

# Global Nicotine Reduction Strategy

## *Personal Insights on the View From FDA and the WHO TobReg Study Group*

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# Disclosures

Through Pinney Associates, I have and/or presently consult to GlaxoSmithKline on smoking cessation, NJOY on electronic cigarettes, Reynolds American Vapor Products, and to pharmaceutical companies on the development and regulation of drugs that pose abuse-related concerns. I share interest in a patent for a new nicotine gum for smoking cessation that is under license to Nicinovum, a smoking cessation product subsidiary of Reynolds American, Inc.

# Nicotine Reduction (NR) in a (small) Nutshell

- Reducing maximum allowable levels of nicotine in cigarettes reduce their risk of leading to or sustaining dependence
- I believe and FDA and WHO agree that the level would be as low as feasible (lower than Benningfield <0.5mg), but not zero
- NR is understood by WHO, FDA, and 2014 US SG Report to be a policy requiring comprehensive enabling conditions that include adequate access to acceptable (and adopted) alternatives (including ENDS) to minimize unintended consequences
- In my opinion, no country is close to meeting enabling conditions and many country's actions (e.g., FDA Deeming Rule) could delay achievement. I believe the US is at 5-10 years from such achievement
- Rapid progress toward enabling conditions and declines in smoking prevalence may also reduce the apparent need and tolerance for NR risks

Benowitz, Donny and Hatsukami, Reduced Nicotine Content Cigarette, E-Cigarettes and the Cigarette End Game (Addiction, October, 2016)

*“The reduced nicotine content cigarette and the emergence of non-combusted nicotine products like e-cigarettes should be viewed not as alternatives but as complementary components of regulatory interventions that could virtually end combusted tobacco use.”*

# 2014 US Surgeon General's Report

- *“The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.”*
- *“Reducing levels of nicotine in cigarettes and other combusted products can lead to the rapid elimination of their use.”*
- *“.....promotion of e-cigarettes and other innovative products is...likely to be beneficial where the appeal, accessibility and use of cigarettes are rapidly reduced.”*

# Plausible FDA Approach: Rule Making Process Requiring Consideration of Stakeholder Comments

- Not required but likely to get early public comment
  - FDA would issue an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register
  - Then, a Notice of Proposed Rulemaking (NPRM)
- Required: Proposed Rule for public comment
- Required: Final Rule – revised considering comments
- Companies comply with Effective Date – or not
- Litigation would be likely with Effective Date delayed
  - If it goes to the Supreme Court the court might send it to congress as it did concerning FDA tobacco regulation? If so then ---
- Congress must work together to pass a bill which must then be signed into law by the President
- Meanwhile FDA's approach to ENDS regulation will either strengthen or weaken the path to implementation
- Precedent (e.g., deeming rule) suggests 5+year for process

# My Opinion on the Status of NR in Near Term

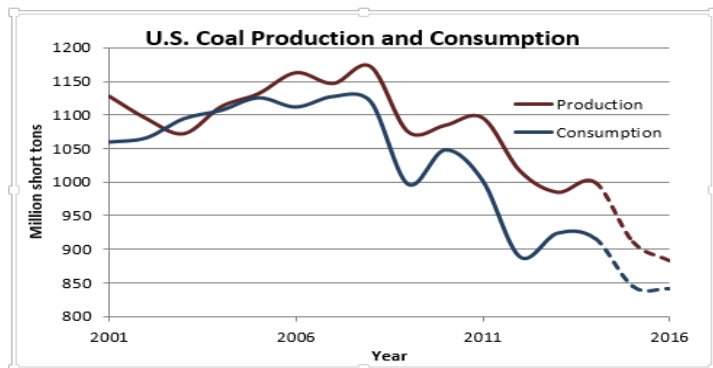
- Despite objections to NR, arguments against bans and prohibitions in general, as well as concerns about unintended consequences, I believe that FDA and WHO will continue to support evaluation and research and that this is a valuable exercise that will serve tobacco control broadly regardless of whether NR is ever implemented.
- It is equally in the interests of proponents and opponents of NR to make every effort to achieve the enabling conditions because these will both increase the viability of NR AND may reduce the strength of arguments for the need for such a policy.

*See discussions in Henningfield, Benowitz, Slade et al, 1998; US Surgeon General's Report, 2014, ch. 15&16; Benowitz and Henningfield, 2013; Benowitz, Donny & Hatsukami, 2016)*

# Coal Supplied Energy: Model for Nicotine Reduction Policy and Alternative Cleaner Nicotine Sources?



Regulation, treaties, tax incentives to consumers and industry, education, etc. are transforming energy supply from most harmful to less harmful. It is working



- Coal fueled energy production is harmful to people and the environment: pressure is increasing reduce or eliminate it
- Banning coal in near term is not feasible in many countries including the US due to dependence on coal-provided energy
- Rapid and substantial progress would make it easier to ban coal but would also lessen the need if levels were low enough that the residual level of overall harm did not justify the unintended consequences of a ban and hurt populations and regions that remain reliant on this form of energy production



With sincere apology  
for not being with you  
at the meeting –  
hopefully next year –  
Thank you very much  
jack

