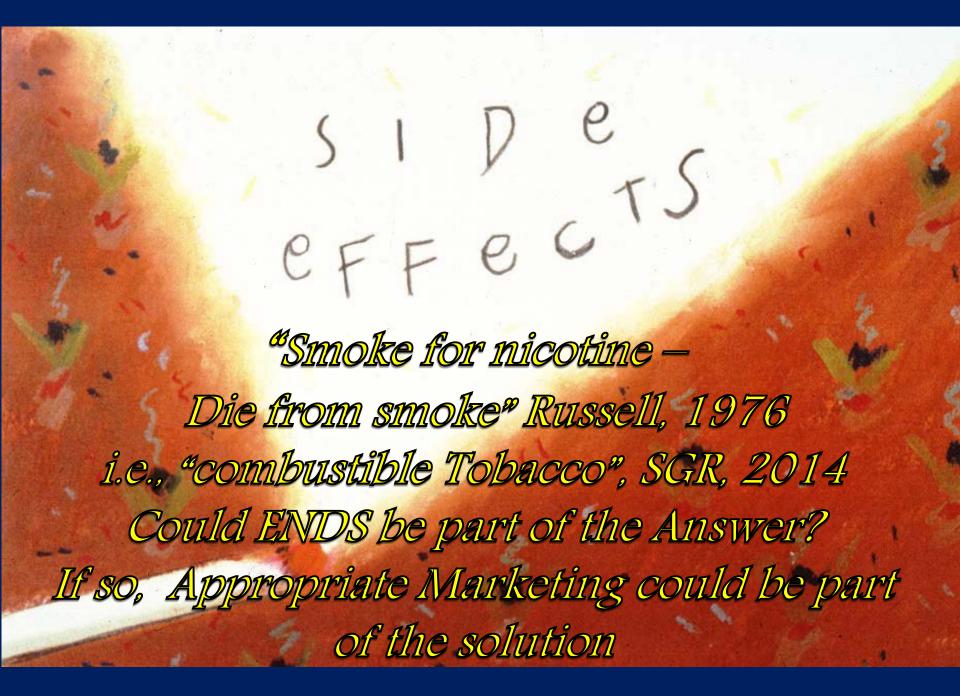
Marketing E-Cigarettes & Other Tobacco Products to Youth and Young Adults Jack E. Henningfield

The Johns Hopkins University School of Medicine and Pinney Associates

Disclosure: I consult to GlaxoSmithKline on smoking cessation, NJOY on electronic cigarette regulation, and to pharmaceutical companies on addiction-related issues. I serve as an expert witness against the tobacco industry. I share patents on a potential oral nicotine delivery system.

(Texas Tobacco Summit, Houston, 27 June 2014)





Premise of the PromiseSGR 2014

"Death... is overwhelmingly caused by cigarettes and other combustibles... promotion of e-cigarettes and other innovative products is... likely to be beneficial where the appeal, accessibility and use of cigarettes are rapidly reduced."

The Strategic Dialog, Zeller et al. 2009

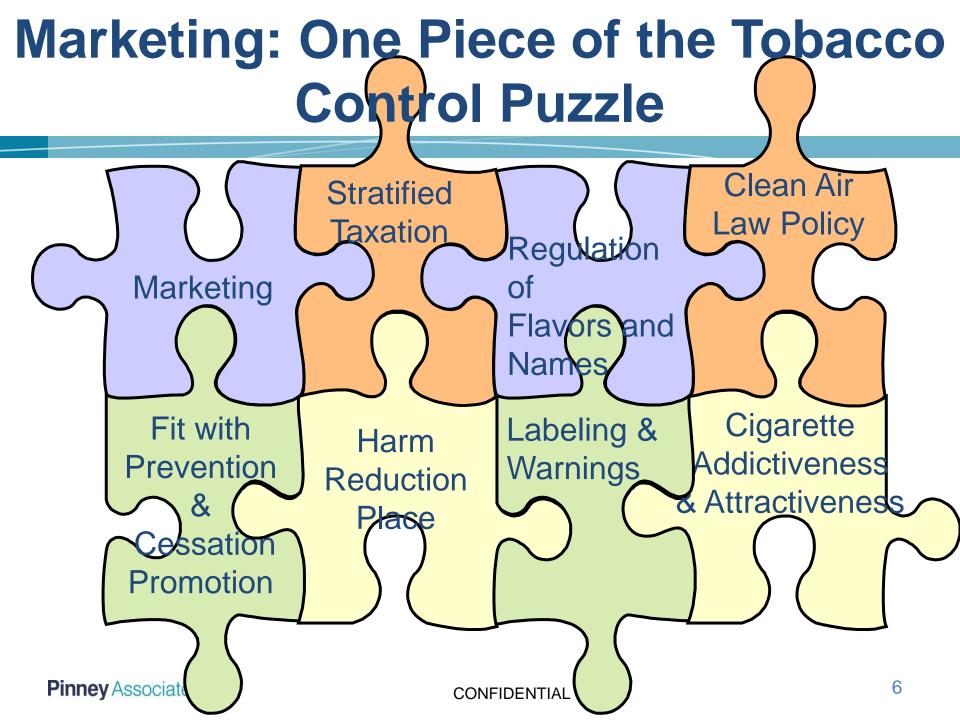
"...dare to envision a future world where almost no one uses combustible tobacco"

ENDS: The Promise and the Peril

 Could ENDS be part of the Tobacco END game, fostering mass migration from combustible tobacco and possibly enabling stronger measures to reduce combustible tobacco use such as reducing the addictiveness of cigarettes?

OR

- Will ENDS undermine prevention and cessation, serve as gateways to combustible tobacco use?
- Marketing is the interface between the product and the consumer. It will be a factor in who uses, why they use, how they use, and what they use



What do we actually know about the factors driving initiation and use and the role of marketing?

- Not much but we are learning quickly, thanks to NIH, FDA, CDC collaborations and other recently initiated research
- See FDA' special issue of Tobacco Control (May, 2014), and output of November, 2013 NIH Research Needs Conference

NIH Electronic Cigarette Workshop: Developing a Research Agenda

November 20, 2013

- Led by NIDA, supported by multiple NIH Institutes as well as the CDC and FDA (Tobacco and Drug Centers)
- The goal of this workshop was to identify future research directions relating to the effects of electronic cigarettes on safety, potential for addiction as well as for smoking cessation, and public health
- Participants included leading researchers and representatives from CDC, FDA (Tobacco and Drug Centers), WHO, and NIH

NIH Electronic Cigarette Workshop: 5 Categories of Research Gaps

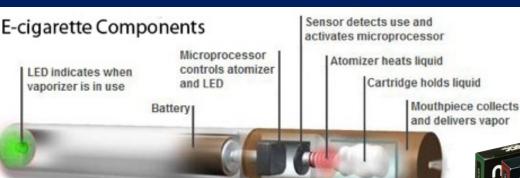
- 1. Definitions, Methods, Moderating Factors
- 2. Design and Constituents
- 3. Indicators of health risk, addiction and sensory appeal
- 4. Behavior, Cessation and Harm Reduction
- 5. Cessation and Harm Reduction

Marketing factors cut cross all of these categories

Electronic Nicotine Delivery Systems (ENDS) Diverse and Rapidly Evolving



Ehoo.





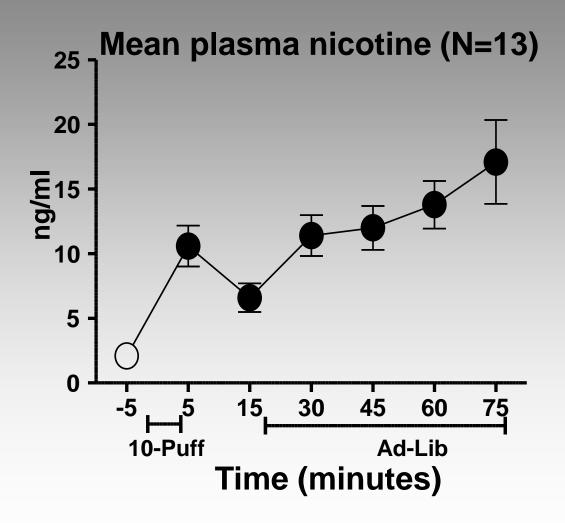
NJOY



NEW: DIY Tank Systems Fill With Drug & Dose of Choice

MARKTEN

Some ECIGs Deliver Nicotine at Similar Levels as Cigarettes in Experienced Users - Most Don't



Data from Vansickel and Eissenberg, 2013 + additional participants

Not a Fad: First Serious Competitor to Combustible Tobacco Products – *A Disruptive Technology?*

Wells Fargo: Consumption of e-cigs may overtake traditional cigarettes in the next decade.

Morgan Stanley: E-cigarettes will take the place of around 1.5 billion cigarettes this year...

Goldman Sachs: E-cigs could accelerate the decline of cigarette consumption

 Cigarette volume decline could accelerate from 3.5% in the past three years to 4.5-5.5% in the next several years

2013 Focus Groups: Reasons for Initiation NIH/FDA Supported Research at Yale by Krishan-Sarin

Factors that Promote E-Cigarette Initiation

Student Responses	College	High School	Middle School		
Curiosity	/	√	✓		
Flavors	/	√	✓		
Friends and family use E-Cigs	/	√			
To quit smoking	/	√			
Sign of independence			✓		
Availability		✓			
E-Cigs are cool	1				
Convenience (e.g., use at parties)	1				
Easters that Daton E. Gigaratta Initiation					

Convenience (e.g., use at parties)	/				
Factors that Deter E-Cigarette Initiation					
Not cool to smoke	✓	√	√		
Expensive	✓	✓			
Similarity to cigarettes	/	✓			
Unknown Health Risks	✓				
Parental disapproval		√	√		
Friend Disapproval		√			

Reasons for E-Cigarette Discontinuation				
Reason Given	Smokers	Non-Smokers		
Not the same as cigarettes	✓			
"Did not like it"	✓			
Novelty wore off		/		



Krishnan-Sarin, CPDD 2014

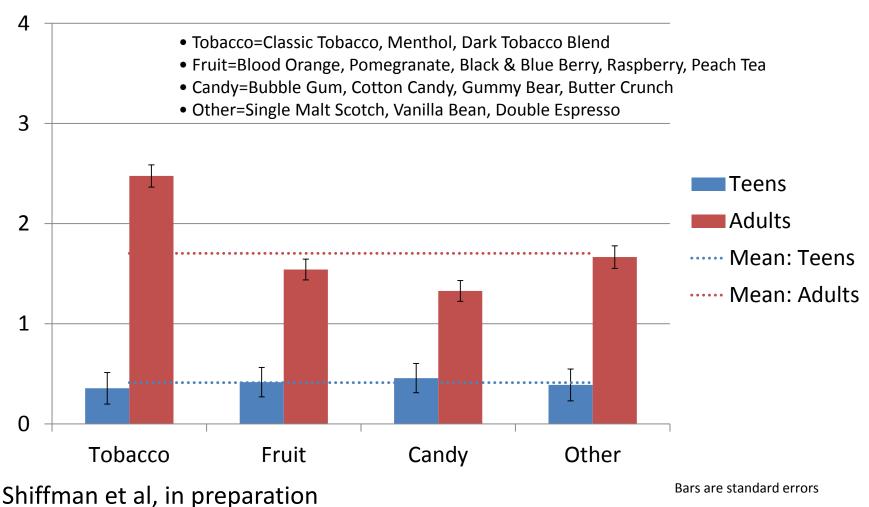
Example of Recent Research on Flavor and Appeal

- Premise: The greatest aggregate public health benefit is likely related to the number of smokers who switch ENDS
- THEREFORE: ENDS need to appeal to adult smokers
- BUT: Adoption by nonsmokers, especially nonsmoking teens, is not a benefit but a potential public health harm (nicotine risks + potential gateway effects)
- THEREFORE: We need product features, flavors, and promotion that appeals primarily to adult smokers, but not to nonsmoking teens

Internet Survey of Potential ENDS Flavors on Adult Smoker vs Teen Nonsmoker Appeal

- The Tobacco Control Act bans flavored cigarettes, based on concern of appeal to nonsmoking teens, largely based on evidence from tobacco industry documents
- Potential ENDS flavors of concern include candy & fruit
- Shiffman et al., surveyed 432 smoking adults and 216 nonsmoking teens by an online Internet survey method
- Interest in ENDS was evaluated on a 0-10 scale comparing tobacco, food, fruit, and candy flavors
- The project was supported by NJOY but designed, implemented, and interpreted by Shiffman and other Pinney Associates scientists

Smoking Adult & Nonsmoking Teen e-cigarette interest, by flavor classes: Flavor influenced Adult Smoker but not NonSmoking Teen Interest



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NICOTINE Regulatory Landscape



Center for Tobacco Products MARKETING REGULATED:

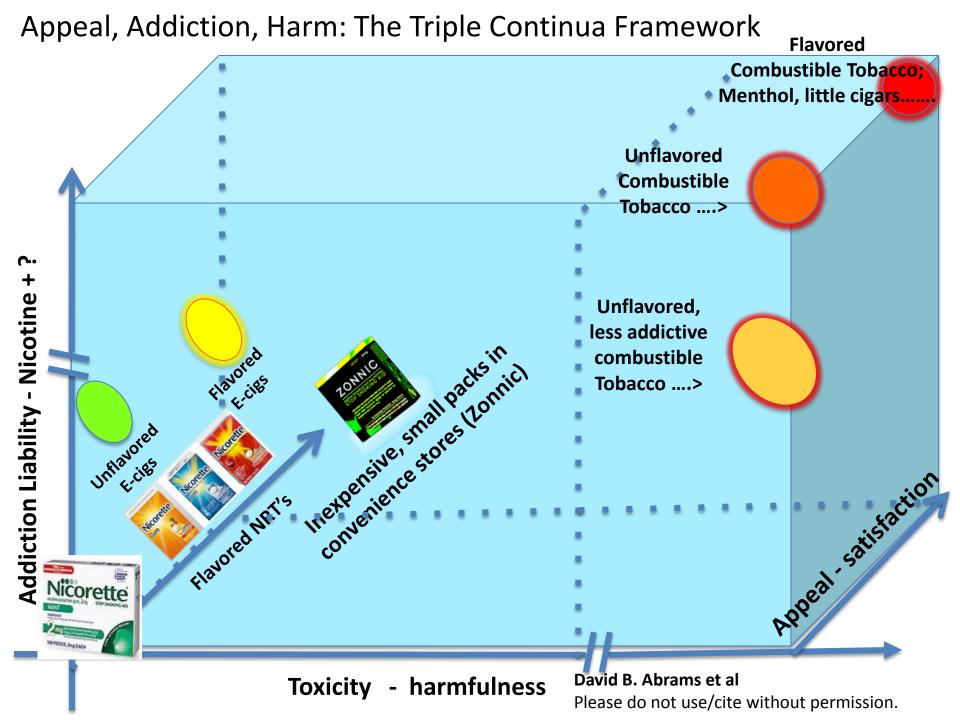
- **✓** Cigarettes
- ✓ Roll-your-own tobacco
- √ Smokeless tobacco

MARKETING NOT REGULATED:

- ☐ Hookah tobacco
- □ Cigars/cigarillos/LCCs
- **LENDS**

Center for Drug Evaluation and Research MARKETING REGULATED:

- ✓ Pharma NRT, Zyban, Chantix
- ✓ Other medications for cessation
- **✓** RJR Zonnic: Package, Price, Placement



Marketing Priorities -- Find the Balance:

- Encourage uptake by adult smokers as exclusive alternatives to combustible tobacco
- Discourage marketing to nonsmokers especially youth
- Prohibit marketing that promotes use ENDS in ways that may delay smoking cessation, e.g., "for where you cannot smoke")
- Prohibit co-branding of ENDS and tobacco products
- Prohibit any health claims for ENDS until and unless approved by FDA (CTP or CDER)

New

April 2014 FDA proposed deeming and future rulemaking

FDA regulation: For non-combustibles (e-cigs):

- Restrict sales to over 18 years of age, no free samples.
- Warning label that nicotine is an addictive chemical
- Registration and product disclosure
- Product standards, safe ingredients, child-resistant package
- MRTP applications to claim reduced harm: individual and population standard. Pre approval and post market surveillance
- No proposed Advertising Restrictions
- Concerns about flavors but seeking comments
- Therapeutic claims for combustible smoking cessation?
- Need comprehensive nicotine / tobacco regulatory policy

Promoting Mass Migration from Combustibles Additional Big, Hotly Debated, Unresolved Questions Got Answers?

- How should ENDS be taxed as compared to cigarettes?
- Where should ENDS use be allowed? How about in some places where you can't smoke, perhaps closer to place of work than designated smoking areas?
- What flavors and flavor names should be allowed, e.g., tobacco? Menthol seems vital but other flavors may require case by case evaluation to assess youth attractiveness
- What advertising and communications will be allowed to foster migration from combusted to ENDS?
- What labeling and claims would be most likely to foster migration from combustibles moving toward the End Game?

Prevention – Extant Cigarette Prevention Approaches may be Counterproductive

Content and focus need to recognize differences from combustible tobacco as to contents and documented risks

Need to be nimble to keep up with the ENDS products and lore

Messages implying "possibly as deadly as cigarettes" are not credible. Messages such as, "We don't know if they are less harmful than cigarettes" may appear naïve at best

Users are diverse, ranging tobacco using youth looking for less harmful alternatives and youth who are strongly opposed to Big Tobacco and are seeking to differentiate themselves

Anti-Big Tobacco messages have been effective in smoking prevention but painting all ENDS developers as the same as Big Tobacco ignores that strongly anti-tobacco stance of many developers/marketers and their customers

Foster substitution for combustible tobacco – especially cigarettes

Minimize extended dual use that delays smoking cessation

Minimize uptake by youth & transition to combustible tobacco by ENDS initiators

The Tobacco
End Game

Public Health Goals for Marketing and Communications

oP de grâce STATSKAL