WNY Center for Research on Flavored Tobacco Products (CRoFT)

PIs: O'Connor, Richard J. and Goniewicz, Maciej L.
Institution: Roswell Park Comprehensive Cancer Center
1 U54 CA228110-01

Overall Center Abstract:
Flavors increasingly drive the use of emerging tobacco products (cigarillos, waterpipe, electronic nicotine delivery systems (ENDS)). Effective regulation of these products requires comprehensive examination of flavors and flavorings, for which the toxicological, health, and behavioral implications are poorly understood. Many tobacco flavoring ingredients labeled 'Generally Recognized as Safe (GRAS)' were intended for foods but have not been evaluated for inhalation toxicity. Flavors appear to play an important role in attracting users to these emerging tobacco products. FDA's scope of regulatory authority allows it to address flavored tobacco products in a number of ways, ranging from packaging and labeling rules, to restricting the use of specific flavorings via product standards, and as far as banning characterizing flavors in tobacco products. Data are needed to understand how consumers perceive and use flavored tobacco products and whether these have implications for health. We propose a **Center for Research on Flavored Tobacco Products (CRoFT),** the goal of which is to develop a novel framework and approaches for assessing the impact of tobacco product flavors and flavorings on consumer behavior, exposures, and health. Overall, the projects will generate findings to inform regulatory science in four areas of relevance to FDA: **Toxicity, Behavior, Health Effects,** and **Communications**. Our team is drawn together by a common interest in the impact of flavors in tobacco on health of individuals and the population as a whole. Project 1 will apply state-of-the art methods to assess the chronic toxicity of specific flavorings used in tobacco products using chemical reactivity, *in vitro* models, and *in vivo* research studies. Project 2 will apply consumer sensory and behavioral laboratory approaches to examine the behavioral impacts of flavors, including sensory thresholds for single and combinations of flavorings, and the impact of flavoring concentration on use patterns (topography, inhalation). Project 3 will apply longitudinal cohort and product-switching designs to examine the chronic respiratory health effects of flavorings in tobacco products among current users. Project 4 will apply qualitative, quantitative, and experimental approaches to examine the effects of information on flavor choice and flavored product use. Our ultimate goal is to develop a framework for integrative data analysis that combines multiple data streams (toxicity, behavior, health effects, communication, product chemistry, biomarkers) to estimate a flavor risk profile. Three center-named cores (Product Analysis; Biomarkers, Genomics, and Epigenomics; Biostatistics and Informatics), along with the required Administrative and Career Enhancement cores, support these projects. The focus on flavor positions our center to address a topic relevant across product types, and to be nimble in expanding the methodologies to new products. In developing CRoFT, we considered multiple approaches to ensure the proposed comprehensive suite of studies best addresses FDA's regulatory science needs by *focusing on a critical attribute that is amenable to regulation and applicable across different tobacco product classes*.