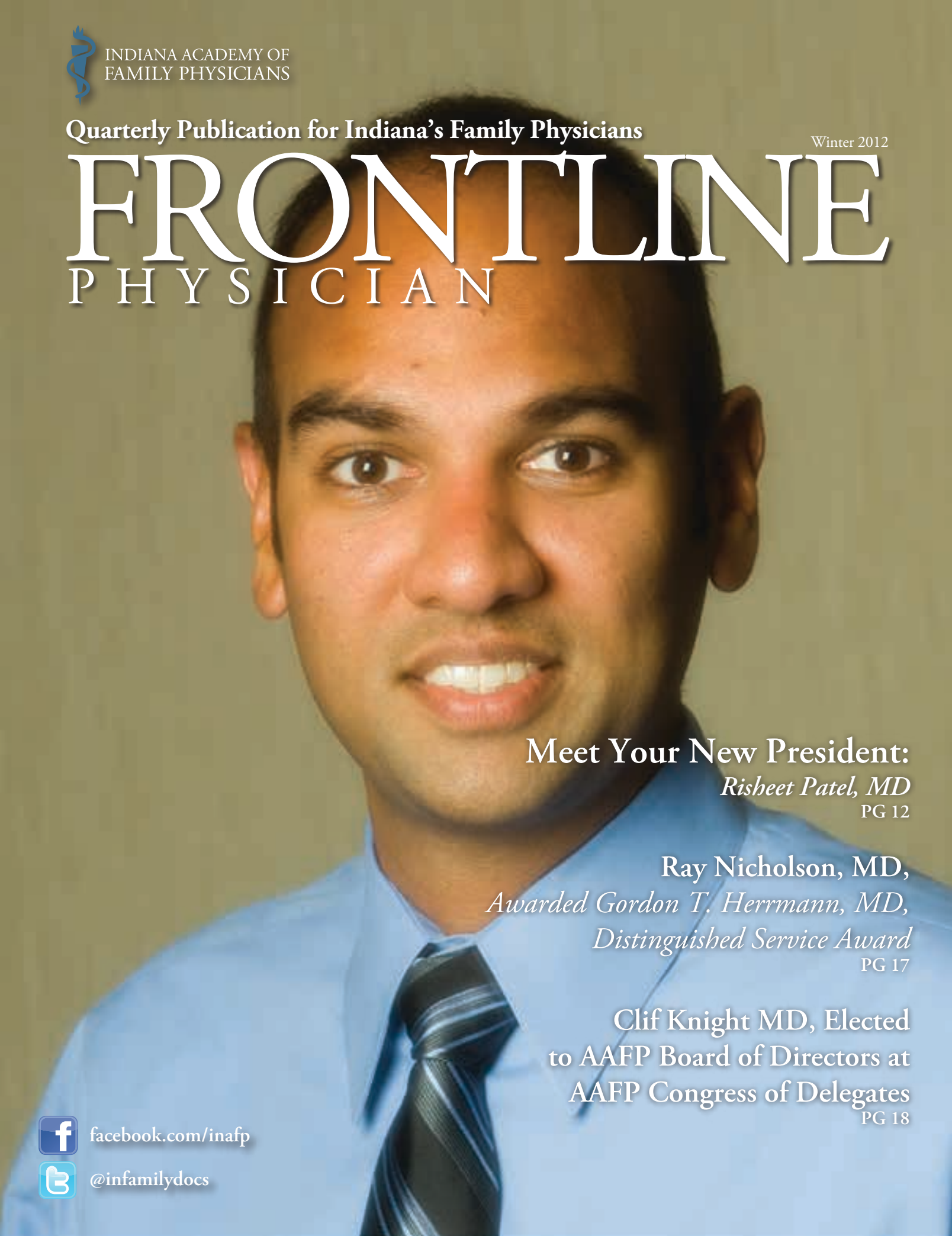
INDIANA ACADEMY OF
FAMILY PHYSICIANS

Quarterly Publication for Indiana's Family Physicians

Winter 2012

FRONTLINE PHYSICIAN



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FRONTLINE PHYSICIAN

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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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President's Message

Risheet R. Patel, MD

For the Future of Family Medicine

Welcome to the winter issue of the IAFP's *FrontLine Physician*. The last three months have been quite eventful for me and for the Academy as a whole. In October, the AAFP held its annual Congress of Delegates in Philadelphia, where Dr. Clif Knight ran for the AAFP Board of Directors. As I'm sure many of you have heard, congratulations are in order, as Clif was elected to a full three-year term. All of us in the Academy leadership are proud that Clif will carry on strong leadership from Indiana at the national level. Along with our many members who hold national positions, Clif will be the fourth member of the AAFP Board of Directors from the state of Indiana in the last 10 years. Our previous three members were Dr. Tom Felger (2008-2011), Dr. Jason Marker (2007-2008) and Dr. Tom Kintanar (2003-2006). We wish Clif the best of luck as he begins his time on the board.

Our Academy will work closely with the AAFP to provide resources to members to help them navigate the progress of the ACA. Our legislative staff is also getting ready for the 2013 Indiana General Assembly starting in January.

In November, I had the chance to attend the Annual Meeting of the Illinois Academy of Family Physicians. It was a nice opportunity to network with our neighboring colleagues by attending their fall board meeting, their All Member Assembly, and their Awards Banquet. It was a great venue to share and discuss challenges and solutions common to both states. The meeting was also held in conjunction with the inaugural Family Medicine Midwest conference. This new conference brought together medical students and residency programs from 12 Midwestern states. Along with the residency fair, two days of CME tracks were offered that were geared toward students, residents and faculty members. I hope the continued success of this conference will help improve medical student interest in family medicine into the future.

Finally, is anyone missing those campaign commercials? Neither am I. But, with the outcome of the November elections finalized, the future of the Affordable Care Act does have a level of certainty. Our Academy will work closely with the AAFP to provide resources to members to help them navigate the progress of the ACA. Our legislative staff is also getting ready for the 2013 Indiana General Assembly starting in January. As usual, there will be a number of healthcare-related bills, and we will work with other health care organizations in the state to represent our members. If you'd like to participate in the legislative process, feel free to contact our Academy office to find out how you can get involved.

I hope you enjoy this issue of the *FrontLine Physician*. As always, if you have any questions or comments, feel free to e-mail me at risheetp@yahoo.com or contact the IAFP office. From all of us here at the Academy, I wish you and your family a warm and safe holiday season and a happy new year.

Thanks,

Risheet R. Patel, MD

Mark Your Calendar

IAFP Events

2013 IAFP Trip to Ireland
Emerald Isle CME and Golf
Sunday, June 29-Saturday, July 6
Ireland

IAFP Annual Convention
Thursday, July 25-Sunday, July 28
Indianapolis

AAFP Events

September 23-25
Congress of Delegates
San Diego, California
San Diego Marriott Marquis and Marina/San Diego Convention Center

Annual Scientific Assembly
San Diego, California: September 24-28, 2013
San Diego Convention Center

Plan Now to Serve as Physician of the Day in 2013

Interested in politics? There is a reason many of our physicians of the day serve year after year, because serving as the Physician of the Day puts you in the heart of the action at the Indiana Statehouse.

The Indiana Academy of Family Physicians and the Indiana State Medical Association will once again sponsor the Physician of the Day program at the 2013 General Assembly. Your assistance is needed! This interesting and fun program allows you to observe the legislative process firsthand, meet with your state legislators and leave a great impression about family medicine on the General Assembly.

IAFP members can volunteer to spend one or more days at the Statehouse during the legislative session. As the Physician of the Day, you will provide episodic primary care services for the legislators and their staffs during the time the state legislature is in session. On days when the full House and Senate are in session, the Physician of the Day is introduced on the floor of both houses. Your day at the Statehouse will last from 8:30 a.m. to 4:30 p.m.

We are currently scheduling physician volunteers for the months of February and April 2013. The program operates Mondays through Thursdays, and, at press time, we have seven open days in February and five open days in April.

If you are interested in serving as the Physician of the Day, please e-mail Chris Barry (cbarry@in-afp.org), or call the IAFP office at 888.422.4237 (toll-free, in-state only) or 317.237.4237 to schedule your day. **THANK YOU!**

2012 IAFP Fall
CME Conference Held in Carmel

At the end of October, IAFP members from across the state gathered at the Medical Academic Center in Carmel, Indiana, to earn some live CME credits on a variety of topics. In the morning, we focused on pediatrics, with talks on pediatric esophagus, overuse injuries, sleep apnea and the autism spectrum. In the afternoon, we learned how to improve adult vaccination rates, followed by a two-part activity focusing on the care of our returning veterans. Finally, we wrapped up with information on the ordering and interpretation of anticoagulation tests and an update on Von Willebrand disease.

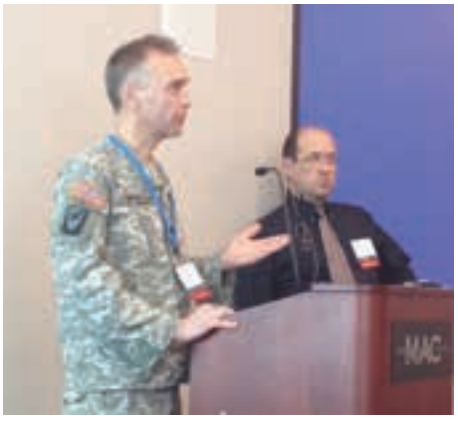

The Medical Academic Center features a large auditorium.

Thank you to all of our speakers: **Sandeep Gupta, MD; Tim Von Fange, MD; Leila Akanli, MD; Julie Rusyniak, MS; Charlene Graves, MD; Rodney Deaton, MD; James Wakefield, MD; Ashwin Vasudevamurthy, MD; and Sweta Gupta, MD**. Thank you to **Richard Kiovsky, MD, FAAFP,** professor of clinical family medicine and executive director of the IN-AHEC Network, who was instrumental in developing the veterans activity.


Charlene Graves, MD, presents Take Your Best Shot: Optimizing Adult Vaccination Rates in Your Practice.

Thanks also to our two exhibitors:

- **Travis Field, MA, MSW, LCSW,** suicide prevention coordinator of the Roudebush Veterans Medical Center — helping family physicians understand how to contact the VA for referrals (regular and in crisis mode), providing maps illustrating VA services across the state of Indiana, and links to other VA services.
- **Bob Strange, BA,** of ASPIN (Affiliated Service Providers of Indiana, Inc.). Bob is a lieutenant colonel, MS, AUS (ret.), and served in Vietnam. He now serves as project director for the Indiana Veterans Behavioral Health network and is working closely with the IN-AHEC (Indiana Area Health Education Centers) Network to help educate primary care doctors about the physical and mental health issues of our returning military veterans.


Dr. James Wakefield and Dr. Rodney Deaton present a two-part session on Improving the Care of Veterans in Your Office.

The conference was generously sponsored by Indiana Spine Group. Visit the website at www.indianaspinegroup.com. Find out more about the Medical Academic Center at www.medicalacademiccenter.com.

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.

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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 by 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 (DPP4) 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 (9.8% versus 2.6% for diarrhea and 6.3% versus 1.5% 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=882	Placebo N=799
Upper respiratory tract infection	68 (7.7)	51 (6.4)
Urinary tract infection	40 (4.5)	29 (3.6)
Headache	37 (4.2)	27 (3.4)

*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 2.6% versus 1.6%, 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=328
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 to the saxagliptin add-on to metformin immediate-release trial, the incidence of diarrhea was 5.9%, 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 3.6% 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 4.2% 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% (758 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 2958 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 falsi 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 to 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 1500 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.

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Meet Your New President:
Risheet Patel, MD

Your new IAFP president, Dr. Risheet Patel, was installed at the IAFP's Annual Awards Banquet and Installation of Officers during our Annual Convention this summer.

Dr. Patel is currently a full-time family physician with Olio Road Family Care in Fishers, Indiana. As an original TransforMed practice, Olio Road Family Care has consistently been on the forefront of practice change, including implementation of an EHR, open-access scheduling, online services and transforming into a Patient-Centered Medical Home. He is also currently working with Community Health Network to implement a new networkwide EHR. As well as serving as president of the Academy, Dr. Patel also serves as vice chairman of the IAFP Commission on Education and is instrumental in the planning of our educational offerings, as well as having presented several CME activities himself in the past.

Dr. Patel was born and raised in Indianapolis. He attended Union College for his undergraduate education, which is right outside of Albany, New York. He then received his medical degree from Albany Medical College. Dr. Patel returned to Indianapolis for his residency training with Community Health Network and has since been practicing in Fishers.

Outside of work, Dr. Patel enjoys sports of all varieties. He is an avid basketball and football fan. He enjoys running and playing sports as well. He enjoys music and going to concerts, traveling, and outdoor activities such as hiking and camping with his dog, Hugo.

ENDING CHILDHOOD OBESITY WITHIN A GENERATION

We support school-based nutrition and physical fitness initiatives, such as Fuel Up to Play 60, that help achieve these guiding principles:

1. Increase access to and consumption of affordable and appealing fruits, vegetables, whole grains, low-fat dairy products and lean meats in and out of school.

2. Stimulate children and youth to be more physically active for 60 minutes every day in and out of school.

3. Boost resources (financial/rewards/incentives/ training/technical assistance) to schools in order to improve physical fitness and nutrition programs.

4. Educate and motivate children and youth to eat the recommended daily servings of nutrient-rich foods and beverages.

5. Empower children and youth to take action at their school and at home to develop their own pathways to better fitness and nutrition for life.

IU School of Medicine – Department of Family Medicine Update

Greetings and happy fall. It has been another busy season here in the Department of Family Medicine at the Indiana University School of Medicine. Our department faculty has been highly involved in the school's curricular reform and has played a leadership role in the reform process. We are nearing the implementation phase, which will undoubtedly create more family medicine opportunities for educational change management with an emphasis on early primary care exposure and longitudinal primary care mentoring. Dr. Scott Renshaw and the entire predoctoral team have not only continued to be innovative in the current family medicine clerkship training but have also have become highly engaged in our educational research initiative. Dr. Deanna Willis has been promoted to vice chair for the Department of Family Medicine and is leading the educational research mission within the department. You may ask why education research as opposed to clinical services research. The answer is this: We as a department see a great opportunity to advance family medicine training not only in the state of Indiana but throughout the country. It is no secret that there is currently a shortage of primary care providers, which will increase dramatically during the course of the next eight years. Family medicine is and will continue to be the specialty best positioned to provide care for the entire population. The department will be well represented at the 2013 Society of Teachers of Family Medicine Conference in Baltimore, Maryland. The following are presentations that have already been accepted for that meeting.

1. Using Motivational Interviewing to Improve Patient Activation for Efficient and Cost Effective Outcomes (Pais)
2. HRSA-funded online faculty development modules (Dankoski)
3. Seminar: Extending the Reach: Best Practices for Recruiting, Developing and Retaining Volunteer Community Faculty (Renshaw, Custer, Burba, Cooper)
4. Completed Projects and Research: Comparing Student Encounter Distributions in a 2009/2011 Family Medicine Clerkship with 1997/1999 and 2009 Namcs (Renshaw, Burba, Saywell, Butler, Zollinger, Kiovsky, Willis, Allen)
5. Lecture-Discussion: The Art of Giving Feedback (Holley, Renshaw, Custer, Burba)
6. Scholarly Topic Roundtable Presentation: International Crisis Management: Making the Decision to Cancel a Global Health Experience (Renshaw, Custer)
7. Works In-Progress: How Does Curriculum Integration of FM-Cases Affect Performance on a Nationally Validated Exam (Renshaw, additional medical schools' faculty members)
8. Completed Projects and Research: The relationship of Evidence Based Care Adherence and Resource Utilization in an OSCE (Willis, Renshaw, Saywell, Carolyn Hayes-UME, Kiovsky)

As you can see, there are a number of exciting programs and opportunities evolving here in the Department of Family Medicine. Please feel free to contact me, Dr. Renshaw or Dr. Willis with any questions regarding these ongoing initiatives and to find out how you can be more involved.

Thanks and Happy Holidays,

Kevin B. Gebke, MD

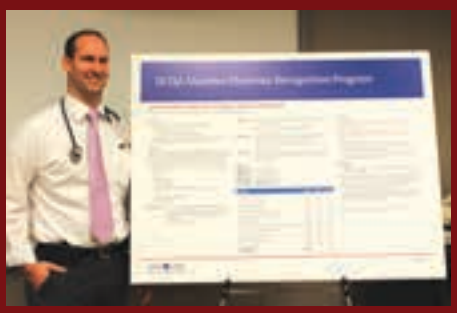
Saint Joseph Regional Medical Center Family Medicine Residency

Mishawaka, Indiana

Family medicine training remains strong in northern Indiana. The SJRMC Family Medicine Residency (9/9/9) matched this past March with nine residents from seven different medical schools.

The residency as a whole was awarded NCQA recognition in diabetes care — a first in the state of Indiana. This work also gained first prize in the annual Quality Summit at SJRMC and provided the opportunity to share our work at the Trinity (national) Quality Summit in Chicago.

Scholarly activity has included multiple publications in FPIN (Family Physicians Inquiries Network), national presentations by our sports medicine director (Steve Simons, MD) and authorship by faculty members Julia Fashner, MD, and Kevin Ericson, MD, along with Sarah Werner, DO (resident), the cover article for the July 15, 2012, issue of *American Family Physician*.



The family medicine residents not only learn inpatient medicine at a state-of-the-art facility (SJRMC-Mishawaka, which was recently named one of the most wired hospitals in the United States) but also obtain their outpatient training in our new 20,000-square-foot FMC. This past June, the family medicine residency, along with

Continued on page 21

Marian University College *of* Osteopathic Medicine Update

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

MU-COM is moving forward successfully toward a planned opening day in August 2013 for an entering class of 150 osteopathic medical students. Construction of the new Michael Evans Center for Health Sciences is now about 60 percent completed. Our outside brickwork and inside drywalling is almost completed on the medical-school side and is progressing to close up the building for winter construction on the nursing-school side; inside structure for glass features has been installed. Work has started to prepare the building for high-technology wiring and systems installations later this winter and spring. We anticipate moving in around mid-July.

We are continuing our recruiting and hiring of faculty members both from biomedical science disciplines and for clinical positions (part-time and full-time). To date, we are about two-thirds complete in hiring faculty members, with final contracts in progress for OMM, family medicine, microbiology/immunology and anatomy, among others. Bryan Larsen, PhD, associate dean for biomedical sciences, is also recruiting other PhD faculty members in anatomy, physiology, pharmacology, cell and molecular biology, microbiology and immunology, and biochemistry. Charles E. Henley, DO, MPH, is also searching for a chair for primary care (a general internist, a pediatrician or a family physician) who is AOA board-certified.

MU-COM has had more than 2,500 applications to date. We have already completed about 125 of about 600 planned interviews, with about 70 offers made to outstanding candidates to date. Our community physicians have been instrumental in helping us in interviews and on our admissions committee, serving as "pioneers" in assisting Marian select our first class. The Multi Mini Interview plan (MMI), using noncognitive assessment stations to supplement GPA, MCAT and application data, has worked very well. Our clinical education network continues to grow for both clerkship rotations and for planning future graduate medical education slots. Dr. Henley has reported strong enthusiasm from many different hospitals to teach MU-COM students, with more than 4,000 community physicians expressing an interest in taking students. We now have more than 25 formal hospital affiliations across the state either complete or in progress. Our first clinical faculty appointments have already started for community preceptors.

The recent combined announcement from the ACGME and the AOA to have all residencies and fellowships accredited under the ACGME by 2015 will mean some new procedures in both DO and MD training programs. These changes will need work on issues such as devising a single match system, developing a unified set of institutional standards for everyone, defining how to work with both specialty board bodies, creating inclusion criteria for osteopathic-specific specialty programs and even possibly accepting MD graduates into osteopathic programs. All will require creative policymaking and the time to work through planning and implementation of appropriate steps. More information will become available at the beginning of 2013, when the initial committee work will produce details.

This fall at MU-COM will see a continuing focus on refining the case-based and competency-based curriculum, assigning local physician experts in preparation for teaching our new students, fine-tuning classroom and lab spaces, and orientation and first-term assignments for the new medical students who will come to Marian University. We will have an accepted student open house in March and a ribbon-cutting ceremony probably in July or August. We will publish the date when it is selected.

In our new curriculum and rotation requirements, we are placing an emphasis on primary care education and experiences. We plan a rural medicine rotation, a two-month community hospital experience, and significant instruction in wellness and prevention. As a family physician, I know the importance of these topics for all physicians. We plan to work closely with the FM residencies and family doctors in the state in ensuring a quality exposure to good family physician role models for our students.

With your help, we hope to build a strong foundation from which to provide exceptional medical education experiences and expand the presence of our new medical school in Indiana in the years to come.

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- 10,000 annual ED with 12 & 24 hour shifts available
- 45 min from Indianapolis

Sullivan County Community Hospital – Sullivan
- 8,600 annual ED
- 12 & 24 Hour Shifts available

Community Westview Hospital – Indianapolis
- 7 days on 7 days off
- Paid night call

William S. Major Hospital – Shelbyville
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- Double coverage during peak hours

For more information Contact:

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Ray Nicholson, MD,

Awarded Gordon T. Herrmann, MD, Distinguished Service Award at IUSM Evansville Ruby Ball

IAFP Past President and longtime friend of the Academy Raymond "Nick" Nicholson, MD, was honored at the recent Ruby Ball in Evansville. Dr. Nick was awarded the Gordon T. Herrmann, MD, Distinguished Service Award. The Ruby Ball was a 40th-anniversary celebration commemorating the longstanding dedication of the physicians, community leaders, faculty members and staff members of the Indiana University School of Medicine Evansville. The following appeared in the Ruby Ball attendee handbook:

Raymond W. Nicholson Jr. remembers the first time he was the recipient of an award. A student of Bosse High School, Ray recalls receiving the J.C. Duncan award presented by the Junior Chamber of Commerce. He was completely surprised by that event and recalls the pride in his mom's and dad's eyes. That was more than 60 years ago. Since then, "Dr. Nick," as he likes to be addressed, continues to accrue awards from national, state and local organizations for his selfless giving of his time, knowledge and resources over the years. As you might expect from someone who naturally shares with others, Dr. Nicholson has amassed countless service awards from the many arts, education and medical organizations he has supported and continues to support.

Among them is the Indiana University School of Medicine. A graduate of Indiana University, Dr. Nicholson completed his undergraduate, graduate and residency training with the IU School of Medicine in Indianapolis. He was a captain in the U.S. Army, where he served as a pediatrician. He entered private practice in family medicine in 1958 and became director of the St. Mary's Family Practice Residency Program in 1970, where he served until 2001. He served as director emeritus from 2001 to 2007. In May 2000, the St. Mary's Family Practice Center was named after him.

Dr. Nicholson has been a volunteer clinical faculty member of the IU School of Medicine, both Evansville and Indianapolis, for more than 50 years. When asked recently why he enjoys teaching, he replied, "I've always been involved in teaching. I don't know why, but some of the most important influences in my life were teachers." In addition, he has been a member of the Community Advisory Council to the school since its opening in Evansville 40 years ago.

Dr. Nick also believes in assisting young medical students through scholarship support. In 1996, Dr. Nicholson's children, Diane and David, created a student endowment in honor of their late mother, Joyce Nicholson. Since that time, 16 local medical students have been recipients of this scholarship.

Despite all of the public accolades that Dr. Nicholson has received, he still considers the greatest joys in life to be the births of his two children, David and Diane. Dr. Nicholson is also blessed with the presence of his wife, Cynthia, who shares his passion for philanthropy in all areas of life. We are deeply grateful for the lifetime of service Dr. Nicholson has given and proud to designate him as a 2012 recipient of the IU School of Medicine – Evansville Gordon T. Herrmann Distinguished Service Award.

Clif Knight, MD, Elected to AAFP Board of Directors at AAFP Congress of Delegates

The IAFP is thrilled to announce the successful campaign of Clif Knight, MD, for the AAFP Board of Directors. Dr. Knight, an IAFP past president, past member of the AAFP Commission on Membership and Member Services and current chief medical officer of Community Health Network, was elected by the AAFP Congress of Delegates on October 17, 2012.

Dr. Knight will serve a three-year term on the board. Also elected to serve three-year terms were Dr. Carlos Gonzalas of Arizona and Dr. Lloyd Van Winkle of Texas. Dr. Rebecca Jaffe of Delaware was elected to fill a vacancy on the board and will serve a two-year term. Dr. Reid Blackwelder of Tennessee was elected to the position of AAFP president-elect. He will assume the presidency at the AAFP Congress in 2013.

The IAFP leadership and staff are proud of Dr. Knight and his lengthy service to the Academy that has culminated in this accomplishment. Thank you to all the IAFP members who came to Philadelphia to support Dr. Knight's campaign.

Besides electing the officers and board of the AAFP, the AAFP Congress of Delegates hears resolutions sent to the Congress from chapters. The AAFP Congress is comprised of two delegates from each chapter of the AAFP.

Clif Knight, MD, makes a speech to the AAFP Congress of Delegates outlining why he wishes to serve of the Board of Directors.

Indiana was represented by Dr. Clif Knight and Dr. Richard Feldman as delegates and Dr. David Pepple and Dr. Windel Stracener as alternate delegates. With Dr. Knight's new position on the AAFP Board, Teresa Lovins, MD, of Columbus, was elected as an AAFP alternate delegate at the October 28 IAFP Board of Directors meeting, and Windel Stracener, MD, was elected as delegate.

Below are the results of a few key resolutions. To see the full actions and determinations of the AAFP Congress of Delegates, visit aafp.org/congress.

Updates to AAFP Bylaws

The 2012 AAFP Congress of Delegates passed multiple updates and revisions to the AAFP Bylaws. The bylaws have never undergone a full update since 1948, so much of the changes were to modernize the language and reduce extraneous information, all while maintaining the same core principles. In 2009, the AAFP Board of Directors appointed a task force to review the AAFP Bylaws. The first of the bylaws were released in January 2011 and were made available for comment by members and chapters. Comments were taken into account, and the final draft was prepared in June 2012. The AAFP Congress of Delegates made some minor clarifying amendments to the definition of a "state" in the bylaws and then proceeded to accept the new bylaws.

Resolution #308 – Telemedicine

The AAFP Board of Directors has been tasked with creating policy guidelines for telemedicine that balance the needs of rural communities without fragmenting existing physician/patient relationships.

Resolution #502 – Patient-Centered Medical Home Certification

The AAFP has been asked to advocate for the usage of other certifying agencies besides NCQA for federal and state PCMH pilot programs. The AAFP will also be investigating creating its own certifying process and report back in 2013.

Dr. Knight answers AAFP members' questions about his campaign.

Resolution #504 – Critical Access Hospitals

Resolution #504 mandates the AAFP to lobby for the preservation of the Critical Access Hospital program.

Resolution #509 – Survival of Independent Practices

Compared to large hospital systems and physician groups, independent practices have a disadvantage when negotiating with health insurers. As a result of resolution #509, the AAFP Board of Directors will research the feasibility of legislation to allow primary care physicians to collectively negotiate with immunity from antitrust statutes. The board has been asked to report back to the 2013 Congress with a plan for action.

Resolution #510 – Same-Gender Marriage

The AAFP Congress of Delegates voted to approve a policy statement on civil marriage, following other organizations like the AMA and the American Psychiatric Association.

IAFP Adopts Apple Use

Improves Efficiency and Lowers IT Costs

by Chris Barry

If you've attended an IAFP event recently, you may have noticed that Academy staff are now exclusively using Apple computers. Comparing the initial purchase cost of Apple versus Windows PCs, you may wonder why we chose to go with Apple. While it is true that the initial cost of Macs is higher, we have been able to greatly reduce our dependence on IT support staff at IAFP headquarters due to the vastly increased reliability of our hardware. When using PCs, we were contracted with an IT company that, often, helped us to troubleshoot problems, maintain updates and upgrade machines. Now we often go for months at a time without any IT support whatsoever, greatly reducing our costs.

Similarly, at live meetings, we are able to reduce the costs incurred from on-site IT support due to the increased reliability and ease of use of the Apple hardware.

We have also been able to completely eliminate the use of costly servers to store our information by switching to Google Drive to store our files and Google Mail to handle our e-mail accounts. Google Drive is a Web-based office suite and data-storage service that allows the IAFP staff to create and edit documents online while collaborating in real-time with colleagues. This method of online file storage is commonly referred to as "the cloud" and allows us to work on documents, spreadsheets and slideshows from any location at any time. As one of the first chapters of the AAFP to adopt this technology, we have been ahead of the curve when it comes to finding new ways to improve office efficiency and better serve our members' needs.

If you have any questions about our technology, or if you think that moving to a Web-based platform in your office might be beneficial to you, please contact us! We'd love to share our experiences and insight from our move to Web-based computing.

Are You Eligible for the AAFP Degree of Fellow?

Have you been an AAFP member for six years? Have you served as Physician of the Day? Do you work in an underserved area? Have you served on a board of directors — ours or one in your community? Are you a volunteer teacher, preceptor or speaker at an IAFP meeting? If so, you are probably eligible for the AAFP Degree of Fellow!

The Degree of Fellow was established in 1971 by the AAFP Congress of Delegates as a way to recognize AAFP members who have distinguished themselves among their colleagues, and in their communities, by their service to family medicine, the advancement of health care to the American people and professional development through medical education and research.

The Degree of Fellow will be conferred during the President's Banquet at the 2013 IAFP Annual Convention, on Saturday evening, July 27, in Indianapolis. Those wishing to receive their Degree of Fellow at that time should have their application submitted to the AAFP no later than Friday, May 24, 2013.

To be awarded the Degree of Fellow, one must have been an AAFP member (Resident and/or Active) for six years and must accrue 100 points from any of the sections as described below.

Lifelong Learning (65 points possible)
Board certification and recertification; certificates of added qualifications; additional degrees and fellowships; CME meetings and activities; and current certifications

Practice/Quality Improvement (80 points possible)
Practice in underserved areas; military deployment; services provided outside regular office practice; obstetrical care and special procedures; performance improvement activities in office; service as medical chief of staff or department chair; service on board or committee of hospital, system, HMO, etc.; leadership positions held in practice; TransforMED or Patient-Centered Medical Home participation, incorporation of METRIC into practice or program

Volunteer Teaching (114 points possible)
Lecturing at AAFP and state chapter meetings, as well as meetings such as RAP, STFM, AFMRD, ADFM and NAPCRG; volunteer teaching at a FM residency program; volunteer precepting or mentoring for medical students and/or residents; teaching METRIC in a residency program; volunteer lectures for students and/or residents; service as chair of or advisor to a chapter student interest committee or student interest group; instruction of a national certification program (e.g., ALSO, ATLS, PALS, ACLS)

Public Service (82 points possible)
Charitable medical services and humanitarian missions; government/community services in an elected or appointed office; public relations activities that explain the specialty; health education outside of the office; community nonprofit awards; leadership in community, voluntary or religious organizations; volunteer medical services

Publishing and Research (95 points possible)
Published research or articles and non-published research presented at an AAFP-sponsored function; service on an editorial board; contributions to chapters of a medical book; participation in research, practice-based or as part of a group

Service to the Specialty (93 points possible)
Serving as a legislative Key Contact; presenting legislative testimony; participation as Physician of the Day; service as committee chair, officer or delegate/alternate in another medical organization; service as IAFP or AAFP president or officer, board member, commission chair or committee member; service as board member of IAFP PAC or Foundation Board of Trustees; family medicine awards given by IAFP or another FM organization; participation in AAFP non-clinical education; Speak Out participation

For more information, visit: http://www.aafp.org/online/en/home/membership/fellowship/fellow.html.

Call for Nominations for 2013 IAFP Officers

At least 90 days prior to the IAFP Annual Assembly each year, the Nominating Committee shall announce nominations as required by the Bylaws. These nominations shall be formally presented at the first meeting of the Congress of Delegates, which this year will be July 26 and 27 in Indianapolis. At the time of the meeting, additional nominations from the floor may be made. The said election of officers shall be the first order of business at the second session of the Congress of Delegates on July 27.

Offices to be filled for 2013-2014 are: president-elect, second vice president, speaker of the Congress of Delegates, vice speaker of the Congress of Delegates, one AAFP delegate (two-year term) and AAFP alternate delegate (two-year term).

The Nominating Committee's objective is to select the most knowledgeable and capable candidates available. The committee is also responsible for determining the availability of those candidates to serve, should they be selected.

If you are an Active member of the IAFP and are interested in submitting your name as a candidate, you must submit a letter of intent, a glossy black-and-white photo and a curriculum vitae. The deadline for nominations for 2013 IAFP officers is Friday, March 1, 2013. If you have questions, please contact Kevin Speer or Deeda Ferree at 317.237.4237.

"Saint Joseph Regional Medical Center Family Medicine Residency," continued from page 14

the Family Medicine Center, moved into its new (and expanded) FMC. This move allows residents to be physically, electronically and culturally joined to the care given at the inpatient sponsoring institution.

Our program director, Martin Wieschhaus, MD, completed a four-year term as a board member with the Association of Family Medicine Residency Directors (AFMRD) this past June. He was involved in the initial work on the soon-to-be-released Residency Program Index (RPI), as well as initial work on a national curriculum for family medicine training.

Present Your Research in 2013

Each year the IAFP's Research Day takes place in Indianapolis with over 100 residents, faculty members, and other IAFP members in attendance. Residents and IAFP members from across the state make 15-minute presentations and display posters detailing their original research projects and performance improvement initiatives. We also hear several case presentations about patients who presented with unusual and/or rare diseases.

You are invited to plan now to take part in 2013's Research Day, which will take place in Indianapolis on Thursday, May 2. At our website, www.in-afp.org, you can now download our information packet to find out how to submit an abstract, see last year's winners, and find out more. You can also submit your abstract using an online form. Look under Events to find this information.

We hope to see you in May!

IAFP Awards
Call for Nominations

In an effort to recognize the achievements and dedication of our members, the IAFP Board of Directors invites members to honor their peers with the following awards each year:

Family Physician of the Year Award
Lester D. Bibler Award (for long-term service and leadership)
A. Alan Fischer Award (for outstanding contributions to family medicine education)

The IAFP Commission on Membership and Communication will review all entries and present its recommendation to the IAFP Board of Directors for approval at the spring board meeting. Recipients will be recognized on Saturday night, July 27, at the IAFP Awards Banquet and Installation of Officers during the IAFP Annual Convention in Indianapolis.

Nomination forms are available on our website (www.in-afp.org). Nominations will be accepted from January 15-March 15, 2013. A complete list of past award winners is also available on the website. Thank you for serving as an advocate for your specialty by nominating a family physician today!

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