Abstract:

Project 4 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 “mixed” quantitative and qualitative methods to inform regulation. Project 4 will show how, once an MRTP is marketed, mixed method approaches can provide context that helps explain patterns of MRTP consumption and prevalence. Project 4 will also demonstrate how mixed methods can be used to generate empirically-based, descriptive models of MRTP-related attitudes, beliefs, motivations and perceived effects (including adverse events) associated with the product when it is used as it is marketed, as well as non-marketed, “unorthodox” use behaviors. Finally, Project 4 will demonstrate how alternative data sources can be used to refine regulation by providing detailed information about marketed and unorthodox MRTP use methods. To demonstrate our model, we begin with a programmatic evaluation of a novel and increasingly popular tobacco product marketed as a “healthy smoking alternative”: “electronic cigarettes” (ECIGs). There are two specific aims for Project 4. First, we will characterize and describe the attitudes and beliefs, motivations, and perceived effects associated with MRTP behaviors. Concept mapping (CM), an integrated mixed method participatory research approach, will be used to characterize and describe user attitudes and beliefs regarding ECIGs, motivations or reasons for ECIG use and perceived beneficial and adverse effects of ECIG use. Second, we will examine methods of unorthodox MRTP behaviors. We will use alternative data sources (e.g., YouTube, internet forums) to conduct a descriptive content analysis of videos and text depicting unorthodox ECIG use behavior such as mixing high-dose nicotine liquids and/or dripping liquid directly on the ECIG heater. In sum, Project 4 demonstrates how an innovative, mixed method approach can be used to describe the attitudes, beliefs, and motivations of MRTP users and investigate MRTP effects as well as describe unorthodox MRTP use behavior. These methods are relevant to developing and refining MRTP regulation in a comprehensive and iterative fashion, as described in the Center’s overarching evaluation model. Thus, this project provides FDA essential tools for ongoing, empirically-driven MRTP regulation.