

Does Real World Exposure to FDA Graphic Warnings Affect Tobacco Use Behavior?  
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Abstract:

The 2009 Tobacco Control Act gave the Food and Drug Administration (FDA) regulatory authority over tobacco products. One of the first actions of the FDA, under this law, was to develop graphic warnings to appear on cigarette packaging. Tobacco companies challenged the new warnings as a violation of their first amendment rights, and the court ruled for tobacco in *R.J. Reynolds v. FDA*. The ruling found that available research did not show that graphic warnings placed on cigarette packs were associated with changes in tobacco use behavior. This is because, in part, experimental research to date has relied on onetime exposure to graphic labels, and these paradigms are too brief to measure change in tobacco use behavior. This application develops and tests an experimental approach that simulates real-world and prolonged exposure to FDA graphic warnings. In collaboration with a large community-based behavioral health provider, smokers are recruited from three residential addiction treatment programs. Key features of residential treatment are: a concentration of smokers, daily patient contact in which experimental labels can be affixed to the patient's own cigarette packs, ability to observe changes in smoking behavior. The project creates the 9 approved FDA warnings using adherence paper and measures behavioral and communication impacts associated with prolonged exposure to the warnings. The design is a sequence of off-on-off-on recruitment periods, each lasting 4 months, during which participants are either exposed to transparent labels (attention control condition) or to graphic warnings (experimental condition) on their own cigarette packs. 450 smokers will be enrolled, evenly distributed across conditions. For each participant there is a baseline interview, a 30 day exposure period (to transparent or graphic labels) and a follow up interview. Behavioral measures include intent to quit, quit attempts, cigarettes per day, and initiation of cessation services. Communication measures include tobacco risk perception, impacts of cigarette pack warnings, and thoughts about abstinence. The general hypothesis is that persons exposed to graphic labels, compared to those in an attention control condition, are more likely to change smoking behavior. The short term goal is to test an original experimental approach that will improve understanding of how graphic labels affect smoking-related behavior. The long term goal is to provide scientific information in support of the FDA regulatory mission.