

Psychedelics in the Real World: Using Real World Evidence to Prepare for Approval

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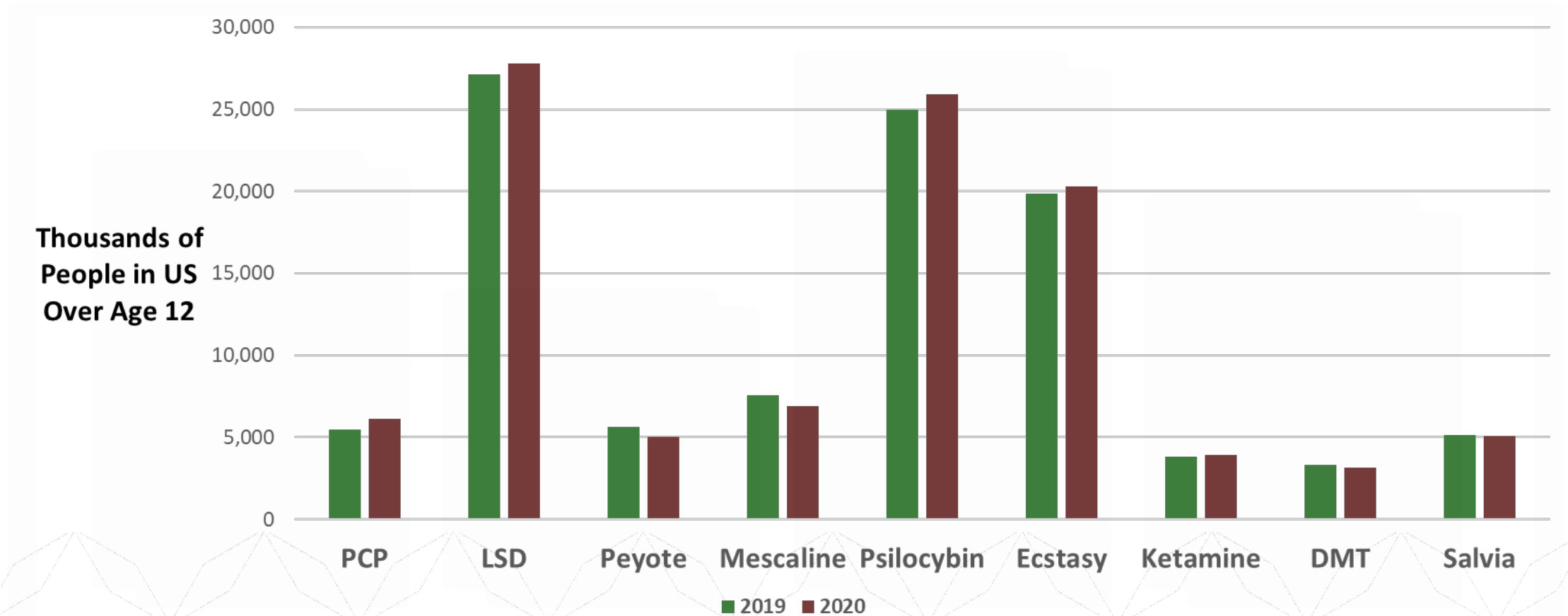
Roadmap

- Existing Data on Psychedelic Use
- Snapshots of Epidemiology of Psychedelic Use
- Balancing Benefits and Risks of Psychedelics
- Future Considerations in Psychedelic Epidemiologic Research

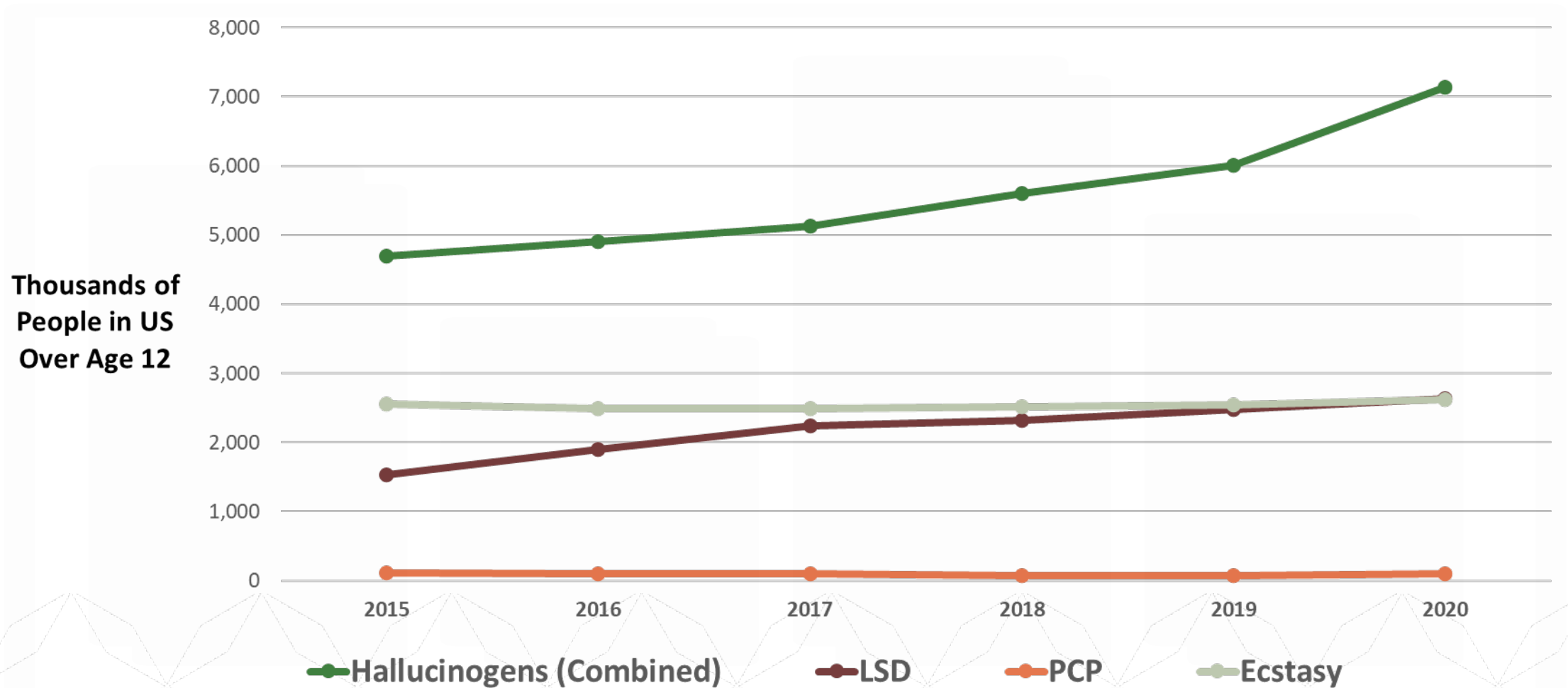
Existing Data on Psychedelic Use

- Data sources
 - National Survey for Drug Use and Health (NSDUH)
 - National Poison Data System (NPDS)
 - Monitoring the Future (MTF)
- Challenges in data collection
 - Bias toward non-reporting
 - Substance patient is using and substance patient *thinks* they are using may not be the same
 - Lack of specificity
 - Motivations for use poorly captured
 - Delays in data availability
 - No single perfect data system

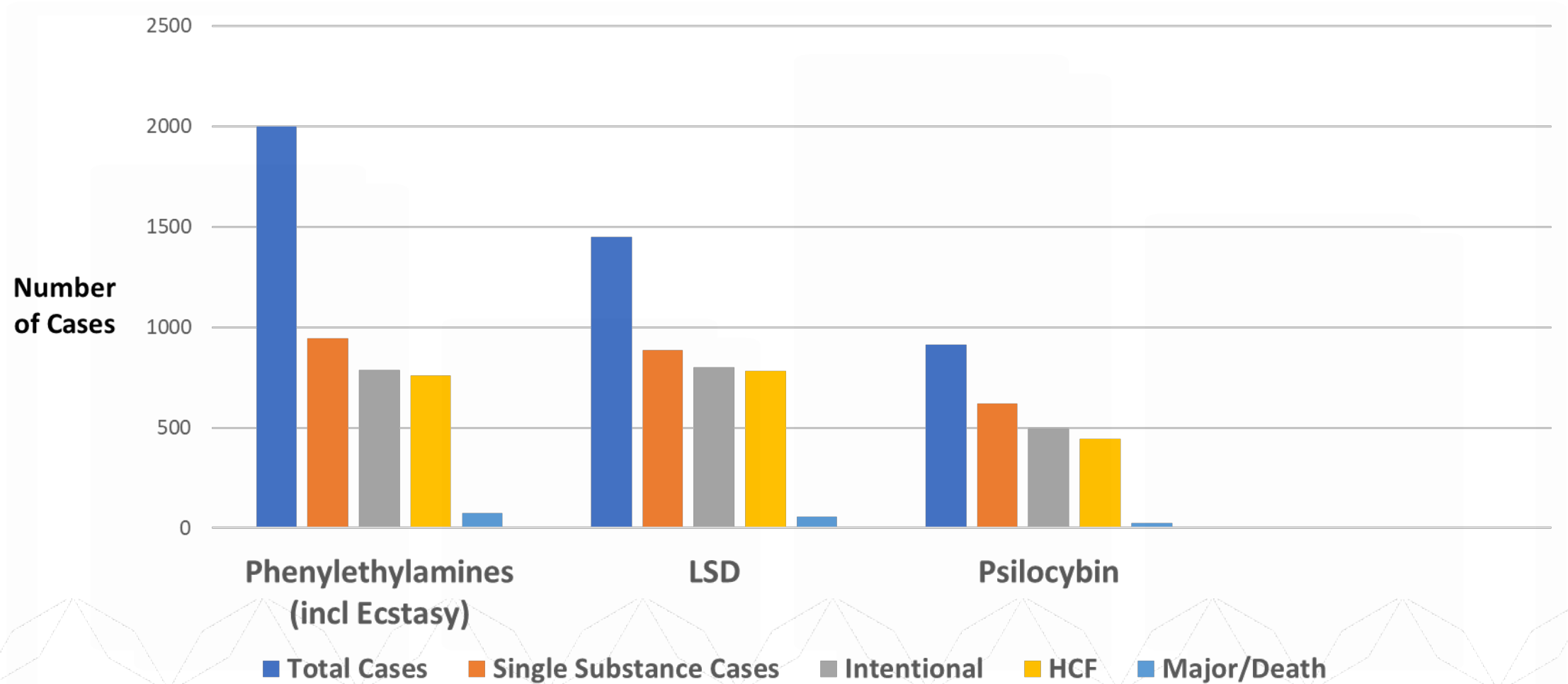
NSDUH, Lifetime Use, 2019-2020



NSDUH, Past Year Use, 2015-2020

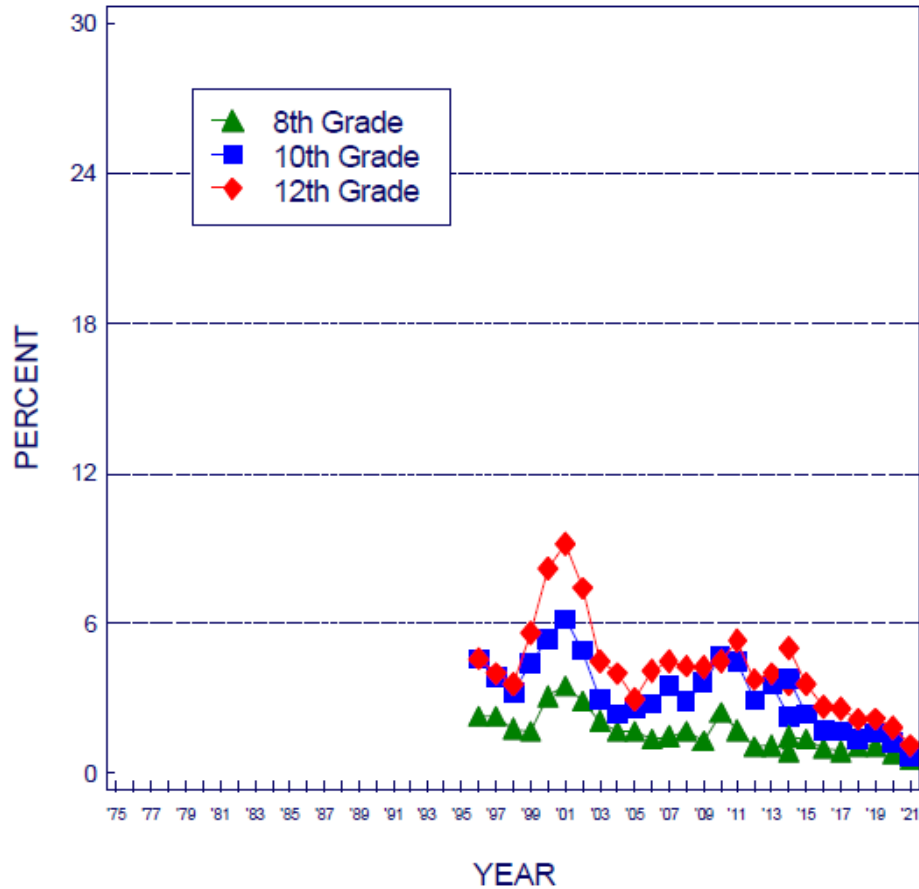


NPDS, Cases by Category, 2020

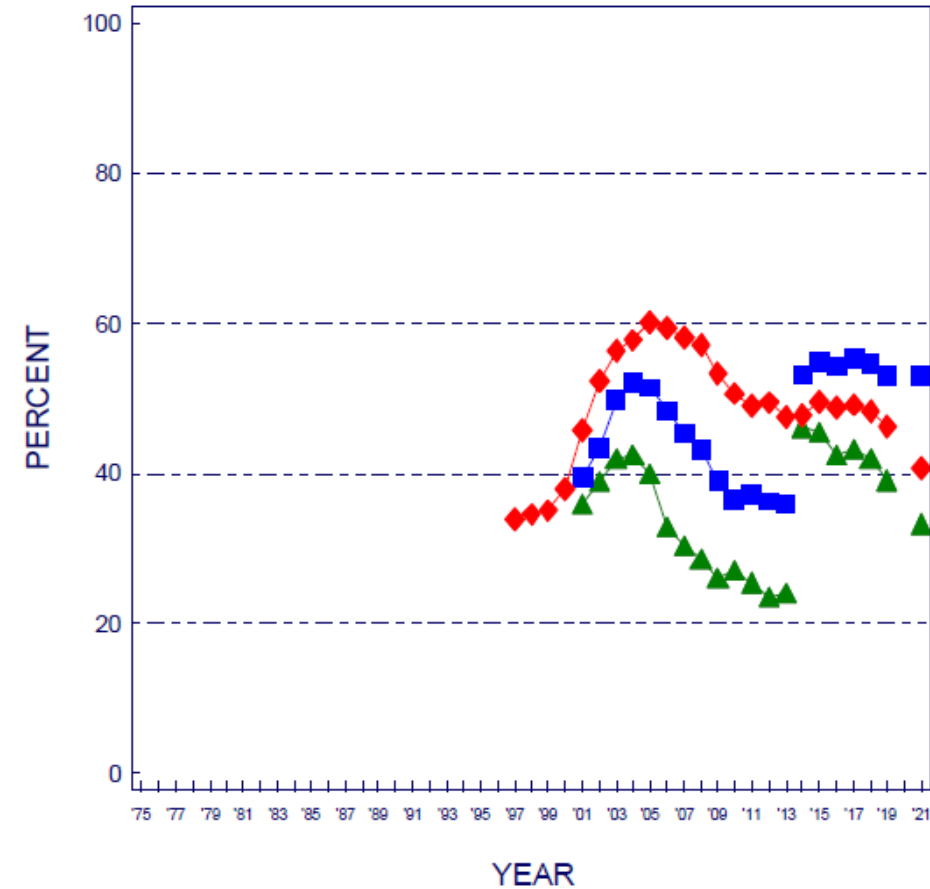


MTF, Adolescents 1996-2020, Ecstasy

Use
% who used in last 12 months

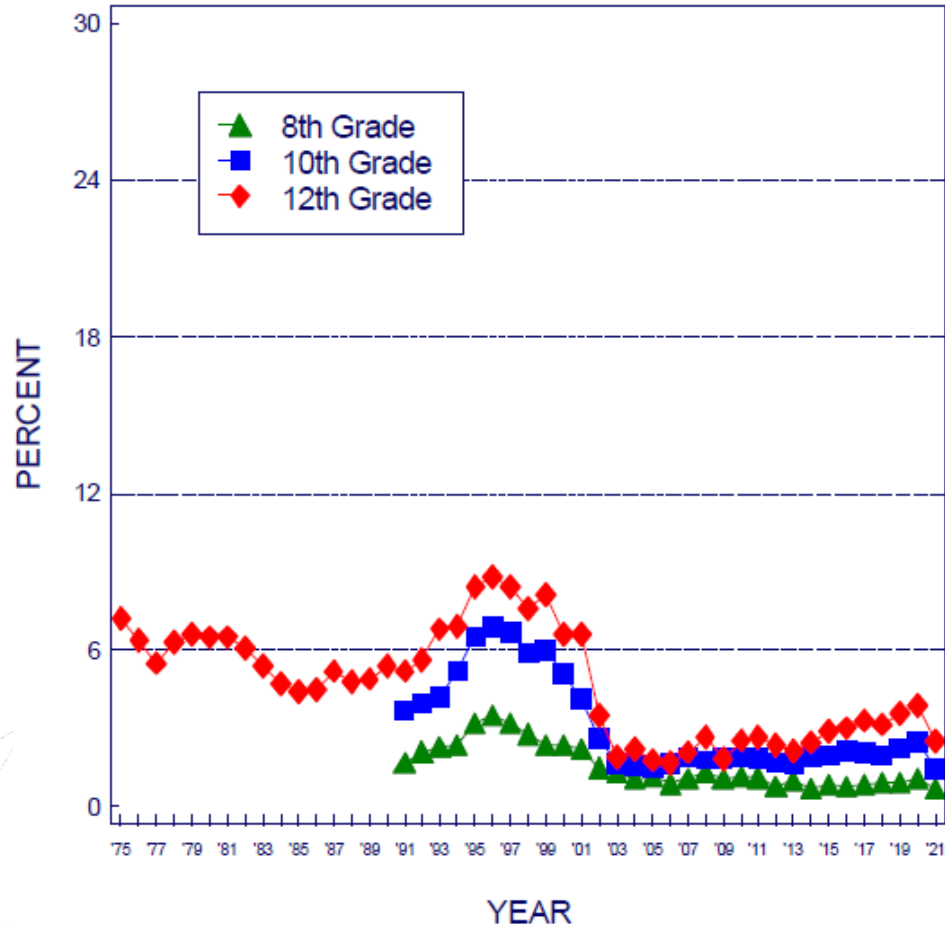


Risk
% seeing "great risk" in using once or twice

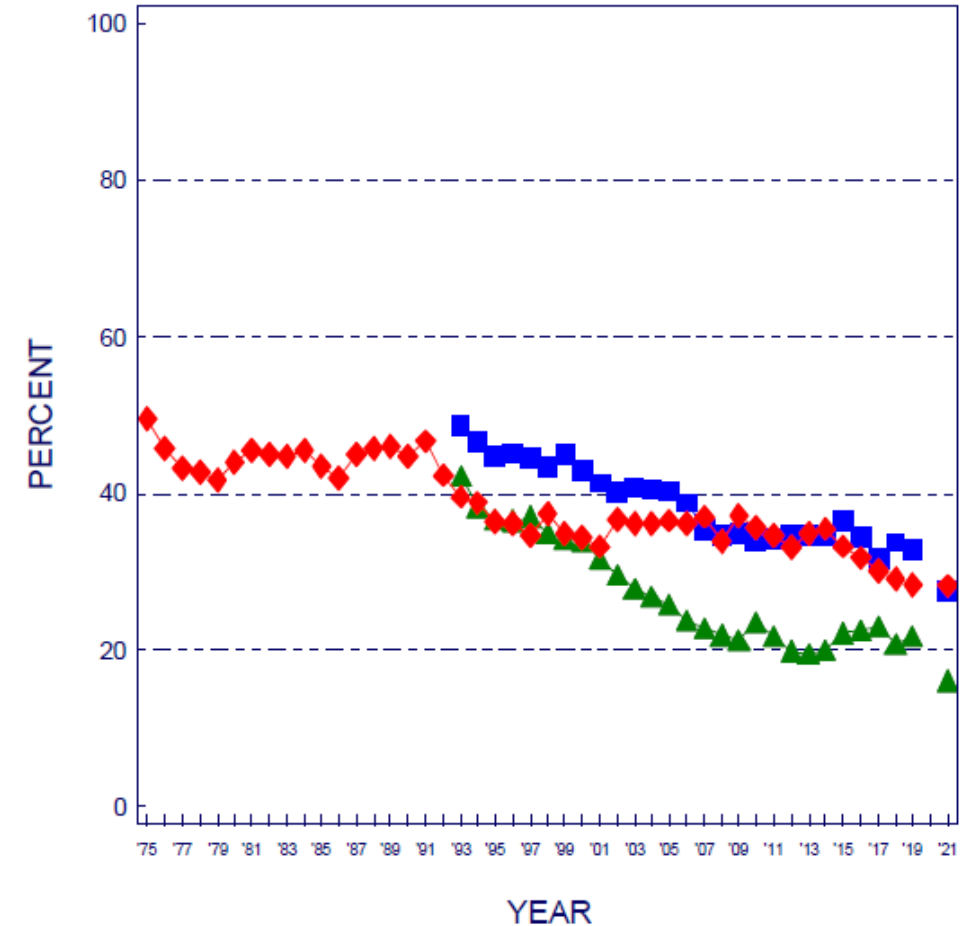


MTF, Adolescents 1975-2020, LSD

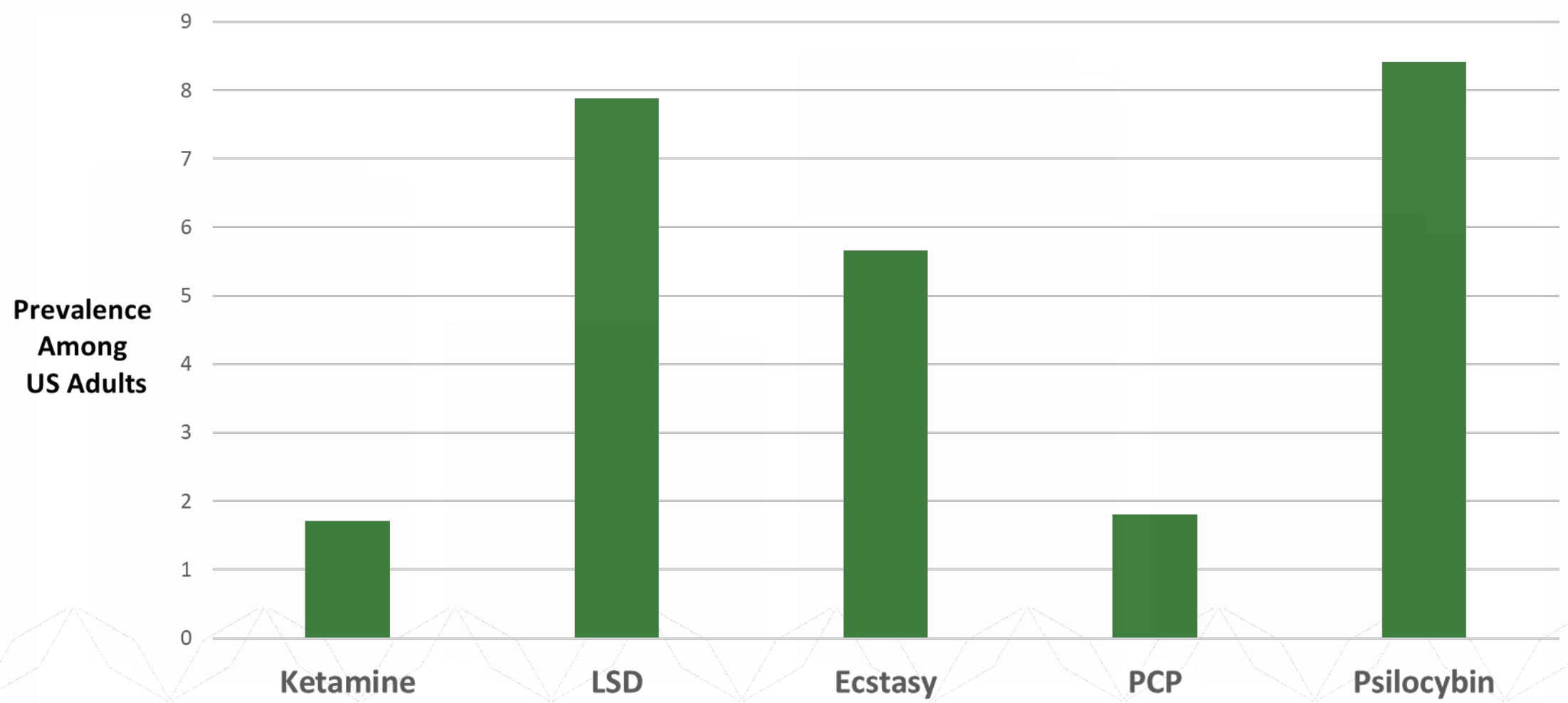
Use
% who used in last 12 months



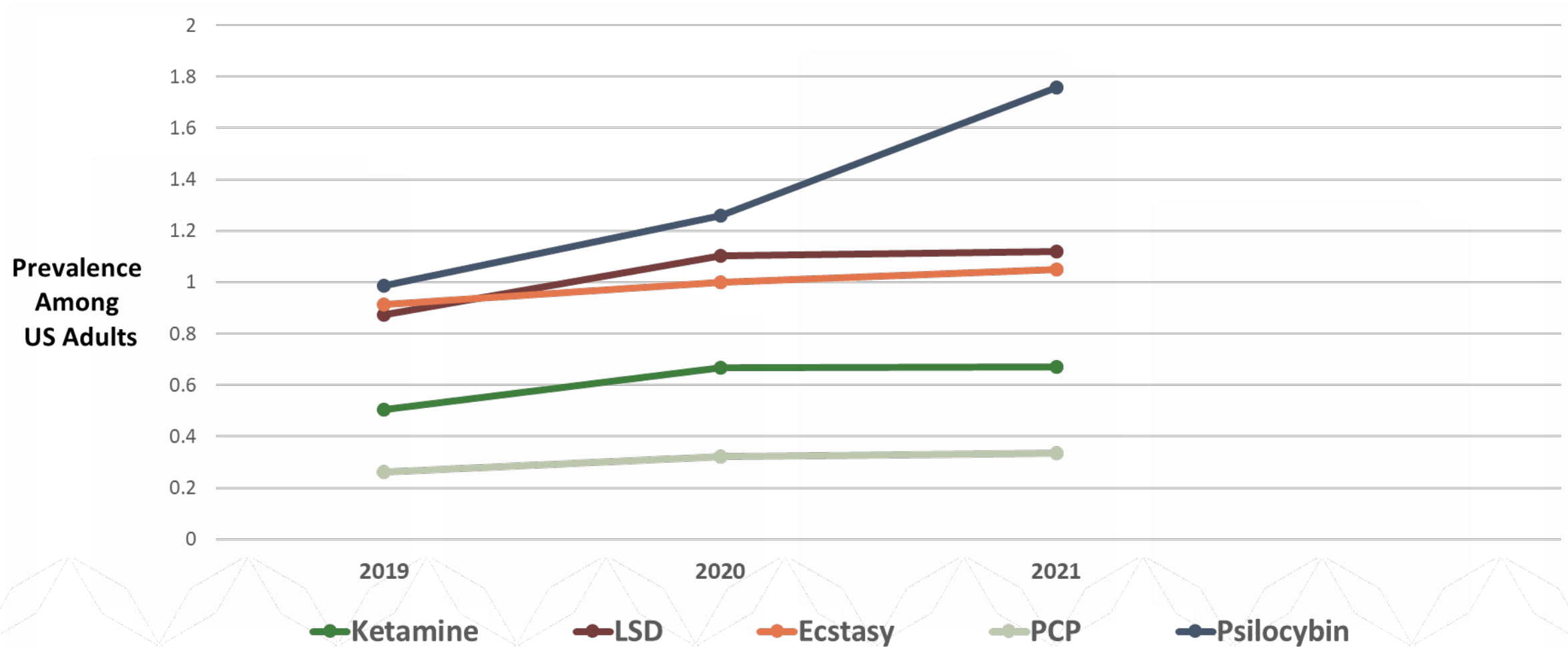
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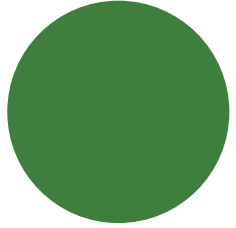
Snapshot of 2021 Lifetime Use, RADARS System NMURx Program



Snapshot of 2019-2021 Past Year Use, RADARS System NMURx Program

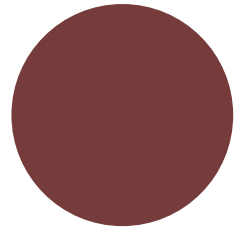


Developing a Postmarketing Surveillance Strategy: Considerations



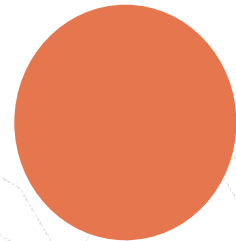
Product Specificity

- Street vs medical
- High risk of counterfeits



Molecular Differences

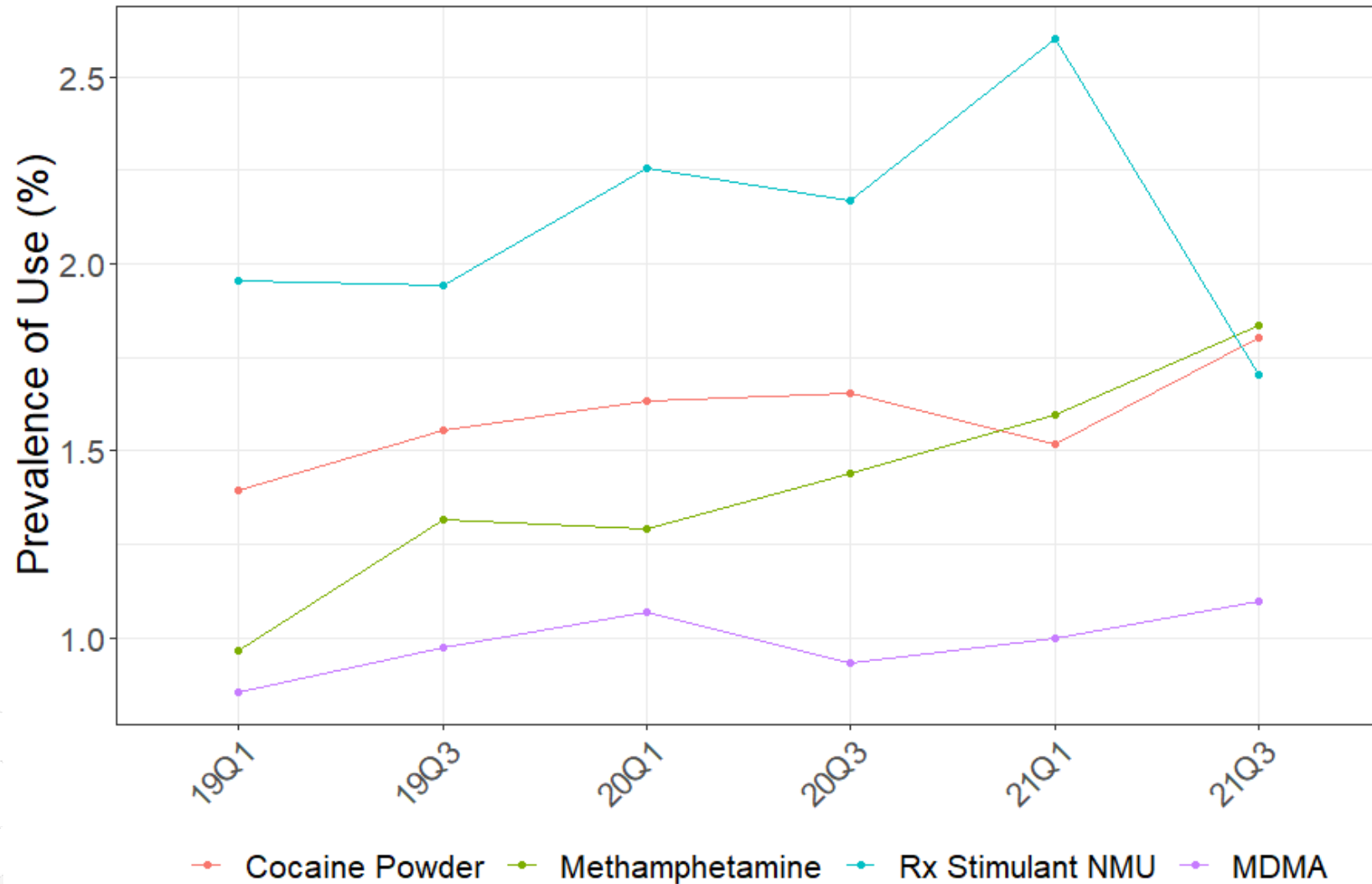
- Not all psychedelics are the same
- Differential needs for each molecule



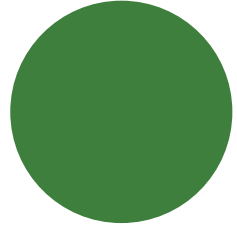
Comparator Development

- What makes sense for appropriate comparators?
- Rx meds, street drugs, ?

Conceptualizing Comparators

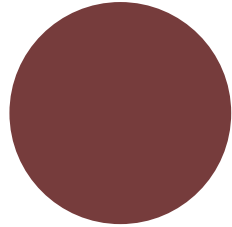


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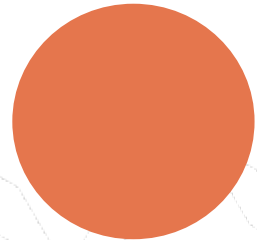
Benefit/Risk Balance

- Measuring unmet needs, benefits, AEs
- Measuring impacts on perceptions and behaviors



Adverse Event Tracking

- How to track AEs from multiple sources
- Do we also need to understand “AEs” from non-Rx sources?



Regulatory Challenges

- Differential regulations by state
- Range from illegal -> deprioritized -> decriminalized-> legalized

Thank you!

Questions???

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