

## BACKGROUND

- Hemp-derived products, particularly cannabidiol (CBD), have emerged as some of the most widely consumed cannabis-based substances worldwide.
- Unlike cannabis-derived products containing tetrahydrocannabinol (THC), hemp is federally legal in the United States if it contains less than 0.3% THC, and hemp-derived tinctures, capsules, and edibles have become ubiquitous.<sup>1,2</sup>
- A pressing concern is the limited understanding of adverse drug reactions (ADRs) associated with hemp-derived product use.
- The absence of age- and gender-specific safety data associated with hemp use prevents clinicians from stratifying risk, policymakers from issuing nuanced regulations, and public health authorities from tailoring education and harm reduction strategies.
- The U.S. Food and Drug Administration's Adverse Event Reporting System (FAERS) is the world's largest spontaneous adverse event reporting database, capturing millions of real-world ADR reports submitted by clinicians, consumers, and manufacturers.<sup>3</sup>
- While FAERS does not track individuals longitudinally, its breadth and duration enable detection of rare ADRs and characterization of demographic disparities.

## OBJECTIVE

- The objective of this study was to comprehensively evaluate the safety profile of hemp-derived products using the FDA Adverse Event Reporting System (FAERS).

## METHODS

### Data source

- Data was sourced from the FDA Adverse Event Reporting System (FAERS).
- Data includes patient demographic information (age and sex), drug information (drug name, active ingredient, and route of administration), and reaction information through standardized preferred terms (PT).
- The adverse drug reaction data is made publicly available on a quarterly basis by the FDA.

### Study design

- FAERS data from January 1, 2004 to June 30, 2025 were included in this study.
- If a report was submitted to the FDA multiple times with updated information, only the most recently submitted version was included in this study to avoid duplicate data.

### Drug Exposure Definition

- Reports were identified through FDA-coded product names using search terms such as "hemp" and "CBD".

### Reporting Odds Ratio (ROR)

- Reporting Odds Ratios and corresponding 95% confidence intervals (95% CI) were calculated for the association between hemp and its top 20 adverse drug reactions (ADRs).
- ROR was calculated as the ratio of the odds of reporting an adverse event versus all other events for a given drug compared with the reporting odds for other drugs present in FAERS.
- An association was considered to be statistically significant when the lower limit of the 95%CI was greater than 1.

### Subgroup analysis

- RORs for ADRs of hemp among male and female patients were calculated.
- RORs for ADRs of hemp among patients less than 65 years old and patients 65 years old or older were calculated.

### Statistical software

- Microsoft Excel Office 365
- SAS 9.4

## RESULTS

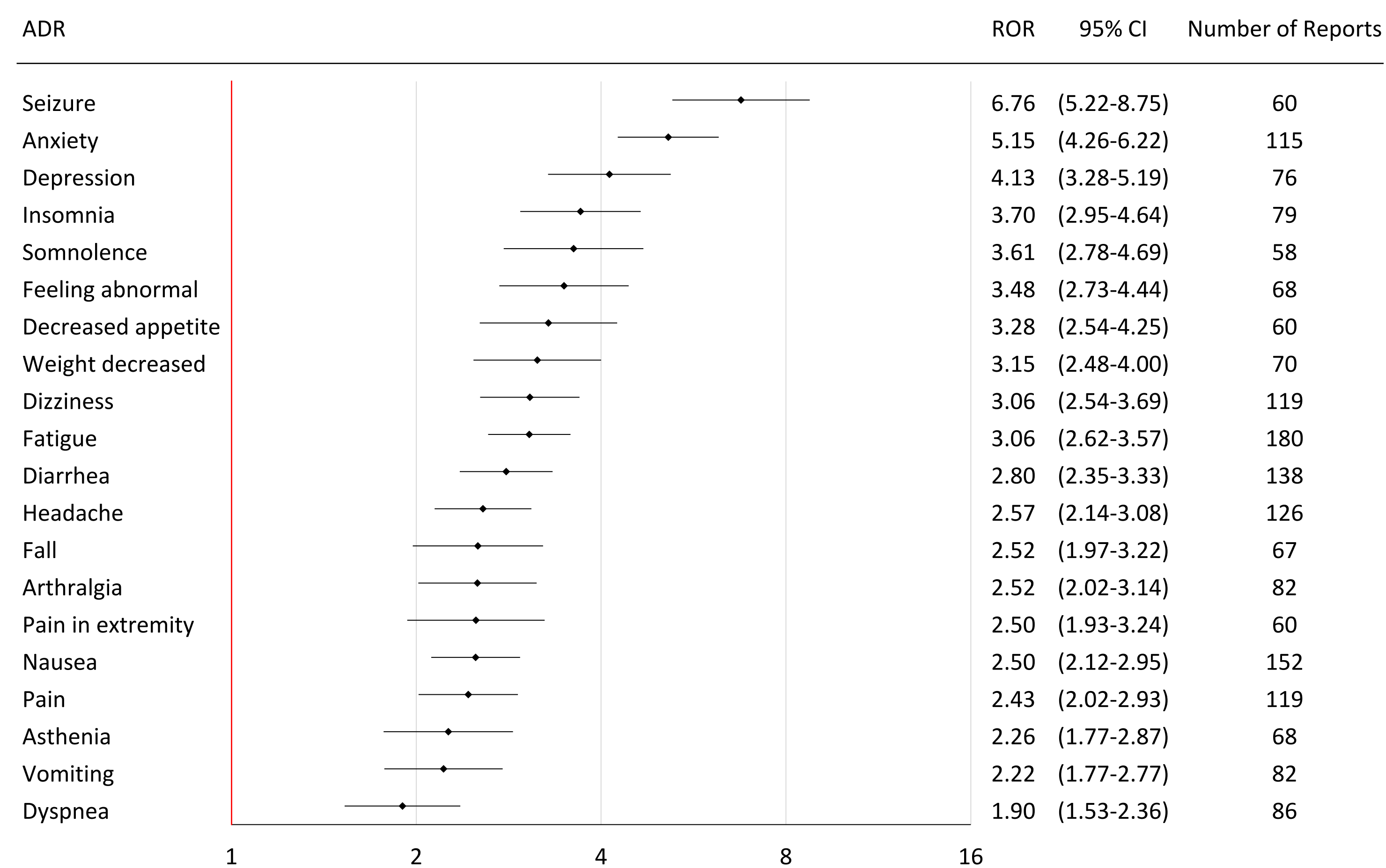


Figure 1. Reporting Odds Ratios (ROR) and 95% Confidence Interval (95% CI) between hemp and its top 20 ADRs.

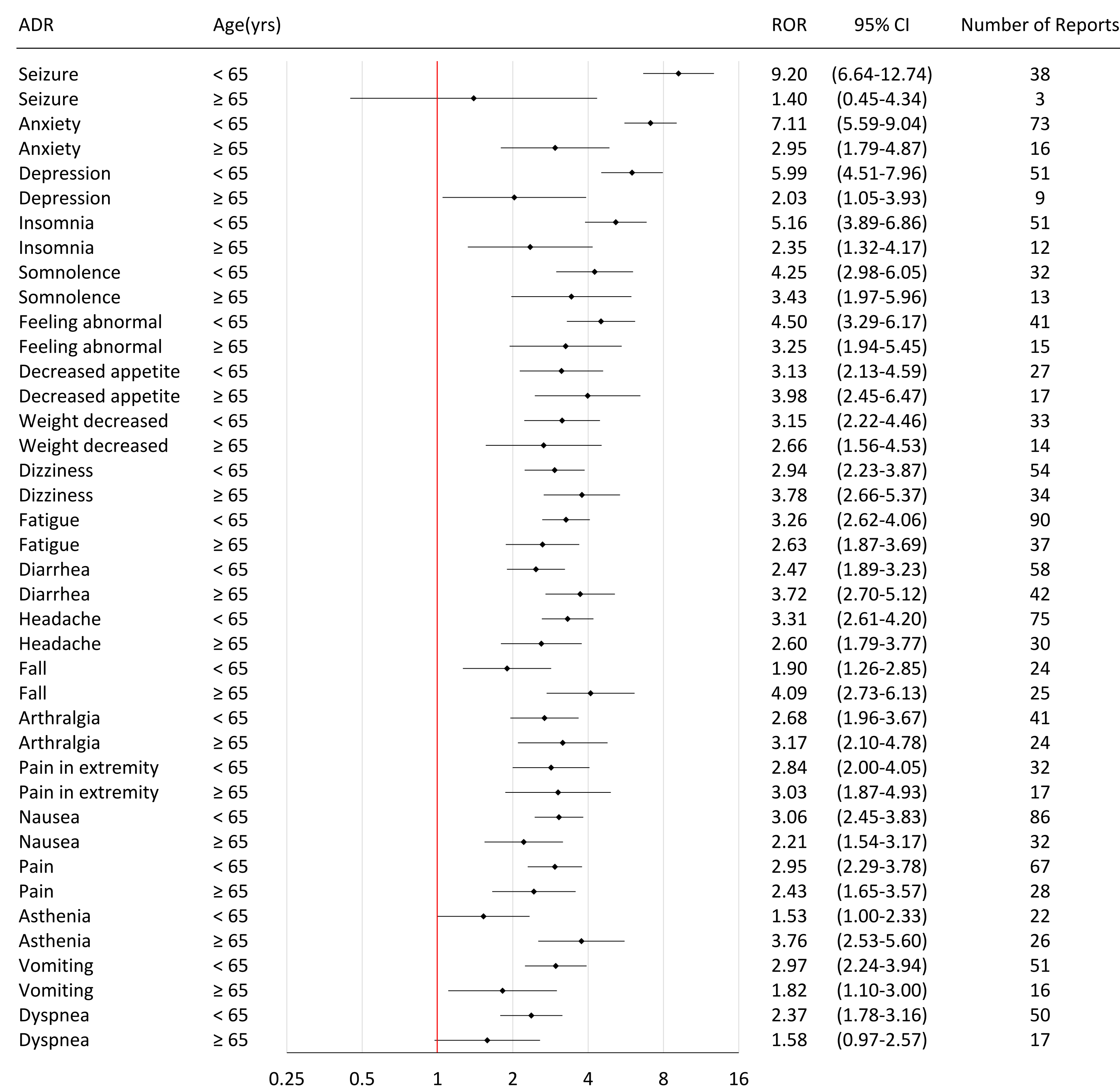


Figure 2. Reporting Odds Ratios (ROR) and 95% Confidence Interval (95% CI) between hemp and its top 20 ADRs stratified by age.

## RESULTS

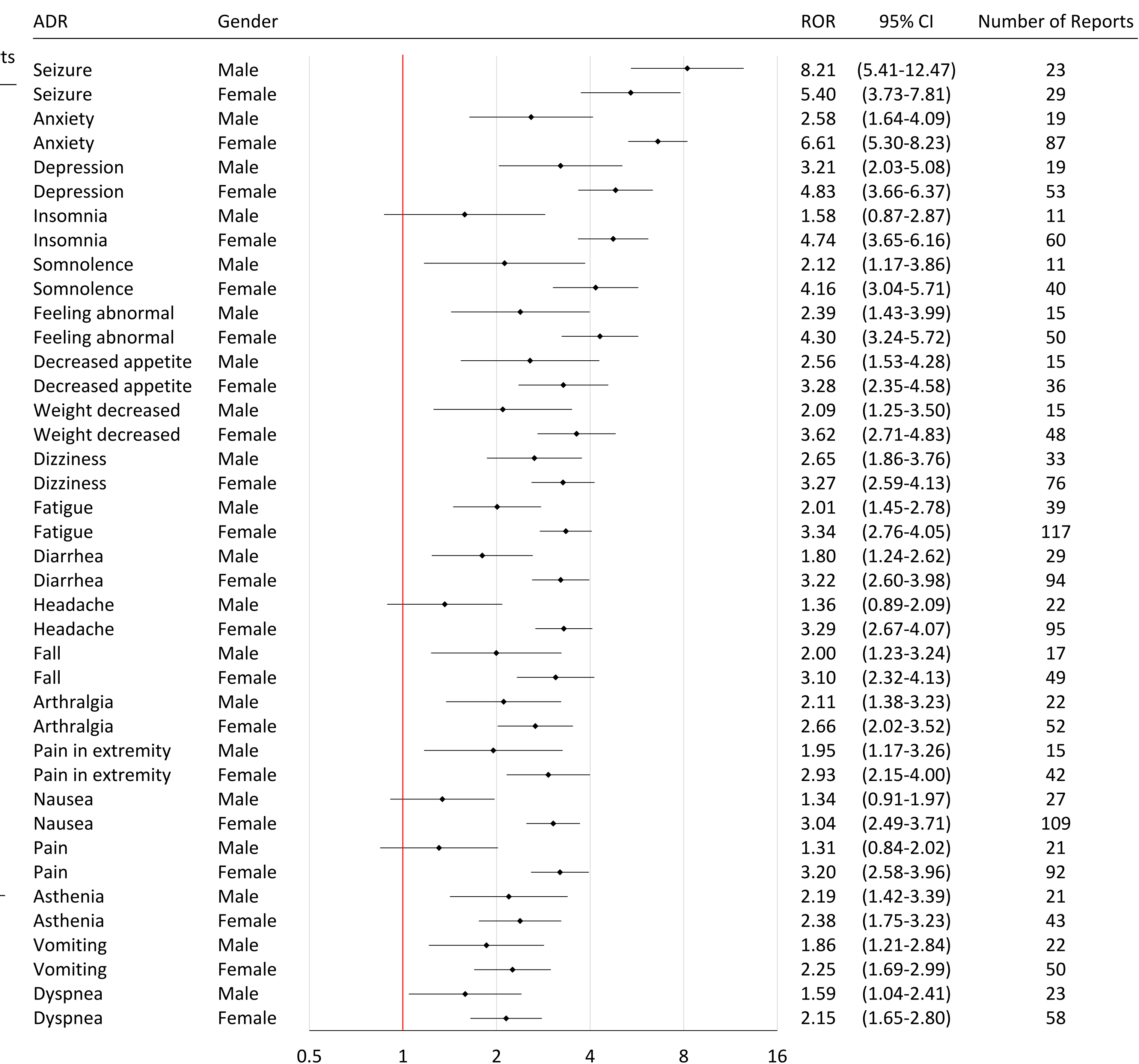


Figure 3. Reporting Odds Ratios (ROR) and 95% Confidence Interval (95% CI) between hemp and its top 20 ADRs stratified by gender.

- A total of 19,345,024 reports were considered, after inclusion criteria were applied.
- The total number of reports for hemp was 1,712.
- The number of reports for the top 20 ADRs of hemp were fatigue (180), nausea (152), diarrhea (138), headache (126), dizziness (119), pain (119), anxiety (115), dyspnea (86), arthralgia (82), vomiting (82), insomnia (79), depression (76), weight decreased (70), asthenia (68), feeling abnormal (68), fall (67), decreased appetite (60), pain in extremity (60), seizure (60), and somnolence (58).

## CONCLUSIONS

- Hemp use is associated with a wide range of ADRs, including serious neuropsychiatric and seizure-related outcomes, and that these risks differ significantly by age and gender.

## FUNDING

- This study is supported by American Association of Colleges of Pharmacy New Investigator Award.

## REFERENCES

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