

Enhancing Neonatal Care: A Call for Industry-Wide Collaboration

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In neonatal health, a pressing concern has surfaced that demands the attention of industry stakeholders and regulatory bodies. As the National Coalition for Infant Health (NCfIH), we find ourselves at the forefront of advocating for the well-being of our most vulnerable population—infants, particularly those grappling with neonatal seizures.

The catalyst for this discourse is the [Citizen Petition](#) filed by Sun Pharma Advanced Research Company Limited (SPARC) on July 24, 2023, spotlighting certain excipients—benzyl alcohol, propylene glycol, and ethanol—embedded in phenobarbital sodium products used for neonatal seizure treatment. Notably, these excipients lack approval from the U.S. Food and Drug Administration (FDA), prompting our call for comprehensive industry-wide collaboration to address these concerns. (1–6)

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Neonatal seizures, impacting infants within their first four weeks of life, require a nuanced therapy response. The NCfIH, as a representative body, emphasizes the imperative of specialized care for infants, considering their unique attributes in terms of size, weight, metabolism, and overall health condition.

Our advocacy extends beyond the immediate concerns raised by the Citizen Petition to encompass a broader perspective on the evolving landscape of neonatal care. It is paramount that industry stakeholders, including pharmaceutical companies, regulatory bodies, and healthcare providers, engage in a collaborative effort to ensure the highest standards of care for neonates. (7)

The historical context surrounding benzyl alcohol serves as a stark reminder of the potential consequences of inadequately

scrutinized excipients. Incidents in the 1980s, resulting in severe adverse events and fatalities, underscore the need for heightened vigilance in the development and deployment of pharmaceutical products tailored for neonatal use. The FDA’s categorical warnings and restrictions on benzyl alcohol-containing drugs in neonatal patients reinforce the gravity of these risks.

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Similarly, the inclusion of propylene glycol in neonatal medications poses substantial risks, particularly when compounded by the concurrent presence of ethanol. The FDA’s 2011 drug safety communication, revealing life-threatening events associated with propylene glycol and ethanol in neonates, underscores the critical importance of vigilant oversight and collaboration among industry stakeholders. (3,6)

However, amidst these concerns lies a significant development—in November of 2022, the FDA’s approval of a treatment for neonatal seizures devoid of harmful excipients. This marks a milestone in the quest for safer alternatives, providing healthcare providers with a viable option to ensure the well-being of their neonatal patients.

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As leaders and providers, we are responsible for fostering open communication and collaboration. We urge the FDA to play a pivotal role in disseminating information about the risks associated with phenobarbital sodium products containing unapproved harmful excipients. Furthermore, the FDA's endorsement of a therapeutic intervention free from these excipients should be highlighted to healthcare providers, empowering them with the knowledge to make informed decisions in the best interests of their patients.

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In conclusion, our call for industry-wide collaboration transcends the immediate concerns outlined in the Citizen Petition. It is an invitation to collectively prioritize and elevate neonatal care standards. By fostering a culture of collaboration, transparency, and commitment to the highest patient safety standards, we can pave the way for our neonates’ healthier and safer future.

As we navigate these challenges, let us remember that our actions today shape the trajectory of neonatal care tomorrow. Together, we can ensure that every infant receives the specialized and safe care they deserve.

References:

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National Coalition for Infant Health Values (SANE)

Safety. Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

Access. Budget-driven health care policies should not preclude premature infants' access to preventative or necessary therapies.

Nutrition. Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

Equality. Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.