

May 23, 2008



Peter Moore, Editor
Morgan Lord, Reporter
Men's Health
733 Third Avenue, 15th Floor
New York, NY 10017

Dear Mr. Moore and Ms. Lord,

I am writing to express my disappointment at the article "8 Drugs Doctors Would Never Take" in the June issue of *Men's Health* and to invite you to discuss more fully the communication of information about medicines, in general, and your characterization of Avandia and Advair, specifically.

The health of every individual is a very personal matter and should be treated with great respect. The health choices each of us makes affects the quality and duration of our lives. Each person is entitled to complete information about the choices they face, including the consequences of those choices. When it comes to medicine, our country tightly regulates the information provided on medicines, requiring substantial scientific evidence vetted by experts in the field. Interpretation of that evidence is always complicated. That is why regulatory authorities throughout the world seek extensive expert opinion before deciding on the safe and effective use of medicines. But I'm sure you know this.

I respect the right individuals have to express opinions about medicines and I support your rights, as a reporter and a magazine, to share those opinions with your readers. I do object, however, to you presenting those opinions as the opinions of all doctors, and doing so without presenting multiple sources of evidence and points of view. I object because readers are likely to act on those opinions without understanding the consequence of their actions.

Let's take a man in his late twenties who has suffered from asthma since his teens. Let's suppose that after a trial of inhaled steroids alone, he and his physician decided he might be better controlled on a combination of an inhaled steroid and long acting beta-agonist and he began taking Advair. Suppose that decision was made with full knowledge of the data included in the Advair prescribing information. Suppose further, as is often the case, this man's asthma has been well controlled for several years on Advair. Let's suppose this man reads your article. What might he think and do? At best he might, as you recommend, make an appointment to talk over what he read with his doctor. At worst, he stops his Advair without consulting his doctor, and later ends up in the hospital with an acute asthma attack.

I could describe the same scenario for each of the medicines in your article. In short, the consequences of your reporting are as likely, in my view far more likely, to do harm than good. Your article encourages readers trying to manage serious diseases to walk away from effective, FDA-approved therapies that have helped many millions of patients.

Let me be specific. Diabetes kills more than 75,000 each year in the U.S. Asthma kills more than 3,700. In both cases, control of the disease has been linked to better outcomes and fewer

hospitalizations. In both cases, getting control often requires carefully tailored combination treatment. Disrupting an established treatment puts patients at serious risk.

With regard to Avandia, the FDA has spent a great deal of time analyzing the data on Avandia and has approved the drug as safe and effective when prescribed according to product information. The product label has been updated to include full information to help doctors make the best prescribing decisions for their patients. You chose not to look at all the data but instead focused on a single meta-analysis, which regrettably is not only unrepresentative, but flawed.

The article's recommendation that diabetes patients rely on metformin ignores the fact that patients often need several or different medications to help control their blood sugar. In a large, long-term study, Avandia kept patients at or below blood sugar goals longer than other diabetes medications, including metformin. GSK believes these data represent a rationale for using Avandia as first treatment for diabetes. A large percentage of type 2 diabetes patients require multiple drugs to keep their blood sugar under control. Avandia is a valuable option to add to medicines like metformin for these patients. In short, doctors for millions of patients have decided that Avandia is right for them. To suggest that the majority of doctors think otherwise is simply not true.

The same is true of Advair. Patients with mild asthma may be well treated with only an inhaled corticosteroid. But the NIH asthma guidelines are clear: dual therapy with a corticosteroid and a LABA (the two classes of medicine contained in Advair) is a preferred option for those with more severe asthma. A substantial body of scientific evidence involving many clinical trials and thousands of patients support Advair as a highly effective medication in controlling persistent asthma, a disease which if poorly controlled can lead to severe consequences including emergency room visits, hospitalization, and even death. The suggestion that a corticosteroid alone or a corticosteroid plus a leukotriene modifier is adequate to treat all asthma patients is dangerous misinformation.

In fact, before the introduction of medicines like Advair, asthma death had been on the rise. Most recent data from the U.S. Center for Disease Control indicate that deaths due to asthma have been declining in the U.S. and worldwide as the use of asthma treatments like this have increased.

Finally, it is particularly troubling that the article does not actually cite the many studies of Advair, but relies only on data from a study of only one of the two components of Advair.

Medical discussion of the risks and benefits of these two drugs goes well beyond what is included in this letter, and we welcome a fuller discussion with you – or anyone on your staff – to dive deeper into these issues. We share your goal of keeping readers well informed about their health, and we want to do everything we can to make sure that the advice they receive leads to appropriate decisions, not rash ones based on incomplete information.

Sincerely,

A handwritten signature in black ink, appearing to read "Ron Krall", with a horizontal line underneath.

Ronald L. Krall
Chief Medical Officer

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