Abstract:

The proposed administrative supplement is responsive to PA-14-320, “Administrative Supplements for Tobacco Regulatory Research on the Role and Impact of Flavors in Cigarettes, Cigars, E-Cigarettes and Smokeless Tobacco.” Maternal cigarette use during pregnancy is an enormous public health problem. Despite pervasive medical and social sanctions, 11-30% of pregnant mothers continue to smoke leading to greater than one in ten infants born exposed. The parent grant (R01 DA036999, 2013-2018) for the proposed supplement is an intensive prospective study of pregnant smokers and non-smokers designed to investigate novel biobehavioral markers of risk in the fetus. The parent grant offers a unique opportunity to investigate perceptions and use of flavors and flavored products in pregnant smokers and non-smokers. Section 907 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA; Public Law 111-31) banned characterizing flavors, except menthol and tobacco, from cigarettes and cigarette components. Scientific data is needed to inform the FDA regarding the impact of menthol and numerous emerging flavors on perceptions and use of cigarettes, cigars, e-cigarettes, and smokeless tobacco. The impact of flavors on perceptions and use of tobacco products is especially salient during pregnancy due to impact of maternal use on both mother and fetus and potential for fetal toxicity from flavors. Further, pregnant mothers may be particularly vulnerable to the appeal of flavorings due to alterations in taste, cravings, and nausea during pregnancy and variable patterning of tobacco use over gestation. Novel preliminary data from our group shows high rates of menthol cigarette use (85-89%) in two samples of pregnant smokers and increasing rates of non-cigarette tobacco use in pregnant mothers from 2012-2014. Our preliminary data highlights the need to further understand perceptions and use of flavored cigarettes, cigars, e-cigs, and smokeless tobacco in pregnant smokers and non-smokers. Capitalizing on participants, measures, and infrastructure from the parent grant, 50 pregnant smokers and non-smokers will be recruited for the proposed supplement. Participants will complete detailed interviews and self-report measures regarding perceptions and use of flavors/flavored products. Aims focus on: 1) the impact of flavors/sweetness on perceptions and attractiveness of tobacco products in pregnant smokers and non-smokers, and 2) the impact of perceptions of flavors/ sweetness on use of flavored tobacco products in pregnant smokers and non-smokers. Aims fit Topic 3 from the FDA Center for Tobacco Products focused on the impact of flavors and sweetness on use behaviors, (d) perception and attractiveness among users and nonusers. The proposed supplement will significantly increase the sustained impact of the parent grant on the field and will provide critical information to the FDA to inform the marketing and distribution of flavored tobacco products for reproductive age women in order to protect public health.