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

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 Merck & Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ” or to read at the end of another similar paper that it was “supported by Merck Sharp & Dohme, a subsidiary of Merck” 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.6,7 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 suspicious claim 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 author declares there is no conflicts of interest.
References

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