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The Dosing Project: An Analysis of Adverse Events & Effective Dosages for Cannabis Products

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Abstract: With estimates of over five million registered users, Cannabis product sales have climbed to nearly \$13 billion per year. This increase in consumption brings up questions of safety and marketed product certification. In response, many US states have established testing requirements for cannabinoid potency, toxins, and microbials. However, there is no required market surveillance of adverse events associated with Cannabis products. Post-market surveillance studies are often used to monitor their severity and frequency for FDA regulated products. Cannabis, as a variable, multi-agent botanical, presents complexity to the traditional FDA paradigm. The CESC, therefore, offers The Dosing Project™, as an approach to Cannabis product safety certification and dosage evaluation.

The Dosing Project™ is a non-interventional surveillance study platform investigating the acute effects of Cannabis products used in a naturalistic setting. Participants using community-accessible Cannabis products are recruited to respond to an anonymous survey on dosage, beneficial effect, and adverse events. In this presentation, we review our work discovering usage patterns and preferred dosages based on contingency analysis and logistic regression modeling of responses for smoked or vaped Cannabis Flowers for Pain and Disordered Sleep symptoms. We present dose-response models for Cannabis Flower chemotypes encompassing different cannabinoid ratio types and aroma categories (a surrogate for terpene content). We evaluate adverse event relationships between response categories using multiple correspondence analysis (MCA). Additionally, we propose an Effect Index (EI) as a comparative measurement of product safety. A primary objective of The Dosing Project™ is to predict safe and effective dosage of Cannabis products.