

Sara Azimi-Bolourian, PhD<sup>1</sup>; Emily C. Welch, MPH<sup>2</sup>; Candace C. Fuller, MPH, PhD<sup>2</sup>; Rajani Rajbhandari, MS<sup>2</sup>; Christian Hampp, PhD<sup>1</sup>; Michael D. Nguyen, MD<sup>1</sup>

<sup>1</sup> Food and Drug Administration, Silver Spring, MD, USA, <sup>2</sup> Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

## Background

- Obesity is major public health concern affecting 40% of adults and is associated with \$147 billion in medical costs in the United States.
- Despite the availability of pharmacotherapy options to augment diet and exercise lifestyle interventions, evidence of low adoption of anti-obesity medications (AOM) exists<sup>1</sup>.

## Objective

- To characterize the utilization patterns and treatment duration of Anti-Obesity Medications (AOM) approved for use in adults included in the U.S. FDA's Sentinel System.

## Methods

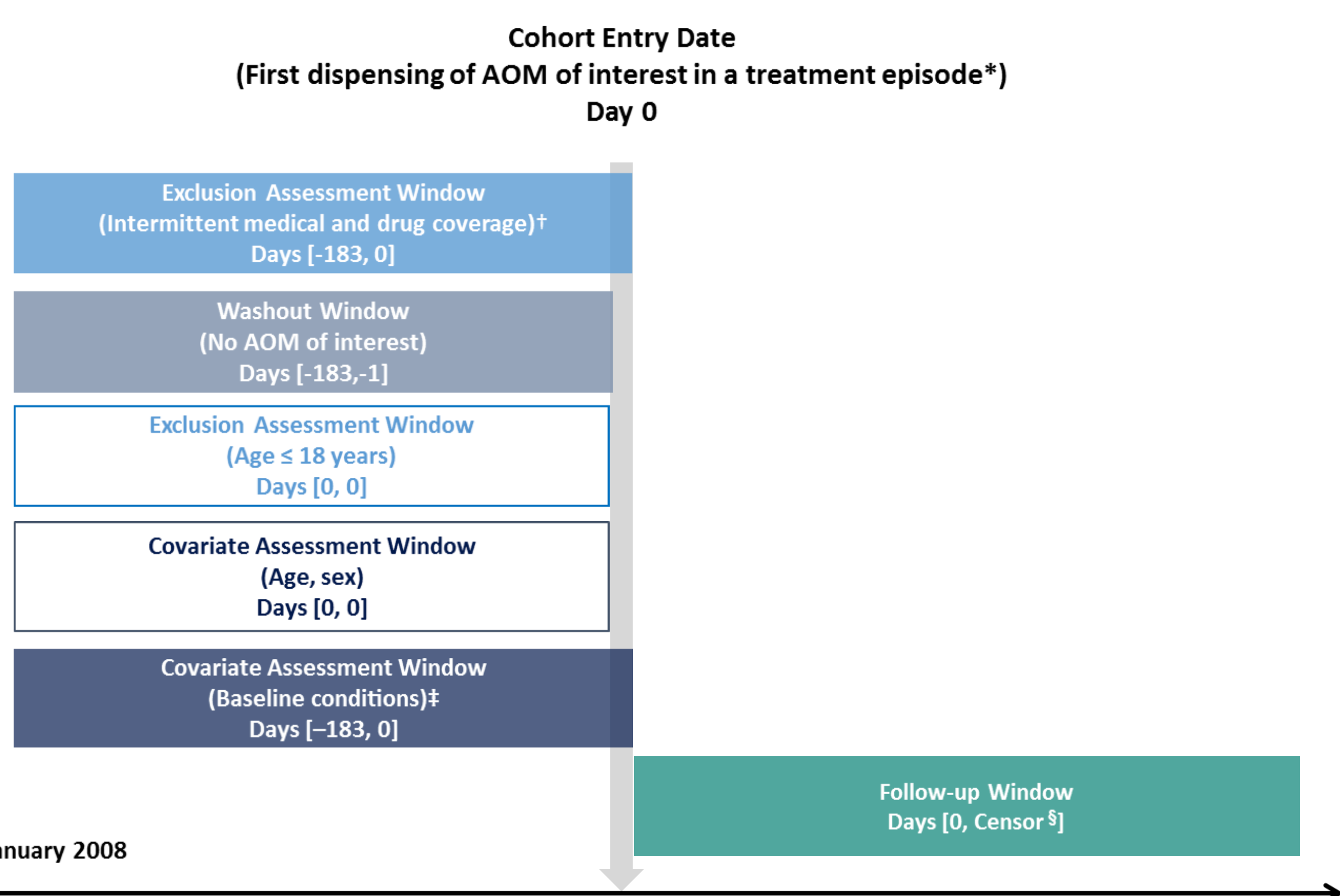
### Data Source:

- Sentinel Distributed Database (SDD)
  - Consists of claims data from a distributed network of 18 Data Partners, (generally commercial insurers, but Medicare contributed fee for service enrollee data)

### Study Design and Analysis:

- Descriptive Drug Utilization Analysis
- Time Period: 2008-2017
- Selected medications: 9 AOMs
- Long Term AOM:** No limit in Duration of use according to the AOM label (lorcaserin, bupropion/naltrexone, liraglutide, phentermine/topiramate, orlistat)
- Short Term AOM:** Limit in duration of use [ $\leq$  12 weeks according to the AOM label (phentermine, benzphetamine, diethylpropion, phendimetrazine)
- We conducted a descriptive drug utilization analysis in adults  $\geq$ 18 years initiating AOMs in 17 Sentinel Data Partners from 2008-2017.
  - We characterized new users (first dispensing in 183 days) of any AOM and individual AOMs.
- Baseline patient characteristics, including Body Mass Index (BMI) and cardiovascular history were described in the 183 days prior to first dispensing.
- Treatment duration was depicted with Kaplan Meier survivor curves; persistence was assessed primarily allowing for a 60 day gap between dispensings to account for inconsistent medication use.

Figure 1: Obesity Drugs study Diagram



† Up to 45 day gaps in medical or pharmacy enrollment allowed

‡ Baseline conditions included diabetes, hypertension, hyperlipidemia, and ischemic heart disease

§ Earliest occurrence of discontinuing study drugs, disenrollment, or end of study period

- We formed treatment episodes by following patients from date of medication dispensing through days supplied, and used a stockpiling algorithm to adjust the treatment episode length if a new dispensing occurred before the end of days supplied.
- We also conducted a sensitivity analysis utilizing an episode gap of 14 and 60 days.

## Acknowledgements

- Many thanks are due to the Data Partners who provided data used in the analysis.

## Results

- We identified 267,836 AOM new users, predominately female (82%) and less than 65 years of age (92%) (Figure 2).
- Only 50% of AOM users had a diagnostic code for obesity and only 14% had one for BMI; among AOM users with a BMI diagnosis code, 87% had a BMI  $\geq$ 30 (obese).
- Hypertension (30%) and hyperlipidemia (28%) were the most common comorbidities among AOM users. However, ischemic heart disease (2.6%) was not common.
- Phentermine (n= 198,203) was the most common AOM, followed by bupropion/naltrexone (n= 29,106).
- Across AOM, duration of use was generally short (median, 62 days); at 1 month, 59% of AOM users remained on treatment and persistence declined substantially thereafter (2 months=51%, 3 months=37%). After 6 months, 17% of AOM users were still on treatment (Figures 3 & 4).

Figure 2. Number of New users by Year

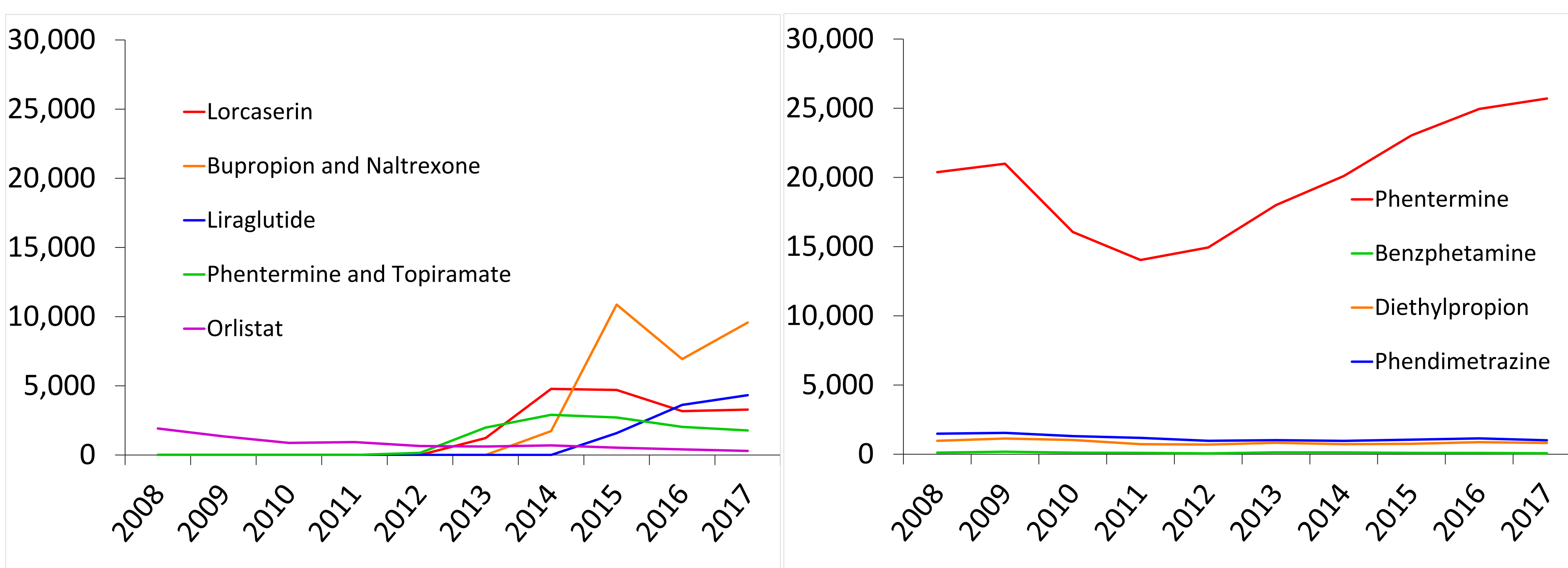


Figure 3. Duration of First Treatment Episodes- in Days

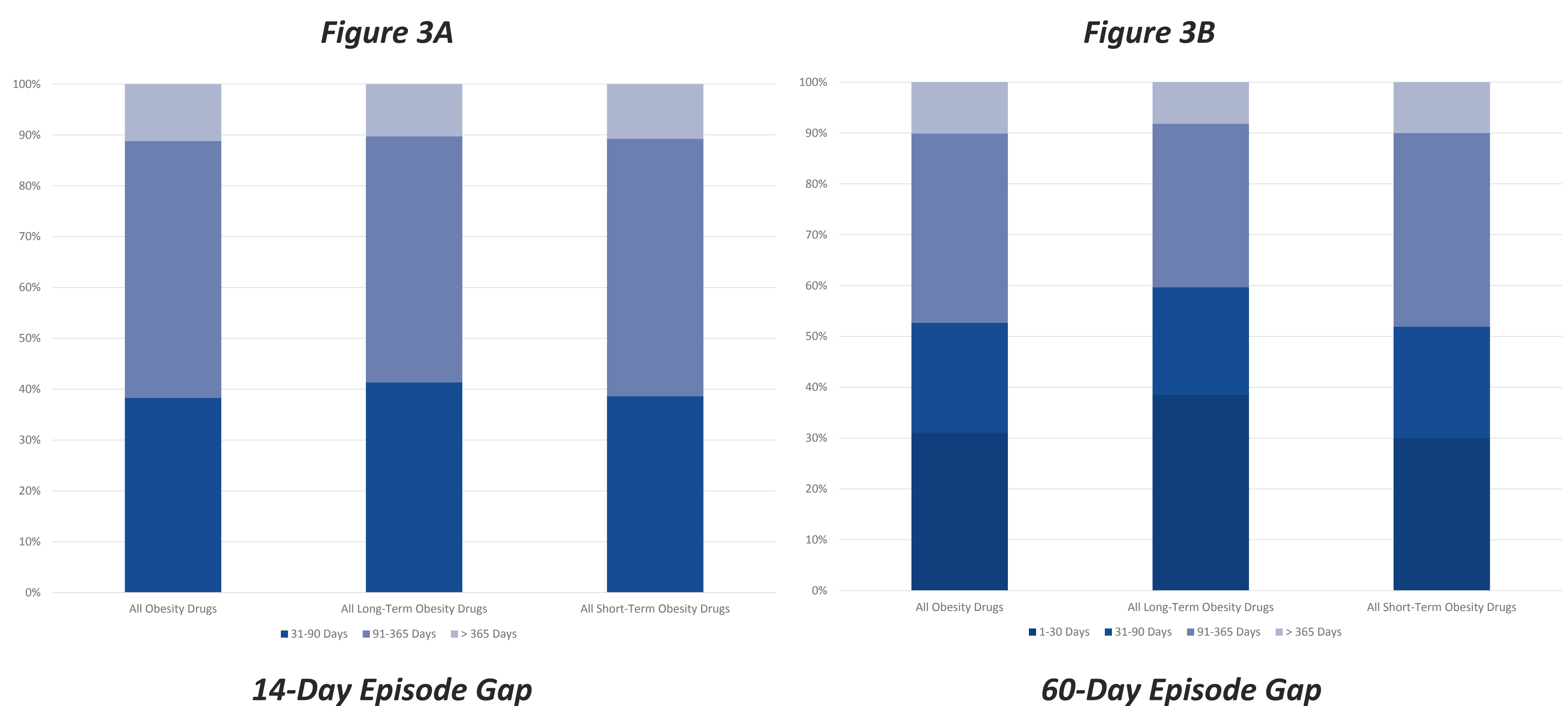
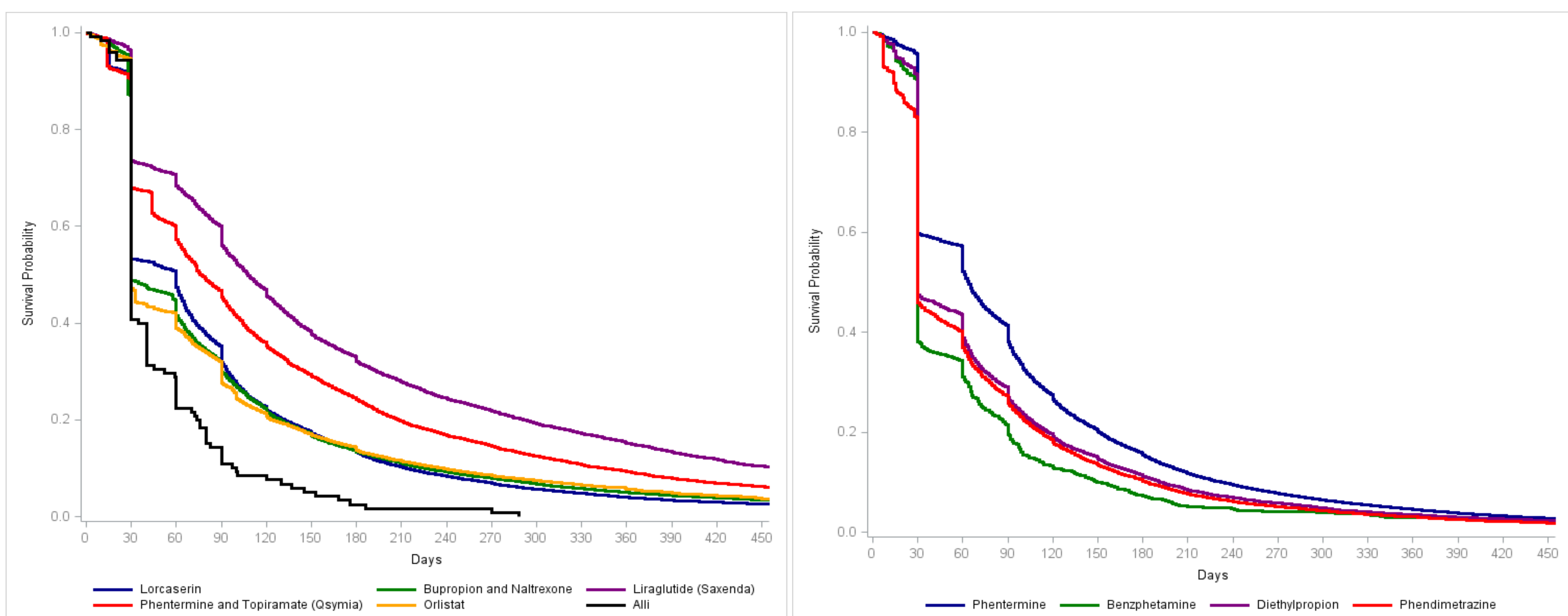


Figure 4. Drug Persistence Survival Curve for Length of First Episode



## Conclusion

- The most commonly used AOM was phentermine, followed by bupropion/naltrexone. Most AOM users were female and <65 years of age. Overall, in the majority of AOM users, treatment duration was short.

## Disclaimer

- The authors have no conflicts of interest to disclose.
- The opinions expressed in this poster are those of the authors and not necessarily of the U.S. FDA.