

Dear Editor,

This is to confirm that the article entitled “**Understanding 2013 Orphan Drug Act Addendum in the Context of Pharmacogenomics Application in Orphan Drug Designation and Approval**” submitted to the *Indian Journal of Medical Ethics* is original and has been co-authored by the undersigned. All authors have participated in the work sufficiently to meet the ICMJE guidelines for authorship. All have read and approved the manuscript.

The submission is not under consideration for publication in any other journal.

We give consent to Dr. Dipanjan Bhattacharjee to act as the author for correspondence.

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Dr. Dipanjan Bhattacharjee is employed with Janssen India in the capacity of Zonal Medical Advisor at the time of submission of this article. Dr. Prudwidhar S. is employed with Janssen India in the capacity of Medical Advisor at the time of submission of this article.

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We have read the terms and conditions of authorship of IJME and accept them.

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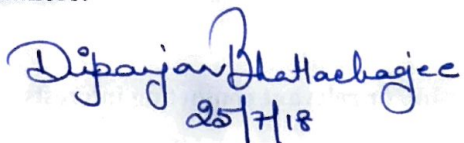
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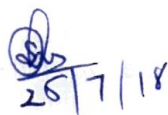
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