Reviewer's report

Title: Delays in the post-marketing withdrawal of drugs to which deaths have been attributed: a systematic investigation and analysis

Version: 3 Date: 25 November 2014

Reviewer: Joel Lexchin

Reviewer's report:

Major compulsory revisions

This revised version of the manuscript has addressed most of my initial concerns but I think that the authors need to recognize that the regulatory response to drugs that cause death even with proper use and drugs that cause death from improper use may be quite different. For example, if a drug is used properly and causes deaths then removing it from the market may be the best option. Whereas, if a drug is being used incorrectly (taken in supratherapeutic doses or where pills are crushed and injected) and causes deaths then the best option may be to restrict its use to only certain groups of doctors, restrict its use to hospital setting, alter the formulation of the drug, conduct an educational campaign, etc.

In the Limitations section the authors state that the interval between when a drug first caused death and when a death was reported is likely to have been short but earlier they state that it took 127 years between the introduction of ethyl nitrite and the first reported death. I don’t have any evidence, but I find it hard to believe that this product was used for 127 years before it first caused a death.

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests