

Center for the Study of Tobacco Products

Human Lab Methods for MRTP Evaluation (Project 2)

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Abstract:

Project 2 of this Center is part of a four-project effort with the overarching goal of providing an empirical demonstration of an integrated, iterative model of MRTP evaluation that uses analytic lab, human lab, randomized control trial (RCT), and quantitative/qualitative methods to inform tobacco product regulation. In particular, Project 2 will show how human lab methods can inform pre-market evaluation by determining the behavior, effects, and toxicant exposure associated with MRTP use, and also how these methods can inform abuse liability assessment, a critical factor in effective regulation. It also demonstrates the utility of human lab methods for post-market evaluation of MRTPs, especially when products are used differently than intended. To accomplish this demonstration we begin with a systematic evaluation of a novel and increasingly popular tobacco product that is marketed as a “healthy smoking alternative”: “electronic cigarettes” (ECIGs). The specific aims of Project 2 are to: 1) Demonstrate how human lab methods can reveal product use behaviors, toxicant exposure, and effects; 2) Demonstrate how human lab methods can determine product abuse liability; 3) Determine how unorthodox use behavior influences MRTP effects. In sum, Project 2 draws on our record of expertise and innovation in human lab evaluation of tobacco products to demonstrate how these methods contribute to an integrated and iterative model of MRTP evaluation that will inform FDA regulation of these products.