Who Benefits From the ACA? Not the Patients!

By G. Keith Smith, MD, contributing editor

I am intrigued with the Austrian economist Murray Rothbard. His method for evaluating the events of governments and economies was simple: “cui bono,” or “Who benefits?”

Many industries have benefitted from the Affordable Care Act (ACA), which was upheld by the Supreme Court: Quite simply, they wrote the bill. Numerous leaked e-mails, and the surge in stock prices of the major players in these industries just moments after the Court’s June decision, confirm this.

The medical loss ratio provision is particularly nefarious in that it virtually ensures the elimination of small insurance companies, leaving only the big players. Twenty percent of a huge number is sufficient to cover overhead, while 20% of a smaller number might not be. Combining this with a rebate check to the people completes the demagoguery.

Many people will obtain insurance who never had it before, only to find that no one will see them, as the Independent Payment Advisory Board will set the price of care below the market cost to ensure rationing. Physicians will bear the blame.

Adding morbidly obese, smoking, diabetic, and hypertensive patients to healthy plans...
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I believe the free market is the only system that results in a rational allocation of scarce resources. Medicine differs from other industries only because the government intervened early in history. The notion that more government could answer a problem that government caused is like offering an alcoholic a drink.

I choose freedom. I exhibit the prices for surgeries at my facility online for all to see. I shun government money. I embrace the competition that all other businesses must endure. I believe physicians who choose this path will thrive. The others will become slaves of the state, just as the ACA intends.

If the presidency changes hands this fall, we’ll know very soon whether the political machine looks more to the industry giants in health care or the patients for whom we care.
Primary care physicians’ (PCPs) attitudes toward complementary and alternative medicine (CAM) approaches range from skepticism to cautious interest to enthusiastic support. Most, however, understandably reserve their judgment about particular therapies and approaches until studies confirm a meaningful clinical benefit. The good news for both physicians and diabetes patients is that some CAM approaches have been proven to generate measurable improvements in outcomes. A study published in the April 2012 issue of BMC Complementary and Alternative Medicine suggests that naturopathy, a long-standing CAM approach, can serve as a positive adjunct to usual care for diabetes patients by leading to improvements in blood glucose control, patient self-management behaviors, and self-efficacy.

Focus of Naturopathy

“Active health promotion counseling and an emphasis on self-care form the foundation for naturopathic medicine,” says Ryan Bradley, ND, MPH, a naturopathic physician with Bastyr University’s Center for Natural Health and lead author of the study. “Naturopathy heavily focuses on dietary and activity counseling, stress management, and select nutritional supplementation.”

Certain aspects of naturopathy particularly resonate with patients, says Bradley, who has published several studies summarizing clinical outcomes of naturopathic approaches. “Although patients are hearing similar messages about lifestyle changes from conventional providers, naturopathic physicians have more time to spend with their patients in setting behavior change goals and acknowledging that these are hard changes to make,” he says, emphasizing the value in having patients hear multiple providers make these recommendations. “In addition, patients who seek naturopathic care trust the philosophy of naturopathic medicine. This makes patients ready to listen, and helps reinforce the messages provided by PCPs. Naturopathic physicians identify the individual barriers to change that a patient faces and then emphasize practical solutions for fitting behavior modification techniques into a busy lifestyle.”

Naturopathic physicians may recommend specific nutritional supplements that may have benefits for glucose control. Supplements whose benefits for diabetes patients are supported by clinical trial evidence include chromium, common botanical medicines like cinnamon, vitamin D replacement, and supplements with cardiovascular benefits.

Naturopathy is a reasonable approach to diabetes management, believes William Huff, MD, a practicing family physician who serves as the director of alternative services at Group Health in Seattle. “Management of type 2 diabetes requires the patient to address a number of lifestyle issues and other factors that have a meaningful impact on outcomes,” he says. “Naturopathic physicians generally have more time to spend with patients than most allopathic physicians do. So while PCPs may cover some of the same topics, these discussions are often truncated due to limitations on visit times. Medical doctors and naturopaths who have close referral relationships often feel their skills complement each other.”

Comparing Approaches

The one-year prospective study, conducted by researchers from Bastyr University and Group Health, a large nonprofit integrated health system in Seattle, measured the effects of adjunctive naturopathic care in primary care patients whose type 2 diabetes was inadequately controlled. Forty Group Health patients with type 2 diabetes and HbA1c levels between 7.5% and 9.5% and at least one additional cardiovascular risk factor received up to eight visits with a naturopathic physician in addition to usual care from their Group Health PCP. These patients were aged 21–65 years and had had no prior experience with naturopathic care. The outcomes in this intervention group were compared to changes in a cohort of 329 comparable type 2 diabetes patients who received only usual care.

On average, intervention patients had approximately four visits with a naturopathic physician over the course of the study. Patients received recom-
Recommendations from naturopaths related to physical activity increases (100% of patients), dietary changes (95%), stress management (59%), and dietary supplementation (74%). Supplements most frequently recommended included omega-3 fatty acids, chromium, and a multivitamin with B-complex; others included fiber, vitamins D, C, and E, cinnamon, probiotics, bioflavonoid/polyphenol, and coenzyme Q10.

The researchers found that patients receiving naturopathic care experienced a greater reduction in HbA1c than patients receiving usual care only. “We knew that we had a very small sample of patients, and therefore we were apprehensive about our potential to detect changes in blood glucose control,” says Bradley. “However, we did measure a 0.9% reduction in HbA1c within the first six months of the study in people who sought naturopathic care. This magnitude of change is similar to that achieved by some diabetes medications.” This reduction was about a half a percentage point greater than that observed in the usual care group. Improvements in glycemic control were also greater in the intervention group at 12 months, although the difference was smaller and not statistically significant. Changes in lipid and blood pressure measures were minimal in both groups.

In addition, the researchers found differences in patient-reported outcomes such as increased frequency of self-care practices, increased self-efficacy, improved motivation for pursuing lifestyle changes, reduced diabetes problem areas, and improved mood. These changes were measured using validated instruments including the

**PCPs might want to investigate the potential benefits of naturopathy and other CAM approaches and consider whether their patients could benefit.**

A qualitative analysis of post-intervention focus group results found that comments from patients with diabetes supported the notion that naturopathic care was complementary to their primary care, and that they received different benefits from each type of care. “Some participants also stated that their naturopathic care helped reinforce recommendations that they had heard from their PCP or cardiologist,” adds Ryan Bradley, ND, MPH, a naturopathic physician at Bastyr University’s Center for Natural Health.

“This is a small study that will form the basis for a larger research effort, but the take-away message is that the naturopath can add something valuable in diabetes care,” states family physician William Huff, MD, director of alternative services at Group Health in Seattle.

Previous research has also found that naturopathic approaches can have a positive impact on diabetes outcomes. Two retrospective observational studies (in the March 2006 issue of *Alternative Medicine Review* and the June 2009 issue of *the Journal of Alternative and Complementary Medicine*) found an increase in the proportion of patients who had good blood sugar control, a reduction in HbA1c levels, and high rates of delivery of advice related to diet, physical activity, and stress management. In a small, prospective clinical trial of a naturopathic nutritional approach to diabetes in the August 2011 issue of *Complementary Therapies in Clinical Practice*, Oberg et al demonstrated improved blood sugar control as well as various improvements in self care such as blood glucose checks, increased frequency of following a healthy diet plan, and increased physical activity. Finally, a retrospective study of patients with hypertension, a common diabetes comorbidity, in the March 2011 issue of *Evidence-Based Complementary and Alternative Medicine* found that naturopathic care led to blood pressure reduction and a significant number of participants who met blood pressure control goals. Bradley believes that, taken together, study findings to date provide justification for a large, randomized, controlled trial to measure the impact of naturopathic care on clinical risk factors and patient-reported outcomes measures.

—DJN
ments in mood suggest that the inter-
vention group may have experienced a fundamental change in their activation and empowerment. These patients may have developed new skills that gave them more confidence and feelings of control over their health.”

Enforcing Normal Care
Interestingly, the number of pri-
mary care visits increased in the inter-
vention group but remained the same in the usual care group. “Clearly, patients were not replacing their primary care with naturopathic care,” Bradley notes. Three-quarters of patients were given advice that reinforced their use of medications prescribed by their PCP. The use of oral diabetes medications and insulin increased in the intervention group over the study period, with a number of patients initiating new therapies. The total number of pre-
scription refills also increased in the intervention group, compared with no change in patients receiving usual care.

Huff notes that some conventional physicians do not believe in CAM. “There has been an increasing awareness of the value of CAM, thanks to more education and the growing interaction among providers,” he says. “We are finding that an increasing number of doctors are open to CAM, even if they don’t fully agree with all of the treatments.”

Washington State requires payers to cover certain CAM services, including naturopathy, as long as they are offered by a licensed provider. Patients are not required to obtain a referral from a PCP to access these CAM services. “With this mandate, we have seen more integration of care and a greater acceptance of CAM approaches,” Huff adds.

“Care provision is all about relationships,” says Huff. “If PCPs can develop relationships with naturopaths whom they trust, they can have an open conversation in which they share and coordinate care for a given patient.”

“Patients who are motivated to make changes in their behavior should have access to sources of information that will help them do so successfully,” Bradley states, adding that PCPs might want to investigate the potential benefits of naturopathy and other CAM approaches and consider whether their patients could benefit. “My hope is that PCPs remain open-minded and consider facilitating referrals for patients who are interested in naturopathy and alternative therapies.”

—DJN

PCPs Should Be Open to Patients’ Use of Naturopathic Providers, Researcher Says

R yan Bradley, ND, MPH, a naturopathic physician at Bastyr University’s Center for Natural Health, believes his study on naturopathy and diabetes in the April 2012 issue of BMC Complementary and Alternative Medicine carries a positive message for both primary care physicians (PCPs) and patients. “Patients need all the help they can get to self-manage their condition and improve their long-term health,” he says. “We are hoping that our results are reassuring to many conventional providers who may be apprehensive or may have questions about what naturopathy includes and how it may work. Naturopaths do not offer crazy recommendations that conflict with those made by conventional physicians. In some sense, referring patients to naturopathic physicians for adjunctive care is not that different from making referrals to other medical professionals such as registered dietitians and diabetes educators.”

Many patients may already be seeking complementary and alternative medicine (CAM) approaches to care. A study by Egede et al in the February 2002 issue of Diabetes Care found that patients with diabetes were 1.6 times more likely to use CAM than those without diabetes, and that diabetes was an independent predictor of CAM use. A national survey of diabetes patients by Yeh et al in the October 2002 issue of the American Journal of Public Health found that 57% of patients had used a CAM therapy over the past year.

Practicing family physician William Huff, MD, the director of alternative services at Group Health in Seattle, acknowledges that many patients who seek out alternative treatments are reluctant to share their experiences with their PCPs. However, doctors should be open to discussing these treatments. “Even if PCPs do not support CAM approaches, it serves the patient better if physicians are aware of the services he or she is receiving,” he says. For example, the patient may be taking herbs or supplements that might interact with other medications or treatments they are using. “Regardless of whether PCPs believe CAM is valuable, they still may treat patients who are choosing to see naturopaths, chiropractors, or other CAM providers—and this is something they have to factor into the care of those patients.”

—DJN
Financial advisors are often asked to help doctors to protect assets against future lawsuits. In doing so, we often learn what misconceptions physicians have regarding how to protect their assets from potential lawsuits. Some practical advice can help dispel some of the incorrect assumptions physicians may make, and shed some new light on opportunities for further asset protection.

**Protect Practice AR**

A practice's cash flow and income are its most important assets. Fortunately, the tools that protect a practice's cash flow also typically help physicians save on income taxes and build retirement wealth. These tools include qualified retirements plans (including defined benefit plans, 401(k)s, and combination plans), non-qualified plans, fringe benefit plans, captive insurance arrangements, and others.

Beyond its cash flow, the practice's accounts receivable (AR) are an important asset. AR is what physicians actually work for. A lawsuit against the practice, caused by a wrongful act of any of the partners, threatens all of the AR in a typical practice setup. There have been cases where physicians had to work for free for a number of months because the lawsuit judgment resulting from the act of one physician created a loss of the AR for the entire practice. Don’t let this happen at your practice.

Other important practice assets include real estate, if the practice owns any, and equipment. If your practice has real estate or equipment, it must separate these assets from the main practice. There are a number of tactics that can be used to protect real estate and valuable equipment from potential lawsuits against any of the physicians or the practice itself.

**Eliminate Bad Habits**

The most common asset protection misconception physicians have regards shielding their personal assets from potential lawsuits. Asset protection attorneys approach this challenge in much the same way that a physician approaches the experience of being a patient. Like physicians, asset protection professionals first will try to get a client to avoid bad habits. Bad financial habits of physicians might include owning property in their own name, owning it jointly with a spouse, or operating a medical practice with business assets exposed.

Financial advisors use an asset protection rating system to describe a client’s overall level of risk, from -5 (totally vulnerable) to +5 (superior protection). Risks such as exposing a practice’s business assets or owning property in a physician’s own name are examples of a -5 risk situation.

Before implementing any sophisticated asset protection planning, advisors attempt to move the client from a -5 to at least a low negative number or zero. This is accomplished by eliminating any of the bad habits mentioned earlier, and others. Any physician who has business assets exposed and owns the -5 category, as it’s only a matter of time until you get “sick.”

**Protecting Assets**

When a physician sees a patient with a harmful condition or disease, he or she tries to treat it. Financial advisors try to treat physicians to solve their lawsuit vulnerability, using particular structures to protect their assets.

Physicians who want good basic asset protection, but do not want to pay for more advanced tools, should consider using basic asset protection tools like family limited partnerships.
Help adult patients grab type 2 diabetes by the roots.

Powerful A1C reductions
—Lowered FPG and PPG
-0.8% to -1.5%*

Increased beta-cell function
—Improves insulin secretion

Low rate of hypoglycemia

May reduce weight
—Victoza® is not indicated for the management of obesity, and weight change was a secondary end point in clinical trials

To hear what patients are saying and why Victoza® is the #1 prescribed GLP-1 agonist by endocrinologists, visit VictozaPro.com/Voices.

Indications and usage
Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

In clinical trials of Victoza®, there were more cases of pancreatitis with Victoza® than with comparators. Victoza® has not been studied sufficiently in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis while using Victoza®. Use with caution in patients with a history of pancreatitis.

Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

The concurrent use of Victoza® and insulin has not been studied.

Important safety information
Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza®, is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

If pancreatitis is suspected, Victoza® should be discontinued. Victoza® should not be re-initiated if pancreatitis is confirmed.

When Victoza® is used with an insulin secretagogue (e.g. a sulfonylurea) serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

Renal impairment has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration, which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment.

There have been no studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

The most common adverse reactions, reported in ≥5% of patients treated with Victoza® and more commonly than in patients treated with placebo, are headache, nausea, diarrhea, and anti-liraglutide antibody formation. Immuneogenicity-related events, including urticaria, were more common among Victoza®-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials.

Victoza® has not been studied in type 2 diabetes patients below 18 years of age and is not recommended for use in pediatric patients.

Victoza® should be used with caution in patients with hepatic impairment.

Please see brief summary of Prescribing Information on adjacent page.

*Victoza® 1.2 mg and 1.8 mg when used alone or in combination with OADs.

†IMS Health Inc. SilversLink Longitudinal Prescription Database (LPR)™, April 2010–March 2011.

Patients new to a GLP-1 agonist regimen from a previous regimen without a GLP-1 agonist.

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1111-00006038-1

January 2012
WARNINGS AND PRECAUTIONS: Vizacta is contraindicated in patients with a history of thyroid cancer. Vizacta should be used in patients with multiple endocrine neoplasia type 2 (MEN 2).

INDICATIONS AND USAGE: Vizacta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Important Limitations of Use: Because of the uncommon occurrence of the rodent thyroid cell tumor findings in humans, Vizacta is not recommended for use in patients with known or suspected thyroid neoplasms or in patients with solid tumors of the breast, colon, or prostate.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-cell Tumors: Largiludil causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) in rats and mice. Largiludil-induced rodent thyroid tumors were not detected in rats and mice. A statistically significant increase in cancer was observed in rats receiving largiludil at 128 times clinical exposure (compared to controls). It is unknown whether largiludil will cause thyroid C-cell tumors in human beings, but epidemiological studies suggest that it may.

CONTRAINDICATIONS: Vizacta is contraindicated in patients with a family or personal history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).

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. The safety of Vizacta has been evaluated in a 52-week combination therapy trial and a 28-week combination therapy trial. The most common adverse reactions reported were hypoglycemia, nausea, vomiting, diarrhea, constipation, and rash.

Table 1: Adverse events reported in ≥5% of Vizacta-treated patients or ≥5% of glimepiride-treated patients: 52-week monotherapy trial

<table>
<thead>
<tr>
<th>Adverse Event Term</th>
<th>All Vizacta N = 497</th>
<th>Glimepiride N = 248</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>28.4</td>
<td>8.5</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>17.1</td>
<td>8.9</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Constipation</td>
<td>9.3</td>
<td>4.8</td>
</tr>
<tr>
<td>Respiratory Infection</td>
<td>9.5</td>
<td>5.6</td>
</tr>
<tr>
<td>Headache</td>
<td>9.1</td>
<td>9.3</td>
</tr>
<tr>
<td>Influenza</td>
<td>7.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>6.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>5.8</td>
<td>2.5</td>
</tr>
<tr>
<td>Sialorrhoea</td>
<td>5.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>5.7</td>
<td>2.2</td>
</tr>
<tr>
<td>Back Pain</td>
<td>5.0</td>
<td>4.4</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

Table 2: Adverse events reported in ≥5% of Vizacta-treated patients and occurring more frequently with Vizacta compared to placebo: 28-week combination therapy trials

<table>
<thead>
<tr>
<th>Adverse Event Term</th>
<th>All Vizacta N = 274</th>
<th>Placebo N = 121</th>
<th>Glimepiride + Metformin N = 242</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>15.2</td>
<td>4.1</td>
<td>3.3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>10.8</td>
<td>4.1</td>
<td>3.7</td>
</tr>
<tr>
<td>Headache</td>
<td>9.1</td>
<td>9.1</td>
<td>8.6</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6.0</td>
<td>0.6</td>
<td>0.0</td>
</tr>
</tbody>
</table>

ADDENDUM TO GP393:

Table 3: Adverse events reported in ≥5% of Vizacta-treated patients: 28-week combination therapy trials

<table>
<thead>
<tr>
<th>Adverse Event Term</th>
<th>All Vizacta N = 695</th>
<th>Placebo N = 469</th>
<th>Glimepiride + Metformin N = 695</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>7.5</td>
<td>1.8</td>
<td>2.6</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7.2</td>
<td>2.8</td>
<td>2.0</td>
</tr>
</tbody>
</table>

ADDENDUM TO GP394:

Table 4: Adverse events reported in ≥5% of Vizacta-treated patients: 28-week combination therapy trials

<table>
<thead>
<tr>
<th>Adverse Event Term</th>
<th>All Vizacta N = 695</th>
<th>Placebo N = 469</th>
<th>Glimepiride + Metformin N = 695</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>7.5</td>
<td>1.8</td>
<td>2.6</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7.2</td>
<td>2.8</td>
<td>2.0</td>
</tr>
</tbody>
</table>

ADDENDUM TO GP395:

Table 5: Adverse events reported in ≥5% of Vizacta-treated patients: 28-week combination therapy trials

<table>
<thead>
<tr>
<th>Adverse Event Term</th>
<th>All Vizacta N = 695</th>
<th>Placebo N = 469</th>
<th>Glimepiride + Metformin N = 695</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>7.5</td>
<td>1.8</td>
<td>2.6</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7.2</td>
<td>2.8</td>
<td>2.0</td>
</tr>
</tbody>
</table>
Add-on to Metformin + GlimiprIDE

Table 3: Treatment-Emergent Adverse Events in 26 Week Open-Label Trial versus Exenatide (Adverse events with frequency ≥5% and occurring more frequently with Victoz® compared to exenatide are listed)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Victoz© Treatment</th>
<th>Active Comparator</th>
<th>Placebo Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>12.5%</td>
<td>12.1%</td>
<td>12.1%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>9.5%</td>
<td>9.5%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Constipation</td>
<td>5.1%</td>
<td>5.1%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

Gastrointestinal adverse events: In the five clinical trials of 26 weeks duration or longer for the presence of a specific gastrointestinal adverse event at the end of treatment. The treatment differences are not significant within 2% of patients.

Table 4: Incidence (%) and Rate (episodes/patient year) of Hypoglycemia in the 52-Week Monotherapy Trial and in the 26-Week Combination Therapy Trials

<table>
<thead>
<tr>
<th>Monotherapy</th>
<th>Victoz© (N=497)</th>
<th>GlimiprIDE (N=248)</th>
<th>Placebo (N=175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient able to self-treat</td>
<td>97.0 (2.24)</td>
<td>25.0 (1.06)</td>
<td>---</td>
</tr>
<tr>
<td>Not classified</td>
<td>1.2 (0.03)</td>
<td>2.4 (0.04)</td>
<td>---</td>
</tr>
<tr>
<td>Add-on to Metformin</td>
<td>Victoz® + Metformin (N=724)</td>
<td>Glimepiride + Metformin (N=242)</td>
<td>Placebo + Metformin (N=112)</td>
</tr>
<tr>
<td>Patient able to self-treat</td>
<td>0.1 (0.001)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not classified</td>
<td>3.6 (0.05)</td>
<td>22.3 (0.87)</td>
<td>25.0 (0.06)</td>
</tr>
<tr>
<td>Add-on to GlimiprIDE</td>
<td>Victoz® + GlimiprIDE (N=256)</td>
<td>Rosiglitazone + GlimiprIDE (N=145)</td>
<td>Placebo + GlimiprIDE (N=112)</td>
</tr>
<tr>
<td>Patient able to self-treat</td>
<td>0.1 (0.003)</td>
<td>4.0 (0.12)</td>
<td>25.0 (0.07)</td>
</tr>
<tr>
<td>Not classified</td>
<td>7.5 (0.38)</td>
<td>4.3 (0.12)</td>
<td>25.0 (0.07)</td>
</tr>
<tr>
<td>Add-on to Metformin + Rosiglitazone</td>
<td>Victoz® + Metformin + Rosiglitazone (N=325)</td>
<td>Placebo + Metformin + Rosiglitazone (N=175)</td>
<td></td>
</tr>
<tr>
<td>Patient able to self-treat</td>
<td>7.2 (0.49)</td>
<td>---</td>
<td>4.0 (0.15)</td>
</tr>
<tr>
<td>Not classified</td>
<td>0.5 (0.01)</td>
<td>---</td>
<td>1.1 (0.03)</td>
</tr>
<tr>
<td>Add-on to Metformin + GlimiprIDE</td>
<td>Victoz® + Metformin + GlimiprIDE (N=230)</td>
<td>Placebo + Metformin + GlimiprIDE (N=114)</td>
<td></td>
</tr>
<tr>
<td>Patient able to self-treat</td>
<td>2.2 (0.06)</td>
<td>26.5 (0.16)</td>
<td>16.0 (0.08)</td>
</tr>
<tr>
<td>Not classified</td>
<td>27.4 (0.16)</td>
<td>25.0 (0.16)</td>
<td>17.0 (0.04)</td>
</tr>
</tbody>
</table>

In a pooled analysis of clinical trials, the incidence rate (per 1,000 patient-years) for malignant neoplasms (based on investigational reports, medical history, pathology reports, and surgical reports from both blinded and open-label study periods) was 10.3 for Victoz®, 6.5 for placebo, and 7.2 for active comparator. After excluding papillary thyroid carcinoma events (see Adverse Reactions), no papillary cancer cell type predominate within the set of malignant neoplasms. Data was reported beyond 1 year of exposure to study medication, six events among Victoz®-treated patients (4 colon, 1 prostate and 1 nasopharyngeal), no events with placebo and one event with active comparator (colon). Causality has not been established for all malignant events. In the clinical trials, approximately 25% of patients on exenatide achieved at least 70% reduction in elevated serum bilirubin concentrations (equivalents to no more than twice the upper limit of the reference range) occurred in 4.0% of Victoz®-treated patients, 2.1% of placebo-treated patients and 3.5% of active-comparator-treated patients. This finding was not accounted for by abnormalities in liver enzymes. The occurrence of this clinical finding is unknown. Peripheral Neuropathy: The following adverse reactions have been reported during (post-approval) use of Victoz®. Because these events 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. Gastrointestinal: nausea, vomiting and diarrhea sometimes resulting in dehydration (see Warnings and Precautions).

OVERDOSAGE: In a clinical trial, one patient with type 2 diabetes experienced a single overdose of Victoz® 17 mg, resulting in 201 times the maximum recommended dose. Effects of the overdose included severe nausea and vomiting requiring hospitalization. No hypoglycemia was reported. The patient recovered without complications. In the event of overdose, appropriate supportive treatment should be initiated according to the patient’s clinical signs and symptoms.

More detailed information is available upon request.

For information about Victoz® contact: Novo Nordisk Inc., 100 College Road West, Princeton, New Jersey 08540, 1-877-404-2869

Data of Issue: May 18, 2011

Version: 3

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

Victoz® is a registered trademark of Novo Nordisk A/S. "Victoz®" is covered by US Patent Nos. 6,288,983, 6,459,924, and 7,325,627 and other patents pending. Victoz® Pen is covered by US Patent Nos. 6,004,261, 6,356,044, 6,362,404 and other patents pending.

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Liraglutide (Liraglutide) (dNOMa) injection
(FLPs) and limited liability companies (LLCs). These tools will provide good asset protection against future lawsuits, allow for maintenance of control by the physician, and can provide income and estate tax benefits in certain situations.

These tools generally will keep a creditor outside the structure through “charging order” protections. These protections typically enable a physician to create enough of a hurdle against creditors to negotiate a favorable settlement. FLPs and LLCs are therefore often referred to as the building blocks of a basic asset protection plan. Advisors may also layer in domestic irrevocable trusts, such as life insurance trusts or charitable remainder trusts.

These tools will provide adequate asset protection, raising the physician’s asset protection score to +2. Obviously, their asset protection benefits depend upon proper drafting of the documentation, proper maintenance and respect for formalities, and proper ownership arrangements. If all these are in place, the physician can enjoy basic asset protection for a relatively low cost.

**Taking Protection Further**

For many physicians, a basic asset protection plan, which has some potential vulnerability, is not good enough. A +2 on their asset protection score is not enough to give them the psychological comfort they want. Other physicians realize that the best protection comes from tools that actually can help them create wealth. These physicians utilize advanced structures to put themselves at a +4 or +5, the ultimate asset protection score. Like a physician prescribing the best medicine or using the most effective surgical procedure, asset protection consultants rely on a number of tools to provide ultimate asset protection. These include qualified retirement plans, non-qualified and fringe benefit plans, captive insurance companies (CICs), and funding of exempt assets.

A qualified retirement plan complies with certain Department of Labor and Internal Revenue Service rules. Qualified retirement plans include pension plans, profit sharing plans, money purchase plans, 401(k)s, and 403(b)s. Under federal bankruptcy law, and under nearly every state’s law, these plans are totally protected against lawsuits and creditor claims, enjoying +5 protection status.

Non-qualified plans and fringe benefit plans allow a physician to put funds away at the practice level and enjoy them in retirement. These types of plans can be used in addition to qualified plans. In many states, these can be funded by exempt (+5) asset classes. Even in states where there is no (+5) exemption, a (+2) LLC can typically be used to provide a solid level of protection.

When using a CIC, the owners of a medical practice actually create their own properly licensed insurance company to insure all types of risks that might be incurred in the practice. CICs can cover economic risks (drops in reimbursement), business risks (destroyed electronic medical records), litigation risks (coverage for defense of harassment claims or Health Care Financing Administration audits), and medical malpractice risks (keeping some risk in the CIC and reinsuring the rest). To maximize the protection of the CIC, many physicians establish trusts to own the CIC.

Under each state’s laws, certain assets are absolutely exempt from creditor claims, thereby achieving a +5 status. Many states provide unlimited exemptions for cash within life insurance policies, annuities, and primary homes. Physicians should seek an advisor to help find out the exemptions in their states, and distribute their funds accordingly.

Asset protection planning, like any sophisticated multidisciplinary effort, is a matter of degree. Nothing in life is 100% certain. For asset protection planning, this adage holds true. When initiating an asset protection plan, physicians should make sure they understand the costs and benefits associated with the various tools employed. These tools will help physicians not only protect the wealth they have already built, but may assist them in building greater after-tax wealth for retirement and beyond. Remember to consult with a qualified financial advisor to begin planning your strategy.

---

**Practices’ Assets, Not Personal Assets, Are Most Vulnerable to Lawsuit**

The first misconception most physicians have is that they should only protect their personal assets from potential lawsuits. Nothing could be further from the truth. The practice’s assets are actually the most vulnerable to lawsuits, especially in a group practice. That is because any malpractice claim or employee claim against any of the doctors threatens all of the assets of the practice. In other words, a physician in a group practice is underwriting all the acts and omissions of all his or her partners, to the extent of his or her practice’s assets.

—DM
Affordable Care Act Elicits Largely Negative Reactions From Young Physicians

The future of the U.S. health care system is bleak, according to most young physicians surveyed by The Physicians Foundation (www.physiciansfoundation.org), a Boston, Mass.-based nonprofit organization that promotes the work of practicing physicians and improves health care quality through grants and research. The survey also assessed young physicians’ satisfaction with their current practice arrangement.

**Telling Numbers**

Of the 500 physicians surveyed (40 years of age and younger), the majority (57%) say they are pessimistic about the future of the U.S. health care system (Figure 1, page 16). Of those, more than 30% identified themselves as highly pessimistic. Twenty-one percent of the physicians are neutral about the future of U.S. health care, while 22% are optimistic—with only 4% saying they are highly optimistic. While reasons for the considerable pessimism vary, new health care legislation tops the list, with more than twice as many respondents (49%) thinking the Patient Protection and Affordable Care Act (PPACA) will hurt their practices compared with those who think it will have a positive effect (23%). The PPACA, upheld as constitutional by the U.S. Supreme Court on June 28, 2012, has been hailed as President Barack Obama’s signature domestic policy achievement. In stark contrast with their overwhelmingly pessimistic views regarding the future of the U.S. health care system, most young physicians (80%) are satisfied with their current practice arrangement. Thirty-five percent of physicians surveyed are highly satisfied, and 45% are somewhat satisfied, the survey found. Most respondents expect to remain with their current practice for at least the next eight years (52%) and, not surprisingly, many young physicians (39%) desire some form of ownership position within their current practice in the near future. “I feel like I could run my own practice better than it is being run by my boss, the current owner,” said one respondent.

Although satisfaction was relatively high across all practice groups, the survey revealed some differences among these subsets. For example, hospital-based physicians anticipate shorter tenures (≤2 years) compared with the other practice groups surveyed. Hospital-based physicians also tend to be part of larger group practices, a practice arrangement preferable to only 12% of respondents. They are significantly more likely to consider changing their current arrangement (43%) compared with primary care physicians (23%) and medical/surgical office-based physicians (27%), suggesting a higher level of dissatisfaction compared with the other groups. Money is the most important factor in the choice of practice arrangement, and in the decision to change practice arrangement, according to the survey. Most respondents (65%) cited income/cash flow as prominent in their workplace decision. More than half of young physicians (53%) considered employment security in their practice choice. However, 25% of physicians said they took the only job available.

Regardless of practice type, young physicians declared that they would like to have some form of ownership in their practice. Among the total sample, 26% currently have an ownership position, and 39% aspire to such a position. Of those who have changed or considered changing their practice arrangement, 10% cited the need for autonomy. “I considered changing due to [the] desire to be a partner-owner and work for myself,” said one respondent. Financial and economic issues, however, remained the most compelling reason (31% of respondents) for switching—or contemplating switching—practices.

**A Troubling Trend**

The level of pessimism identified by the survey is both “surprising” and “troubling,” says Lou Goodman, PhD, president of The Physicians Foundation and chief executive officer of the Texas Medical Association. “One would think the level of pessimism would be low, given how much effort and time they have put into it, and the best and brightest students are still going into medicine,” Goodman says. “What I think they find is that their expectations aren’t being met. And if these doctors are pessimistic, and they have gone through all this incredible training and feel their expectations are not being met, we have a national problem. Already, we have a shortage of 150,000 primary care physicians, and then we will have 30 million more [insured patients] from the [ACA]. We will need more doctors.”

Self-identified optimists cited their reasons for being optimistic, too. These included better patient care, better
HEALTH CARE TRENDS

HEALTH CARE REFORM CONTINUES TO FACE OBSTACLES

The Affordable Care Act (ACA) may have leaped a hurdle when the U.S. Supreme Court judged the health care reform legislation to be constitutional on June 28, but it may face its biggest challenge yet, according to an article in the July 2, 2012 issue of the New England Journal of Medicine. With the November 6 presidential and congressional elections looming, the fate of the ACA hangs in the balance. In fact, one of the fears of young U.S. physicians, captured by a survey conducted by The Physicians Foundation, is that the ACA will be overturned by the next U.S. president. “I feel the next president will reverse Obamacare,” said one respondent.

“The policy consequences of the election will be most immediately and compellingly felt in connection with health care reform,” says John E. McDonough, DrPH, the author of the New England Journal of Medicine article. “In January 2013, if Democrats hold the White House and Senate and regain control of the House, the ACA will be implemented mostly as constructed. If Republicans capture the White House and Senate and retain House control, the ACA will face major deconstruction in 2013,” he says.

In the meantime, the positive Supreme Court ruling allows for the continued implementation of health care innovations such as accountable care organizations, patient-centered medical homes, the Prevention and Public Health Fund, the Patient-Centered Outcomes Research Institute, and stateoptional Medicaid expansion—an option on which some Republican governors have faded. However, attractive financial incentives are expected to entice a number of states to expand Medicaid. The federal government plans to subsidize Medicaid expansion 100% between 2014 and 2016, and then no less than 90% by 2020—a considerably more magnanimous offer than past federal contributions ranging from 53% to 83%.

Most states have yet to determine whether they will assist consumers and small businesses in purchasing health care coverage, or whether they will rely on the federal government for assistance. For many states, this decision will rest on the outcomes of the November elections—specifically, whether the ACA survives beyond January. If so, McDonough notes that many states will develop their own exchanges in lieu of ceding insurance markets to the federal government.

The magnitude of the ACA is largely unappreciated, according to McDonough. “The ACA is the first U.S. law to attempt comprehensive reform touching nearly every aspect of our health system,” he says. Unfortunately, the current political climate is not a collaborative one. “Perhaps we will still get there, as the Supreme Court ruling begins to recede in the rearview mirror and the dust from the November elections settles. For now, there are still many obstacles ahead.”

—SC

Looking Forward

“With the Supreme Court’s decision to keep the PPACA intact, policy makers must now address the ongoing challenges faced by America’s physicians and their patients,” notes Goodman. “From the very beginning of the health care debate, The Physicians Foundation unequivocally stated that physicians need to be included in the formulation of any legislation that carries such significant implications. Specific issues, such as widespread physician shortages and substantial burdens related to running

Continued on page 16

Not surprisingly, many young physicians (39%) desire some form of ownership position within their current practice in the near future.

health care accessibility, and other general health care improvements, with no one reason standing out. However, even the optimists’ responses often had negative undertones. When asked, “Why do you feel optimistic about the future of the U.S. health care system?” some of the responses were: “It has to get better,” and, “It can’t get any worse.”

One respondent said, “I am mostly optimistic but have pessimism towards Congress and the public’s ability to enact decent change and regulation.” Another optimist said, “I am concerned about the efforts and actions of those in Washington [who are] more worried about [themselves] than the current health care system, which is very broken right now.”

For unknown reasons, primary care physicians (n=250) tend to be significantly less negative about the impact of the PPACA compared with members of the other practice types identified in the survey: medical/surgical office-based specialists (n=175) and hospital-based specialists (n=75). Twenty percent of primary care physicians identified themselves as somewhat positive about the effects of the PPACA on their practices, compared with only 8% of hospital-based physicians. Thirty-two percent of hospital-based physicians say they are somewhat negative about the new health system reform legislation compared with 18% of primary care physicians and 21% of medical/surgical office-based physicians. Regarding the future of the U.S. health care system in general, primary care physicians are significantly more optimistic overall (27% of respondents) compared with medical/surgical office-based physicians (16% of respondents).

Continued on page 16
For your patients with type 2 diabetes who need more than A1C control, choose Levemir® (insulin detemir [rDNA origin] injection)

24/7 GLUCOSE CONTROL

Karen’s doctor said taking Levemir® (insulin detemir [rDNA origin] injection) once-daily may get her the control she needs & more

Low rates of hypoglycemia

In 1 study, approximately 45% of patients in each treatment arm achieved A1C <7% with no hypoglycemic events within the last 4 weeks of observation.¹

- A single major hypoglycemic event was reported in the 70-90 mg/dL group; no major hypoglycemic events in the 80-110 mg/dL group.
- Minor hypoglycemia rates were 5.09 (70-90 mg/dL) and 3.16 (80-110 mg/dL) per patient-year*.

Covered on more than 90% of managed care plans².

Indications and Usage

Levemir® (insulin detemir [rDNA origin] injection) is indicated to improve glycemic control in adults and children with diabetes mellitus.

Important Limitations of Use:
Levemir® is not recommended for the treatment of diabetic ketoacidosis. Intravenous rapid-acting or short-acting insulin is the preferred treatment for this condition.

Important Safety Information

Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Do not dilute or mix Levemir® with any other insulin solution, or use in insulin infusion pumps. Do not administer Levemir® intravenously or intramuscularly because severe hypoglycemia can occur.

Hypoglycemia is the most common adverse reaction of insulin therapy, including Levemir®. The timing of hypoglycemia usually reflects the time action profile of the administered insulin formulations. Glucose monitoring is essential for all patients receiving insulin therapy. Any changes to an insulin regimen should be made cautiously and only under medical supervision.

Needles and Levemir® FlexPen® must not be shared.

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including Levemir®. Adverse reactions associated with Levemir® include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, rash and pruritus. Careful glucose monitoring and dose adjustments of insulin, including Levemir®, may be necessary in patients with renal or hepatic impairment.

Levemir® has not been studied in children with type 2 diabetes, and in children with type 1 diabetes under the age of six.

Please see brief summary of Prescribing Information on adjacent page.

Needles are sold separately and may require a prescription in some states.


*Minor=SMG<56 mg/dL and not requiring third-party assistance.

² Intended as a guide. Lower acquisition costs alone do not necessarily reflect a cost advantage in the outcome of the condition treated because other variables affect relative costs. Formulary status is subject to change.


*Minor=SMG<56 mg/dL and not requiring third-party assistance.

² Intended as a guide. Lower acquisition costs alone do not necessarily reflect a cost advantage in the outcome of the condition treated because other variables affect relative costs. Formulary status is subject to change.

Levemir® FlexPen®
insulin detemir (rDNA origin) injection
LEVEMIR® (insulin detemir [rDNA origin] injection)

Rx ONLY

BRIEF SUMMARY: Please consult package insert for full prescribing information.

INDICATIONS AND USAGE: LEVEMIR® is indicated to improve glycemic control in adults and children with diabetes mellitus. Importantly, LEVEMIR® is not recommended for the treatment of diabetic ketoacidosis. Intravenous rapid-acting or short-acting insulin is the preferred treatment for this condition.

CONTRAINDICATIONS: LEVEMIR® is contraindicated in patients with hypersensitivity to LEVEMIR® or any of its excipients. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS: Dosage adjustment and monitoring: Glucose monitoring is essential for all patients receiving insulin therapy. Changes to an insulin regimen should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a dosage adjustment. In the presence of insulin resistance, the dosage of insulin may have to be increased to achieve adequate glycemic control.

Administration: LEVEMIR® should only be administered subcutaneously. Do not administer LEVEMIR® intravenously or intramuscularly. The intended duration of activity of LEVEMIR® is dependent on injection into subcutaneous tissue. Intravenous or intramuscular administration of the usual subcutaneous dose could result in severe hypoglycemia. Do not use LEVEMIR® in insulin infusion pumps. Do not dilute or mix LEVEMIR® with any other insulin or solution. If LEVEMIR® is diluted or mixed, the pharmacokinetic or pharmacodynamic profile (e.g., onset of action, peak time, duration) of LEVEMIR® and the mixed insulin may be altered in an unpredictable manner. Hypoglycemia: Hypoglycemia is the most common adverse reaction of insulin therapy, including LEVEMIR®. The risk of hypoglycemia increases with intensive glycemic control. Patients must be educated to recognize and manage hypoglycemia. Severe hypoglycemia can lead to unconsciousness or convulsions and may result in temporary or permanent impairment of brain function or death. Severe hypoglycemia requiring assistance of another person or parenteral glucose infusion, or glucagon administration has been observed in clinical trials with insulin, including trials with LEVEMIR®. The timing of hypoglycemia usually reflects the time-action profile of the administered insulin formulations. Other factors such as changes in food intake (e.g., amount of food or timing of meals), exercise, and concurrent medications may also alter the risk of hypoglycemia. The prolonged effect of LEVEMIR® may alter the risk of hypoglycemia. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long-standing diabetes, diabetic neuropathy, use of medications such as beta-blockers, or intensified glycemic control. These settings may result in severe hypoglycemia, also, loss of consciousness) prior to the patient's awareness of hypoglycemia. Hypersensitivity and allergic reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including LEVEMIR®. Renal Impairment: No difference was observed in the pharmacokinetics of insulin detemir between non-diabetic individuals with renal impairment and healthy volunteers. However, some studies with human insulin have shown increased circulating insulin concentrations in patients with renal impairment. Careful glucose monitoring and dose adjustments of insulin, including LEVEMIR®, may be necessary in patients with renal impairment. Hepatic Impairment: No studies have been conducted specifically in hepatic impairment. Careful glucose monitoring and dose adjustments of insulin, including LEVEMIR®, may be necessary in patients with hepatic impairment.

ADVERSE REACTIONS: The following adverse reactions are discussed elsewhere: Hypoglycemia; Hypersensitivity and allergic reactions. Clinical trial experience: Because clinical trials are conducted under widely varying designs, the adverse reaction rates reported in one clinical trial may not be easily compared to those rates reported in another clinical trial, and may not reflect the rates actually observed in clinical practice. The frequency of adverse reactions (excluding hypoglycemia) reported during LEVEMIR® clinical trials in patients with type 1 diabetes mellitus and type 2 diabetes mellitus are listed in Tables 1-4 below. See Tables 5 and 6 for the hypoglycemia findings.

**Table 1: Adverse reactions (excluding hypoglycemia) in two pooled clinical trials of 16 weeks and 24 weeks duration in adults with type 1 diabetes (adverse reactions with incidence ≥5%)**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>LEVEMIR®, % (n = 767)</th>
<th>NPH, % (n = 388)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>26.1</td>
<td>21.4</td>
</tr>
<tr>
<td>Headache</td>
<td>22.6</td>
<td>22.7</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>9.5</td>
<td>8.0</td>
</tr>
<tr>
<td>Influenza-like illness</td>
<td>7.8</td>
<td>7.0</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>6.0</td>
<td>2.6</td>
</tr>
</tbody>
</table>

**Table 2: Adverse reactions (excluding hypoglycemia) in a 26-week trial comparing insulin aspart + LEVEMIR® to insulin aspart + insulin glargine in adults with type 1 diabetes (adverse reactions with incidence ≥5%)**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>LEVEMIR®, % (n = 161)</th>
<th>Glargine, % (n = 159)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>26.7</td>
<td>32.1</td>
</tr>
<tr>
<td>Headache</td>
<td>14.3</td>
<td>19.5</td>
</tr>
<tr>
<td>Back pain</td>
<td>8.1</td>
<td>6.3</td>
</tr>
<tr>
<td>Influenza-like illness</td>
<td>6.2</td>
<td>8.2</td>
</tr>
<tr>
<td>Gastritis</td>
<td>5.6</td>
<td>4.4</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>5.0</td>
<td>1.9</td>
</tr>
</tbody>
</table>

**Table 3: Adverse reactions (excluding hypoglycemia) in two pooled clinical trials of 22 weeks and 24 weeks duration in adults with type 2 diabetes (adverse reactions with incidence ≥5%)**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>LEVEMIR®, % (n = 432)</th>
<th>NPH, % (n = 437)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>12.5</td>
<td>11.2</td>
</tr>
<tr>
<td>Headache</td>
<td>6.5</td>
<td>5.3</td>
</tr>
</tbody>
</table>

**Table 4: Adverse reactions (excluding hypoglycemia) in a 26-week clinical trial of children and adolescents with type 1 diabetes (adverse reactions with incidence ≥5%)**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>LEVEMIR®, % (n = 232)</th>
<th>NPH, % (n = 115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>35.8</td>
<td>42.6</td>
</tr>
<tr>
<td>Headache</td>
<td>31.0</td>
<td>32.2</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>17.2</td>
<td>20.9</td>
</tr>
<tr>
<td>Gastritis</td>
<td>16.8</td>
<td>11.3</td>
</tr>
<tr>
<td>Influenza-like illness</td>
<td>13.8</td>
<td>20.9</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>13.4</td>
<td>13.0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>10.3</td>
<td>6.1</td>
</tr>
<tr>
<td>Cough</td>
<td>8.2</td>
<td>4.3</td>
</tr>
<tr>
<td>Viral infection</td>
<td>7.3</td>
<td>7.6</td>
</tr>
<tr>
<td>Nausea</td>
<td>6.5</td>
<td>7.0</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>6.5</td>
<td>3.5</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6.5</td>
<td>10.4</td>
</tr>
</tbody>
</table>

Hypoglycemia: Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including LEVEMIR®. Tables 5 and 6 summarizes the incidence of severe and non-severe hypoglycemia in the LEVEMIR® clinical trials. Severe hypoglycemia was defined as an event with symptoms consistent with hypoglycemia requiring assistance of another person and associated with either a blood glucose below 50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose or glucagon administration. Non-severe hypoglycemia was defined as an asymptomatic or symptomatic plasma glucose < 56 mg/dL (≤50 mg/dL).
## Table 5: Hypoglycemia in Patients with Type 1 Diabetes

<table>
<thead>
<tr>
<th></th>
<th>Study A</th>
<th>Study B</th>
<th>Study C</th>
<th>Study D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type 1 Diabetes</td>
<td>Type 1 Diabetes</td>
<td>Type 1 Diabetes</td>
<td>Type 1 Diabetes</td>
</tr>
<tr>
<td></td>
<td>Adults</td>
<td>16 weeks</td>
<td>Adults</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>Percent of patients</td>
<td>Twice-Daily LEVEMIR®</td>
<td>Twice-Daily LEVEMIR®</td>
<td>Once-Daily LEVEMIR®</td>
<td>Once-Twice Daily LEVEMIR®</td>
</tr>
<tr>
<td>with at least 1 event (incidence N)</td>
<td>8.7 (24/276)</td>
<td>10.6 (14/132)</td>
<td>5.0 (8/161)</td>
<td>7.5 (37/491)</td>
</tr>
<tr>
<td></td>
<td>Twice-Daily LEVEMIR®</td>
<td>Once-Daily LEVEMIR®</td>
<td>Once-Daily LEVEMIR®</td>
<td>Twice-Daily LEVEMIR®</td>
</tr>
<tr>
<td></td>
<td>10.1 (16/159)</td>
<td>0.31 (3/101)</td>
<td>10.2 (26/256)</td>
<td>0.32 (2/64)</td>
</tr>
<tr>
<td>Event/patient/year</td>
<td>0.52</td>
<td>0.43</td>
<td>0.13</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>0.38</td>
<td>0.13</td>
<td>0.31</td>
<td>0.90</td>
</tr>
</tbody>
</table>

## Table 6: Hypoglycemia in Patients with Type 2 Diabetes

<table>
<thead>
<tr>
<th></th>
<th>Study E</th>
<th>Study F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type 2 Diabetes</td>
<td>Type 2 Diabetes</td>
</tr>
<tr>
<td></td>
<td>Adults</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Percent of patients</td>
<td>Twice-Daily LEVEMIR®</td>
<td>Twice-Daily LEVEMIR®</td>
</tr>
<tr>
<td>with at least 1 event (incidence N)</td>
<td>0.4 (1/237)</td>
<td>2.5 (6/238)</td>
</tr>
<tr>
<td></td>
<td>2.5 (6/238)</td>
<td>1.5 (3/205)</td>
</tr>
<tr>
<td>Event/patient/year</td>
<td>0.01</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>0.01</td>
<td>0.08</td>
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### Insulin Initiation and Intensification of Glucose Control

Intensification or rapid improvement in glucose control has been associated with a transient, reversible ophthalmologic refractive disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy. Lipodystrophy: Long-term use of insulin, including LEVEMIR®, can cause lipodystrophy at the site of repeated insulin injections. Lipodystrophy includes lipoatrophy (thinning of adipose tissue) and lipoatrophy (thinning of adipose tissue), and may affect insulin adsorption. Rotate insulin injection sites within the same region to reduce the risk of lipodystrophy. Weight Gain: Weight gain can occur with insulin therapy, including LEVEMIR®, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria. Peripheral Edema: Insulin, including LEVEMIR®, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Allergic Reactions: Local Allergy: As with any insulin therapy, patients taking LEVEMIR® may experience injection site reactions, including localized erythema, pain, pruritus, urticaria, edema, and inflammation. In clinical studies in adults, three patients treated with LEVEMIR® reported injection site pain (0.25%) compared to one patient treated with NPH insulin (0.12%). The reports of pain at the injection site did not result in discontinuation of therapy. Rotation of the injection site within a given area from one injection to the next may help to reduce or prevent these reactions. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique. Most minor reactions to insulin usually resolve in a few days to a few weeks. Systemic Allergy: Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including LEVEMIR®, and may be life-threatening. Antibody Production: All insulin products can elicit the formation of insulin antibodies. These insulin antibodies may increase or decrease the efficacy of insulin and may require adjustment of the insulin dose. In phase 3 clinical trials of LEVEMIR®, antibody development has been observed with no apparent impact on glycemic control. Postmarketing experience: The following adverse reactions have been identified during post approval use of LEVEMIR®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Medication errors have been reported during post-approval use of LEVEMIR® in which other insulin, particularly rapid-acting or short-acting insulins, have been accidentally administered instead of LEVEMIR®. To avoid medication errors between LEVEMIR® and other insulins, patients should be instructed always to verify the insulin label before each injection.

For more detailed information, please visit: [LEVEMIR® Information Page](https://www.novonordisk.com/levemir).
medical practices, continue to be areas of concern that have not been addressed by policy makers.”

“Regardless of the Court’s decision, significant health care reform is already well underway in this country. As the landscape changes due to marketplace forces as well as government policies, The Physicians Foundation stands ready to offer its knowledge, informational resources, and perspectives to meet the needs of patients and physicians,” Goodman concludes.


—Reported and written by Stacy Clapp, in Orangeburg, N.Y.

**HEALTH CARE TRENDS**

Continued from page 12

**FIGURE 1. YOUNG PHYSICIANS’ PERCEPTION OF THE IMPACT OF THE AFFORDABLE CARE ACT**

How do you feel the Affordable Care Act will affect your practice?

- Highly positive: 6%
- Somewhat positive: 21%
- Neutral: 28%
- Somewhat negative: 29%
- Highly negative: 17%

**YOUNG PHYSICIANS VOICE DOUBTS OVER THE FUTURE OF U.S. HEALTH CARE**

Fears about excessive and/or botched government involvement and an overriding emphasis on the bottom line rather than on the quality of patient care are recurring concerns expressed by young physicians with negative outlooks regarding the future of U.S. health care, according to a survey conducted by The Physicians Foundation. Other concerns include increased regulatory burdens and medical liability insurance premiums. Comments from the physicians surveyed included the following:

- “I don’t trust government to do the right thing for patients and physicians or to enact lasting improvements.”
- “The U.S. health care system isn’t concerned about the employees or patients; they’re just concerned about the money.”
- “Government control is a recipe for disaster. They cannot run a business and cannot control expenses. How could they do a good job on health care? It is a real joke!”
- “Government-controlled health care will be the downfall. Anyone who has worked in a government environment such as [Veterans Affairs (VA)] would know this—ask any vet who receives their care through VA how good the system is!”
- “The current administration is only concerned with money and maintaining their power and socialism.”
- “Government regulation has too many strings attached. It will bankrupt the country. [We are] pushing toward socialist medicine.”
- “I do not feel optimistic because of all the increased regulatory burdens on physicians. There will be an increased shortage of physicians to provide primary care and decreased access to care.”
- “The very reasons why people come to the U.S. to obtain care (research, quality, availability, cutting edge, good physicians, etc.) are being taken away one at a time. The changes that are being made are not made with the patient in mind, but with the ‘bottom line’ economically in mind. Not once is the patient mentioned in all these changes.”
- “I think the government is destroying health care.”
- “Large amounts of money are being spent on things outside actual health care; CEO bonuses, pharmaceuticals, malpractice insurance premiums, lawyers, etc. This, accompanied by the new ‘Customer Service’ initiatives that reward physicians who practice bad medicine, is clouding the future of medicine.”
- “Physicians have no say; rather, insurance companies dictate care. The focus is saving money for insurance companies, not patient care.”

—SC
Physicians who use electronic health records (EHRs) are less likely to be sued for malpractice compared with those who use paper records, suggests a study published in the June 25, 2012 issue of Archives of Internal Medicine. Investigators reported an approximate six-fold reduction in the rate of malpractice claims when EHRs were used instead of paper medical records.

Collecting Data
The study authors collected and examined closed-claims data for the years 1995-2007 from 275 physicians insured by a Massachusetts malpractice insurer, as well as 189 random sample surveys collected from Massachusetts physicians in 2005 and 2007. Because the study was conducted over a long period of time, a number of practices adopted EHRs during the study period, allowing for both pre-EHR and post-EHR assessment. Of the 189 physicians surveyed, 14.3% reported at least one malpractice claim in 2005 or 2007, the report says. The closed-claims data showed that 12% of 275 physicians from multiple surgical and medical specialties had 51 unique claims during those same time periods, it says. Notably, 49 of those claims occurred before the adoption of EHRs; only two claims were made after EHR adoption, neither of which resulted in a payment, the report says.

Results were most notable in general surgery and internal medicine, the practice specialties that saw the highest number of pre-EHR claims (13 and eight, respectively) in this study. After EHR adoption, no malpractice claims were made in general surgery, and only one (which did not result in payment) in internal medicine, the report says.

"By examining all closed claims, rather than only those for which a payment was made, our findings suggest that a reduction in errors is likely responsible for at least a component of this association, since the absolute rate of claims was lower post-EHR adoption," say the investigators.

Other factors may partially explain the observation of fewer malpractice claims following the implementation of an EHR. For example, physicians who are early adopters of new technology may practice medicine in a way that makes them less likely to incur malpractice claims, the study authors suggest. Or, use of other electronic platforms besides an EHR may contribute to a lower incidence of malpractice claims, they say.

However, this recent study supports and amplifies the conclusions of prior studies by the same authors, suggesting the potential of EHRs to lower the risk of paid claims among physicians using EHRs. The investigators’ prior research failed to show a causative relationship between EHR adoption and paid malpractice claims. It also lacked the power to determine whether the actual rate of claims was attributable to EHR adoption or to proportionately fewer claims leading to payment.

Additional EHR Benefits
These data add to a growing body of research showing other merits of EHRs, including enhanced documentation, increased efficiency of office visits, and better tracking and management of patients. It has been speculated that a reduction in medical errors (and possible associated malpractice claims) could be another boon of EHR adoption. Such a system can help address some of the problems that may lead to medication errors, such as difficulty accessing patient information in a timely manner, suboptimal prescribing practices, and nonadherence to clinical guidelines.

"Implementation of EHRs may reduce malpractice claims and, at the least, appears not to increase claims as providers adapt to using EHRs," the study authors write. "The reduction in claims seen in this study among physicians who adopted EHRs lends support to the push for widespread implementation of health information technology," they conclude. The full report can be viewed at http://archinte.jamanetwork.com/article.aspx?articleid=1203517.

—Reported and written by Stacy Clapp, in Orangeburg, N.Y.
The American College of Physicians (ACP; www.acponline.org) and the Society of General Internal Medicine (SGIM; www.sgim.org) explore the ethical dimensions of the patient-centered medical home (PCMH) in a new position paper published by the Journal of General Internal Medicine: “The Patient-Centered Medical Home: An Ethical Analysis of Principles and Practice.” The text is also available on ACP’s website.

In the paper, ACP and SGIM examine how the PCMH meets four fundamental ethical principles by facilitating a patient-centered approach to care, which reaffirms the core principles of medical ethics and professionalism; access to a personal physician who provides coordinated, comprehensive care through an integrated team; involvement of patients, families, and caregivers in care, thereby supporting respect for patient wishes and autonomy; and practice-based system improvement and explicit attention to quality.

The organizations also note practical barriers to meeting some goals. For example, access to a personal physician responsible for coordination of care presents a challenge because of the shortage of primary care physicians.

ACP and SGIM say that the PCMH strongly supports the “bedrock principle” of patient autonomy because the concept of patient-centeredness that forms its foundation emphasizes patient engagement, provision of health information to patients, and involvement of patients in shared decision making. By integrating system improvements into the practice environment, the PCMH could help physicians meet the ethical obligations for quality improvement and patient safety, ACP and SGIM say.

Physicians reported modest shifts in compensation in 2011, according to respondents to the Medical Group Management Association (MGMA) Physician Compensation and Production Survey: 2012 Report Based on 2011 Data. For example, primary care physicians reported a 5.16% increase in median compensation. Physicians in family practice (without OB) reported median earnings of $200,114, and those in pediatric/adolescent medicine earned $203,948 in median compensation. Internists also reported a 5% increase in compensation.

This year’s report provides data on more than 62,000 providers and includes data for providers in more than 170 specialties. The report also contains various performance ratios illustrating the relationship between compensation and production and data on collections for professional charges and work RVUs.

The full report is available for purchase at http://tinyurl.com/7y5r33w.
Aetna Adapts to Changing Market by Embracing ACO Model

As a result of the Affordable Care Act, over 5.2 million seniors and patients with disabilities have saved over $3.9 billion on prescription drugs since the law was enacted. The Centers for Medicare & Medicaid Services on July 25 also released data showing that in the first half of 2012, over one million people with Medicare saved a total of $687 million on prescription drugs in the “donut hole” coverage gap, for an average of $629 in savings this year.

These savings are automatically applied to prescription drugs that patients with Medicare purchase, after they hit the Medicare Part D prescription drug coverage gap, or “donut hole.” Coverage for both brand name and generic drugs in the gap will continue to increase over time until 2020, when the coverage gap will be closed. More information on how the Affordable Care Act closes the Medicare drug benefit coverage gap “donut hole” can be found at http://tinyurl.com/7dtxzzl.

ACP President: Physician-Led Quality Initiatives Could Solve Medicare Payment Problems

Repeal of Medicare’s Sustainable Growth Rate (SGR) is essential, but repeal by itself will not move Medicare to better ways to deliver care,” David L. Bronson, MD, FACP, president of the American College of Physicians (ACP), told the House Ways and Means Subcommittee on Health on July 24. “We need to transition from a fundamentally broken physician payment system to one that is based on the value of services to patients, building on physician-led initiatives to improve outcomes and lower costs.”

Bronson described how physician organizations’ efforts and initiatives to promote high quality care could contribute to a solution to fixing the Medicare physician payment system. He suggested that Congress establish a transitional value-based payment initiative, so that physicians who voluntarily participate in physician-led programs to improve quality and value would be eligible for higher Medicare updates.

As part of this transitional program, he recommended that higher Medicare updates be provided to physicians in recognized patient-centered medical home (PCMH) and patient-centered medical home neighborhood (PCMH-N) practices.

Bronson also recommended that Medicare payment policies support efforts by the medical profession to encourage high-value, cost-conscious care. Finally, he urged that existing Medicare quality improvement programs—meaningful use standards for electronic health records, e-prescribing incentive payments, and the Physicians Quality Reporting System—be improved and harmonized, by providing more timely performance data to physicians and having greater consistency in the measures and reporting requirements for each program.
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