

American Association of Clinical Endocrinologists, American Diabetes Association and The Endocrine Society Joint Statement on Potential Cardiovascular Risks Associated with Rosiglitazone

July 12, 2010

Collectively, the American Association of Clinical Endocrinologists (AACE), the American Diabetes Association, and The Endocrine Society continue to carefully review the information on rosiglitazone available in the public domain and await further information from the Food and Drug Administration (FDA) following the completion of the *Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee*.

Over the past several weeks, additional information regarding the cardiovascular safety of rosiglitazone has been reported. As with previous reports, some analyses have suggested a possible increase in risk while others have not provided evidence of increased risk with this drug. The purpose of the advisory panel is to review this and other available information and make a decision on whether rosiglitazone should remain on the market and whether a study (TIDE) using the drug should be continued.

Patients should continue taking all currently prescribed medications unless instructed otherwise by their health care provider. Stopping diabetes medications can result in higher levels of blood glucose that may cause serious short term health problems and could increase the risk of diabetes-related complications in the long term.

Additionally, patients and health care professionals should be aware that multiple classes of drugs, often with more than one agent per class, are available to maintain glucose control in patients with type 2 diabetes. Until further clarification is provided by the FDA, the decision whether or not to use any medication must remain that of the treating provider in direct discussion with the individual patient.

Following any decision from the FDA, AACE, American Diabetes Association and The Endocrine Society will provide detailed information interpreting any FDA action for both health care professionals and patients with diabetes.

Key Points:

1. Additional review of Avandia (Rosiglitazone) related safety information is planned for July 13-14 by the FDA Advisory Committee.
2. Diabetes patients should continue taking all currently prescribed medications unless specifically instructed otherwise by their health care providers.
3. Regardless of the opinion and decisions on rosiglitazone, patients should be aware that there are numerous drugs available to maintain glucose control in people with type 2 diabetes. Patients should discuss these options with their health care providers.

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