Communicating the Risk of Nicotine Delivery Products

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Key Points

- The popularity of e-cigarettes has increased the need to communicate about nicotine.

- Nicotine: “…there is a large body of evidence that medicinal nicotine (in currently licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease.”

- Nicotine Replacement Therapies (NRT) have been regulated by FDA for many years and are sold over the counter.

- 2009 Tobacco Control Act includes a provision for characterizing products as “modified risk tobacco products”.
Tobacco harm reduction was addressed in the 2001 Institute of Medicine Report *Clearing the Smoke*.

Risk continuum refers to the range of risk posed by varying nicotine products.

2009 Tobacco Control Act addresses harm reduction in Section 911 Modified Risk Tobacco Products (MRTP).

Act does not address NRT or any other cessation device; and does not address e-cigarettes or cigars.

It was “deemed” that e-cigs are tobacco products and can be regulated under the Act. FDA has issued draft deeming regulations.

But for now e-cig companies can advertise but can’t claim reduced risk.

FDA currently does not have a nicotine “policy” that addresses cessation devices such as NRT, modified risk products, and e-cigs.
My Involvement

- Swedish Match manufactures snus, a smokeless, traditional Scandinavian product.

- I was a consultant to Swedish Match and joined the company in 2012 and am co-project manager for a Modified Risk Tobacco Product Application (MRTPA).

- Directed risk and science policy at the American Chemistry Council for 12 years.
Swedish Experience

- Swedish men use tobacco at similar rates of other western men, but the majority don’t smoke; they use snus, and they don’t suffer from smoking-related diseases.

- The scientific foundation of the Swedish Experience consists of several cohort studies, conducted by Scandinavian and international authorities, assessing habits and life styles of large groups of people.

- The studies include questions regarding tobacco use and provide a strong collection of evidence on the health effects of snus use.

- And the studies are often used when examining the relative safety of long-term use of NRT products, and when demonstrating the concepts of tobacco harm reduction and continuum of risk.
Norwegian Experience

- Snus use has been increasing in Norway and the Ministry of Health and Care Services instructed the Institute for Alcohol and Drug Research (SIRUS) to examine this development and address the public health implications.

- **2009 SIRUS report:** A Tobacco-Free Society or Harm Reduction? Which Objective is Best for the Remaining Smokers in Scandinavia?

- **2013 SIRUS report:** Tobacco Harm Reduction in the Real World: Has the Availability of Snus in Norway Increased Smoking Cessation?

- **Study Director Karl Erik Lund:**
  - “The use of snus has not increased overall tobacco consumption but has reduced cigarette smoking in Norway, and this has happened without people becoming new users.”
  - “If the aim is to reduce tobacco-related mortality, letting snus compete with cigarettes is a good idea.”
  - “The aim should be to combat mortality, and there both snus and electronic cigarettes can play a role.”
Establishes a process for a company to submit a scientific evidence-based application.

Application must demonstrate reduced risk to the individual and benefit to the public health.

Swedish Match submitted a MRTPA on June 6. If FDA determines it is complete it will become publicly available and will be reviewed by the Tobacco Product Scientific Advisory Committee.
**Review of Three Types of Nicotine Delivery Products**

- **NRT: Regulated as a drug, a smoking cessation device**
  - There is an abundance of evidence
  - Has not been overly successful as a cessation aide
  - Manufacturers can seek a harm reduction label

- **Swedish snus: Seeking MRTP status**
  - Abundance of human health evidence
  - Very popular among men in Sweden and Norway
  - Less successful in the US
  - Will label change result in switching?

- **E-cigs**
  - Very popular
  - Very limited evidence
  - Uncertain regulatory status
There is now a long history of public health organizations promoting the message that tobacco kills, with no differentiation between smoked and smokeless products.

There has been little said about the impact of nicotine, other than it is highly addictive.

FDA CTP has been issuing subtle messages:
- CTP Director Mitch Zeller publicly uses the phrase (first stated by researcher Michael Russell in the mid-1970s) “people smoke for the nicotine but die from the tar.”
- He has said everyone, including regulators, should recognize that there is a continuum of risk in different tobacco products.
- He has cited the reduced individual risk scenario of a smoker switching to a smokeless product.
- In the preamble to the e-cigs draft deeming regulations there is statements about harm reduction and continuum or risk, prefaced by “some believe …”
Those who follow the FDA process can detect the subtle change in messages.

But the smoker who is considering e-cigs just wants to know: Should I try this product? Are there health risks? Is it better than smoking?

FDA cannot directly answer those questions because there is a regulatory science process that must be followed; and there is limited evidence on the health effects of e-cigs.
If there were no regulatory concerns, what are the science based messages to be communicated?

- Nicotine is addictive but it is the smoke that causes disease.
- Thus, it is significantly less risky to use a smokeless product than smoke.
- But use of tobacco or nicotine products of any type should be discouraged
What is the Consumer Risk Perception?

- Norwegian studies indicate those who switch from smoking to snus understand there is a risk reduction but do not understand the full extent of risk reduction.

- Swedish Match premarket consumer perception study prepared for the MRTPA indicates findings similar to the Norwegian studies.

- Public health agencies in Sweden and Norway do not encourage switching from cigarettes to snus (they encourage quitting tobacco use.)

- There is no snus advertising in Sweden and Norway.

- Whereas in the US there is television advertising for e-cigs
Questions

- Should FDA be more aggressive about communicating the science of nicotine?
- Should FDA be more aggressive about communicating the Swedish and Norwegian snus experiences?
- Should e-cigs advertising be banned?
- Should there be stringent e-cigs regulations?