

Science leaders urge diabetes patients to talk with doctor before making changes to medication use

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The Endocrine Society, American Diabetes Association and American Association of Clinical Endocrinologists issue joint statement in response to an FDA panel's recommendation to keep rosiglitazone (Avandia) on the market

The U.S. Food and Drug Administration's (FDA) Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee has completed their evaluation of the scientific research available on the safety of rosiglitazone. The deliberations of the panel reflected the complexity of the issues, with several members voting to add additional warnings or to withdraw the drug from the U.S. market. Ultimately, the final recommendation was to allow Avandia to remain on the market. Now that the expert panel has concluded its meeting, the FDA will review their recommendations and make the final decision on whether the drug remains available to patients.

Even with the panel's recommendation, the amount of scrutiny the drug has received may lead some diabetes patients who currently take rosiglitazone to want to stop taking the drug. The Endocrine Society, American Diabetes Association and the American Association of Clinical Endocrinologists urge patients to not make any changes to their medication use without discussing their treatment with their physician.



"Patients should continue taking all currently prescribed medications unless instructed otherwise by their health care provider," said Dr. Robert A. Vigersky, immediate Past President of The Endocrine Society. "Stopping diabetes medications can cause significant harm and result in higher levels of <u>blood glucose</u> that may cause severe short term health problems and could increase the risk of diabetes-related complications in the long term."

"The worst outcome would be to not treat diabetes properly, thereby risking its complications," said Dr. Daniel Einhorn, President of the American Association of Clinical Endocrinologists. "This unintended consequence has happened with past inquiries into diabetes medications, and we very much want to avoid it happening again."

Reports regarding the cardiovascular safety of rosiglitazone have not been definitive. While some analyses have suggested an increased cardiovascular risk with use of the diabetes drug others have not shown substantial evidence of such an association.

"Patients should be aware that regardless of the opinion and decisions on rosiglitazone, 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," said Dr. Richard Bergenstal, President, Medicine and Science, American Diabetes Association.

Following any decision from the FDA, The Endocrine Society, The American Diabetes Association and the American Association of Clinical Endocrinologists will provide detailed information interpreting FDA action for both health care professionals and patients with <u>diabetes</u>.

Provided by The Endocrine Society



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