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# How to Identify and Avoid the Bad Guys

Recently while on vacation with our two grandsons, ages three and six, we came across a crime scene with two police cars, four officers, and one "bad guy." The boys' first question to me was, "What did he do, Grandpa?" I told them I didn't know what the "bad guy" did. Next they asked, "How can you tell he is a bad guy, Grandpa?" I answered, "Because he's in handcuffs." They continued, "He doesn't look like a bad guy: his face looks nice and his clothes are clean." I explained to them that you can

only tell who the bad guys are after they are caught. Before the discovery of their wrong doings they look just like good guys, and most of them even believe themselves to be good guys. Finally, my grandsons wanted to know if the bad guy was going to hurt them. But I assured the boys: "The bad guy won't be able to hurt anyone if the authorities do their job."

The story is much the same when it comes to the businesses of making people healthier and relieving their sickness: you only find out who the bad guys are after they are caught. This usually happens when scientific research proves a product or procedure to be harmful after it has been used on patients for a long time. On July 13-14, 2010 a US advisory panel for the FDA (Food and Drug Administration) reviewed the safety of Avandia (rosiglitazone maleate), once one of the top-selling diabetic medications in the world, and found for the second time that this medication is dangerous.



The FDA first approved Avandia in 1999. Heart problems began appearing shortly after its release and were well established by the scientists at GlaxoSmithKline, the manufacturers of the drug, by 2005.<sup>1</sup> Subsequently, sales increased to \$3.3 billion annually. In 2006 when reports came to the public's attention showing an increase in the risk of heart attacks and death, sales plummeted to \$520 million. In 2007 an advisory panel voted 20 to 3 that Avandia increased the risk of a heart attack; but then, by a vote of 22 to 1, the very same panel recommended that the drug stay on the market. The authorities failed their duties, and the public remains at risk.

During the July 2010 meeting, one of the good guys, FDA reviewer David Graham, stated that risks were real enough "to put you in a hospital or a cemetery." Dr. Graham published an analysis this past week (July 28, 2010) in the Journal of the American Medical Association estimating that as many as 100,000 heart-related problems among seniors on Medicare may have been caused by Avandia.<sup>2</sup> These problems included a 27% higher chance of stroke, a 25% higher risk of heart failure, and 14% overall increased risk of dying in patients 65 years or older. Just as damning was a review of the studies on Avandia published last month (June 28, 2010) in the Archives of Internal Medicine, which found that this drug increased the risk of heart attacks by about 39% and death from cardiovascular disease by 46%.<sup>3</sup> The study's principal author, Steven Nissen, said, "Any potential benefit from lowering blood sugar modestly can't possibly compensate for increasing an event as serious as a heart attack."

But even after all the harm that Avandia has been found to cause, the result of this month's two-day meeting was that 20 members of the 33-member panel voted yet again to keep Avandia on the market. (Twelve people voted to remove the product from the market and one person abstained.) The fate of the drug awaits definitive FDA action, to be taken later this year. But my guess is that Avandia will, unfortunately, remain on the market. The people keeping this medication on the market do so because of profits, and disregard the harms caused by it. Most of them work directly or indirectly for the drug maker, GlaxoSmithKline. Investors are worried because the company could face even more lawsuits than they currently have if the drug is pulled from the market by the FDA.

Diabetic medications are approved by the FDA for sale to the public based on their abilities to lower patients' blood sugars, not based on their ability to reduce the risk of dying or diabetic complications, such as kidney failure and going blind; in part, because the medications lack these benefits. This failure to improve patients' lives is compounded by the fact that treatments for type-2 diabetes harm people and cost

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patients large sums of money. Even my three-year-old grandson knows that hurting other people and stealing (taking under false pretences) money is what bad guys do.

## Is Your Personal Doctor Protecting You from the Bad Guys?

With all of this readily available knowledge about the failure of current tests and treatments to help patients, and the undeniable harms done to patients, you would expect your personal physician to be there to intervene for you. But, in most cases they won't save you. Last year I worked on a California Assembly Bill to require physicians to tell patients that aggressive treatment of diabetes does great harm and even kills. During the process, I asked George Lundberg, MD, former editor of the *Journal of the American Medical Association,* for his help. He replied to me, "But as a physician and a long time educator, I just hate having to pass legislation to require physicians to do the right things, like to stop lying." Even I was shocked by the boldness of his words.

On December 2, 2009, I led a teleconference, the Doctor's Forum for PCRM (the Physicians Committee for Responsible Medicine), titled, "Should Doctors Be Regulated by State Mandates?" In this discussion I paraphrased Dr. Lundberg and said that doctors "need to be more honest" with their patients about the limited benefits and great harms from most of the currents tests and treatments for chronic diseases (heart disease, type-2 diabetes, and most forms of cancer). The next day I received a correction by e-mail from one of the doctors who had listened to my comments. He explained that it was not a matter of honesty; it was just that doctors don't know. Excuse me! Is a doctor's ignorance a valid excuse for allowing a patient to take Avandia or other dangerous therapies?

Common Instances Where Doctors Could Save Their Patients from the Bad Guys
Aggressive treatment of type-2 diabetes with pills and insulin
Treatment of CHD with angioplasty or bypass surgery
Recommendations to get PSA and DRE for prostate cancer detection
Excessive use of mammography and colonoscopy screening
Recommendations for radical breast or prostate surgery
Overaggressive treatment of hypertension with medication
Recommendations to treat healthy people with statins
Recommendations for bone mineral density testing
Routine use of bisphosphonates (Fosamax, Boniva, Actonel)
Radical surgeries, chemotherapy and radiation for most kinds of cancer
Treatment of multiple sclerosis with highly toxic ineffective drugs
Generalized over-testing and -treating for business / to avoid law suits
Failure to recommend diet, exercise, and clean habits first

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Doctors spend at least seven years becoming experts on the care of the human being, and they are required to be up-to-date. The end result of recommending harmful and useless tests and treatments is the same, whether your doctor is lying (Dr. Lundberg's words) or is incompetent: you, the patient, get hurt by the bad guys. Fortunately, more doctors are taking responsibility and refusing to recommend tests and treatments that hurt their patients, even when this puts them at risk of criticism from their colleagues and lawsuits.

I (John McDougall, MD) have written several articles that you can share with your doctors on how I treat type-2 <u>diabetes</u>, <u>high blood pressure</u>, <u>cholesterol</u>, <u>obesity</u>, <u>inflammatory arthritis</u>, and <u>multiple</u> <u>sclerosis</u>.

Many other diseases are discussed on my web site under my <u>Hot Topics</u>. There is also a <u>free program</u> on my web site for you and your doctors. You can also spend time at one of my <u>10-day live in programs</u> in Santa Rosa, California, where I will have the opportunity to become one of your doctors for a life-time.

## The Best Chance You Have Is to Get Out of the Business

I find it a good rule of thumb to not be on a first name basis with car mechanics, morticians, lawyers, and/or doctors. You do not want to have visits with these professionals scattered throughout your planning calendar—consorting with these people means that you are in trouble somehow. When it comes to doctors, the only way to stay safely away from them is to remain healthy. The most common reason people are unhealthy is because they eat the rich Western diet. Your best means to avoid being involved in medical scandals like the one that is currently going on with Avandia is to avoid getting (or to cure yourself of) type-2 diabetes. Following a starch-based diet and exercising moderately, with the expected loss of excess body fat, almost always accomplish these goals. If you are on medications, find a doctor honest enough and sufficiently well educated to be able to advise you about your illnesses, food, and medications. These professionals are out there and growing in numbers.

#### **References:**

1) Nissen SE. The rise and fall of rosiglitazone. *Eur Heart J*. 2010 Apr;31(7):773-6.

2) Graham DJ, Ouellet-Hellstrom R, Macurdy TE, Ali F, Sholley C, Worrall C, Kelman JA. Risk of acute myocardial infarction, stroke, heart failure, and death in elderly Medicare patients treated with rosiglitazone or pioglitazone. *JAMA*. 2010 Jul 28;304(4):411-8.

3) Nissen SE, Wolski K. Rosiglitazone Revisited: An Updated Meta-analysis of Risk for Myocardial Infarction and Cardiovascular Mortality. *Arch Intern Med.* 2010 Jun 28 [Epub ahead of print]