

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

June 13, 2007 - Issue #368

Top Diabetes Stories:

New Study Shows No Increased Heart Risk With Avandia*

<http://www.diabetesincontrol.com/results.php?storyarticle=4883>

FDA Orders New Safety Labels for Rosiglitazone (Avandia) and Pioglitazone (Actos)*

<http://www.diabetesincontrol.com/results.php?storyarticle=4882>

FDA Approves JANUMET™ - DPP-4 Inhibitor And Metformin In A Single Tablet*

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Once-Weekly Exenatide Formulation Improves Glycemic Control and Body Weight*

<http://www.diabetesincontrol.com/results.php?storyarticle=4878>

Saliva A Marker for Type 2 Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=4876>

Researchers Find New Target For Type 2 Diabetes That Reduces Stored Fat*

<http://www.diabetesincontrol.com/results.php?storyarticle=4875>

A1c Level During Gestational Diabetes Predicts Long-Term Diabetes Risk*

<http://www.diabetesincontrol.com/results.php?storyarticle=4873>

Abbott Receives European Approval for the Navigator(R) Continuous Glucose Monitoring System*

<http://www.diabetesincontrol.com/results.php?storyarticle=4869>

From the editor's desk

This past week I listened to **James R. Bailes, Jr. MD, F.A.A.P.** from Marshall University, discuss his research and experience working with lower carb choices and obese children. His recent study has shown a high protein, low carbohydrate, unlimited calorie diet was superior to a restricted calorie protocol for weight loss in obese school age children; moreover, compliance was better. We are working with **Dr. Bailes** to get his study protocols for you.

To often our patients tell us they can't increase their physical activity because of the complications of their disease. **Dr. Sheri Colberg**, author of *The 7 Step Diabetes Fitness Plan: Living Well and Being Fit with Diabetes*, has the right things to do in this weeks feature *Exercising with Complications: Overview of Precautions for Safety* <http://www.diabetesincontrol.com/results.php?storyarticle=4884>

Dr. Bernstein will participate in another 60 minute Tele-Seminar on June 21st 2007, at 7:00 PM CST, 8:00 PM EST and 5:00 PM West Coast time, that we invite you to attend, and ask your patients to attend. In addition to calling in, this upcoming call will also be broadcast through a LIVE web-cast on the Internet. Don't miss it. Click here to register for this free teleconference.

<http://www.diabetes911.net/askdrb/index.php>

Would you be interested in going on a diabetes cruise? We are planning a 7-9 day Diabetes Education Cruise with Dr. Richard K. Bernstein for next spring or fall. We will provide CME for medical professionals to learn Dr. Bernstein's treatment methods and education for patients with diabetes. If you might be interested, just send us an email with "Diabetes Cruise" in the subject line. Send to publisher@diabetesincontrol.com

June 17, 7PM ET on CNBC

On the rodeo circuit with World-Champion Steer Wrestler Luke Branquinho; knowing all your numbers for good diabetes health; and dLife investigates sugar-free chocolate. Catch this episode of dLifeTV on: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT Check your local listings for details.

We can make a difference!

This week's overview:

Item #4: Insulin Resistance Predicts Cardiovascular Disease

- Item #5: Comparison of Vildagliptin and Rosiglitazone in Patients With Type 2 Diabetes
- Item #7: Type 2 Diabetes Tied to Brain Atrophy in the Elderly
- Item #10: Hormone Linked to Stored Fat Could Explain Atkins Diet
- Item #12: E-Medical Records No Shortcut to Good Diabetes Care
- Item #13: Exenatide Can Be Added to Single Oral Therapy in Type 2 Diabetes
- Item #14: FDA Approves DexComs Continuous 7-Day Glucose Monitoring System

Check out this weeks **“Test Your Knowledge”** question.

<http://www.diabetesincontrol.com/results.php?storyarticle=4885>

Dave Joffe, *Editor-in-Chief*

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NEWS FLASH:

Abbott gets EU approval for the Navigator CGMS system.

The FDA is set to release its Acomplia review this week, ahead of a Wednesday meeting at which outside experts will vote on whether it should be approved. The agency does not have to follow the experts' vote, though it often does. The product by Sanofi-Aventis, if approved will be called Zimulti in the U.S.

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Tools for your Practice:

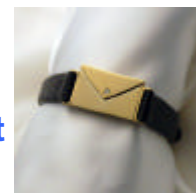
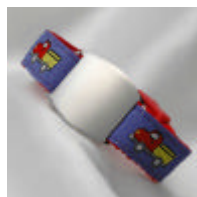
This week we have a hand out on “How to Keep Your Teeth” [Peridontal Disease](#)

<http://www.diabetesincontrol.com/issues/Issue 368/FightingGumDisease.pdf>

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New Product:

Whether it’s a \$9.99 kids bracelet or a \$500.00 14K Gold Envelope Locket with Diamonds, [StickyJ](#) has the best selection of ID wear that I have ever seen. To learn more about what they have click here.



editor@diabetesincontrol.com?subject=stickyJ

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This Week’s Items:

1. **New Study Shows No Increased Heart Risk With Avandia***
<http://www.diabetesincontrol.com/results.php?storyarticle=4883>
2. **FDA Orders New Safety Labels for Rosiglitazone (Avandia) and Pioglitazone (Actos)***
<http://www.diabetesincontrol.com/results.php?storyarticle=4882>
3. **FDA Approves JANUMET™ - DPP-4 Inhibitor And Metformin In A Single Tablet***
<http://www.diabetesincontrol.com/results.php?storyarticle=4881>
4. **Insulin Resistance Predicts Cardiovascular Disease**
<http://www.diabetesincontrol.com/results.php?storyarticle=4880>
5. **Comparison of Vildagliptin and Rosiglitazone in Patients With Type 2 Diabetes**
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6. **Once-Weekly Exenatide Formulation Improves Glycemic Control and Body Weight***
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12. E-Medical Records No Shortcut to Good Diabetes Care

<http://www.diabetesincontrol.com/results.php?storyarticle=4872>

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<http://www.diabetesincontrol.com/results.php?storyarticle=4871>

14. FDA Approves DexComs Continuous 7-Day Glucose Monitoring System

<http://www.diabetesincontrol.com/results.php?storyarticle=4870>

15. Abbott Receives European Approval for the Navigator(R) Continuous Glucose Monitoring System*

<http://www.diabetesincontrol.com/results.php?storyarticle=4869>

ITEMS For The Week:

Item 1

New Study Shows No Increased Heart Risk With Avandia

Findings from an interim analysis of RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of glycemia in Diabetes), shows further proof the safety of Avandia.

<http://www.diabetesincontrol.com/results.php?storyarticle=4883>

In a prospective clinical trial designed specifically to determine cardiovascular outcomes in more than 4,400 patients with type 2 diabetes, adds further evidence to the overall cardiovascular safety profile of Avandia(R) (rosiglitazone maleate).

The study results, authored by Philip D. Home and colleagues on the RECORD Steering Committee, were published Tuesday in the online edition of *The New England Journal of Medicine*.

The study compares cardiovascular hospitalization and death in patients treated with Avandia dual therapy (Avandia plus metformin or sulfonylurea) and in patients treated with metformin and sulfonylurea in combination.

After following patients for an average of 3.75 years, the interim analysis found a low number of events overall, and a similar number of events in each group. The study is scheduled to complete in late 2008.

Like all interim analyses, these data do not offer final conclusions. Based on the interim analysis, key findings include:

-- The interim data show no significant difference between the Avandia and control groups in the key outcomes of hospitalization or death due to cardiovascular events.

-- There was no difference between the groups in mortality, whether cardiovascular deaths or deaths from all causes.

-- The interim data show that Avandia was not significantly different than the control groups in several secondary outcomes, including heart attack.

-- A significant difference between the Avandia and control groups was seen only in the secondary outcome of congestive heart failure (CHF), where significantly more cases were seen in Avandia patients - consistent with the well known association between fluid retention and TZDs, the class of medicine to which Avandia belongs. Fluid retention can worsen or lead to CHF. Importantly, despite the increase in CHF, there was no difference between the Avandia group and the control groups in the key outcome of cardiovascular hospitalizations and death.

"The interim findings do not show evidence of a significant difference in cardiovascular death and heart attack between Avandia and the control groups, and therefore do not confirm the hypothesis generated by the recently published meta-analysis in the *New England Journal of Medicine* that raised concerns about these events with Avandia," said Moncef Slaoui, chairman, R&D for GSK. "They add to the weight of evidence, from both previously published long-term clinical trials and other studies, that the overall ischemic cardiovascular safety profile of Avandia is comparable to the traditional anti-diabetes treatments. Patients and physicians should find these data reassuring."

Professor Home, Vice President, International Diabetes Federation, University of Newcastle-upon-Tyne, UK, and chairman of the RECORD Steering Committee, said that although the study is not expected to be complete until late 2008, the committee concluded that an interim analysis should be published as soon as possible.

"Ideally, we would have allowed RECORD to complete before analyzing and releasing the results," Home said. "However, in light of the questions raised recently about Avandia, we felt it critical that interim data from this important study be made available to physicians and patients immediately so that treatment decisions may be based on all the available evidence."

Richard Nesto, MD, Chairman of the Department of Cardiovascular Medicine at the Lahey Clinic Medical Center, said these new findings provide important information for physicians caring for diabetic patients. "Despite its limitations, the recent meta-analysis in the *New England Journal of Medicine* raised important questions about the cardiac safety of rosiglitazone. These questions can only be answered with better evidence from clinical trials. This interim analysis of RECORD, a randomized prospective clinical trial, helps to establish the overall cardiac safety profile of the drug," said Dr. Nesto, who is an author of the American Heart Association and American Diabetes Association consensus statement on the use of thiazolidinediones in diabetic patients with heart disease. "Additional clinical trials are underway to specifically address this issue, but the data from RECORD should be reassuring for physicians who need effective drugs to lower blood sugar levels -- the main cornerstone of treatment for diabetic patients."

The RECORD study's robust design and breadth make it uniquely suited to answer questions about cardiovascular risk with Avandia.

First, the study was designed to include a wide range of Type 2 diabetes patients, including those with and without existing cardiovascular disease, making it highly representative of real-world diabetes patients.

Second, patients in RECORD were managed such that blood sugar remained within current guidelines, thereby eliminating a variable that may affect results, as inadequate blood sugar control is itself associated with cardiovascular events.

Third, although an open-label design, each cardiovascular event was verified by an independent panel of physicians who did not know which medicines the patients were taking.

Under these rigorous standards, the interim analysis shows that the incidence of cardiovascular hospitalization and death were comparable for the patients taking the Avandia combination and the patients taking the metformin-sulfonylurea combination. *SOURCE: GlaxoSmithKline*

For more answers to the Avandia debate, see what Dr. Richard K. Bernstein has to say!

Misreading Avandia

<http://www.diabetesincontrol.com/results.php?storyarticle=4886>

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Item 2

FDA Orders New Safety Labels for Rosiglitazone (Avandia) and Pioglitazone (Actos)

The FDA Commissioner Andrew C. von Eschenbach, M.D., told a congressional hearing that the FDA will beef up the cardiovascular warnings on the labels of both rosiglitazone (Avandia) and pioglitazone (Actos).

<http://www.diabetesincontrol.com/results.php?storyarticle=4882>

Moreover, the FDA announced it will convene a safety panel on June 30 to review the cardiovascular risks of rosiglitazone.

Rep. Henry Waxman (D-Calif.) convened the hearing to investigate the FDA's handling of rosiglitazone from its approval in 1999 through recent reports that linked the drug to increased risk of cardiovascular events.

In general, Dr. von Eschenbach defended the FDA's handling of rosiglitazone, but he conceded that the agency asked for the label changes on May 23--two days after the *New England Journal of Medicine* published a meta-analysis that found a 43% increase in risk of myocardial infarction among patients taking rosiglitazone.

The lead author of that analysis -- Steven E. Nissen, M.D., chairman of cardiovascular medicine at the Cleveland Clinic -- was aggressively questioned by Republican members of the committee who accused Dr. Nissen of sensationalizing what they characterized as questionable findings.

The Republicans also grilled Dr. Nissen over his decision to share his concerns about the safety of rosiglitazone with Waxman in February.

Rep. Darrell E. Issa (R-Calif.) was prosecutorial as he repeatedly attempted to limit Dr. Nissen to "yes" or "no" answers. Issa said that if Dr. Nissen had safety concerns about the drug, he should have taken those concerns to the FDA, not to committee staff appointed by Democrats.

Several times Issa and other Republicans pressed Dr. Nissen about whether he had shared his findings with Democrats on the committee before the meta-analysis was published.

Dr. Nissen repeatedly stated that his interest in rosiglitazone was purely that of a physician-scientist, whose goal was to disseminate information to both physicians and patients.

Moncef Slaoui, Ph.D., chairman of research and development for GlaxoSmithKline, presented the company's case testifying that rosiglitazone had demonstrated superiority over two diabetes drugs -- metformin and sulfynurea -- and that the company has gone out of its way to confirm the safety of rosiglitazone.

Dr. Slaoui testified that the interim results from the RECORD trial, published online last Thursday by the *New England Journal of Medicine*, provided reassuring data about the drug's safety. The study did not find a significant increase in MIs, but found a significant increase in heart failure. But three accompanying editorials pointed out that although the data did not confirm the risk found in the earlier meta-analysis, neither did they refute that finding.

American Society of Clinical Oncology Independent Satellite Symposium

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DID YOU KNOW:

Index ranks U.S. health care 66th out of a possible 100: A majority of Americans say they are worried about their ability to afford health care services and would be willing to pay higher taxes to support universal health coverage, according to a recent national survey. The survey results are part of the first annual "Health Security Index" by Catholic Healthcare West. The index, which ranks Americans' health security at 66 out of a possible 100, reflects a troubling portrait about issues such as health care affordability, access and prevention. The survey also found that 65 percent of Americans are concerned about their ability to manage a chronic disease and 71 percent say they are not sure they could afford health insurance if they lost their job. In addition to affordability being the top concern for Americans when it comes to health care, the study also found that 72 percent said they want universal coverage and 63 percent said universal health coverage is necessary even if it requires tax increases. [Health Care Survey \(pdf\)](#)

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Item 3

FDA Approves JANUMET™ - DPP-4 Inhibitor And Metformin In A Single Tablet

Merck & Co., Inc. announced that the U.S. Food and Drug Administration (FDA) approved JANUMET™, the first and only tablet combining a dipeptidyl peptidase-4 (DPP-4) inhibitor, sitagliptin (also known as JANUVIA™), and metformin for the treatment of type 2 diabetes.

<http://www.diabetesincontrol.com/results.php?storyarticle=4881>

JANUMET has been approved, as an adjunct to diet and exercise, to improve blood sugar (glucose) control in patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin.

The FDA approved JANUMET based upon clinical data including sitagliptin plus metformin as separate tablets. A clinical bioequivalence study has demonstrated the equivalence between JANUMET and sitagliptin plus metformin as separate tablets.

A 24-week, randomized, double-blind, placebo-controlled study with 701 patients with mildly to moderately elevated HbA1c levels (mean baseline 8.0 percent) inadequately controlled on metformin, showed that patients taking JANUMET2 (n=453) experienced significant additional mean placebo-subtracted reductions in HbA1c of 0.7 percent beyond that achieved by patients who continued on metformin alone (n=224) (p<0.001). In the study, more than twice as many patients on JANUMET (213 of 453 patients, or 47 percent) reached the American Diabetes Association's HbA1c goal of <7 percent compared with patients on metformin alone (41 of 224 patients, or 18 percent) (p<0.001).

Patients treated with JANUMET experienced weight loss comparable to metformin alone, with no increased risk of hypoglycemia, edema, or GI disturbances beyond metformin alone

By incorporating the novel mechanism of DPP-4 inhibition, JANUMET uniquely addresses the three key defects of type 2 diabetes. With the two active components, sitagliptin and metformin, JANUMET has a comprehensive mechanism of action that targets all three key defects of type 2 diabetes for improved glycaemic control: diminished insulin release, uncontrolled production of glucose, and insulin resistance.

The sitagliptin component in JANUMET address two of the three key defects that cause poor glucose control: diminished insulin release due to beta-cell dysfunction and uncontrolled production of glucose by the liver due to alpha-cell and beta-cell dysfunction. By inhibiting the DPP-4 enzyme, sitagliptin significantly increases the levels of active incretin hormones, increasing the synthesis and release of insulin from the pancreatic beta cells and decreasing the release of glucagon from the pancreatic alpha cells.

JANUMET also contains metformin, which addresses the other key defect: insulin resistance. Metformin improves insulin sensitivity by increasing uptake and utilization of glucose by the muscles and tissues of the body. Metformin also decreases hepatic glucose production in a manner that is complementary to sitagliptin.

JANUMET provides powerful HbA1c lowering through combined reductions of both post- prandial glucose and fasting plasma glucose. JANUMET has been demonstrated to provide 24-hour glucose response -at mealtimes, between meals and overnight. In a 24-week, placebo-controlled study of patients with inadequate glycemic control on metformin alone, JANUMET significantly reduced post prandial, or post-meal, glucose (PPG) levels beyond metformin alone by a mean of 51 mg/dL in patients with a mean baseline 2-hour PPG of 275 mg/dL (n=387, p<0.001) and fasting plasma glucose levels (FPG) beyond metformin alone by a mean of 25 mg/dL in patients with a mean baseline FPG of 170 mg/dL (n=454, p<0.001).

JANUMET is indicated, as an adjunct to diet and exercise, to improve glycemic control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. Consistent with the labeling for metformin alone, JANUMET is contraindicated in patients with renal disease, renal dysfunction, or abnormal creatinine clearance; and acute or chronic metabolic acidosis, including diabetic ketoacidosis. JANUMET should not be used in patients with type 1 diabetes.

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Multivitamin Supplements & Diabetes:

Recent research confirmed that taking a daily multivitamin and mineral supplement has a positive impact on the quality of life for people with diabetes. So regularly taking a multiple is an easy choice, but for most finding the right one to trust with their health proves to be a more difficult matter. alpha betic(r) is uniquely balanced to meet the special dietary needs of people with diabetes and those predisposed to diabetes. alpha betic(r) contains 23 important nutrients in safe and balanced doses, with no copper. For more information: Click Here <http://www.diabetesincontrol.com/ads/alphabetic/dest.php>

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Item 4

Insulin Resistance Predicts Cardiovascular Disease

Study shows that insulin resistant can be an independent risk factor for cardiovascular disease.
<http://www.diabetesincontrol.com/results.php?storyarticle=4880>

The goal of the study was to clarify if insulin resistance (IR) would predict cardiovascular disease (CVD) independent of the metabolic syndrome (MetSyn). Although the cause of MetSyn is not well defined, IR has been proposed to be an important cause. Only a small number of population-based studies have sought to clarify if IR predicts CVD independent of MetSyn.

This was a prospective population-based study of 2,493 men and women, age 41 to 72 years, without major CVD at baseline. We defined MetSyn according to both the International Diabetes Foundation (IDF) and the National Cholesterol Education Program (NCEP) criteria, and we quantified IR by the homeostasis model assessment (HOMA-IR). Prevalence of MetSyn was 21% according to IDF criteria and 16% according to NCEP criteria. Accordingly, we defined IDF-HOMA-IR as belonging to the highest 21% of the HOMA-IR distribution, and NCEP-HOMA-IR as belonging to the highest 16% of the HOMA-IR distribution.

Over a median follow-up of 9.4 years, the incidence of CV end points (CV death, nonfatal ischemic heart disease, and nonfatal stroke) amounted to 233 cases. In proportional hazard models, adjusting for age, gender, smoking, and low-density lipoprotein cholesterol, and with IDF-HOMA-IR and IDF-MetSyn included in the same model, the relative risk of an end point was 1.67 (95% confidence interval [CI] 1.22 to 2.29) for IDF-HOMA-IR and 1.16 (95% CI 0.84 to 1.60) for IDF-MetSyn. The corresponding figures for NCEP-HOMA-IR and NCEP-MetSyn included in the same model were 1.49 (95% CI 1.07 to 2.07) and 1.56 (95% CI 1.12 to 2.17).

The present study provided interesting results: 1) IR predicted incident CVD independent of the MetSyn based on either IDF or NCEP criteria; 2) adjusted for IR, the MetSyn based on NCEP criteria was a significant predictor of CVD, whereas the MetSyn based on IDF criteria was not; 3) the MetSyn and IR were significant risk factors of CVD in the nondiabetic population; 4) IR, defined as belonging to the highest 20.6% of the HOMA-IR distribution, predicted incident CVD independent of the Framingham risk score with an approximate 1.5-fold increased risk; and 5) the rate of concordance among those individuals with the MetSyn and IR amounted to around 50%.

Although IR has been proposed as an important cause of the MetSyn, the present results showed that other causes must be present. Accordingly, the rate of concordance among those individuals with the MetSyn and IR only amounted to around 50%, and the correlation coefficients between HOMA-IR and the continuously distributed components of the MetSyn were not that high either. However, based on the medical literature,^[2-4] it is reasonable to believe that IR is a major cause of the MetSyn, although the exact percentage of MetSyn cases caused by IR remains to be defined.

In conclusion from this study it was determined that, both HOMA-IR and NCEP-MetSyn were independent predictors of incident CVD.

R. Kahn, J. Buse, E. Ferrannini, M. Stern. The metabolic syndrome: time for a critical appraisal. Joint statement from the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetologia*; 48 (2005), 1684-1699

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FACT:

BLACK patients approximately 30% less likely than whites to receive treatment such as angioplasty after heart attack, compared to white patients, black patients were 23% less likely to be transferred to hospitals that provide specialized services, and overall they were about thirty-percent less likely to

get those services. The risk of death for black patients was lower than for white patients during the first 30 days after hospital admission, but was up to 17% higher at one year. Ioana Popescu, M.D., M.P.H. University of Iowa

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Item 5

Comparison of Vildagliptin and Rosiglitazone in Patients With Type 2 Diabetes

Positive results are dependent upon BMI at start of therapy

<http://www.diabetesincontrol.com/results.php?storyarticle=4879>

This 24-week, double-blind, randomized study performed in 11 countries was designed as a head-to-head comparison of the efficacy and tolerability of vildagliptin and rosiglitazone as monotherapy in drug-naive type 2 diabetes patients. Seven hundred eighty-six adult subjects (age 18-80 years) with glycated hemoglobin (A1C) levels in the range of 7.5% to 11.0% and who did not have cardiovascular disease, congestive heart failure, liver disease, or various laboratory abnormalities were randomized on a 2:1 ratio to 100 mg vildagliptin (n = 519) or 8 mg rosiglitazone (n = 267), and were assessed at weeks 4, 12, 16, and 24 of active treatment. Analyzed on an intent-to-treat basis, the primary efficacy variable was change from baseline A1C after 24 weeks. Secondary variables were changes in fasting glucose, fasting lipids, and body weight.

A1C improved by -1.1% among vildagliptin users and -1.3% among rosiglitazone users, meeting the statistical criterion for noninferiority. It is interesting that a stratified analysis showed that greater A1C reductions among the vildagliptin group were achieved by those with body mass index (BMI) < 30 kg/m², whereas rosiglitazone appeared more efficacious in patients with BMI = 30 kg/m². Fasting glucose levels decreased more with rosiglitazone compared with vildagliptin, and high-density lipoprotein increases also favored rosiglitazone. However, body weight increased by 1.6 kg among rosiglitazone-treated patients, but did not change in the vildagliptin group. In addition, compared with rosiglitazone, vildagliptin significantly decreased triglycerides as well as total and low-density lipoprotein cholesterol.

Vildagliptin is in the new dipeptidyl peptidase (DPP)-IV inhibitor class of antihyperglycemic drugs that increases alpha- and beta-cell responsiveness to glucose.^[1] Its apparent ability to reduce A1C without inducing weight gain makes it a promising new agent. The favorable lipid effects are also intriguing, and need further study. Rosiglitazone is a thiazolidinedione that targets insulin resistance by enhancing peripheral and hepatic insulin action.^[2] Although the end result is similar (reduction in A1C), the vastly different mechanistic actions of these 2 drugs likely explain some of the differences found in the secondary outcomes. In theory, the fact that vildagliptin worked best in subjects who were not obese suggests that this drug may be preferred when substantial beta-cell failure is the primary cause of hyperglycemia. On the other hand, rosiglitazone worked better in obese subjects and had a greater effect on fasting glucose, suggesting that it might be preferred in those with high insulin resistance. Such patients are often obese. Weight gain is never desirable; it may be of less concern in already obese patients, especially if body fat is being redistributed.^[2] In reality, beta-cell failure and insulin resistance usually coexist, and there is debate over which is the dominant cause of diabetes. The key point is that clinicians now have more options than ever to appropriately treat the variations of hyperglycemia that we singularly call type 2 diabetes.

Diabetes Care, (Volume 30, Number 2)

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<http://www.diabetesincontrol.com/annodyne/index.php>

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Item 6

Once-Weekly Exenatide Formulation Improves Glycemic Control and Body Weight

A new once-weekly formulation of exenatide improves glycemic control and fosters weight loss in patients with type 2 diabetes, according to a new report.

<http://www.diabetesincontrol.com/results.php?storyarticle=4878>

Dr. Kim and colleagues studied the effects of once-weekly subcutaneous administration of exenatide long-acting release (LAR) formulation for 15 weeks on glycemic parameters, weight, pharmacokinetics, safety, and tolerability in 45 patients with type 2 diabetes.

Both doses of exenatide LAR (0.8 mg and 2.0 mg) significantly reduced fasting plasma glucose and average daily blood glucose concentration, the authors report, whereas both fasting plasma glucose and average daily blood glucose concentration increased in the placebo group.

A1C decreased progressively throughout the treatment period in the exenatide LAR groups and increased in the placebo group, the results indicate.

Body weight decreased progressively, reaching an average loss of 3.8 kg, in the 2.0-mg exenatide LAR group, the researchers note, but remained stable in the 0.8-mg exenatide LAR and placebo groups.

There were no serious adverse events related to exenatide use, the report indicates, and none of the mild to moderate adverse events required discontinuation of exenatide LAR.

"It is important that physicians know that a currently available therapy, BYETTA, contains a twice-daily formulation of exenatide, the same active ingredient as the once-weekly exenatide LAR used in this study," Dr. Kim added. "BYETTA offers patients with type 2 diabetes sustained A1C control with a secondary benefit of weight loss."

Diabetes Care 2007;30:1487-1493.

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For the diabetic patient, it's not the cholesterol that's the problem. It's the number of LDL particles, especially small LDL particles. To see the real risk, use the NMR LipoProfile(r) test, the only test that directly measures the number of LDL particles and the number of small LDL particles - the particles shown to be more predictive of CHD events than LDL-C. Click here to learn more.

<http://www.diabetesincontrol.com/ads/liposcience/dest.php>

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Item 7

Type 2 Diabetes Tied to Brain Atrophy in the Elderly

Type 2 diabetes has a negative effect on brain tissue volumes and regional cerebral perfusion in elderly patients, according to researchers

<http://www.diabetesincontrol.com/results.php?storyarticle=4877>

Senior investigator Dr. Vera Novak stated that, "Type 2 diabetes is associated with brain atrophy involving preferentially frontal and temporal lobes, and with impaired vascular reactivity.

In the May issue of *Diabetes Care*, Dr. Novak, of Beth Israel Deaconess Medical Center, Boston and colleagues hypothesize that the condition might be associated with microvascular disease. To investigate, they studied 26 diabetics, mean age of 61.6 years, and 25 comparable controls.

The diabetic group had significantly smaller global white and gray matter and larger cerebrospinal fluid (CSF) volumes than controls.

This was also true of white matter and CSF in the frontal region, of CSF in the temporal region, and of gray matter and CSF in the parieto-occipital region.

In addition, diabetes was associated with significantly reduced regional cerebral blood flow and CO₂ reactivity. Hypoperfusion in the frontal region was significantly associated with gray matter atrophy, and higher glycosylated hemoglobin was associated with significantly lower cerebral blood flow and greater CSF within the temporal region.

The researchers note that uncontrolled diabetes may contribute to such problems. "These findings may have clinical implications for development of cognitive impairment, executive dysfunction and balance problems in people with diabetes," Dr. Novak said.

"New preventive and therapeutic strategies improving vascular reactivity and preventing brain atrophy are needed," she concluded.

Diabetes Care 2007;30:1193-1199.

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Advertisement

Dr. Philip A. Wood has written a book for healthcare professionals and students of medicine, nursing, pharmacy, and graduate studies, as well lay people interested in understanding the influences of genetics, nutrition, activity level and drugs on diseases associated with excess fat such as obesity, insulin resistance, metabolic syndrome and type 2 diabetes. The book is composed of short, readable chapters with helpful figures to further explain the mechanisms discussed. For further information please click here.

http://www.amazon.com/exec/obidos/tg/detail/-/0674019474/qid=1132176956/sr=8-1/ref=pd_bbs_1/002-7853569-1175265?v=glance&s=books&n=507846

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Item 8

Saliva A Marker for Type 2 Diabetes

Saliva may be a marker for both periodontal disease activity and hyperglycemia in uncontrolled type 2 diabetes, according to new research.

<http://www.diabetesincontrol.com/results.php?storyarticle=4876>

Carol W. Bassim, DMD, doctor of medical dentistry, research fellow, National Institutes of Health, Bethesda, Maryland, United States, noted that saliva holds much potential as a marker for disease in periodontitis and type 2 diabetes.

"We are seeing that saliva may be a way to check for periodontal disease and diabetes, more than is serum," said Dr. Bassim. "We know that inflammation and infection in periodontal disease is associated with poorly controlled type 2 diabetes."

Investigators prospectively studied subjects who presented with either severe periodontitis or moderate periodontal disease. All had uncontrolled type 2 diabetes. Specifically, they were measuring salivary procalcitonin (ProCT) correlated with diabetic glucose control.

"We know that if you get septic, for instance, and have severe systemic inflammation or infection, the degree of procalcitonin is significantly increased," said Dr. Bassim.

Dr. Bassim and colleagues collected samples of non-stimulated whole saliva through expectoration from 22 patients with periodontitis with uncontrolled type 2 diabetes; their HgbA_{1c} exceeded 7.0. They also conducted a complete periodontal examination and collected serum from each subject.

Researchers discovered salivary-ProCT correlated with bleeding-on-probing, bleeding that indicates active periodontal disease ($r=0.50$, $P=.03$, $n=18$). In addition, salivary-ProCT was correlated with HgbA_{1c} in each patient, at baseline measurements and at a three-month follow-up visit ($r=0.43$, $P=.01$, $n=33$).

Investigators found periodontal indicators were not directly correlated with HgbA_{1c}. Moreover, serum levels of ProCT were not correlated with either periodontal indicators or glucose control. Serum levels of ProCT were decreased compared to that of saliva: mean 92 vs. 246 pg/ml. "Salivary amounts seem to matter more than serum," observed Dr. Bassim.

Future research may lead to the potential for a salivary biomarker of both periodontitis and poorly controlled type 2 diabetes, according to Dr. Bassim.

"There is no quick and easy test for periodontitis," said Dr. Bassim. "It would be a wonderful thing to have a biomarker like saliva in that sense. For endocrinologists, it would be a quick and easy way to look at HbA_{1c} values in a clinical setting and track those values."

Presented at the annual 89th meeting of the Endocrine Society (ENDO). [Presentation title: Procalcitonin: A Salivary Biomarker for Periodontal Disease Activity and Hyperglycemia in Uncontrolled Type II Diabetes. Abstract P2-231]

FACT:

Black patients as compared to white patients were less likely to die within the first 30 days after a heart attack, but they were more likely to die thereafter, no matter what type of hospital they were initially treated at. These differences do not seem to be related to geographic access to specialized heart services because black patients were less likely to receive these services regardless of what type of hospital they were treated at. In other words, it's not a matter of where you go in this case, it's a matter of what happens after you get there. *Ioana Popescu, M.D., M.P.H. University of Iowa*

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Item 9

Researchers Find New Target For Type 2 Diabetes That Reduces Stored Fat

Researchers have discovered a potential new target for treating type 2 diabetes, according to a new study that appeared online in Nature. The target is a protein, along with its molecular partner, that regulates fat metabolism.
<http://www.diabetesincontrol.com/results.php?storyarticle=4875>

“Over the last 10 years, we have begun to understand the importance of fat metabolism in diabetes,” notes lead author Morris J. Birnbaum, MD, PhD, the Willard and Rhoda Ware Professor of Diabetes and Metabolic Diseases at Penn and an Investigator of the Howard Hughes Medical Institute. “Type 2 diabetics are at a higher risk for cardiovascular disease because they also have disorders in fat metabolism as a result of obesity and abnormal insulin action.” Birnbaum is also the Associate Director of the Type 2 Diabetes Unit for Penn’s Institute for Diabetes, Obesity, and Metabolism.

When a person eats a meal, the pancreas usually responds by secreting insulin that signals the liver to stop making glucose and burning fat. When a type 2 diabetic eats a meal, insulin cannot stop the manufacture of glucose in the liver, but it can stop the burning of fat stores. This gives the diabetic person a “double whammy:” fatty acids accumulate from food and from the liver. Consequently, more fat is deposited in tissues and obesity worsens.

Until now there was no clear connection between insulin and the control of fat metabolism. This study shows that when insulin is present, as it is after a meal, the protein Akt2/PKB adds a phosphate group to its molecular partner PGC-1a. When this happens, PGC-1a cannot activate the genes needed for fat metabolism.

The findings suggest that if a drug could induce Akt2/PKB to add the phosphate group (phosphorylation) to PGC-1a, then the liver of a diabetic might be “fooled” into stopping the oxidation of fat stores. “Muscle and fat tissue also burn fat stores, and we are currently investigating whether PGC-1a and Akt2/PKB have the same role in those tissues,” says Birnbaum.

The researchers also found that insulin-stimulated phosphorylation of PGC-1a was blunted in mice that had non-functional Akt2/PKB. Finally, they showed that livers with too much PGC-1a or with PGC-1a that could not be phosphorylated put out many copies of the genes for fat metabolism. Each approach pointed to the same conclusion: PGC-1a had phosphate groups added to it by Akt2/PKB in the presence of insulin and this prevented the turning on of genes that make fat.

There are currently no drugs that target PGC-1a and Akt2/PKB. “We hope that drug companies will look for new ways to modify fat metabolism in type 2 diabetics using these possible targets,” says Birnbaum.

News release issued by University of Pennsylvania School of Medicine.

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Item 10

Hormone Linked to Stored Fat Could Explain Atkins Diet

In a discovery that may explain the successes of the Atkins diet, investigators have found that a single hormone may switch on the use of stored fat for fuel when all else fails.

The hormone, fibroblast growth factor 21 (FGF21), is expressed in the liver and drives the production of so-called ketone bodies, which in some circumstances provide up to 70% of the energy required by the brain, according to two studies. The findings may explain the fat-burning benefits sometimes seen in high-fat, low-carbohydrate diets, such as the Atkins diet, said Eleftheria Maratos-Flier, M.D., of Beth Israel Deaconess Medical Center.

And the discovery may lead to new approaches to obesity, Dr. Maratos-Flier said. "We think these findings would increase the desirability of a drug that (might work through this mechanism) to increase fat oxidation in the liver," she said.

Dr. Maratos-Flier and colleagues reported that in order for mice on a carbohydrate-restricted diet -- or simply kept without food -- to switch gears and begin burning fat, they need increased blood levels of FGF21.

The accompanying study, led by Steven Kliewer, Ph.D., of the University of Texas Southwestern Medical Center in Dallas, also found that the hormone breaks down fat -- both in animals forced to fast, as well as those with chronically elevated concentrations of FGF21.

The Dallas researchers also showed that as animals adapt to a food shortage, the hormone leads to energy-conserving behavioral changes. They move less and sleep more.

"It's startling that you can give one hormone and flip the whole metabolic profile," Dr. Kliewer said. What's more, he said, the hormone appears to counteract the effects of too much food. "What's really exciting is that mice with excess FGF21 -- even when they are fed -- look like they are fasted," Dr. Kliewer said.

Feeding mice a high-fat, low-carbohydrate diet -- a ketogenic diet -- leads to the breakdown of fatty tissue and weight loss, accompanied by the production of ketone bodies, which are used by tissues as replacement energy sources, Dr. Maratos-Flier and colleagues said.

But the details of the process were not completely understood, so they performed a genetic scan on mice fed such a diet for 30 days, looking for changes in gene activity. "We saw a dramatic increase in FGF21 in the livers of the mice," she said. "We thought, 'Maybe there is something to this.'"

In a series of experiments, she and colleagues showed that fasting mice and those fed a ketogenic diet both developed high levels of the hormone in the liver and in the blood. Feeding the mice a normal diet resulted in a rapid decline of the hormone levels.

Moreover, they found, feeding the ketogenic diet to mice genetically engineered to lack the hormone led to a fatty liver, high blood lipids, and reduced levels of ketone bodies.

The Dallas group showed that FGF21 is induced by peroxisome proliferator-activated receptor alpha (PPAR-alpha), which is known to be involved in the regulation of fat metabolism during starvation.

PPAR-alpha is also the target of the fibrate drugs used to treat high cholesterol and triglycerides.

"When you step back, the whole thing makes sense," Dr. Kliewer said. "During fasting, the liver hormone communicates with adipose tissue to send fat to the liver. It turns on the metabolism of fat into ketone bodies -- and at the same time, it sensitizes the animals to going into torpor to conserve energy." "It's clear that FGF21 is a principal component of the fasting or starvation response," he added.

Dr. Kliewer said there's an "obvious possibility" that the hormone is responsible for the benefits seen by some people when they follow the high-fat, low-carbohydrate Atkins diet.

But Dr. Maratos-Flier cautioned that it's still not clear that the effect of such a diet in humans is the same as that seen in mice. For instance, she said, "it may be that some people are more likely to turn on FGF21 than others." To find out, she now plans to study FGF21 levels in people.

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Item 11

A1c Level During Gestational Diabetes Predicts Long-Term Diabetes Risk

High glycosylated hemoglobin levels in women with gestational diabetes are associated with the development of diabetes in the future, new research indicates.

<http://www.diabetesincontrol.com/results.php?storyarticle=4873>

The results also suggest, contrary to some earlier reports, that gestational diabetes is a risk factor for future diabetes regardless of ethnicity, according to the report in the June issue of the Postgraduate Medical Journal.

The findings stem from a follow-up study of 73 women who were diagnosed with gestational diabetes between 1995 and 2001 and were reevaluated with oral glucose tolerance testing 4.38 years later, on average. Thirty-six of the women were South Asian and 37 were Caucasian.

On follow-up, 48.6% of South Asian women and 25.0% of Caucasian women had developed diabetes, lead author Dr. Matthew D. Oldfield, from Kingston Hospital in Surrey, UK, and colleagues note.

Risk factors for developing diabetes included older age at follow-up, and higher body mass index, more severe hyperglycemia, and insulin requirement during pregnancy.

An elevated HbA1c value during pregnancy increased the odds of future diabetes by 4.09- and 9.15-fold in South Asian and Caucasian women, respectively.

"Further examination of the value of HbA1c measurement in the gestational diabetes pregnancy should be undertaken as it has the potential to target screening away from those at minimal risk," the authors conclude.

Postgrad Med J 2007;83:426-430.

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DID YOU KNOW:

Alzheimer's cases expected to quadruple by mid-century: More than 26 million people worldwide have Alzheimer's disease, and a new forecast says the number will quadruple by 2050. At that rate, one in 85 people will have the brain-destroying disease in 40 years, researchers from Johns Hopkins University conclude. A recent U.S. study estimated that this nation's Alzheimer's toll will reach 16 million by 2050, compared with more than 5 million today. The new estimate is significantly lower, suggesting only 3.1 million North American cases today and 8.8 million by 2050.

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Item 12

E-Medical Records No Shortcut to Good Diabetes Care

Doctors need to use these systems as part of overall improvement plan, but the electronic medical record systems are no guarantee that diabetes patients will get better care, a new study finds.

<http://www.diabetesincontrol.com/results.php?storyarticle=4872>

When used in a primary-care setting, "having an electronic medical record is not sufficient for insuring the quality of diabetes care," said study author Jesse C. Crosson, from the Department of Family Medicine at UMDNJ-New Jersey Medical School. "It really isn't going to change care by itself, it has to be implemented in a context in which people are trying to improve the quality of care."

This finding, published in the May/June issue of the *Annals of Family Medicine*, contradicts the common wisdom on health information technology in general and about electronic medical records specifically, Crosson said. Many electronic medical record systems have been sold claiming that they will help improve quality care, he said.

To measure the impact of electronic medical record systems on the quality of care, Crosson and his colleagues collected data on the care of 927 diabetic patients in 50 doctor's offices.

They found that in offices that used electronic medical records actually offered poorer quality of care compared with those doctors who didn't use them. Patient care in the 37 offices that didn't use electric medical records was more likely to meet guidelines for treatment and intermediate outcomes compared with the 13 offices using a computerized medical record system, Crosson's group found.

These findings would apply to the care for other chronic conditions, Crosson said. "I think this is true for other conditions," he said. "I think it's more true for chronic illness care than for other conditions handled in primary care."

Crosson believes an electronic medical record system is only as good as the job it is being asked to do. "You can use a hammer to drive nails or break windows," he said. "It really matters who's using it and what they are trying to do with it."

Electronic medical records can be effective when they are part of a system designed to improve care, Crosson said. Studies have shown that electronic records can be effective when they are used in conjunction with other efforts at improving quality, he added.

"The question is, how do we translate these findings from big institutions with lots of resources out to where most of the care is being given," Crosson said. "The technology itself won't enhance the process, but rather the people in the practice working on ways to improve quality have to ask 'how can they use this tool?'"

"Just having electronic medical records is simply not enough," added Dr. John Hsu, a physician scientist in the division of research at Kaiser Permanente in Oakland, Calif. "How you integrate it into clinical practice is critical."

Hsu noted that many of the offices had rudimentary electronic systems which are underpowered with limited information-handling abilities. "It is not a question of whether we should use electronic medical records," Hsu said. "It is a question of when and how should we use them."

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Item 13

Exenatide Can Be Added to Single Oral Therapy in Type 2 Diabetes

Exenatide can be an alternative to insulin glargine as an add-on treatment in patients with type 2 diabetes who are already receiving single-agent oral therapy, as presented as new research.

<http://www.diabetesincontrol.com/results.php?storyarticle=4871>

A randomized, 2-period, open-label, crossover study of 114 patients compared the effects of exenatide (5 ug), given twice a day for 4 weeks, followed by a dose of 10 ug given twice daily for 12 weeks to insulin glargine, given once daily and titrated to fasting blood glucose levels less than or equal to 100mg/dL (5.6 mmol/L). Patients continued single-agent oral therapy at the maximal dose.

Results of the study, indicate that patients with type 2 diabetes have another option outside of insulin to achieve good glycemic control, said Michael Trautmann, MD, PhD, the study's lead investigator and a medical fellow with Eli Lilly Inc.

Dr. Trautmann feels that, "It's an effective alternative to starting insulin in patients with type 2 diabetes. "We can say that these patients are candidates for starting insulin or exenatide."

Because beta-cell function worsens over time in type 2 diabetes, it is important to offer patients several possible therapies, Dr. Trautmann said.

"This is why drugs work for a number of years, and then they are no longer effective because the disease is worsening," he said. "This is why after having tried diet and exercise, one oral agent is added to the regimen. Often a second oral agent is added. Typically, insulin is the last resort when all the other options are exhausted."

Dr. Trautmann added that patients might have contraindications to metformin or sulfonylurea.

Exenatide or insulin glargine was added to ongoing monotherapy with metformin in 56% of patients and sulfonylurea in the remaining patients in two 16-week treatment periods. In terms of baseline characteristics, patients were a mean age of 54 years, mean weight was 86 kg, mean HbA_{1c} level was 8.9%, and the mean fasting blood glucose level was (217mg/dL)12.09 mmol/L.

Investigators witnessed similar decreases in HbA_{1c} from baseline in patients receiving exenatide vs those receiving insulin glargine: -1.43 and -1.41, respectively. Comparable proportions of patients achieved target HbA_{1c} levels, 7% or less, with 40% of patients receiving exenatide achieving that level and 41% of those receiving insulin glargine achieving it. Further reductions in HbA_{1c} level to 6.5% and below were achieved by 24% of patients receiving exenatide and 14% of those treated with insulin glargine, a difference that approached statistical significance ($P = .056$), stressed Dr. Trautmann. Both therapies maintained decreased HbA_{1c} in the first and second treatment intervals.

Weight loss that occurred with exenatide was offset by weight gain that occurred when insulin was administered in the subsequent treatment period. Conversely, weight gain occurred when insulin was the initial treatment, and that weight was lost when exenatide treatment followed. The change in weight from baseline was significantly different ($P < .001$) between exenatide (-1.95 kg) and insulin glargine (+0.35 kg).

The combined 2-hour glucose excursions after breakfast, lunch, and dinner were significantly reduced in patients receiving exenatide compared with those treated with insulin ($P = .036$).

The incidence of nausea was 33.0% during exenatide treatment, and the incidence of headache was 8.7% during insulin therapy.

Dr. Trautmann said that one of the advantages in using exenatide is that patients do not have to adjust the dose of the medication, relative to their HbA_{1c} levels.

"Exenatide is given before the morning and evening meal at a fixed dose," Dr. Trautmann said. "Insulin is given once daily, often at bedtime, but it can be given at anytime of day. However, it needs to be titrated. "Consequently, it is much more cumbersome to arrive at an optimal dose for insulin because one needs to test himself," said Dr. Trautmann. "You increase the insulin dose as long as hypoglycemia doesn't develop and then cut back if it does develop."

Daniel Drucker, MD, an endocrinologist at the Samuel Lunenfeld Research Institute/Mount Sinai Hospital and director of the Banting and Best Diabetes Center at the University of Toronto in Ontario, Canada, said the research demonstrates another treatment option for patients.

"There are now multiple studies that have compared exenatide to insulin," said Dr. Drucker, a professor of medicine in the division of endocrinology at the University of Toronto. "They all seem to show that there is fairly equivalent glucose control and the amount of hypoglycemia is the same. Weight ends up being a bit lower with exenatide and a bit higher with insulin. This isn't saying one drug is better than another. It gives physicians and patients more options, which is a good thing."

Dr. Drucker described insulin as the gold standard therapy, but noted that exenatide is attractive in terms of patients avoiding the need to adjust the dose of medication.

Endo 2007 Annual Meeting: Abstract OR28-5. Presented June 3, 2007.

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FACT:

Acumplia review will be announced this week. Sanofi-Aventis, the French pharmaceutical company seeks Food and Drug Administration approval of Acomplia, a drug approved in Europe for fighting obesity. The FDA is set to release its Acomplia review ahead of a Wednesday meeting at which outside experts will vote on whether it should be approved. The agency does not have to follow the experts' vote, though it often does. The drug is considered a potential blockbuster despite hitting several regulatory bumps."With the initial demand for Acomplia likely to be massive, the known neuropsychiatric side effects may make it difficult for the FDA to see a positive risk-benefit ratio. In recent weeks, the FDA has been widely criticized over a lag in getting new safety data about a GlaxoSmithKline diabetes drug to the public. Analysts say that controversy might give regulators pause at approving a new drug with potentially dangerous side effects. Studies of Acomplia have shown instances of depression, insomnia and anxiety in patients who take it. If approved in the U.S., Sanofi said it would market the drug under the name Zimulti, because FDA reviewers felt the name Acomplia could potentially mislead consumers.

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Item 14

FDA Approves DexComs Continuous 7-Day Glucose Monitoring System

The U.S. FDA last week approved the 7-day use sensor to go with their CGMS system, a device that measures glucose levels continuously for up to seven days in people with diabetes.

<http://www.diabetesincontrol.com/results.php?storyarticle=4870>

While a standard fingerstick test records a person's glucose level as a snapshot in time, the STS-7 Continuous Glucose Monitoring System (STS-7 System) measures glucose levels every five minutes throughout a seven-day period. This additional information can be used to detect trends and track patterns in glucose levels throughout the week that wouldn't be captured by fingerstick measurements alone. However, diabetics must still rely on the fingerstick test to decide whether additional insulin is needed.

"The STS-7 System supplements standard fingerstick meters and test strips, providing diabetics ages 18 and older with a way to see trends and track patterns," said Daniel Schultz, M.D., director of FDA's Center for Devices and Radiological Health. "It can help detect when glucose levels drop during the overnight hours, show when glucose levels rise between meals and suggest how exercise and diet might affect glucose levels."

The STS-7 System, manufactured by DexCom Inc. of San Diego, Calif., uses a disposable sensor placed just below the skin in the abdomen to measure the level of glucose in the fluid found in the body's tissues (interstitial fluid). Sensor placement causes minimal discomfort and can easily be done by patients themselves. The sensor must be replaced weekly. An alarm can be programmed to sound if a patient's glucose level reaches pre-set lows or pre-set highs.

Diabetes can lead to wide fluctuations in blood sugar levels. Over time, abnormally high levels of glucose can damage the small and large blood vessels, leading to diabetic blindness, kidney disease, amputations of limbs, stroke, and heart disease. While there is no known cure, studies have shown that patients who regularly monitor and regulate their blood glucose levels have lower incidences of complications associated with the disease.

FDA

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Item 15

Abbott Receives European Approval for FreeStyle Navigator(R) Continuous Glucose Monitoring System

Abbott announced last week that it received European CE Mark approval for the FreeStyle Navigator(R) Continuous Glucose Monitoring System for people with diabetes. U.S. Approval should also happen soon.

<http://www.diabetesincontrol.com/results.php?storyarticle=4869>

The FreeStyle Navigator System is designed to discreetly measure glucose levels once per minute without the recurring pain and hassle that can accompany conventional blood glucose testing. With early warning alarms that alert the patient to potential highs and lows, and by providing glucose information once per minute (equivalent to 1440 times per day), the FreeStyle Navigator system provides a more complete picture of where the person's glucose level is, and where it is going -- up or down. For people with diabetes, less time spent in either a hypoglycemic (low blood sugar) or hyperglycemic (high blood sugar) state has been correlated with better diabetes management and reduced risk for a number of serious short- and long-term diabetes-related complications.

Abbott's FreeStyle Navigator System offers a number of key advances for people with diabetes. The system monitors glucose levels by measuring and transmitting glucose information once per minute to the pager-sized receiver, which can be clipped to a belt or carried in a pocket or purse. It also provides alarms before glucose levels become too high or too low, displays five directional trend arrows to help people understand if glucose is rising or falling, and stores historical data and glucose trend information. The FreeStyle Navigator System features a disposable sensor that is worn for up to five days, then replaced; a transmitter with a 10 foot (3 meter) range; and a wireless receiver with a built-in FreeStyle(R) blood glucose meter.

The FreeStyle Navigator Continuous Glucose Monitoring System is indicated for adults with diabetes, age 18 and older. The system may be used to continually measure glucose levels, however, to confirm hypoglycemia or pending hypoglycemia, or prior to injecting insulin, a confirming blood glucose test (fingerstick measurement) should be done.

The FreeStyle Navigator System is composed of three parts: a sensor, a transmitter and a receiver. The sensor, worn for five days and then replaced, is placed just under the skin and is attached to plastic sensor mount with adhesive to adhere to the skin, like a patch. The transmitter snaps into the sensor mount and sends glucose information wirelessly to the pager-sized receiver. The system discreetly measures glucose levels once per minute; provides high / low glucose alarms based on customizable, physician- and patient-determined levels; and delivers early-warning alarms that indicate if glucose levels are likely to be too high or too low 10, 20 or 30 minutes in advance. The system also stores up to 60 days worth of glucose information that can be analyzed by the user or a healthcare professional.

The accuracy, safety and efficacy of the FreeStyle Navigator System have been demonstrated in two separate pivotal clinical trials, including a five-day in-clinic study and a study of people with type 1 and type 2 diabetes at home.

Diabetes Care May 2007

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Quote of the Week!

"Great leaders are almost always great simplifiers, who can cut through argument, debate and doubt, to offer a solution everybody can understand."

Colin Powell, Chairman (Ret), Joint Chiefs of Staff (1937-)

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Richard K. Bernstein's New Book, Diabetes Solution 2007 is available. Containing new and revised information, this new book is on special at <http://www.diabetes911.net>. Also Dr. Bernstein's New 5 CD Set "Secrets to Normal Blood Sugars" is available. Recorded Individually For Type 1 and Type 2 Diabetes, These "LIVE" 5 CD Sets Contain The Personal Diabetes Education Program taught by Dr. Bernstein to his patients.

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