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New Novel, Fit-For-Purpose Framework for Monitoring
The Health Impact of Psychedelic Medication Use

DENVER (May 3, 2024) – As psychedelic medicines emerge as a promising therapeutic option for treating psychiatric illness, we must establish a dynamic data system to understand their real-world effectiveness and safety profiles.

Rocky Mountain Poison & Drug Safety (RMPDS) developed a novel framework for monitoring the health impact of psychedelic medication use and has published their concept in Nature Mental Health.

Interest in psychedelic medications for treating mental health conditions is surging backed by clinical trials affirming their efficacy. With a recent new drug application filed with the FDA for approval of MDMA to treat PTSD, use and access are likely to expand. However, traditional medication monitoring frameworks are not suited for psychedelics' unique traits. Rocky Mountain calls for a fit-for-purpose postmarketing surveillance approach to fill this gap.

The framework stresses a comprehensive approach for evaluating the context of psychedelic use, considering many factors that affect patient outcomes. Both real-world effectiveness and safety factors should be monitored to ensure these promising medications equitably reach those who need them. Correct attribution of positive and negative outcomes to the medications used is essential. The framework relies on monitoring tools like targeted surveys, medical information from treatment facilities and direct patient feedback.

"We believe that by adopting the framework and collecting essential information about the use of approved medications, regulators, policymakers and industry sponsors will make well-reasoned decisions that ensure safe, effective and equitable access to psychedelic medications," Joshua C. Black, Ph.D., lead author and Sr Research Scientist at RMPDS, said.

Rooted in Rocky Mountain's decades of experience leading the monitoring of prescription drug safety, this proposed framework aligns with our commitment to Saving Lives with Answers™.

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About Rocky Mountain Poison & Drug Safety

Rocky Mountain Poison & Drug Safety, a department within Denver Health, provides specialized services spanning the lifecycle of a drug or consumer product to public health, government agencies, and the pharmaceutical and consumer products industries. Our Poison Center & Health Information and Drug & Consumer Product Services groups provide 24/7/365 contact center communication, exposure management, and toxicology consulting. We offer research, analysis and surveillance, and consulting through our Research & Consulting Services group, including our industry-leading RADARS® system.

About lead author Joshua C. Black, Ph.D.:

Dr. Joshua C. Black is a Senior Research Scientist at RMPDS, a Division of Denver Health and Hospital Authority. His research focuses on developing innovative data science and biostatistical methods to study drug use epidemiology. Dr. Black can provide valuable insights into the implications of this groundbreaking study and its potential impact on the field of mental health and substance use disorder prevention.

About Denver Health

Denver Health is a comprehensive health and hospital system that provides high-quality care and proudly serves as the city's safety net hospital. For more than 160 years, Denver Health has been guided by its mission to serve the people of Denver, to educate the next generation of health care professionals and to engage in research and community partnerships to better deliver the health care needs of our patients while strengthening our community.