FDLI – Tobacco Products Regulation and Policy Conference

Joe Murillo
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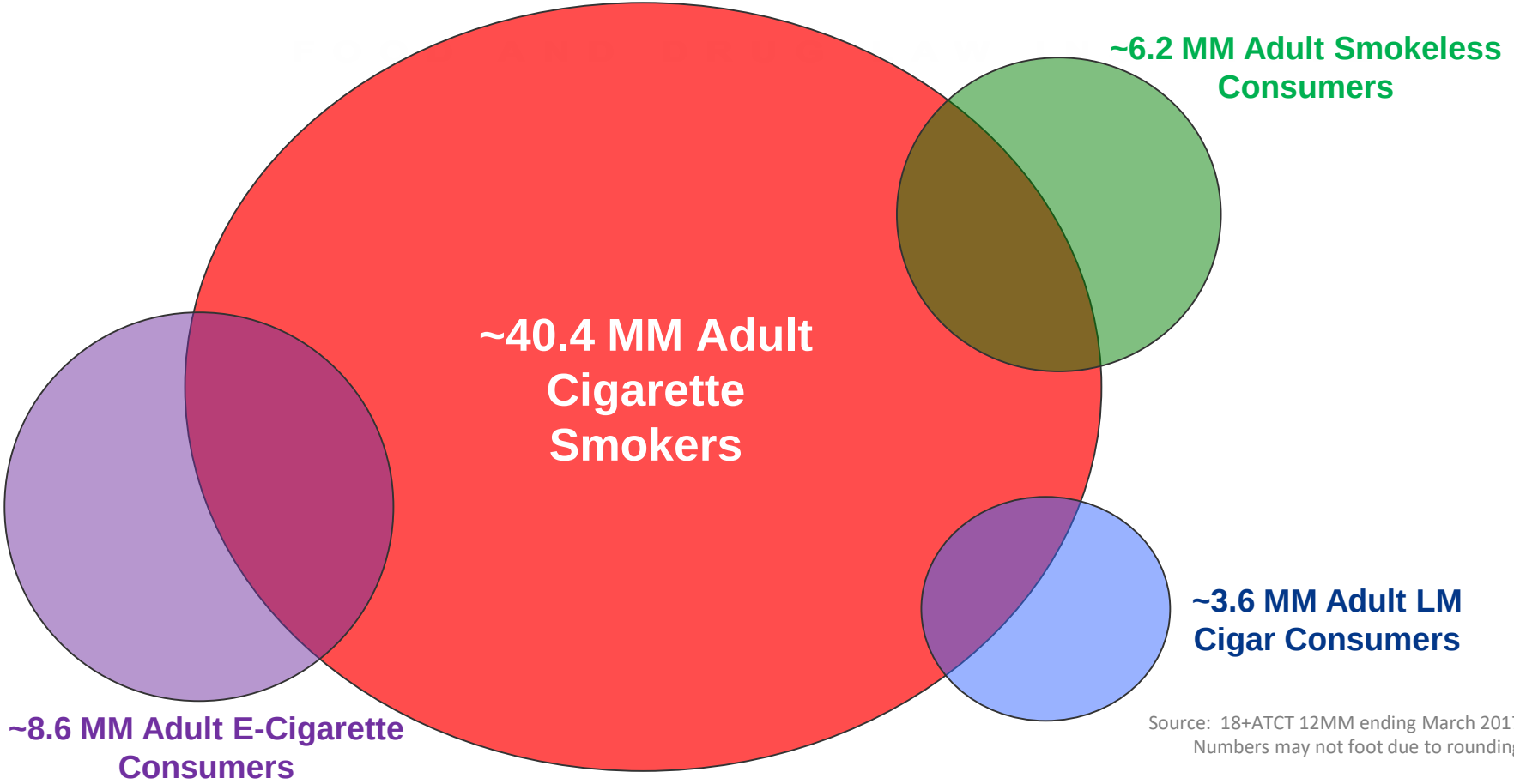
Altria

FDLI

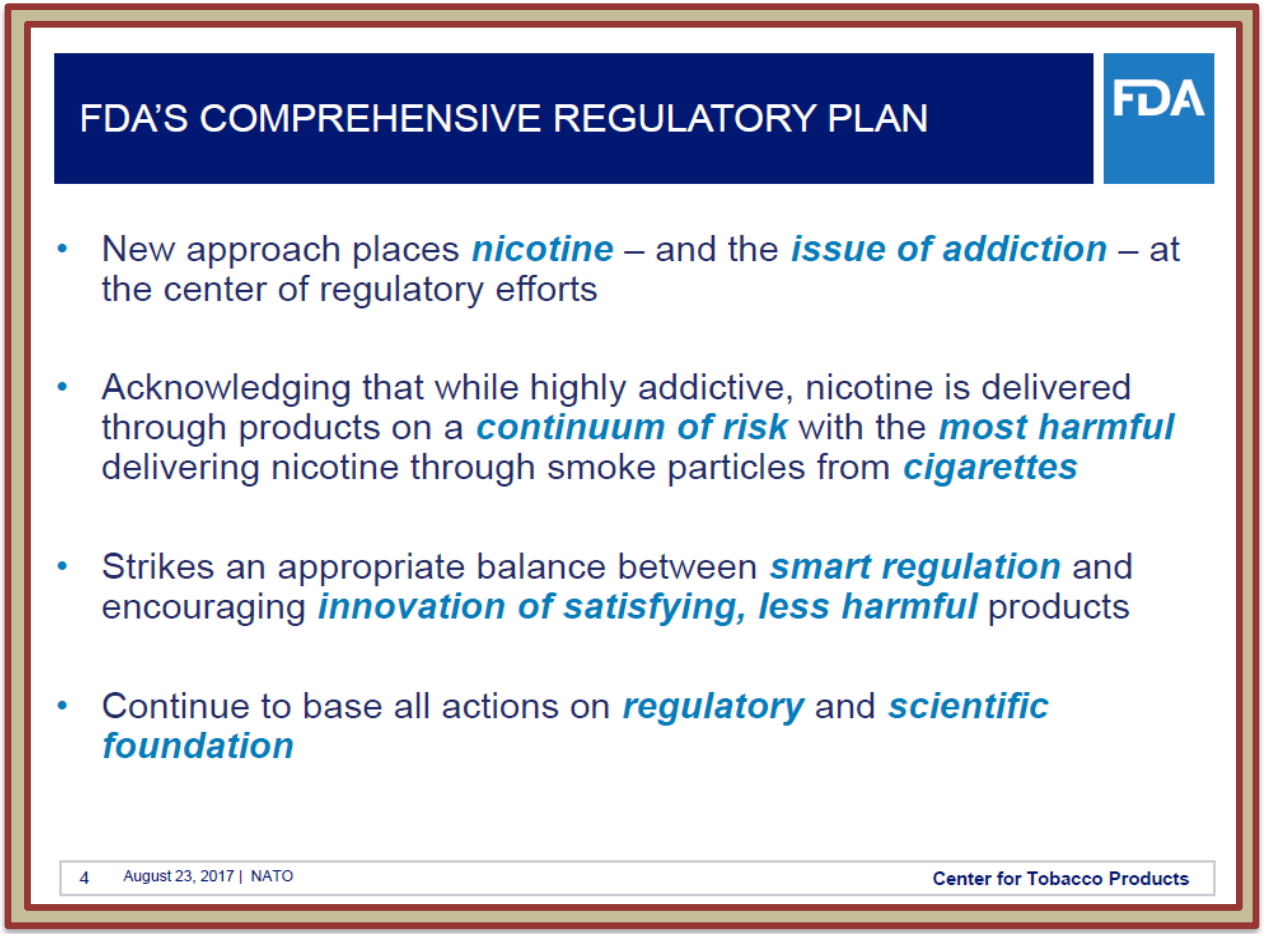
Altria's Tobacco Operating Companies

Estimated Adult Tobacco Consumers 18+ by Category



Source: 18+ATCT 12MM ending March 2017
Numbers may not foot due to rounding

FDA's New Plan for Tobacco and Nicotine Regulation



Areas of Difference Between E-Cigarette Enthusiasts & Skeptics

Issue	Enthusiasts	Skeptics
Degree of risk reduction	≥95%	Unknown; likely much <95%
Primary articulated concern	Maximizing adults quitting smoking	Minimizing risks to kids
Nature/magnitude of risks to kids	Minimal; e-cigarettes may substitute for smoking	Feared substantial: gateway to smoking; renormalization; effects on developing brain
Impact on adult quitting	Potential to help millions	May reduce quitting
Precautionary principle	Smoking toll requires support of novel products	Need to first prove (relative) safety & effectiveness
Long-term nicotine addiction	Acceptable if eliminates smoking	Not acceptable
Cigarette and e-cig companies	Open to working with them	Not to be trusted
Free market	Strongly support	Worry about "Wild West"
Scientific studies	Support/discredit	Support/discredit
Product regulation	Favor limited regulation that won't disrupt innovation	Support strong regulation to ensure safety/effectiveness
Information dissemination	Emphasize harm reduction potential for adult smokers	Emphasize risks for kids and risks of dual use for adults
Policies, e.g., vaping where smoking prohibited; flavors; taxation	Oppose location restrictions; support flavors (to assist in adult quitting); no/low tax	Support location restrictions; oppose flavors (to reduce attractiveness to kids); tax

Warner, K. *How to Think – Not Feel – About Tobacco Harm Reduction*, Mar. 9, 2017, Public Health Theme Lecture presented at the annual meeting of SRNT (Direct pull from Slide 6 of Warner presentation.)

Levy – Potential Deaths Averted in USA by Replacing Cigarettes With E-Cigarettes

Findings:

Compared with the status quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the optimistic scenario. Under the pessimistic scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost.

Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Levy, D., et. al., *Tobacco Control*, Oct. 2, 2017, doi: 10.1136/tobaccocontrol-2017-053969

Research paper

OPEN ACCESS

Potential deaths averted in USA by replacing cigarettes with e-cigarettes

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/tobaccocontrol-2017-053759).

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ABSTRACT

Introduction US tobacco control policies to reduce cigarette use have been effective, but their impact has been relatively slow. This study considers a strategy of switching cigarette smokers to e-cigarette use ('vaping') in the USA to accelerate tobacco control progress.

Methods A Status Quo Scenario, developed to project smoking rates and health outcomes in the absence of vaping, is compared with Substitution models, whereby cigarette use is largely replaced by vaping over a 10-year period. We test an Optimistic and a Pessimistic Scenario, differing in terms of the relative harms of e-cigarettes compared with cigarettes and the impact on overall initiation, cessation and switching. Projected mortality outcomes by age and sex under the Status Quo and E-Cigarette Substitution Scenarios are compared from 2016 to 2100 to determine public health impacts.

Findings Compared with the Status Quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost. The largest gains are among younger cohorts, with a 0.5 gain in average life expectancy projected for the age 15 years cohort in 2016.

Conclusions The tobacco control community has been divided regarding the role of e-cigarettes in tobacco control. Our projections show that a strategy of replacing cigarette smoking with vaping would yield substantial life year gains, even under pessimistic assumptions regarding cessation, initiation and relative harm.

INTRODUCTION

Harms from cigarette smoking remain unacceptably high even though smoking prevalence in the USA has decreased steadily over the past 50 years.[1 2] Two of three long-term smokers will likely die prematurely of a smoking-attributable disease.[3–5] Although many tobacco control policies, such as higher cigarette taxes, smoke-free public places, media campaigns, cessation treatment programmes and advertising restrictions, have already been implemented with substantial effectiveness, their pace in averting preventable deaths has been relatively slow and their potential to secure quick and substantial new smoking declines is limited.[6 7] Accordingly, tobacco control experts and national governments have begun considering what might be done to accelerate declines in tobacco-caused health harms and eventually eliminate all tobacco consumption (often termed an 'endgame'). The 2014 US Surgeon General Report recommended an endgame strategy for the tobacco epidemic.[6] Finland, New Zealand, Hong Kong and Iceland have already set the goal of reaching an endgame.[8]

While some refer to an endgame for all tobacco, most appear to focus on cigarettes as a more realistic and most important target, since they cause the vast majority of harm.[7 9–12] However, a credible plan to minimise cigarette use has yet to be implemented. At the same time, emerging nicotine-delivery products, such as e-cigarettes, call for an updating of traditional tobacco control strategies to better address new opportunities and threats that they present.[13]

Rather than focusing on policies designed exclusively to reduce cigarette use, some public health experts suggest a complementary approach to encourage the use of less harmful nicotine delivery products, such as e-cigarettes, as a substitute for cigarettes.[4 9 12–21] Some public health experts and officials fear that e-cigarette use ('vaping') may increase overall tobacco-related harms by serving as a gateway to smoking or prompting smokers to vape or engage in dual use instead of quitting all use.[22–32] However, evidence is mounting that e-cigarettes deliver only a small percentage of the toxicants delivered by cigarettes.[14–21] In addition, newer e-cigarettes models have been shown to more efficiently deliver nicotine[29 30 32] than older models and provide sensorimotor experiences and 'throat-hit' similar to smoking,[24] thus increasing their potential to serve as effective substitutes for cigarettes.

The goal of this paper is to show the potential health impact from an endgame strategy directed at replacing all or most cigarette smoking by e-cigarette use over a 10-year period. The 10-year time frame is used for illustrative purposes to show the potential health gains that could be secured by a potent switching-based strategy. To address the major concerns about switching smokers to e-cigarettes, some of the projections assume a much smaller net reduction in health harms from switching to e-cigarette from cigarette use than existing research suggests, and that the switching strategy will increase initiation into regular vaping by youth and others who would not otherwise use any nicotine delivery products and will prompt some smokers who would otherwise have quit all tobacco and nicotine use to instead use e-cigarettes. To distinguish the effect of policies on younger and older cohorts, we present separate analyses for the cohorts age 15 years and age 35 years in 2016.

CrossMark

To cite: Levy DT, Borland R, Lindblom EN, *et al*. *Tob Control* Published Online First: [please include Day Month Year]. doi:10.1136/tobaccocontrol-2017-053759

Modernizing the Regulatory Framework

Regulation provides significant benefits to adult tobacco consumers:

- A common set of rules for all tobacco manufacturers
- Framework for evaluating potentially less harmful tobacco products
- Guidelines for accurate and scientifically grounded communications

Modernizing the Regulatory Framework

Regulation should also:

- Encourage innovation
- Provide viable pathways to get reduced harm products to market

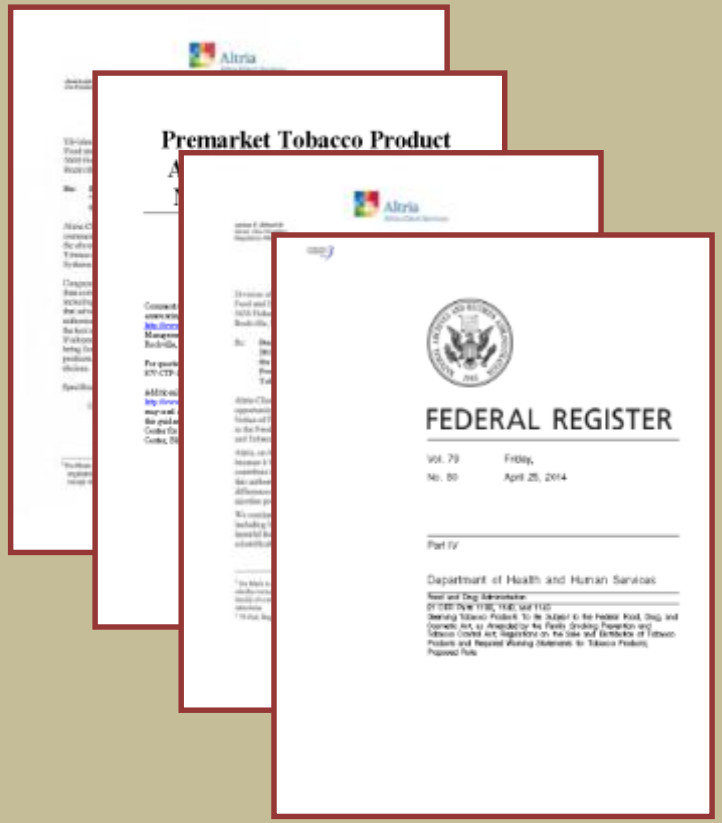
FDA U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR TOBACCO PRODUCTS

PMTA Pathway

The PMTA Process Should be Modified

- Draft guidance for ENDS PMTA applications is unduly burdensome
- Lacks an accelerated review process
- Does not include a change management process after issuance of a market order

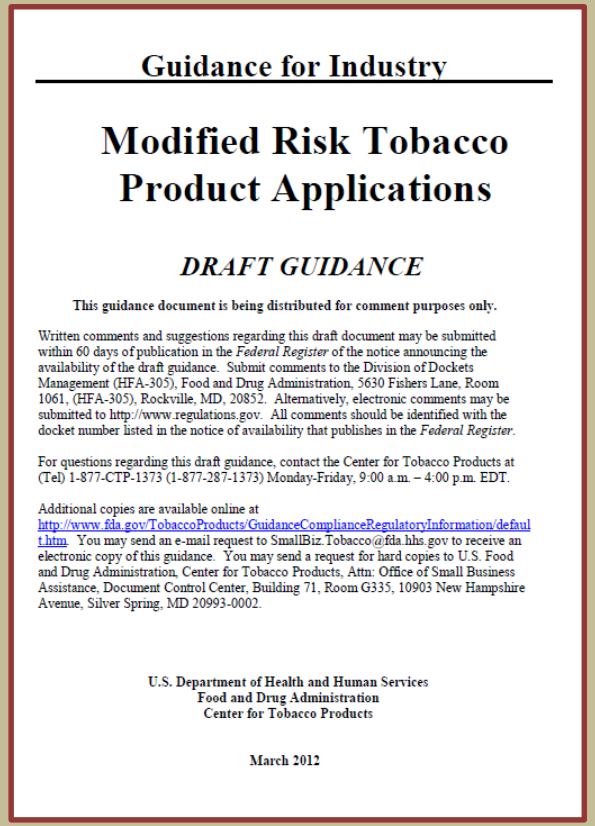


Comments on behalf of Nu Mark to FDA's draft guidance on PMTAs for ENDS and proposed deeming rule

MRTP Pathway

Regulations for MRTP Applications

- Clear, reasonable and include provisions for abbreviated applications and accelerated authorizations
- Must be consistent with the First Amendment
- Facilitate truthful and accurate communications to consumers



Guidance for Industry

Modified Risk Tobacco Product Applications

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Written comments and suggestions regarding this draft document may be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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