

FDA Grand Rounds

[fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm486711.htm](https://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm486711.htm)



The FDA Grand Rounds is an educational presentation that is webcast monthly to highlight cutting-edge research underway across the Agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities. The 45-minute educational presentation is followed by questions from the audience. #FDAGrandRounds.

Thursday, October 11, 2018

12:00 p.m. - 1:00 p.m. EST

Presented by

Lynn Hull, PhD

Lead Pharmacologist

Division of Individual Health Science

FDA's Center for Tobacco Products

Webcast Lecture

The Science to Inform a Tobacco Product Standard for the Level of Nicotine in Combusted Cigarettes

About the Presentation

This presentation will give an overview of the systematic literature review that FDA's Center for Tobacco Products has done on the likely effects of reducing nicotine in combusted tobacco, as well as on consumer knowledge, attitudes, perceptions, beliefs, and planned behavior on reduced nicotine tobacco products.

Use of combusted tobacco products like cigarettes, kreteks, bidis, cigarette tobacco, roll-your-own tobacco, cigars, pipe tobacco, and water pipe tobacco causes a heavy burden of death and disease every year. These negative health effects are ultimately the result of users' addiction to the nicotine in tobacco products, which in turn results in their repeated use. This continuously exposes users and non-users (via second- or third-hand smoke) to toxicants in the smoke.

FDA has issued an Advanced Notice of Proposed Rulemaking for a product standard to set a maximum nicotine level in cigarettes. FDA continues to assess the best available science to determine a level at which these products would be minimally addictive and, therefore, appropriate for protecting the public health.

FDA's Center for Tobacco Products has suggested that extended exposure to combusted cigarettes containing tobacco filler in the 0.02 - 0.07 mg nicotine content per cigarette range (i.e., very low nicotine content) could be associated with reduced addiction potential, dependence levels, the number of cigarettes smoked per day, and increased quit rates among current smokers, without evidence of increased toxicant exposure, craving, withdrawal, or compensatory smoking.

The reviewed literature also indicates that, although a substantial portion of adult American consumers understand that nicotine is the addictive chemical in cigarettes, a substantial number of adults also incorrectly believe that nicotine is carcinogenic and a main cause of smoking-related disease. Therefore, increased efforts to communicate the science behind a nicotine product standard will be needed to educate the public before any implementation of a nicotine product standard.

About the Presenter

Dr. Hull, Lead Pharmacologist within FDA's Center for Tobacco Products, joined the Center in 2014 from NIH's National Cancer Institute. Her research interests include the behavioral and clinical pharmacology aspects of tobacco product use and the impact use patterns have on addiction and dependence. Dr. Hull is responsible for the design, implementation, and oversight of contractual clinical and preclinical studies related to evaluating the abuse liability of tobacco products, as well as reviewing tobacco product regulatory submissions.

She is also FDA's Behavioral and Clinical Pharmacology Representative on the Population Assessment of Tobacco and Health (PATH) Study, a national longitudinal study of tobacco use and how it affects the health of people in the United States. She received her Ph.D. in Pharmacology and Toxicology from Virginia Commonwealth University in 2009.

Past Grand Rounds

2018

2017

2016

- **The Host Response to Whooping Cough Infection and Vaccination**
- **Antibiotic resistance surveillance in the age of genomics: New answers to old questions**
- **FDA Research into 3D Printing of its Regulated Products**
- **Rapid Screening of Dietary Supplements for Undeclared Ingredients**
- **Metabolomics and Proteomics Biomarkers: Discovery and Validation in Toxicity Studies**

