INDIANA ACADEMY OF
FAMILY PHYSICIANS

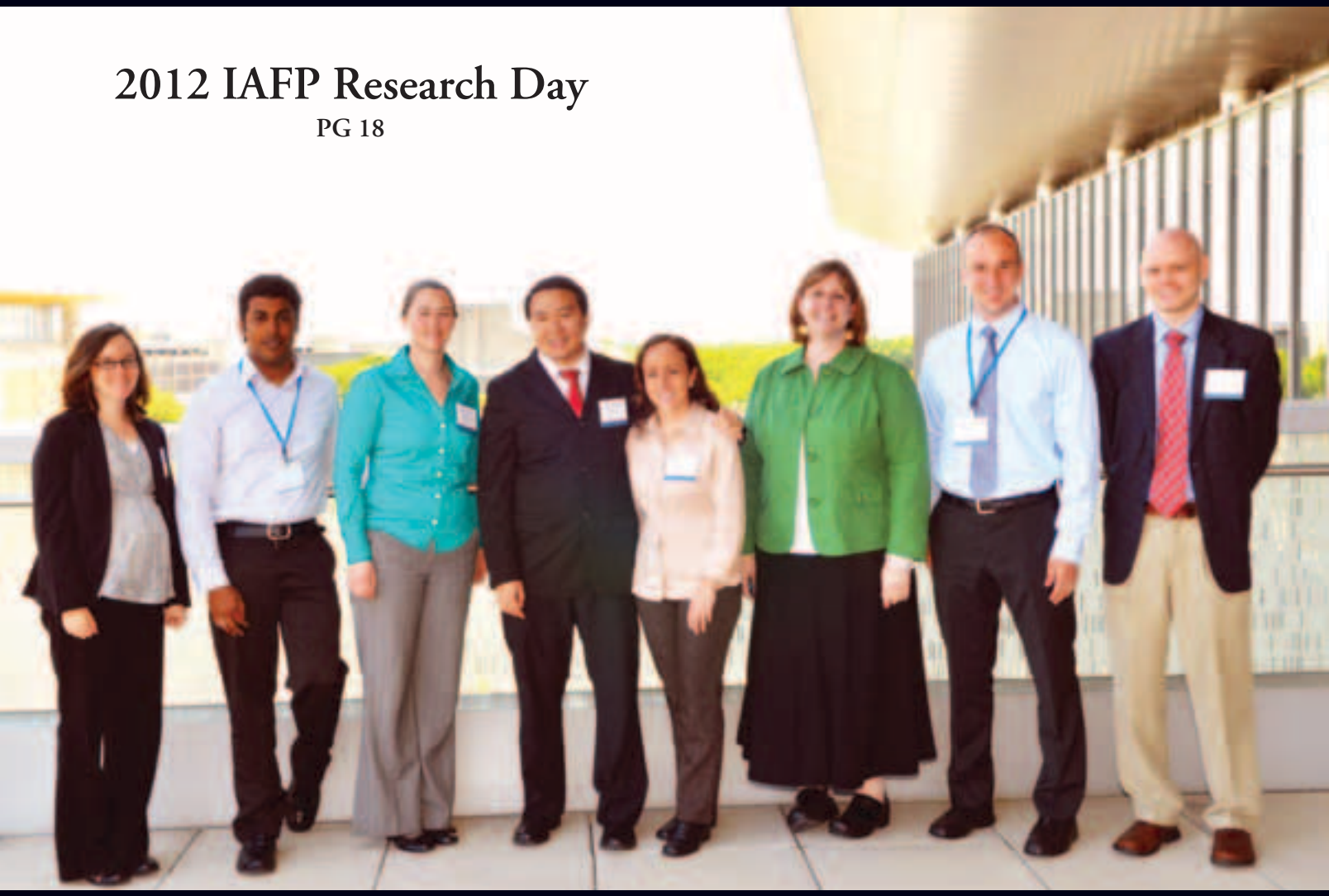
Quarterly Publication for Indiana's Family Physicians

Summer 2012

FRONTLINE PHYSICIAN

2012 IAFP Research Day

PG 18



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2012 IAFP Annual Convention

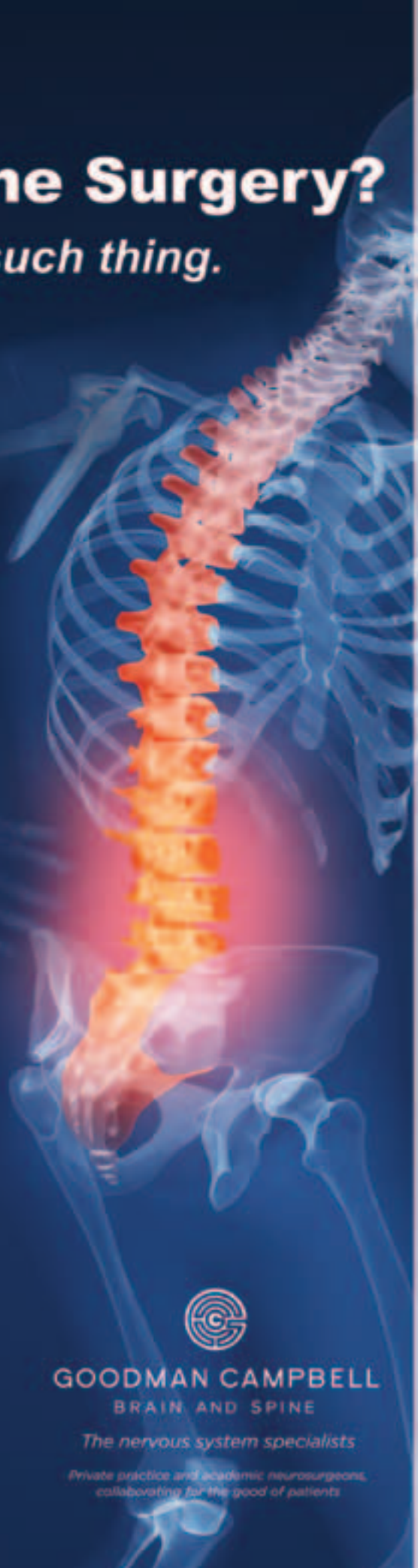
PG 14

Marian University College of Osteopathic Medicine Update

PG 19

Simple Spine Surgery?

There's no such thing.



And yet, we hear it time and time again: I send my "simple spine" one place but my complex cases go to a neurosurgeon.

Every spine surgery involves carefully working around delicate, inflamed nerves. When nerves are involved, a "simple spine" case can turn complex quickly.

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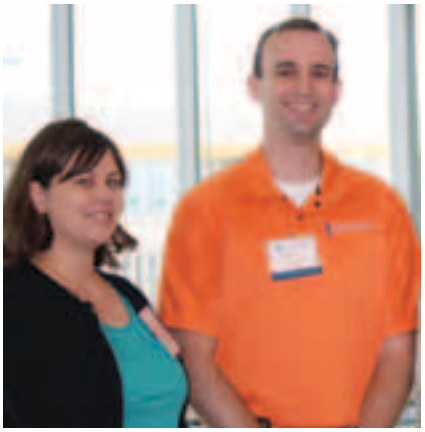

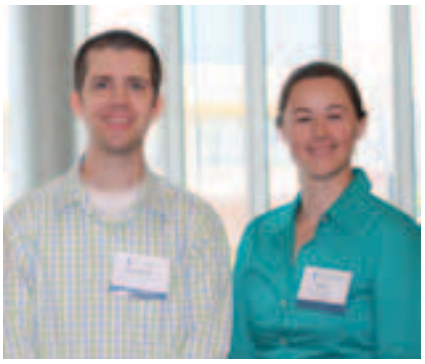

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Printed June 2012

FRONTLINE PHYSICIAN

Volume 13 • Issue 2

FrontLine Physician is the official magazine of the Indiana Academy of Family Physicians and is published quarterly.

Our Mission

The mission of the Indiana Academy of Family Physicians is to promote and advance family medicine in order to improve the health of Indiana.

Advocacy

Shaping health care policy in Indiana through interactions with government, the public, businesses, the health care industry and our patients

Membership

Serving as the essential resource for the professional success of the Family Physician workforce in Indiana

Education

We aim to be the provider of choice for family physician education in Indiana

Family Medicine: Exceptional Physicians, Exceptional Care

INDIANA ACADEMY OF FAMILY PHYSICIANS

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FrontLine Physician is published by Innovative Publishing Ink.
10629 Henning Way, Suite 8 • Louisville, Kentucky 40241
502.423.7272
www.ipipub.com

Innovative Publishing Ink specializes in creating custom magazines for associations. Please direct all inquiries to Aran Jackson, ajackson@ipipub.com.

President's Message

Deanna Willis, MD

Greetings!

As you read this, planning will be ramping into high gear for your Academy's 2012 Annual Convention. The JW Marriott will be a great place to bring your whole family this July, as its location on the White River is just steps from exciting attractions like the Indianapolis Zoo, White River Gardens, the Indiana State Museum, IMAX® Theater, the Eiteljorg Museum of American Indians and Western Art and the NCAA Hall of Champions. All of these attractions are within easy walking distance of the hotel.

For those of you who enjoy nightlife, you'll love Indy even more now that it's smokefree! Thanks to the tireless work of our Academy and its partners, the smokefree ordinance went into effect on June 1, making almost every workplace in Indianapolis smokefree. Indianapolis has world-class restaurants, bars and sporting venues for your enjoyment, too.

As an IAFP member, you are a vital part of our Annual Congress of Delegates. All IAFP members are delegates, and all IAFP members can have their vote at the Congress and have their voices heard. Resolutions introduced at our Congress directly affect your Academy's future policies and ways of doing business. Hear this year's resolutions, and make your vote. Other meeting highlights include Hot Topic CME, an MC-FP SAM Study Group, the Exhibit Show and your chance to catch up with your friends and colleagues from across the state.

Family Medicine Day at Victory Field takes place just after the Annual Convention wraps up. This is your chance to see the Indianapolis Indians play the Buffalo Bisons, and it's completely free of charge for IAFP members and their families. We've had a huge response from members requesting tickets, so plan on joining a big crowd of Indiana family physicians and their families for a delicious picnic and refreshing drinks, followed by a fun baseball game.

As the year comes to an end, looking back at the amazing work of the Academy and the wonderful people working to support family medicine in Indiana, it was a great honor to serve in this role. I look forward to the great possibilities next year under the leadership of Dr. Risheet Patel.

Welcome to Our New Members and Transfers

David Nicholas Dahl, DO (Washington)

Michael DaRosa, DO (Indianapolis)

Jason Matthew Fish, MD (Bloomington)
Transfer from: Alabama

Laura Anne Foudy, MD (Huntington)

Alex I. Garrido, MD (Carmel)

Jennifer Kathleen Malcolm, DO (Granger)

Haihong Mao, MD (Indianapolis)

John Earl Reaves, MD (Noblesville)
Transfer from: Virginia

Aditee S. Satpute, MD (Indianapolis)

Peter Baenziger (Indianapolis)

Maria A. Cuda, DO (Wabash)
Transfer from: Arizona

Edith M. Cullen, MD (Fishers)

Derryl Miller (Indianapolis)

Jacklyn Marie Oakley (Indianapolis)

Leah Napolitano Ortiz, MD (South Bend)
Transfer from: New Jersey

Jeremy Lawrence Riehm, DO (Granger)

Formulary Update

onglyza
(saxagliptin) 5 mg tablets

kombiglyze XR
(saxagliptin and metformin HCl extended-release) tablets

Available on Formulary at Indiana Medicaid

For more information about these products, visit
www.onglyza-hcp.com or www.kombiglyzexr-hcp.com

Please read adjacent Brief Summary of US Full Prescribing Information for KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) (5/500•5/1000•2.5/1000 mg tablets), including **Boxed WARNING** about lactic acidosis.

Bristol-Myers Squibb

AstraZeneca

1743100

KOMBIGLYZE XR **℞ ONLY**

(saxagliptin and metformin HCl extended-release) tablets

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

WARNING: LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure.

The onset of lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) should be discontinued and the patient hospitalized immediately. [See *Warnings and Precautions*.]

INDICATIONS AND USAGE

KOMBIGLYZE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. [See *Clinical Studies* (14) in Full Prescribing Information.]

Important Limitations of Use

KOMBIGLYZE XR should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

KOMBIGLYZE XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using KOMBIGLYZE XR. [See *Warnings and Precautions*.]

CONTRAINDICATIONS

KOMBIGLYZE XR is contraindicated in patients with:

- Renal impairment (e.g., serum creatinine levels ≥1.5 mg/dL for men, ≥1.4 mg/dL for women, or abnormal creatinine clearance which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- Hypersensitivity to metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin.
- History of a serious hypersensitivity reaction to KOMBIGLYZE XR or saxagliptin, such as anaphylaxis, angioedema, or exfoliative skin conditions. [See *Warnings and Precautions* and Adverse Reactions.]

WARNINGS AND PRECAUTIONS

Lactic Acidosis: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with KOMBIGLYZE XR; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels >5 µg/mL are generally found.

The reported incidence of lactic acidosis in patients receiving metformin hydrochloride is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). In more than 20,000 patient-years exposure to metformin in clinical trials, there were no reports of lactic acidosis. Reported cases have occurred primarily in diabetic patients with significant renal insufficiency, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking metformin and the use of the minimum effective dose of metformin. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin treatment should not be initiated in patients ≥80 years of age unless measurement of creatinine clearance demonstrates that renal function is not reduced, as these patients are more susceptible to developing lactic acidosis. In addition, metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. Because impaired hepatic function may significantly limit the ability to clear lactate, metformin should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake when taking metformin since alcohol potentiates the effects of metformin hydrochloride on lactate metabolism. In addition, metformin should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure [see *Warnings and Precautions*].

The onset of lactic acidosis often is subtle and accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. There may be associated hypothermia, hypotension, and resistant bradyarrhythmias with more marked acidosis. The patient and the patient's physician must be aware of the possible importance of such symptoms and the patient should be instructed to notify the physician immediately if they occur [see *Warnings and Precautions*]. Metformin should be withdrawn until the situation is clarified. Serum electrolytes, ketones, blood glucose, and if indicated, blood pH, lactate levels, and even blood metformin levels may be useful. Once a patient is stabilized on any dose level of metformin, gastrointestinal symptoms, which are common during initiation of therapy, are unlikely to be drug related. Later occurrence of gastrointestinal symptoms could be due to lactic acidosis or other serious disease.

Levels of fasting venous plasma lactate above the upper limit of normal, but less than 5 mmol/L, in patients taking metformin do not necessarily indicate impending lactic acidosis and may be explainable by other mechanisms, such as poorly controlled diabetes or obesity, vigorous physical activity, or technical problems in sample handling. [See *Warnings and Precautions*.]

Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia).

Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking metformin, the drug should be discontinued immediately and general supportive measures promptly instituted. Because metformin hydrochloride is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin. Such management often results in prompt reversal of symptoms and recovery [see *Contraindications* and *Warnings and Precautions*].

Pancreatitis: There have been postmarketing reports of acute pancreatitis in patients taking saxagliptin. After initiation of KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release), patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, KOMBIGLYZE XR should promptly be discontinued and appropriate management should be initiated. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using KOMBIGLYZE XR.

Assessment of Renal Function: Metformin is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Therefore, KOMBIGLYZE XR is contraindicated in patients with renal impairment [see *Contraindications*].

Before initiation of KOMBIGLYZE XR, and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and KOMBIGLYZE XR discontinued if evidence of renal impairment is present.

Impaired Hepatic Function: Metformin use in patients with impaired hepatic function has been associated with some cases of lactic acidosis. Therefore, KOMBIGLYZE XR is not recommended in patients with hepatic impairment.

Vitamin B_{12} Concentrations: In controlled clinical trials of metformin of 29-week duration, a decrease to subnormal levels of previously normal serum vitamin B_{12} levels, without clinical manifestations, was observed in approximately 7% of patients. Such decrease, possibly due to interference with B_{12} absorption from the B_{12}-intrinsic factor complex, is, however, very rarely associated with anemia and appears to be rapidly reversible with discontinuation of metformin or vitamin B_{12} supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on KOMBIGLYZE XR and any apparent abnormalities should be appropriately investigated and managed [see *Adverse Reactions*].

Certain individuals (those with inadequate vitamin B_{12} or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B_{12} levels. In these patients, routine serum vitamin B_{12} measurements at 2- to 3-year intervals may be useful.

Alcohol Intake: Alcohol potentiates the effect of metformin on lactate metabolism. Patients should be warned against excessive alcohol intake while receiving KOMBIGLYZE XR.

Surgical Procedures: Use of KOMBIGLYZE XR should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal.

Change in Clinical Status of Patients with Previously Controlled Type 2 Diabetes: A patient with type 2 diabetes previously well controlled on KOMBIGLYZE XR who develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness) should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. Evaluation should include serum electrolytes and ketones, blood glucose and, if indicated, blood pH, lactate, pyruvate, and metformin levels. If acidosis of either form occurs, KOMBIGLYZE XR must be stopped immediately and other appropriate corrective measures initiated.

Use with Medications Known to Cause Hypoglycemia

Saxagliptin — When saxagliptin was used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, the incidence of confirmed hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. [See *Adverse Reactions*.] Therefore, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia when used in combination with KOMBIGLYZE XR. [See *Dosage and Administration* (2.3) in Full Prescribing Information.]

Metformin hydrochloride — Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as sulfonylureas and insulin) or ethanol. Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly and in people who are taking beta-adrenergic blocking drugs.

Concomitant Medications Affecting Renal Function or Metformin Disposition: Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or may interfere with the disposition of metformin, such as cationic drugs that are eliminated by renal tubular secretion [see *Drug Interactions*], should be used with caution.

Radiologic Studies with Intravascular Iodinated Contrast Materials: Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, KOMBIGLYZE XR should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

Hypoxic States: Cardiovascular collapse (shock), acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on KOMBIGLYZE XR therapy, the drug should be promptly discontinued.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with saxagliptin. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions. Onset of these reactions occurred within the first 3 months after initiation of treatment with saxagliptin, with some reports occurring after the first dose. If a serious hypersensitivity reaction is suspected, discontinue KOMBIGLYZE XR, assess for other potential causes for the event, and institute alternative treatment for diabetes. [See *Adverse Reactions*.]

Use caution in a patient with a history of angioedema to another dipeptidyl peptidase-4 (DPP-4) inhibitor because it is unknown whether such patients will be predisposed to angioedema with KOMBIGLYZE XR.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) or any other antidiabetic drug.

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.

Monotherapy and Add-On Combination Therapy

Metformin hydrochloride — In placebo-controlled monotherapy trials of metformin extended-release, diarrhea and nausea/vomiting were reported in >5% of metformin-treated patients and more commonly than in placebo-treated patients (9.6% versus 2.6% for diarrhea and 6.3% versus 1.3% for nausea/vomiting). Diarrhea led to discontinuation of study medication in 0.6% of the patients treated with metformin extended-release.

Saxagliptin — In two placebo-controlled monotherapy trials of 24-week duration, patients were treated with saxagliptin 2.5 mg daily, saxagliptin 5 mg daily, and placebo. Three 24-week, placebo-controlled, add-on combination therapy trials were also conducted: one with metformin immediate-release, one with a thiazolidinedione (pioglitazone or rosiglitazone), and one with glyburide. In these three trials, patients were randomized to add-on therapy with saxagliptin 2.5 mg daily, saxagliptin 5 mg daily, or placebo. A saxagliptin 10 mg treatment arm was included in one of the monotherapy trials and in the add-on combination trial with metformin immediate-release.

In a prespecified pooled analysis of the 24-week data (regardless of glycemic rescue) from the two monotherapy trials, the add-on to metformin immediate-release trial, the add-on to thiazolidinedione (TZD) trial, and the add-on to glyburide trial, the overall incidence of adverse events in patients treated with saxagliptin 2.5 mg and saxagliptin 5 mg was similar to placebo (72.0% and 72.2% versus 70.6%, respectively). Discontinuation of therapy due to adverse events occurred in 2.2%, 3.3%, and 1.8% of patients receiving saxagliptin 2.5 mg, saxagliptin 5 mg, and placebo, respectively. The most common adverse events (reported in at least 2 patients treated with saxagliptin 2.5 mg or at least 2 patients treated with saxagliptin 5 mg) associated with premature discontinuation of therapy included lymphopenia (0.1% and 0.5% versus 0%, respectively), rash (0.2% and 0.3% versus 0.3%), blood creatinine increased (0.3% and 0% versus 0%), and blood creatine phosphokinase increased (0.1% and 0.2% versus 0%). The adverse reactions in this pooled analysis reported (regardless of investigator assessment of causality) in >5% of patients treated with saxagliptin 5 mg, and more commonly than in patients treated with placebo are shown in Table 1.

Table 1: Adverse Reactions (Regardless of Investigator Assessment of Causality) in Placebo-Controlled Trials* Reported in ≥5% of Patients Treated with Saxagliptin 5 mg and More Commonly than in Patients Treated with Placebo

	Number (%) of Patients	
	Saxagliptin 5 mg N=862	Placebo N=799
Upper respiratory tract infection	69 (7.7)	51 (7.6)
Urinary tract infection	50 (5.8)	49 (6.1)
Headache	37 (4.3)	47 (5.9)

* The 5 placebo-controlled trials include two monotherapy trials and one add-on combination therapy trial with each of the following: metformin, thiazolidinedione, or glyburide. Table shows 24-week data regardless of glycemic rescue.

In patients treated with saxagliptin 2.5 mg, headache (6.5%) was the only adverse reaction reported at a rate ≥5% and more commonly than in patients treated with placebo.

In this pooled analysis, adverse reactions that were reported in ≥2% of patients treated with saxagliptin 2.5 mg or saxagliptin 5 mg and ≥1% more frequently compared to placebo included: sinusitis (2.9% and 2.8% versus 1.8%, respectively), abdominal pain (2.4% and 1.7% versus 0.5%), gastroenteritis (1.9% and 2.3% versus 0.9%), and vomiting (2.2% and 2.3% versus 1.3%).

The incidence rate of fractures was 1.0 and 0.6 per 100 patient-years, respectively, for saxagliptin (pooled analysis of 2.5 mg, 5 mg, and 10 mg) and placebo. The incidence rate of fracture events in patients who received saxagliptin did not increase over time. Causality has not been established and nonclinical studies have not demonstrated adverse effects of saxagliptin on bone.

An event of thrombocytopenia, consistent with a diagnosis of idiopathic thrombocytopenic purpura, was observed in the clinical program. The relationship of this event to saxagliptin is not known.

Use in Combination with Insulin

In the add-on to insulin trial [see *Clinical Studies* (14.4) in Full Prescribing Information], the incidence of adverse events, including serious adverse events and discontinuations due to adverse events, was similar between saxagliptin and placebo, except for confirmed hypoglycemia (see **Hypoglycemia** subsection).

Adverse Reactions Associated with Saxagliptin Coadministered with Metformin Immediate-Release in Treatment-Naive Patients with Type 2 Diabetes

Table 2 shows the adverse reactions reported (regardless of investigator assessment of causality) in ≥5% of patients participating in an additional 24-week, active-controlled trial of coadministered saxagliptin and metformin in treatment-naive patients.

Table 2: Coadministration of Saxagliptin and Metformin Immediate-Release in Treatment-Naive Patients: Adverse Reactions Reported (Regardless of Investigator Assessment of Causality) in ≥5% of Patients Treated with Combination Therapy of Saxagliptin 5 mg Plus Metformin Immediate-Release (and More Commonly than in Patients Treated with Metformin Immediate-Release Alone)

	Number (%) of Patients	
	Saxagliptin 5 mg + Metformin* N=320	Placebo + Metformin* N=329
Headache	24 (7.5)	17 (5.2)
Nasopharyngitis	22 (6.9)	13 (4.0)

* Metformin immediate-release was initiated at a starting dose of 500 mg daily and titrated up to a maximum of 2000 mg daily.

In patients treated with the combination of saxagliptin and metformin immediate-release, either as saxagliptin add-on to metformin immediate-release therapy or as coadministration in treatment-naive patients, diarrhea was the only gastrointestinal-related event that occurred with an incidence

≥5% in any treatment group in both studies. In the saxagliptin add-on to metformin immediate-release trial, the incidence of diarrhea was 9.9%, 5.8%, and 11.2% in the saxagliptin 2.5 mg, 5 mg, and placebo groups, respectively. When saxagliptin and metformin immediate-release were coadministered in treatment-naive patients, the incidence of diarrhea was 6.9% in the saxagliptin 5 mg + metformin immediate-release group and 7.3% in the placebo + metformin immediate-release group.

Hypoglycemia

In the saxagliptin clinical trials, adverse reactions of hypoglycemia were based on all reports of hypoglycemia. A concurrent glucose measurement was not required or was normal in some patients. Therefore, it is not possible to conclusively determine that all these reports reflect true hypoglycemia.

The incidence of reported hypoglycemia for saxagliptin 2.5 mg and saxagliptin 5 mg versus placebo given as monotherapy was 4.0% and 5.6% versus 4.1%, respectively. In the add-on to metformin immediate-release trial, the incidence of reported hypoglycemia was 7.8% with saxagliptin 2.5 mg, 5.8% with saxagliptin 5 mg, and 5.0% with placebo. When saxagliptin and metformin immediate-release were coadministered in treatment-naive patients, the incidence of reported hypoglycemia was 3.4% in patients given saxagliptin 5 mg + metformin immediate-release and 4.0% in patients given placebo + metformin immediate-release.

In the active-controlled trial comparing add-on therapy with saxagliptin 5 mg to glipizide in patients inadequately controlled on metformin alone, the incidence of reported hypoglycemia was 3% (19 events in 13 patients) with saxagliptin 5 mg versus 36.3% (750 events in 156 patients) with glipizide. Confirmed symptomatic hypoglycemia (accompanying fingerstick blood glucose ≤50 mg/dL) was reported in none of the saxagliptin-treated patients and in 35 glipizide-treated patients (8.1%) (p<0.0001).

In the add-on to insulin trial, the overall incidence of reported hypoglycemia was 18.4% for saxagliptin 5 mg and 19.9% for placebo. However, the incidence of confirmed symptomatic hypoglycemia (accompanying fingerstick blood glucose ≤50 mg/dL) was higher with saxagliptin 5 mg (5.3%) versus placebo (3.3%). Among the patients using insulin in combination with metformin, the incidence of confirmed symptomatic hypoglycemia was 4.8% with saxagliptin versus 1.9% with placebo [see Warnings and Precautions].

Hypersensitivity Reactions

Saxagliptin — Hypersensitivity-related events, such as urticaria and facial edema in the 5-study pooled analysis up to Week 24 were reported in 1.5%, 1.5%, and 0.4% of patients who received saxagliptin 2.5 mg, saxagliptin 5 mg, and placebo, respectively. None of these events in patients who received saxagliptin required hospitalization or were reported as life-threatening by the investigators. One saxagliptin-treated patient in this pooled analysis discontinued due to generalized urticaria and facial edema.

Infections

Saxagliptin — In the unblinded, controlled, clinical trial database for saxagliptin to date, there have been 6 (0.12%) reports of tuberculosis among the 4959 saxagliptin-treated patients (1.1 per 1000 patient-years) compared to no reports of tuberculosis among the 2868 comparator-treated patients. Two of these six cases were confirmed with laboratory testing. The remaining cases had limited information or had presumptive diagnoses of tuberculosis. None of the six cases occurred in the United States or in Western Europe. One case occurred in Canada in a patient originally from Indonesia who had recently visited Indonesia. The duration of treatment with saxagliptin until report of tuberculosis ranged from 144 to 929 days. Post-treatment lymphocyte counts were consistently within the reference range for four cases. One patient had lymphopenia prior to initiation of saxagliptin that remained stable throughout saxagliptin treatment. The final patient had an isolated lymphocyte count below normal approximately four months prior to the report of tuberculosis. There have been no spontaneous reports of tuberculosis associated with saxagliptin use. Causality has not been established and there are too few cases to date to determine whether tuberculosis is related to saxagliptin use.

There has been one case of a potential opportunistic infection in the unblinded, controlled clinical trial database to date in a saxagliptin-treated patient who developed suspected foodborne fatal salmonella sepsis after approximately 600 days of saxagliptin therapy. There have been no spontaneous reports of opportunistic infections associated with saxagliptin use.

Vital Signs

Saxagliptin — No clinically meaningful changes in vital signs have been observed in patients treated with saxagliptin alone or in combination with metformin.

Laboratory Tests

Absolute Lymphocyte Counts

Saxagliptin — There was a dose-related mean decrease in absolute lymphocyte count observed with saxagliptin. From a baseline mean absolute lymphocyte count of approximately 2200 cells/microL, mean decreases of approximately 100 and 120 cells/microL with saxagliptin 5 mg and 10 mg, respectively, relative to placebo were observed at 24 weeks in a pooled analysis of five placebo-controlled clinical studies. Similar effects were observed when saxagliptin 5 mg and metformin were coadministered in treatment-naive patients compared to placebo and metformin. There was no difference observed for saxagliptin 2.5 mg relative to placebo. The proportion of patients who were reported to have a lymphocyte count ≤750 cells/microL was 0.5%, 1.5%, 1.4%, and 0.4% in the saxagliptin 2.5 mg, 5 mg, 10 mg, and placebo groups, respectively. In most patients, recurrence was not observed with repeated exposure to saxagliptin although some patients had recurrent decreases upon rechallenge that led to discontinuation of saxagliptin. The decreases in lymphocyte count were not associated with clinically relevant adverse reactions.

The clinical significance of this decrease in lymphocyte count relative to placebo is not known. When clinically indicated, such as in settings of unusual or prolonged infection, lymphocyte count should be measured. The effect of saxagliptin on lymphocyte counts in patients with lymphocyte abnormalities (e.g., human immunodeficiency virus) is unknown.

Platelets

Saxagliptin — Saxagliptin did not demonstrate a clinically meaningful or consistent effect on platelet count in the six, double-blind, controlled clinical safety and efficacy trials.

Vitamin B_{12} Concentrations

Metformin hydrochloride — Metformin may lower serum vitamin B_{12} concentrations. Measurement of hematologic parameters on an annual basis is advised in patients on KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) and any apparent abnormalities should be appropriately investigated and managed. [See Warnings and Precautions.]

Postmarketing Experience: Additional adverse reactions have been identified during postapproval use of saxagliptin. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions. [See Contraindications and Warnings and Precautions.]
- Acute pancreatitis. [See Indications and Usage and Warnings and Precautions.]

DRUG INTERACTIONS

Strong Inhibitors of CYP3A4/5 Enzymes

Saxagliptin — Ketoconazole significantly increased saxagliptin exposure. Similar significant increases in plasma concentrations of saxagliptin are anticipated with other strong CYP3A4/5 inhibitors (e.g., atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin). The dose of saxagliptin should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor. [See Dosage and Administration (2.2) and Clinical Pharmacology (12.3) in Full Prescribing Information.]

Cationic Drugs

Metformin hydrochloride — Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems. Such interaction between metformin and oral cimetidine has been observed in healthy volunteers. Although such interactions remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

Use with Other Drugs

Metformin hydrochloride — Some medications can predispose to hyperglycemia and may lead to loss of glycemic control. These medications include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers, and isoniazid. When such drugs are administered to a patient receiving KOMBIGLYZE XR, the patient should be closely observed for loss of glycemic control. When such drugs are withdrawn from a patient receiving KOMBIGLYZE XR, the patient should be observed closely for hypoglycemia.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B — There are no adequate and well-controlled studies in pregnant women with KOMBIGLYZE XR or its individual components. Because animal reproduction studies are not always predictive of human response, KOMBIGLYZE XR, like other antidiabetic medications, should be used during pregnancy only if clearly needed.

Coadministration of saxagliptin and metformin, to pregnant rats and rabbits during the period of organogenesis, was neither embryolethal nor teratogenic in either species when tested at doses yielding systemic exposures (AUC) up to 100 and 10 times the maximum recommended human doses (MRHD; saxagliptin 5 mg and metformin 2000 mg), respectively, in rats; and 249 and 1.1 times the MRHDs in rabbits. In rats, minor developmental toxicity was limited to an increased incidence of wavy ribs; associated maternal toxicity was limited to weight decrements of 11% to 17% over the course of the study, and related reductions in maternal food consumption. In rabbits, coadministration was poorly tolerated in a subset of mothers (12 of 30), resulting in death, moribundity, or abortion. However, among surviving mothers with evaluable litters, maternal toxicity was limited to marginal reductions in body weight over the course of gestation days 21 to 29; and associated developmental toxicity in these litters was limited to fetal body weight decrements of 7%, and a low incidence of delayed ossification of the fetal hyoid.

Saxagliptin — Saxagliptin was not teratogenic at any dose tested when administered to pregnant rats and rabbits during periods of organogenesis. Incomplete ossification of the pelvis, a form of developmental delay, occurred in rats at a dose of 240 mg/kg, or approximately 1503 and 66 times human exposure to saxagliptin and the active metabolite, respectively, at the MRHD of 5 mg. Maternal toxicity and reduced fetal body weights were observed at 7986 and 328 times the human exposure at the MRHD for saxagliptin and the active metabolite, respectively. Minor skeletal variations in rabbits occurred at a maternally toxic dose of 200 mg/kg, or approximately 1432 and 992 times the MRHD.

Saxagliptin administered to female rats from gestation day 6 to lactation day 20 resulted in decreased body weights in male and female offspring only at maternally toxic doses (exposures ≥1629 and 53 times saxagliptin and its active metabolite at the MRHD). No functional or behavioral toxicity was observed in offspring of rats administered saxagliptin at any dose.

Saxagliptin crosses the placenta into the fetus following dosing in pregnant rats.

Metformin hydrochloride — Metformin was not teratogenic in rats and rabbits at doses up to 600 mg/kg/day. This represents an exposure of about 2 and 6 times the maximum recommended human daily dose of 2000 mg based on body surface area comparisons for rats and rabbits, respectively. Determination of fetal concentrations demonstrated a partial placental barrier to metformin.

Nursing Mothers: No studies in lactating animals have been conducted with the combined components of KOMBIGLYZE XR. In studies performed with the individual components, both saxagliptin and metformin are secreted in the milk of lactating rats. It is not known whether saxagliptin or metformin are secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when KOMBIGLYZE XR is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of KOMBIGLYZE XR in pediatric patients have not been established.

Geriatric Use: *KOMBIGLYZE XR* — Elderly patients are more likely to have decreased renal function. Because metformin is contraindicated in patients with renal impairment, carefully monitor renal function in the elderly and use KOMBIGLYZE XR with caution as age increases. [See Warnings and Precautions and Clinical Pharmacology (12.3) in Full Prescribing Information.]

Saxagliptin — In the six, double-blind, controlled clinical safety and efficacy trials of saxagliptin, 634 (15.3%) of the 4148 randomized patients were 65 years and over, and 59 (1.4%) patients were 75 years and over. No overall differences in safety or effectiveness were observed between patients ≥65 years old and the younger patients. While this clinical experience has not identified differences in responses between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

Metformin hydrochloride — Controlled clinical studies of metformin did not include sufficient numbers of elderly patients to determine whether they respond differently from younger patients, although other reported clinical experience has not identified differences in responses between the elderly and young patients. Metformin is known to be substantially excreted by the kidney. Because the risk of lactic acidosis with metformin is greater in patients with impaired renal function, KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) should only be used in patients with normal renal function. The initial and maintenance dosing of metformin should be conservative in patients with advanced age due to the potential for decreased renal function in this population. Any dose adjustment should be based on a careful assessment of renal function. [See Contraindications, Warnings and Precautions, and Clinical Pharmacology (12.3) in Full Prescribing Information.]

OVERDOSAGE

Saxagliptin — In a controlled clinical trial, once-daily, orally-administered saxagliptin in healthy subjects at doses up to 400 mg daily for 2 weeks (80 times the MRHD) had no dose-related clinical adverse reactions and no clinically meaningful effect on QTc interval or heart rate.

In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status. Saxagliptin and its active metabolite are removed by hemodialysis (23% of dose over 4 hours).

Metformin hydrochloride — Overdose of metformin hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin hydrochloride has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases [see Warnings and Precautions]. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdosage is suspected.

PATIENT COUNSELING INFORMATION

See FDA-approved Medication Guide in Full Prescribing Information.

Instructions

Patients should be informed of the potential risks and benefits of KOMBIGLYZE XR and of alternative modes of therapy. Patients should also be informed about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and A1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment of diabetes complications. During periods of stress such as fever, trauma, infection, or surgery, medication requirements may change and patients should be advised to seek medical advice promptly.

The risks of lactic acidosis due to the metformin component, its symptoms and conditions that predispose to its development, as noted in Warnings and Precautions (5.1), should be explained to patients. Patients should be advised to discontinue KOMBIGLYZE XR immediately and to promptly notify their healthcare provider if unexplained hyperventilation, myalgia, malaise, unusual somnolence, dizziness, slow or irregular heart beat, sensation of feeling cold (especially in the extremities), or other nonspecific symptoms occur. Gastrointestinal symptoms are common during initiation of metformin treatment and may occur during initiation of KOMBIGLYZE XR therapy; however, patients should consult their physician if they develop unexplained symptoms. Although gastrointestinal symptoms that occur after stabilization are unlikely to be drug related, such an occurrence of symptoms should be evaluated to determine if it may be due to lactic acidosis or other serious disease.

Patients should be counseled against excessive alcohol intake while receiving KOMBIGLYZE XR.

Patients should be informed about the importance of regular testing of renal function and hematological parameters when receiving treatment with KOMBIGLYZE XR.

Patients should be informed that acute pancreatitis has been reported during postmarketing use of saxagliptin. Before initiating KOMBIGLYZE XR, patients should be questioned about other risk factors for pancreatitis, such as a history of pancreatitis, alcoholism, gallstones, or hypertriglyceridemia. Patients should also be informed that persistent severe abdominal pain, sometimes radiating to the back, which may or may not be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. Patients should be instructed to promptly discontinue KOMBIGLYZE XR and contact their physician if persistent severe abdominal pain occurs [see Warnings and Precautions].

Patients should be informed that the incidence of hypoglycemia may be increased when KOMBIGLYZE XR is added to an insulin secretagogue (e.g., sulfonylurea) or insulin.

Patients should be informed that serious allergic (hypersensitivity) reactions, such as angioedema, anaphylaxis, and exfoliative skin conditions, have been reported during postmarketing use of saxagliptin. If symptoms of these allergic reactions (such as rash, skin flaking or peeling, urticaria, swelling of the skin, or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing) occur, patients must stop taking KOMBIGLYZE XR and seek medical advice promptly.

Patients should be informed that KOMBIGLYZE XR must be swallowed whole and not crushed or chewed, and that the inactive ingredients may occasionally be eliminated in the feces as a soft mass that may resemble the original tablet.

Patients should be informed that if they miss a dose of KOMBIGLYZE XR, they should take the next dose as prescribed, unless otherwise instructed by their healthcare provider. Patients should be instructed not to take an extra dose the next day.

Healthcare providers should instruct their patients to read the Medication Guide before starting KOMBIGLYZE XR therapy and to reread it each time the prescription is renewed. Patients should be instructed to inform their healthcare provider if they develop any unusual symptom or if any existing symptom persists or worsens.

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 and AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

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Mark Your Calendar

IAFP Events

2012 IAFP Annual Convention
July 26-29, JW Marriott, Indianapolis
Business and CME for Indiana's Family Physicians

2012 IAFP Family Medicine Day
July 29
Picnic and baseball at Victory Field

AAFP Meetings

AAFP Annual Scientific Assembly
October 16-20
Philadelphia, Pennsylvania

The Family Medicine Midwest Collaborative

As the cornerstone of a health care system, family medicine is at the forefront of an effective delivery system and reducing health care disparities in urban, rural and underserved populations.

The **Family Medicine Midwest Collaborative** is committed to communicating the value of family medicine to practicing colleagues, future colleagues and the public through the following:

1. Promote the development of family medicine among students with the goal that 40 percent of all medical graduates will enter family medicine by 2020
2. Provide a yearly forum for disseminating scholarly work and research by junior faculty members, residents and students
3. Develop a workforce project to encourage high school and college students to consider family medicine as a career
4. Promote and support community-based practice and education
5. Work with key health care stakeholders in the area to promote cooperative health care innovation.
6. Ensure that every medical student knows, understands and values what family medicine physicians do
7. Promote and link practice-based research networks

Our first conference event:

November 10-11 at Eaglewood Resort in Itasca, Illinois

Enjoy the entire two-day conference filled with topical peer-reviewed education and presentation sessions for faculty members, residents and students and social events for all!

Steering Committee

Janice Benson, MD, University of Chicago/North Shore University; David Deci, MD, University of Wisconsin; Andrew Slattengren, DO, University of Minnesota; and Theresa Zink, MD, University of Minnesota

For more information, contact Vince Keenan, executive director at vkeenan@iafp.com or 630.427.8002.

Illinois • Indiana • Iowa • Kansas • Kentucky • Michigan • Minnesota
Missouri • Nebraska • North Dakota • South Dakota • Wisconsin

Member News

St. Francis Health Physician Appointed to Marian Osteopathic Dean's Advisory Board

Richard D. Feldman, MD, has been appointed to the Dean's Advisory Board of the newly established Marian University College of Osteopathic Medicine. The board is composed of business leaders and health care professionals who advise Dean Paul Evans and help guide the development of the college.

Feldman, who has served as Indiana's state health commissioner, is the director of medical education and residency training for Franciscan St. Francis Health.

Minnesota National Guard Gains New Air Force General Officer

Richard Feldman, MD; Worthe Holt, MD; Debbie Allen, MD; Becky Feldman, MD; Deeda Ferree; and Missy Lewis celebrate Dr. Holt's promotion.

Air Force Brig. Gen. **Worthe S. Holt Jr.**, a former Indiana National Guardsman, was recently promoted to the rank of brigadier general and assigned as the Minnesota National Guard assistant adjutant general — air.

"We are looking forward to the depth of knowledge and leadership experience Gen. Holt will bring to this position and Minnesota," said Army Maj. Gen. Richard C. Nash, Minnesota National Guard adjutant general.

In this new role as the senior Air Force officer in Minnesota, Holt will advise the adjutant general on service component issues and will assist in the supervision and leadership of all Air National Guard units in Minnesota, said Air Force Maj. Anna R. Long, Minnesota National Guard public affairs officer. Holt is also charged with oversight of all current and future Minnesota Air National Guard overseas operations.

A distinguished Air Force officer and fighter pilot, Holt began his military career as a flight surgeon after being commissioned in 1981 through the Medical Corps at the Indiana University School of Medicine, Long said. He went on to pilot training, where he graduated in 1984 as the distinguished graduate, the top academic student and the top aircraft commander. He has logged more than 2,000 hours as a fighter pilot on multiple aircraft, including the F-4 and the F-16.

His command experience from the Indiana National Guard includes serving as the command fighter pilot and the assistant operations officer for the 113th Fighter Squadron, as well as the chief flight surgeon and the chief of professional services within the 181st Medical Group, Long said.

In his civilian career, Holt has 25 years of health care leadership experience, Long said. He currently serves as vice president of Humana, Inc., a Fortune 100 health benefits company that offers coordinated health insurance coverage and related services. Humana has 35,000 employees and serves 17 million members in medical and specialty products with gross revenues of $7 billion.

Holt will continue to reside in Indiana and commute to Minnesota for this new position with the Minnesota National Guard, Long said.

2012 IAFP Spring SAMs & CME

Our spring meeting combined hot-topic CME with SAM Study Groups to create an intensive two-day event held in an all-new location in Carmel, Indiana, just north of Indianapolis.

On the morning of Friday, March 9, we kicked off the meeting with a SAM Study Group on diabetes facilitated by **Cindy Meneghini, MD**. After lunch, **Fred Ridge, MD**, presented another SAM Study Group on asthma. The next day, our attendees benefited from some hot topic CME, including an update on Medicare and health care reform from **Risheet Patel, MD**; a comprehensive adolescent vaccines update from **Richard Feldman, MD**; an activity centered around wound care for the family physician from **Fred Ridge, MD**; and, finally, **Mark Lisby, MD**, presented "Lipid Management in the CKD Patient: A Patient-Centered Approach to Care." On Saturday afternoon, our final SAM Study Group on pain management was facilitated by **Tom Kintanar, MD**. This was the first time we have held a meeting at the new Medical Academic Center in Carmel, and our members told us they were impressed with the location. Stay tuned for more information about upcoming CME events and SAM Study Groups!

This meeting was sponsored by Indiana Spine Group (www.indianaspinegroup.com).

Indiana Spine Group

2012 IAFP Annual Convention

Date: July 26-29, 2012
Location: JW Marriott Indianapolis
10 S. West Street
Indianapolis, IN 46204

The IAFP's leadership and staff are looking forward to meeting in Indianapolis this year, and we hope you can join us.

Location
The JW Marriott is located in the heart of Indianapolis' thriving downtown area, within walking distance of such attractions as the NCAA Hall of Champions; the Indiana State Museum; the Eiteljorg Museum; Lucas Oil Stadium; and all the unique shopping, dining and entertainment options Indy has to offer. Your whole family is sure to enjoy the city this summer!

We have secured a block of rooms at the low rate of $135. Avoid disappointment — take time TODAY to plan your attendance! To make your room reservations, call 877.303.0104, and mention the Indiana Academy of Family Physicians. There are several events taking place in downtown Indianapolis this weekend, including the Brickyard 500, which will increase demand for rooms.

Agenda
View our meeting schedule with CME topics and speakers on page 16.

Register Early
- Register online: visit http://in-afp.ticketleap.com/2012ac/
- Register by fax: download the registration form, complete it, and fax it to 317.237.4006
- Register by mail: download the registration form, complete it, and mail it to IAFP, 55 Monument Circle, Suite 400, Indianapolis, IN 46204

Special Event
Annual President's Banquet and Installation of Officers, Followed by All-Member Family Party – Saturday, July 28
We have again combined our President's Banquet and All-Member Party into one exciting event for the whole family. An elegant dinner is held to honor our incoming and outgoing president and the contributors to our *Family Practice Stories* book. A special dinner is offered simultaneously for children. At 8:30 p.m., children may join their parents for a dessert buffet and dancing, with entertainment by the Marlins. Purchase tickets on the registration form.

All-Member Congress of Delegates
The IAFP will hold its All-Member Congress of Delegates on July 27 and 28. All members are invited and encouraged to attend the Congress, because every IAFP member is a delegate, and every participant will have a vote and voice at the Congress. The Academy looks forward to each and every member's participation in this year's Congress of Delegates. Come make your voice heard!

Fellowship and Networking Opportunities
Meet colleagues from around the state, and visit with old friends.

Exhibit Show
Call on them! Visit the Exhibit Show to learn about the newest clinical advances, practice management tips and services.

Confirmed exhibitors include:
Abbott
Achieve EHR
Advanced Physical Therapy
American Express
American Health Network
Balance MD
Biomet
Boehringer Ingelheim Pharmaceuticals
Bristol-Myers Squibb
Care Improvement Plus
Community Health Network
Covidien
EmCare
Esacote North America
Goodman Campbell Brain and Spine
Grifols, Inc.
Health Diagnostic Laboratory, Inc
Indiana Academy of Family Physicians
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Indiana Spine Group
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Northwest Radiology Network
OrthoIndy
ProAssurance
Purdue Pharma L.P.
Reid Hospital
Sanofi Pasteur
South Bend Medical Foundation
St. Vincent
SuccessEHS
U.S. Air Force
Urology of Indiana
Vein Clinics of America
ViroPharma, Inc.
We Care TLC

Family Medicine Day at Victory Field
Immediately following the close of the Scientific Assembly on Sunday, July 29, join us for a picnic at Victory Field, and then cheer on the Indianapolis Indians at the "Best Minor League Ball Park in America!" Visit www.in-afp.org/events/2012/07/29/general-event/family-medicine-day-at-victory-field/ to learn more.

Town Hall Dinner
Each year, the IAFP hosts an opportunity at our Annual Convention to hear new policy topics from the thought-leaders of Indiana and the nation. In 2012, we are welcoming to the convention Bob Phillips, MD, the distinguished director of the Robert Graham Center, to discuss the necessary changes the current graduate medical education funding system requires to support primary care. This interactive town hall dinner is a free event open only to IAFP members that takes place at 5:30 p.m. on Friday, July 27.

Students and Residents
Students, residents and residency faculty members are invited to a "Preparing for the Match" panel, followed by our Congress Orientation on Friday, July 27. Bring your Congress book to follow along. The session will end with a reception — a great chance for students to learn more about our residencies.

Indiana's Premier CME Event!
Planned especially for family physicians by family physicians.

We have included additional opportunities to earn CME credit this year. Earn more than 20 Prescribed AAFP CME credits with clinical topics and practice management sessions. All CME plans are based on previous attendee evaluations and IAFP member CME Needs Assessments.

Educational Objectives: This program is designed by family physicians for family physicians. The sessions will highlight new advances, preventative medicine strategies, enhancements of clinical skills, emergency preparedness and practice management issues.

Attendee comments from last year's meeting included:
- "Well educated speakers provided excellent care for practices. Very entertaining."
- "Once again, the IAFP has provided an excellent Annual Convention that has provided both a venue to meet and interact with our colleagues and gain practical knowledge to improve our practices and better care for our patients — thank you!"
- "An excellent CME offering with immediate operational advice. Most CME was fully practicable and implementable."

MC-FP SAM Study Group on Cerebrovascular Disease – Thursday, July 26
Please register early — SAMs sell out fast! Select the SAM Study Group on the registration form/online registration page.

Our SAM Study Groups feature reference slides showing sources used in each of the 60 questions in the ABFM's Self-Assessment Modules, as well as an overview of the MC-FP process and how this study group fits into it. Facilitator: Curt Ward, MD.

The SAM Study Group will enable family physicians to:
- Explore the topic via interactive discussions
- Complete the Knowledge Assessment portion of their MC-FP Part II Self-Assessment Module, from which the IAFP will report the answers to the ABFM
- Earn 12 AAFP CME credits after this session by completing online Clinical Simulation

Visit www.in-afp.org for more information or to register. We look forward to seeing you at this year's Annual Convention!

Legislative Wrap-Up

At 1:23 a.m. on Saturday, March 10, the Indiana General Assembly closed the 2012 session. Although the legislature was not mandated to adjourn until March 14, the leaders of the General Assembly determined that they could easily finish the session with a few days to spare.

See the IAFP's list of the bills that passed or failed in the 2012 session below. If you have any questions about the IAFP's legislative activity, or if you wish to get involved, please contact Meredith Edwards at medwards@in-afp.org or by phone at 317.237.4237.

Bills That Are Now Law…

Smoking Ban in Public Places (House Bill 1149)

The smokefree air bill, which went through several iterations during the legislation process, passed, covering restaurants, hotels, movie theaters, bowling alleys, health care facilities, nursing homes, mental health facilities and most other workplaces. Cigar bars must be in existence before December 31, 2012, to be exempt. Private clubs, casinos and bars are all exempt from the law, unless a local law states otherwise. The IAFP fought for all public places covered by the smokefree air law, but the political situation in the General Assembly made that impossible. Our smokefree air champions, Rep. Eric Turner, Rep. Charlie Brown, Sen. Beverly Gard and Sen. Vi Simpson, worked tirelessly this session and deserve great thanks. The law goes into effect July 1, 2012.

Self-Donated Blood (House Bill 1216)

Indiana law was unclear as to whether patients with HIV or other infectious diseases can donate blood for their own use for stem-cell transplantation. This bill, authored by Rep. Cindy Kirchofer, clarified Indiana law and made it clearly legal. The IAFP supported this legislation, and IAFP member Topper Doehring, MD, testified at the committee hearings for the bill. The law goes into effect July 1, 2012.

Pharmacy Matters (Senate Bill 407)

This bill originally was limited to expanding the number of pharmacy technicians a pharmacist can supervise. In conference committee, Senate Bill 334, which failed to receive a hearing in the House, was added to the bill. The IAFP expressed concerns about the change in the prescribing law, especially at the last minute of the session. The provisions added to the bill allow a pharmacist to give a patient up to a 90-day supply of a prescription drug without approval from the prescribing physician, with several conditions:

1. The prescription must contain at least 90 days' worth of medication.
2. The patient must request that his or her prescription be changed from 30 days at a time to 90 days at a time.
3. The medication may not be a controlled substance.
4. The patient must have already been on this medication for 30 days before switching to 90 days at a time.
5. The pharmacist must tell the patient whether a 90-day supply will be covered by the patient's insurance.
6. The pharmacist must notify the physician after the prescription has been changed. If a physician does NOT want a pharmacist altering the amount of medication dispensed, he or she must write on the prescription or tell the pharmacist, "The quantity of the prescription may not be changed."

This law goes into effect July 1, 2012.

Bills That Failed to Pass…

Tobacco Self-Service Displays (House Bill 1031)

The original legislation would have moved cigars and loose tobacco products out from behind the retail counter, where it could be easily accessed by youth. But the bill was amended to instead study the issue of roll-your-own-tobacco machines and then failed to be heard on the floor of the House before the third reading deadline. It could become a summer study item if the House and Senate leadership adds this topic to other health-related issues it wants studied.

Physician Scope-of-Treatment Forms (House Bill 1114)

This legislation, authored by Rep. Tim Brown, who is also a physician and chair of the Public Health Committee, would have created a legal and medical form on which patients could express their wishes for end-of-life care. Patients could express whether they want interventions like antibiotics, ventilation and nutrition. Then, a physician would sign the form, and it becomes a legal medical order. Unlike living wills, these "POST forms" can be followed by EMS, nursing homes and hospitals. Thirteen other states have made this form legal. The IAFP testified in support of this legislation at its committee hearing. The IAFP began working on POST because of a resolution to the IAFP Congress of Delegates, and we will continue to work on perfecting the legislation for the 2013 legislative session.

Collection of Medicaid Spend-Down (House Bill 1351)

The bill would have allowed physicians and other providers to collect remaining balances of a patient's Medicaid Spend-Down at the time of service if the provider so chooses. Currently, only pharmacists can collect at the time of service. The bill never received a committee hearing.

Various Scope-of-Practice Bills

In 2012, we saw many of the same scope-of-practice expansions that we have opposed in the past three or more years. In House Bill 1067, pharmacists sought out the ability to provide the pneumonia vaccine through protocol without a physician

prescription. Currently in Indiana, pharmacists can do this with the shingles (herpes zoster) and flu immunizations. There were multiple attempts to revive this bill as an amendment to other bills; the IAFP successfully stopped those attempts.

Other scope bills introduced included licensing non-nurse midwives with only limited training to provide home birth services (HB 1127), permitting physical therapists to see patients for 30 days without the need for a physician referral (HB 1124) and expanding physician assistants' scope of practice by removing all limitations on the location of supervising physician and removing the requirement of chart reviews after three years (HB 1142). None of the scope-of-practice bills introduced in 2012 received an initial committee hearing.

Summer Election Update

After the recent filing deadline, we know the scope of upcoming elections. There will be unprecedented change in House and Senate membership after the primary and general elections. Nineteen House members (12 Democrats and seven Republicans) have announced their retirements. With redistricting, there is also one seat that has both a Democrat and Republican incumbent running against each other. Two Senate members (both Republicans) have also announced their retirements. Before the election begins, we will have lost 21 incumbent legislators.

In 2010, 19 new House members were elected. After November 2012, more than 40 percent of the House members will have fewer than two years' experience. Many of these retiring legislators are from Public Health and Ways and Means. This change will give our physicians and the IAFP opportunities to meet and encourage new legislators to better understand our positions.

2012 IAFP Research Day

This year's Research Day took place at the IUPUI Campus Center on Thursday, May 17, with more than 100 residents, faculty members, and other IAFP members in attendance. Residents from across the state made 15- to 20-minute presentations and displayed posters detailing their original research projects and performance improvement initiatives. We also heard several case presentations about patients who presented with unusual and/or rare diseases.

Thank you to our Research Day Planning Committee: **Carrie Anderson, MD; John Fleming, MD; Sharron Grannis, MD; Amy LaHood, MD; and Curt Ward, MD.** Dr. Anderson served as moderator for the day.

Thank you to our three judges: **Komal Kochhar, MBBS, MHA; Carolyn Muegge, MS, MPH; and Ray Nicholson, MD.**

Thank you to our exhibitors: St. Vincent Health and Suburban Health Organization. Our awards were sponsored by St. Vincent Health, strategic partner of the IAFP.

Congratulations to our prize winners:

Original Research Category

First: *Review of Adherence to Published Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain by Medical Residents in a Resident Clinic*
Virginia Reed, MD. St. Francis Family Medicine Residency Program
Co-authors: Amy LaHood, MD; Victor Collier, MD; and Karie Morrical-Kline, PharmD, St. Vincent Family Medicine Residency Program

Second: *Assessing Potentially Inappropriate Medication Use in Elderly Patients in Outpatient Family Medicine Offices*
Angela Hackman, MD, St. Francis Family Medicine Residency Program

Third: *Being Hispanic May Not Increase Your Risk For Type 2 Diabetes Mellitus*
Sofy Sendoya, MD
Co-author: Ian Chua, MD, Indiana University School of Medicine Family Medicine Residency Program

Performance Improvement Category

Improving Pertussis Vaccination Rates in Pregnant Women at the PCC
Jason Lewis, MD
Co-author: Maurice Henein, MD, St. Vincent Family Medicine Residency Program

Case Presentation Category

First: *Fulminant Heart Failure in a 2-Year-Old*
Kari Sears, MD, Memorial Family Residency Program

Second: *Not Just Scabies*
Naveen Bondalapati, MD, Union Hospital Family Medicine Residency Program

Posters

First: Case Presentation: *Mother Knows Best: Late Onset Group B Strep in a 20-Day-Old Female*
Kurtis Ellis, MD

Second: Performance Improvement: *Performance Improvement Focused on the Clinical Management of Unhealthy Pediatric Weight*
Alan Young, MD
Co-authors: Justin Whitt, MD; Linda Daniel, PhD; and Carolyn Shue, PhD, Indiana University Health Ball Memorial Hospital Family Medicine Residency Program

We are also grateful to the Fort Wayne Medical Education Program for displaying the results of their FPIN projects in poster form at this meeting.

The following residents were elected at our Resident Region business meeting during lunch:

- **Director:** Brendan Sweeney, MD (St. Francis)
- **Alternate Director:** Kari Sears, MD (Memorial)
- **NC Delegate:** Tiffany Meador, MD (St. Vincent)
- **NC Alternate Delegate:** Holly Wheeler, DO (Community)

Marian University College *of* Osteopathic Medicine Update

by Paul Evans, DO, FAAFP, FACOFP, Vice President and Dean

The Marian dream is finally moving toward becoming a reality!

MU-COM is progressing toward a planned opening day in August 2013 for an entering class of 150 osteopathic medical students. We are now hiring faculty members both from biomedical science disciplines and for clinical positions (part-time and full-time). Charles E. Henley, DO, MPH, our associate dean for clinical affairs, is starting to interview physicians (DO and MD) for positions now, with some to start in fall 2012 and others a bit later in 2013. Bryan Larsen, PhD, associate dean for biomedical sciences, is also recruiting PhD faculty members in anatomy, physiology, pharmacology, cell and molecular biology, microbiology and immunology, and biochemistry. We are also filling positions in admissions, financial aid and other administrative areas.

Our accreditation steps are on schedule toward an anticipated full accreditation by 2017. MU-COM earned provisional status to start on July 1, 2012. We are publicizing our new program in the pre-medical education community, and our deans have almost completed introduction visits to many colleges and universities with pre-medical applicants in Indiana and surrounding states. Student excitement appears high! Our application process starts in summer 2012 through the application service of AACOM. We anticipate about 2,000 applications and will likely offer about 500 interviews starting in the fall of 2012. MU-COM plans to use an innovative station-interview process (multi-mini-interview, or MMI) that better measures traits such as ethical behavior, communication skills and compassion. These key elements are felt to be critical for successful physicians. If you have an interest in helping to select our charter class, please contact me, and I will connect you with the chair of our Admissions Committee, Angie Wagner, DO. We are signing up community physicians (DO and MD) to assist in this exciting process.

MU-COM is now growing our clinical education network for both clerkship rotations and for future graduate medical education. Dr. Henley has reported strong interest from Indiana physicians to teach MU-COM students, with more than 3,000 network physicians expressing an interest in taking students. We have also discovered an interest in new graduate medical education positions to support our graduates. We will continue to develop these opportunities.

Our virtual tour of the new facility, lasting about seven minutes, will show the design and features of our new Center for Health Sciences (CHS) (www.marian.edu/osteopathic-medical-school/Pages/virtual-tour.aspx). Our webcam is on our Web page (marian.edu), and it shows real-time progress on our new CHS, now about 30 percent complete.

We will keep the medical community updated regularly on our achievement of continuing milestones.

ISDH Releases Guidelines *for* Expedited Partner Therapy

In 2010, the IAFP All-Member Congress of Delegates passed a resolution asking the IAFP to support regulation or legislation to allow the practice of expedited partner therapy (EPT) in Indiana. With the IAFP's support, in late 2011, the Indiana Medical Licensing Board finalized regulations legalizing the use of expedited partner therapy by physicians in Indiana; and, in April 2012, the Indiana State Department of Health (ISDH) released physician guidelines for EPT.

Expedited partner therapy (EPT) is the practice of prescribing or dispensing antibiotics to the sexual partner(s) of a physician-diagnosed patient without an exam of the sexual partner(s). Since 2006, the Centers for Disease Control has recommended EPT as an option for preventing sexually transmitted disease reinfection for certain infections.

Prior to the Medical Licensing Board rule, EPT was considered illegal in Indiana because regulations forbid the prescribing of medication to patients without first being seen (except in on-call and specific other settings). With the new law, physicians can use EPT for the partners of patients with chlamydia and gonorrhea but are not required to. ISDH still recommends that physicians try to motivate patients to refer their partners for clinical care, where full evaluation, testing and treatment can take place.

The new ISDH advisory documents for physicians include guidance on documentation, information on appropriate antibiotics, chart inserts and patient documents. Physicians who wish to prescribe through EPT should review and use the health department's guidelines.

The Indiana State Department of Health's STD program page: www.in.gov/isdh/17440.htm

Direct link to ISDH Guidelines: Guidance for Health Care Professionals in Indiana: www.in-afp.org/index.php?cid=36582&forward=60&curlid=62

Direct link to ISDH FAQs about expedited partner therapy frequently asked questions: www.in-afp.org/index.php?cid=36582&forward=61&curlid=63

For physicians who wish to read the final Medical Licensing Board rule:

844 IAC 5-4-1

Authority: Affected:

General provisions

IC 25-22.5-2-7 IC 25-1-9; IC 25-22.5-1-2; IC 25-23-1-19.4

Sec. 1. (a) Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements, as described in subsection (d), a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

(b) Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with the requirements of IC 25-23-1-19.4 and 848 IAC 5, as described in subsection (d), a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any legend drug that is not a controlled substance to a person who the physician has never personally physically examined and diagnosed unless the physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's use of the drug or drugs to be provided.

(c) A physician shall not advertise or offer, or permit the physician's name or certificate to be used in an advertisement or offer, to provide any legend drug in a manner that would violate subsection (a) or (b).

(d) Subsections (a) and (b) do not apply to or prohibit the following: (1) The provision of drugs to a person who is admitted as an inpatient to or is a resident of an institutional facility. (2) The provision of controlled substances or legend drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on-call or cross-coverage arrangement between the physicians. (3) The provision of controlled substances or legend drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals as permitted by IC 25-22.5-1-2. (4) The provision of controlled substances or drugs by an advanced practice nurse with prescriptive authority practicing in accordance with a standard care arrangement that meets the requirements of IC 25-23-1-19.4 and 848 IAC 5.

(Medical Licensing Board of Indiana; 844 IAC 5-4-1; filed Oct 1, 2003, 9:32 a.m.: 27 IR 524; errata filed Oct 8, 2003, 1:45 p.m.: 27 IR 538; readopted filed Dec 1, 2009, 9:13 a.m.: 20091223-IR-844090779RFA; readopted filed Jun 16, 2010, 12:14 p.m.: 20100630-IR-844090779RFA)

844 IAC 5-4-2

Authority: Affected:

Expedited partner therapy

IC 25-22.5-2-7 IC 25-1-9

STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

Sec. 2. Section 1 of this rule does not apply if the physician is prescribing or dispensing medications for the treatment of Chlamydia trachomatis or Neisseria gonorrhoeae to sex partner(s) of the physician's diagnosed patient without requiring examination of the sex partner(s). Medications must be in accordance with current professional theory or practice for the treatment of these infections. The current Centers for Disease Control and Prevention of Sexually Transmitted Diseases Treatment Guidelines shall be considered an authoritative source of such current professional theory or practice. Partner management of patients with gonorrhea or chlamydia shall include providing the following items:

(1) Notification to the infected patient that all partners should be evaluated and treated; (2) Written materials for the infected patient to give partners that state that a clinical evaluation is desirable; lists common medication side effects and the appropriate response to them; fact sheets regarding sexually transmitted diseases; and emergency contact information; (3) Prescriptions or dispensed medications and accompanying written materials shall be given to the physician's patient for distribution to named partners; and (4) The physician shall maintain appropriate documentation of partner management. Documentation shall include the names of partners, if available, and a record of treatment provided. If the partner's name is not available, documentation shall be kept within patient's file.

(Medical Licensing Board of Indiana; 844 IAC 5-4-2; filed Sep 28, 2011, 11:06 a.m.: 20111026-IR-844110044FRA)

Franciscan St. Francis Health Family Medicine Residency

Indianapolis, Indiana

The Franciscan St. Francis Health Family Medicine Residency prides itself on its humanistic approach to medical education, which maintains an atmosphere that supports the residents' personal and professional growth. Our commitment to the individual fosters a sense of family and promotes a productive setting in which we all are able to make significant contributions to each other. We have designed our program to provide a balanced environment, allowing time for study, family, church, outside interests, community service, mental and physical well-being, and the opportunity to nurture interests both within and beyond the practice of medicine.

Flexibility is built into the program to ensure that the individual's personal interests and priorities can be met. Because of growing interest in several specialized areas of family medicine, the residency has developed four intensive tracks that residents can electively participate in:

Optional Obstetrics-Intensive Track
All residents receive a strong obstetrical experience. Most residents get 40 to 60 total deliveries during the required first year two-month rotation. Residents may opt for either our regular track or our intensive OB track.

Underserved Medicine Curriculum/Optional Intensive Track
The residency has developed a curriculum in underserved medicine. Any resident can choose from a variety of urban, rural and international sites to customize an experience, allowing focus on one or a combination of underserved populations.

Sports Medicine Curriculum/Optional Intensive Track
Residents receive excellent training in sports medicine, which is both clinical and didactic. The curriculum has been developed and is coordinated among three family physician community physicians with fellowship training in sports medicine.

Master's of Medical Management Degree (in Conjunction with Carnegie Mellon University)
The Franciscan St. Francis Health Family Medicine Residency participates in a formal relationship with Carnegie Mellon University in Pittsburgh for a master's of medical management. Participation in this program necessitates a fourth-year fellowship position.

Don't see an update from your residency program? All programs are invited to share news/updates with our members. Watch this space!

FAQs – Indiana's Smokefree Air Law

Indiana's new partial smokefree air law goes into effect soon. People are generally law-abiding citizens when they know and understand the law. Be sure that you know Indiana's law — help us ensure a smooth (and healthy) transition!

1. When does Indiana's new statewide smoking ban go into effect?
The new law goes into effect July 1, 2012.

2. Where is smoking prohibited?
Smoking is prohibited in most public places and places of employment. Smoking is also prohibited in state-owned vehicles and school buses under certain circumstances.

3. Where is smoking permitted?
Smoking is permitted in the following establishments: a horse-racing facility, a riverboat, a facility with a gambling game license, a satellite-gaming facility, cigar bars, hookah bars, certain fraternal clubs, a retail-tobacco store, a bar or tavern meeting certain requirements, a cigar-manufacturing facility, a cigar-specialty store and a business in a private residence, provided that each establishment meets the requirements of I.C. 7.1-5-12.

4. How far must someone be from the entrance of a public place or place of employment in order to smoke?
Smoking is prohibited within 8 feet of a public entrance to a public place and place of employment.

5. Who enforces the law?
The Alcohol & Tobacco Commission is the primary enforcement agency. Additionally, the Indiana State Department of Health, a local health department, a health and hospital corporation (Marion County), the Division of Fire and Building Safety and any law enforcement officer may enforce the law.

6. Where may I file a complaint for a violation of the smoking ban?
A complaint system is being developed and will be available on July 1, 2012. Instructions will be posted online at www.in.gov/atc.

7. Is smoking prohibited in vehicles?
Smoking is only prohibited in state-government vehicles owned, leased and operated for governmental functions. Smoking is permitted in private vehicles.

8. How does the state law affect local ordinances on smoking?
The new state statute does not supersede a local county, city or town ordinance previously adopted, if that local ordinance is more restrictive than state law. Additionally, the new state statute does not prohibit a local county, city or town from adopting an ordinance more restrictive than state law.

9. May a business exempt from the state smoking law choose to prohibit smoking?
Yes. A business owner or manager may voluntarily choose to prohibit smoking, even if the type of business is one of the exemptions to the state's smoking law. For example, a tavern owner may choose to prohibit smoking.

Source: Indiana Alcohol & Tobacco Commission

Community Health Network Family Medicine Residency Program Launches Program That Provides Group Approach to Prenatal Care

Centering Pregnancy Increases Patient Satisfaction and Improves Health Outcomes

Community Health Network's Family Medicine Residency Program has launched a patient-centered prenatal health program for women looking for a different approach to prenatal care.

The program, called Centering Pregnancy, provides a practitioner-led group approach to prenatal care and combines three essential elements of care every pregnant woman needs — health assessment, education and support. Rather than having one-on-one visits, groups of eight to 12 women with similar due dates meet together, learning care skills, participating in a facilitated discussion and developing a support network with other group members. Each pregnancy group meets for a total of 10 sessions throughout pregnancy and early postpartum. Individual prenatal health assessments are included.

"Through this group approach to care, women are empowered to choose health-promoting behaviors for themselves and their babies," said Susan L. Helsel, MD, assistant director and leader of the Centering Pregnancy Program at the Shadeland Family Care Center. "It also creates an environment for women to share their experiences and knowledge about pregnancy, childbirth and parenting."

Centering is a care model that was developed in 1993 and has been implemented at sites of care throughout the country. It is an evidence-based redesign of health care delivery that engages patients to participate in their care and allows providers to have dynamic partnerships with their patients.

This model has been shown in studies to have statistically significant improvements in preterm birth outcomes, both in having healthier preterm babies and in decreasing preterm delivery rates. Also in studies, there was a large increase in patient satisfaction and education as rated by the patients themselves.

This program is currently funded by a generous grant from the Indiana Chapter of the March of Dimes, whose mission is to help moms have healthy full-term pregnancies and babies.

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