients on digitalis, because hypercalcemia may precipitate cardiac arrhythmias. Always start PhosLo at low dose and do not increase without careful monitoring of serum calcium. An estimate of daily calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

**Information for the Patient:** Inform the patient about: 1) compliance with dosage; 2) adherence to diet instructions and avoidance of nonprescription antacids; and 3) symptoms of hypercalcemia. **Drug Interactions:** PhosLo may decrease the bioavailability of tetracyclines. Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed.

**Pregnancy:** Teratogenic Effects: Category C. Animal reproduction studies have not been conducted. It is not known whether PhosLo can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Give to a pregnant woman only if clearly needed.

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

**Geriatric Use:** Of the total number of subjects in clinical studies of PhosLo (n = 91), 25 percent were 65 and over, while 7 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and

younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS:** In clinical studies, patients have occasionally experienced nausea during PhosLo therapy. Hypercalcemia may occur during treatment with PhosLo. Mild hypercalcemia (Ca > 10.5 mg/dl) may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia (Ca > 12 mg/dl) is associated with confusion, delirium, stupor and coma. Mild hypercalcemia is easily controlled by reducing the PhosLo dose or temporarily discontinuing therapy. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing PhosLo therapy. Decreasing dialysate calcium concentration could reduce the incidence and severity of PhosLo-induced hypercalcemia. The long-term effect of PhosLo on the progression of vascular or soft-tissue calcification has not been determined. Isolated cases of pruritus have been reported which may represent allergic reactions.

**OVERDOSAGE:** Administration of PhosLo in excess of appropriate daily dosage can cause severe hypercalcemia (see **ADVERSE REACTIONS**).

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# ASN in Review

*Continued from page 6*

provided by ASN, and 98.8 percent indicated they will continue ASN membership after completing their training. The information from the more than 400 respondents will help guide the efforts of the Society in 2010.

## Continuing the ASN Public Policy Board in 2010

ASN will continue to advocate for improvements in patient care, research, and education related to kidney disease. After a national search, ASN selected Thomas H. Hostetter, MD, to succeed Jonathan Himmelfarb, MD, as Chair of the Society's Public Policy Board. A former ASN President, Dr. Hostetter has served on the public policy board since its inception in 2006.

In addition, the Society has hired two new individuals to contribute to

policy agendas that affect ASN members and advance patient care and kidney research. Reporting to ASN Director of Policy and Public Affairs Paul Smedberg, Rachel N. Shaffer will specialize in clinical and patient care issues, Christine Keersmaekers will focus on research, and Susan Owens will continue to address education issues.

## Grants and Funding

After a national search, Detlef O. Schlondorff, MD, was selected this year as the new ASN Research Grants Program Director. Under the direction of Dr. Schlondorff, ASN received 63 career development applications—the highest number ASN has received since the inception of this program. ASN funds approximately 20 grants per year and provides nearly \$3 million to support advances in clinical and basic research

in kidney disease.

In 2009, the Society also funded 12 medical students to complete research in nephrology labs across the United States. ASN will support more than 300 trips for members to attend ASN Renal Week or other scientific meetings sponsored by other organizations in 2009, including a partnership with Boehringer Ingelheim to support fellows seeking to attend Renal Week.

All grant applications are now available online, providing a streamlined process for applicants and reviewers. Also, ASN has created a task force charged with “developing a vision for how ASN’s travel support programs help the Society accomplish its mission.”

## Member Services

### Membership

Continuing to expand its membership in 2009, ASN is on track to meet or exceed last year’s total of 11,000 members in 82 countries, with 68 percent of ASN members residing in the United States. Eighty-six percent of members have earned MDs (or equivalent), 15 percent have earned PhDs, and 10 percent of members hold both MD and PhD degrees. More than eight in 10 ASN members have an academic appointment, including both part- and full-time faculty members. Nearly 55 percent of members are involved in clinical research, and 45 percent are involved in laboratory research.

ASN continues to make joining and renewing membership easy by providing online membership renewal on the ASN website. ASN remains committed to increasing services for its members while providing membership at a low cost. To date, nearly 1000 ASN members have earned the distinction of becoming Fellows of ASN (FASN).

### Web Services



During the first six months of 2009, the ASN website received 565,680 unique visits, a 32 percent increase over the same time period last year. Part of this increase results from new content on the website and activity on the ASN Career Center, viewed over 8000 times by members.

Building on an enhanced design and new infrastructure, ASN now offers several new publication supplements, including the Audio *NephSAP* Podcast, *ASN Kidney News* Podcast, and new

educational offerings such as the Online Geriatric Nephrology Curriculum.

ASN expanded its web services to mobile devices by offering mobile-optimized and iPhone/iPod versions of the ASN website. These versions are formatted for easy viewing “on-the-go.” This upgrade ensures viewing compatibility across all browsers, contributing to ASN’s goal of making the website accessible to everyone including those with disabilities. In the future ASN will provide more web services and interactivity to ASN members, including calendar options for the upcoming Renal Week Program and further integration with ASN’s multimedia educational materials.

Finally, ASN Administrative Assistant Mark Kerlin was named ASN Information Services Coordinator. In this new role, Mr. Kerlin will advance the Society’s technological capabilities by providing technical support to help ASN members navigate the Society’s website, add content to the site, and help administer the ASN database.

## Administration

### ASN Council and Board of Advisors

The ASN Council repopulated most of the Society’s 26 committees, advisory groups, and other panels for 2010. More than 150 ASN members volunteered to fill open positions on these panels. Of those selected to fill positions, approximately one-third renewed terms, one-third were appointed, and one-third volunteered. In addition to existing panels, ASN created the Geriatric Nephrology Advisory Group, the Interventional Nephrology Advisory Group, and the Physiology and Cell Biology Advisory Group.

Consisting of the chairs of ASN’s committees, advisory groups, and other panels—as well as other key leaders (such as the editors-in-chief of the Society’s publications)—the ASN Board of Advisors (BOA) provides essential insights, advice, and counsel. To improve communications among BOA members, ASN staff created an email listserve for BOA members and provided a midyear report.

With the input and support of its members, ASN continues to lead the fight against kidney disease. ASN provides the highest caliber and widest range of educational offerings, promotes and disseminates research, highlights clinical advances, and addresses the concerns that will most benefit patients. ●

## National Kidney Foundation 2010 SPRING CLINICAL MEETINGS

Orlando, Florida April 13–17  
Walt Disney World Swan and Dolphin

JOIN MORE THAN 2,000 KIDNEY HEALTH CARE PROFESSIONALS,  
for information-filled courses, practical workshops, thought-provoking symposia and well-argued debates.

**REGISTER TODAY**  
[www.nkfclinicalmeetings.org](http://www.nkfclinicalmeetings.org)

### Important Dates:

December 4, 2009: Abstract Submission Deadline

December 4, 2009: Internal Medicine/Pediatric Trainees Program Educational Stipend Deadline

- Special activities for residents throughout the program

January 8, 2010: Fellows Educational Stipend Deadline

- Special activities for fellows throughout the program

January 15, 2010: Advance Registration Deadline. Take advantage of the special early bird rates!

March 5, 2010: Advance Housing Deadline

Visit the SCM10 website for additional program information:

[www.nkfclinicalmeetings.org](http://www.nkfclinicalmeetings.org)

Questions about SCM10? E-mail  
[nkfclinicalmeetings@kidney.org](mailto:nkfclinicalmeetings@kidney.org)  
or call **888.JOIN.NKF**



National Kidney  
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# CLINICALS



# The **NGAL** test

For your clinical chemistry analyzer

**EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY**

For more information please visit our **booth 315** at the ASN Renal Week



# 2009 Corporate Supporters

The ASN Corporate Support Program recognizes year-round supporters for their generous contributions to the Society. Through this program, supporters help ASN lead the fight against kidney disease.

ASN gratefully acknowledges the following companies for their contributions in 2009.

## DIAMOND LEVEL



## PLATINUM LEVEL



## GOLD LEVEL

Astellas Pharma US, Inc.

Otsuka America Pharmaceutical, Inc.

Watson

## SILVER LEVEL

Baxter Healthcare Corporation

IKARIA

Novo Nordisk Inc.

Takeda

## BRONZE LEVEL

Affymax, Inc.

AstraZeneca

Genentech

Merck & Co., Inc.



# QUICK TIPS FOR SEEING SAN DIEGO

## Plan ahead:

If there is a show you don’t want to miss, check the attraction’s website so you’ll be sure to plan your itinerary appropriately.

## Check for free stuff:

Some sites, like the museums, are open free to the public on certain days, and some offer free tours. Also check out deals on combo tickets.

## Check for special events:

Especially around holidays and on week-ends, some attractions or local spots host special events that may not otherwise be available.



Balboa Park fountains

## Ocean temp:

The ocean water can be chilly, so you may want to bring or rent a wetsuit for any prolonged dip in the seas.



San Diego Bay

## RenVela<sup>®</sup>

sevelamer carbonate

**[se vel' a mer]**  
See package insert for full prescribing information.

### BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

**INDICATIONS AND USAGE**  
Renvela<sup>®</sup> (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis. The safety and efficacy of Renvela in CKD patients who are not on dialysis have not been studied.

**DOSAGE AND ADMINISTRATION**  
Because of the rapid disintegration of the carbonate salt tablet and its rapid reaction with the hydrochloric acid in the stomach, the dosing of Renvela is anticipated to be similar to that of the hydrochloride salt.  
*Patients Not Taking a Phosphate Binder:* The recommended starting dose of Renvela is 800 to 1600 mg, which can be administered as one or two Renvela 800 mg Tablets, with meals based on serum phosphorus level. Table 1 provides recommended starting doses of Renvela for patients not taking a phosphate binder.

Table 1. Starting Dose for Dialysis Patients Not Taking a Phosphate Binder

SERUM PHOSPHORUS	RENVELA <sup>®</sup> 800 MG
> 5.5 and < 7.5 mg/dL	1 tablet three times daily with meals
≥ 7.5 and < 9.0 mg/dL	2 tablets three times daily with meals
≥ 9.0 mg/dL	2 tablets three times daily with meals

*Patients Switching From Sevelamer Hydrochloride:* For patients switching from sevelamer hydrochloride, sevelamer carbonate should be prescribed on a gram per gram basis. Further titration to the desired phosphate levels may be necessary. The highest daily dose of sevelamer carbonate studied was 14 grams in CKD patients on dialysis.  
*Patients Switching From Calcium Acetate:* In a study in 84 CKD patients on hemodialysis, a similar reduction in serum phosphorus was seen with equivalent doses (approximately mg for mg) of sevelamer hydrochloride and calcium acetate. Table 2 gives recommended starting doses of Renvela based on a patient's current calcium acetate dose.

Table 2. Starting Dose for Dialysis Patients Switching From Calcium Acetate to Renvela

CALCIUM ACETATE 667 MG (TABLETS PER MEAL)	RENVELA <sup>®</sup> 800 MG (TABLETS PER MEAL)
1 tablet	1 tablet
2 tablets	2 tablets
3 tablets	3 tablets

*Dose Titration for All Patients Taking Renvela:* The dose should be increased or decreased by one tablet per meal at two week intervals, as necessary, with the goal of controlling serum phosphorus within the target range of 3.5 mg/dL to 5.5 mg/dL.

**DOSAGE FORMS AND STRENGTHS**  
800 mg white oval, film-coated, compressed tablets imprinted with "RENVELA 800".

**CONTRAINDICATIONS**  
Renvela is contraindicated in patients with hypophosphatemia or bowel obstruction.

**WARNINGS AND PRECAUTIONS**  
**Use Caution in Patients with Gastrointestinal Disorders.** The safety of Renvela has not been established in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery. Use caution in patients with these GI disorders.  
**Monitor Serum Chemistries.** Bicarbonate and chloride levels should be monitored.  
**Monitor for Reduced Vitamins D, E, K (clotting factors) and Folic Acid Levels.** In preclinical studies in rats and dogs, sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, reduced vitamins D, E, and K (coagulation parameters) and folic acid levels at doses of 6-10 times the recommended human dose. In short-term clinical trials, there was no evidence of reduction in serum levels of vitamins. However, in a one-year clinical trial, 25-hydroxyvitamin D (normal range 10 to 55 ng/mL) fell from 39 ± 22 ng/mL to 34 ± 22 ng/mL (p<0.01) with sevelamer hydrochloride treatment. Most (approximately 75%) patients in sevelamer hydrochloride clinical trials received vitamin supplements, which is typical of patients on dialysis.

**ADVERSE REACTIONS**  
**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug can not be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.  
There are limited data on the safety of Renvela. However, based on the fact that it contains the same active ingredient as the hydrochloride salt, the adverse event profiles of the two salts should be similar. In a cross-over study in hemodialysis patients with treatment durations of eight weeks each and no washout the adverse reactions on sevelamer carbonate were similar to those reported for sevelamer hydrochloride.  
In a parallel design study of sevelamer hydrochloride with treatment duration of 52 weeks, adverse reactions reported for sevelamer hydrochloride (n=99) were similar to those reported for the active-comparator group (n=101). Overall adverse reactions among those treated with sevelamer hydrochloride occurring in > 5% of patients included: vomiting (22%), nausea (20%), diarrhea (19%), dyspepsia (16%), abdominal pain (9%), flatulence (8%) and constipation (8%). A total of 27 patients treated with sevelamer and 10 patients treated with comparator withdrew from the study due to adverse reactions.  
Based on studies of 8-52 weeks, the most common reason for withdrawal from sevelamer hydrochloride was gastrointestinal adverse reactions (3-16%).  
In one hundred and forty-three peritoneal dialysis patients studied for 12 weeks using sevelamer hydrochloride, most adverse reactions were similar to adverse reactions observed in hemodialysis patients. The most frequently occurring treatment emergent serious adverse reaction was peritonitis (8 reactions in 8 patients [8%] in the sevelamer group and 2 reactions in 2 patients [4%] on active-control). Thirteen patients (14%) in the sevelamer group and 9 patients (20%) in the active-control group discontinued, mostly for gastrointestinal adverse reactions. Patients on peritoneal dialysis should be closely monitored to ensure the reliable use of appropriate aseptic technique with the prompt recognition and management of any signs and symptoms associated with peritonitis.  
**Postmarketing Experience:** The following adverse reactions have been identified during post-approval use of sevelamer hydrochloride, which has the same active moiety as sevelamer carbonate: pruritus, rash, abdominal pain, fecal impaction, and uncommon cases of ileus, intestinal obstruction, and intestinal perforation. Appropriate medical management should be given to patients who develop constipation or have worsening of existing constipation to avoid severe complications. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or to establish a causal relationship to drug exposure.

**DRUG INTERACTIONS**  
No drug interaction studies have been performed with sevelamer carbonate. Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been studied in human drug-drug interaction studies with ciprofloxacin, digoxin, warfarin, enalapril, metoprolol and iron.  
*Ciprofloxacin:* In a study of 15 healthy subjects, a co-administered single dose of 2.8 grams of sevelamer hydrochloride decreased the bioavailability of ciprofloxacin by approximately 50%.  
*Digoxin:* In 19 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals for 2 days, sevelamer did not alter the pharmacokinetics of a single dose of digoxin.  
*Warfarin:* In 14 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals for 2 days, sevelamer did not alter the pharmacokinetics of a single dose of warfarin.  
*Enalapril:* In 28 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of enalapril.  
*Metoprolol:* In 31 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of metoprolol.  
*Iron:* In 23 healthy subjects, a single 2.8 gram dose of sevelamer hydrochloride did not alter the absorption of a single oral dose of iron as 200 mg exsiccated ferrous sulfate tablet.  
*Other Concomitant Drug Therapy:* There are no empirical data on avoiding drug interactions between Renvela and most concomitant drugs. During postmarketing experience, very rare cases of increased thyroid stimulating hormone (TSH) levels have been reported in patients co-administered sevelamer hydrochloride and levothyroxine. Closer monitoring of TSH levels is therefore recommended in patients receiving both medications.  
When administering an oral medication where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, the drug should be administered at least one hour before or three hours after Renvela, or the physician should consider monitoring blood levels of the drug. Patients taking anti-arrhythmic medications for the control of arrhythmias and anti-seizure medications for the control of seizure disorders were excluded from the clinical trials. Special precautions should be taken when prescribing Renvela to patients also taking these medications.

**USE IN SPECIFIC POPULATIONS**  
**Pregnancy: Pregnancy Category C:** The effect of sevelamer hydrochloride on the absorption of vitamins and other nutrients has not been studied in pregnant women. Requirements for vitamins and other nutrients are increased in pregnancy. In pregnant rats given doses of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred. In pregnant rabbits given oral doses of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred. *[See NONCLINICAL TOXICOLOGY]*  
**Labor and Delivery:** No sevelamer hydrochloride treatment-related effects on labor and delivery were seen in animal studies. The effects of sevelamer carbonate on labor and delivery on humans is unknown. *[See NONCLINICAL TOXICOLOGY]*  
**Pediatric use:** The safety and efficacy of Renvela has not been established in pediatric patients.  
**Geriatric use:** Clinical studies of Renvela did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

**OVERDOSAGE**  
Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been given to normal healthy volunteers in doses of up to 14 grams per day for eight days with no adverse effects. In CKD patients on dialysis, the maximum dose studied was 14 grams of sevelamer carbonate and 13 grams of sevelamer hydrochloride. There are no reports of overdosage with sevelamer carbonate or sevelamer hydrochloride in patients. Since sevelamer is not absorbed, the risk of systemic toxicity is low.

**NONCLINICAL TOXICOLOGY**  
**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Standard lifetime carcinogenicity bioassays were conducted in mice and rats. Rats were given sevelamer hydrochloride by diet at 0.3, 1, or 3 g/kg/day. There was an increased incidence of urinary bladder transitional cell papilloma in male rats of the high dose group (human equivalent dose twice the maximum clinical trial dose of 13 g). Mice received dietary administration of sevelamer hydrochloride at doses of up to 9 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose). There was no increased incidence of tumors observed in mice.  
In an *in vitro* mammalian cytogenetic test with metabolic activation, sevelamer hydrochloride caused a statistically significant increase in the number of structural chromosome aberrations. Sevelamer hydrochloride was not mutagenic in the Ames bacterial mutation assay. Sevelamer hydrochloride did not impair the fertility of male or female rats in a dietary administration study in which the females were treated from 14 days prior to mating through gestation and the males were treated for 28 days prior to mating. The highest dose in this study was 4.5 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose of 13 g).  
In pregnant rats given dietary doses of 0.5, 1.5 or 4.5 g/kg/day of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred in mid- and high-dose groups (human equivalent doses less than the maximum clinical trial dose of 13 g). In pregnant rabbits given oral doses of 100, 500 or 1000 mg/kg/day of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred in the high-dose group (human equivalent dose twice the maximum clinical trial dose).

**HOW SUPPLIED/STORAGE AND HANDLING**  
Renvela<sup>®</sup> 800 mg Tablets are supplied as white oval, film-coated, compressed tablets, imprinted with "RENVELA 800", containing 800 mg of sevelamer carbonate on an anhydrous basis, microcrystalline cellulose, hypromellose, diacetylated monoglycerides, sodium chloride, and zinc stearate. Renvela<sup>®</sup> 800 mg Tablets are packaged in 500 cc bottles of 270 tablets.  
1 Bottle of 30 ct 800 mg Tablets (NDC 58468-0130-2)  
1 Bottle of 270 ct 800 mg Tablets (NDC 58468-0130-1)

**STORAGE**  
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).  
(See USP controlled room temperature)  
Protect from moisture.  
Shelf life is 24 months.

**PATIENT COUNSELING INFORMATION**  
**Dosing Recommendations:** The prescriber should inform patients to take Renvela with meals and adhere to their prescribed diets. Instructions should be given on concomitant medications that should be dosed apart from Renvela.  
**Adverse Reactions:** Renvela may cause constipation that if left untreated, may lead to severe complications. Patients should be cautioned to report new onset or worsening of existing constipation promptly to their physician.

Distributed by:

**genzyme**

Genzyme Corporation  
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Cambridge, MA 02142 USA

<sup>1</sup> Renvela is a Registered Trademark of Genzyme Corporation



**COMING SOON: NEW POWDER FORMULATION.**

# Before you start, stop.

## Because the benefits should accumulate. Not the risks.

Renvela® is an effective first-line monotherapy for controlling serum phosphorus in dialysis patients – without calcium or metal<sup>1</sup> accumulation. **Renvela will soon be available in both tablet and powder formulations.**



### Important Treatment Considerations

Renvela® (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis. Renvela is contraindicated in patients with hypophosphatemia or bowel obstruction. Caution should be exercised in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery. Common adverse events reported with Renvela include vomiting, nausea, diarrhea, dyspepsia, abdominal pain, and constipation. Other events reported include pruritus, rash, fecal impaction, and intestinal obstruction. Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients how to take Renvela. Patients should be informed to take Renvela with meals and to adhere to their prescribed diets. For more information on Renvela, call Genzyme Medical Information at 1-800-847-0069 or visit [renvela.com](http://renvela.com).

Please see Brief Summary of full Prescribing Information on adjacent page.

**Reference:** 1. Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2007.

**Renvela**®  
sevelamer carbonate

**Right from the start<sup>SM</sup>**



# ASN President and President-Elect Address

## Society Goals & Transition of Power

**For the Renal Week edition of ASN Kidney News, editor-in-chief Pascale Lane, MD, interviewed ASN President Thomas Coffman, MD, and incoming ASN President Sharon Anderson, MD.**

**KN:** Thomas Coffman, MD, currently serves as President of the American Society of Nephrology. He is also the James R. Clapp Professor, Chief of the Division of Nephrology, and Senior Vice Chair for Academic Affairs in the Department of Internal Medicine at Duke.

How long have you been participating in ASN activities?



**Thomas Coffman, MD**

**Coffman:** I have been an ASN member since completing my fellowship training. In 1999, I chaired the Program Committee and began a stint on the Transplant Advisory Group. I continued to work on a number of committees until my election as Councilor in 2003.

**KN:** What is new during your term as ASN president?

**Coffman:** I hope I don't forget anything! Expansion of the internal staff to a size and structure appropriate for the scope of activities of the Society is the most important process, ongoing

since hiring Executive Director Tod Ibrahim last year. Our staff now includes the expertise and personnel to provide an ever-expanding array of quality services for our members. New leaders include Adrienne Lea, Director of Communications, and Phillip Kokemueller, Chief Learning Officer, providing staff oversight for burgeoning educational programs.

ASN's most visible products are publications. My term saw the birth of *ASN Kidney News* and the transition of *Clinical Journal of the American Society of Nephrology* to monthly publication. Podcasts of various publications have also been added.

New educational efforts include the appointments of Drs. John Burkart and Marc Pohl as Education Directors for the ASN Board Review Course. Web site offerings have expanded, including an online geriatric nephrology curriculum and audio versions of *NephSAP*.

**KN:** Is there anything new in the policy arena?

**Coffman:** We continue expanding our efforts to shape implementation of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) as it relates to the care of patients with kidney disease. We also provide input and feedback in the conversation regarding the Patient-Centered Medical Home. ASN leadership also lobbied on Capitol Hill for improved funding for research at NIH and enhanced support for kidney disease research in particular.

With the assistance of our Corporate Relations Task Force, we developed a set of principles to steer the Society through the choppy waters of

conflict of interest so we may continue to provide an array of balanced and unbiased educational programs for our members while maintaining productive and transparent relationships with our corporate partners.

**KN:** Please describe the transition process for the presidency.

**Coffman:** Transition starts with your election to Council. Over five years, you learn the scope of the ASN's operations, as well as its structure-function relationships. Your activities and responsibilities accelerate significantly during the President-Elect year, providing an opportunity to gear up for the Presidency year. Then you coast toward the sunset for one year as Past President.

**KN:** Sharon Anderson, MD, is the Society's President-Elect. You earned a nontraditional premedical degree?



**Sharon Anderson, MD**

**Anderson:** I received my BA in Government and Politics from the University of Maryland; it is a topic useful for academic medicine!

**KN:** How have you prepared for the Presidency?

**Anderson:** Given the complexity of the organization and its responsibilities, it is fortunate that the ASN has a long "apprenticeship" before the presidency. Council members serve five years learning about all of the various facets of the organization and rotating on all of the major ASN committees. Established

communication processes with meetings and conference calls have given me a pretty clear idea of the scope and duties of the presidency. There will undoubtedly be numerous details not currently apparent to me, but I trust that the lines of communication will stay open. The practice of having the Past President remain on Council for one year adds valuable continuity to the business of the Council, as well as veteran advice for the current and future presidents.

**KN:** What do you hope to accomplish during your term as ASN president?

**Anderson:** ASN must recognize the needs of its membership, including ever-changing challenges to nephrology and the larger medical community. Obviously, we want to continue to be the leading source of education for our members, and to innovate in methods for delivering our educational products. Our growing online presence and development of usable delivery methods, such as podcasts, are examples of initiatives that will expand. We plan to provide products to assist Maintenance of Certification (MOC) through the American Board of Internal Medicine. We plan expanded tools for trainee education, addressing future workforce needs.

*Continued on page 14*



*Continued from page 13*

ASN must continue to be a voice in public policy, advocating for wide-ranging initiatives including expanded research funding and better care for kidney patients through the Centers for Medicare and Medicaid Services (CMS). Nephrologists could be playing a stronger role in the national discussions regarding quality and patient safety. I hope we can encourage these efforts.

Finally, I hope we can develop stronger routes of communication with our membership to more rapidly and accurately

identify new and ongoing concerns. We need the ability to rapidly tap into the expertise of our membership and engage them in the approaches to the challenges we face.

**KN:** Dr. Coffman, do you have any advice for the incoming President?

**Coffman:** Time management is key! I wish I had known the amount of time that is actually required to do the job...and the number of emails that come in everyday related to ASN business. I also wish I had known that I would be

writing three NIH grant applications during my presidency.

**KN:** Is there anyone you would like to acknowledge?

**Coffman:** First I must thank my fellow Councilors and the ASN staff for their help and support. This year's Program Chair, Ray Harris, with his outstanding Program Committee, developed a superb program for Renal Week 2009. I must also acknowledge my division members and laboratory group for keeping the ball rolling at Duke despite my frequent

absences and consistent state of distraction this year. My family also deserves a nod for tolerating all of the extra work and travel.

**Anderson:** The leadership of Tod Ibrahim, Executive Director of ASN, has been instrumental in bringing a modern and professional structure to the staffing of the ASN office, lending confidence that we can continue to support and grow our various missions. The wisdom and guidance of more senior Council members is invaluable, and the dedicated ASN members who serve on our Committees and Advisory Groups do a great job keeping Council on track. Finally, the success of Renal Week is due in large part to the efforts of the Program Committee. I am pleased to report that David Ellison, Chair of the 2010 Program Committee, has assembled a terrific group for that most important task.

**KN:** What advice do you have for members who wish to become more engaged with ASN?

**Coffman:** Volunteer for Advisory Groups and lobbying efforts. Provide feedback on our services. One of the strengths of the ASN is a broad membership with a diverse array of talents, skills, and experiences.

**Anderson:** ASN cannot continue to be a relevant and effective organization without membership participation on Committees and Advisory Groups. Watch for the periodic requests for volunteers, and let us know you are interested. Members are welcome to send comments, suggestions, or concerns to the ASN staff, any Council member, or any Committee or Advisory Group Chair.

**KN:** So when is the transition complete?

**Anderson:** By tradition, the presidency changes with the passing of the gavel at the business meeting on the last day of Renal Week. To my knowledge, this is usually an orderly process accomplished without the need for a coup d'état or placing the outgoing president under house arrest.

**KN:** . . . although that would make for an exciting article in *ASN Kidney News*. ●

**NEW!**

**SCIENTIFICALLY DEVELOPED AND CLINICALLY TESTED  
PATENTED AND PROPRIETARY PROBIOTIC FORMULATION**

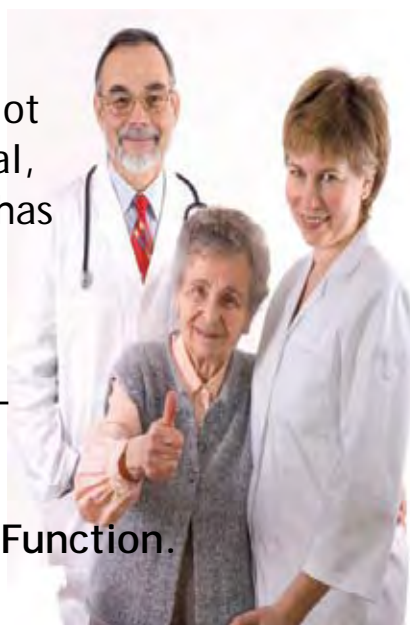
# A proven probiotic dietary supplement for kidney health (with money-back guarantee)

Kibow Biotics® probiotic formulation safely removes nitrogenous waste metabolites via the bowel, aiding in maintaining healthy kidney function\*.

In a limited pilot scale clinical trial, Kibow Biotics® has shown positive effects<sup>1</sup>.

Kibow Biotics® -- bringing hope for maintaining Healthy Kidney Function.

<sup>1</sup>Probiotic Dietary Supplement in patients with stage 3 and 4 chronic kidney disease: a 6-month pilot scale trial in Canada - Current Medical Research and Opinion (CMRO), Aug 2009



Kibow Biotics® is available exclusively from our online store [www.kibow.com](http://www.kibow.com) or by calling 1-888-271-2560 to order.

**90 Enteric-coated capsules**

**Safe, Natural  
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Easy to swallow**

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It is suggested that Kibow Biotics® be taken daily for a minimum period of three months to observe the positive effects and the usage continued thereafter.

\*These statements and product have not been evaluated by the US Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



# FAQs

A map of the San Diego Convention Center is included in both the Renal Week Onsite Book and the Day-at-a-Glance Pocket Guide, available at Materials Pickup. For extensive meeting information, please reference these resources.

## REGISTRATION

**Does my registration for an Early Program (In-Depth Nephrology Course, Advances in Research Conference, or Professional Development Seminar) include my registration for the rest of the week?**

No. The Early Programs and the Annual Meeting have separate registration fees.

### Where is the registration area?

Registration will be located in Hall D Foyer of the San Diego Convention Center. Registration will be open during the following times:

#### Early Programs:

Tuesday, October 27	7 a.m.–6 p.m.
Wednesday, October 28	7–10 a.m.

#### Annual Meeting:

Wednesday, October 28	7 a.m.–6 p.m.
Thursday, October 29	7 a.m.–6 p.m.
Friday, October 30	7:30 a.m.–5 p.m.
Saturday, October 31	7:30 a.m.–4 p.m.

**I preregistered and received my meeting badge in the mail. Do I still need to go to registration?**

No, but you still need to pick up your meeting bag from the Materials Pickup counter, located across from registration in Hall D Foyer of the San Diego Convention Center.

**A family member wants to accompany me to a session. Can she or he attend without registration?**

No. All participants must pay full registration and wear a meeting badge. Participants who do not wear a meeting badge will not be admitted entrance to Renal Week sessions or the ASN Scientific Exposition. Children under 12 are not permitted in any ASN meeting or session rooms or in the ASN Scientific Exposition at any time.

## MEETING MATERIAL

**Where do I pick up my meeting bag?**

The Materials Pickup counter will be located across from the registration area in Hall D Foyer of the San Diego Convention Center.

**Is there a daily schedule that I can reference?**

A convenient Day-at-a-Glance Pocket Guide will be included with your meeting materials.



## ASN SCIENTIFIC EXPOSITION and ABSTRACTS

**When does the ASN Scientific Exposition open?**

The ASN Scientific Exposition is located in Halls A/B/C of the San Diego Convention Center. The hall will be open during the following times:

Thursday, October 29	9:30 a.m.–5 p.m.
Friday, October 30	9:30 a.m.–5 p.m.
Saturday, October 31	9:30 a.m.–4 p.m.

**Where are the poster sessions?**

Posters will be located in Halls A/B/C of the San Diego Convention Center.

**When do I set up my poster?**

Marathon Multimedia sent all poster presenters an email providing them the date and time of their poster presentation. This email also included setup times. The check-in desks for poster presenters will be located outside of Hall A of the convention center.

**My poster was created by Marathon Multimedia and sent to Renal Week. Where do I pick it up?**

You may retrieve your poster at Marathon Multimedia's Call4Posters desk, located in the Hall A Foyer of the convention center.

**Where do I pick up my free Renal Week 2009 Abstracts CD?**

All abstracts that are submitted to Renal Week 2009 are recorded on compact disk (CD). Participants will receive a CD voucher in their meeting bag. This voucher can be redeemed at the Genzyme exhibit booth (#1015), while supplies last.

## PROGRAM and SESSION INFORMATION

**Where are the Early Programs located?**

All Early Programs will take place in the San Diego Convention Center. Room lists will be available at the ASN Information Booth, in your Onsite Book, in your Day-at-a-Glance Pocket Guide, and at each program check-in desk.

**Where do the Plenary (State of the Art/Award) Sessions take place?**

The Thursday, Friday, and Saturday morning plenary sessions will take place in Hall D of the San Diego Convention Center from 8 to 9:30 a.m., and the Sunday morning plenary session will take place from 8:30 to 9:30 a.m.

**How do I sign up to use the Microscope Room?**

Please sign up outside Room 18 of the convention center prior to Saturday, October 31, for a hands-on review session that will prepare you for Saturday's case discussions in the Clinical Nephrology Conference (CNC), Renal Biopsy: Clinical Correlations.

**Will the sessions be audio- or videotaped? Will they be available for purchase?**

All Plenary Sessions, Basic and Clinical Science Symposia, and Clinical Nephrology Conferences will be audio recorded, provided that the speaker has granted permission. In addition, selected Early Programs will be audio recorded. State-of-the-Art lectures will be video recorded. To order a Renal Week recording, please visit the audio/video recording sales desk located in the Hall A Foyer of the San Diego Convention Center.

*Continued on page 16*



# FAQs

*Continued from page 15*

## How do I attend educational symposia?

Educational Symposia attendance is on a first-come, first-served basis. These symposia will be held at the San Diego Marriott Hotel & Marina. For further details, see the Guide to Educational Symposia available at Materials Pickup.

## CONTINUING MEDICAL EDUCATION (CME) CREDITS/ATTENDANCE CERTIFICATES

### How do I obtain CME credits for Renal Week?

To obtain CME credits for attendance at Renal Week, participants must complete the online evaluation. The evaluation must be completed by Thursday, December 31, 2009. Members of the ASN staff are available to answer CME questions at the CME booth, which is located in ASN Services in Hall B of the San Diego Convention Center.

### I am an International participant and need a certificate of attendance. How do I get one?

Certificates of attendance will be available at the CME booth, which is located in ASN Services in Hall B of the San Diego Convention Center.

## GENERAL MEETING INFORMATION

### How do I get from my hotel to the airport?

A one-way taxi ride between the airport and downtown San Diego costs approximately \$12 per person.

### Who do I contact if I have problems with my hotel reservation?

Please visit the housing desk, located in the Hall D Foyer, near the registration area, in the convention center. The housing desk will be open Tuesday, October 27, to Saturday, October 31.

### How do I get back and forth to the convention center from my hotel?

Complimentary shuttle service will be available Tuesday, October 27, to Sunday, November 1, between the San Diego Convention Center and all participating hotels except those within immediate walking distance of the convention center (San Diego Marriott Hotel & Marina, Manchester Grand Hyatt, Omni, Hard Rock Hotel, Marriott Gaslamp, Hilton Gaslamp, Hilton San Diego, Bayfront in front of Omni, Hotel Solamar, Horton Grand, and Embassy Suites). A shuttle schedule will be posted at each hotel and in the San Diego Convention Center.

### What are my meal options?

Concession stands are located throughout the San Diego Convention Center as well as in the ASN Scientific Exposition hall, and a number of restaurants surround the convention center area. For dinner options, see page 50 in this issue of *ASN Kidney News*.

### Where can I check my coat/baggage?

A baggage and coat check will be available Tuesday, October 27, to Sunday, November 1, in Foyer A of the San Diego Convention Center.

### Bags, Inc.

Additionally, if you are bringing bags to the convention center on your day of departure, you may want to take advantage of Bags, Inc. The San Diego Convention Center, in partnership with Bags, Inc. (Baggage Airline Guest Services), offers an advanced airport check-in program with Alaska, American, Continental, Delta, jetBlue and United Airlines. Take advantage of this flight check-in service by visiting Bags, Inc., inside the lobby of the convention center. For a \$10 per person fee, you can obtain a boarding pass and check up to two bags for your return flight, saving you time and eliminating the check-in lines at the airport. Standard baggage policies for each airline will apply.

### Where is the Lost and Found?

Lost and found items will be turned in to the San Diego Convention Center's Security Department. If you have lost or found an item, please use one of the many white house phones located throughout the lobby areas of the convention center to contact security directly by dialing extension 5490. Security personnel will provide you with further instructions.

### How do I access the Internet?

Is there Internet access in the convention center?

The ASN Cyber Center is located in Halls A/B/C of the San Diego Convention Center. All attendees can access the Internet from this computer bank. Additionally, wifi access is available Tuesday, October 27, through Sunday, November 1, in the lobbies, hallways, and meeting rooms of ASN's Renal Week sessions.

### Is there a place where I can charge my laptop?

ASN has created several charging station areas throughout the convention center. Please stop by the foyer areas of rooms 1-5, room 6, room 20, and inside the Scientific Exposition in Halls A/B/C to take advantage of our charging stations. Please note, you must remain with your computer at all times as ASN accepts no liability for computers that are left unattended.

### Where is the ASN management office?

The ASN Management Office is located in room 14 of the San Diego Convention Center.

### Where is the ASN Speaker Ready Room?

The Speaker Ready Room is located in room 11 of the San Diego Convention Center.

### Where is the ASN Press Room?

The ASN Press Room, available to journalists reporting from Renal Week 2009, is located in room 13 of the San Diego Convention Center.

## HOW DO I CONTACT . . . ?

ASN Management Office . . . . .	619-525-6270
ASN Registration . . . . .	619-525-6258
ASN Renal Week Shuttle Information . . . . .	619-525-6280
ASN Press Room . . . . .	619-525-6267
ASN Services . . . . .	619-525-6262
ASN Speaker Ready Room . . . . .	619-525-6275





# THEY'RE MAKING YOU SWITCH.

## BUT YOU DECIDE TO WHICH.

47% of CKD Stage 5 patients failed to meet serum phosphorus targets (DOPPS).<sup>1</sup> When you're forced to switch this summer, choose FOSRENOL®.

**Don't just switch. Change — to FOSRENOL.**

FOSRENOL is indicated to reduce serum phosphate in patients with end stage renal disease.

### Important Safety Information

- The most common adverse events were gastrointestinal, such as nausea and vomiting, and generally abated over time with continued dosing
- The most common side effects leading to discontinuation in clinical trials were gastrointestinal events (nausea, vomiting, and diarrhea)
- Other side effects reported in trials included dialysis graft complications, headache, abdominal pain, and hypotension
- Although studies were not designed to detect differences in risk of fracture and mortality, there were no differences demonstrated in patients treated with FOSRENOL® compared to alternative therapy for up to 3 years
- The duration of treatment exposure and time of observation in the clinical program were too short to conclude that FOSRENOL® does not affect the risk of fracture or mortality beyond 3 years
- While lanthanum has been shown to accumulate in the GI tract, liver, and bone in animals, the clinical significance in humans is unknown
- Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease, or bowel obstruction were not included in FOSRENOL® clinical studies. Caution should be used in patients with these conditions
- FOSRENOL® should not be taken by patients who are nursing or pregnant
- FOSRENOL® should not be taken by patients who are under 18 years of age

**Reference: 1.** Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis.* 2008;52(3):519-530.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please see brief summary of Full Prescribing Information on adjacent page.

[www.fosrenol.com](http://www.fosrenol.com)

FOSRENOL® is registered with the US Patent and Trademark Office.

©2009 Shire US Inc., Wayne, PA 19087 FOS-00524 05/09

 **FOSRENOL®**  
(lanthanum carbonate)

 Shire



**BRIEF SUMMARY:** Consult the Full Prescribing Information for complete product information.

**FOSRENOL® (foss-wren-all)**  
(Lanthanum Carbonate) 500, 750, and 1000 mg Chewable Tablets.

**INDICATIONS AND USAGE**  
FOSRENOL® is indicated to reduce serum phosphate in patients with end stage renal disease.

**CONTRAINDICATIONS**  
None known.

**PRECAUTIONS**  
**General:**  
Patients with acute peptic ulcer, ulcerative colitis, Crohn’s disease or bowel obstruction were not included in FOSRENOL® clinical studies. Caution should be used in patients with these conditions.

**Diagnostic Tests:**  
Abdominal x-rays of patients taking lanthanum carbonate may have a radio-opaque appearance typical of an imaging agent.

**Long-term Effects:**  
There were no differences in the rates of fracture or mortality in patients treated with FOSRENOL® compared to alternative therapy for up to 3 years. The duration of treatment exposure and time of observation in the clinical program are too short to conclude that FOSRENOL® does not affect the risk of fracture or mortality beyond 3 years.

**Information for the Patient:**  
FOSRENOL® tablets should be taken with or immediately after meals. Tablets should be chewed completely before swallowing. To aid in chewing, tablets may be crushed. Intact tablets should not be swallowed.

Notify your physician that you are taking FOSRENOL® prior to an abdominal x-ray (see **PRECAUTIONS, Diagnostic Tests**).

**Drug Interactions:**  
FOSRENOL® is not metabolized.

Studies in healthy subjects have shown that FOSRENOL® does not adversely affect the pharmacokinetics of warfarin, digoxin or metoprolol. The absorption and pharmacokinetics of FOSRENOL® are unaffected by co-administration with citrate-containing compounds (see **CLINICAL PHARMACOLOGY: In Vitro/In Vivo Drug Interactions**).

An *in vitro* study showed no evidence that FOSRENOL® forms insoluble complexes with warfarin, digoxin, furosemide, phenytoin, metoprolol and enalapril in simulated gastric fluid. However, it is recommended that compounds known to interact with antacids should not be taken within 2 hours of dosing with FOSRENOL®.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**  
Oral administration of lanthanum carbonate to rats for up to 104 weeks, at doses up to 1500 mg of the salt per kg/day [2.5 times the maximum recommended daily human dose (MRHD) of 5725 mg, on a mg/m² basis, assuming a 60-kg patient] revealed no evidence of carcinogenic potential. In the mouse, oral administration of lanthanum carbonate for up to 99 weeks, at a dose of 1500 mg/kg/day (1.3 times the MRHD) was associated with an increased incidence of glandular stomach adenomas in male mice.

Lanthanum carbonate tested negative for mutagenic activity in an *in vitro* Ames assay using *Salmonella typhimurium* and *Escherichia coli* strains and *in vitro* HGPRT gene mutation and chromosomal aberration assays in Chinese hamster ovary cells. Lanthanum carbonate also tested negative in an oral mouse micronucleus assay at doses up to 2000 mg/kg (1.7 times the MRHD), and in micronucleus and unscheduled DNA synthesis assays in rats given IV lanthanum chloride at doses up to 0.1 mg/kg, a dose that produced plasma lanthanum concentrations >2000 times the peak human plasma concentration.

Lanthanum carbonate, at doses up to 2000 mg/kg/day (3.4 times the MRHD), did not affect fertility or mating performance of male or female rats.

**Pregnancy:**  
Pregnancy Category C. No adequate and well-controlled studies have been conducted in pregnant women. The effect of FOSRENOL® on the absorption of vitamins and other nutrients has not been studied in pregnant women. FOSRENOL® is not recommended for use during pregnancy.

In pregnant rats, oral administration of lanthanum carbonate at doses as high as 2000 mg/kg/day (3.4 times the MRHD) resulted in no evidence of harm to the fetus. In pregnant rabbits, oral administration of lanthanum carbonate at 1500 mg/kg/day (5 times the MRHD) was associated with a reduction in maternal body weight gain and food consumption, increased post-implantation loss, reduced fetal weights, and delayed fetal ossification. Lanthanum carbonate administered to rats from implantation through lactation at 2000 mg/kg/day (3.4 times the MRHD) caused delayed eye opening, reduction in body weight gain, and delayed sexual development (preputial separation and vaginal opening) of the offspring.

**Labor and Delivery**  
No lanthanum carbonate treatment-related effects on labor and delivery were seen in animal studies. The effects of lanthanum carbonate on labor and delivery in humans is unknown.

**Nursing Mothers:**  
It is not known whether lanthanum carbonate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FOSRENOL® is administered to a nursing woman.

**Geriatric Use:**  
Of the total number of patients in clinical studies of FOSRENOL®, 32% (538) were ≥ 65, while 9.3% (159) were ≥ 75. No overall differences in safety or effectiveness were observed between patients ≥ 65 years of age and younger patients.

**Pediatric Use:**  
While growth abnormalities were not identified in long-term animal studies, lanthanum was deposited into developing bone including growth plate. The consequences of such deposition in developing bone in pediatric patients are unknown. Therefore, the use of FOSRENOL® in this population is not recommended.

**ADVERSE REACTIONS**  
The most common adverse events for FOSRENOL® were gastrointestinal events, such as nausea and vomiting and they generally abated over time with continued dosing.  
In double-blind, placebo-controlled studies where a total of 180 and 95 ESRD patients were randomized to FOSRENOL® and placebo, respectively, for 4-6 weeks of treatment, the most common events that were more frequent (≥5% difference) in the FOSRENOL® group were nausea, vomiting, dialysis graft occlusion, and abdominal pain (Table 1).

Table 1. Adverse Events That Were More Common on FOSRENOL® in Placebo-Controlled, Double-Blind Studies with Treatment Periods of 4-6 Weeks.		
	FOSRENOL® % (N=180)	Placebo % (N=95)
Nausea	11	5
Vomiting	9	4
Dialysis graft occlusion	8	1
Abdominal pain	5	0

The safety of FOSRENOL® was studied in two long-term clinical trials, which included 1215 patients treated with FOSRENOL® and 943 with alternative therapy. Fourteen percent (14%) of patients in these comparative, open-label studies discontinued in the FOSRENOL®-treated group due to adverse events. Gastrointestinal adverse events, such as nausea, diarrhea and vomiting were the most common type of event leading to discontinuation.  
The most common adverse events (≥5% in either treatment group) in both the long-term (2 year), open-label, active controlled, study of FOSRENOL® vs. alternative therapy (Study A) and the 6-month, comparative study of FOSRENOL® vs. calcium carbonate (Study B) are shown in Table 2. In Table 2, Study A events have been adjusted for mean exposure differences between treatment groups (with a mean exposure of 0.9 years on lanthanum and 1.3 years on alternative therapy). The adjustment for mean exposure was achieved by multiplying the observed adverse event rates in the alternative therapy group by 0.71.

Table 2. Incidence of Treatment-Emergent Adverse Events that Occurred in ≥ 5% of Patients (in Either Treatment Group) and in Both Comparative Studies A and B				
	Study A %		Study B %	
	FOSRENOL® (N = 682)	Alternative Therapy Adjusted Rates (N=676)	FOSRENOL® (N=533)	Calcium Carbonate (N=267)
Nausea	36	28	16	13
Vomiting	26	21	18	11
Dialysis graft complication	26	25	3	5
Diarrhea	23	22	13	10
Headache	21	20	5	6
Dialysis graft occlusion	21	20	4	6
Abdominal pain	17	17	5	3
Hypotension	16	17	8	9
Constipation	14	13	6	7
Bronchitis	5	6	5	6
Rhinitis	5	7	7	6
Hypercalcemia	4	8	0	20

**OVERDOSAGE**  
There is no experience with FOSRENOL® overdosage. Lanthanum carbonate was not acutely toxic in animals by the oral route. No deaths and no adverse effects occurred in mice, rats or dogs after single oral doses of 2000 mg/kg. In clinical trials, daily doses up to 4718 mg/day of lanthanum were well tolerated in healthy adults when administered with food, with the exception of GI symptoms. Given the topical activity of lanthanum in the gut, and the excretion in feces of the majority of the dose, supportive therapy is recommended for overdosage.

**DOSAGE AND ADMINISTRATION**  
The total daily dose of FOSRENOL® should be divided and taken with meals. The recommended initial total daily dose of FOSRENOL® is 1500 mg. The dose should be titrated every 2-3 weeks until an acceptable serum phosphate level is reached. Serum phosphate levels should be monitored as needed during dose titration and on a regular basis thereafter.

In clinical studies of ESRD patients, FOSRENOL® doses up to 3750 mg were evaluated. Most patients required a total daily dose between 1500 mg and 3000 mg to reduce plasma phosphate levels to less than 6.0 mg/dL. Doses were generally titrated in increments of 750 mg/day.

**Tablets should be chewed completely before swallowing. To aid in chewing, tablets may be crushed. Intact tablets should not be swallowed.**

Store at 25°C (77°F): excursions permitted to 15-30°C (59-86°F)  
[See USP controlled room temperature]  
Protect from moisture

**Rx only**  
Manufactured for Shire US Inc., Wayne, PA 19087, USA 1-800-828-2088  
Rev: 4/2008  
251 0107 003A  
FOS-00502







# Grants and Funding Opportunities

**ASN funds clinical and basic research, and provides grant support to members at various points in their careers.**

**Career Development Grants for New Investigators –**

Advancing the independent careers of young investigators in biomedical research, ASN awards these grants to applicants within seven years of initial faculty appointment.

Next application deadline: Friday, January 29, 2010

**Interim Funding Grants for Established Investigators –**

ASN provides bridge grant support to investigators who have submitted a competitive renewal R01 application, but were not funded.

Upcoming application deadlines: Friday, November 13, 2009; Friday, March 5, 2010; Friday, June 4, 2010

**Grants for Medical Student Research –** ASN enables selected medical students with an interest in either basic or clinical research to spend time engaged in work on a kidney research project.

Upcoming application deadlines: Friday, March 5, 2010; Friday, October 1, 2010

**Travel Support Opportunities –** Various travel support opportunities are available to ASN members to attend Renal Week 2010.

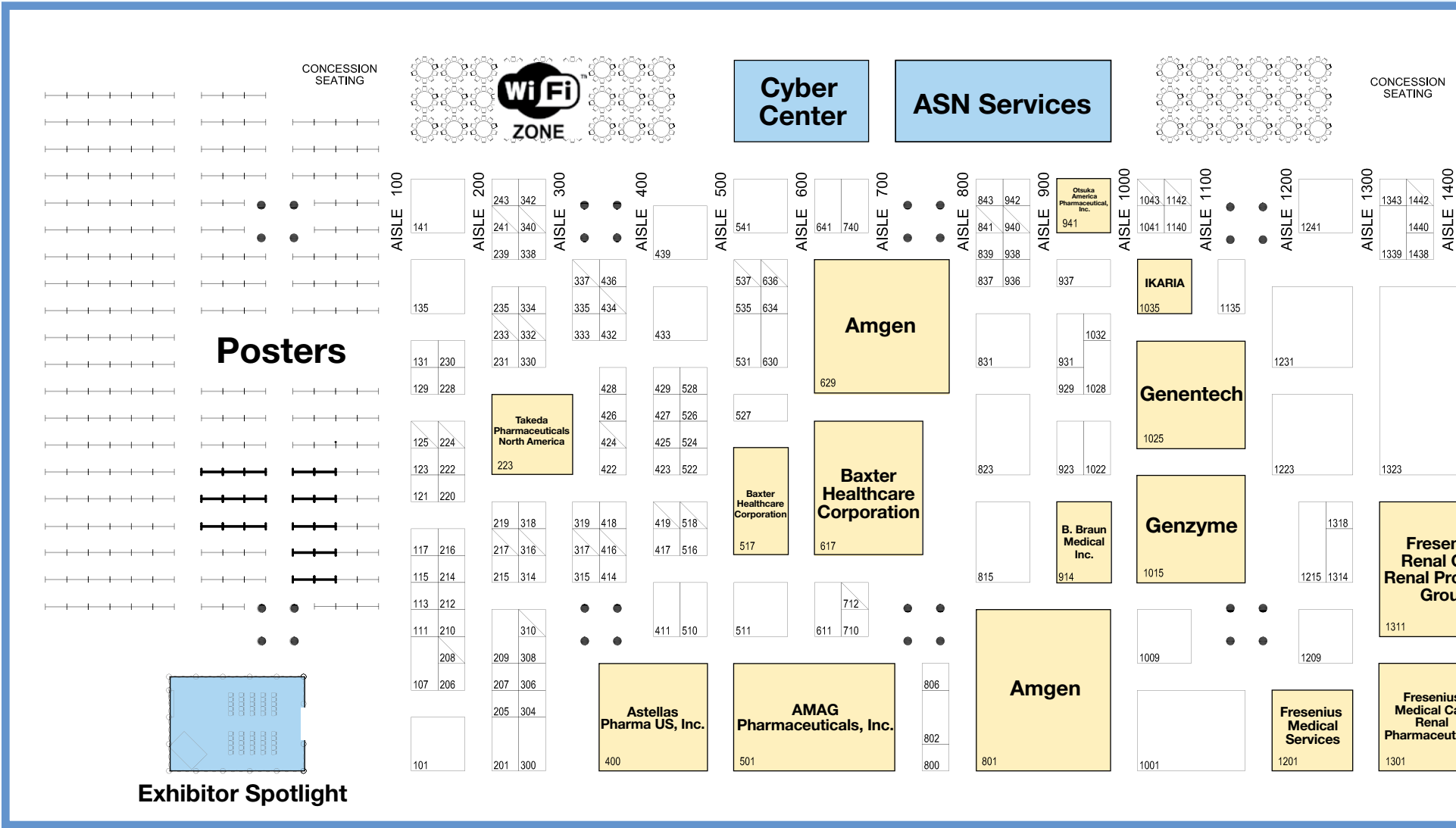
Next application deadline: Friday, July 30, 2010

**For more information regarding ASN Grants and Funding, please contact [grants@asn-online.org](mailto:grants@asn-online.org) or visit [www.asn-online.org](http://www.asn-online.org).**



# ASN Scientific Exposition

Thursday, October 29 – Saturday, October 31



## Exhibitor Spotlight Schedule

### Thursday, October 29

#### 9:30 a.m. – 10:00 a.m.

The Consequences and Risks of Biochemical Abnormalities Associated with Secondary Hyperparathyroidism  
*presented by*



#### 11:30 a.m. – 12:00 p.m.

A New Approach to Hyponatremia Treatment  
*presented by*



Otsuka America Pharmaceutical, Inc.

#### 1:30 p.m. – 2:00 p.m.

The Coming Bundled Environment: Effects on IV Iron and ESA Utilization – Appropriate Provision of Anemia Care and Cost Containment  
*presented by*



#### 3:30 p.m. – 4:00 p.m.

Real-time Monitoring of Dialysis Dose.  
Precise Measurement in Spent Dialysate.  
*presented by*



### Friday, October 30

#### 9:30 a.m. – 10:00 a.m.

Challenging the ESRD Treatment Default to Improve Outcomes  
*presented by*



#### 11:30 a.m. – 12:00 p.m.

Improving Quality of Care in the First Year of Dialysis  
*presented by*



#### 1:30 p.m. – 2:00 p.m.

A New Approach to Hyponatremia Treatment  
*presented by*



Otsuka America Pharmaceutical, Inc.

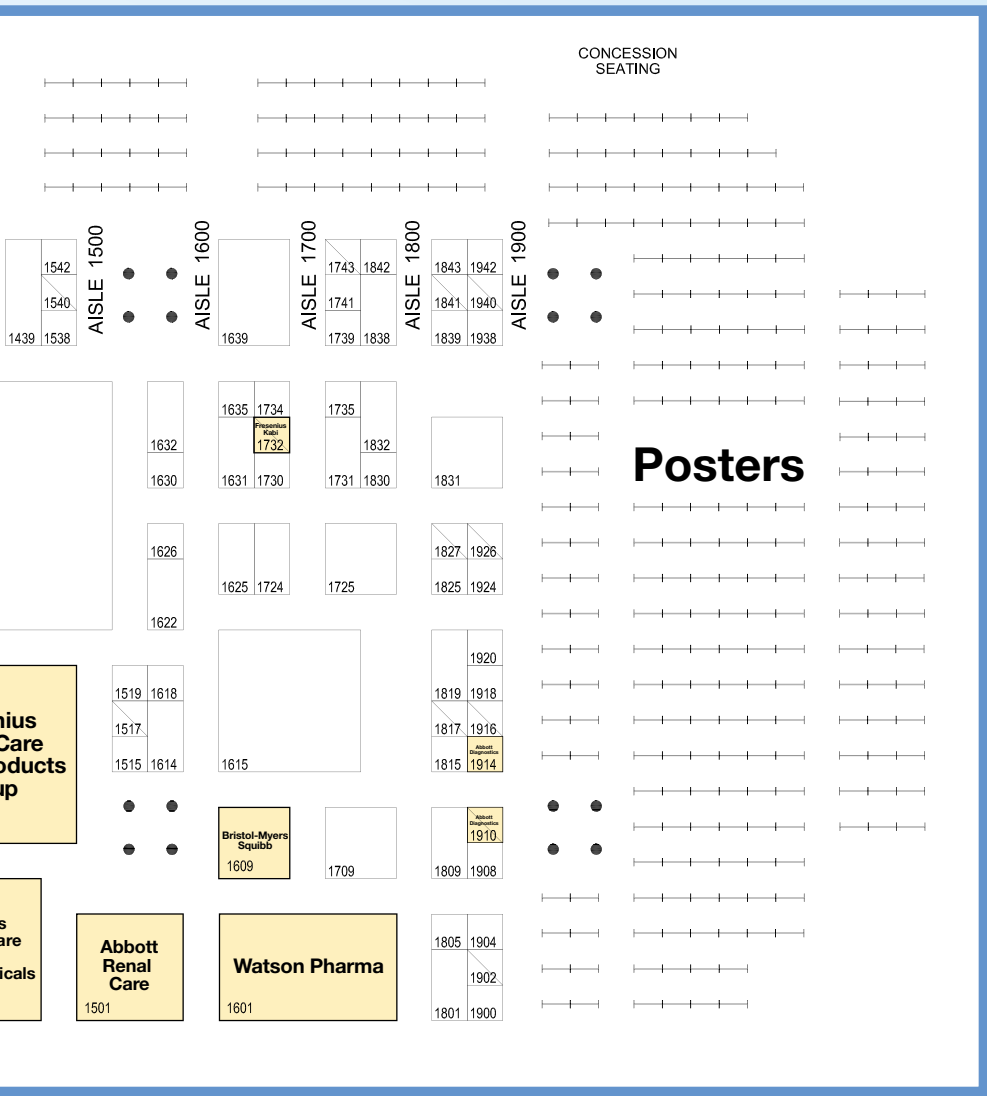
### Saturday, October 31

#### 9:30 a.m. – 10:00 a.m.

The Coming Bundled Environment: Effects on IV Iron And ESA Utilization – Iron Replacement Therapy: Assessing Today's Options  
*presented by*







# ASN Scientific Exposition Hours:

Thursday, October 29	9:30 a.m. – 5:00 p.m.
Friday, October 30	9:30 a.m. – 5:00 p.m.
Saturday, October 31	9:30 a.m. – 4:00 p.m.

## The 2009 ASN Scientific Exposition includes:

- Over 170 Exhibiting Companies
- ASN Exhibitor Spotlight
- ASN Services
- Complimentary Refreshment Breaks
- Cyber Center
- Poster Sessions



## ASN Services

- ASN Career Center
- ASN Membership
- ASN Publications – JASN, CJASN, NephSAP,
- ASN Kidney News
- ASN Web Services
- ABIM – Certification/MOC
- CME Information
- General Information

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# Tips for Renal Week

October 27 – November 1 • San Diego

## Know your priorities

### Plan ahead with Learning Pathways:

- Acute Kidney Injury
- Bone and Mineral Metabolism
- Cell and Transport Physiology
- Chronic Kidney Disease
- Development
- Dialysis
- Glomerulonephritis
- Hypertension & Cardiovascular Disease
- Novel Translational Approaches
- Pathology
- Renal Cystic Diseases
- Transplantation/Immunology

### Consider “Meetings-Within-a-Meeting”

- Epithelial Transport & Cell Biology
- Renal Immunology & Transplantation
- New Insights into Glomerular Structure & Function
- Kidney Development & Stem Cells

*Each Meeting-Within-a-Meeting will take place in the same location throughout Renal Week and will feature clinical and basic science symposia, as well as free communication (oral) sessions on the topic*

**Use the “Day at a Glance Pocket Guide” to search for programs;  
see what catches your eye**

**Check out the online program for key word searches**

- [www.asn-online.org/renalweek](http://www.asn-online.org/renalweek)

## Enjoy San Diego!

**Learn about San Diego before you go:**

- [www.sandiego.org/visitorcenter.asp](http://www.sandiego.org/visitorcenter.asp)

**Meals are less expensive outside of the convention center**

**Network, network, network in both formal and informal settings**

## There are very few rules:

**No photography or videotaping during presentations**

**Silence cell phones and pagers during sessions**

**You don't have to sit through a whole session, but be considerate  
of those around you if you move from room to room**



# 2009 Renal Week Corporate Supporters

ASN gratefully acknowledges the following companies for their support of Renal Week 2009.

## Basic and Clinical Science Symposia

"An Expanding Role for HIF  
and VHL in the Kidney"  
and  
"Novel Therapeutic  
Approaches Against AKI"



"Renal Anemia and ESA"



## Convention Center Banners



Day-at-a-Glance Pocket Guide  
and  
ASN Onsite Program Book



## General Support



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## Plenary Session I



## Preliminary Program



## President's Dinner



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# CHART YOUR COURSE:

## Thursday, October 29, 2009

8–9:30 a.m.

### Plenary Session

Presidential Address

*Thomas M. Coffman, MD, FASN*

John P. Peters Award

*William E. Mitch, MD*

State-of-the-Art Lecture

*Roger Y. Tsien, PhD*

“Breeding and Building Molecules for Whole-Animal and Clinical Imaging”

9:30 a.m.–5 p.m.

**ASN Scientific Exposition open** (pharmaceutical, device, imaging, and nephrology services exhibits and display of basic science, clinical science, and nephrology education research posters)

10 a.m.–noon

### Scheduled authors present at posters

#### Clinical Nephrology Conferences

- Cardiorenal Syndrome
- Desperately Seeking a Donor: Difficult Choices in Kidney Donation
- Peritoneal Dialysis: A Bright Past and Unknown Future
- Primary Care for Nephrologists: HIV Nephropathy
- Reducing Health Disparities in CKD

Noon–1:15 p.m.

#### Educational Symposia

Controversies in Anemia Management of CKD Patients

*Support for this session is provided by an educational grant from Fresenius Medical Care North America*

Racial Disparities in Patients with Chronic Kidney Disease

*Support for this session is provided by an educational grant from Amgen*

Update in Transplant Immunology for the Clinician

*Support for this session is provided by an educational grant from Bristol-Myers Squibb*

1:30–3:30 p.m.

#### Basic and Clinical Science Symposia

- A Fresh Look at Atherogenesis
- A Picture is Worth a Thousand Words: Novel Imaging Techniques and Biology
- Aging: Is the End Inevitable?
- Biomarkers in Kidney Disease
- Immunosuppression Update
- Macrophages and Mast Cells in Renal Injury and Health
- Molecular and Cellular Mechanisms of Phosphate Control
- Molecular Mechanisms of Nephrotic Syndrome: Novel Insights
- Renal Anemia and ESA
- Reprogramming and Induced Pluripotency: Does this Apply to the Kidney?
- The Epigenetic Epidemic: Understanding the Grammar of Genetic Language
- Thrombotic Microangiopathies: The Complement-Clot Connection
- Updates on Clinical Trials: CRIC, CKiD, AASK Cohort and FSGS Trial Findings

#### Meetings-Within-a-Meeting

- Thick Ascending Limb Function and Dysfunction: The Steven C. Hebert Memorial Symposium

Public Policy Forum

- Conflicts of Interest in Medicine  
*The Christopher R. Blagg Endowed Lectureship will be presented in this session by Bernard Lo, MD*

United States Renal Data System (USRDS)

4–6 p.m.

#### Clinical Nephrology Conferences

- Are We Making Progress in Vascular Access?
- Hepatitis C and Renal Disease
- Hypertensive Nephrosclerosis: Cause or Consequence of Hypertension
- Literature Review: ICU Nephrology and Critical Care Medicine
- Management of Common Problems in Polycystic Kidney Disease

#### Meetings-Within-a-Meeting

- ENaC and ROMK

#### Free Communication Sessions

- Advances and Controversies in GFR
- Biomarkers and Imaging in Glomerular Disease
- Cell Survival, Regeneration, and Growth
- Clinical Aspects of Chronic Kidney Disease: Prognosis and Complications I
- Clinical Aspects of Hypertension
- Clinical Transplantation: Complications, Graft Dysfunction, and Antibody-Mediated Injury
- Experimental Transplantation: Immune Regulation and Tolerance
- Improving Survival and Decreasing Morbidity on Dialysis
- Long-Term Outcomes and Methodologic Considerations in AKI
- Mechanisms of Renal Fibrosis
- Methods and Adequacy of Renal Dialysis
- Molecular Basis of Cystic Disease
- New Insights into Diabetic Nephropathy
- Protein Sorting and Epithelial Polarity
- Structure and Function of Acid/Base Transporters
- Vascular Calcification

7–8:30 p.m.

#### Basic Science Symposium

Using GUDMAP: A Resource for Scientists and Clinicians

## Friday, October 30, 2009

6:30–7:45 a.m.

#### Educational Symposia

Hepatorenal Syndrome

*Support for this session is provided by an educational grant from IKARIA*

Innovations in Caring for Patients with Hyponatremia

*Support for this session is provided by an educational grant from Otsuka America Pharmaceutical, Inc.*

8–9:30 a.m.

#### Plenary Session

Young Investigator Award and Address

*Matthias Kretzler, MD*

Robert G. Narins Award

*Burton D. Rose, MD*

State-of-the-Art Lecture

*Kári Stefánsson, MD*

“Genetic Associations in Complex Human Diseases”

9:30 a.m.–5 p.m.

**ASN Scientific Exposition open**

10 a.m.–noon

### Scheduled authors present at posters

#### Clinical Nephrology Conferences

- Debates in Renal Disease 1: Does How We Dialyze People with AKI Make a Difference?
- Debates in Renal Disease 2: Combination with ACEI and ARB is More Efficacious than Monotherapy
- Infectious Risk in Renal Replacement Therapy
- The Changing Face of FSGS/MCD
- Thrombotic Microangiopathies
- Vascular Calcification

Noon–1:15 p.m.

#### Educational Symposia

Innovative Approaches and Prevention Strategies for CKD-MBD

*Support for this session is provided by an educational grant from Abbott Laboratories Inc.*

New Frontiers in Chronic Kidney Disease—Mineral and Bone Disorders (CKD-MBD)

*Support for this session is provided by an educational grant from Genzyme Corporation*

The Role of Iron in Outpatient CKD Management

*Support for this session is provided by an educational grant from AMAG Pharmaceuticals, Inc.*

1:30–3:30 p.m.

#### Basic and Clinical Science Symposia

- Appealing to the Base: New Approaches to Diagnosis and Treatment of Acidosis in the ICU
- A Bench-to-Bedside View of Uremic Toxins
- An Expanding Role for HIF and VHL in the Kidney
- Defense Mechanisms Against AKI
- Kidney-Brain: Emerging Parallels in Cell Biology
- Nephrolithiasis
- The History and Challenges Involving Nephrology and the FDA
- Therapies and Therapeutic Targets on the Horizon for Hypertension
- Vascular Calcification in CKD: Roles of Mineral Metabolism Disorder and Cross-Talk with Bone
- What's New in Diabetic Nephropathy Research

Modifiable Hemodialysis Practices: Latest Trends and Outcomes from Dialysis Outcomes and Practice Patterns Study (DOPPS)

#### Free Communication Sessions

- Novel Insights in Experimental Renal Disease

#### Meetings-Within-a-Meeting

- Inflammation and Immune Tolerance
- Nephron Formation from Beginning to End
- Signaling at the Slit and Beyond: Podocytes and Fruit Flies
- The Renal Basis of Hypertension and Edema  
*The Robert W. Schrier Endowed Lectureship will be presented in this session by Thomas Kleyman, MD*

ASN Public Policy Board Symposium

- Health Care Delivery: Repairing a Broken System

4–6 p.m.

#### Clinical Nephrology Conferences

- Glomerular Injury in Progressive Renal Disease
- Nephrology Quiz & Questionnaire
- Quotidian (Daily) Dialysis
- The Importance of Proteinuria as a Surrogate for Outcome in CKD
- Update in Acute Kidney Injury



## Meetings-Within-a-Meeting

- Clinical Transplantation: Outcomes
- Kidney Development: Patterning and Morphogenesis
- Renal Pathology: Glomerular Cell Biology
- Trafficking and Phosphorylation: Regulation of Na-Cl Transport

## Free Communication Sessions

- Biomarkers and Therapies for AKI
- Cardiovascular Disease and Risk Factors in Dialysis
- Cell Signaling Networking and Kidney Disease
- CKD: Disparities in Risk Access and Outcomes
- Experimental Transplantation: Innate and Adaptive Immune Mechanisms
- FGF23, Klotho, Parathyroid Hormone and Vitamin D
- Genetics of Common Kidney Diseases
- Novel Aspects of Renal Tubular Phosphate Handling
- Understanding the Mechanism of CKD Progression
- Vascular Access in Hemodialysis
- Vascular Pathology of Kidney Disease
- Where Do We Stand with ACEs and ARBs in Patients with Diabetic Kidney Disease?

**4-6 p.m.**

## Late-Breaking Clinical Trials Session

**Saturday, October 31, 2009**

**6:30-7:45 a.m.**

## Educational Symposia

Controlling Diabetes Mellitus by Targeting the Kidney

*Support for this session is provided by an educational grant from AstraZeneca and Bristol-Myers Squibb*

Understanding the Kidney-Heart Connection

*Support for this session is provided by an educational grant from Astellas Pharma US, Inc.*

**8-9:30 a.m.**

## Plenary Session

Homer W. Smith Award and Address: Minerals in Motion: From Renal Transportation to New Concepts

*Rene J.M. Bindels, PhD*

State-of-the-Art Lecture

*Bruce Beutler, MD*

“Genetic Insights into the Innate Immune System”

**9:30 a.m.-4 p.m.**

## ASN Scientific Exposition open

**10 a.m.-noon**

## Scheduled authors present at posters

## Clinical Nephrology Conferences

- Diabetic Nephropathy
- Important Clinical Trials in Transplantation
- Is Peritoneal Dialysis Membrane Failure Inevitable with Long-Term Use?
- Renal Diseases of Children in Adults
- The Kidney in End Stage Liver Disease

**Noon-1:15 p.m.**

## Educational Symposium

Impact of Bundled Payments on Care for ESRD Patients

*Support for this session is provided by an educational grant from Amgen*

**1:30-3:30 p.m.**

## Basic and Clinical Science Symposia

- Advances in Research on the Renin-Angiotensin System
- Beyond SNPs: Novel Functional Genetic Polymorphisms and Human Disease
- CKD-MBD and Outcomes  
*The Jack W. Coburn Endowed Lectureship will be presented in this session by L. Darryl Quarles, MD*
- Emerging Angiogenic Therapies and the Renal Vasculature
- Hemodialysis Vascular Access
- How Shall I Eat You: The Art and Science of Autophagy
- Novel Therapeutic Approaches Against AKI

- Obesity and Kidney Disease
- The Genome Gets Personal: Progress, Uncertainty, and Challenges

## Meetings-Within-a-Meeting

- Kidney Repair: How Does it Occur and do Renal Stem Cells Exist?
- Monitoring the Renal Transplant Recipient
- Novel Insights of Glomerular Function and Structure (Controversies)

*The Barry M. Brenner Endowed Lectureship will be presented in this session by Oliver Smithies, PhD*

- Tight Junctions in Kidney Health and Disease

## Free Communication Sessions

- Inflammation and Oxidation from Bench to Bedside

*Continued on page 26*

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## DAYS-AT-A-GLANCE

Continued from page 25

- Update on Peritoneal Dialysis

ClinicoPathologic Conference

**4–6 p.m.**

### Clinical Nephrology Conferences

- Batten Down the Hatches: The Approaching Tidal Wave of Hypertension and Its Sequelae in the Young
- Management of Hyponatremia
- Multiple Myeloma
- Renal Biopsy: Clinical Correlations
- Sex and the Kidney

### Meetings-Within-a-Meeting

- Clinical Advances in Glomerular Disease
- Clinical Transplantation: Novel Clinical Trials
- Renal Progenitors/Stem Cells, Regeneration, and Novel Therapies
- Urea Transporters, Aquaporin and Water Balance

### Free Communication Sessions

- Anemia, Nutrition and Metabolism in Dialysis
- Clinical Aspects of Chronic Kidney Disease: Prognosis and Complications II

- Experimental Glomerulonephritis and Renal Immunology
- Genomics and Systems Biology of Renal Disease
- Injury Repair Mechanisms and New Therapeutic Approaches in AKI
- Inflammatory Mechanisms of Renal Disease
- Molecular Mechanisms in Kidney Physiology and Pathophysiology
- Pathogenesis and Features of CKD Related Bone Disease
- Physiology and Pathophysiology of Hypertension
- Putting the Pathways Together in Diabetic Nephropathy
- Vascular Pathophysiology and Renal Hemodynamics

## Sunday, November 1, 2009

**8–8:30 a.m.**

### ASN Business Meeting

**8:30–9:30 a.m.**

### Plenary Session

Belding H. Scribner Award Presentation  
*James E. Cimino, MD*

State-of-the-Art Lecture  
*Tony Pawson, PhD*

“Signal Transduction Mechanisms in the Kidney”

**10–11:30 a.m.**

### Kidney Disease Improving Global Outcomes (KDIGO) Update

**10 a.m.–noon**

### Basic and Clinical Science Symposia

- AKI in the ICU
- Environmental Exposure and Kidney Disease
- Fetal Programming: The Benefits of Being Well-Endowed
- IgA Nephropathy Update
- Lipid Mediators in the Kidney
- Molecular Nephropathology
- Personalized Medicine: From Here to Application in Nephrology

### Meetings-Within-a-Meeting

- A Polarized View of Cysts
- B Cells in Transplantation: From Bench to Clinic
- Disease Association and Functionalization of DNA Variants
- Flow Regulation of Nephron Function

ESRD: State-of-the-Art and Charting the Challenges for the Future

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## ASN Recognizes Grant Supporters

The American Society of Nephrology (ASN) gratefully acknowledges the continued support of the following organizations. Their commitment assists the Society in its ongoing efforts to fund research that improves treatment and care for patients with kidney disease.

- ▶ The Alaska Kidney Foundation for support of the Alaska Kidney Foundation-ASN Research Grant
- ▶ The Association of Specialty Professors (ASP) for support of the ASN-ASP Junior Development Grant in Geriatric Nephrology
- ▶ The Halpin Foundation for support of The Halpin Foundation-ASN Research Grant





Kidney disease affects one out of every nine adults. If kidney disease is detected and treated early, kidney function can be preserved. At Yale-New Haven Hospital we are dedicated to delivering compassionate, high-quality care for people with kidney conditions. We provide the latest therapies to minimize the impact of kidney disease and allow our patients to lead healthy and fulfilling lives.

Our doctors have particular expertise in treating kidney stones, hypertension, pregnancy-associated kidney problems, polycystic kidney disease, glomerulonephritis and inflammation of the kidney. For advanced kidney disease we offer a wide range of care options including transplantation and all forms of dialysis.

Our researchers are internationally recognized leaders in the study of acute kidney injury, kidney stones, and inherited kidney diseases including polycystic kidney disease. We are home to two Kidney Centers funded by the National Institutes of Health and numerous clinical trials for kidney patients.

Being on the forefront of the clinical research and treatment means our physicians and surgeons are considered national leaders in the current understanding of kidney disease, and most importantly, are positioned to provide the best care possible to our patients.

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# 2009 ASN Grant Recipients

## **Carl W. Gottschalk Research Scholar Grant**

Francesca Di Sole, PhD  
University of Texas Southwestern Medical Center at Dallas

William H. Fissell, MD  
Cleveland Clinic Health System

Benjamin D. Humphreys, MD, PhD, FASN  
Brigham and Women's Hospital

Sung Il Kim, PhD  
Brigham & Women's Hospital

Sean X. Li, PhD  
Children's Hospital Boston  
Harvard Medical School

Hua A. Jenny Lu, MD, PhD  
Massachusetts General Hospital

Nuria M. Pastor-Soler, MD, PhD, FASN  
University of Pittsburgh School of Medicine

Uptal D. Patel, MD  
Duke University School of Medicine

Ganesan Ramesh, PhD  
Pennsylvania State University College of Medicine

Johannes S. Schlondorff, MD, PhD  
Brigham and Women's Hospital

Shuxia Wang, MD, PhD  
University of Kentucky College of Medicine

Daniel E. Weiner, MD  
Tufts University School of Medicine

Jing Yu, PhD  
University of Virginia School of Medicine

## **The Halpin Foundation-ASN Research Grant**

Laurence H. Beck, Jr., MD, PhD  
Boston University School of Medicine

## **Alaska Kidney Foundation-ASN Research Grant**

Susan B. Gurley, MD, PhD  
Duke University School of Medicine

## **John Merrill Grant in Transplantation**

Dorry L. Segev, MD, PhD  
Johns Hopkins University School of Medicine

## **ASN-ASP Junior Development Grant in Geriatric Nephrology**

Peter P. Reese, MD  
University of Pennsylvania School of Medicine

## **Norman Siegel Research Scholar Grant**

Christoph Licht, MD, FASN  
The Hospital for Sick Children

## **Student Scholar Grant**

Kamna S. Balhara  
Jessica D. Bauerle  
Mallika S. Dhawan  
Mitra Dowlathshahi  
Ritu Gupta  
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# Identifying optimal predictive markers

## Better predictors of long-term outcomes are needed in renal transplantation

Treatment advances have resulted in improved short-term posttransplant outcomes.<sup>1</sup> Clinical endpoints have evolved along with these improvements.<sup>1</sup> For years, acute rejection was the standard endpoint used in clinical trials to evaluate immunosuppressants and assess posttransplant outcomes.<sup>1</sup> Data suggest that decreasing acute rejection rates, however, have not led to an increase in long-term graft survival.<sup>2</sup> Therefore, acute rejection may not be considered a reliable predictor of long-term outcomes.<sup>1</sup>

Alternative short-term surrogate markers, such as renal function, histologic findings, and immunologic markers, have been assessed.<sup>1</sup> Markers that reliably predict long-term graft and patient survival in renal transplantation are needed to better assess therapeutic success.<sup>1,3</sup>

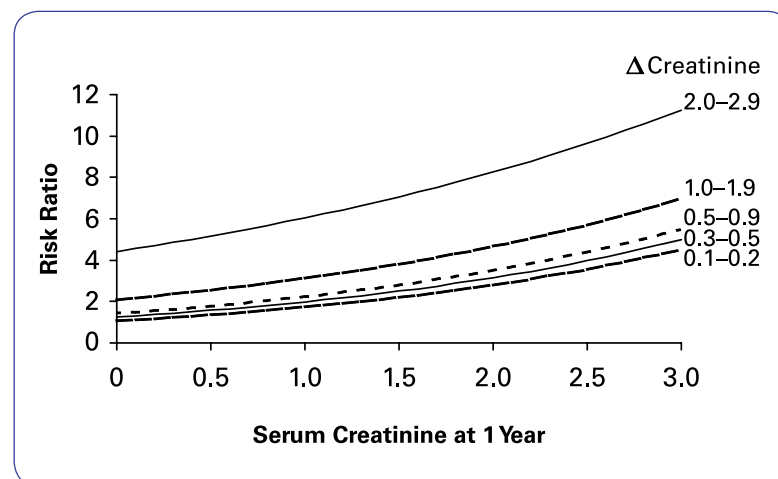
## Is renal function a better predictor of long-term outcomes?

Renal function has emerged as a better marker than acute rejection in predicting long-term patient and graft survival.<sup>4-6</sup> Studies demonstrate that preservation of renal function is critical for long-term graft survival.<sup>2,4</sup>

Hariharan et al conducted a retrospective study in 105,742 adult renal transplants performed between 1988 and 1998, examining renal function 1 year posttransplant to determine long-term renal graft survival.<sup>4</sup> Results demonstrated a statistically significant link between renal function and long-term graft survival: elevations in 1-year serum creatinine and change in serum creatinine from 6 to 12 months increase the relative hazard for graft failure (Figure 1).<sup>4</sup>

When assessing the impact of posttransplant variables on long-term outcomes, 1-year serum creatinine and change in serum creatinine from 6 to 12 months had a significant effect ( $P<.0001$ ) on graft failure.<sup>4</sup> Acute rejection within 1 year, however, did not reach significance ( $P=.8853$ ).<sup>4</sup>

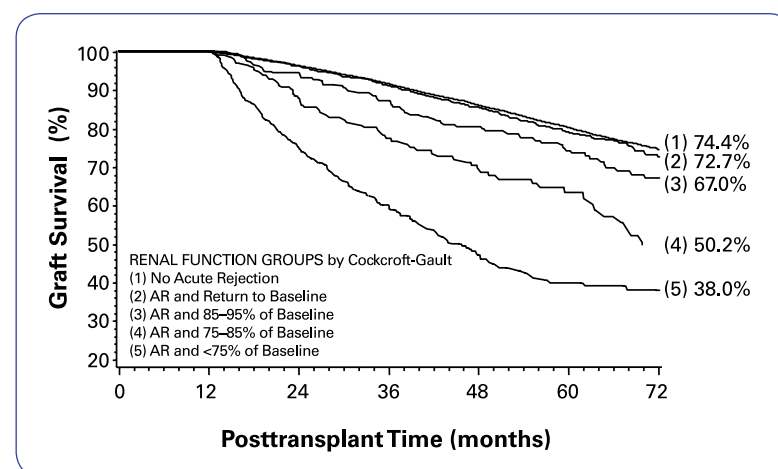
**Figure 1.** Relative hazard for graft failure according to 1-year creatinine and  $\Delta$  creatinine values.<sup>4</sup>



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To evaluate the impact of renal function on long-term graft survival in the absence or presence of acute rejection, Meier-Kriesche et al retrospectively studied 38,426 adult renal transplants performed between 1995 and 2001.<sup>2</sup> This study reported that only those acute rejection episodes that impair renal function negatively affect long-term graft survival.<sup>2</sup> Three- and 6-year graft survival rates were comparable among patients who had an acute rejection episode with renal function returning to baseline and those who had no acute rejection episodes (Figure 2).<sup>2</sup> The data showed that in the presence of acute rejection episodes, renal function is the better predictor of long-term outcomes.<sup>2</sup>

**Figure 2.** Kaplan-Meier graph of overall graft survival by acute rejection/GFR grouping levels.<sup>2</sup>



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# in solid organ transplantation

## GFR: An important marker of renal function

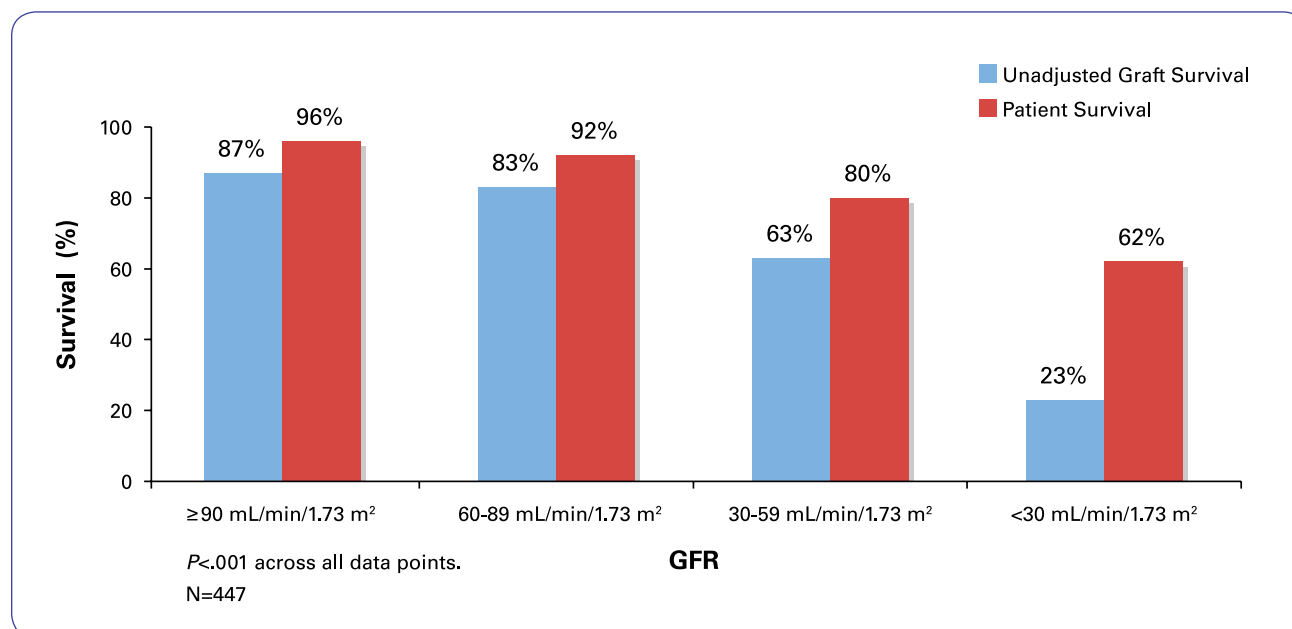
Glomerular filtration rate (GFR), measured through clearance assays, may be a more accurate method of estimating renal function versus serum creatinine, by avoiding the dependence on age, gender, race, and body weight.<sup>3</sup>

In a retrospective study of 447 renal transplant recipients who received organs from deceased donors between 1980 and 1994, Marcén et al examined whether calculated GFR at 12 months posttransplant was predictive of 10-year, long-term graft and patient survival (Figure 3).<sup>7</sup> Results from this study are consistent with the findings from Hariharan et al, demonstrating renal function, as measured by GFR, to be an important marker of long-term graft survival.<sup>7</sup> In addition, this research shows GFR at 12 months also correlates to long-term patient survival.<sup>7</sup>

## Signaling the future: Using renal function to predict long-term outcomes

Short-term, surrogate endpoints that predict long-term renal transplant survival are needed to better evaluate success in renal transplantation.<sup>1,3</sup> Research findings demonstrate renal function may be the best predictor of long-term outcomes.<sup>6,7</sup> Renal function should therefore be incorporated into clinical studies as a clinical endpoint to assess posttransplant success.<sup>1</sup>

**Figure 3.** 10-year graft and patient survival by GFR levels at 12 months posttransplant.<sup>7</sup>



### References:

1. Hariharan S, McBride MA, Cohen EP. Evolution of endpoints for renal transplant outcome. *Am J Transplant.* 2003;3(8):933-941.
2. Meier-Kriesche HU, Schold JD, Srinivas TR, Kaplan B. Lack of improvement in renal allograft survival despite a marked decrease in acute rejection rates over the most recent era. *Am J Transplant.* 2004;4(3):378-383.
3. Hariharan S, Kasiske B, Matas A, Cohen A, Harmon W, Rabb H. Surrogate markers for long-term renal allograft survival. *Am J Transplant.* 2004;4(7):1179-1183.
4. Hariharan S, McBride MA, Cherikh WS, Tolleris CB, Bresnahan BA, Johnson CP. Post-transplant renal function in the first year predicts long-term kidney transplant survival. *Kidney Int.* 2002;62(1):311-318.
5. Meier-Kriesche HU, Baliga R, Kaplan B. Decreased renal function is a strong risk factor for cardiovascular death after renal transplantation. *Transplantation.* 2003;75(8):1291-1295.
6. Salvadori M, Rosati A, Bock A, et al. Estimated one-year glomerular filtration rate is the best predictor of long-term graft function following renal transplant. *Transplantation.* 2006;81(2):202-206.
7. Marcén R, Pascual J, Tenorio M, et al. Chronic kidney disease in renal transplant recipients. *Transplant Proc.* 2005;37(9):3718-3720.



Bristol-Myers Squibb



## Plenary Session

### Breeding and Building Molecules For Whole-Animal and Clinical Imaging



Roger Tsien

STATE-OF-THE-ART LECTURE

**R**oger Tsien, PhD, will present a state-of-the-art lecture on “Breeding and Building Molecules for Whole-Animal and Clinical Imaging” during the Thursday, October 29, plenary session, which begins at 8 a.m. Renowned for designing and building molecules that gauge signal transduction, Dr. Tsien has revolutionized the fields of cell biology and neurobiology by making it possible to look inside living cells and study the behavior of molecules in real time.

An investigator at the Howard Hughes Medical Institute at the University of California, San Diego (UCSD), Dr. Tsien is also professor of pharmacology at the UCSD School of Medicine and professor of chemistry and biochemistry at UCSD.

Dr. Tsien will address two complementary topics: the use of fluorescent and singlet-oxygen-generating proteins for imaging at nanometer to millimeter resolution in genetically manipulable cells and organisms, and synthetic peptides aimed at clinical imaging and therapy.

Dr. Tsien developed dyes to track levels of cellular calcium—an ion that regulates many physiological processes, including nerve impulses, muscle contractions, and fertilization. By genetically modifying molecules that make

jellyfish and corals glow, Dr. Tsien created fluorescent-colored proteins that can track where and when certain genes are expressed in cells or in whole organisms. Scientists worldwide have used these multicolored fluorescent proteins to study biological processes from the most basic to the most complex.

Over the years, Dr. Tsien has expanded the color palette of fluorescent proteins. He also developed a method to monitor the interactions of two proteins, each labeled with different hues of fluorescent proteins.

Because fluorescent proteins usually require introduction of foreign genes—an action difficult to justify in clinical practice—Dr. Tsien has developed novel, nongenetic ways to image and one day even treat cancer by delivering targeted drugs to tumors. Recently, he and his colleagues built U-shaped peptide molecules to carry an imaging molecule or chemotherapy drug to a tumor. The peptides are substrates for certain proteases—protein-splitting enzymes—that are exuded from tumor cells but rarely seen on normal cells. When the protease splits the bottom of the U, the two arms of the U are separated, unleashing one arm to drag the imaging or drug portion of the peptide into a neighboring cancer cell.

Dr. Tsien was awarded the Nobel Prize in Chemistry in 2008 (shared with Dr. Osamu Shimomura and Dr. Martin Chalfie) for the discovery and development of the green fluorescent protein. He received the Gairdner Foundation International Award in 1995 and the Wolf Prize in Medicine in 2004 for his contribution to the design and application of novel fluorescent and photolabile molecules to analyze and perturb cell signal transduction. He co-founded two bioscience companies; is a member of the National Academy of Sciences, the Royal Society, and the Institute of Medicine; and has published countless scientific papers.

Dr. Tsien received his PhD in physiology from the University of Cambridge in 1977 and remained there to complete his Research Fellowship in 1981.

### William E. Mitch to Receive John P. Peters Award at Thursday Plenary Session



William E. Mitch

**T**he American Society of Nephrology announces William E. Mitch, MD, as this year's recipient of the John P. Peters Award. The award recognizes Dr. Mitch's outstanding contributions to improving the lives of patients with kidney disease and to furthering the understanding of the kidney in health and disease.

Established in 1983, the Peters award honors individuals who have made substantial research contributions to the discipline of nephrology and have sustained achievements in one or more areas of academic medicine, including clinical care, education, and leadership.

For four decades Dr. Mitch has improved the lives of patients with renal disease—as a practicing physician, a medical researcher, and a medical school professor. He is widely recognized as an expert in the care of patients with hypertension and chronic kidney disease, with a particular focus on nutrition and diet. Among an extensive list of professional publication credits, Dr. Mitch is an editor of “The Handbook of Nutrition and the Kidney,” a publication—now in its sixth edition—that guides physicians and nutritionists in applying dietary approaches to treat patients with kidney stones and hypertension.

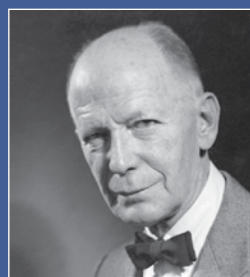
Dr. Mitch's research identified how breakdown of muscle protein, or muscle wasting, is accelerated by chronic kidney disease and can be linked specifically to complications of kidney disease, such as metabolic acidosis, high levels of angiotensin II, and impaired signaling through the insulin/GF-1 pathway. His current research focus includes developing ways to block such pathways to correct the loss of muscle protein. His work has already helped in the development of a method for assessing muscle protein metabolism.

Dr. Mitch has earned numerous awards and accolades. Featured in several patient guides to top physicians, he was named one of “The Best Doctors in America” by *American Health Magazine*. He also received the National Torchbearer Award from the American Kidney Fund, which recognizes extensive work in nephrology and its impact on kidney patients' quality of life.

A graduate of Harvard University Medical School, Dr. Mitch practices in the Houston area and is the Gordon A. Cain Professor of Medicine and Chief of Nephrology at Baylor College of Medicine in Houston.

Dr. Mitch will receive the John P. Peters Award at Thursday morning's plenary session, which begins at 8 a.m.

### John P. Peters



John P. Peters, MD, was one of the fathers of nephrology and former chief of the Metabolic Division in the Department of Medicine at Yale University. He transformed clinical chemistry from a discipline of qualitative impressions to one in which precise quantitative measurements of body fluids comprise a vital part of the patient examination and provide great explanatory value.

He advanced the view that disease is a quantitative abnormality of normal physiological processes and that, by understanding disease, one could gain a deeper understanding of normal physiology. His enduring scientific contributions paralleled his intense commitment to the care of the sick, as well as his fervent mission to ensure that the physician be an advocate for the patient.



## Christopher R. Blagg Endowed Lecturer Bernard Lo to Discuss Conflict Management at Public Policy Forum



Bernard Lo

**B**ernard Lo, MD, will present the 8th Christopher R. Blagg Endowed Lecture on "How to Identify and Manage Conflicts," during the Public Policy Forum, "Conflicts of Interest in Medicine." The forum will be held from 1:30 to 3:30 p.m. on Thursday, October 29.

Dr. Lo is a professor of medicine and director of the Program in Medical Ethics at the University of California, San Francisco (UCSF), and National Program Director of the Greenwall Faculty Scholars Program in Bioethics.

From stem cells to end-of-life care, Dr. Lo's work touches on many of today's hot button issues in clinical medical ethics.

During the lecture, Dr. Lo will present recommendations from a report by an Institute of Medicine panel he chaired on conflicts of interest in medicine. The panel considered how to manage conflicts of interest in medical research and education, in patient care, and in development of practice guidelines. He will discuss the reasoning behind the report's recommendations and the conceptual model of conflicts of interest that the panel adopted.

Dr. Lo and his research group have conducted extensive research on ethical issues in stem cells. He has analyzed consent to donate materials for derivation of new stem cell lines, oversight of stem cell research, use of stem cell lines derived at other institutions, and ethical issues in stem cell clinical trials. As co-chair of the Standards Working Group of the California Institute of Regenerative Medicine, Dr. Lo also recommends regulations for stem cell research funded by the state of California.

Regarding dilemmas in end-of-life care, Dr. Lo recommended guidelines for palliative sedation in terminally ill patients and for improving attention to the spiritual aspects of palliative care. His empirical studies of actual discussions among doctors, patients, and families about decisions near the end of life led to suggestions for improving these conversations. Dr. Lo has also

studied the impact of the Internet on the doctor-patient relationship.

Through his work with health policy research, Dr. Lo has made recommendations on federal health privacy regulations and responses to public health emergencies, including allocation of ventilators during an influenza pandemic.

Improving ethics education is a top priority for Dr. Lo. More than 100 postdoctoral fellows and junior faculty take his course on Responsible Conduct of Research at UCSF each year. Content from the course comprises the textbook "Ethical Issues in Clinical Research." For many years, he directed teaching of clinical ethics to medical students, and his book "Resolving Ethical Dilemmas: A Guide for Clinicians" now is in its fourth edition.

Dr. Lo is a member of the Institute of Medicine, was elected to serve on its council, and served as chair of the Board of Health Sciences Policy. He was the UCSF Distinguished Clinical Lecturer in 2009 for his research achievements. Dr. Lo received his medical degree from Stanford University School of Medicine and completed his residency at the University of California, Los Angeles, and at Stanford University. He finished his fellowship at the Robert Wood Johnson Clinical Scholars Program at Stanford University.

## Tweet the Week

Download free twitter applications on your BlackBerry or iPhone—or access twitter via the web—and join *ASN Kidney News* Editor-in-Chief Pascale Lane, MD, as she "tweets the week." All Renal Week participants are encouraged to join the conversation.

Learn more by reading the "Tweet the Week" article on page 42.



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# Plenary Session

## Genetic Associations in Complex Human Diseases



Kári Stefánsson

STATE-OF-THE-ART LECTURE

The ASN is pleased to welcome Kári Stefánsson, MD, to present a state-of-the-art lecture on Friday, October 30, during the plenary session starting at 8 a.m. Dr. Stefánsson is Chief Executive Officer and Chairman of the Board of Directors for deCODE genetics, a biopharmaceutical company in Reykjavik, Iceland, which he co-founded in 1996.

A neurologist, Dr. Stefánsson has helped unravel the links between genes and specific diseases. His work paves the way for development of new tests and treatments for many of today's most insidious diseases, including cancer and diabetes. His lecture is titled "Genetic Associations in Complex Human Diseases."

During the 1990s, Dr. Stefánsson was a professor of neurology, neuropathology, and neuroscience at Harvard University and Director of Neuropathology at Beth Israel Hospital in Boston. He left academia to pursue his am-

bition of studying genetics on a large scale. In 1996, he returned to Iceland to establish the first commercial venture—deCODE genetics—to research population-based molecular genomics. The company's first focus is to isolate key genes contributing to major public health challenges such as cardiovascular disease and stroke. These genes then provide targets for drugs to treat the diseases.

Dr. Stefánsson and his colleagues search for disease genes by first choosing a target disorder, such as osteoporosis or schizophrenia, whose genetic contribution is unknown. They then identify family groups in which the disease genes are statistically more prevalent than in the general population. Scientists collect blood samples from these individuals and analyze their DNA to identify regions of the genome that are linked to the disease. More than 65 percent of adult Icelanders have allowed deCODE genetics to study their DNA. The company has identified more than 15 variants thus far, each linked to a greater risk of one of a range of disorders.

Aside from DNA-based diagnostics and drug discovery, deCODE is working to offer innovative products and services in bioinformatics, genotyping, structural biology, and clinical development.

Dr. Stefánsson received his medical degree in 1976 and his DrMed in 1986 from the University of Iceland School of Medicine. He completed postdoctoral training in neurology, neuropathology, and neuroscience at the University of Chicago, and is board-certified in neurology and neuropathology in the United States. Dr. Stefánsson has published numerous articles on the genetics of common and complex diseases.

## Kretzler to be Honored with Young Investigator Award at Friday Plenary Session



Matthias Kretzler

The American Society of Nephrology is delighted to present this year's Young Investigator Award to Matthias Kretzler, MD, whose work to define the molecular mechanisms of kidney disease is helping to identify better ways to predict and treat it.

Initiated in 1985, the Young Investigator Award each year recognizes an individual with an outstanding record of achievement and creativity in basic or patient-oriented research related to the functions and diseases of the kidney. The award is co-sponsored by the American Heart Association's Council

on the Kidney and is limited to individuals who are younger than 41 on the first day of the ASN meeting at which the award is presented, or who are less than eight years from the start of their first faculty or staff research scientist position beyond postdoctoral training.

Dr. Kretzler is an associate professor of internal medicine in the division of nephrology at the University of Michigan, Ann Arbor, where he teaches medical students, internal medicine residents, and nephrology fellows.

In addition to his teaching responsibilities, he is involved in a number of research initiatives at the state, national, and international levels. His research on chronic kidney disease addresses mechanisms for diabetic nephropathy, nephrotic syndrome, lupus nephritis, and IgA nephritis.

Since arriving at the University of Michigan in 2005, Dr. Kretzler has established the Personalized Molecular Nephrology Laboratory and the Michigan Renal Biobank.

The laboratory uses modern molecular biology tools to better understand disease mechanisms activated in human renal biopsies. Dr. Kretzler and his team use these tools for molecular diagnosis of kidney and transplant failure in international multicenter studies.

The Michigan Renal Biobank is a registry of medical histories, biopsy tissues, and specimens from patients with nephrotic syndrome and focal segmental glomerulosclerosis (FSGS). The biobank allows for development of a system of markers to subdivide different forms of FSGS, providing finer details as to prognosis, responsiveness to various drugs, and why some patients fail to respond to treatment.

At the national level, Dr. Kretzler initiated the Nephcure Biobank to establish prospective cohorts of patients with nephrotic syndrome for molecular phenotyping. In the international realm, he continues to integrate regional and national resources with the European Renal cDNA Bank, which he founded.

Dr. Kretzler serves on the advisory board of the European Kidney Research Association and on the editorial boards of the *Journal of the American Society of Nephrology*, the *Journal of Nephrology*, *Clinical Nephrology*, and *Nephrology, Dialysis, and Transplantation*.



## For Work in Educating Kidney Specialists, Burton D. Rose to be Honored with Robert G. Narins Award



Burton D. Rose

In recognition of his work as a teacher, textbook author, and creator of UpToDate, a respected online educational resource for physicians, the American Society of Nephrology has selected Burton D. Rose, MD, to receive the 2009 Robert G. Narins Award. The award honors those who have made substantial contributions to education and teaching.

Dr. Rose is a clinical professor of medicine at Harvard University. Among his achievements, Dr. Rose has written several well-regarded textbooks, including *Clinical Physiology of Acid-Base and Electrolyte Disorders*, which is now in its fourth edi-

tion and has been translated into Spanish, Portuguese, Italian, and Chinese. He also wrote *Pathophysiology of Renal Disease* and co-authored *Renal Pathophysiology: The Essentials*.

In 1989, Dr. Rose co-founded UpToDate, and he has served as its editor-in-chief ever since. UpToDate is an educational resource available on the Web, on CD, and on PDAs that provides doctors with continuously updated answers to medical questions that arise when treating patients. To build and refresh its content, UpToDate collaborates regularly with more than 3000 experts from leading medical institutions around the world. The resource addresses questions in nephrology, primary care, family medicine, obstetrics and gynecology, and pediatrics. The objective, Dr. Rose said, is to help doctors "carry with them an entire library of medical knowledge and find answers to their questions within minutes."

Dr. Rose has been nominated five times for the Harvard Medical School Prize for Excellence in Teaching and has received similar awards recognizing his teaching talent from Brigham and Women's Hospital, the University of Massachusetts Medical School, and Saint Vincent Hospital.

He will receive the Narins award during Friday's plenary session, which begins at 8 a.m.

## Robert G. Narins



Robert G. Narins, MD, was the first recipient of the award bearing his name. He taught and mentored countless students, serving on the faculties of the University of Pennsylvania, UCLA, Harvard University, Temple University, and Henry Ford Hospital.

Well recognized for his contributions in the fields of fluid-electrolyte and acid-base physiology, Dr. Narins has also led numerous education efforts at the national and international levels. Among these, he has chaired the American Board of Internal Medicine's Nephrology Board and worked on the American College of Physicians' Annual Program Committee. From 1994 to 2006, he developed and guided ASN's educational programs, including working to expand educational programs during Renal Week. In addition, he was instrumental in the development of ASN's newest journal, the *Clinical Journal of the American Society of Nephrology*; in establishing the Fellow of the American Society of Nephrology program; and in negotiating ASN's partnership agreements with Hypertension, Dialysis, & Clinical Nephrology (HDCN) and UpToDate. Dr. Narins is also credited with working with organizations in Europe and Asia to help promote education and teaching in nephrology.

## Ion Channel Expert Kleyman to Give Robert W. Schrier Endowed Lecture



Thomas Kleyman

Known for his work on epithelial ion channels, Thomas Kleyman, MD, is this year's recipient of the Robert W. Schrier Endowed Lectureship. He will give his lecture, "Proteolytic Regulation of ENaC in Health and Disease," during Friday's Meeting-Within-a-Meeting on "The Renal Basis of Hypertension and Edema," held from 1:30 to 3:30 p.m. The ASN welcomes Dr. Kleyman as he addresses the mechanisms by which proteases activate the epithelial sodium

channel, as well as the role of proteases in activating the channel in certain disease states.

Dr. Kleyman is professor of medicine, cell biology and physiology, and pharmacology at the University of Pittsburgh, where he also serves as chief of the Renal-Electrolyte Division. He directs the Pittsburgh Center for Kidney Research, a National Institutes of Health (NIH)-funded center established in 2008. His work on epithelial ion channels has advanced our understanding of many disorders.

Most recently, Dr. Kleyman's research has involved conducting cellular and molecular studies to identify important sites within the epithelial sodium channel's extracellular domain. These sites play key roles in the modulation of channel activity in response to extracellular factors, including proteases and metal ions. Dr. Kleyman studies mechanisms by which specific proteases, such as furin, activate epithelial sodium channels. He and his colleagues are also investigating mechanisms by which mechanical forces regulate epithelial sodium channels and large conductance calcium-activated potassium channels.

To gain a deeper understanding of the epithelial ion channel, Dr. Kleyman examines the channel in disease states. Inherited mutations in ion channels are responsible for many genetic diseases like cystic fibrosis. Studying the functional interactions between epithelial sodium channels and cystic fibrosis transmembrane conductance regulator chloride channels helps shed light on the disease.

Dr. Kleyman is editor of the *American Journal of Physiology: Renal Physiology* and has served in an editorial capacity for several scientific journals. He has been granted many awards to continue his work in nephrology, including the Established Investigatorship Award from the American Heart Association from 1991 to 1996, the NIH Merit Award in 2006, and the NIH Director's Bridge Award in 2008. Dr. Kleyman was elected for membership in the American Society for Clinical Investigation in 1996 and the Association of American Physicians in 2004. He has authored many scientific publications.

Dr. Kleyman received his medical degree from Washington University in St. Louis in 1978. He completed his internship and residency in medicine in 1981 and his fellowship in nephrology in 1983, both at the Presbyterian Hospital in New York.



## Plenary Session

### Genetic Insights into the Innate Immune System



Bruce Beutler

STATE-OF-THE-ART LECTURE

The ASN welcomes Bruce Beutler, MD, as he presents a state-of-the-art lecture, “Genetic Insights into the Innate Immune System,” during the Saturday, October 31, plenary session, which begins at 8 a.m. Dr. Beutler is professor and chair of the department of genetics at the Scripps Research Institute in La Jolla, Calif.

As an immunologist and geneticist, Dr. Beutler has made fundamental contributions to our understanding of the inflammatory processes. His work revealed precisely how the body senses diverse infections, leading to the initiation of an immune response.

While at Rockefeller University in New York, Dr. Beutler isolated mouse tumor necrosis factor (TNF) and discovered its inflammatory properties. He was the first to use anti-TNF antibodies to block inflammation in animals. He invented recombinant inhibitors of TNF activity, made by fusing the TNF receptor ectodomain to IgG heavy chains. These molecules now are widely applied in clinical medicine.

Returning to Dallas as a Howard Hughes Medical Institute Investigator in 1986, Dr. Beutler turned his research to

the persistent question of how microbes are initially perceived as nonself by the host immune system—an event that triggers an inflammatory response. He mapped and positionally cloned a critical mutation of the *Lps* locus that prevented mice from sensing bacterial lipopolysaccharide and enhanced their susceptibility to Gram-negative infection. This work established Toll-like receptors (TLRs) as the principal sensors used by the innate immune system to perceive infection. At the same time, this research marked TLRs as the proximal cause of systemic inflammation during infection and ushered in a new era of research in immunology. Dr. Beutler’s laboratory subsequently established many of the essential proteins active in TLR signal transduction.

In 2000, Dr. Beutler moved to the Scripps Research Institute in La Jolla, where he developed a prolific N-ethyl-N-nitrosourea (ENU) mutagenesis program, focusing on variant phenotypes related to the innate immune response. He researches genes required for normal immune function through germline mutagenesis and positional cloning, identifying mutations that shed light on other biological phenomena, including hearing, sight, iron absorption, and development.

Dr. Beutler is a member of the National Academy of Sciences and the Institute of Medicine. His discoveries have been recognized by several prestigious awards, including the Robert Koch Prize in 2004 for his discovery of molecular mechanisms of sensing and effector responses in innate immunity, the Balzan Prize in 2007 for his discovery of the genetic mechanisms responsible for innate immunity, and the Albany Medical Center Prize in 2009 for his discovery of the role of TNF and TLRs in inflammation.

Dr. Beutler received his medical degree from the University of Chicago in 1981, and was a resident at the University of Texas Southwestern Medical Center from 1981 to 1983. He completed his postdoctoral studies at Rockefeller University between 1983 and 1985.

### Renal Transport Expert Bindels to be Honored with Homer W. Smith Award



René Jan Maria Bindels

René Jan Maria Bindels, PhD, a physiology professor and researcher studying renal transport systems, is this year’s recipient of the Homer W. Smith Award. With this award, the American Society of Nephrology recognizes those who have made outstanding contributions to understanding how kidneys function in normal and diseased states.

Presented annually since 1964, the award recognizes Dr. Smith’s use of comparative approaches to explain normal human physiology, providing a model for students and scientists attempting to unravel the mysteries of normal and disordered renal function.

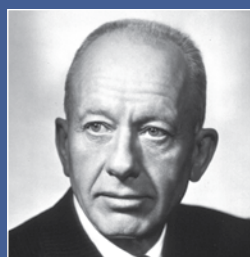
Dr. Bindels is a professor of physiology at the Nijmegen Centre for Molecular Life Sciences at Radboud University’s Nijmegen Medical Centre in The Netherlands, where he has taught medical, biomedical, and dental students since 1988 and mentored numerous doctoral candidates.

His research focuses on the regulation of ion transport processes in the kidneys and small intestine. He is currently investigating the molecular mechanisms that control calcium and magnesium balance, with particular emphasis on the regulation of the new family of epithelial calcium and magnesium TRP (transient receptor potential) channels. Dr. Bindels’ work has advanced the understanding of calcium channels and helped identify the major sites of calcium uptake along the nephron.

In addition to his teaching and research responsibilities, Dr. Bindels serves on the editorial boards of the *European Journal of Physiology*, the *American Journal of Physiology*, and the *Journal of the American Society of Nephrology*. He has lectured worldwide and authored more than 200 articles. In 2005, he was elected to the Academia Europaea, a group of leading scientists and scholars from several fields whose members include more than 40 Nobel Prize laureates.

Dr. Bindels will receive the Homer W. Smith award at Saturday’s plenary session, which begins at 8 a.m. His address is titled “Minerals in Motion: From Renal Transportation to New Concepts.

### Homer W. Smith



Homer W. Smith was chairman of physiology at the University of Virginia before moving in 1928 to New York University (NYU). As director of the Physiology Laboratories at NYU, he developed and refined the concepts of glomerular filtration and tubular absorption and secretion of solutes.

The clarity of Dr. Smith’s logic and the skill with which he explained his ideas transformed them into vivid and powerful concepts that are the cornerstones of our present understanding of normal and abnormal renal function. He attracted the best and brightest to the field, to NYU, and to the Mount Desert Island Biological Laboratory, where he spent many summers studying renal physiology in fish.

The Homer W. Smith award recognizes individuals who contribute to our basic understanding of how the kidneys function in health and disease.



## Nobel Winner Smithies to Discuss Gel Permeation in the Kidney



Oliver Smithies

The ASN welcomes Oliver Smithies, PhD, as he presents the Barry M. Brenner Endowed Lecture on “Gel Permeation in the Kidney” during Saturday’s Meeting-Within-a-Meeting on “Novel Insights of Glomerular Function and Structure (Controversies).” The session will be held from 1:30 to 3:30 p.m.

Dr. Smithies’ innovations in genetics have revolutionized genetic research and have led to improvements in the treatment of many diseases. He is the Weatherspoon distinguished professor of pathology and laboratory medicine at the University of North

Carolina, Chapel Hill, School of Medicine.

Dr. Smithies will discuss his hypothesis that the kidney glomerular basement membrane separates molecules by gel permeation. He also will describe experiments testing this idea.

In the 1950s, Dr. Smithies invented gel electrophoresis—a technique now used to separate DNA, RNA, and protein molecules using an electric current applied to a gel matrix. This method helps to identify genes and is used in many analytic methods such as DNA sequencing and mass spectrometry (a technique for analyzing the composition of a sample or molecule). Gel electrophoresis is now a standard practice in laboratories worldwide.

Dr. Smithies advanced all fields of biomedicine when, in the mid-1980s, he (along with Mario Capecchi, independently) devised a technique to introduce DNA into cells in a manner that replicates the natural process of homologous DNA recombination. This technique—now called gene targeting—allows an investigator to alter genes in a pre-planned manner. When carried out in embryonic stem cells, the genetic changes can be introduced into living animals.

Dr. Smithies’ original work was aimed at helping people with genetic disorders by correcting mutations in bone marrow stem cells. Although this still

is not possible, gene targeting led to the development of mice that replicated human disease. Gene targeting is widely used to study specific genes by creating “knockout mice.” After knocking out a specific gene, researchers can uncover what happens when the product of the gene is missing.

Dr. Smithies and his colleagues produced the first animal model of cystic fibrosis, a disease caused by one defective gene. He has used the technique to study high blood pressure, atherosclerosis, and other diseases. The genetic research methods he developed are now routine in biomedical research and have greatly helped advance genetic medicine and therapy.

Dr. Smithies received the Nobel Prize in Physiology or Medicine in 2007 (with Mario Capecchi and Martin Evans) for his “discoveries of principles for introducing specific gene modifications in mice by the use of embryonic stem cells.” Among other honors, Dr. Smithies received the Wolf Prize in Medicine in 2003 and the Albert Lasker Award for Basic Medical Research in 2001 for work on homologous recombination. He was elected to the U.S. Institute of Medicine in 2003 and is a member of the University of North Carolina’s Lineberger Comprehensive Cancer Center. Dr. Smithies received his DPhil in biochemistry in 1951 at Balliol College, University of Oxford, England.

## Coburn Endowed Lecturer Quarles to Address Hormone-Bone-Kidney Axis



L. Darryl Quarles

L. Darryl Quarles, MD, will present the 6th Annual Jack W. Coburn Endowed Lecture on “FGF23 and its Receptors: Lessons from Studies in Mice.” He will give the lecture during the Basic and Clinical Science Symposium “CKD-MBD and Outcomes,” held Saturday, October 31, from 1:30 to 3:30 p.m.

Dr. Quarles is known for his research on how kidney disease affects other organ systems, such as bone. He is currently the Summerfield Endowed Professor of Nephrology at the University of Kansas Medical Center, where he is director of the Kidney Institute, the division of nephrology, and the National Institutes of Health (NIH) T32 fellowship training program in nephrology.

Dr. Quarles will discuss the fibroblastic growth factor 23 (FGF23) hormone-bone-kidney axis as a conceptual framework for understanding the pathogenesis, diagnosis, and treatment of disorders characterized by high or low levels of phosphates in the blood and urine. Produced by osteocytes in the endocrine organ bone, FGF23 helps to regulate phosphate, vitamin D, and mineral homeostasis.

New knowledge is emerging regarding the complex systems biology surrounding FGF23 regulation and function. In helping to elucidate these studies, Dr. Quarles has investigated the cross-talk between bone and other organs that plays a role in adjusting phosphate balance and bone mineralization in

response to changing physiological requirements.

Dr. Quarles has maintained an active NIH-funded research laboratory that studies disorders of mineral metabolism using mouse genetic approaches. In addition to studying the regulation and function of FGF23 in health and in chronic kidney disease, the laboratory also studies the role of polycystins and calcium-sensing receptors in bone, and the differential function of Runx2 isoforms.

Dr. Quarles is an elected member of the American Society of Clinical Investigation and the Association of American Physicians. He has authored more than 148 peer-reviewed articles and 15 book chapters.

Dr. Quarles received his medical degree in 1979 and completed his residency in internal medicine in 1982, both at the University of Alabama, Birmingham. He completed his fellowship in nephrology at Duke University Medical Center in 1985, and was professor of medicine and director of the Bone Center at Duke until 2004.





# Don't Miss

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1. Dispenzieri, et al. *Leukemia* 2009;**23**:215-224
2. Durie, et al. *Hemat. Meet.* 2008;**2**(2):19

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## Plenary Session

### Signal Transduction Mechanisms in the Kidney



Tony Pawson

The ASN invites Tony Pawson, PhD, to present a state-of-the-art lecture on "Signal Transduction Mechanisms in the Kidney" during the plenary session on Sunday, November 1, from 8:30 to 9:30 a.m.

A distinguished investigator at the Samuel Lunenfeld Research Institute of Mount Sinai Hospital in Toronto, Dr. Pawson also is a professor in the department of molecular genetics at the University of Toronto. He leads the Dynactome Project, which studies protein interactions within human cells and defines the deviations that characterize malignancy at the systems level.

Internationally recognized for his work in cellular organization and signal transduction, Dr. Pawson has increased our understanding of how cells respond to their environment. He identified the basic mechanisms through which cells react to growth signals and how they communicate with each other.

Dr. Pawson's laboratory focuses on how cells convert an external signal into an intracellular response and on the molecular principles underlying cellular organization. He showed that cellular proteins are constructed in a modular fashion of functional domains, many of which mediate specific protein-to-protein interactions. He identified the Src homology 2 (SH2) domain as the prototypic interaction module. Dr.

Pawson demonstrated that these unique structures bind to specific phosphotyrosine-containing protein motifs located on activated growth factor receptors to induce cascades of intracellular signaling that control cellular growth and differentiation. This concept established one of the basic paradigms of signal transduction.

Using a combination of structural, biochemical, proteomic, and genetic tools, Dr. Pawson and his colleagues are investigating how the cell is wired through protein interactions. This research shows that tyrosine kinases and SH2 domains work in tandem to transmit commands from hormones that regulate cellular reproduction and metabolism to their targets within the cell. Dr. Pawson originally detected the integrated functions of tyrosine kinases and SH2 domains in the context of oncogene products necessary for the cancer-like behavior of cells. These discoveries have contributed to development of drugs that block the action of tyrosine kinases, thus arresting the production of some types of cancer cells.

Since the discovery of SH2 domains, dozens of other modular protein domains have been found to control protein-to-protein interactions, many of which Dr. Pawson's laboratory continues to investigate. Dr. Pawson and his colleagues are researching the pathways involved in reciprocal cell signaling and processes such as axon guidance in the nervous system and spatial organization of cells in complex tissues.

Dr. Pawson is a Fellow of the Royal Societies of London and Canada, a Foreign Member of the National Academy of Sciences, and serves on scientific advisory boards for several organizations. He has received many awards, including the AACR-Pezcoller International Award for Cancer Research in 1998, the Dr. H.P. Heineken Prize for Biochemistry and Biophysics in 1998, and the Kyoto Prize in Basic Sciences in 2008 for his work and discoveries in signal transduction.

Dr. Pawson conducted his graduate training at the Imperial Cancer Research Fund in London and received his PhD in molecular biology from King's College, University of London, in 1976.

### Belding H. Scribner Award to Honor James E. Cimino



James E. Cimino

The 2009 Belding H. Scribner Award goes to James E. Cimino, MD, who in the 1960s engineered a breakthrough approach to accessing the veins of hemodialysis patients, before dedicating his career to palliative care. Established in 1995, the Belding H. Scribner Award is presented to one or more individuals who have made outstanding contributions to the care of patients with renal disorders or have substantially changed the clinical practice of nephrology.

Dr. Cimino is highly regarded for his role in finding an improved method of accessing the veins of dialysis patients. He

led the team that developed the arteriovenous (AV) needle technique for vascular access in 1966—still a primary means for vascular access in chronic dialysis patients. The procedure creates a surgical connection between the artery and vein in the forearm that lasts longer than previously developed shunts, including the one developed by Dr. Scribner. The AV fistula is widely credited with prolonging the lives of patients with end stage renal disease and for simplifying their hemodialysis treatment.

Shortly after completing his medical residency and Air Force tour of duty, Dr. Cimino returned to the Bronx, where he was raised, to set up a practice. He worked first at the Bronx Veterans Administration Hospital. In 1960, he started a chronic dialysis program and established a nephrology residency. During the '60s, he was responsible for assisting in the placement of artificial kidneys in six New York metropolitan area hospitals. He was one of the first board-certified nephrologists.

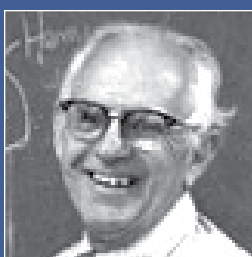
Subsequently, he moved on to Calvary Hospital for advanced cancer patients in the Bronx, where he has held numerous positions, including chief of medicine and medical director. In 1994, he became director of the Palliative Care Institute at Calvary, serving until he retired from that position. Palliative care was Dr. Cimino's focus for many years. He not only cared for terminally ill cancer patients, but also lectured and wrote extensively on the subject, emphasizing nutrition, pain management, comfort care, and ethical issues.

Dr. Cimino has received numerous awards and honors, including the American Cancer Society's Hope Award and the American College of Physicians' Ralph Claypoole Sr. Memorial Award for Devotion of a Career in Internal Medicine to the Care of Patients. He also received two Laureate Awards from the American College of Physicians and is an Alpha Omega Alpha honorary faculty member.

In addition to his many years as a practicing physician, Dr. Cimino has taught medical students for more than five decades. He has been a clinical professor of medicine at New York Medical College since 1980. He is an honorary member of the American Dietetic Association for establishing and teaching a course in medical nutrition at New York University Graduate School for more than 20 years. Renal nutrition was an important part of the curriculum.

The American Society of Nephrology is pleased to present the Belding H. Scribner award to Dr. Cimino during Sunday's plenary session, which begins at 8:30 a.m., directly following ASN's Business Meeting.

### Belding H. Scribner



Belding H. Scribner, MD, developed the arteriovenous shunt, which made possible long-term hemodialysis for chronic renal failure.

Dr. Scribner served as head of the University of Washington's Division of Nephrology in the Department of Medicine from 1958 to 1982. He and his co-workers at the Seattle university made numerous contributions to helping patients with end stage renal disease, including establishing the world's first out-of-hospital dialysis unit, developing a home hemodialysis program, improving techniques and equipment for hemodialysis and peritoneal dialysis, and studying the adequacy and complications of chronic renal disease treated by dialysis. Dr. Scribner's work made a significant contribution to transforming nephrology into a major subspecialty of internal medicine.





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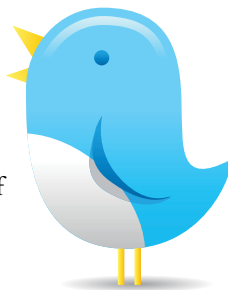
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# Join in ASN's First Ever Tweet the Week



**Are you overwhelmed by Renal Week's many offerings and wonder where to head next? Or would you like to post a few words about findings at a session you just attended? Then join Twitter and help us Tweet the Week.**

## What is Twitter?

Twitter is a microblogging service in which participants (Tweeps) answer the question, "What are you doing?" in 140 characters or less. As the service has evolved, photos and shortened URLs may be tweeted, making it a great way to share longer, more complex thoughts with more immediacy than a blog entry or email. Twitter is used to "point" people to stuff of interest. Family and friends may want to see photos of your activities; other followers may want to read blog posts you find interesting or irritating.

The real power of Twitter is the "retweet." Your followers can repeat your tweet, sending it on to their followers, and so on, and so forth, exponentially forwarding your information to the world (or at least to the Twitterverse).

## Why would I Tweet?

Tweeting is a strong way to make connections. One day I tweeted a link to an important issue for research scien-

tists. It was retweeted by three of my followers in the science blogging community. Between my direct followers and their direct followers, we got the link to ~1000 people in 15 minutes, something that no email chain could accomplish. One of my followers has ~67,000 secondary followers; you can see how that could spread the word! Our goals for Tweet the Week are more modest.

## What will Tweet the Week accomplish?

Tweet the Week involves a closed network, one in which no one outside of our group can see the tweets. We want to get a feel for how the "nephrologist in the convention center" experiences Renal Week. Opinions, great presentations, and disappointing events can be shared; no participant has to worry about their tweets haunting them in the future because the general public will not see the tweets. We are hoping to get ideas for what *ASN Kidney News* should cover during our annual meeting, ways to improve the annual meeting, and what our attendees are thinking.

Another Twitter-based phenomenon is the Tweet-Up. It is a "meet-up" arranged via Twitter! My local shopping mall plays tag this way. First, they send a tweet with relevant information; the first person to find the manager of a store and say, "Tweet, you're it" gets a \$25 gift card to the mall! We probably won't do give-aways at Renal

Week, but we may do a Tweet-Up of some sort.

## Do I have to carry a laptop to participate?

Twitter is a web-based service that can be accessed through any web-enabled device. Tweeting via text message is another option. For those with smart phones, there are plenty of Twitter applications that deliver all sorts of interface options. Many for BlackBerry and iPhone are free!

## How do I get started?

Create a Twitter account, if you don't already have one. It's free and requires very little information other than a valid email.

Go to <http://twitter.com/RenalWeek> and click on the button to request to follow. This is a closed group, so the general public will not be able to see what we say.

Send an email ([tweet@asn-online.org](mailto:tweet@asn-online.org)) when you make the follow request. I need to know your status (practicing nephrologist, fellow, research scientist, professor, etc.) and your screen name. I will then OK your membership in the group and follow your updates. ●

—Pascale H. Lane, editor-in-chief, ASN Kidney News

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No test  
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## PROVEN Safety and Efficacy in CKD

A first-line versatile IV iron choice for patients with chronic kidney disease (CKD) in the treatment of iron deficiency anemia

- Hemodialysis dependent (HDD) patients receiving an erythropoietin
- Peritoneal dialysis dependent (PDD) patients receiving an erythropoietin
- Patients on dialysis intolerant to other IV irons<sup>†,4,5</sup>

## With...Convenient and Flexible Dosing

Administration of a total cumulative dose of 1000 mg given as<sup>4</sup>:

- **HDD-CKD:** 100 mg slow IV injection over 2 to 5 minutes, or 100 mg IV infusion in 100 mL NS over at least 15 minutes at each of 10 consecutive hemodialysis sessions
- **PDD-CKD:** 2 infusions of 300 mg in 250 mL NS over 1.5 hrs days 1 and 15 followed by one 400 mg infusion in 250 mL NS over 2.5 hrs day 29

**IMPORTANT SAFETY INFORMATION:** Venofer<sup>®</sup> (iron sucrose injection, USP) is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to Venofer<sup>®</sup> or any of its inactive components, and in patients with anemia not caused by iron deficiency. Hypersensitivity reactions have been reported with IV iron products. Hypotension has been reported frequently in hemodialysis dependent (HDD)- and peritoneal dialysis dependent (PDD)-chronic kidney disease (CKD) patients receiving IV iron, and may be related to rate of administration and total dose delivered.

In multi-dose efficacy studies in HDD-CKD patients, the most frequent adverse events (>5%), whether or not related to Venofer<sup>®</sup> administration, were hypotension, muscle cramps, nausea, headache, graft complications, vomiting, dizziness, hypertension, chest pain and diarrhea. In the study of PDD-CKD patients, the most frequent adverse events, whether or not related to Venofer<sup>®</sup>, reported by ≥5% of these patients were diarrhea, peritoneal infection, vomiting, hypertension, pharyngitis, peripheral edema and nausea.

\*No test dose was required in 2 US pivotal studies (100 patients); however, some physicians used a test dose at their discretion.

†In 4 US clinical trials in HDD-CKD patients with prior intolerance to iron dextran, ferric gluconate, or both (n=130 Venofer<sup>®</sup> patients): there were no serious adverse drug reactions (ADRs) and no treatment discontinuations due to ADRs.

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Fresenius Medical Care

Please see brief summary and references on adjacent page.

**Venofer<sup>®</sup>**  
iron sucrose injection, USP

100986-01 Rev. 02 08/2009



**References:** **1.** Based on IMS Health, IMS National Sales Perspective™ (April 2009) 1st quarter 2009 results-dollar volume (\$) and units (100 mg equivalents); **2.** Charytan G, Levin N, Al-Saloum M, Hafeez T, Gagnon S, Van Wyck DB. Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anemia: North American clinical trial. *Am J Kidney Dis* 2001;37:300-307. **3.** Van Wyck DB, Cavallo G, Spinowitz BS, et al. Safety and efficacy of iron sucrose in patients sensitive to iron dextran: North American clinical trial. *Am J Kidney Dis* 2000;36:88-97. **4.** Venofer® [package insert]. Waltham, MA: Fresenius Medical Care. Rev. 8/08. **5.** Charytan G, Schwenk MH, Al-Saloum MM, Spinowitz BS. Safety of iron sucrose in hemodialysis patients intolerant to other parenteral iron products. *Nephron Clin Pract*. 2004;96:c63-c66.

# Venofer®

## iron sucrose injection, USP

**Brief Summary (See Package Insert For Full Prescribing Information)**

**Therapeutic Class:** Hematinic

**CLINICAL INDICATIONS AND USAGE**

Venofer® (iron sucrose injection, USP) is indicated in the treatment of iron deficiency anemia in the following patients:

- hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin.
- peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin.

**CONTRAINDICATIONS**

The use of Venofer® is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to Venofer® or any of its inactive components, and in patients with anemia not caused by iron deficiency.

**WARNINGS**

Hypersensitivity reactions have been reported with injectable iron products. See **PRECAUTIONS** and **ADVERSE REACTIONS**.

**PRECAUTIONS**

**General:** Because body iron excretion is limited and excess tissue iron can be hazardous, caution should be exercised to withhold iron administration in the presence of evidence of tissue iron overload. Patients receiving Venofer® require periodic monitoring of hematologic and hematonic parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Iron therapy should be withheld in patients with evidence of iron overload. Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing. See **DOSAGE AND ADMINISTRATION** and **OVERDOSAGE**.

**Hypersensitivity Reactions:** Serious hypersensitivity reactions have been reported in patients receiving Venofer®. No life-threatening hypersensitivity reactions were observed in the clinical studies. Several cases of mild or moderate hypersensitivity reactions were observed in these studies. There are post-marketing spontaneous reports of life-threatening reactions in patients receiving Venofer®. See **ADVERSE REACTIONS**.

**Hypotension:** Hypotension has been reported frequently in hemodialysis dependent chronic kidney disease patients receiving intravenous iron. Hypotension also has been reported in peritoneal dialysis dependent-chronic kidney disease patients receiving intravenous iron. Hypotension following administration of Venofer® may be related to rate of administration and total dose administered. Caution should be taken to administer Venofer® according to recommended guidelines. See **DOSAGE AND ADMINISTRATION**.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:**

No long-term studies in animals have been performed to evaluate the carcinogenic potential of Venofer®.

Venofer® was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK+) forward mutation test, the human lymphocyte chromosome aberration test, or the mouse micronucleus test.

Venofer® at IV doses up to 15 mg iron/kg/day (about 1.2 times the recommended maximum human dose on a body surface area basis) was found to have no effect on fertility and reproductive performance of male and female rats.

**Pregnancy Category B:** Teratology studies have been performed in rats at IV doses up to 13 mg iron/kg/day (about 0.5 times the recommended maximum human dose on a body surface area basis) and rabbits at IV doses up to 13 mg iron/kg/day (about 1 times the recommended maximum human dose on a body surface area basis) and have revealed no evidence of impaired fertility or harm to the fetus due to Venofer®. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** Venofer® is excreted in milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Venofer® is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of Venofer® in pediatric patients have not been established. In a country where Venofer® is available for use in children, at a single site, five premature infants (weight less than 1,250 g) developed necrotizing enterocolitis and two of the five expired during or following a period when they received Venofer®, several other medications and erythropoietin. Necrotizing enterocolitis may be a complication of prematurity in very low birth weight infants. No causal relationship to Venofer® or any other drugs could be established.

**Geriatric Use:** The five pivotal clinical trials did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects. No overall differences in safety were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS**

**Adverse Events observed in all treated populations**

The frequency of adverse events associated with the use of Venofer® has been documented in six randomized clinical trials involving 231 hemodialysis dependent and 75 peritoneal dialysis dependent-CKD patients; and in two post-marketing safety studies involving 1,051 hemodialysis dependent-CKD patients for a total of 1,496 patients. In addition, over 2,000 patients treated with Venofer® have been reported in the medical literature.

Treatment-emergent adverse events reported by ≥ 2% of treated patients in the randomized clinical trials, whether or not related to Venofer® administration, are listed by indication in Table 2.

Table 2. Most Common Treatment-Emergent Adverse Events Reported in ≥ 2% of Patients By Clinical Indication (Multidose Safety Population)

Adverse Events (Preferred Term)	HDD-CKD	PDD-CKD	
	Venofer® (N=231) %	Venofer® (N=75) %	EPO Only (N=46) %
<b>Subjects with any adverse event</b>	78.8	72.0	65.2
<b>Eye Disorders</b>			
Conjunctivitis	0.4	2.7	0
<b>Gastrointestinal Disorders</b>			
Abdominal pain NOS*	3.5	4.0	6.5
Constipation	1.3	4.0	6.5
Diarrhea NOS	5.2	8.0	4.3
Dysgeusia	0.9	0	0
Nausea	14.7	5.3	4.3
Vomiting NOS	9.1	8.0	2.2
<b>General Disorders and Administration Site Conditions</b>			
Asthenia	2.2	2.7	0
Chest pain	6.1	2.7	0
Edema NOS	0.4	0	2.2
Fatigue	1.7	0	4.3
Feeling abnormal	3.0	0	0
Peripheral edema	2.6	5.3	10.9
Pyrexia	3.0	1.3	0
<b>Infections and Infestations</b>			
Catheter site infection	0	4.0	8.7
Nasopharyngitis	0.9	2.7	2.2
Peritoneal infection	0	8.0	10.9
Sinusitis NOS	0	4.0	0
Upper respiratory tract infection NOS	1.3	2.7	2.2
Urinary tract infection NOS	0.4	1.3	2.2
<b>Injury, Poisoning and Procedural Complications</b>			
Graft complication	9.5	0	0
<b>Investigations</b>			
Cardiac murmur NOS	0.4	0	0
Fecal occult blood positive	0	2.7	4.3
<b>Metabolism and Nutrition Disorders</b>			
Fluid overload	3.0	1.3	0
Hyperglycemia NOS	0	0	2.2
Hypoglycemia NOS	0.4	4.0	0
<b>Musculoskeletal and Connective Tissue Disorders</b>			
Arthralgia	3.5	4.0	4.3
Arthritis NOS	0	0	4.3
Back pain	2.2	1.3	4.3
Muscle cramp	29.4	2.7	0
Myalgia	0	1.3	0
Pain in extremity	5.6	2.7	6.5
<b>Nervous System Disorders</b>			
Dizziness	6.5	1.3	4.3
Headache	12.6	4.0	0
Hypoesthesia	0	0	4.3
<b>Respiratory, Thoracic and Mediastinal Disorders</b>			
Cough	3.0	1.3	0
Dyspnea	3.5	1.3	2.2
Nasal congestion	0	1.3	0
Pharyngitis	0.4	6.7	0
<b>Skin and Subcutaneous Tissue Disorders</b>			
Pruritus	3.9	2.7	0
Rash NOS	0.4	0	2.2
<b>Vascular Disorders</b>			
Hypertension NOS	6.5	8.0	6.5
Hypotension NOS	39.4	2.7	2.2

\*NOS=Not otherwise specified

Treatment-emergent adverse events reported in ≥ 2% of patients by dose group are shown in Table 3.

Table 3. Most Common Treatment-Emergent Adverse Events Reported in ≥ 2% of Patients by Dose Group (Multidose Safety Population)

Adverse Events (Preferred Term)	HDD-CKD	PDD-CKD
	100 mg (N=231) %	300 mg for 2 doses followed by 400 mg for 1 dose (N=75) %
<b>Subjects with any adverse event</b>	78.8	72.0
<b>Eye Disorders</b>		
Conjunctivitis	0.4	2.7
<b>Gastrointestinal Disorders</b>		
Abdominal pain NOS*	3.5	4.0
Constipation	1.3	4.0
Diarrhea NOS	5.2	8.0
Dysgeusia	0.9	0
Nausea	14.7	5.3
Vomiting NOS	9.1	8.0

(Table 3 continued)

Adverse Events (Preferred Term)	HDD-CKD	PDD-CKD
	100 mg (N=231) %	300 mg for 2 doses followed by 400 mg for 1 dose (N=75) %
<b>General Disorders and Administration Site Conditions</b>		
Asthenia	2.2	2.7
Chest pain	6.1	2.7
Edema NOS	0.4	0
Fatigue	1.7	0
Feeling abnormal	3.0	0
Peripheral edema	2.6	5.3
Pyrexia	3.0	1.3
<b>Infections and Infestations</b>		
Catheter site infection	0	4.0
Nasopharyngitis	0.9	2.7
Peritoneal infection	0	8.0
Sinusitis NOS	0	4
Upper respiratory tract infection	1.3	2.7
<b>Injury, Poisoning and Procedural Complications</b>		
Graft complication	9.5	0
<b>Investigations</b>		
Cardiac murmur NOS	0.4	0
Fecal occult blood positive	0	2.7
<b>Metabolism and Nutrition Disorders</b>		
Fluid overload	3.0	3
Hypoglycemia NOS	0.4	4.0
<b>Musculoskeletal and Connective Tissue Disorders</b>		
Arthralgia	3.5	4.0
Back pain	2.2	1.3
Muscle cramp	29.4	2.7
Myalgia	0	1.3
Pain in extremity	5.6	2.7
<b>Nervous System Disorders</b>		
Dizziness	6.5	1.3
Headache	12.6	4.0
<b>Respiratory, Thoracic and Mediastinal Disorders</b>		
Cough	3.0	1.3
Dyspnea	3.5	1.3
Pharyngitis	0.4	6.7
<b>Skin and Subcutaneous Tissue Disorders</b>		
Pruritus	3.9	2.7
<b>Vascular Disorders</b>		
Hypertension NOS	6.5	8.0
Hypotension NOS	39.4	2.7

\*NOS=Not otherwise specified

Drug related adverse events reported by ≥ 2% of Venofer® (iron sucrose injection, USP) treated patients are shown by dose group in Table 4.

Table 4. Most Common Adverse Events Related to Study Drug Reported in ≥ 2% of Patients by Dose Group (Multidose Safety Population)

Adverse Events (Preferred Term)	HDD-CKD	PDD-CKD
	100 mg (N=231) %	300 mg for 2 doses followed by 400 mg for 1 dose (N=75) %
<b>Subjects with any adverse event</b>	14.7	10.7
<b>Gastrointestinal Disorders</b>		
Diarrhea NOS*	0.9	2.7
Dysgeusia	0.9	0
Nausea	1.7	1.3
<b>Vascular Disorders</b>		
Hypotension NOS	5.2	0

\*NOS=Not otherwise specified

**Adverse Events Observed in Hemodialysis Dependent Chronic Kidney Disease (HDD-CKD) Patients**

Adverse reactions, whether or not related to Venofer® administration, reported by >5% of treated patients from a total of 231 patients in the 3 pivotal HDD-CKD Studies were as follows: hypotension (39.4%), muscle cramps (29.4%), nausea (14.7%), headache (12.6%), graft complications (9.5%), vomiting (9.1%), dizziness (6.5%), hypertension (6.5%), chest pain (6.1%), and diarrhea (5.2%).

In the first post-marketing safety study, 665 chronic hemodialysis patients were treated with Venofer® doses of 100 mg at each dialysis session for up to 10 consecutive dialysis sessions for their iron deficiency or on a weekly basis for 10 weeks for maintenance of iron stores. In this study, 72% of the patients received up to 10 doses, 27% received between 11-30 doses, and 1% received 40 to 50 doses of Venofer®. Serious adverse events and drug-related non-serious adverse events were collected. In the second post-marketing safety study, 386 hemodialysis patients were exposed to a single dose of Venofer® (100 mg IV by slow injection over 2 minutes or 200 mg IV by slow injection over 5 minutes). Adverse events reported by > 1% of 1,051 treated patients were: cardiac failure congestive, sepsis NOS and dysgeusia.

**Adverse Events Observed in Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD) Patients**

In the pivotal study of 121 treated PDD-CKD patients, 75 patients were exposed to Venofer®. Adverse events, whether or not related to Venofer® reported by ≥5% of these patients are as follows: diarrhea, peritoneal infection, vomiting, hypertension, pharyngitis, peripheral edema and nausea.

In these 75 patients exposed to Venofer®, 9 patients experienced serious adverse events as follows: peritoneal infection (2 patients) and 1 patient each with cardiopulmonary arrest, myocardial infarction, upper respiratory infection NOS, anemia, gangrene, hypovolemia and tuberculosis. None of these events were considered drug-related. Two Venofer® patients experienced a moderate hypersensitivity/allergic reaction (rash or swelling/itching) during the study.

The only drug related adverse reaction to Venofer® administration reported by ≥2% of patients was diarrhea.

Three patients in the Venofer® study group discontinued study treatment due to adverse events (cardiopulmonary arrest, peritonitis and myocardial infarction, hypertension) which were considered to be not drug-related.

**Hypersensitivity Reactions:** See **WARNINGS** and **PRECAUTIONS**.

In clinical studies, several patients experienced hypersensitivity reactions presenting with wheezing, dyspnea, hypotension, rashes, or pruritus. Serious episodes of hypotension occurred in 2 patients treated with Venofer® at a dose of 500 mg.

The post-marketing spontaneous reporting system includes reports of patients who experienced serious or life-threatening reactions (anaphylactic shock, loss of consciousness or collapse, bronchospasm with dyspnea, or convulsion) associated with Venofer® administration.

One hundred thirty (11%) of the 1,151 patients evaluated in the 4 U.S. trials in HDD-CKD patients (studies A, B and the two post marketing studies) had prior other intravenous iron therapy and were reported to be intolerant (defined as precluding further use of that iron product). When these patients were treated with Venofer® there were no occurrences of adverse events that precluded further use of Venofer®.

**OVERDOSAGE**

Dosages of Venofer® (iron sucrose injection, USP) in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. Venofer® should not be administered to patients with iron overload and should be discontinued when serum ferritin levels equal or exceed established guidelines [1]. Particular caution should be exercised to avoid iron overload where anemia unresponsive to treatment has been incorrectly diagnosed as iron deficiency anemia.

Symptoms associated with overdosage or infusing Venofer® too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. Most symptoms have been successfully treated with IV fluids, hydrocortisone, and/or antihistamines. Infusing the solution as recommended or at a slower rate may also alleviate symptoms.

**Preclinical Data:**

Single IV doses of Venofer® at 150 mg iron/kg in mice (about 3 times the recommended maximum human dose on a body surface area basis) and 100 mg iron/kg in rats (about 8 times the recommended maximum human dose on a body surface area basis) were lethal.

The symptoms of acute toxicity were sedation, hypactivity, pale eyes, and bleeding in the gastrointestinal tract and lungs.

**DOSAGE AND ADMINISTRATION**

The dosage of Venofer® is expressed in terms of mg of elemental iron. Each mL contains 20 mg of elemental iron.

Most CKD patients will require a minimum cumulative repletion dose of 1,000 mg of elemental iron, administered over sequential sessions, to achieve a favorable hemoglobin response and to replenish iron stores (ferritin, TSAT). Hemodialysis patients may continue to require therapy with Venofer® or other intravenous iron preparations at the lowest dose necessary to maintain target levels of hemoglobin, and laboratory parameters of iron storage within acceptable limits.

**Administration:** Venofer® must only be administered intravenously either by slow injection or by infusion.

**Recommended Adult Dosage:**

**Hemodialysis Dependent-Chronic Kidney Disease Patients (HDD-CKD):** Venofer® may be administered undiluted as a 100 mg slow intravenous injection over 2 to 5 minutes or as an infusion of 100 mg, diluted in a maximum of 100 mL of 0.9% NaCl over a period of at least 15 minutes per consecutive hemodialysis session for a total cumulative dose of 1,000 mg.

**Peritoneal Dialysis Dependent-Chronic Kidney Disease Patients (PDD-CKD):**

Venofer® is administered as a total cumulative dose of 1,000 mg in 3 divided doses, given by slow intravenous infusion, within a 28 day period: 2 infusions of 300 mg over 1.5 hours 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. The Venofer® dose should be diluted in a maximum of 250 mL of 0.9% NaCl.

**Rx Only**

**REFERENCE:** [1] National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000. *Am J Kidney Dis*. 37: S182-S238, (suppl 1) 2001.

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# Three ASN Grant Recipients to Speak at Renal Week

More than a decade ago, ASN recognized the importance of helping early-career faculty gain independent funding and initiated a grants program to help them transition from mentored trainee to independent investigator.

In 2009, the career development grants program for young investigators supported 16 renal researchers. The growth of this program reflects ASN's commitment to helping young faculty develop promising research initiatives and share their findings with

their colleagues.

Three 2008 research grant recipients will present their work at ASN Renal Week 2009. Marcelo D. Carattino, PhD, 2008 recipient of the Carl W. Gottschalk Research Scholar Grant, Steven G. Coca, DO,

2008 recipient of the ASN-ASP Junior Development Grant in Geriatric Nephrology, and Arjang Djamali, MD, FASN, 2008 recipient of the ASN-AST John Merrill Grant in Transplantation, will speak during Renal Week.

Dr. Carattino will speak during the Basic Science Symposia on Sunday, November 1. His presentation will focus on Tubular Flow Regulation of Renal Sodium Reabsorption.

Dr. Coca will speak

*Continued on page 46*



Marcelo D. Carattino



Steven G. Coca



Arjang Djamali



## ULORIC powerfully lowers serum uric acid levels for long-term control of gout.

### In the largest phase 3 study (6 months):

- 45% of patients who received ULORIC 40 mg achieved serum uric acid level  $<6$  mg/dL (N=757) compared to 42% of patients who received allopurinol 300 mg (N=755;  $p=0.233$ )<sup>1</sup>
- 67% of patients who received ULORIC 80 mg achieved serum uric acid level  $<6$  mg/dL (N=756) compared to 42% of patients who received allopurinol 300 mg (N=755;  $p<0.001$ )<sup>1</sup>

### Indication

ULORIC is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. ULORIC is not recommended for the treatment of asymptomatic hyperuricemia.

### Important Safety Information

- ULORIC is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.
- An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including ULORIC. If a gout flare occurs during treatment, ULORIC need not be discontinued. Prophylactic therapy (i.e. - NSAIDs or colchicine) upon initiation of treatment may be beneficial for up to six months.
- **Cardiovascular Events:** In randomized controlled studies, there was a higher rate of cardiovascular thromboembolic events (cardiovascular deaths, non-fatal myocardial

infarctions, and non-fatal strokes) in patients treated with ULORIC [0.74 per 100 P-Y (95% CI 0.36-1.37)] than allopurinol [0.60 per 100 P-Y (95% CI 0.16-1.53)]. A causal relationship with ULORIC has not been established. Monitor for signs and symptoms of MI and stroke.

- **Liver Enzyme Elevations:** In randomized controlled studies, transaminase elevations greater than 3 times the upper limit of normal (ULN) were observed (AST: 2%, 2%, and ALT: 3%, 2% in ULORIC and allopurinol-treated patients, respectively). No dose-effect relationship for these transaminase elevations was noted. Laboratory assessment of liver function is recommended at, for example, 2 and 4 months following initiation of ULORIC and periodically thereafter.
- Adverse reactions occurring in at least 1% of ULORIC-treated patients, and, at least 0.5% greater than placebo, are liver function abnormalities, nausea, arthralgia, and rash.

**Individual results may vary based on factors such as baseline serum uric acid levels.**

**Please see brief summary of complete Prescribing Information on adjacent pages.**

Reference:  
1. ULORIC® (febuxostat) full prescribing information, February 2009.



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# Three Grant Recipients

Continued from page 45

during the Basic Science Symposia, Biomarkers in Kidney Disease, on Thursday, October 29. His presentation will focus on using biomarkers to predict clinical outcomes and other potential

applications in medical treatment and research.

Dr. Djamali will speak during the In-Depth Nephrology Course, Kidney Transplantation for the General Nephrologist, on Wednesday, October 28. His presentation will focus on cardiovascular disease and anemia in kidney transplant

recipients.

Receiving ASN funds has helped investigators develop independent research initiatives and defray study costs. ASN funds have helped researchers hire staff and purchase critical supplies, as well as provided protected time for investigators to complete research in kidney health and

disease.

ASN’s overall Grants and Funding portfolio encompasses four main components: career development grants for young investigators, interim funding for established investigators, grants for medical student research, and travel support for ASN members. The majority of

**BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION for ULORIC® (febuxostat) tablets**

**INDICATIONS AND USAGE**  
ULORIC® is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout.

ULORIC is not recommended for the treatment of asymptomatic hyperuricemia.

**CONTRAINDICATIONS**  
ULORIC is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline [see Drug Interactions].

**WARNINGS AND PRECAUTIONS**

**Gout Flare**  
After initiation of ULORIC, an increase in gout flares is frequently observed. This increase is due to reduction in serum uric acid levels resulting in mobilization of urate from tissue deposits.

In order to prevent gout flares when ULORIC is initiated, concurrent prophylactic treatment with an NSAID or colchicine is recommended.

**Cardiovascular Events**  
In the randomized controlled studies, there was a higher rate of cardiovascular thromboembolic events (cardiovascular deaths, non-fatal myocardial infarctions, and non-fatal strokes) in patients treated with ULORIC [0.74 per 100 P-Y (95% CI 0.36-1.37)] than allopurinol [0.60 per 100 P-Y (95% CI 0.16-1.53)] [see Adverse Reactions]. A causal relationship with ULORIC has not been established. Monitor for signs and symptoms of myocardial infarction (MI) and stroke.

**Liver Enzyme Elevations**  
During randomized controlled studies, transaminase elevations greater than 3 times the upper limit of normal (ULN) were observed (AST: 2%, 2%, and ALT: 3%, 2% in ULORIC and allopurinol-treated patients, respectively). No dose-effect relationship for these transaminase elevations was noted. Laboratory assessment of liver function is recommended at, for example, 2 and 4 months following initiation of ULORIC and periodically thereafter.

**ADVERSE REACTIONS**

**Clinical Trials Experience**  
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 2757 subjects with hyperuricemia and gout were treated with ULORIC 40 mg or 80 mg daily in clinical studies. For ULORIC 40 mg, 559 patients were treated for ≥ 6 months. For ULORIC 80 mg, 1377 subjects were treated for ≥ 6 months, 674 patients were treated for ≥ 1 year and 515 patients were treated for ≥ 2 years.

**Most Common Adverse Reactions**  
In three randomized, controlled clinical studies (Studies 1, 2 and 3), which were 6 to 12 months in duration, the following adverse reactions were reported by the treating physician as related to study drug. Table 1 summarizes adverse reactions reported at a rate of at least 1% in ULORIC treatment groups and at least 0.5% greater than placebo.

Table 1: Adverse Reactions Occurring in ≥ 1% of ULORIC-Treated Patients and at Least 0.5% Greater than Seen in Patients Receiving Placebo in Controlled Studies				
Adverse Reactions	Placebo	ULORIC		allopurinol*
	(N=134)	40 mg daily (N=757)	80 mg daily (N=1279)	(N=1277)
Liver Function Abnormalities	0.7%	6.6%	4.6%	4.2%
Nausea	0.7%	1.1%	1.3%	0.8%
Arthralgia	0%	1.1%	0.7%	0.7%
Rash	0.7%	0.5%	1.6%	1.6%

\*Of the subjects who received allopurinol, 10 received 100 mg, 145 received 200 mg, and 1122 received 300 mg, based on level of renal impairment.

The most common adverse reaction leading to discontinuation from therapy was liver function abnormalities in 1.8% of ULORIC 40 mg, 1.2% of ULORIC 80 mg, and in 0.9% of allopurinol-treated subjects.

In addition to the adverse reactions presented in Table 1, dizziness was reported in more than 1% of ULORIC-treated subjects although not at a rate more than 0.5% greater than placebo.

**Less Common Adverse Reactions**  
In phase 2 and 3 clinical studies the following adverse reactions occurred in less than 1% of subjects and in more than one subject treated with doses ranging from 40 mg to 240 mg of ULORIC. This list also includes adverse reactions (less than 1% of subjects) associated with organ systems from Warnings and Precautions.

*Blood and Lymphatic System Disorders:* anemia, idiopathic thrombocytopenic purpura, leukocytosis/leukopenia, neutropenia, pancytopenia, splenomegaly, thrombocytopenia; *Cardiac Disorders:* angina pectoris, atrial fibrillation/flutter, cardiac murmur, ECG abnormal, palpitations, sinus bradycardia, tachycardia; *Ear and Labyrinth Disorders:* deafness, tinnitus, vertigo; *Eye Disorders:* vision blurred; *Gastrointestinal Disorders:* abdominal distention, abdominal pain, constipation, dry mouth, dyspepsia, flatulence, frequent stools, gastritis, gastroesophageal reflux disease, gastrointestinal discomfort, gingival pain, haematemesis, hyperchlorhydria, hematochezia, mouth ulceration, pancreatitis, peptic ulcer, vomiting; *General Disorders and Administration Site Conditions:* asthenia, chest pain/discomfort, edema, fatigue, feeling abnormal, gait disturbance, influenza-like symptoms, mass, pain, thirst; *Hepatobiliary Disorders:* cholelithiasis/cholecystitis, hepatic steatosis, hepatitis, hepatomegaly; *Immune System Disorder:* hypersensitivity; *Infections and Infestations:* herpes zoster; *Procedural Complications:* contusion; *Metabolism and Nutrition Disorders:* anorexia, appetite decreased/increased, dehydration, diabetes mellitus, hypercholesterolemia, hyperglycemia, hyperlipidemia, hypertriglyceridemia, hypokalemia, weight decreased/increased; *Musculoskeletal and Connective Tissue Disorders:* arthritis, joint stiffness, joint swelling, muscle spasms/twitching/tightness/weakness, musculoskeletal pain/stiffness, myalgia; *Nervous System Disorders:* altered taste, balance disorder, cerebrovascular accident, Guillain-Barré syndrome, headache, hemiparesis, hypoesthesia, hyposmia, lacunar infarction, lethargy, mental impairment, migraine, paresthesia, somnolence, transient ischemic attack, tremor; *Psychiatric Disorders:* agitation, anxiety, depression, insomnia, irritability, libido decreased, nervousness, panic attack, personality change; *Renal and Urinary Disorders:* hematuria, nephrolithiasis, pollakiuria, proteinuria, renal failure, renal insufficiency, urgency, incontinence; *Reproductive System and Breast Changes:* breast pain, erectile dysfunction, gynecomastia; *Respiratory, Thoracic and Mediastinal Disorders:* bronchitis, cough, dyspnea, epistaxis, nasal dryness, paranasal sinus hypersecretion, pharyngeal edema, respiratory tract congestion, sneezing, throat irritation, upper respiratory tract infection; *Skin and Subcutaneous Tissue Disorders:* alopecia, angio-edema, dermatitis, dermatographism, ecchymosis, eczema, hair color changes, hair growth abnormal, hyperhidrosis, peeling skin, petechiae, photosensitivity, pruritus, purpura, skin discoloration/altered pigmentation, skin lesion, skin odor abnormal, urticaria; *Vascular Disorders:* flushing, hot flush, hypertension, hypotension; *Laboratory Parameters:* activated partial thromboplastin time prolonged, creatine increased, bicarbonate decreased, sodium increased, EEG abnormal, glucose increased, cholesterol increased, triglycerides increased, amylase increased, potassium increased, TSH increased, platelet count decreased, hematocrit decreased, hemoglobin decreased, MCV increased, RBC decreased, creatinine increased, blood urea increased, BUN/creatinine ratio increased, creatine phosphokinase (CPK) increased, alkaline phosphatase increased, LDH increased, PSA increased, urine output increased/decreased, lymphocyte count decreased, neutrophil count decreased, WBC increased/decreased, coagulation test abnormal, low density lipoprotein (LDL) increased, prothrombin time prolonged, urinary casts, urine positive for white blood cells and protein.

**Cardiovascular Safety**  
Cardiovascular events and deaths were adjudicated to one of the pre-defined endpoints from the Anti-Platelet Trialists' Collaborations (APTC) (cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke) in the randomized controlled and long-term extension studies. In the Phase 3 randomized controlled studies, the incidences of adjudicated APTC events per 100 patient-years of exposure were: Placebo 0 (95% CI 0.00-0.16), ULORIC 40 mg 0 (95% CI 0.00-1.08), ULORIC 80 mg 1.09 (95% CI 0.44-2.24), and allopurinol 0.60 (95% CI 0.16-1.53).

In the long-term extension studies, the incidences of adjudicated APTC events were: ULORIC 80 mg 0.97 (95% CI 0.57-1.56), and allopurinol 0.58 (95% CI 0.02-3.24).

Overall, a higher rate of APTC events was observed in ULORIC than in allopurinol-treated patients. A causal relationship with ULORIC has not been established. Monitor for signs and symptoms of MI and stroke.

**DRUG INTERACTIONS**  
**Xanthine Oxidase Substrate Drugs**  
ULORIC is an XO inhibitor. Drug interaction studies of ULORIC with drugs that are metabolized by XO (e.g., theophylline, mercaptopurine, azathioprine) have not been conducted. Inhibition of XO by ULORIC may cause increased plasma concentrations of these drugs leading to toxicity [see Clinical Pharmacology]. ULORIC is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline [see Contraindications].

**Cytotoxic Chemotherapy Drugs**  
Drug interaction studies of ULORIC with cytotoxic chemotherapy have not been conducted. No data are available regarding the safety of ULORIC during cytotoxic chemotherapy.

**In Vivo Drug Interaction Studies**  
Based on drug interaction studies in healthy subjects, ULORIC does not have clinically significant interactions with colchicine, naproxen, indomethacin, hydrochlorothiazide, warfarin or desipramine. Therefore, ULORIC may be used concomitantly with these medications.



ASN funding continues to assist investigators early in their research careers, such as for Drs. Carattino, Coca, and Djamali.

Career development grants include the Carl W. Gottschalk Research Scholar Grant, the Norman Siegel Research Scholar Grant, the Alaska Kidney

Foundation-ASN Research Grant (co-funded by the Alaska Kidney Foundation), the Halpin Foundation-ASN Research Grant (co-funded by the Halpin Foundation), the John Merrill Grant in Transplantation, and the ASN-ASP Junior Development Grant in Geriatric Nephrology (co-

funded by the Association of Specialty Professors).

Under the leadership of Peter S. Aronson, MD, FASN, ASN has improved several aspects of its grant program, such as expanding funding opportunities, simplifying the applications process, and streamlining review procedures. In

2009, Dr. Aronson led the efforts to hire Detlef O. Schlondorff, MD, as the Society's first Research Grant Program Director. Dr. Schlondorff works with ASN Grants Coordinator Holly Osborne to continue to build on Dr. Aronson's efforts to maintain the scientific rigor of the grants program and to strengthen funding opportunities for those working to advance treatment and research in kidney disease.

The success achieved by ASN grant recipients is the strongest measure of the success of the ASN grants program. For more information regarding ASN Grants and Funding, please visit [www.asn-online.org](http://www.asn-online.org).

*Marcelo D. Carattino, PhD, is Assistant Professor of Medicine at the University of Pittsburgh School of Medicine. His presentation, Tubular Flow Regulation of Renal Na Reabsorption, will occur on Sunday, November 1, 10:30–11 a.m., Room 8.*

*Steven Coca, DO, is Assistant Professor of Medicine at Yale University School of Medicine. He will present Biomarkers in AKI on Thursday, October 29, 3–3:30 p.m., Room 20A.*

*Arjang Djamali, MD, FASN, is Associate Professor of Medicine and Surgery at the University of Wisconsin Madison School of Medicine and Public Health. He will present Cardiovascular Disease and Anemia in the Transplant Patient, on Wednesday, October 28, 10:15–10:50 a.m., Room 6C.*

USE IN SPECIFIC POPULATIONS

Pregnancy

*Pregnancy Category C:* There are no adequate and well-controlled studies in pregnant women. ULORIC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Febuxostat was not teratogenic in rats and rabbits at oral doses up to 48 mg per kg (40 and 51 times the human plasma exposure at 80 mg per day for equal body surface area, respectively) during organogenesis. However, increased neonatal mortality and a reduction in the neonatal body weight gain were observed when pregnant rats were treated with oral doses up to 48 mg per kg (40 times the human plasma exposure at 80 mg per day) during organogenesis and through lactation period.

Nursing Mothers

Febuxostat is excreted in the milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ULORIC is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients under 18 years of age have not been established.

Geriatric Use

No dose adjustment is necessary in elderly patients. Of the total number of subjects in clinical studies of ULORIC, 16 percent were 65 and over, while 4 percent were 75 and over. Comparing subjects in different age groups, no clinically significant differences in safety or effectiveness were observed but greater sensitivity of some older individuals cannot be ruled out. The C<sub>max</sub> and AUC<sub>24</sub> of febuxostat following multiple oral doses of ULORIC in geriatric subjects (≥ 65 years) were similar to those in younger subjects (18-40 years).

Renal Impairment

No dose adjustment is necessary in patients with mild or moderate renal impairment (Cl<sub>cr</sub> 30-89 mL per min). The recommended starting dose of ULORIC is 40 mg once daily. For patients who do not achieve a sUA less than 6 mg per dL after 2 weeks with 40 mg, ULORIC 80 mg is recommended.

There are insufficient data in patients with severe renal impairment (Cl<sub>cr</sub> less than 30 mL per min); therefore, caution should be exercised in these patients.

Hepatic Impairment

No dose adjustment is necessary in patients with mild or moderate hepatic impairment (Child-Pugh Class A or B). No studies have been conducted in patients with severe hepatic impairment (Child-Pugh Class C); therefore, caution should be exercised in these patients.

Secondary Hyperuricemia

No studies have been conducted in patients with secondary hyperuricemia (including organ transplant recipients); ULORIC is not recommended for use in patients whom the rate of urate formation is greatly increased (e.g., malignant disease and its treatment, Lesch-Myhan syndrome). The concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract.

OVERDOSAGE

ULORIC was studied in healthy subjects in doses up to 300 mg daily for seven days without evidence of dose-limiting toxicities. No overdose of ULORIC was reported in clinical studies. Patients should be managed by symptomatic and supportive care should there be an overdose.

CLINICAL PHARMACOLOGY

Pharmacodynamics

*Effect on Uric Acid and Xanthine Concentrations:* In healthy subjects, ULORIC resulted in a dose dependent decrease in 24-hour mean serum uric acid concentrations, and an increase in 24-hour mean serum xanthine concentrations. In addition, there was a decrease in the total daily urinary uric acid excretion. Also, there was an increase in total daily urinary xanthine excretion. Percent reduction in 24-hour mean serum uric acid concentrations was between 40% to 55% at the exposure levels of 40 mg and 80 mg daily doses.

*Effect on Cardiac Repolarization:* The effect of ULORIC on cardiac repolarization as assessed by the QTc interval was evaluated in normal healthy subjects and in patients with gout. ULORIC in doses up to 300 mg daily, at steady state, did not demonstrate an effect on the QTc interval.

Special Populations

*Renal Impairment:* Following multiple 80 mg doses of ULORIC in healthy subjects with mild (Cl<sub>cr</sub> 50-80 mL per min), moderate (Cl<sub>cr</sub> 30-49 mL per min) or severe renal impairment (Cl<sub>cr</sub> 10-29 mL per min), the C<sub>max</sub> of febuxostat did not change relative to subjects with normal renal function (Cl<sub>cr</sub> greater than 80 mL per min). AUC and half-life of febuxostat increased in subjects with renal impairment in comparison to subjects with normal renal function, but values were similar among three renal impairment groups. Mean febuxostat AUC values were up to 1.8 times higher in subjects with renal impairment compared to those with normal renal function. Mean C<sub>max</sub> and AUC values for 3 active metabolites increased up to 2- and 4-fold, respectively. However, the percent decrease in serum uric acid concentration for subjects with renal impairment was comparable to those with normal renal function (58% in normal renal function group and 55% in the severe renal function group).

No dose adjustment is necessary in patients with mild to moderate renal impairment [see *Dosage and Administration and Use in Specific Populations*]. The recommended starting dose of ULORIC is 40 mg once daily. For patients who do not achieve a sUA less than 6 mg per dL after 2 weeks with 40 mg, ULORIC 80 mg is recommended. There is insufficient data in patients with severe renal impairment; caution should be exercised in those patients [see *Use in Specific Populations*].

ULORIC has not been studied in end stage renal impairment patients who are on dialysis.

*Hepatic Impairment:* Following multiple 80 mg doses of ULORIC in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment, an average of 20-30% increase was observed for both C<sub>max</sub> and AUC<sub>24</sub> (total and unbound) in hepatic impairment groups compared to subjects with normal hepatic function. In addition, the percent decrease in serum uric acid concentration was comparable between different hepatic groups (62% in healthy group, 49% in mild hepatic impairment group, and 48% in moderate hepatic impairment group). No dose adjustment is necessary in patients with mild or moderate hepatic impairment. No studies have been conducted in subjects with severe hepatic impairment (Child-Pugh Class C); caution should be exercised in those patients [see *Use in Specific Populations*].

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

*Carcinogenesis:* Two-year carcinogenicity studies were conducted in F344 rats and B6C3F1 mice. Increased transitional cell papilloma and carcinoma of urinary bladder was observed at 24 mg per kg (25 times the human plasma exposure at maximum recommended human dose of 80 mg per day) and 18.75 mg per kg (12.5 times the human plasma exposure at 80 mg per day) in male rats and female mice, respectively. The urinary bladder neoplasms were secondary to calculus formation in the kidney and urinary bladder.

*Mutagenesis:* Febuxostat showed a positive mutagenic response in a chromosomal aberration assay in a Chinese hamster lung fibroblast cell line with and without metabolic activation *in vitro*. Febuxostat was negative in the *in vitro* Ames assay and chromosomal aberration test in human peripheral lymphocytes, and L5178Y mouse lymphoma cell line, and *in vivo* tests in mouse micronucleus, rat unscheduled DNA synthesis and rat bone marrow cells.

*Impairment of Fertility:* Febuxostat at oral doses up to 48 mg per kg per day (approximately 35 times the human plasma exposure at 80 mg per day) had no effect on fertility and reproductive performance of male and female rats.

Animal Toxicology

A 12-month toxicity study in beagle dogs showed deposition of xanthine crystals and calculi in kidneys at 15 mg per kg (approximately 4 times the human plasma exposure at 80 mg per day). A similar effect of calculus formation was noted in rats in a six-month study due to deposition of xanthine crystals at 48 mg per kg (approximately 35 times the human plasma exposure at 80 mg per day).

PATIENT COUNSELING INFORMATION

[see *FDA-Approved Patient Labeling in the full prescribing information*]

General Information

Patients should be advised of the potential benefits and risks of ULORIC. Patients should be informed about the potential for gout flares, elevated liver enzymes and adverse cardiovascular events after initiation of ULORIC therapy.

Concomitant prophylaxis with an NSAID or colchicine for gout flares should be considered.

Patients should be instructed to inform their healthcare professional if they develop a rash, chest pain, shortness of breath or neurologic symptoms suggesting a stroke. Patients should be instructed to inform their healthcare professional of any other medications they are currently taking with ULORIC, including over-the-counter medications.

Distributed by  
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Deerfield, IL 60015

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For more detailed information, see the full prescribing information for ULORIC (febuxostat) tablets (PI1114 R1; February 2009) or contact Takeda Pharmaceuticals America, Inc. at 1.877.825.3327.

PI1114 R1-Brf; February 2009

L-TXF-0209-3



# ***CHECK IRON***



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# ***early and often***



- More than 50% of anemic CKD patients have iron deficiency<sup>1</sup>
- KDOQI™ guidelines recommend monitoring TSAT, ferritin, and hemoglobin as early as CKD Stage 3<sup>2,3</sup>
- Regular monitoring of TSAT and ferritin along with hemoglobin is a critical part of optimal anemia management

**[www.IDanemia.com](http://www.IDanemia.com)**





# Dining near the San Diego Convention Center

The 16-block Gaslamp Quarter near the convention center houses restaurants, nightclubs, shops, and commercial buildings. Listed below are a few of the notable restaurants located near the downtown area. The list of web sites (at bottom) offers a wider range of options for dining in San Diego farther afield from the downtown area. Near or far from the meeting site, you will enjoy San Diego dining: The area is home to some of California's premier restaurants.

## Anthony's Fish Grotto on the Bay (\$\$\$)

1360 Harbor Drive  
619 232 5103

[www.gofishanthony.com/grotto.html](http://www.gofishanthony.com/grotto.html)

Built over San Diego Bay, Anthony's has provided San Diego natives and visitors alike the freshest seafood cooked for more than 60 years. Voted San Diego's best seafood 11 years in a row. Bay views. Lunch and dinner served daily.

## Bertrand at Mister A's (\$\$\$\$)

2250 5th Avenue  
866 839 1605

[www.bertrandatmisteras.com/](http://www.bertrandatmisteras.com/)

The twelfth-floor dining area features spectacular views and a menu with French and Mediterranean influences. Bertrand's has been voted Best New Restaurant by San Diego Magazine and the California Restaurant Association. Open daily for lunch and dinner.

## Blue Point Coastal Cuisine (\$\$\$)

565 5th Avenue  
619 233 6623

[www.cohnrestaurants.com/restaurants/bluepoint/](http://www.cohnrestaurants.com/restaurants/bluepoint/)

Excellent selection of seafood in an atmosphere reminiscent of a 1930s supper club. Intimate dining atmosphere with a focus on inventive preparation of fresh seafood. Open Sunday through Thursday 5–10 p.m., Friday and Saturday 5–11 p.m.

## Café Sevilla (\$\$)

555 4th Avenue  
(619) 233-5979

[www.cafesevilla.com](http://www.cafesevilla.com)

A Spanish-courtyard-like dining room and lively tapas bar offer two settings to enjoy authentic and inventive tapas, paella, and entrees showcasing the flavors of the Iberian Peninsula. Flamenco and Rumba guitarists play nightly in the tapas bar, filling the space with the sounds of Spanish gypsy music. After dinner, enjoy the underground nightclub. Open Sunday through Thursday 5–11 p.m., Friday and Saturday 5 p.m. to 1 a.m.

## Candelas (\$\$\$)

416 3rd Avenue  
619 702 4455

Candelas' central Mexican cuisine emphasizes fresh local ingredients and innovation in a casual and relaxed atmosphere. Open daily.

## De Medici (\$\$\$)

815 5th Avenue  
866 627 7059

[www.demedici.signonsandiego.com/](http://www.demedici.signonsandiego.com/)

Old World Italian setting and cuisine, an extensive menu including seafood, rich pasta, and aged beef. Open for dinner daily.

## The Fleetwood (\$\$)

639 J Street  
858 634 5577

This restaurant/sports bar/lounge features an eclectic menu with offerings ranging from casual to elegant. The large circular bar is very comfortable with plenty of TV screens for those who need a sports fix during the meeting. Open Monday through Friday for lunch, dinner, and late-night dining.

## George's on Fifth (\$\$\$\$)

835 5th Avenue  
619 702 0444

[www.georgesonfifth.com/](http://www.georgesonfifth.com/)

Prime Angus beef, veal, fresh seafood, and sushi. Entertainment some nights. Open from 5 to 10 p.m. Monday through Thursday, 5–11 p.m. Friday and Saturday. Closed Sunday.

## Greystone the Steakhouse (\$\$\$\$)

658 5th Avenue  
866 368 3773

Located on the site of San Diego's old Bijou Theater, Greystone boasts dramatic architecture and provides an elegant atmosphere for its gourmet steak and seafood. Open from 5 to 10 p.m. daily.

## Hexagone (\$\$\$)

495 Laurel Street  
619 236 0467

<http://hexagone.thechamberworks.com/index.php>

Hexagone blends traditional French fare with California cuisine, impeccable service, an impressive wine list, and a relaxed atmosphere. Open for lunch and dinner daily.

## House of Blues (\$\$)

1055 5th Avenue  
619 299 2583

[www.houseofblues.com](http://www.houseofblues.com)

The House of Blues serves classics like gumbo, jambalaya, and fried catfish along with wild mushroom pasta and other California favorites. Open daily, with information about performers and ticket sales available on their web site.

## JSix Restaurant (\$\$)

616 J Street  
619 531 8744

Rooftop restaurant next to the Hotel Solamar, JSix offers the freshest artisan cuisine and a wonderful rooftop dining experience. Enjoy the neighboring LoungeSix atop the Solamar Terrace, with cabanas and pool. Open daily.

## Oceanaire Seafood Room (\$\$\$\$)

400 J Street  
619 858 2277

[www.theoceanaire.com](http://www.theoceanaire.com)

Voted best of Citysearch, 2008, Oceanaire serves fresh seafood with frequent menu changes based on the best catch any given day. Excellent wine list.

## Osetra Watergrill (\$\$\$\$)

904 East 5th Street  
619 708 7690

A beautifully designed restaurant centered on a two-story wine tower, this restaurant offers gourmet seafood, Kobe beef, and caviar parfait. Excellent wine list and bar service. Open Sunday through Thursday 5–10 p.m., Friday and Saturday 5–11 p.m.

## Red Pearl Kitchen (\$\$)

440 J Street, Ste 108  
619 231 1100

Red Pearl provides traditional pan-Asian cuisine suitable for individual or family style dining. The Chinese/East Asian food, with accompanying creative sake and vodka cocktails, has been voted Best of Citysearch. Open daily.

## Salvatores Cucina Italiana (\$\$\$\$)

750 Front Street  
619 544 1865

[www.salvatoresdowntown.com/](http://www.salvatoresdowntown.com/)

Winner of several Food Critic Awards, Salvatores serves elegant Italian cuisine. This restaurant has been providing a romantic dining experience and exquisite food for almost two decades. Open for dinner Monday through Saturday.

## Websites with more information on San Diego area dining

[www.gaslamp.org/](http://www.gaslamp.org/)  
Official Website of the Gaslamp Quarter

<http://www.sandiegorestaurants.com/>  
Comprehensive restaurant guide with reviews and online reservations available for most listed restaurants

[www.sandiegomagazine.com/](http://www.sandiegomagazine.com/)  
*San Diego Magazine*. Excellent guide to restaurants, shopping, and recreational activities in the San Diego area

[www.sandiego.org/nav/Visitors](http://www.sandiego.org/nav/Visitors)  
San Diego Convention and Visitors Bureau site

<http://entertainment.signonsandiego.com/sections/restaurants/>  
*The San Diego Union Tribune* restaurant and entertainment guide





## San Diego Sights

*Continued from page 3*

primary flight control, and interactive flight simulators. A self-guided audio tour helps make the most of your adventure, along with museum docents throughout the ship who share personal stories. For more intimate and in-depth information, you may reserve a docent tour for an additional cost.

### San Diego on a shoestring

To enjoy San Diego without spending a lot of cash, hit the beach!—or parkland, or one of San Diego's quaint town areas.

San Diego's beaches not only are some of the most beautiful in the world—they are free to the public. **Coronado** is a not-to-miss site, with its top-rated, white, sandy beaches and beautiful views of the San Diego skyline. Coronado is home to the North Island U.S. Naval Air Station and the U.S. Navy SEALs center, as well as *Hotel del Coronado*, a beautiful Victorian designated a National Historic Landmark. On the ocean side, you can walk to the boardwalk and rent anything from an umbrella to a four-person bicycle. You can get to Coronado via a 10- to 15-minute water taxi or ferry ride that places you on the bay side. You can then cab or walk up Orange Avenue to the ocean side. Alternatively, you can drive or cab from downtown San Diego directly to Coronado's ocean side.

Another spot for beautiful beaches and rocky cliff views is **La Jolla**, where you will also find upscale shops and some of San Diego's best-rated restaurants.

Check out the panoramic views as you walk along the wide, gently sloping beach of *La Jolla Shores*, or enjoy a magnificent sunset at *La Jolla Cove*, with its small sandy beach and rocky cliffs. La Jolla Cove is located on an ecological preserve with clear water, making it a popular place for scuba diving. Dabble in the tide pools along the half-mile Coast Walk between the La Jolla Cove and Children's Pool, or enjoy the harbor seal colony at Seal Rock. If hard-breaking surf is your thing, stop at *Windansea*, a great beach for whale-watching during their migration to and from Mexico.

If you want to extend your visit on La Jolla Shores, take a stroll from the beach through the historic Scripps Campus (picking up a free walking tour map along the way), and head to Birch Aquarium via the footbridge over La Jolla Shores Drive. **Birch Aquarium** is not only smaller and more intimate than some of the larger and better-known attractions like SeaWorld, but also much less expensive. Birch Aquarium is a place to get close to animals, interact with exhibits, and have fun learning about sea life along the Pacific coast. Feeding times for many exhibits

are open to the public.

For the younger and young-at-heart, head to **Pacific Beach**. Surf, sun, or play volleyball on the beach; or run, rollerblade, or bicycle down the boardwalk until the sun goes down. With a plethora of beach bars, local pubs, and dance clubs, "PB" also comes alive at night.

If you're looking for sun and sand plus more, visit one of San Diego's parklands. Take a beach walk and then hike up the cliffs to overlook the ocean at **Torrey Pines State Natural Reserve**, home of the famous Torrey Pines Golf Course. There are plenty of hiking routes, from easy and kid-friendly to more challeng-

ing. You also can watch the hang gliders and paragliders launching from the Gliderport nearby.

Fly a kite along the grassy field of Tecolote Shores at **Mission Bay Park**, a 4235-acre aquatic park great for water sports, jogging, and biking. Or, go boating on Lake Murray during a visit to **Mission Trails Regional Park**, where you can explore the cultural, historical, and recreational aspects of San Diego.

For more culture, see the murals in **Chicano Park**, painted on the support system of the San Diego-Coronado Bay Bridge. The 70-plus colorful murals showcase Mexican and Chicano history and represent some of San Diego's most important pieces of public art. ●



Gaslamp Quarter



ZEMPLAR is indicated for the prevention and treatment of secondary hyperparathyroidism (SHPT) associated with chronic kidney disease (CKD) stage 3 and 4 (ZEMPLAR Capsules) and stage 5 (ZEMPLAR Injection)<sup>1,2</sup>

## HELP FIGHT A COMPLICATION OF CKD

### Important Safety Information<sup>1,2</sup>

- ZEMPLAR Capsules and Injection are contraindicated in patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any product ingredient.
- Excessive administration of vitamin D compounds can cause over suppression of parathyroid hormone (PTH), hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. High intake of calcium and phosphate concomitant with vitamin D compounds may lead to similar abnormalities, and patient monitoring and individualized dose titration is required. Progressive hypercalcemia due to overdosage of vitamin D may require emergency medical attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis. Use caution when digitalis compounds are prescribed concomitantly with ZEMPLAR. Chronic hypercalcemia can lead to vascular and soft-tissue calcifications. Chronic administration of ZEMPLAR Injection may place patients at risk for hypercalcemia, elevated Ca x P product, and metastatic calcification.

- ZEMPLAR is partially metabolized by CYP3A. Care should be taken while dosing ZEMPLAR with ketoconazole and other strong cytochrome P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.
- During ZEMPLAR Capsules therapy withhold pharmacologic doses of vitamin D compounds. PTH, calcium and phosphorus levels should be monitored at least every 2 weeks for 3 months after initiation or following dose adjustments, then monthly for 3 months, and every 3 months thereafter. Patient monitoring and individualized dose titration are required to maintain physiologic targets and optimum reduction/levels of PTH. The dose of ZEMPLAR Capsules should be reduced or interrupted if hypercalcemia or elevated Ca x P is observed.
- During ZEMPLAR Injection therapy withhold phosphate or vitamin D related compounds. PTH should be monitored at least every 3 months and more frequently at initiation and dosage changes. Calcium and phosphorus should be measured at least monthly and

more frequently at initiation or following dosage changes. If clinically significant hypercalcemia develops or an elevated Ca x P product greater than 75 mg<sup>2</sup>/dL<sup>2</sup> is noted, the dose should be immediately reduced or interrupted.

- Patients should be informed to adhere to their diet and phosphorus restriction, to take prescribed phosphate binders, and should be knowledgeable about the symptoms of hypercalcemia. While taking ZEMPLAR Capsules patients should be informed to comply with dosage instructions.

- Adverse events reported by at least 5% and at a frequency of at least twice that of placebo were allergic reaction, rash, arthritis, and vertigo for the ZEMPLAR Capsules Stage 3 and 4 treated patients and chills, fever, sepsis, gastrointestinal bleeding, vomiting, edema, light-headedness, and pneumonia for the ZEMPLAR Injection Stage 5 treated patients.

**ZEMPLAR**  
(PARICALCITOL)

Goal achievement across  
the treatment continuum

[www.zemplar.com](http://www.zemplar.com)

Please see brief summary of Prescribing Information for ZEMPLAR Injection and ZEMPLAR Capsules on following pages.

**References:** 1. ZEMPLAR (paricalcitol) Capsules [package insert]. North Chicago, IL; Abbott Laboratories. 2. ZEMPLAR (paricalcitol) Injection [package insert]. Lake Forest, IL; Abbott Laboratories.

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# WEB RESOURCES



- San Diego Convention and Visitors Bureau [www.sandiego.org](http://www.sandiego.org)
- San Diego Zoo [www.sandiegozoo.org/zoo](http://www.sandiegozoo.org/zoo)
- San Diego Wild Animal Park [www.sandiegozoo.org/park](http://www.sandiegozoo.org/park)
- SeaWorld [www.seaworld.com/sandiego](http://www.seaworld.com/sandiego)
- Legoland [www.legoland.com](http://www.legoland.com)
- Belmont Park [www.belmontpark.com](http://www.belmontpark.com)
- Knott's Soak City [http://tickets.knotts.com/shop/soak\\_city.cfm](http://tickets.knotts.com/shop/soak_city.cfm)
- Balboa Park [www.balboapark.org](http://www.balboapark.org)
- USS Midway Museum [www.midway.org](http://www.midway.org)

PROFESSIONAL BRIEF SUMMARY  
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

## Zemplar®

(paricalcitol) Capsules

R<sub>x</sub> only

INDICATIONS AND USAGE

Zemplar Capsules are indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 3 and 4.

CONTRAINDICATIONS

Zemplar Capsules should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any ingredient in this product (see **WARNINGS**).

WARNINGS

Excessive administration of vitamin D compounds, including Zemplar Capsules, can cause over suppression of PTH, hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. Progressive hypercalcemia due to overdosage of vitamin D and its metabolites may be so severe as to require emergency attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. High intake of calcium and phosphate concomitant with vitamin D compounds may lead to similar abnormalities and patient monitoring and individualized dose titration is required.

Pharmacologic doses of vitamin D and its derivatives should be withheld during Zemplar treatment to avoid hypercalcemia.

PRECAUTIONS

General

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar Capsules.

Information for Patients

The patient or guardian should be informed about compliance with dosage instructions, adherence to instructions about diet and phosphorus restriction, and avoidance of the use of unapproved nonprescription drugs. Phosphate-binding agents may be needed to control serum phosphorus levels in patients, but excessive use of aluminum containing compounds should be avoided. Patients also should be informed about the symptoms of elevated calcium (see **ADVERSE REACTIONS**).

Laboratory Tests

During the initial dosing or following any dose adjustment of medication, serum calcium, serum phosphorus, and serum or plasma iPTH should be monitored at least every two weeks for 3 months after initiation of Zemplar therapy or following dose-adjustments in Zemplar therapy, then monthly for 3 months, and every 3 months thereafter.

Drug Interactions

Paricalcitol is not expected to inhibit the clearance of drugs metabolized by cytochrome P450 enzymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1 or CYP3A nor induce the clearance of drugs metabolized by CYP2B6, CYP2C9 or CYP3A.

A multiple dose drug-drug interaction study demonstrated that ketoconazole approximately doubled paricalcitol AUC<sub>(0-∞)</sub>. Since paricalcitol is partially metabolized by CYP3A and ketoconazole is known to be a strong inhibitor of cytochrome P450 3A enzyme, care should be taken while dosing paricalcitol with ketoconazole and other strong P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole. Dose adjustment of Zemplar Capsules may be required, and iPTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor such as ketoconazole.

Drugs that impair intestinal absorption of fat-soluble vitamins, such as cholestyramine, may interfere with the absorption of Zemplar Capsules.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, an increased incidence of uterine leiomyoma and leiomyosarcoma was observed at subcutaneous doses of 1, 3, 10 mcg/kg given three times weekly (2 to 15 times the AUC at a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The incidence rate of uterine leiomyoma was significantly different than the control group at the highest dose of 10 mcg/kg. In a 104-week carcinogenicity study in rats, there was an increased incidence of benign adrenal pheochromocytoma at subcutaneous doses of 0.15, 0.5, 1.5 mcg/kg (< 1 to 7 times the exposure following a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The increased incidence of pheochromocytomas in rats may be related to the alteration of calcium homeostasis by paricalcitol. Paricalcitol did not exhibit genetic toxicity *in vitro* with or without metabolic activation in the microbial mutagenesis assay (Ames Assay), mouse lymphoma mutagenesis assay (L5178Y), or a human lymphocyte cell chromosomal aberration assay. There was also no evidence of genetic toxicity in an *in vivo* mouse micronucleus assay. Paricalcitol had no effect on fertility (male or female) in rats at intravenous doses up to 20 mcg/kg/dose (equivalent to 13 times a human dose of 14 mcg based on surface area, mcg/m<sup>2</sup>).

Pregnancy

Pregnancy category C

Paricalcitol has been shown to cause minimal decreases in fetal viability (5%) when administered daily to rabbits at a dose 0.5 times a human dose of 14 mcg or 0.24 mcg/kg (based on body surface area, mcg/m<sup>2</sup>), and when administered to rats at a dose two times the 0.24 mcg/kg human dose (based on body surface area, mcg/m<sup>2</sup>). At the highest dose tested, 20 mcg/kg administered three times per week in rats (13 times the 14 mcg human dose based on surface area, mcg/m<sup>2</sup>), there was a significant increase in the mortality of newborn rats at doses that were maternally toxic and are known to produce hypercalcemia in rats. No other effects on offspring development were observed. Paricalcitol was not teratogenic at the doses tested. Paricalcitol (20 mcg/kg) has been shown to cross the placental barrier in rats.

There are no adequate and well-controlled clinical studies in pregnant women. Zemplar Capsules should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers

Studies in rats have shown that paricalcitol is present in the milk. It is not known whether paricalcitol is excreted in human milk. In the nursing patient, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Geriatric Use

Of the total number (n = 220) of patients in clinical studies of Zemplar Capsules, 49% were 65 and over, while 17% were 75 and over. No overall differences in safety and effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Pediatric Use

Safety and efficacy of Zemplar Capsules in pediatric patients have not been established.

ADVERSE REACTIONS

The safety of Zemplar Capsules has been evaluated in three 24-week (approximately six-month), double-blind, placebo-controlled, multicenter clinical studies involving 220 CKD Stage 3 and 4 patients. Six percent (6%) of Zemplar Capsules treated patients and 4% of placebo treated patients discontinued from clinical studies due to an adverse event. All reported adverse events occurring in at least 2% in either treatment group are presented in Table 3.

Table 3. Treatment - Emergent Adverse Events by Body System Occurring in ≥ 2% of Subjects in the Zemplar-Treated Group of Three, Double-Blind, Placebo-Controlled, Phase 3, CKD Stage 3 and 4 Studies; All Treated Patients

Body System <sup>a</sup> COSTART V Term	Number (%) of Subjects	
	Zemplar Capsules (n = 107)	Placebo (n = 113)
Overall	88 (82%)	86 (76%)
<b>Body as a Whole</b>	<b>49 (46%)</b>	<b>40 (35%)</b>
Accidental Injury	10 (9%)	8 (7%)
Pain	8 (7%)	7 (6%)
Viral Infection	8 (7%)	8 (7%)
Allergic Reaction	6 (6%)	2 (2%)
Headache	5 (5%)	5 (4%)
Abdominal Pain	4 (4%)	2 (2%)
Back Pain	4 (4%)	1 (1%)
Infection	4 (4%)	4 (4%)
Asthena	3 (3%)	2 (2%)
Chest Pain	3 (3%)	1 (1%)
Fever	3 (3%)	1 (1%)
Infection Fungal	3 (3%)	0 (0%)
Cyst	2 (2%)	0 (0%)
Flu Syndrome	2 (2%)	1 (1%)
Infection Bacterial	2 (2%)	1 (1%)
<b>Cardiovascular</b>	<b>27 (25%)</b>	<b>19 (17%)</b>
Hypertension	7 (7%)	4 (4%)
Hypotension	5 (5%)	3 (3%)
Syncope	3 (3%)	1 (1%)
Cardiomyopathy	2 (2%)	0 (0%)
Congestive Heart Failure	2 (2%)	5 (4%)
Myocardial Infarct	2 (2%)	0 (0%)
Postural Hypotension	2 (2%)	0 (0%)
<b>Digestive</b>	<b>29 (27%)</b>	<b>31 (27%)</b>
Diarrhea	7 (7%)	5 (4%)
Nausea	6 (6%)	4 (4%)
Vomiting	6 (6%)	5 (4%)
Constipation	4 (4%)	4 (4%)
Gastroenteritis	3 (3%)	3 (3%)
Dyspepsia	2 (2%)	2 (2%)
Gastritis	2 (2%)	4 (4%)
Rectal Disorder	2 (2%)	0 (0%)
<b>Hemic and Lymphatic System</b>	<b>4 (4%)</b>	<b>10 (9%)</b>
Hypervolemia	2 (2%)	4 (4%)
Ecchymosis	2 (2%)	4 (4%)

(Continued..)	Number (%) of Subjects	
Body System <sup>a</sup> COSTART V Term	Zemplar Capsules (n = 107)	Placebo (n = 113)
Overall	88 (82%)	86 (76%)
<b>Metabolic and Nutritional Disorders</b>	<b>24 (22%)</b>	<b>34 (30%)</b>
Edema	7 (7%)	5 (4%)
Uremia	7 (7%)	9 (8%)
Gout	4 (4%)	6 (5%)
Dehydration	3 (3%)	1 (1%)
Acidosis	2 (2%)	1 (1%)
Hyperkalemia	2 (2%)	3 (3%)
Hyperphosphatemia	2 (2%)	4 (4%)
Hypoglycemia	2 (2%)	4 (4%)
Hypokalemia	2 (2%)	1 (1%)
<b>Musculoskeletal</b>	<b>12 (11%)</b>	<b>9 (8%)</b>
Arthritis	5 (5%)	1 (1%)
Leg Cramps	3 (3%)	0 (0%)
Myalgia	2 (2%)	5 (4%)
<b>Nervous</b>	<b>18 (17%)</b>	<b>12 (11%)</b>
Dizziness	5 (5%)	5 (4%)
Vertigo	5 (5%)	0 (0%)
Depression	3 (3%)	0 (0%)
Insomnia	2 (2%)	2 (2%)
Neuropathy	2 (2%)	1 (1%)
<b>Respiratory</b>	<b>26 (24%)</b>	<b>25 (22%)</b>
Pharyngitis	11 (10%)	12 (11%)
Rhinitis	5 (5%)	4 (4%)
Bronchitis	3 (3%)	1 (1%)
Cough Increased	3 (3%)	2 (2%)
Sinusitis	3 (3%)	1 (1%)
Epistaxis	2 (2%)	1 (1%)
Pneumonia	2 (2%)	0 (0%)
<b>Skin and Appendages</b>	<b>17 (16%)</b>	<b>10 (9%)</b>
Rash	6 (6%)	3 (3%)
Pruritus	3 (3%)	3 (3%)
Skin Ulcer	3 (3%)	0 (0%)
Skin Hypertrophy	2 (2%)	0 (0%)
Vesiculobullous Rash	2 (2%)	1 (1%)
<b>Special Senses</b>	<b>9 (8%)</b>	<b>11 (10%)</b>
Amblyopia	2 (2%)	0 (0%)
Retinal Disorder	2 (2%)	0 (0%)
<b>Urogenital System</b>	<b>10 (9%)</b>	<b>10 (9%)</b>
Urinary Tract Infection	3 (3%)	1 (1%)
Kidney Function Abnormal	2 (2%)	1 (1%)

a. Includes all patients with events in that body system.

Potential adverse effects of Zemplar Capsules are, in general, similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms of hypercalcemia associated with vitamin D overdoses include:

**Early:** Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, and metallic taste.

**Late:** Anorexia, weight loss, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, hypercholesterolemia, elevated AST and ALT, ectopic calcification, hypertension, cardiac arrhythmias, somnolence, death, and, rarely, overt psychosis.

OVERDOSAGE

Excessive administration of Zemplar Capsules can cause hypercalcemia, hypercalciuria, and hyperphosphatemia, and over suppression of PTH (see **WARNINGS**).

Treatment of Overdosage

The treatment of acute overdosage of Zemplar Capsules should consist of general supportive measures. If drug ingestion is discovered within a relatively short time, induction of emesis or gastric lavage may be of benefit in preventing further absorption. If the drug has passed through the stomach, the administration of mineral oil may promote its fecal elimination. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low-calcium diet are also indicated in accidental overdosage. Due to the relatively short duration of the pharmacological action of paricalcitol, further measures are probably unnecessary. If persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives that may be considered depending on the patient's underlying condition. These include the use of drugs such as phosphates and corticosteroids, as well as measures to induce an appropriate forced diuresis.

Ref: 03-5368-R1

Revised: May, 2005

05E-131-J612-2 MASTER



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PROFESSIONAL BRIEF SUMMARY  
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**Zemplar®**  
(paricalcitol) Injection

Fliptop Vial

Rx only

INDICATIONS AND USAGE

Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.

CONTRAINDICATIONS

Zemplar should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any ingredient in this product (see **WARNINGS**).

WARNINGS

Acute overdose of Zemplar may cause hypercalcemia, and require emergency attention. During dose adjustment, serum calcium and phosphorus levels should be monitored closely (e.g., twice weekly). If clinically significant hypercalcemia develops, the dose should be reduced or interrupted. Chronic administration of Zemplar may place patients at risk of hypercalcemia, elevated Ca x P product, and metastatic calcification.

Treatment of patients with clinically significant hypercalcemia consists of immediate dose reduction or interruption of Zemplar therapy and includes a low calcium diet, withdrawal of calcium supplements, patient mobilization, attention to fluid and electrolyte imbalances, assessment of electrocardiographic abnormalities (critical in patients receiving digitalis), hemodialysis or peritoneal dialysis against a calcium-free dialysate, as warranted. Serum calcium levels should be monitored frequently until normocalcemia ensues.

Phosphate or vitamin D-related compounds should not be taken concomitantly with Zemplar.

PRECAUTIONS

General

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar. Adynamic bone lesions may develop if PTH levels are suppressed to abnormal levels.

Information for the Patient

The patient should be instructed that, to ensure effectiveness of Zemplar therapy, it is important to adhere to a dietary regimen of calcium supplementation and phosphorus restriction. Appropriate types of phosphate-binding compounds may be needed to control serum phosphorus levels in patients with chronic kidney disease (CKD) Stage 5, but excessive use of aluminum containing compounds should be avoided. Patients should also be carefully informed about the symptoms of elevated calcium (see **ADVERSE REACTIONS**).

Laboratory Tests

During the initial phase of medication, serum calcium and phosphorus should be determined frequently (e.g., twice weekly). Once dosage has been established, serum calcium and phosphorus should be measured at least monthly. Measurements of serum or plasma PTH are recommended every 3 months. An intact PTH (iPTH) assay is recommended for reliable detection of biologically active PTH in patients with CKD Stage 5. During dose adjustment of Zemplar, laboratory tests may be required more frequently.

Drug Interactions

Paricalcitol is not expected to inhibit the clearance of drugs metabolized by cytochrome P450 enzymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, or CYP3A nor induce the clearance of drug metabolized by CYP2B6, CYP2C9 or CYP3A.

Specific interaction studies were not performed with Zemplar Injection.

A multiple dose drug-drug interaction study with ketoconazole and paricalcitol capsule demonstrated that ketoconazole approximately doubled paricalcitol AUC<sub>0-∞</sub>. Since paricalcitol is partially metabolized by CYP3A and ketoconazole is known to be a strong inhibitor of cytochrome P450 3A enzyme, care should be taken while dosing paricalcitol with ketoconazole and other strong P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, an increased incidence of uterine leiomyoma and leiomyosarcoma was observed at subcutaneous doses of 1, 3, 10 mcg/kg (2 to 15 times the AUC at a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The incidence rate of uterine leiomyoma was significantly different than the control group at the highest dose of 10 mcg/kg.

In a 104-week carcinogenicity study in rats, there was an increased incidence of benign adrenal pheochromocytoma at subcutaneous doses of 0.15, 0.5, 1.5 mcg/kg (<1 to 7 times the exposure following a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The increased incidence of pheochromocytomas in rats may be related to the alteration of calcium homeostasis by paricalcitol.

Paricalcitol did not exhibit genetic toxicity *in vitro* with or without metabolic activation in the microbial mutagenesis assay (Ames Assay), mouse lymphoma mutagenesis assay (L5178Y), or a human lymphocyte cell chromosomal aberration assay. There was also no evidence of genetic toxicity in an *in vivo* mouse micronucleus assay. Zemplar had no effect on fertility (male or female) in rats at intravenous doses up to 20 mcg/kg/dose [equivalent to 13 times the highest recommended human dose (0.24 mcg/kg) based on surface area, mg/m<sup>2</sup>].

Pregnancy

Pregnancy Category C.

Paricalcitol has been shown to cause minimal decreases in fetal viability (5%) when administered daily to rabbits at a dose 0.5 times the 0.24 mcg/kg human dose (based on surface area, mg/m<sup>2</sup>) and when administered to rats at a dose 2 times the 0.24 mcg/kg human dose (based on plasma levels of exposure). At the highest dose tested (20 mcg/kg 3 times per week in rats, 13 times the 0.24 mcg/kg human dose based on surface area), there was a significant increase of the mortality of newborn rats at doses that were maternally toxic (hypercalcemia). No other effects on offspring development were observed. Paricalcitol was not teratogenic at the doses tested.

There are no adequate and well-controlled studies in pregnant women. Zemplar should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers

Studies in rats have shown that paricalcitol is present in the milk. It is not known whether paricalcitol is excreted in human milk. In the nursing patient, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of Zemplar were examined in a 12-week randomized, double-blind, placebo-controlled study of 29 pediatric patients, aged 5-19 years, with end-stage renal disease on hemodialysis and nearly all had received some form of vitamin D prior to the study. Seventy-six percent of the patients were male, 52% were Caucasian and 45% were African-American. The initial dose of Zemplar was 0.04 mcg/kg 3 times per week, based on baseline iPTH level of

less than 500 pg/mL, or 0.08 mcg/kg 3 times a week based on baseline iPTH level of ≥ 500 pg/mL, respectively. The dose of Zemplar was adjusted in 0.04 mcg/kg increments based on the levels of serum iPTH, calcium, and Ca x P. The mean baseline levels of iPTH were 841 pg/mL for the 15 Zemplar-treated patients and 740 pg/mL for the 14 placebo-treated subjects. The mean dose of Zemplar administered was 4.6 mcg (range: 0.8 mcg – 9.6 mcg). Ten of the 15 (67%) Zemplar-treated patients and 2 of the 14 (14%) placebo-treated patients completed the trial. Ten of the placebo patients (71%) were discontinued due to excessive elevations in iPTH levels as defined by 2 consecutive iPTH levels > 700 pg/mL and greater than baseline after 4 weeks of treatment.

In the primary efficacy analysis, 9 of 15 (60%) subjects in the Zemplar group had 2 consecutive 30% decreases from baseline iPTH compared with 3 of 14 (21%) patients in the placebo group (95% CI for the difference between groups –1%, 63%). Twenty-three percent of Zemplar vs. 31% of placebo patients had at least one serum calcium level > 10.3 mg/dL, and 40% vs. 14% of Zemplar vs. placebo subjects had at least one Ca x P ion product > 72 (mg/dL)<sup>2</sup>. The overall percentage of serum calcium measurements > 10.3 mg/dL was 7% in the Zemplar group and 7% in the placebo group; the overall percentage of patients with Ca x P product > 72 (mg/dL)<sup>2</sup> was 8% in the Zemplar group and 7% in the placebo group. No subjects in either the Zemplar group or placebo group developed hypercalcemia (defined as at least one calcium value > 11.2 mg/dL) during the study.

Geriatric Use

Of the 40 patients receiving Zemplar in the three phase 3 placebo-controlled CKD Stage 5 studies, 10 patients were 65 years or over. In these studies, no overall differences in efficacy or safety were observed between patients 65 years or older and younger patients.

ADVERSE REACTIONS

Zemplar has been evaluated for safety in clinical studies in 454 CKD Stage 5 patients. In four, placebo-controlled, double-blind, multicenter studies, discontinuation of therapy due to any adverse event occurred in 6.5% of 62 patients treated with Zemplar (dosage titrated as tolerated) and 2.0% of 51 patients treated with placebo for 1 to 3 months. Adverse events occurring with greater frequency in the Zemplar group at a frequency of 2% or greater, regardless of causality, are presented in the following table:

Adverse Event Incidence Rates For All Treated Patients In All Placebo-Controlled Studies		
Adverse Event	Zemplar (n=62) %	Placebo (n=51) %
<b>Overall</b>	71	78
<b>Body as a Whole</b>		
Chills	5	0
Feeling unwell	3	0
Fever	5	2
Flu	5	4
Sepsis	5	2
<b>Cardiovascular</b>		
Palpitation	3	0
<b>Digestive System</b>		
Dry mouth	3	2
Gastrointestinal bleeding	5	2
Nausea	13	8
Vomiting	8	4
<b>Metabolic and Nutritional Disorders</b>		
Edema	7	0
<b>Nervous System</b>		
Light-headedness	5	2
<b>Respiratory System</b>		
Pneumonia	5	0

A patient who reported the same medical term more than once was counted only once for that medical term.

Safety parameters (changes in mean Ca, P, Ca x P) in an open-label safety study up to 13 months in duration support the long-term safety of Zemplar in this patient population.

Potential adverse events of Zemplar Injection are, in general, similar to those encountered with excessive vitamin D intake. Signs and symptoms of vitamin D intoxication associated with hypercalcemia include:

**Early**  
Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, and metallic taste.

**Late**  
Anorexia, weight loss, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, hypercholesterolemia, elevated AST and ALT, ectopic calcification, hypertension, cardiac arrhythmias, somnolence, death, and rarely, overt psychosis.

**Adverse events during post-marketing experience:** Taste perversion, such as metallic taste, and allergic reactions, such as rash, urticaria, pruritus, facial and oral edema rarely have been reported.

OVERDOSAGE

Overdosage of Zemplar may lead to hypercalcemia, hypercalciuria, hyperphosphatemia, and over suppression of PTH. (see **WARNINGS**).

Treatment of Overdosage and Hypercalcemia

The treatment of acute overdosage should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low calcium diet are also indicated in acute overdosage.

General treatment of hypercalcemia due to overdosage consists of immediate suspension of Zemplar therapy, institution of a low calcium diet, and withdrawal of calcium supplements. Serum calcium levels should be determined at least weekly until normocalcemia ensues. When serum calcium levels have returned to within normal limits, Zemplar may be reinitiated at a lower dose. If persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives that may be considered. These include the use of drugs such as phosphates and corticosteroids as well as measures to induce diuresis. Also, one may consider dialysis against a calcium-free dialysate.

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## Star of India under sail

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