



SDI Review Form 1.6

Journal Name:	Asian Journal of Research in Medical and Pharmaceutical Sciences
Manuscript Number:	Ms_AJRIMPS_40776
Title of the Manuscript:	Questionable International Pediatric Studies in the United States and Russia Triggered by Regulatory Authorities
Type of the Article	Original Research Article

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound.

To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)

PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<u>Compulsory</u> REVISION comments	This manuscript is not an "original research article". The paper is a political, ethical and policy discussion in a debate on the subject.	<p>Thank you for your feedback. We humbly would like to emphasize that this is an original research article. We analyzed data in www.clinicaltrials.gov, the worldwide largest registry on clinical trials. We analyzed those studies with centers in both the US and Russia. We clearly described the methods we used to analyze the design of the clinical studies, specifically the age limits that were used as inclusion criteria, and explained the historical background where these inclusion criteria come from.</p> <p>We hope that the reviewer wanted to emphasize that our methodology is not the routine methodology of most scientific papers. We would take that as a compliment. The data in international clinical trials registries are, in our view, utilized too little in comparison to published study data. In our view, if by analyzing the design of ongoing studies a problem is identified, it is better to discuss it now instead of years after the study publication.</p> <p>It would be even better if questionable studies would be rejected by Institution Review Boards (IRBs)/ ethics committees (ECs) before the study has started. We hope that our paper will help IRBs/ECs in this decision making. We have identified a serious problem in ongoing global clinical research and we noticed that IRBs/ECs have so far not realized the dimension of this problem.</p> <p>We agree that our paper has ethical and political implications and might even lead to change of policies of IRBs/ECs. But this doesn't make our paper a political discussion paper.</p>
<u>Minor</u> REVISION comments		
<u>Optional/General</u> comments		