



Educate. Advocate. Integrate.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

RE: FDA-2018-N-1184

Dear Pediatric Advisory Committee:

The National Perinatal Association (NPA) is an interdisciplinary organization of professionals, parents, and advocates that is the leading voice in perinatal care in the United States. We educate, advocate, and integrate all voices with equality and respect to support pregnant women, infants, and their families and the professionals who care for them. NPA works to create positive change in perinatal care by partnering with healthcare, government, and nonprofit organizations. NPA brings all stakeholders to the table to promote optimal perinatal care in the United States. Our uniqueness in the non-profit sector is our commitment that all voices are heard equally and respectfully. NPA is families and professionals working together with advocates to support practice and policy changes based on evidence-based literature and family experiences.

The National Perinatal Association supports innovation in the treatment of all neonatal medical conditions including hyperbilirubemia. We commend Mallinckrodt for the development of the first medication to treat hyperbilirubemia in many decades. Hyperbilirubemia treatment currently requires separation of mother and infant. This impacts the attachment process for the dyad, breastfeeding and causes significant anxiety and distress for parents and families. Best practices in dyad care emphasizes close physical contact of mother and infant. Treatments that support these best practices are critical to positive outcomes. In addition, as you know hyperbilirubemia is the leading cause of hospital re-admission for infants under 30 days of age. Innovative treatments that can maintain the physical contact of mother and infant and decrease re-hospitalization for hyperbilirubemia are needed.

NPA thanks you for your review of FDA-2018-N-1184. We look forward to your review of the effectiveness and safety for treatments addressing neonatal medical conditions.

Sincerely,

National Perinatal Association Executive Committee

References

Watchko J. Extreme Neonatal Hyperbilirubinemia: A View from Down Under. DOI:
<https://doi.org/10.1016/j.jpeds.2015.09.055>.

De Regnier RA Neonatal jaundice: more than a number. <https://doi.org/10.1016/j.jpeds.2017.02.018>

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