Post-Launch Adverse Events Reported to FDA Adverse Event Reporting System for Long-Acting Injectable Buprenorphine

Brian J. Dawson[1], Michael P. Frost[2], Natalie R. Budilovsky-Kelley[3], Adam Friedman[3], Joshua M. Cohen[3]

[1]Ideal Option, Renton, WA; [2]The Frost Medical Group LLC, Conshohocken, PA; [3]Braeburn Inc, Plymouth Meeting, PA

BACKGROUND

- Two long-acting injectable buprenorphine (LAIB) medications are FDA-approved for the treatment of moderate to severe opioid use disorder (OUD): RBP-6000 (monthly) and CAM2038 (weekly and monthly).[1,2]
- Randomized controlled trials have demonstrated the safety of LAIB medications.[3,4] However, post-marketing data provide valuable insights into the safety of treatments within real-world populations.
- The FDA Adverse Event Reporting System (FAERS) is a centralized public database used for post-marketing drug safety surveillance, and researchers have used FAERS to evaluate early safety experience across classes of medications.[5,6]
- Adverse event (AE) rates from FAERS for RBP-6000 and CAM2038 were previously evaluated for the 12-month periods following their commercial launches in the United States (US).[7]

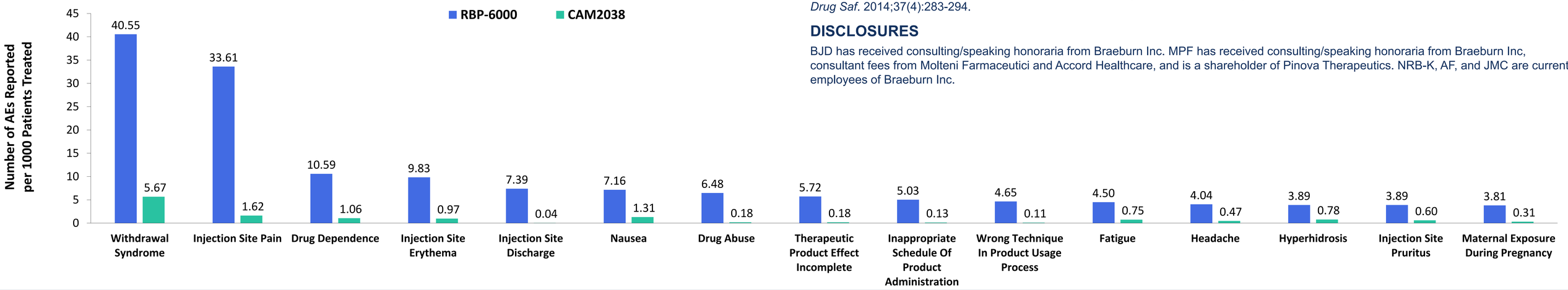
METHODS

- This retrospective analysis evaluated AEs spontaneously reported to FAERS during the 18-month periods following the US commercial launches of RBP-6000 (March 1, 2018 to August 31, 2019) and CAM2038 (September 5, 2023 to February 28, 2025).
- AE reporting rates were calculated based on the total number of AEs reported per 1000 patients treated (RR_{pt}).
  - The total number of patients treated with RBP-6000 and CAM2038 during these post-launch periods was estimated based on publicly-reported figures and specialty pharmacy and distributor data.
- The 15 most frequently reported AEs to FAERS across both medications were identified based on the highest individual RR_{pt}.

RESULTS

- During the first 18 months following their US commercial launches, an estimated 13,120 patients were treated with RBP-6000 and 45,161 with CAM2038, with a total of 3848 and 2080 AEs reported, respectively.

Figure 1. Top 15 AEs Reported in the First 18 Months Post-Launch per 1000 Patients Treated



LIMITATIONS

- There is no certainty that reported AEs were caused by RBP-6000 or CAM2038, given the spontaneous and inconsistent manner in which cases are submitted to FAERS.[5]
- Some real-world AEs related to LAIB medications may not be reported.[5]
- These data may be impacted by the "Weber effect," which is the tendency for increased AE reporting during the initial period following a drug's approval. However, it has been suggested that the Weber effect is generally not observed for AE reporting to FAERS.[6,8]
- The total number of patients treated with RBP-6000 and CAM2038 in the 18-month periods following their US commercial launches was estimated using publicly-reported figures and specialty pharmacy and distributor data, which may be limited by incomplete data capture, duplication, and lack of direct linkage to drug administration.

CONCLUSIONS

- Overall, AEs reported for both RBP-6000 and CAM2038 were infrequent during the 18-month periods following their US commercial launches.
- These data provide insights into the real-world safety profile of LAIB medications for the treatment of moderate to severe OUD and may help inform clinical decision-making.

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DISCLOSURES

BJD has received consulting/speaking honoraria from Braeburn Inc. MPF has received consulting/speaking honoraria from Braeburn Inc, consultant fees from Molteni Farmaceutici and Accord Healthcare, and is a shareholder of Pinova Therapeutics. NRB-K, AF, and JMC are current employees of Braeburn Inc.

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