

Tobacco Regulatory Science Investigating the Intersections of Products with Diverse Populations

Institution: University of Southern California

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Project 4: Human Laboratory Research to Inform Precision Regulation of E-Cigarettes Across Populations

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Project 4 Abstract:

E-cigarettes pose a regulatory challenge because they may adversely impact the health of some populations (e.g., young never-smokers), but reduce health risk in others (e.g., middle-aged/older smokers who switch to e-cigarettes). P4 aims to provide FDA with evidence to inform regulatory restrictions of dimensions of e-cigarette product diversity that put young adult never-smokers at risk of using e-cigarettes, yet does not deter middle/older adult smokers from adopting and potentially switching to e-cigarettes. P4 will test the hypotheses regarding how product diversity impacts the user experience—a key channel of exposure: a) Young never-smokers may prefer e-liquids with sweet flavorings due to age-related taste preferences and menthol flavors that mask the bitterness of nicotine; yet, middle-age/adult smokers may be more accustomed to tobacco flavorings, b) E-liquid labels with cartoon images and youth-oriented product names (e.g., ‘Killer Kustard’) may appeal more to young (vs. middle-age/older) adults. c) Low propylene glycol (PG)/vegetable glycerin (VG) ratio in e-liquids produces thick ‘vapor clouds’ and a weak throat hit, which may appeal to young adults, but middle-age/older adult smokers may prefer vapor that resembles cigarette smoke. Method: Drawing from the USC-TCORS cohort and Population Core resources, P4 will compare never-smoking young adult e-cigarette users to middle-age/older adult smokers with an interest in, but no significant experience with, e-cigarettes. In two studies, subjects will self-administer e-cigarette products systematically varied according to Flavor (sweet vs. menthol vs. tobacco) × PG/VG ratio (20:80 vs. 40:60 vs. 60:40 vs. 80:20) × Packaging (e-liquid characterizing flavor label [e.g., “peach”] vs. youth-oriented non-characterizing flavor [e.g., “gummy heaven”] vs. non-characterizing flavor + cartoon) design. The Aim 1 study will test product exposure effects on subjective ratings of appeal (e.g., liking, desire to use again). The Aim 2 study will test product exposure effects on choice to use (vs. earn money): a) The previously-exposed e-cigarette product (an abuse liability test; never-smoking young adults only), or b) Own brand cigarettes (test of ability to resist smoking; middle-age/older adult smokers only). Aim 1. Determine which dimensions of e-cigarette product diversity differentially affect appeal across never-smoking young adult e-cigarette users (N=200) and middle-age/older smokers (N=200). Aim 2. Determine which dimensions of e-cigarette product diversity differentially affect abuse liability in never-smoking young adult e-cigarette users (N=360) and ability to resist smoking in middle-age/older adult smokers (N=360). Integration with “Intersections of Products with Populations” theme: P4 will study dimensions of e-cigarette product diversity common to those studied in other USC-TCORS projects using a unique controlled experimental paradigm to inform causal mechanisms. P4 has a secondary aim (Aim 3) that will determine how population diversity in sex alters the appeal and abuse liability of e-cigarette products.