Center for the Study of Tobacco Products

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Overall Center 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 its methodological and ECIG expertise to pivot from product evaluation to an integrative theme of impact analysis. FDA tobacco regulation must protect public health, though regulations may also have unintended consequences that cause harm. For example, limiting ECIG liquid nicotine content, as in the European Union, can drive use of higher power ECIGs that aerosolize more liquid, leading users to inhale more nicotine and other toxicants. Other potential ECIG regulations involve constraining amount of nicotine emitted/unit time (nicotine "flux") that may influence product toxicity and abuse liability, or reducing flavor availability that may lead users to mix their own flavored liquids. If FDA could predict a potential regulation's effects, then refinements before the regulation is issued might maximize its health-promoting effects and minimize unintended consequences. Methods exist for assessing a regulation's effects once it is in place, but few data-driven models predict impact beforehand. Any such model must draw from several domains to assess how a potential regulation might change product toxicity, user behavior, and addiction/abuse liability. Also, the model must demonstrate the extent to which predictions about potential regulatory effects describe actual population-level outcomes. CSTP addresses this issue with this application: Projects 1-3 will test hypotheses and generate predictions regarding the impact of three potential ECIG regulations (i.e., limit nicotine, constrain flux, reduce flavor availability); Project 4 will test these predictions at the population level. CSTP's vision is to provide tools to guide regulation development so that, by the time a regulation goes into effect, validated methods have tested it, refined it, and generated data showing that its health-promoting effects are maximized and unintended consequences minimized. The team (Drs. Eissenberg, Breland, Shihadeh, Cobb, Barnes, Cohen, Fagan) will complete 4 integrated projects that aim to: predict product toxicity, predict user behavior, predict abuse liability, and assess potential regulation impact. A Contextual Knowledge Core uses mixed methods to ensure Projects 1-4 reflect the real world. A Career Enhancement Core conducts a tobacco regulatory science course, supports pre- and postdoctoral appointees, and pilot projects. An Administrative Core supports financial/managerial processes, biostatistical needs, receives input from an External Advisory Board, and interfaces with FDA, NIH, and others. Overall, CSTP's integrative theme of impact analysis draws on the team's expertise in tobacco product toxicity, user behavior, and abuse liability. We seek to provide FDA with hypothesis-driven data regarding advanced generation ECIGs and test predictions about some potential regulations now, while developing a model that can be used to shape, refine, and predict the effects of many potential regulatory actions in the future.