

The Potential Impact of Nicotine Reduction

Eric C. Donny, Ph.D.

*Professor, Departments of Physiology and Pharmacology & Social Science
and Health Policy*

Director, Tobacco Control Center of Excellence

Wake Forest School of Medicine

Disclosure

- *This work was supported by the National Institute on Drug Abuse and Food and Drug Administration Center for Tobacco Products (U54 DA031659). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the Food and Drug Administration.*
- *I have received honoraria from the World Health Organization, Food and Drug Administration, Campaign for Tobacco Free Kids, Truth Initiative, and various universities for work on the potential impact of nicotine product standards.*

Family Smoking Prevention and Tobacco Control Act

- 2009 amendment to the Food, Drug and Cosmetic Act
 - Creating new center to regulate tobacco products (CTP)
- Public health standard
 - Must consider the risks and benefits to the population as a whole including users and nonusers
- Section 907 – Product Standards
 - Can limit nicotine
 - Cannot require reducing nicotine to zero

10 years later...



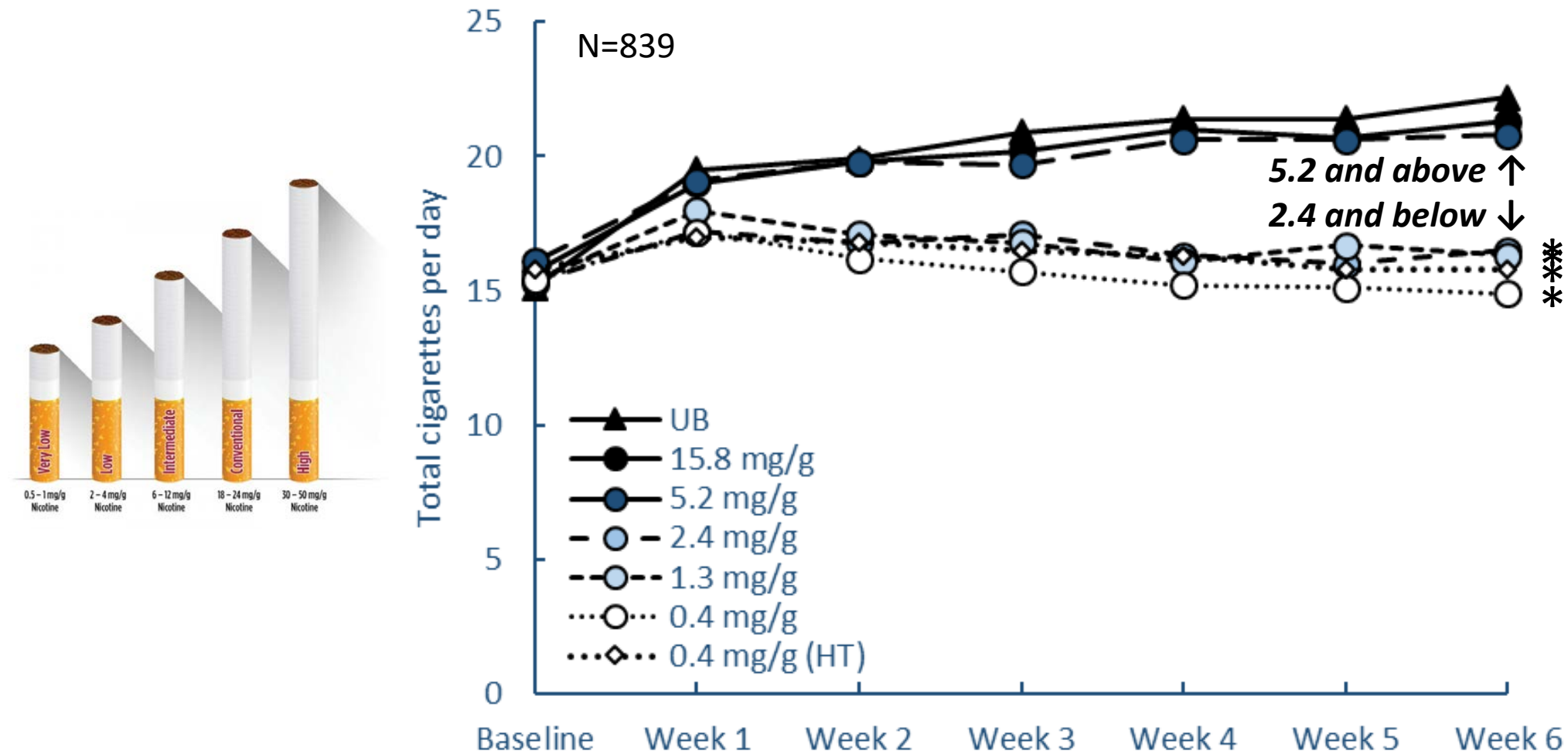


Let's dive in...

Top 6 questions about nicotine reduction

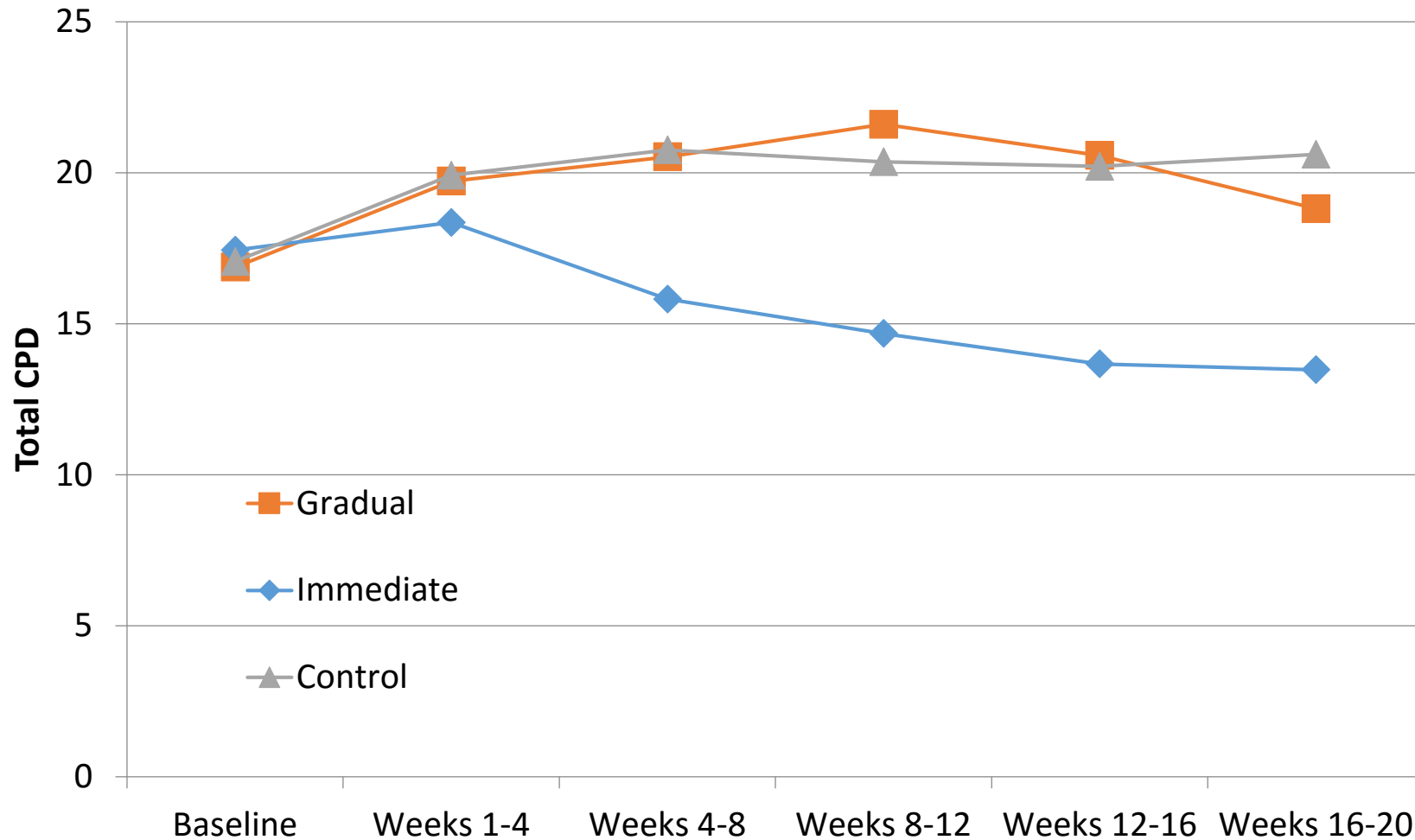
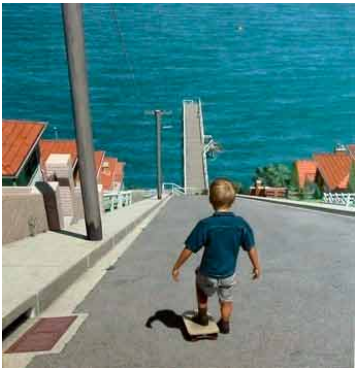
Addressed in 30 seconds each!

How low do you have to go to reduce smoking?

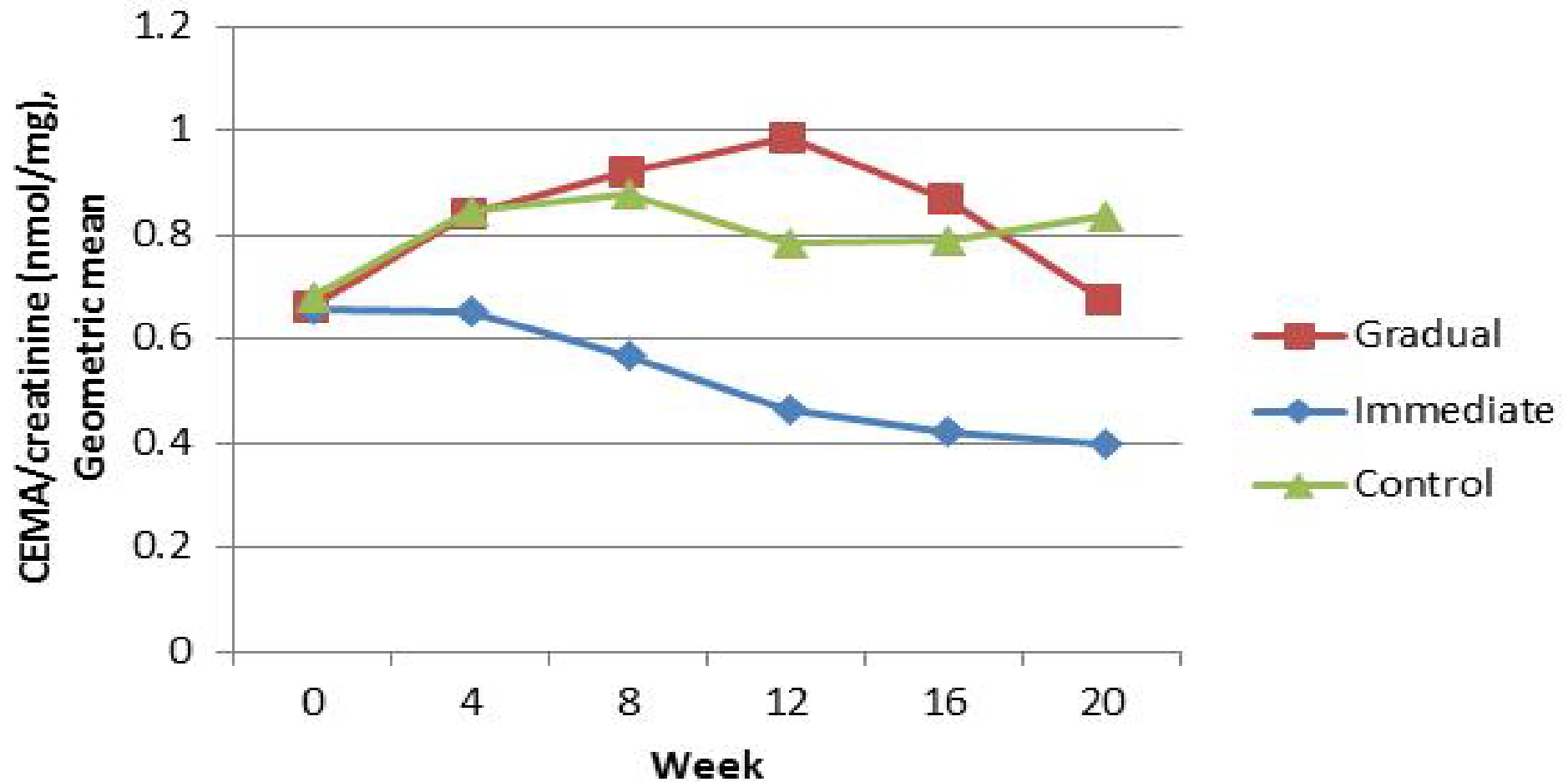


*indicates significant ($p < .0125$) difference compared to 15.8 mg/g (controlling for BL)

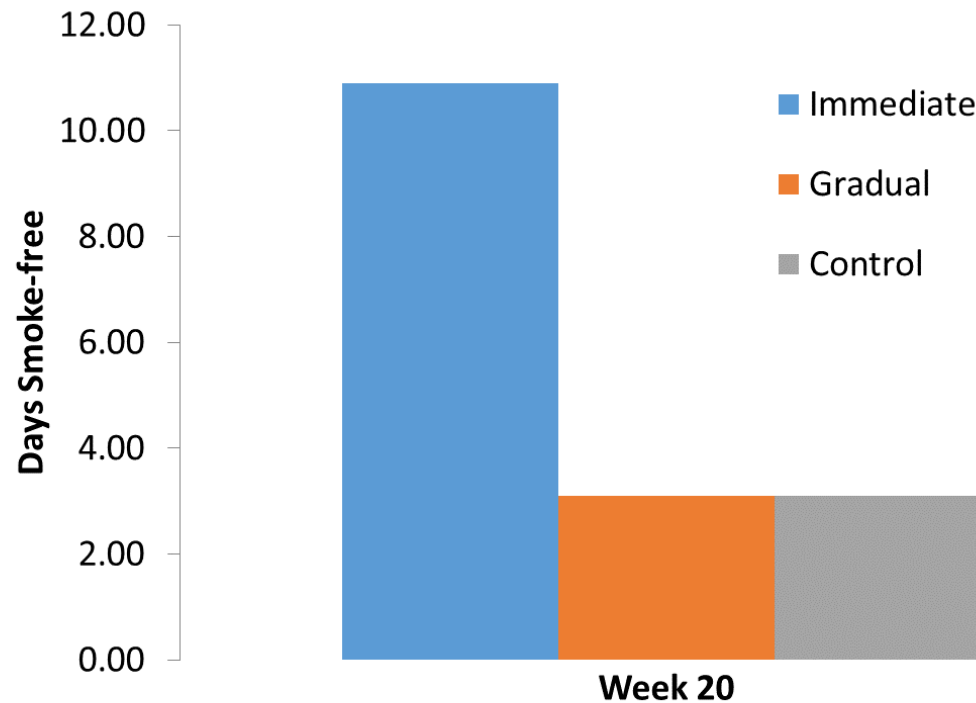
Should FDA reduce nicotine gradually or rapidly?



Could people be exposed to more toxicants because they smoke more intensely?



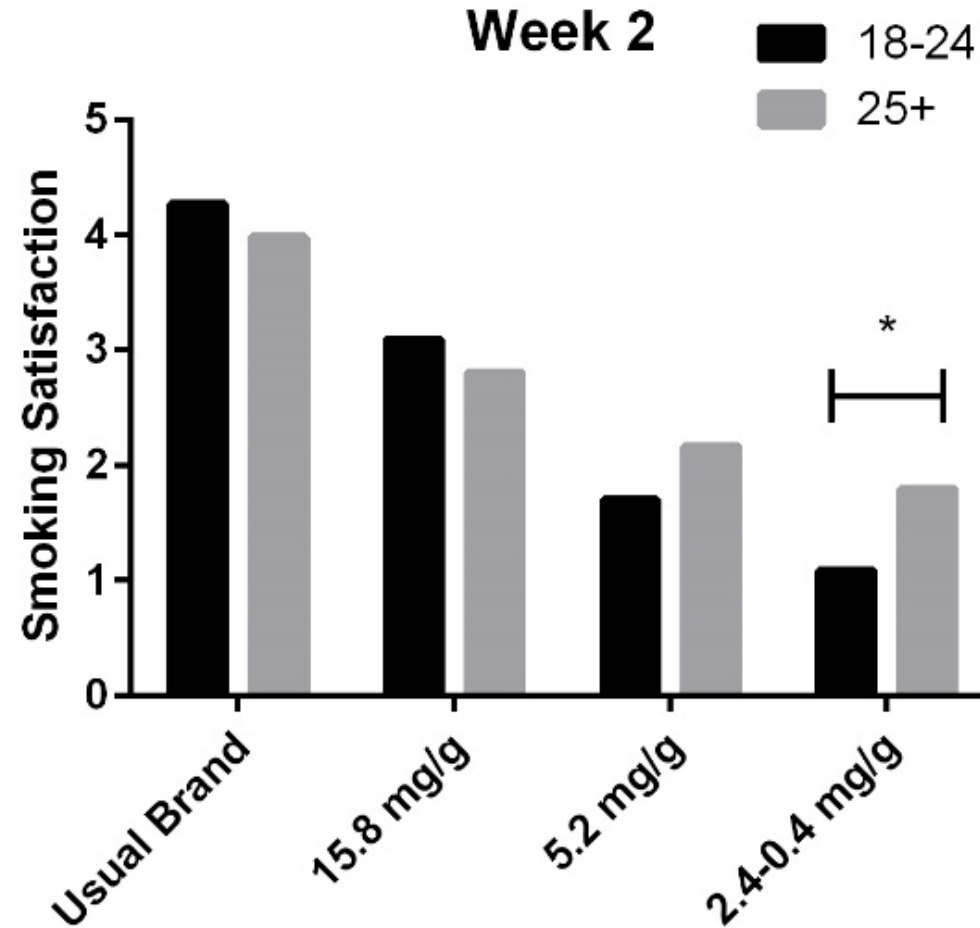
Will it make it easier for smokers to quit?



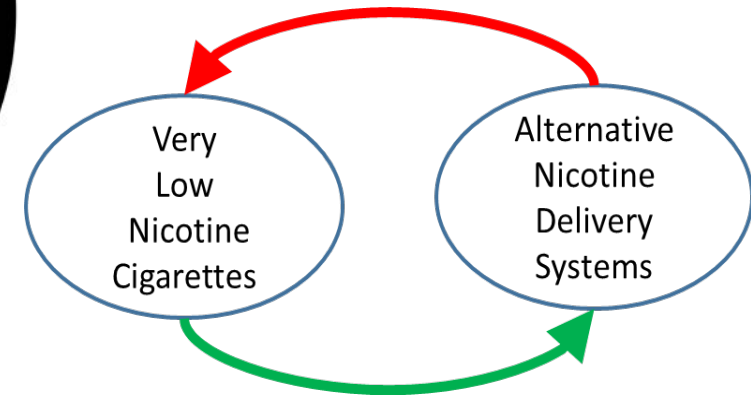
Hatsukami et al. JAMA. 2017

*Immediate
reduction increased
odds of abstinence
at Week 20
(OR: 3.22)*

Will it reduce the likelihood that kids smoke?



Won't this just lead to a massive illicit market?



FDA ANNOUNCES COMPREHENSIVE REGULATORY PLAN

“Addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA’s strategy for addressing the devastating addiction crisis that is threatening American families.”

FDA COMMISSIONER **Scott Gottlieb, M.D.**