

Subject: Medical Science Liaison (MSL) Notes - Detailed Safety Concerns and Side Effects Discussion on PediatricEase

Date: October 10, 2025

Provider: Dr. Angela Bennett

Title: Pediatric Neurologist

Institution: ChildCare Neurology Center

Summary of Key Discussion Points:

1. Introduction:

- Introduced PediatricEase as a potential therapy for pediatric migraines in children under 12.
- Dr. Bennett expressed initial interest but emphasized concerns about safety, especially considering the vulnerable pediatric population.

2. Provider's Current Patient Cases:

- Dr. Bennett shared cautious observations about introducing new medications to children with migraines.
- Discussed specific cases where current treatments have shown established safety records in pediatric neurology.

3. Efficacy and Clinical Data:

- Presented recent clinical data showcasing PediatricEase's efficacy in reducing migraine frequency and improving overall well-being in pediatric patients.
- Dr. Bennett questioned the depth of safety data, especially concerning potential long-term effects on pediatric neurodevelopment.

4. Safety Profile:

- Discussed the favorable safety profile of PediatricEase, emphasizing the rigorous pediatric-specific safety assessments during development.
- Dr. Bennett sought specific details on reported side effects and expressed concerns about the documented instances of gastrointestinal disturbances and headaches observed in the pediatric clinical trials.

5. Mechanism of Action:

- Explained PediatricEase's mechanism, focusing on its targeted modulation of specific neurotransmitter pathways involved in pediatric migraines.
- Dr. Bennett appreciated the detailed explanation but raised concerns about potential cognitive effects, given the intricate nature of neurotransmitter modulation in developing brains.

6. Patient Adherence and Education:

- Discussed strategies for enhancing patient adherence through a once-daily oral solution with a child-friendly flavor.
- Dr. Bennett raised concerns about potential challenges in monitoring pediatric patients for adverse effects, ensuring proper medication administration, and highlighted the need for detailed educational materials for parents.

7. Emerging Research and Future Developments:

- Highlighted ongoing research on PediatricEase's potential in other pediatric headache disorders.
- Dr. Bennett questioned the necessity for expanding research without addressing existing concerns about safety, especially in light of emerging data on potential impacts on growth and development.

8. Competitive Landscape:

- Compared PediatricEase to existing treatments for pediatric migraines, focusing on safety profiles and documented side effects.
- Discussed the importance of transparency in reporting adverse events and addressing pediatric neurologists' concerns.

9. Access and Reimbursement:

- Provided updates on access and reimbursement programs for pediatric clinics.
- Dr. Bennett expressed reservations about recommending a new medication without extensive safety data and clear advantages over existing treatments, particularly with documented cases of treatment discontinuation due to side effects observed in the clinical trials.

10. Action Items and Follow-Up:

- Dr. Bennett declined any further collaboration or follow-up until more comprehensive safety data, especially in real-world settings, becomes available.
- Expressed a preference for observing real-world outcomes and suggested a detailed review of post-marketing surveillance data before considering PediatricEase in her practice.

11. Closing Remarks:

- Acknowledged Dr. Bennett's detailed concerns and thanked her for her cautious approach to pediatric neurology.
- Expressed understanding and commitment to addressing ongoing questions or concerns as additional real-world data becomes available.