



Knowledge leaders in delivering total product safety solutions.

Is there a path forward for FDA to allow consumer CBD products? Challenges and Opportunity

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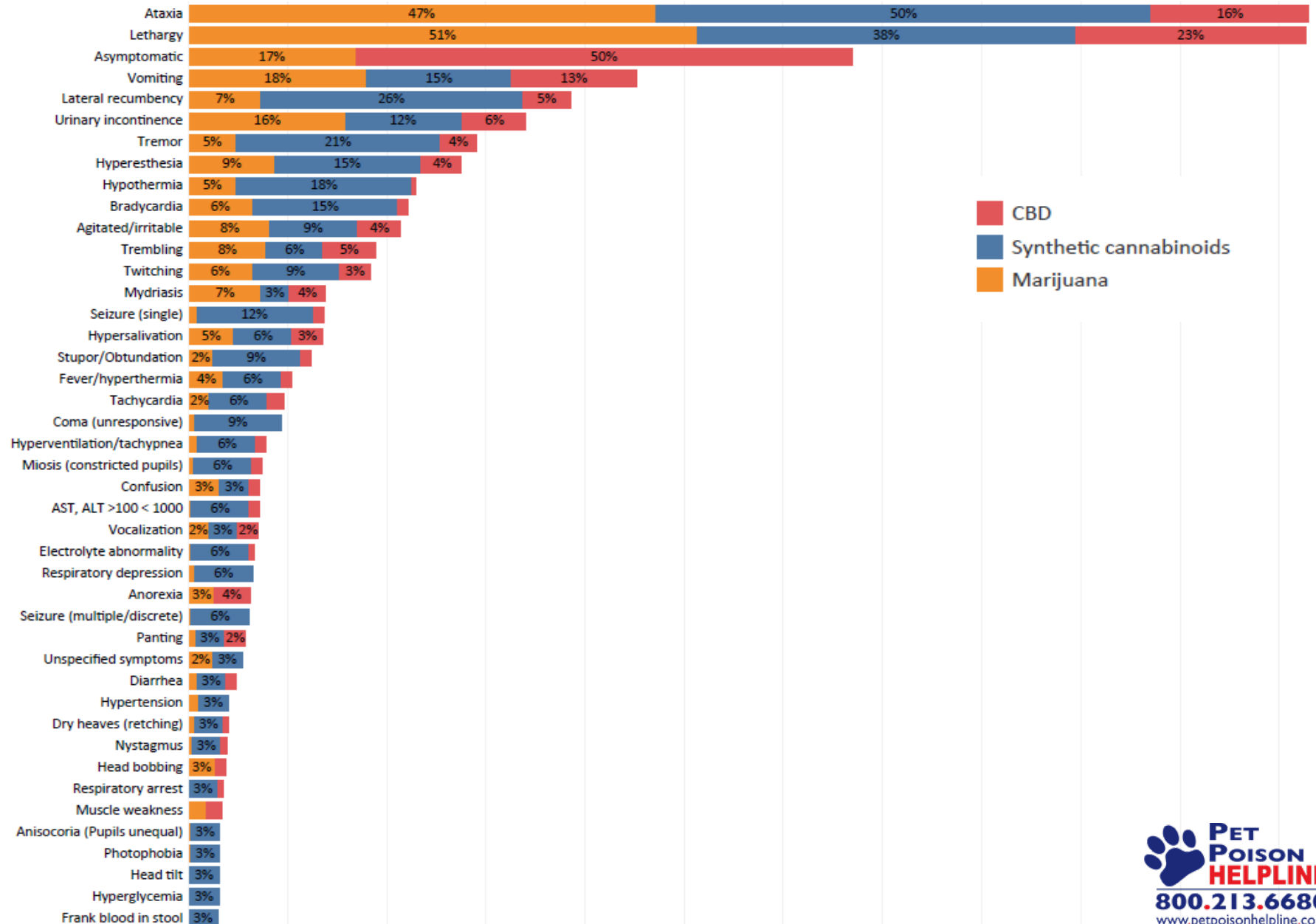


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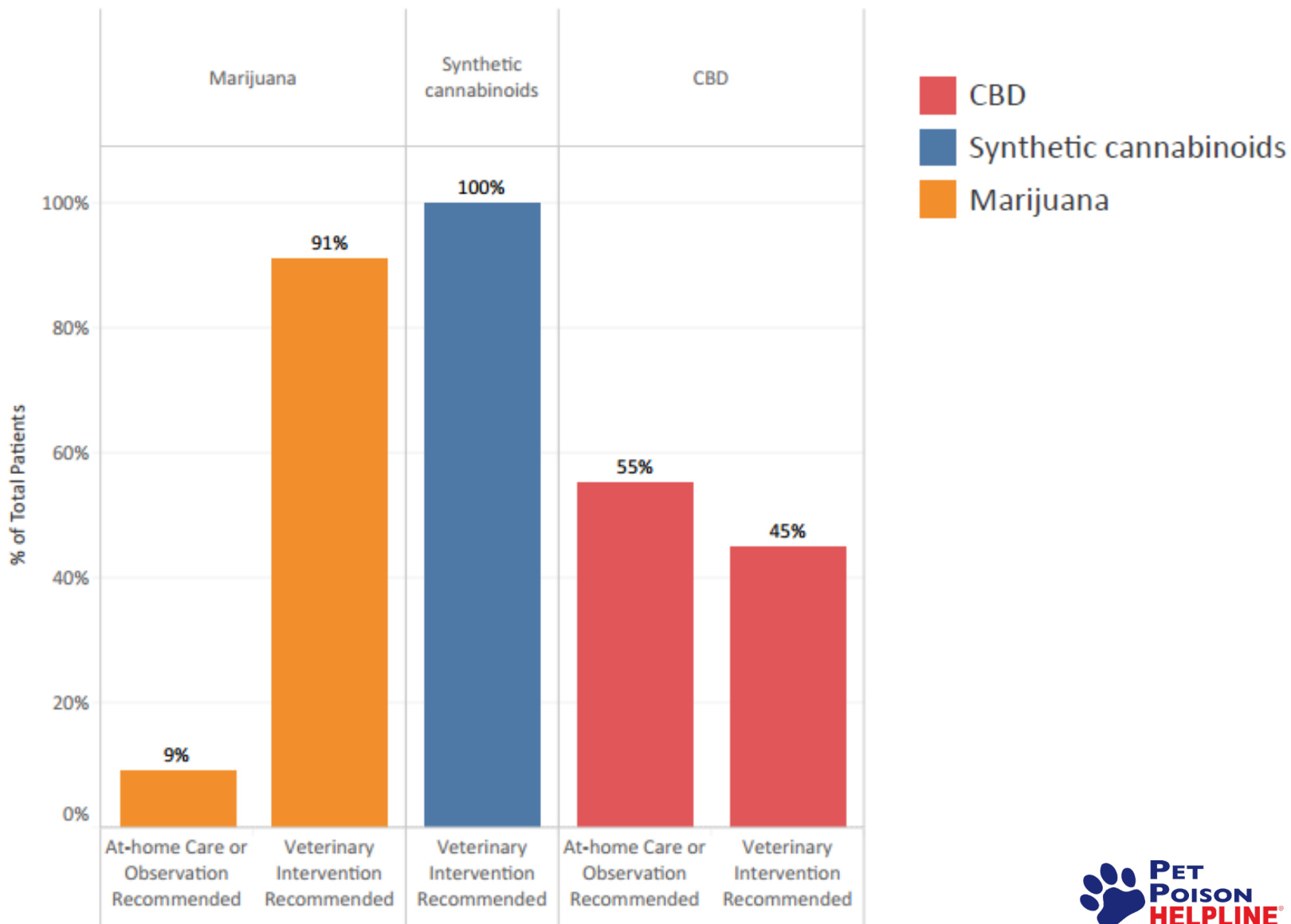
SafetyCall/Pet Poison Helpline Profile

- The only academically affiliated multidisciplinary healthcare practice providing Post Market Surveillance for both human and animal care product categories
- Largest Veterinary Poison Control Center in the world
- Expertise (Veterinary/Human Toxicology and PMS Epidemiology)
- Regulatory support for adverse event reporting compliance in virtually every Canadian and US regulatory agency jurisdiction
- Multiple market experience in clinical risk assessment
- Over 200 corporate clients across all markets
- Currently providing 3rd party, post market surveillance (PMS) for Medical Cannabis companies in multiple states; expanding into the CBD market
- Sole provider of Medical Cannabis PMS for all vendors and dispensaries in Minnesota; established in collaboration with Minnesota Department of Health

Pet Poison Helpline Data Echoes Concerns over Product Quality and Safety in Pets



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Components of Medical Cannabis Safety/Efficacy Program in MN Could Serve as National Model

- Product QC & QA (required integrity issue investigation)
- Patients must enroll in registry and agree that collected data can be used for aggregate reports and research including:
 - Observational studies
 - Active Side effect/interaction profiling and benchmarking; patient interviews at each dispensing (16,000 patients)
- Mandatory post market surveillance with analysis and generation of report: *“Maintain a toll-free telephone line, which must be available 24 hours a day, seven days a week, that is staffed by professionals who are health care practitioners or state-licensed pharmacists trained in detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem;”*

SCI Experience with Cannabis Product Companies

- SCI/PPH already providing pharmaceutical standard-of-care pharmacovigilance support to best practice companies manufacturing and selling cannabis products (CBD, THC, CBD/THC)
 - 24/7 Medical call center support (access to human and veterinary toxicology professionals)
 - Toll-free 800 number on all product labels
 - Documentation of AEs in Part 11 FDA compliant pharmacovigilance database
 - AE data analysis and interpretation including access to normalized incident rates for product dossier safety profiling
 - Regulatory reporting support for products subject to state or local authority oversight

SCI Experience with Cannabis Product Companies

- SCI/PPH already providing pharmaceutical standard-of-care pharmacovigilance support to best practice companies manufacturing and selling cannabis products (CBD, THC, CBD/THC), cont...
 - SCI/PPH routinely collaborates with the **National Center for Natural Product Research (NCPR)** regarding investigations into botanical characterization and quality
 - Supporting current efforts of the American Botanical Council (ABC) to address potential for adulterants in cannabis products through the Botanical Adulterants Prevention Program (BAPP)
 - To date, safety profile for properly manufactured and characterized cannabis products (CBD, THC, CBD/THC) has been positive, especially for CBD

Potential Path Forward for FDA to gather/develop solid safety information on CBD

- Tap into currently available product stewardship programs such as the SCI/NCNPR/BAPP efforts for development of standardized GMPs, safety surveillance using medical professionals, regulatory reporting and identification and prevention of cannabis product adulteration
- Require product registration (already contemplated for supplements)
- Consider conditional registration for CBD manufacturers participating in rigorous safety/quality stewardship programs?

Thank You!

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