



Intensive Therapy Means You Will Die Sooner with Good Looking Numbers

I am outraged that no serious action is being taken by medical doctors to stop the conscious killing of patients by the pharmaceutical companies. Responsible physicians need to stand up—we swore an oath to protect our patients—to keep their welfare as our highest priority—not to safeguard the earnings of any industry. Research over the past four decades has consistently shown that intensive drug treatment will lower **risk factors**, such as cholesterol, blood sugar, and blood pressure; but will also cause patients to die sooner, albeit, with better looking numbers. So far, any changes in medical practices resulting from all this bad news have been imperceptible. In fact, most of my colleagues, without taking a single dime, readily come to the defense of the drugs they prescribe, and their manufacturers—the others take a bribe.

In general, people who have elevations of cholesterol, blood sugar, and blood pressure, known as risk factors, have a greater chance of having heart attacks and strokes in the future. These elevated numbers are the signs of disease, not actual disease. During my forty years in the profession (I started medical school in 1968), I have never seen a patient die of high cholesterol, high blood sugar, and/or high blood pressure. These people die from rotten arteries, manifesting as strokes and heart attacks. Drugs won't heal the sick arteries. The reason pharmaceutical companies sell drugs that treat the **signs of diseases is they can**. The reason they don't sell drugs that cure the **underlying diseases is they can't**.

To compound matters, medications cause "warning messages" to disappear, leading many people to a false sense of security. As a direct result, they fail to take appropriate actions to improve their diets and lifestyles—measures that would make real differences. During patient interviews (a history I

in and was
seen in hy-
nical trials
se interac-
tion of H2-

ng tid) and
and T_{1/2} of
and it de-
l M2 from
ynamic re-
ormal sub-
data from
o evidence
ith uncon-
ters. How-
exercised
trial for hy-

lmeipiride
acokinetic
s following
ic warfarin
n warfarin
result in a
e pharma-
is in mean
maximum
very small
to be clini-

ptide, and
cted by co-
5 mg once
stoma were
ients with
nt adverse
istration of
e and oral
cemia has

1. Known hypersensitivity to the drug.
2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin.

WARNINGS

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY

The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term, prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (Diabetes, 19 supp. 2: 747-830, 1970).

UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2-1/2 times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of AMARYL (glimepiride tablets) and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may also apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS

General

Hypoglycemia: All sulfonylurea drugs are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemic episodes. Patients with impaired renal function may be

Glimepirid
in vivo mu-
tion, chron
mouse mic
There was
animals: e-
times the
surface ar-
male and f
weight (aj
mended ha
Pregnancy
Teratogeni
did not pre-
to 4000 mg
maximum
or in rabbi-
mately 60
based on e
associated
in doses as
area and i
the human
served on l
been simi-
lieved to b
emic) act
There are
nant wom
AMARYL
pregnancy
mal blood
with a hig
experts re-
to maintai-
Nonterato
of dams e
nancy and
ing of sho
during th
olmeipirid

take when people come to my 10-day, live-in program), I often notice that the "disease portion" of their data sheet is left blank, while their medication list is extensive. I ask, "Why have you left this section about your diseases blank, when you are taking three medications for high blood pressure, two for diabetes, and a statin?" Their answer: "I don't have these problems anymore, since I started taking these drugs." They believe they have been cured because the "warning messages" are gone. But this deduction is contrary to common sense and the results of extensive scientific research.

Aggressive Treatment of Diabetes Kills

Diabetic medications are approved 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. A popular diabetic medication, Avandia (rosiglitazone), given at a dosage of 4 mg twice daily, on average, decreases hemoglobin A1c by 1.5 percentage points, reduces fasting plasma sugar by 76 mg/dL (4.22 mmol/L), and reduces insulin resistance by 25%.¹ Urinary

protein excretion also decreases significantly. Logically, these improved numbers should mean healthier patients, but they don'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."^{2,3} That same day the FDA issued a Safety Alert on Avandia. Paradoxically, this study funded by Glaxo, was called "the DREAM study," (an acronym for Results of the Diabetes Reduction Assessment with ramipril and rosiglitazone Medication). In reality, the nightmare for patients continues as this toxic drug is still marketed aggressively to patients and their doctors.

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.⁴ Patients in the intensive group were sometimes taking four shots of insulin and three pills daily, and checking their blood-sugar levels four times a day. The goal of intensive treatment was to make the patients' blood sugar numbers as close to "normal" as possible, as measured by a hemoglobin A1c. (This test reflects long-term sugar control). Those with the "better numbers" died more often.

The DREAM and ACCORD studies are not the first time aggressive treatments with insulin and diabetic pills have been reported to harm and kill people. Since 1972, the *Physicians Desk Reference* (PDR)'s descriptions of every diabetic pill have included two paragraphs in heavy black print that begin with: "**Special Warning on Increased Risk of Cardiovascular Mortality.**" Even more scandalous, three major studies published between 1996 and 2000 have shown more weight gain, higher cholesterol, triglycerides, and blood pressure; and more heart disease, stroke, and/or death with "aggressive" treatment compared to less treatment.⁵⁻⁷

Diabetic Treatments Increase Heart Disease

Unfortunately for the patient, the doctors, and the drug companies, "anti-diabetic treatments"—pills and injected insulin – are actually "anti-diabetic-patient" in the sense that they commonly hurt the customer. Consider the results of these major studies:

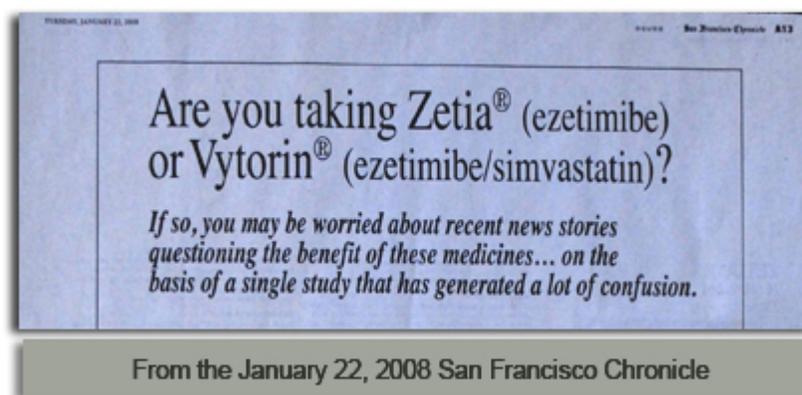
- The Diabetes Control and Complications Trial (DCCT) is the largest study done to show the effects of drug therapy on diabetics.⁵ Six and a half years of treatment with intensive insulin therapy for type-1 diabetics resulted in more weight gain, as well as higher cholesterol, LDL (bad) cholesterol, triglycerides and blood pressure compared to people treated less aggressively. As expected from the rise in cholesterol, there was an increase in the risk of heart disease and stroke for the intensively treated patients.
- The Veterans Affairs Cooperative Study in Glycemia Control and Complications in NIDDM study showed an increase in cardiovascular events in those receiving intensive therapy.⁶ In this research paper diabetic patients with a history of a heart attack were studied, and those treated with insulin or diabetic medications had an increased risk of death.
- In a large European study, The TRACE Study Group, investigators found diabetic patients with a history of heart attacks treated with diabetic pills and/or insulin had almost twice the death rate as those diabetics treated with diet alone.⁷ Diabetics treated without medications (diet only) had the same death rate as people without diabetes.

Aggressive Treatment of Cholesterol Kills

Worldwide, the number one prescribed medications are statins for lowering cholesterol. Doctors have been so seduced by provocatively dressed, attractive, young female "drug reps," and the "science," that many have come to believe that, "these drugs are of such great public benefit that they should be put into the drinking water for everyone to consume." In truth, their benefits have been established only for people with very high risks, such as patients with a history of previous heart surgery, heart attacks,

and/or strokes.⁸ Hardly mentioned are the serious side effects, including death, and the fact that these drugs are approved for market based upon their ability to lower cholesterol levels, not based on any improvements in the quality or quantity of the patients' lives.

Vytorin, a combination of Zocor (a statin which blocks cholesterol synthesis) and Zetia (which blocks intestinal absorption of cholesterol), rocketed to the third best-selling cholesterol-lowering medication soon after its introduction in 2004. In 2007, Vytorin was a \$4 billion-a-year treatment, but sales should be slightly off for 2008. After withholding the results from the public for nearly two years, on January 14, 2008, the company Merck/Schering-Plough Pharmaceuticals, announced, under pressure from the US Congress, that even though patients taking Vytorin dramatically lowered their cholesterol levels, they achieved no improvement in survival, compared to Zocor alone; and doubled the thickness of their arteries (intimal-media thickness).⁹ This thickening is associated with an increased risk of stroke and heart attacks. Not coincidentally, Zocor, ran out of its patent protection in June of 2006. For damage control, one week after this report on Vytorin, Merck/Schering-Plough Pharmaceuticals ran full two-page ads in newspapers worldwide.



Aggressive Treatment of Hypertension Kills

Anti-hypertension drugs are approved for market based upon their ability to lower blood pressure levels, not based on any improvements in the quality or quantity of the patients' lives. Over the past 22 years, multiple studies have shown that aggressive treatment of hypertension with a goal of making the numbers look normal (110/70 mmHg or less), increases the patient's risk of heart attack, stroke, brain damage, and/or death.^{10,11} The phenomenon is known as the "J-shaped curve of mortality." Meaning: lowering the pressure to a certain point is beneficial (that is the first part of the "J" shape), but beyond that point of reduction, the patient is harmed (the second part of the "J"). This harm is found with both systolic (top number) and diastolic (bottom number) pressure changes. Based on solid research, diastolic blood pressure should not be reduced below 85 mmHg by medications.¹²

In June of 2006 an extensive review of the data on 22,576 patients with heart disease and hypertension was published. When treated with medications, the incidence of heart attacks, death, and/or stroke was three times higher for patients with a diastolic blood pressure of 60 mmHg compared to a pressure of 80 to 90 mmHg.¹⁰ Another study of the elderly found a 14% increase in strokes in those whose diastolic pressure was lowered by only 5 mmHg with medications (starting average of 177/77 mmHg).¹³ Furthermore, the brain function in the elderly is impaired by intensive treatment of blood pressure with medication.¹⁴ This loss of intelligence may be permanent in some cases.

Why Does Intensive Therapy Kill?

You might expect the results of pharmaceutical treatments for chronic disease to be neutral, because the therapies are directed at risk factors rather than the underlying illnesses. Not so—the more intense the treatments, the worse the outcomes. Medications have serious, sometimes fatal, side effects—but

this is only a small part of the answer.

The most important reason intensive therapy kills is that drug treatments, which focus on the signs and symptoms of disease, are counterproductive to the body's efforts to stay alive under adverse conditions. We are designed to live optimally under conditions of clean air, water, and food (a starch-based diet). If these ideal surroundings are not met then adaptations must be made to survive. For example, when people smoke cigarettes they cough and produce mucous in an effort to remove the toxic smoke from their lungs. These adjustments also serve as signs of the on-going lung injury. If cough-suppressing medication, for example, codeine syrup, were used intensive to completely suppress the cough, then more of the toxic chemicals from the smoke would be retained—hurrying the person's demise.

In addition to serving as signs of disease, elevation of the blood pressure and blood sugar (and maybe cholesterol) also serve as part of the corrective adaptations that the body makes in response to the burdens caused by the unhealthy Western diet. In the case of hypertension, the blood pressure increases in order to improve circulation. The Western diet reduces the flow of blood to the tissues by creating blockages (atherosclerosis), spasms of the arteries, and the clumping of blood cells. The net effect is an increase in (peripheral) resistance to the flow of blood. To compensate, the blood pressure rises in order to restore adequate perfusion to the tissues. A rise in blood pressure is the correct response for the body to make under these circumstances.

The pharmacological, medical answer to elevated blood pressure is to poison various parts of the cardiovascular system: beta blockers are given to weaken the heart muscle, calcium channel blockers prevent normal contraction of the arteries, anti-angiotensin drugs block the actions of adrenal hormones, and diuretics inhibit the kidneys' ability to conserve water and minerals. Rather than improving the circulation, these drugs cause the opposite: a further decline in perfusion pressure—counteracting the body's efforts to deliver adequate oxygen and nutrients to the tissues.^{15,16} The result, as would be expected from worse circulation, is more damage, seen as an increase in the risk of strokes and heart attacks, and loss of brain function (dementia).

Resistance to the actions of insulin develops in response to the burdens of the Western diet. This adaptation is made in part to stem excessive weight (fat) gain. One of the primary jobs of insulin is to store fat in the fat cells. After the accumulation of the first 30 pounds of fat, the body seems to say "that's enough," and puts the brakes on by reducing the effectiveness of insulin—in other words, *insulin resistance* develops. With weaker insulin activity, the blood sugar rises. Injections of insulin partially override this natural resistance causing weight gain to accelerate. Medications, like Byetta injections and sulfonylurea pills, cause the pancreas to release more insulin with effects similar to insulin shots. Artificially lowering blood sugar with these drugs also prevents excess calories (sugar) from being eliminated through the kidneys (glucosuria), further hindering the body's attempts to make overdue corrections by losing its excess fat. The net result of all this intensive therapy is accelerated accumulation of body fat, which means a sicker patient at more risk of death and complications. (In addition to causing obesity, intensive therapy results in many other biochemical changes that are counterproductive to survival.)

Lowering cholesterol with drugs, like statins, does little or nothing to heal the sick arteries. To make matters worse, Zetia (ezetimibe), an ingredient in Vytorin, appears to further damage a patient's arteries. Zetia works by blocking the absorption of cholesterol (an animal-synthesized sterol) by the intestines. This drug at the same time blocks the absorption of plant-derived sterols in every person taking Zetia.¹⁷ Unlike cholesterol, plant sterols cannot be synthesized within the body; therefore, they must be obtained from a diet of starches, vegetables, and fruits. Plant sterols are essential for our health, and more specifically, they are vital ingredients for healthy arteries. These sterols lower total and LDL (bad) cholesterol by a variety of mechanisms, and reduce oxidative stresses and inflammation, which lead to atherosclerosis.¹⁸

Doctors, It Is Time to Prescribe the Miracle Drug: Food

The facts are indisputable: The intensive pharmaceutical treatment of signs of chronic diseases is a fail-

ure—causing great mental, emotional, physical, and financial harm to patients. Since doctors are the gatekeepers of treatment, they have the opportunity and duty to change medical care. We must stop prescribing treatments that don't work.

The reason pharmaceutical companies don't sell drugs that cure the ***underlying diseases is they can't***. All common chronic diseases are caused by diet and lifestyle. There is little profit in selling sweet potatoes, broccoli, and a pair of walking shoes. Doctors willing to step in front of the crowd and practice lifestyle medicine will reap great rewards. Foremost, they will fulfill their professional dream by helping their patients regain their lost health and appearance, get off all unnecessary medications and avoid all unwarranted surgeries.

References:

- 1) 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.
- 2) <http://www.nytimes.com/2007/05/22/business/22drug.html?pagewanted=print>
- 3) 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
- 4) *BMJ* 2008;336:407, doi:10.1136/bmj.39496.527384.DB
- 5) 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.
- 6) 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.
- 7) 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.
- 8) Abramson J, Wright JM. Are lipid-lowering guidelines evidence-based? *Lancet.* 2007 Jan 20;369(9557):168-9.
- 9) Lenzer J. Unreported cholesterol drug data released by company. *BMJ.* 2008 Jan 26;336(7637):180-1.
- 10) Messerli FH, Mancia G, Conti CR, Hewkin AC, Kupfer S, Champion A, Kolloch R, Benetos A, Pepine CJ. Dogma disputed: can aggressively lowering blood pressure in hypertensive patients with coronary artery disease be dangerous? *Ann Intern Med.* 2006 Jun 20;144(12):884-93.
- 11) The July 2004 McDougall Newsletter: <http://www.nealhendrickson.com/mcdougall/2004nl/040700pubp.htm>
- 12) Kaplan NM. What is goal blood pressure for the treatment of hypertension? *Arch Intern Med.* 2001 Jun 25;161(12):1480-2.
- 13) Somes GW, Pahor M, Shorr RI, Cushman WC, Applegate WB. The role of diastolic blood pressure when treating isolated systolic hypertension. *Arch Intern Med.* 1999 Sep 27;159(17):2004-9.

- 14) Paran E. Blood pressure and cognitive functioning among independent elderly. *Am J Hypertens*. 2003 Oct; 16(10):818-26.
- 15) Cruickshank, J. Benefits and potential harm of lowering blood pressure. *Lancet*. 1:581-4, 1987.
- 16) Strandgaard S. Autoregulation of cerebral blood flow in hypertensive patients. The modifying influence of prolonged antihypertensive treatment on the tolerance to acute, drug-induced hypotension. *Circulation*. 1976; 53:720-7.
- 17) Sudhop T, Lütjohann D, Kodal A, Igel M, Tribble DL, Shah S, Perevozskaya I, von Bergmann K. Inhibition of intestinal cholesterol absorption by ezetimibe in humans. *Circulation*. 2002 Oct 8; 106(15):1943-8.
- 18) Devaraj S, Jialal I. The role of dietary supplementation with plant sterols and stanols in the prevention of cardiovascular disease. *Nutr Rev*. 2006 Jul; 64(7 Pt 1):348-54.