

University of Vermont Tobacco Center of Regulatory Science

Institution: University of Vermont

2 U54 DA036114-06

Project 4: Low Nicotine Content Cigarettes in Vulnerable Populations: Pregnant Women

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Project 4 Abstract:

Cigarette smoking during pregnancy continues to represent a serious public health problem. Approximately 11% of U.S. women (~17 million women) are smokers when they become pregnant, with prevalence as high as 40% among socioeconomically disadvantaged women. Smoking during pregnancy can cause catastrophic pregnancy complications and adverse effects on fetal development that a growing body of evidence suggests can compromise health throughout the lifespan. A national policy of reducing the nicotine content of cigarettes has the potential to be an effective method of reducing the prevalence of cigarette smoking and smoking related adverse health outcomes in this highly vulnerable population. Controlled trials in the general population of smokers, for example, have demonstrated that reduced nicotine content cigarettes decrease cigarette smoking rates, dependence, and toxin exposure levels. Furthermore, our research during the current funding period indicates that socioeconomically disadvantaged non-pregnant women, and other groups vulnerable to persistent tobacco use (smokers with opioid use disorders or affective disorders), also respond to reduced nicotine content of cigarettes with reductions in cigarette demand and other measures of addiction potential. Importantly, there is no evidence of untoward nicotine withdrawal or compensatory smoking associated with use of reduced nicotine content cigarettes in these populations, which is important when considering their use among pregnant women. We know of no empirical information in the literature on the effects of reduced nicotine content cigarettes in pregnant women, although they would be expected to reap the same benefits as non-pregnant women with regard to reduced smoking rates and lower dependence severity, along with additional potential benefits to the fetus from reduced nicotine exposure. For those reasons, we are currently conducting a multi-site study examining acute effects of reduced nicotine content cigarettes on the addiction potential of smoking in pregnant women using a protocol similar to the one we used with the non-pregnant women. The proposed multi-site trial will further this important line of research by examining extended exposure. Pregnant smokers will be randomized to smoke either usual brand cigarettes or very low nicotine content cigarettes (0.4 mg nicotine/g tobacco) for 12 weeks. Patterns of cigarette and other tobacco use, cigarette demand, dependence, biomarkers of toxicant exposure, and sonographic assessments of fetal growth and body composition will be examined. Overall, the proposed research aligns well with CTP's interest in supporting research under the integrative theme of **Vulnerable Populations** and the scientific domains of **Addiction** and **Behavior**, as well as **Health Effects**. The research is **significant** and **innovative** by attempting to model how a national policy of reduced nicotine standards in cigarettes may impact a highly vulnerable population of smokers, and **programmatic** by building incrementally towards a comprehensive assessment of the effects of acute and extended exposure to reduced nicotine content cigarettes in pregnant women.