



## **“Two Reasons, One Recipe” Campaign Launches to Educate Adults with Type 2 Diabetes and High Cholesterol About Healthy Food Choices**

*Acclaimed chef and type 2 diabetes patient, Franklin Becker, developed healthy and flavorful recipes, as well as cooking and shopping tips unique to the campaign*

**November 16, 2010; Parsippany, NJ** – The “Two Reasons, One Recipe” campaign is launching today to focus attention on the importance of reducing A1C (blood sugar) and LDL-C (“bad” cholesterol) in adults with type 2 diabetes and high cholesterol, two important risk factors for cardiovascular disease.\* In fact, more than 50 percent of adults with type 2 diabetes also have high LDL cholesterol.<sup>1</sup>

Franklin Becker, acclaimed Executive Chef of Abe & Arthur’s restaurant in New York City, and Dr. Yehuda Handelsman, Medical Director of the Metabolic Institute of America in Tarzana, Calif., have teamed up with Daiichi Sankyo, Inc., to educate adults who have type 2 diabetes and high LDL cholesterol about making healthy food choices. Diagnosed with type 2 diabetes at age 27, Chef Becker is committed to creating healthy and flavorful recipes for people to create at home, and helping them to make appropriate choices when they are eating out.

“For the millions of American adults with type 2 diabetes and/or high LDL-C, trying to understand what you can and cannot eat may seem like an overwhelming burden. As part of the ‘Two Reasons, One Recipe’ campaign, I’ve developed a number of great new recipes that are flavorful and healthy for people with either or both of these chronic health conditions,” said Chef Becker. “After being diagnosed with type 2 diabetes and seeing other family members also struggle with this condition, I made adjustments to my cooking style. I’ve incorporated these changes into my recipes, which I look forward to sharing with others across the country who, like me, want and need to eat healthier food.”

The “Two Reasons, One Recipe” campaign features an online educational resource, [www.TwoReasonsOneRecipe.com](http://www.TwoReasonsOneRecipe.com), where adults with type 2 diabetes and/or high LDL-C can

find Chef Becker's recipes, cooking and shopping tips, and helpful information about type 2 diabetes and high LDL cholesterol. The campaign is supported by Daiichi Sankyo, Inc., the marketer of Welchol® (colesevelam HCl), and is launching in November 2010, which is recognized around the world as Diabetes Awareness Month.

"For many of my adult patients with type 2 diabetes and elevated LDL-C, managing their diet is one of the greatest challenges they face on a daily basis, which is why I'm excited to be partnering with Chef Franklin Becker on the 'Two Reasons, One Recipe' campaign," said Yehuda Handelsman, MD, FACP, FACE, FNLA Medical Director of the Metabolic Institute of America in Tarzana, Calif. "In my experience, the best approach to help adult patients with type 2 diabetes and elevated LDL-C effectively manage their conditions is one that's comprehensive and includes the right balance of diet, exercise and medications, such as Welchol. Welchol is currently the only product approved by the FDA (U.S. Food and Drug Administration), in addition to diet and exercise, to lower both A1C and LDL-C in adults with type 2 diabetes and high cholesterol.\*\* Ask your healthcare provider if Welchol is right for you."

According to the American Diabetes Association (ADA), about 23.6 million, or 8 percent of people in the United States, have diabetes, and every 21 seconds another person is diagnosed.<sup>2,3</sup> Approximately 90 to 95 percent of those diagnosed with diabetes have type 2 diabetes.<sup>2</sup> The ADA and the American College of Cardiology emphasize that it is critical to reduce both A1C and LDL-C levels, as more than 50 percent of adults with type 2 diabetes also have elevated LDL-C, greatly increasing their risk of cardiovascular disease.<sup>\*1,4,5</sup> The ADA recommends that in general, adult patients with type 2 diabetes target an A1C level of less than 7 percent, and an LDL-C goal of less than 100 mg/dL.<sup>6</sup>

\*Welchol has not been shown to prevent heart disease or heart attacks.

\*\*Welchol should not be used to treat type 1 diabetes or a condition known as ketoacidosis. Welchol has not been studied as a single medicine for T2DM or in combination with all anti-diabetes medications. Welchol is not for everyone, especially those with a history of intestinal blockage, those with blood triglyceride levels of greater than 500 mg/dL, or a history of pancreatitis (inflammation of the pancreas) due to high triglyceride levels.

## **IMPORTANT INFORMATION ABOUT WELCHOL**

### **Indications**

Welchol is indicated as an adjunct to diet and exercise to:

- reduce elevated low-density lipoprotein cholesterol (LDL-C) in patients with primary hyperlipidemia (Fredrickson Type IIa) as monotherapy or in combination with an hydroxymethylglutaryl-coenzyme (HMG CoA) reductase inhibitor (statin)

- reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia, as monotherapy or in combination with a statin after failing an adequate trial of diet therapy
- improve glycemic control in adults with type 2 diabetes mellitus

### **Important Limitations of Use**

- Welchol (colesevelam HCl) should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis
- Welchol has not been studied in type 2 diabetes as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor and has not been extensively studied in combination with thiazolidinediones
- Welchol has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias
- Welchol has not been studied in children younger than 10 years of age or in premenarchal girls

### **Contraindications**

Welchol is contraindicated in individuals with a history of bowel obstruction, those with serum triglyceride (TG) concentrations of >500 mg/dL, or with a history of hypertriglyceridemia-induced pancreatitis.

### **Warnings and Precautions**

The effect of Welchol on cardiovascular morbidity and mortality has not been determined.

Welchol can increase serum TG concentrations particularly when used in combination with sulfonylureas or insulin. Caution should be exercised when treating patients with TG levels >300 mg/dL.

Welchol may decrease the absorption of fat-soluble vitamins A, D, E, and K. Patients on vitamin supplements should take their vitamins at least 4 hours prior to Welchol. Caution should be exercised when treating patients with a susceptibility to vitamin K or fat-soluble vitamin deficiencies. Caution should also be exercised when treating patients with gastroparesis, gastrointestinal motility disorders, a history of major gastrointestinal tract surgery, and when treating patients with dysphagia and swallowing disorders.

Welchol reduces gastrointestinal absorption of some drugs. Drugs with a known interaction with colesevelam (cyclosporine, glyburide, levothyroxine, and oral contraceptives [ethinyl estradiol, norethindrone]), should be administered at least 4 hours prior to Welchol. Drugs that have not been tested for interaction with colesevelam, especially those with a narrow therapeutic index, should also be administered at least 4 hours prior to Welchol. Alternatively, the physician should monitor drug levels of the co-administered drug.

To avoid esophageal distress, Welchol for Oral Suspension should not be taken in its dry form.

Due to tablet size, Welchol for Oral Suspension is recommended for, but not limited to, use in the pediatric population as well as in any patient who has difficulty swallowing tablets.

**Phenylketonurics:** Welchol for Oral Suspension contains 48 mg phenylalanine per 3.75 gram dose.

### **Adverse Reactions**

In clinical trials, the adverse reactions observed in  $\geq 2\%$  of patients, and more commonly with Welchol than placebo, regardless of investigator assessment of causality seen in:

- Adults with Primary Hyperlipidemia were: constipation (11.0% vs 7.0%), dyspepsia (8.3% vs 3.5%), nausea (4.2% vs 3.9%), accidental injury (3.7% vs 2.7%), asthenia (3.6% vs 1.9%), pharyngitis (3.2% vs 1.9%), flu syndrome (3.2% vs 3.1%), rhinitis (3.2% vs 3.1%), and myalgia (2.1% vs 0.4%)
- Pediatric patients with heFH primary hyperlipidemia were: nasopharyngitis (6.2% vs 4.6%), headache (3.9 vs 3.1%), fatigue (3.9% vs 1.5%), creatine phosphokinase increase (2.3% vs 0.0%), rhinitis (2.3% vs 0.0%), and vomiting (2.3% vs 1.5%)

- Adult patients with Type 2 Diabetes were: constipation (8.7% vs 2.0%), nasopharyngitis (4.1% vs 3.6%), dyspepsia (3.9% vs 1.4%), hypoglycemia (3.0% vs 2.3%), nausea (3.0% vs 1.4%), and hypertension (2.8% vs 1.6%)

Post-marketing experience: Due to the voluntary nature of these reports it is not possible to reliably estimate frequency or establish a causal relationship:

- Increased seizure activity or decreased phenytoin levels have been reported in patients receiving phenytoin concomitantly with Welchol (colesevelam HCl)
- Reduced International Normalized Ratio (INR) has been reported in patients receiving warfarin concomitantly with Welchol
- Elevated thyroid-stimulating hormone (TSH) has been reported in patients receiving thyroid hormone replacement therapy

### **Pregnancy**

Welchol is Pregnancy Category B.

Please visit [http://www.welchol.com/pdf/Welchol\\_PI.pdf](http://www.welchol.com/pdf/Welchol_PI.pdf) for full Product Information on Welchol.

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

For more information on Welchol, call 877-4-DSPROD (877-437-7763), or go to the Welchol website at [www.Welchol.com](http://www.Welchol.com).

For patients having difficulty affording their Welchol medication, please call the Daiichi Sankyo, Inc., Open Care Patient Assistance Program at 1-866-268-7327 for more information or visit [www.dsi.com](http://www.dsi.com).

### **About Franklin Becker**

Born and raised in Brooklyn, New York, Chef Becker's life has always been centered on food. By the time he was 14, Becker was working in a professional kitchen. Upon graduation from college, he attended the prestigious Culinary Institute of America from which he graduated with honors. Having cooked in the past for Revlon magnate Ronald Perelman, Becker has also held the post of Executive Chef at several fine New York establishments including Local, Capitale, the Tribeca Grand and Soho Grand Hotels and Brasserie. Chef Becker is currently Executive Chef at Abe & Arthur's.

### **About Yehuda Handelsman, MD, FACP, FACE, FNLA**

Dr. Yehuda Handelsman is an endocrinologist in private practice in Tarzana, Calif. He is currently the Medical Director of the Metabolic Institute of America and Chair and Program Director of the World Congress on Insulin Resistance, Diabetes, and Cardiovascular Disease. He has been a member of the Diabetes Treatment Algorithm and National Lipid Guidelines of the American Association of Clinical Endocrinologists (AACE). Dr. Handelsman is also a member of such professional organizations as the American College of Endocrinology, American Diabetes Association, National Lipid Association and American College of Physicians.

**About Welchol (colesevelam HCl)**

Welchol, along with diet and exercise, lowers LDL or "bad" cholesterol. It can be taken alone or with other cholesterol-lowering medications known as statins. Welchol, along with diet and exercise, also lowers blood sugar levels in adult patients with type 2 diabetes mellitus when added to other anti-diabetic medications (metformin, sulfonylureas, or insulin). Welchol was approved by the FDA to lower bad cholesterol in 2000 and to lower blood sugar levels in 2008. Welchol is available in two formulations, Welchol tablets and Welchol® for Oral Suspension.

Welchol should not be used to treat type 1 diabetes or diabetic ketoacidosis, and it has not been studied with all anti-diabetic medications. Welchol is not for everyone, especially those with a history of intestinal blockage, those with blood triglyceride levels of greater than 500 mg/dL, or a history of pancreatitis (inflammation of the pancreas) due to high triglyceride levels.

In clinical studies of adult patients with type 2 diabetes, Welchol lowered A1C, fasting blood sugar and LDL-C, important risk factors for heart disease. In clinical studies of patients with elevated LDL-C, Welchol lowered LDL-C when used alone or when added to other cholesterol-lowering medications known as statins. Welchol has not been shown to prevent heart disease or heart attacks.

**About Daiichi Sankyo**

In keeping with its vision of becoming a "Global Pharma Innovator," the Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of customers in both developed and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit [www.daiichisankyo.com](http://www.daiichisankyo.com).

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Company, Ltd. For more information on Daiichi Sankyo, Inc., please visit [www.dsi.com](http://www.dsi.com).

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## **References**

1. Cheung BMY et al. Diabetes Prevalence and Therapeutic Target Achievement in the United States, 1999 to 2006. *The American Journal of Medicine*. 2009;122:443-453.
2. Center for Disease Control, National Diabetes Fact Sheet 2007. [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2007.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf). Accessed September 27, 2010.
3. American Diabetes Association. I Decide to Fight Diabetes Fact Sheet. Accessed at: <http://www.diabetes.org/assets/pdfs/id-factsheet.pdf>.
4. Brunzell JD, Davidson M, Furberg CD, et al. Lipoprotein Management in Patients with Cardiometabolic Risk: Consensus Statement from the American Diabetes Association and the American College of Cardiology Foundation. *Diabetes Care*. 2008;31(4):811-822.
5. Buse JB, Ginsberg HN, Bakris GL, et al. Primary Prevention of Cardiovascular Diseases in People With Diabetes Mellitus: A Scientific Statement From the American Heart Association and the American Diabetes Association. *Circulation*. 2007;115:114-126. <http://circ.ahajournals.org/cgi/content/full/115/1/114>. Accessed September 27, 2010.
6. American Diabetes Association: Standards of Medical Care in Diabetes – 2010. *Diabetes Care*. 2010; 33 (Suppl 1): S11-S61

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