

Abstract: Center for the Study of Tobacco Products
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The U.S. 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, which demands an understanding of MRTP constituents using analytic lab methods, toxicant exposure and abuse liability using human lab methods, longer-term effects using randomized control trial (RCT) methods, and attitudes, beliefs, and perceived effects using quantitative and qualitative methods. The overarching goal of the Center for the Study of Tobacco Products is to demonstrate empirically an integrated, iterative MRTP evaluation model that uses all of these methods to inform tobacco product regulation across all product types (combustible, oral, or vapor). The Center unites NIH-funded scientist/educators from multiple disciplines to demonstrate the transdisciplinary MRTP evaluation model. We begin with an evaluation of "electronic cigarettes" (ECigs), novel tobacco products that are marketed now and increasingly popular. ECigs offer an opportunity to demonstrate how the model we propose can inform regulatory policy. To meet the Center's overarching goal we describe four integrated, multi-year projects that aim to: 1) Examine factors that influence MRTP nicotine and toxicant yield; 2) Compare short-term effects of MRTPs to other products in the human lab; 3) Characterize effects of real-world MRTP use in the natural environment using RCT methods; and 4) Study the influence MRTP use and misuse on user attitudes, beliefs, and perceived effects using qualitative and quantitative methods. An Administrative Core will facilitate financial and managerial processes, provide data management and biostatistical support, co-ordinate communication within and across centers, and interface with scientists and policymakers. A Training and Education Core will develop a course on transdisciplinary methods for evaluating products and will support up to 4 pre-doctoral and 4 postdoctoral appointees. Finally, a pilot research program will solicit and fund innovative projects from our Virginia-wide network of scientists and respond to emerging products of any type. The Center is thus structured to address FDA needs and operate collaboratively. Overall, this Center will provide the expertise, innovation, infrastructure, and information necessary for the sustained success of FDA's mandate to regulate novel tobacco products, including MRTPs.