Center for the Study of Tobacco Products
Institution: Virginia Commonwealth University
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Project 3: Using abuse liability data to test hypotheses about advanced-generation ECIGs and generate population-level predictions regarding potential regulatory action
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Project 3 Abstract:
The Center for the Study of Tobacco Products (CSTP) has developed a model for evaluating novel tobacco products using, as exemplars, electronic cigarettes (ECIGs) that heat a liquid that often contains nicotine, forming an aerosol that users inhale. Now, CSTP leverages this ECIG expertise to pivot from product evaluation to an integrative theme of impact analysis. Specifically, the CSTP proposes methods with which FDA can generate predictions regarding a potential regulation's effects and then whether or not the predicted effects occur in the population can be tested. The CSTP's model assesses how potential regulation might influence product toxicity (Project 1), user behavior (Project 2), and product addiction/abuse liability (Project 3). In this context, Project 3 will generate new data regarding the abuse liability of advanced generation ECIGs and will contribute, along with Projects 1 and 2, to population-level predictions. Project 4 will test those population-level predictions.
FDA regulations are intended to promote health, but also may have unintended consequences. For example, limiting ECIG liquids to <20 mg/ml nicotine, as in the European Union (EU), can drive use of higher power devices that aerosolize more liquid/puff, leading users to inhale more nicotine. Unintended consequences may also occur from other actions, such as constraining ECIG nicotine flux (rate of nicotine emission), or reducing flavored ECIG liquid availability. The consequences of these and other potential regulations on ECIG use and dependence can be predicted by assessing abuse liability, or likelihood of persistent drug use/dependence. Behavioral economic tasks are validated indicators of abuse liability and reveal how much people are willing to pay for a drug, how hard they will work to earn a drug, and how sensitive they are to changes in drug prices. Project 3 specific aims use standard abuse liability assessments to examine, in independent lab studies each involving 60 exclusive ECIG users and 60 dual ECIG and tobacco cigarette users, the extent to which responding to a battery of behavioral economic tasks is influenced by three potential regulatory actions: (1) limits on nicotine, (2) constraints on nicotine flux, and (3) reduction in flavor availability. Project 3 is informed by the Contextual Knowledge Core that ensures that independent variables reflect real-world conditions. Overall, results from Project 3 will provide new data regarding ECIG abuse liability in two populations that will likely be impacted by regulatory action differently, and it also will inform testable predictions regarding the consequences of three potential regulatory actions. Project 4 examines these predictions at the population level. Thus, this project is part of a center with an integrative theme of impact analysis that draws from the team's abuse liability expertise to provide FDA tools that can be used to guide regulation development so that, by the time a regulation goes into effect, validated methods have been used to test it, refine it, and generate data that show that its health-promoting effects are maximized and unintended consequences are minimized.