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Reply to *Letter #E14-063AR1, Getting to safer and smarter medication use during pregnancy*

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We thank Umans and Lindheimer for their interest in our meeting summary (1) and welcome the opportunity to respond to their concerns. We agree with the authors about the need for more data to inform various aspects of medication treatment during pregnancy; this was evident to all the subject matter experts who attended the CDC meeting and is likely appreciated by the journal's readership.

The agencies represented at the meeting have continued their efforts to address the current data gap. In an attempt to raise greater awareness among policy makers and the general public about safer medication use in pregnancy as a pressing public health issue, CDC posted an infographic on the Treating for Two website, available at http://www.cdc.gov/pregnancy/meds/treatingfortwo/infographic.html. While this infographic focuses on the lack of medication safety data, CDC continues with its commitment to conduct research on the safety of medications in pregnant women. In addition, as mentioned by the authors, our NICHD (National Institute of Child Health and Human Development) colleagues have documented the parallel alarming dearth of pharmacokinetic/pharmacodynamic data during pregnancy, and continue to do important work in this area. (2) FDA continues its efforts to consider ways to collect safety data in pregnant women, as was demonstrated by the May 2014 public meeting held at the FDA, "Study Approaches and Methods to Evaluate the Safety of Drugs and Biological Products during Pregnancy in the Post-Approval Setting".

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(3) Draft guidance on the scientific and ethical considerations for the inclusion of pregnant women in clinical trials is also being developed by FDA. In regards to the final rule on Pregnancy and Lactation Labeling, the rulemaking process is complex, including several layers of review. We are happy to note that the rule published on December 4, 2014 and will be fully in effect on June 30, 2015 (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm).

Healthcare providers and regulators have to make decisions *now* with whatever data and guidance are currently available. While further research on both safety and efficacy of medication use in pregnancy is obviously needed, the intent of the expert meeting and resulting summary publication was to focus on how to collaboratively move forward and utilize the decades of research that have accumulated thus far to provide better information to improve decision-making. We need to continue to gather data, and develop evidence-based guidance, for *better* informed decisions, ultimately leading to healthier pregnancies and healthier babies.

References

1. Broussard CS, Frey MT, Hernandez-Diaz S, et al. Developing a systematic approach to safer medication use during pregnancy: Summary of a Centers for Disease Control and Prevention-convened meeting. Am J Obstet Gynecol. 2014; 211:208–14. [PubMed: 24881821]
2. Parisi MA, Spong CY, Zajicek A, Guttmacher AE. We don’t know what we don’t study: The case for research on medication effects in pregnancy. Am J Med Genet Part C Semin Med Genet. 2011; 157:247–50. [PubMed: 21766436]
3. FDA. Study Approaches and Methods To Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting. Public Meeting. http://www.fda.gov/drugs/newsevents/ucm386560.htm. Accessed November 14, 2014.