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Should FDA try to move smokers to e-cigarettes or other less-harmful tobacco-nicotine products and, if so, how?

Yes!

FDA has a public health mandate

- Tobacco Control Act: “mandate to promote health and reduce the risk of harm”
- It is “appropriate for the protection of public health” for FDA to communicate accurate risk information

“The FDA's job is to minimize risks through education, regulation, and enforcement. To be credible in all these tasks, the agency must communicate frequently and clearly about risks and benefits — and about what organizations and individuals can do to minimize risk.”

- *The FDA as a Public Health Agency*, MA Hamburg (May 2009)

“If accurate information on relative risks of various products helps even a few users of cigarettes to move from or stay away from cigarettes, it is preferable to a context of providing no information, misinformation, or disinformation to consumers of these products.”

- *Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines*, Kozlowski, Sweanor (June 2016)

Why?

- Although we can't say definitively that e-cigarettes present less risk, available chemistry and toxicology data indicate that e-cigarettes and other vapor products have great potential to reduce smokers' risk of disease
- Moving smokers that choose to continue nicotine use toward acceptable, less harmful products could have substantial public health benefits
- FDA has the authority to communicate accurate information on risk and is a credible source of information for consumers

How?

- FDA should provide relative-risk information to smokers who otherwise will not quit nicotine use
- FDA should provide an innovation pathway with speed, predictability, and flexibility for potentially less harmful products like e-cigarettes
- FDA should move to a standards-based framework for e-cigarettes and other non-combustible products
- Other options for FDA consideration:
  - *Minimizing nicotine levels in cigarettes and similarly smoked tobacco products*
  - *MRTP Fast-Track*

How? *Providing relative-risk information to support choice*

Smokers are confused about nicotine

- Most smokers believe that nicotine is harmful, causing heart disease and cancer
- Fear of nicotine is a barrier to consideration, trial, and adoption of noncombustible nicotine and tobacco products
- Education on nicotine use without combustion can help reverse these misconceptions

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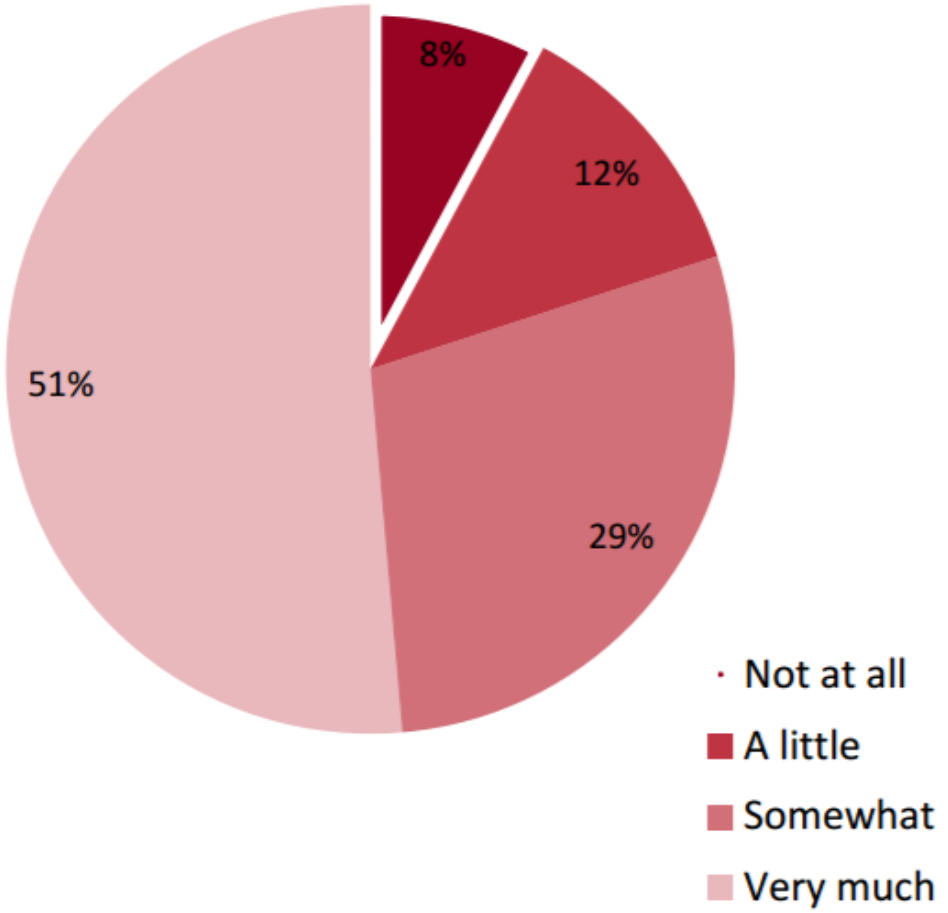
PATH STUDY
FINDINGS: NICOTINE AND CANCER

To what extent, if at all, do you believe the nicotine in cigarettes to be the chemical that causes most of the cancer caused by smoking?

The majority (80%) believe (*very much* or *somewhat*) that nicotine causes cancer.



What the public knows and believes about nicotine, SE Johnson (2016) (data from Population Assessment of Tobacco and Health Study Wave 1 (Sept. 2013 to Dec. 2014))

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How? *Providing relative-risk information to support choice*

Smokers are confused about the relative risks of vapor products

- Many smokers believe that vaping is just as harmful as or more harmful than smoking
- Consumer understanding about the relative risks of e-cigarettes is poor and deteriorating

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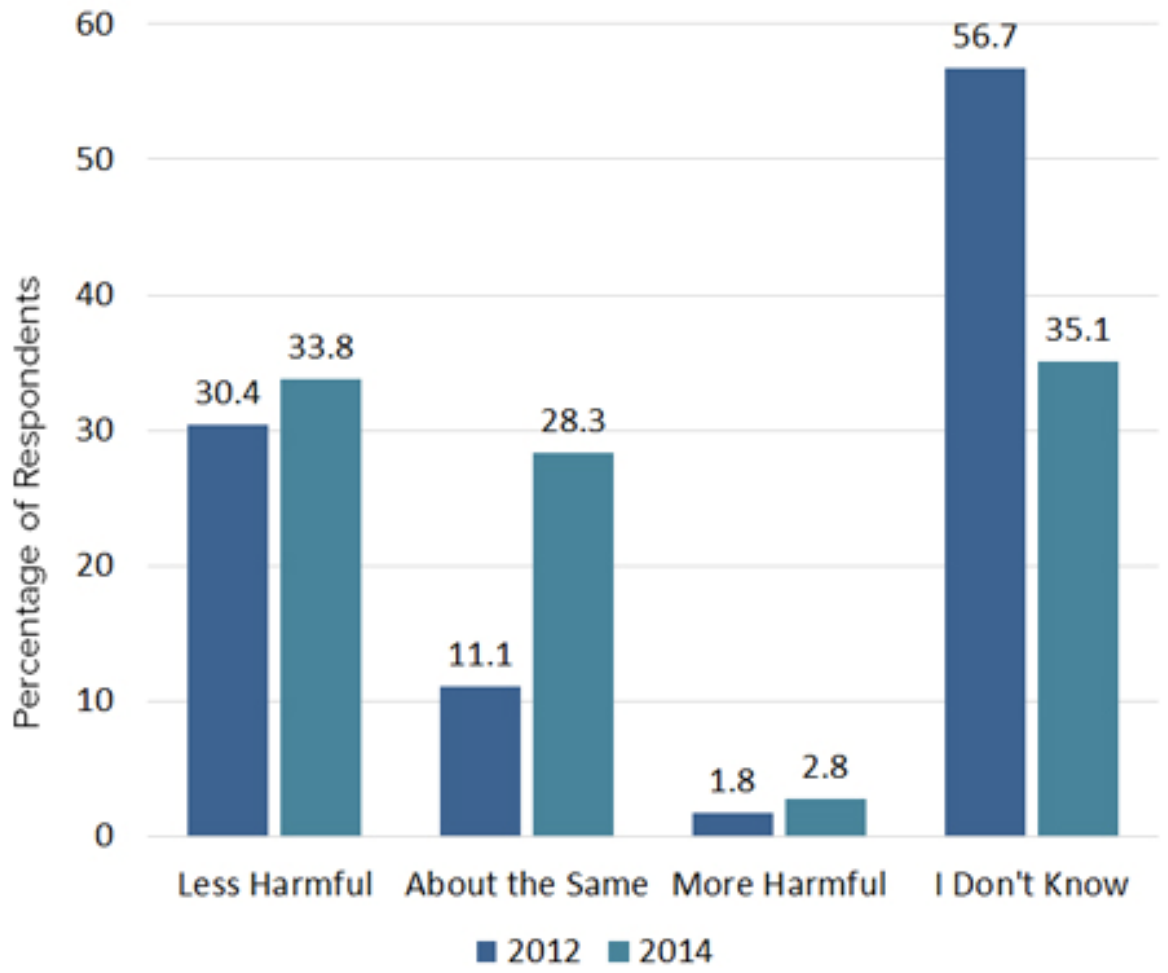
Public Perception of Harm of E-Cigarettes (2012-2014)



Unpublished data from 2012 and 2014 from the Georgia State University (GSU) School of Public Health (SPH) Tobacco Centers of Regulatory Science (TCORS) (provided by Michael P Eriksen, Principal Investigator, GSU TCORS, October 2015)

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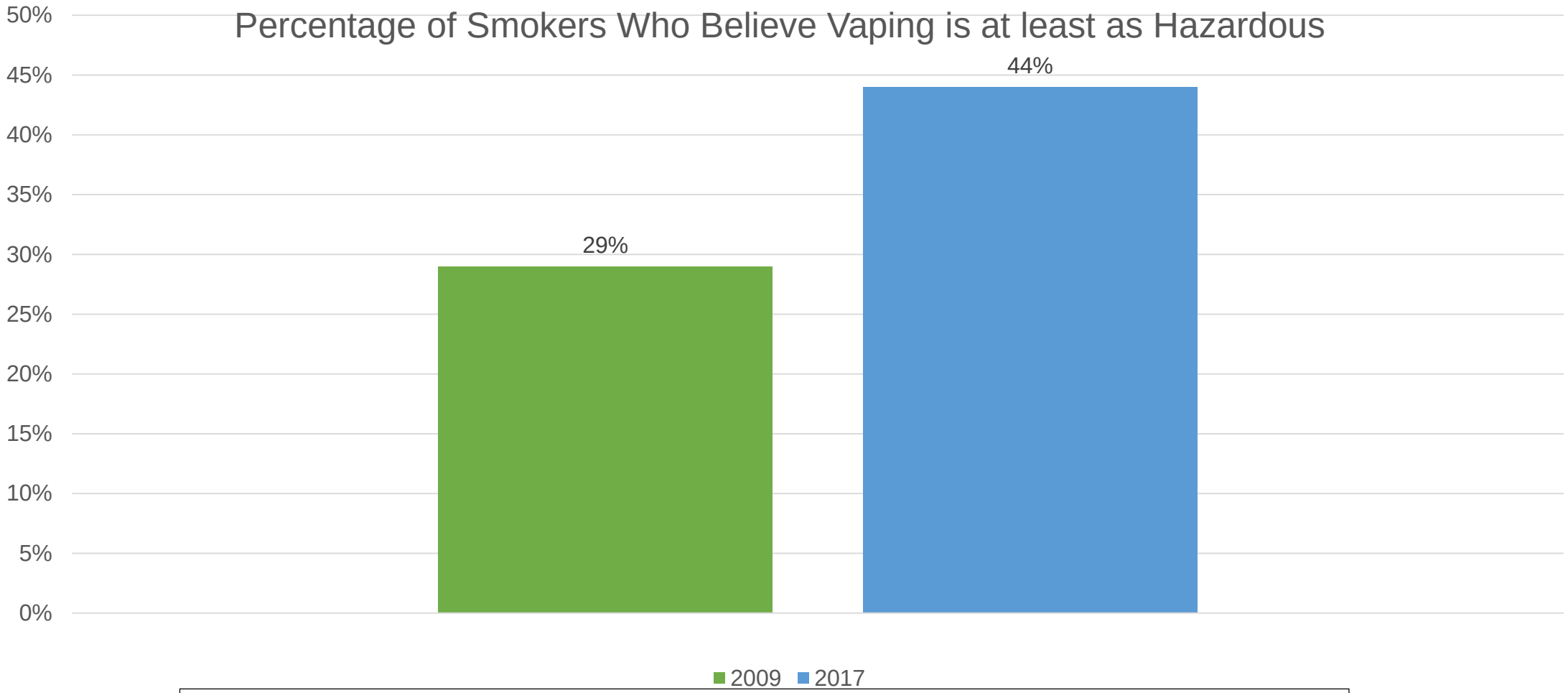
Accurate relative-risk information: Why it's needed



Unpublished data submitted to SRNT 2018 conference by Saul Shiffman et al.

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How? *Providing relative-risk information to support choice*

What is the most impactful way to address misperceptions?

- Trusted authorities (governmental and nongovernmental) need to communicate that smoke – not nicotine – is the problem
- Public health agencies, like FDA and CDC, should use all of their available means of communication to correct consumer misinformation on relative risks

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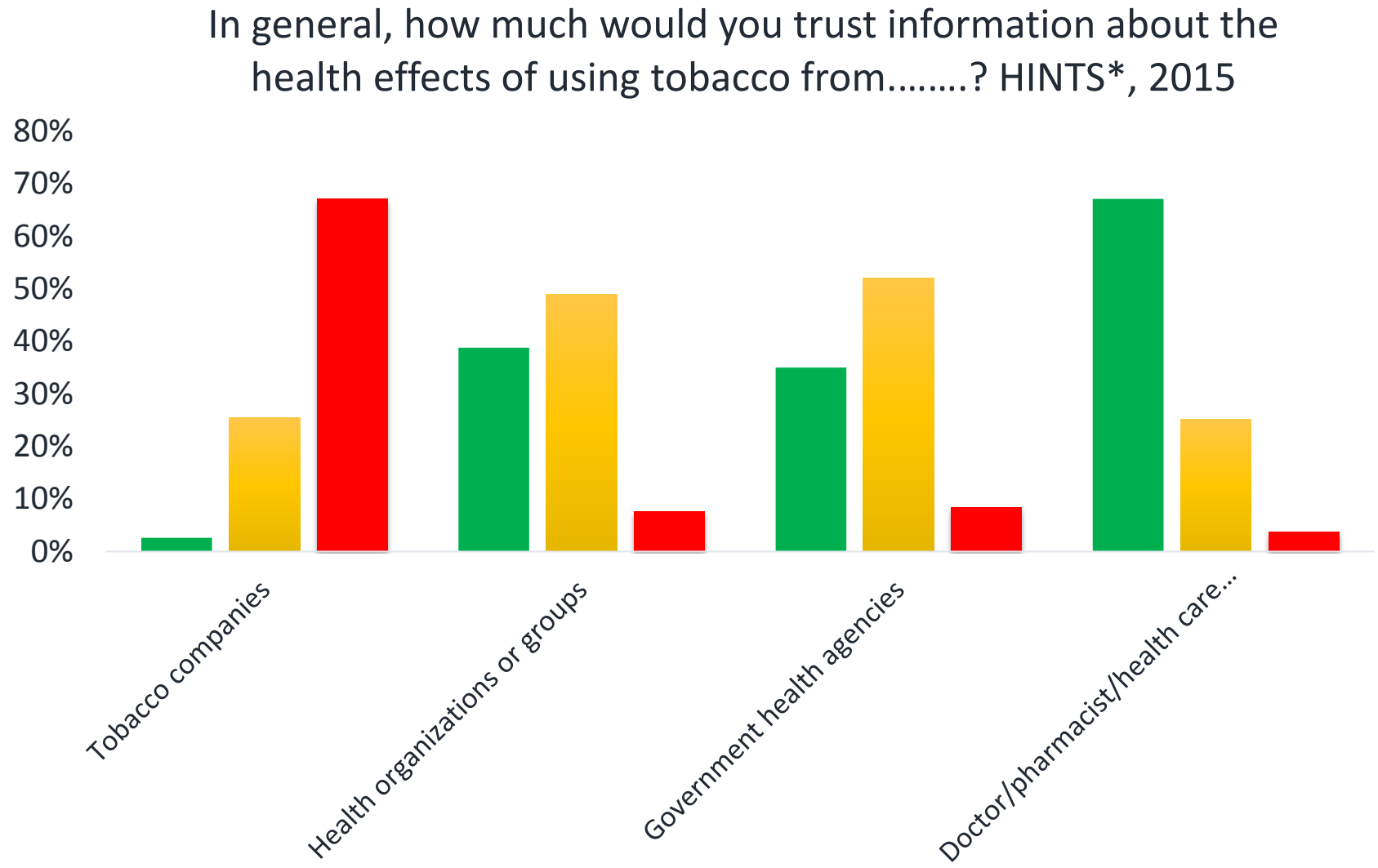
FDA has credibility



*Health Information National Trends Survey

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Examples from England

Public Health England

Protecting and improving the nation's health

July 2016

E-cigarettes: a developing public health consensus

Joint statement on e-cigarettes by Public Health England and other UK public health organisations

We all agree that e-cigarettes are significantly less harmful than smoking. One in two lifelong smokers dies from their addiction. All the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long-term effects.

And yet, millions of smokers have the impression that e-cigarettes are at least as harmful as tobacco. Over 1.3 million UK e-cigarette users have completely stopped smoking and almost 1.4 million others continue to smoke. We have a responsibility to provide clear information on the evidence we have, to encourage complete smoking cessation and help prevent relapse to smoking.

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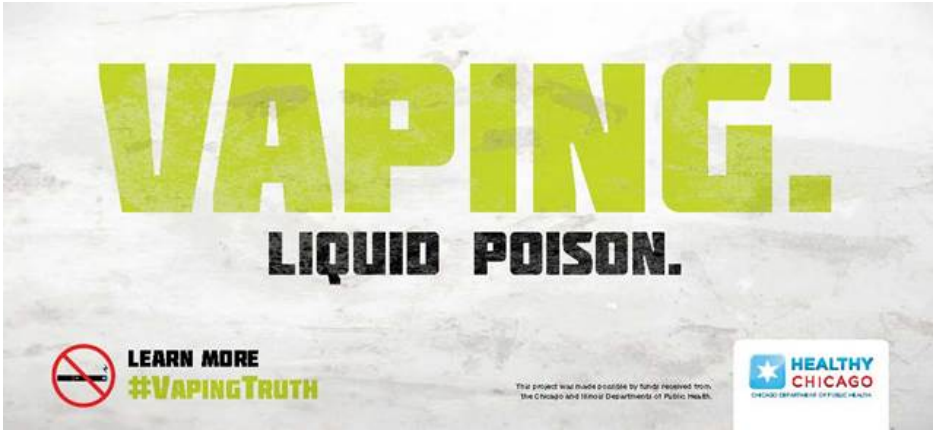
Very different messages in the United States

SURGEON GENERAL .GOV



E-CIGARETTES POSE RISKS TO HEALTH, TURN KIDS INTO ADDICTS, AND GIVE BIG TOBACCO BIG OPPORTUNITIES. WAKE UP.

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Providing relative-risk information to support choice

Electronic Cigarettes

Even in the absence of definitive data, there are ways to improve communication of relative risk

What's the Bottom Line?

- E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products.
- E-cigarettes are not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products.
- While e-cigarettes have the potential to benefit some people and harm others, scientists still have a lot to learn about whether e-cigarettes are effective for quitting smoking.
- If you've never smoked or used other tobacco products or e-cigarettes, don't start.
- Additional research can help understand long-term health effects.

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Providing relative-risk information to support choice

Priorities

- Collaboration by HHS agencies (Surgeon General/FDA/CDC), integrated into operational tobacco programming driven by HHS Strategic Plan
- Development of consensus on relative risks, based on product categories, taking into account non-users and dual use
- Establishment of a task force/committee to perform periodic evaluation of emerging science to ensure communications are aligned with risks

Structure and Implementation

- Dissemination of information via agency public statements, websites, reports, press conferences and releases
- Public awareness and education campaigns for each category of product/users (via cigarette product inserts, media campaigns)
- Work collaboratively with health practitioners to outline the relative risk of different tobacco and nicotine products for patients who smoke
- Development of sustained research program to assess unresolved scientific questions

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Providing relative-risk information to support choice

Main Themes

- The best way for smokers to achieve risk reduction is to quit
- Smokers who don't want to quit tobacco altogether should consider switching completely to tobacco or nicotine products that may present less risk to their health
- If you've never smoked or used other tobacco products or e-cigarettes, don't start

Benefits of Communication

- Better understanding of risks by users will enable them to make informed choices
- Political/legal viability: FDA is broadly empowered to take measures that are "appropriate for the protection of the public health"
- Appropriate risk communication could be accomplished in much less time than development of regulations or product standards
- Tobacco product consumers will receive accurate risk information about entire categories rather than specific products

Providing relative-risk information to support choice

Several recent modeling studies have demonstrated that even with very high estimates of increased initiation, increased uptake of e-cigarettes by smokers would yield a net public health gain

Still, action can be taken to minimize potential risks:

- Prioritize communications to current smokers (targeted education) and emphasize benefits of complete switch
- Support the development of innovative products that are more appealing to smokers
- Utilize communications to discourage initiation of potentially less harmful products by non-tobacco users
- Develop post-marketing surveillance by category to identify any issues and develop an epidemiological base
- Ongoing monitoring of youth is necessary (including carving out e-cigarettes from “all tobacco;” discerning whether trial=use; and monitoring whether nicotine is used)
- Continued utilization of regulatory authority under the Act—reviewing company submissions, obtaining information, taking appropriate enforcement action as needed

How? *Encouraging innovation*

"Part of CTP's task is to reconsider aspects of the implementation of the final deeming rule **with an eye towards fostering innovation where innovation could truly make a public health difference**, and making sure we have the foundational regulations we need in place to **make the entire program transparent, predictable, and sustainable for the long run**."

Commissioner Gottlieb, 28 July

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How? *FDA can accelerate adoption of non-combustible products by encouraging innovation*

- FDA should provide an innovation pathway with predictability and flexibility for e-cigarettes and other non-combustible products
  - Standards-based framework for e-cigarettes and non-combustible products
  - Streamlined PMTA process: certification of compliance with standards, commitment to post-marketing surveillance
  - Provide clarity on internal agency review and standards for approval
- Foster innovation of non-combustible nicotine products:
  - Simplify and clarify the pre-market application process based on relative risk
  - Provide more nimble pathway to allow for safety improvements (*e.g.*, enforcement discretion following consultation with agency, CBE30-type notification within specified parameters) and increase speed to market of innovative products

Smokers need a place to land

- Smokers can understand that smoke is the problem and that they can improve their health by switching to a non-combustible product if they don’t want to quit tobacco
- Better, more consumer-acceptable products in the market to compete with cigarettes and set up a future of diminished smoking-related harm
- People have to understand the rationale to accept the trade-off

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Option: *Minimizing nicotine levels in cigarettes and similarly smoked tobacco products*

- It is important that smokers have a place to land when implementing a VLNC approach
  - Sequencing is crucial: FDA should implement risk communication and innovation strategies that favor less harmful products before requiring nicotine reduction
- Availability of an array of sufficiently satisfying, non-combustible alternative products for current smokers would make it more likely that they would quit—and lessen the need for VLNC
- If the appeal of innovative products is insufficient to drive switching, development of VLNC is feasible, but there are many open scientific, ethical, and technical achievability questions

Proposal: *MRTP Fast-Track for e-cigarettes with reduced-risk claims*

Restricting eligibility to products without characterizing flavors

- Research suggests that elimination of flavors would drive smokers back to cigarettes and reduce the appeal of the products to smokers looking for a place to land
- Issues with flavors largely arise in how they are discussed and marketed – not the flavors themselves
- Research on appeal of flavor descriptors and reasons for youth use indicates more complexity than is commonly believed

Eligible Reduced-Risk Claims

- Claims would apply only to approved products rather than providing category-wide risk information to smokers

Restrictions on Delivery of Reduced-Risk Claims

- Would restrict dissemination to verified smokers who have opted in to such communications and would be insufficient to correct widespread misperceptions of relative risk

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Conclusions

- FDA and other public health agencies should provide actionable risk information to better arm consumers in their search for acceptable non-combustible options
- Innovative, less harmful products will give smokers a satisfying place to land – consumers want to move in this direction and are trying
- There should be a clear, flexible innovation and approval pathway for products commensurate with their relative risk
- RAI's operating companies have a strong portfolio of non-combustible products, reflecting over a decade of work Transforming Tobacco, and we are committed to working with FDA on the understanding and advancement of innovative products