

Center for the Study of Tobacco Products

Analytical Lab Methods for MRTP Evaluation (Project 1)

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Abstract:

Project 1 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 regulation. In particular, Project 1 shows how our analytic lab methods can inform pre-market evaluation to determine whether a proposed MRTP has potential to modify disease risk by producing physiologically relevant doses of nicotine while reducing toxicant yield. Project 1 will also show the utility of these analytic lab methods for post-market evaluation of toxicants produced by MRTPs, especially when they are used in non-marketed, “unorthodox” ways. Thus Project 1 demonstrates how FDA regulation can be informed by analytic lab methods before and after an MRTP is brought to market. To accomplish this demonstration we begin with a systematic evaluation of a novel and increasingly popular product that is marketed as a “healthy smoking alternative”: “electronic cigarettes” (ECIGs). The specific aims of Project 1 are to demonstrate how analytic lab methods can be used to: 1) Determine how design features and behavior interact to influence MRTP nicotine yield; 2) Predict MRTP user toxicant exposure; 3) Study how unorthodox use behavior influences MRTP nicotine and other toxicant yields. In sum, in Project 1 we will draw on our engineering expertise and record of innovation in tobacco product testing to demonstrate application of physical principles for rapid screening and empirical methods for the systematic study of MRTP toxicant yields under real-life use conditions. These principles and methods will provide FDA analytical tools essential for regulating MRTPs efficiently and scientifically.