

Center for Tobacco Products, Food and Drug Administration
Research Priorities
January 2012

The Family Smoking Prevention and Tobacco Control Act (TCA) gives the Food and Drug Administration (FDA) broad authority to regulate tobacco product manufacturing, distribution and marketing. Although a vast and sound science base exists with regard to numerous areas of the TCA, new research will provide scientific evidence in several areas. Research areas include (1) understanding the diversity of tobacco products, (2) reducing addiction to tobacco products, (3) reducing toxicity and carcinogenicity of tobacco products and smoke, (4) understanding the adverse health consequences of tobacco use, (5) understanding communications about tobacco products, (6) understanding tobacco product marketing, and (7) understanding how economics and policies affect tobacco product use. Vulnerable populations referenced in research questions include, but are not limited to age, gender, race, ethnicity, income, occupation, geographic location, people with mental health or medical co-morbidities, the military/veterans, the lesbian, gay, bi-sexual, transgendered, questioning (LGBTQ) community, and pregnant women/women of reproductive age.

Understanding the Diversity of Tobacco Products

1. What are the constituents, components, and design features of new and emerging tobacco products (e.g., dissolvable tobacco products, e-cigarettes, hookah tobacco); and how do these features differ within the same class of products?
2. How do components and design features of new and emerging tobacco products affect the bioavailability of nicotine, other addictive substances, and harmful tobacco constituents?
3. What are the tobacco use behaviors of individuals using new and emerging tobacco products, including the multiple tobacco use behaviors?
4. What are the cognitive and affective factors (e.g., perceptions, attitudes, beliefs) associated with use of new and emerging tobacco products; how does product labeling and marketing influence behaviors related to tobacco product use?
5. What biomarkers of exposure should be used to measure exposure to new and emerging tobacco products?
6. What are the cognitive and affective factors (e.g., perceptions, attitudes, beliefs) influencing use of potential modified-risk tobacco products; how does labeling and marketing to different subpopulations; such as current smokers, former tobacco users, and youth influence behaviors related to modified risk tobacco products?
7. What are the factors, including menthol and other flavorings that influence the appeal of tobacco products to both users and non-users, including youth and other vulnerable populations? What is the impact of these factors on experimentation, initiation, cessation, switching tobacco products, and multiple use?

8. What are individual cognitive and affective factors (e.g., perceptions, attitudes, beliefs) associated with use of smokeless tobacco products; how does product labeling and marketing influence behaviors related to use of tobacco products?
9. What are individual cognitive and affective factors (e.g., perceptions, attitudes, beliefs) associated with use of little cigars; how does product labeling and marketing influence behaviors related to use of little cigars? How do cognitive and affective factors differ among those who smoke little cigars compared to cigarettes?
10. What impact does potential modified-risk tobacco product claims on labels and in advertising have on tobacco use, initiation and relapse? How do modified risk claims affect perceptions, attitudes, beliefs and behaviors of consumers, including those in specific populations, such as non-smokers, new users, current smokers, and former smokers; and youth and other vulnerable populations?
11. At what level do changes to constituent exposure, as well as tobacco product components and design features affect consumer perceptions of the product?

Reducing Addiction to Tobacco Products

12. Beyond nicotine, what other constituents, components and design features of tobacco products, enhance the addictive properties?
13. What is the potential impact of modifying nicotine levels and other addictive substances in tobacco on the prevalence of tobacco use, including rates of initiation, progression to dependence, and cessation, as well as patterns of switching of products and use of multiple tobacco products?
14. How do reductions of nicotine in tobacco products affect consumer perceptions of their ability to quit tobacco product use? How do these perceptions influence product initiation, relapse, and cessation?
15. What high-throughput screens can be developed and/or used to evaluate compounds in tobacco products and smoke that may affect addiction (e.g., act on nicotinic or dopaminergic receptors, impact release and/or removal of nicotine or dopamine, etc.)?
16. How does genetic variation in sensitivity to flavorings and taste influence tobacco addiction?
17. What level of nicotine and other addictive substances in tobacco is associated with progression to dependence among cigar smokers, including users of little and large cigars and cigarillos?
18. What level of nicotine and other addictive substances in tobacco is associated with progression to dependence among smokeless tobacco smokers, including users of chewing tobacco, snuff, snus, and dissolvable tobacco products?
19. In animal models of dependence, what are the appropriate dosing and administration procedures for evaluating smokeless tobacco products?

Reducing toxicity and carcinogenicity of tobacco products and smoke

20. How may reductions in the toxicity of tobacco products affect consumer perceptions of the risks and harms related to tobacco product use? How may these perceptions influence product initiation, relapse, and cessation?
21. What methods and measures best assess biologically relevant changes in harmful and potentially harmful constituents in tobacco products and smoke in both nonclinical models and humans?
22. What *in vitro* and *in vivo* assays are capable of comparative toxicity between two different tobacco products; with special attention to cardiotoxicity, respiratory toxicity, carcinogenicity, and developmental/reproductive toxicity?
23. What constituents, compounds, design features, and tobacco use behaviors impact toxicity and carcinogenicity of tobacco products and smoke?
24. How should the impact of reduced levels of harmful and potentially harmful constituents of tobacco products on toxicity and carcinogenicity be measured?
25. What level of reduction in harmful and potentially harmful constituents results in decreased disease risk?
26. In animal models, what smoke inhalation methods best mimic human exposure?
27. How does reduced toxicity/carcinogenicity in tobacco products affect consumer perceptions of risk/harm and influence behaviors?

Understanding Adverse Health Consequences of Tobacco Use

28. What are the biomarkers of disease (e.g., cancer, cardiovascular disease, pulmonary disease, reproductive and developmental effects), that can be associated with specific measures of tobacco exposure?
29. What magnitude of changes in biomarkers translates into clinically meaningful impacts on human health outcomes?
30. What novel biological and physiological markers (including genetic and epigenetic markers) are predictive of smoking-related and smokeless tobacco-related adverse health outcomes?
31. What animal models can be validated to establish standard toxicity changes and what magnitude observed within *in vivo* assays would correlate with changes in human health outcomes?
32. What are predictive models for adverse health impacts of tobacco products other than cigarettes on vulnerable populations?
33. What are the health risks of use of multiple tobacco product types, and how do these risks compare with single tobacco product use?

34. What is the potential impact on public health of potential modified-risk tobacco products, decreasing nicotine and other addictive substances and reducing harmful and potentially harmful constituents in tobacco products?

Understanding Communications about Tobacco Products

35. What are the most effective messages regarding FDA's regulatory authority over tobacco products and what are the best communication avenues to convey those messages to the public?
36. What factors influence the public perception of FDA as a credible source of information related to tobacco products?
37. How should information regarding tobacco products and tobacco use, including risk, harmful and potentially harmful constituents, new and emerging tobacco products, and potential modified-risk tobacco products be conveyed to the public so that it is understandable and not misleading?
38. What is the impact of health warnings on quit attempts and cessation among vulnerable populations?
39. What is the nature and extent of tobacco product discussions and communications in non-traditional venues such as social networking sites, online videos, blogs, and smartphone applications; do certain subpopulations engage in certain types of non-traditional communication venues involving tobacco products? How do these modes of communication impact tobacco use?
40. What communication channels do vulnerable populations use to seek information and communicate about tobacco and health issues?
41. What is the impact of various factors such as, font size, placement, attribution, text, context, image type, etc., on warning effectiveness including consumer risk perception and tobacco use behavior among youth, young adults, adults and vulnerable populations?
42. How do tobacco control brands and branding designed to promote health impact tobacco initiation and use, particularly among vulnerable populations; and how can these impacts best be measured?

Understanding Tobacco Product Marketing

43. What is the impact of tobacco industry marketing through social media campaigns and other non-traditional communication strategies on tobacco use behavior among vulnerable populations?
44. What is the impact of tobacco industry marketing of different types of smokeless tobacco products on vulnerable populations, such as youth and women?
45. What is the impact of tobacco industry marketing practices of mentholated cigarettes and other flavored tobacco products, as well as new and emerging tobacco products on tobacco use behavior, particularly among youth and other vulnerable populations?

46. What role do tobacco product advertising displays at the retail point-of-sale (POS) have on youth initiation, usage and cessation? What is the relative impact of various ad features (e.g., size, number, location, color, images, and themes) on tobacco use behaviors?
47. What is the impact of tobacco advertising around schools, parks and playgrounds on youth attitudes, beliefs, perceptions, and tobacco use?
48. How do factors related to the packaging, labeling, and advertising of tobacco products, (e.g., colors, descriptors, market claims, branding) influence consumer perceptions about the risks of tobacco products and product use?
49. What is the impact of price promotions (including free samples and discounted products) on consumer behavior for various tobacco products, including the impact on non-users starting to use, and on individuals in various stages of quitting or contemplating quitting?

Understanding Economics and Policies on Tobacco Use and Perceptions

50. What is the trajectory of youth and/or young adult tobacco use (including use of tobacco products other than cigarettes, multiple use, and switching behavior) and how it changing in response to FDA regulatory actions?
51. Among vulnerable populations, what are the knowledge, attitudes, and beliefs about tobacco products and FDA tobacco product regulatory authority?
52. To what extent do findings from regulatory actions on cigarettes generalize to other tobacco products in altering consumer behavior?
53. How does one measure changes in consumer surplus that result from public education initiatives or marketing restrictions to smokers who intend to quit? For example, how does one measure the potential gains to smokers from point-of-sale restrictions that may enhance self-control and efforts to quit smoking, as well as the potential losses that may be associated with quitting?
54. What is the impact of minimum package size (e.g., 20 little cigars, carton-only sales, 5 non-premium cigars) and maximum purchase amount (e.g., maximum purchase of 1 pack, 2 packs, 1 carton, 5 cartons) on consumer behavior and illicit trade?
55. What are the best methods and models for estimating the magnitude and breadth of illicit trade activities related to tobacco products?
56. What is the impact of state, local, and tribal policies, as well as international policies addressing tobacco product manufacturing, marketing, and distribution that may inform FDA tobacco product regulatory authority?