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FDA warning on probiotics

The American Food and Drug Administration (FDA) issued a warning for a probiotic product on 29 September 2023 due to an episode of sepsis caused by a probiotic bacterium resulting in the death of an extremely premature baby with a birth weight <1000 grams. This event has sparked extensive discussion, and the International Scientific Association for Probiotics and Prebiotics (ISAPP) has released a statement summarizing the following:

- The administration of probiotics to premature infants has been shown in large systematic reviews with meta-analyses to significantly reduce the risk of necrotizing enterocolitis (NEC), sepsis and mortality.
- Although sepsis attributed to probiotics has been documented in rare cases, meta-analyses have not identified significant adverse events or safety concerns.
- Strict manufacturing standards are recommended for probiotics used in vulnerable populations, including premature infants.
- Standardized comprehensive reporting of safety aspects in probiotic intervention studies is needed, along with funding for long-term studies.
- Risks and benefits of probiotic therapy should be carefully considered for both the specific population and individual patients, and regulations are needed to enable implementation.
- More information about this death should be made public quickly so that healthcare professionals and researchers can learn from this experience and continue to offer evidence-based care to patients.

The working group for nutrition and gastroenterology within the Swedish Neonatal Society will soon publish a statement alongside the upcoming statement by the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). Neither of these organizations believe that this case described by the FDA gives reason to change the guidelines for probiotic treatment of preterm infants born at gestational weeks 28+0 to 31+6 to prevent NEC, nor to suspend ongoing studies of probiotics in preterm infants born before the 28th week of gestation.

The bacteria strains recommended by ESPGHAN and the Swedish Neonatal Society are either *Lactobacillus rhamnosus* GG ATCC53103 or a combination of *Bifidobacterium infantis* Bb-02, *Bifidobacterium lactis* Bb-12 and *Streptococcus thermophilus* TH-4. It is the latter combination that is used in the PEPS study (distributed under the name, ProPrems). Please note that the FDA warning was issued about a strain that is not recommended by ESPGHAN and the Swedish Neonatal Society.

Sincerely,

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