



**SDI Review Form 1.6**

Journal Name:	<a href="#">Asian Journal of Research in Medical and Pharmaceutical Sciences</a>
Manuscript Number:	<b>Ms_AJRIMPS_40776</b>
Title of the Manuscript:	<b>Questionable International Pediatric Studies in the United States and Russia Triggered by Regulatory Authorities</b>
Type of the Article	<b>Original Research Article</b>

**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)
<b><u>Compulsory</u></b> REVISION comments	<p><b>I have critically read this manuscript over and over again. While the author understandably stated that studies may subject children to some risks and deny them the benefits of some drugs, the overall conclusion of the study is not scientifically factual.</b></p> <p><b>Children are not small adults. Their body structures and functions are different.</b></p> <p><b>Author should rather advocate that where appropriate, children of all ages should be included in phases 1-3 clinical trials instead of having separate clinical trials. Clinical trials that include people of all ages are necessary to establish the pharmacodynamic and pharmacokinetic properties of new drugs.</b></p>	<p>Thank you for reviewing our manuscript.</p> <p>Regarding body structures and functions, we based our argumentation on Kearns GL et al, Developmental Pharmacology - Drug Disposition, Action, and Therapy in Infants and Children NEJM 2003. One central point in our argumentation is that the statement "children are not small adults" has become an often-repeated mantra that is true for newborns, but not true for children after the first 6 months of their life. In contrast to 1968, when Shirkey outlined his concept of children as "therapeutic orphans", today we can measure the functions of the child's organs, see for details Kearns 2003. Thus, our statement about the developing child's body is scientifically factual and backed by well-regarded and often referenced key publications.</p> <p>We would advocate against including newborns into phase 1-3 trials. Newborns and premature newborns need indeed separate trials. Also older children should not be included into phase 1-3 trials. Instead, we advocate inclusion of adolescents with a mature body into phase 3 pivotal trials. For children between 1 and 11 years of age we recommend dose-finding studies, and later registries to follow up safety issues in clinical practice.</p>
<b><u>Minor</u></b> REVISION comments		
<b><u>Optional/General</u></b> comments		