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Pioglitazone and sitagliptin: an urgent call for new regulations controlling all the post marketing drug safety studies

Abstract

In the past few months, a tornado of "newspapers" articles was reporting the results of some scientific studies claiming to deny any relationship between pioglitazone and urinary bladder carcinoma as well as between sitagliptin and major adverse cardiovascular events. Thorough checking of most of these "independent" studies reveals that their independence is not really full and that some, perhaps many, of the scientists directly involved in these studies have financial connections that may include stocks and shares in the manufacturing companies of these and similar drugs which in my opinion demands new regulations of the post marketing drug safety studies.

Keywords: pioglitazone, sitagliptin, urinary bladder carcinoma, major adverse cardiovascular effects, drugs, scientific studies

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Introduction

"No link found between bladder cancer and use of pioglitazone" is one of many similar widely circulating titles in lots of newspapers all over the world in many languages including Arabic; the mother tongue of my people living in the Middle East. It's also a title that closely resembles its recent widely circulating nephew; "TECOS: no cardiovascular disease risks or heart failure with sitagliptin"! reading the details under the first title, one may simply read in a professional medical website a phrase supporting it with the solid assurance that it's "an independent study carried out by a large research consortium" but unlike the vast majority of newspapers, this medical website states at the end of the article the fact of "research support from Roche, Pfizer, Eli Lilly, BoehringerIngelheim" and that one of the major scientists involved in this study has a "membership in a speaker's bureau for and acted as a consultant for Pfizer in addition to membership in an advisory panel for Sanofi, Pfizer, Novartis Pharmaceuticals, and Eli Lilly, and owns Roche stocks and shares"[1] and most of the readers and patients especially in the developing world know nothing about the agreement between Takeda (a very important company manufacturing pioglitazone) and Pfizer to Co-Promote Takeda's Actos® (pioglitazone HCl) for the Treatment of Type 2 Diabetes in China![2] Similarly, many of the newspapers circulating the second title especially in the developing countries haven't declared that "TECOS"; the trial evaluating cardiovascular outcomes with sitagliptin is in fact the "Merck's cardiovascular safety trial of Januvia"and even if they've mentioned the description, most of the readers in the under developed and developing countries know nothing about the relationship between Merck and its offspring Januvia (sitagliptin)! Not to mention the awareness of Merck's declaration that this research was "led by an independent academic research groups" without mentioning the criteria that was followed when these specific groups were selected and who put them.[3]

Again, when I carefully read in a scientific paper that: "a pooled analysis of 25 randomized clinical trials does not indicate that treatment with sitagliptin increases cardiovascular risk in patients with type 2 diabetes mellitus. In a sub analysis, a higher rate of cardiovascular-related events was associated with sulphonylurea relative to sitagliptin" to discover at the end of the paper that "all studies and analyses described in this review were funded by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ"[4] or to read at the end of another similar paper that it was "supported by Merck Sharp & Dohme, a subsidiary of Merck"[5] this simply makes me feel uncomfortable or even suspicious and I don't believe that it's logic not to feel so especially when these results argue with other independent studies.[6-8] I've once stated that: "In my opinion as a physician, pharmacologist and first as a human being; the FDA waiting for more results regarding pioglitazone urinary bladder carcinogenicity is not appropriate at all, this should be disregarded"[9] but perhaps now I should be more precise in my request especially as these results have been already declared with the exact anticipated outcome.

I believe that the FDA dealing with the announcement of Takeda, the manufacturer of pioglitazone (Actos) that "from a longitudinal cohort study, there was no risk for bladder cancer associated with the agent" should be more suspicious than mine! I don't doubt the honesty of fellow colleagues, God forbids but I only admit the logic human suspicion that knowing that even the saints among us are tempted. Thus, humbly, I ask all scientists in the developed world to work together to obligate the FDA and all similar agencies to establish a new mechanism by which the large pharmaceutical companies become forced to fund "real" independent research center(s)not chosen by or related in any way to the pharmaceutical companies and their products; center(s) that will, on behalf of all the patients, honor the human suspicion and will design, perform and analyze all the post marketing drug safety studies and thus defending the noble human soul that seeks science and humanity more than stocks and shares.

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None.

Conflicts of interest

The auhtor declares there is no conflicts of interest.

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