Reviewer's report

Title: Safety and tolerability of sitagliptin in patients with type 2 diabetes: A pooled analysis

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Reviewer: Zachary Bloomgarden

Reviewer's report:

The authors have capably described potential adverse outcomes of sitagliptin treatment, comparing these with events in the control population.

* Major Compulsory Revisions

None

* Minor Essential Revisions

None

* Discretionary Revisions

In table 5, the most robust adverse effect is hypoglcemia seen in 117 sitagliptin-treated vs 296 control patients. Given the importance of this outcome, the authors might comment on whether the high hypoglycemia group comprised only sulfonylurea-treated patients, and give a bit more information, perhaps in a table, allowing the reader to better understand the treatment regimens compared.

There are two somewhat frequent groups of adverse effects of sitagliptin in table 5, painful symptoms (chest pain, tooth abscess, osteoarthritis) in 94 sitagliptin-treated vs 35 controls. Even if one adds sinus headache from the non-exposed> sitagliptin group, this still seems an important finding -- do the authors wish to comment?

The second is dermatologic - if one adds acne and contact dermatitis, there were 31 vs. 7 cases, which seems real and about which the authors also might wish to comment. Also, table 6 has 35 vs. 24 patients with rash, quite different numbers -- could the authors explain this discrepancy? The dermatologic question is as the authors state in the introduction very important. Parenthetically, this reader wonders why a dermatologic category is not included in table 7, since it certainly exceeds 0.5% of patients.

For table 9, it would be interesting to know the frequency of liver chemistry elevations below the arbitrary 3x ULN level. Similarly, are the uric acid, CPK, Ccreat, etc categories based on arbitrary degrees of change deemed clinically important, or do they refer to any increase or decrease?
**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

yes, I have been a consultant and have been on speaker panels for Merck
No other competing interests, either financial or nonfinancial