

## Evaluating Concomitant Use of Very Low Nicotine Content Cigarettes and E-Cigarettes among Daily and Non-Daily Smokers on Abuse Liability

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### Abstract:

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) provides the FDA with authority to limit the nicotine content of cigarettes, which could reduce cigarette reinforcement and lead to less nicotine addiction and exposure to harmful toxicants associated with tobacco combustion. Recently, the FDA announced its intention to regulate the e-cigarettes (e-cig). We have very little information on how such changes in the tobacco market place, specifically e-cigarettes, will affect nicotine abuse liability. The objective of this study is to model abuse liability in a market in which the level of nicotine in combustible cigarettes has been lowered to meet a potential regulatory standard, but one in which an alternate source of nicotine in e-cigs is also available. Aims 1 and 2 will characterize the effects of dual use of VLNCC and ECIG on abuse liability (nicotine compensation and product use, liking, and RRE) among daily (DS) and intermittent (ITS) smokers, respectively. Aim 3 will characterize the effects of dual product use on abuse liability, as measured by retrospective measures, smartphone daily diary, and real-time measures captured using smartphone EMA. Participants will be 80 daily (DS) and 80 intermittent (ITS) non-treatment-seeking adult smokers who are not regular e-cig users. Participants will smoke their usual brand (UB) during Phase 1 (Baseline; week 1) and will exclusively smoke the VLNCC during Phase 2 (weeks 2-4). During phases 3 (weeks 5-7) & 4 (weeks 8-10), smokers will be instructed to freely use any combination of assigned VLNCC and e-cigs (VLNCC+ECIG). All subjects will receive both e-cig doses (ECIG-Hi (36 mg/ml) and ECIG-Lo (8 mg/ml)) with order counter balanced across phases 3 and 4. The significance of this proposal is that it will provide the FDA with critical information about the effects of dual use of very low nicotine content cigarettes (VLNCC) and e-cigs with differing levels of nicotine on nicotine abuse liability, as measured by nicotine compensation, product use and liking, relative reinforcing efficacy (RRE), and multi-modal assessments of withdrawal, craving, affect and satisfaction, among both daily (DS) and intermittent (ITS) smokers in the lab and in their natural environment. The coexistence of these products raises questions about whether the potential public health benefit of VLNCC at reducing nicotine abuse liability might be offset by the concurrent use of e-cigs. The positive impact of this study will be to provide scientific information on the nicotine abuse liability impact of reducing nicotine in combustible cigarettes to a non-reinforcing level within a dual product use environment, which can be used to inform tobacco regulatory strategies designed to promote the public health. The innovativeness of this study is our focus on the nicotine abuse liability of dual use by both DS and ITS, and our use of a multimodal approach to the measurement of abuse liability constructs, including the use of EMA, given that little is known about the effects of dual use on these abuse liability constructs in the natural environment. The value-added feature of this study is that it complements and extends findings from existing TCORS involving VLNC and e-cigarettes.