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Urgent: Support the Proposed New Law in California Requiring Doctors to Provide Patients with Information on Diabetes and Heart Disease. Part 2 - Diabetes

Patients often receive inadequate and/or incorrect information from their doctors on diabetes and heart disease. Last month's newsletter was on the heart disease side of this bill. Concerning type-2 diabetes, health professionals and pharmaceutical companies disseminate incorrect and inadequate information on these four important issues:

New Fax numbers for Assembly Members: Write to these policymakers about the need for change for both heart disease and diabetes treatments.

Please send letters to members of the Business & Professions Committee (who are initially reviewing this bill) asking them for their support of AB 1478. Send a CC to jimlaw@jps.net for an additional hand delivery of your letter to committee members. A sample letter is provided at the end of this article. Here are their e-mail addresses and faxes:

B&P consultants to the Assembly member:

Member	Fax#
For Mary Hayashi:	916 319 2118
For Bill Emmerson:	916 319 2163
For Connie Conway:	916 319 2134
For Mike Eng:	916 319 2149
For Ed Hernandez:	916 319 2157
For Pedro Nava:	916 319 2135
For Roger Niello:	916 319 2105
For John Perez:	916 319 2146
For Curran Price:	916 319 2151
For Ira Ruskin:	916 319 2121
For Cameron Smyth:	916 319 2138
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- 1) Patients are told diabetic medications for type-2 diabetes will prolong life and prevent complications of diabetes, while extensive scientific research says otherwise for the most commonly prescribed oral medications.
- 2) Patients are told that their blood sugars (and hemoglobin A1c levels) must be lowered as close to normal levels as possible. However, all six major studies show intensive therapy increases the risk of heart disease, death, and serious side effects.
- 3) The public receives almost no education about the role of the rich Western diet in the cause of type-2 diabetes and about the right way to eat to prevent this disease.
- 4) Patients are rarely told that changing to a healthy, low-fat, plant-food based diet, exercise, and associated weight loss will improve their health and often cure their type-2 diabetes.

Assembly Bill 1478 has been introduced by California state assembly member Tom Ammiano, representing the 13th District, to require that a physician obtain a patient's written acknowledgment confirming the receipt of information, as specified, regarding treatment through medical nutrition therapy prior to delivering nonemergency treatment for type-2 diabetes. My supporting letter on this matter is provided below. Last month's newsletter (March 2009) has a similar letter from me about heart disease treatments and a request for your support.

<u>Dr. McDougall's Letter of Support</u> <u>for AB 1478:</u>

Requirement to Inform Patients in Writing about the Adverse Ef-

fects of Pharmaceutical Treatments and the Benefits of Nutritional Therapies for Type-2 Diabetes.

The Patients' Right to Informed Consent

Informed consent is a patient right guaranteed by the bylaws of most hospitals. California law requires that a patient's consent be obtained in writing for several specific procedures and treatments, including: sterilizations, hysterectomy, breast cancer, prostate cancer, gynecological cancers, psychosurgery, and electroconvulsive therapy, but not for type-2 diabetes treatments. California patients with type-2 diabetes need to be informed in writing about the lack of benefits and the real harms of current therapies with oral and injectable medications. They also need to be told that the cause of their diabetes is the rich Western diet and associated weight gain, and that their condition is reversible with a change in diet, exercise, and weight loss.

The Diabetes Epidemic

According to the National Institutes of Health (NIH) in 2007 a total of 23.5 million, or 10.7 percent, of all people aged 20 years or older in the US have diabetes at a cost of \$174 billion. The vast majority of this diabetes is type-2 diabetes, caused by over-nutrition from the rich Western diet, and the associated weight gain. Eighty-four percent of diabetics are on medications (insulin and/or oral). Born in the year 2000, a male child's lifetime risk of developing type-2 diabetes is nearly 33%, and a female's risk will be 39% when following the Western diet. The escalating incidence of type-2 diabetes clearly indicates that current efforts at prevention and treatment are failing. The reason for this failure is the almost exclusive emphasis on drug therapies, and the lack of efforts to address the dietary and lifestyle causes and treatments of type-2 diabetes.

The Failure of Non-emergency Diabetic Medications

Diabetic medications are approved by the FDA for market based upon their ability to lower blood sugar levels, not based on any improvements in the quality or quantity of the patients' lives.³ In a major study, a popular diabetic medication, Avandia (rosiglitazone), given at a dosage of 4 mg twice daily, on average, decreased hemoglobin A1c levels by 1.5 percentage points, reduced fasting plasma sugar by 76 mg/dL (4.22 mmol/L), and reduced insulin resistance by 25%.⁴ These improved numbers should have meant healthier patients, but they didn't. On May 21, 2007 the *New York Times* reported, "...patients taking Avandia had 66 percent more heart attacks, 39 percent more strokes and 20 percent more deaths from cardiovascular-related problems." Since 1972, the *Physicians Desk Reference* (PDR) descriptions of most diabetic pills have included two paragraphs in heavy black print that begin with: "Special Warning on Increased Risk of Cardiovascular Mortality." This warning is because a very commonly prescribed oral medication, called sulfonylurea, increases the risk of cardiovascular death by 2½ times compared to diet treatment alone.

Mediations (oral and injectable) for type-2 diabetes are prescribed aggressively by physicians with the unfounded belief that better control of blood sugar will result in better long-term outcomes for the patients. All six major studies published over the past 13 years have shown otherwise. Three major studies published between 1996 and 2000 found more weight gain, higher cholesterol, triglycerides, and blood pressure; and more heart disease, stroke, and/or death with "aggressive" treatment compared to less treatment.⁷⁻⁹

This past year, 2008, three landmark studies, ACCORD, ADVANCE, and VADT, were published in the *New England Journal of Medicine*. All three showed aggressive treatment does more harm than good. ¹⁰⁻¹² On February 6, 2008 the National Heart, Lung, and Blood Institute (NHLBI), stopped the ACCORD study (Action to Control Cardiovascular Risk in Diabetes) when results showed that intensive treatment of diabetics increases the risk of dying compared to those patients treated less aggressively. ¹³ Patients in the intensive group were oftentimes taking four shots of insulin and three pills daily, and checking their blood-sugar levels four times a day. ¹⁰

The Veterans Affairs Diabetes Trial (VADT) was based on 1791 military veterans with type-2 diabetes. 12

Patients were assigned to receive either intensive- or standard-glucose control and studied for 5.6 years. The intensive-therapy reduced their hemoglobin A1c levels to 6.9%; compared to 8.4% in the standard-therapy group. A weight gain of 18 pounds occurred with the intensive-treatment, compared to 9 pounds with standard-therapy. There were 95 deaths from any cause in the standard-therapy group and 102 in the intensive-therapy group. In the intensive-therapy group, the number of sudden deaths was nearly three times the number of those in the standard-therapy group (11 vs. 4). More patients in the intensive-therapy group had at least one serious adverse event, predominantly hypoglycemia, than in the standard-therapy group.

The Efficacy of Diet-therapy

Drug therapy has consistently failed patients with type-2 diabetes, making search for an alternative treatment imperative. Since the rich Western diet is agreed to be the cause of this epidemic, should diet not be the first place to look for the prevention and the cure?¹⁴ Studies on the benefits of a low-fat, high-carbohydrate, plant-food-based diet on type-2 diabetes date back to 1930.¹⁵ Several published studies demonstrate how type-2 diabetics can stop insulin and get off oral diabetic medications with a change in diet.¹⁶⁻¹⁸ Heart disease accounts for 70% of the deaths in diabetics. By great fortune, this same low-fat, low-cholesterol diet (successfully used for diabetes therapy) has been shown to prevent and treat heart and kidney disease, and prevent many common forms of cancer.

A study recently published in *Diabetes Care* found a low-fat, plant-food-based diet improved the health of people with type-2 diabetes even more than the American Diabetes Association (ADA) Diet did. ¹⁹ Forty-three percent of the plant-food group and 26% of the ADA group participants reduced their diabetes medications. Reductions of hemoglobin A1c, LDL "bad" cholesterol, and urine protein were greater in the plant-food group, than those on the ADA diet. People following the plant-based diet could eat unlimited amounts of food, while those on the ADA diet were required to control their portion sizes—and compliance was better on with the plant-food-based diet. Exercise did not play a role in this study. ²⁰

Low-carbohydrate, high-protein diets have also been shown to cause people to lose weight and reduce their blood sugar levels.²¹ However, these kinds of diets are also high in fat, high in cholesterol, and very low in dietary fiber; therefore, they cannot be recommended. The American Heart Association, because of their disease-causing effects, has condemned low-carbohydrate diets.²²

Cost Savings to the State of California

Over 2 million Californians currently have diabetes, and the number of Californians with diabetes is expected to double by 2025. In California in 2003, the total direct and indirect costs of diabetes were estimated to be more than \$17.9 billion per year. Obesity threatens to surpass tobacco as the leading cause of preventable death among Californians and obesity costs the state \$28.5 billion in health care expenses, lost productivity, and workers' compensation. A cost-benefit analysis published in the October-December 2006 issue of the University of California's *California Agriculture* journal has determined that every dollar spent on nutrition education in California saves between \$3.67 and \$8.34 in future medical costs. The current drug therapies for type-2 diabetes promote both obesity and heart disease—widespread utilization of diet-therapy will reduce the costs and incidence of all three epidemics (diabetes, obesity, and heart disease), saving California billions of dollars.

Sample Letter to Assembly Member

Dear Assembly Member (their name):

I am writing to ask you to vote for AB 1478. Chronic diseases like heart disease and diabetes are epidemic in America and California. From my personal experience I know that while drug medication can be of value in emergency situations, drugs ultimately never cure the disease – they only suppress the symptoms of the disease. This is an expensive way to treat diseases. Our state cannot anymore afford the high cost of treating patients with drugs and surgery alone. Diet and lifestyle changes have been found to be helpful in arresting and even curing heart disease and diabetes, and are very inexpensive compared to drugs and surgery. I feel doctors should give their patients the option to be referred out for diet advice and nutrition therapy for their non-emergency heart disease or diabetic condition. Doctors also must be required by law to tell the truth about the limitations of current treatments.

Thank you very much for your support for AB 1478.

Sincerely,

Your name, address, and e-mail

References:

- 1) http://www.calpatientguide.org/ii.html
- 1a) http://diabetes.niddk.nih.gov/DM/PUBS/statistics/
- 2) Narayan KM. Lifetime risk for diabetes mellitus in the United States. *JAMA* 2003; 290: 1884-90.)
- 3) http://www.medscape.com/viewarticle/585593
- 4) Lebovitz HE, Dole JF, Patwardhan R, Rappaport EB, Freed MI; Rosiglitazone Clinical Trials Study Group. Rosiglitazone monotherapy is effective in patients with type 2 diabetes. *J Clin Endocrinol Metab.* 2001 Jan;86(1):280-8.
- 5) http://www.nytimes.com/2007/05/22/business/22drug.html?pagewanted=print
- 6) Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med.* 2007 Jun 14;356(24):2457-71
- 7) Purnell JQ. Effect of excessive weight gain with intensive therapy of type 1 diabetes on lipid levels and blood pressure: results from the DCCT. Diabetes Control and Complications Trial. *JAMA*. 1998 Jul 8; 280(2):140-6.
- 8) Colwell JA, Clark CM Jr. Forum Two: Unanswered research questions about metabolic control in non-insulin-dependent diabetes mellitus. *Ann Intern Med.* 1996 Jan 1;124(1 Pt 2):178-9.
- 9) Gustafsson I, Hildebrandt P, Seibaek M, Melchior T, Torp-Pedersen C, Kober L, Kaiser-Nielsen P. Long-term prognosis of diabetic patients with myocardial infarction: relation to antidiabetic treatment regimen. The TRACE Study Group. *Eur Heart J.* 2000 Dec; 21(23):1937-43.
- 10) Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME, Byington RP, Goff DC Jr, Bigger JT, Buse JB, Cushman WC, Genuth S, Ismail-Beigi F, Grimm RH Jr, Probstfield JL, Simons-Morton DG, Friedewald WT. Effects of intensive glucose lowering in type 2 diabetes. *N Engl J Med.* 2008 Jun 12;358(24):2545-59.

- 11) ADVANCE Collaborative Group, Patel A, MacMahon S, Chalmers J, Neal B, Billot L, Woodward M, Marre M, Cooper M, Glasziou P, Grobbee D, Hamet P, Harrap S, Heller S, Liu L, Mancia G, Mogensen CE, Pan C, Poulter N, Rodgers A, Williams B, Bompoint S, de Galan BE, Joshi R, Travert F. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. *N Engl J Med.* 2008 Jun 12;358(24):2560-72.
- 12) Duckworth W, Abraira C, Moritz T, Reda D, Emanuele N, Reaven PD, Zieve FJ, Marks J, Davis SN, Hayward R, Warren SR, Goldman S, McCarren M, Vitek ME, Henderson WG, Huang GD; the VADT Investigators. Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes. *N Engl J Med.* 2008 Dec 17.
- 13) BMJ 2008; 336: 407, doi:10.1136/bmj.39496.527384.DB
- 14) Bulletin of the World Health Organization 80:952-958. http://www.who.int/bulletin/archives/80(12)952.pdf
- 15) Rabinowitch I. Experiences with a high carbohydrate-low calorie diet for the treatment of diabetes mellitus. *Can Med Assoc J* 23:489, 1930)
- 16) Kiehm T. Beneficial effects of a high carbohydrate, high fiber diet on hyperglycemic diabetic men. *Am J Clin Nutr* 29:895, 1976.
- 17) Singh I. Low-fat diet and therapeutic doses of insulin in diabetes mellitus. Lancet 1:422, 1955.
- 18) Barnard R. Response of non-insulin-dependent diabetic patients to an intensive program of diet and exercise. *Diabetes Care* 5:370, 1982.
- 19) Barnard ND, Cohen J, Jenkins DJ, Turner-McGrievy G, Gloede L, Jaster B, Seidl K, Green AA, Talpers S. A low-fat vegan diet improves glycemic control and cardiovascular risk factors in a randomized clinical trial in individuals with type 2 diabetes. *Diabetes Care*. 2006 Aug; 29(8):1777-83.
- 20) Barnard ND, Gloede L, Cohen J, Jenkins DJ, Turner-McGrievy G, Green AA, Ferdowsian H. A low-fat vegan diet elicits greater macronutrient changes, but is comparable in adherence and acceptability, compared with a more conventional diabetes diet among individuals with type 2 diabetes. *J Am Diet Assoc.* 2009 Feb; 109(2): 263-72.
- 21) Dashti HM, Mathew TC, Khadada M, Al-Mousawi M, Talib H, Asfar SK, Behbahani AI, Al-Zaid NS. Beneficial effects of ketogenic diet in obese diabetic subjects. *Mol Cell Biochem.* 2007 Aug; 302(1-2): 249-56.
- 22) St. Jeor S, Howard B, Prewitt E. Dietary protein and weight reduction. A statement for health professionals from the Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism of the American Heart Association. Circulation 2001;104:1869-74.
- 23) http://gov.ca.gov/pdf/press/Governors_HC_Proposal.pdf
- 24) California DHS, Fast Facts on Diabetes, August 2003. http://www.publichealthadvocacy.org/printable/CCPHA_RDiabetes.pdf
- 25) http://news.ucanr.org/newsstorymain.cfm?story=875