Vermont Center on Tobacco Regulatory Science
Low Nicotine Content Cigarettes in Vulnerable Populations: Childbearing Age Women (Project 1)
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Abstract:

Approximately 23% of U.S. women of childbearing age are regular cigarette smokers, with prevalence being considerably higher among socioeconomically disadvantaged women. Indeed, disadvantaged women are at increased risk for smoking, nicotine dependence, using high nicotine yield cigarettes, and, perhaps most importantly, for smoking during pregnancy. Not surprisingly, disadvantaged female smokers are also at significantly increased risk for smoking-related adverse health consequences, including cervical cancer, thrombosis related to hormone-based contraception, infertility, and early menopause. Specific to smoking during pregnancy, disadvantaged women are at substantially increased risk for catastrophic pregnancy complications, fetal growth restriction, and adverse birth and neonatal outcomes. Studies testing an innovative regulatory strategy of reducing the nicotine content of cigarettes to a non-addictive level (i.e., < 0.2 mg nicotine) have shown promising beneficial effects (decreased smoking rate, reduced toxicant exposure, and increased cessation) in the general population of smokers. However, these studies have uniformly excluded vulnerable populations, especially pregnant women, who may respond differently considering their greater vulnerability to smoking and nicotine dependence. Thus, little is known scientifically about how this highly vulnerable subgroup of smokers might respond to a nicotine reduction policy. This project is designed to address that substantial knowledge gap. In Study 1, we will assess the effects of brief exposure to cigarettes of varying nicotine yield (0.83, 0.28, 0.10, 0.03 mg in non-pregnant women; usual brand, 0.10, 0.03 in pregnant women) on craving, nicotine withdrawal, and the degree to which the reduced nicotine cigarettes substitute for typical-nicotine cigarettes in behavioral-economic tests of smoking preference. In Study 2, following a baseline assessment period, non-pregnant and pregnant smokers will be randomized to smoke one of the above doses during an extended exposure phase (12 weeks in nonpregnant women; through delivery in pregnant women). Over the baseline and extended-exposure phases, patterns of tobacco use, biomarkers of toxicant exposure and thrombotic risk, neurocognitive functioning, and sonographic estimates of fetal growth and birth outcomes (pregnant women only) will be examined. Overall, the proposed project will provide a rigorous experimental analysis of the effects of brief and extended exposure to very low nicotine cigarettes in disadvantaged pregnant and non-pregnant women, which should provide critically important new information to the FDA on this vulnerable group of smokers.