

Evaluating Flavors in Novel Tobacco Products: A Transdisciplinary Approach  
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Abstract:

The US tobacco marketplace is changing fast, and regulatory science lags far behind. The FDA can alter this dynamic, but needs the tools to do so. One necessary tool is a model for evaluating all types of "modified risk tobacco products" (MRTPs): novel tobacco products marketed with the claim that they reduce harm or risk associated with conventional products. There are few demonstrated models for predicting tobacco product harm or risk. The overarching goal of the NIH/FDA-funded Center for the Study of Tobacco Products (CSTP) at Virginia Commonwealth University is to demonstrate empirically an integrated, iterative MRTP evaluation model to inform tobacco product regulation across all product types. The goal of the proposed work is to extend the CSTP model by using its transdisciplinary approach and some of its methods to examine the effects of tobacco product *flavor* and nicotine content on measures related to user initiation and subsequent use in young adults. The CSTP applies these methods to an exemplar product, the electronic cigarette (ECIG), a device that heats a nicotine liquid to produce an inhalable aerosol. We adopt the same approach in this supplement and will use the same mixed and clinical lab methods to evaluate the influence of ECIG flavor and nicotine content on user perceptions and measures of abuse liability. Using mixed methods, we will characterize the perceived effects of ECIG flavors among a sample of young adult (18-21) ECIG users who report a history or preference for flavored liquids (Study 1). Sub-group analyses in Study 1 will examine the influence of preferred ECIG nicotine content. Using clinical lab methods, we will examine the individual and combined effects of ECIG flavors and nicotine content on subjective measures of abuse liability among a sample of young adult (18-21) conventional tobacco cigarette smokers (Study 2). Data collection will occur semi-sequentially with results from Study 1 informing the choice of specific flavors to be tested in Study 2. As with the already-funded CSTP work, we anticipate that the results from this supplement will inform regulation of ECIGs specifically as well as providing a method that can be used to evaluate the influence of flavor and nicotine content in other tobacco products.