PERSPECTIVES ON NICOTINE SCIENCE AND POLICY: ARE WE HAVING THE RIGHT DEBATE?

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March 2, 2016
OVERVIEW OF TODAY’S PRESENTATION

- Implementing the Tobacco Control Act
- Comprehensive FDA-wide nicotine policy
- Perspectives on nicotine
- Are we having the right debate?
IMPLEMENTING THE TOBACCO CONTROL ACT
ACTING TO IMPROVE PUBLIC HEALTH

- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harm and addictiveness
CTP has authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah
Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard.

Take into account the benefits and the risks to both users and non-users of tobacco products.

Assess the “net” population-level health impacts of tobacco products.
FDA must set policies that assess “net” population-level impacts in order to:

• Encourage all tobacco users to quit tobacco use
• Understand the impact of addicted smokers unable or unwilling to quit who switch completely to tobacco products that pose less risk
• Encourage all manufacturers to use innovation to develop tobacco products proven to reduce risk and exposure
COMPREHENSIVE FDA NICOTINE
REGULATORY POLICY
Establish an integrated, FDA-wide policy on nicotine-containing products that is public health-based

Understand implications for tobacco, drug, and device regulatory policy
LOOKING AT TOBACCO, DRUGS AND DEVICES DIFFERENTLY

- Related actions include:
  - Develop FDA-wide jurisdiction policy on nicotine-containing products
  - Work with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
  - Explore options at CTP for an expedited premarket review policy based on principle of relative toxicity and risk
  - Finalize Deeming regulation
In 2013, CDER issued a Notice of Finding announcing that certain statements set forth in the FDA-approved labels of over-the-counter nicotine replacement therapy products, related to concomitant use with other nicotine-containing products and duration of use, could be modified:

- Simultaneous use of OTC NRT products with cigarettes or other nicotine-containing products does not raise significant safety concerns.
- No identified safety risks associated with use of NRTs for periods longer than 12 weeks.
- Although any nicotine-containing product is potentially addictive, NRT products sold OTC do not appear to have significant potential for abuse or dependence.
ALTERING PERSPECTIVES ON NICOTINE
LOOKING AT NICOTINE DIFFERENTLY

- Recognize that there is a continuum of nicotine-containing products
- Understand that people smoke for the nicotine but die from the tar
- Acknowledge public health opportunity
Concerns about nicotine and teens include...

- Nicotine is never safe for non-users
- Nicotine is a highly-addictive drug that can re-wire a teen’s developing brain to crave more nicotine, thereby creating an addiction
- The impact of nicotine on cognitive development in a teen’s brain includes effects on judgment and reasoning
- The earlier a teen becomes addicted to nicotine, the harder it will be for them to quit
Concerns about the toxic mix of chemicals...

- The nicotine in tobacco products creates and sustains addiction
- But smokers don’t ultimately die directly from the nicotine
- So it’s more about the toxic chemicals that come along with the nicotine than the drug
- But the drug itself is not benign, and youth and pregnant women, in particular, should not be using nicotine in any form
- Nicotine-containing products should not be packaged and marketed in ways that appeal to youth and encourage trial by kids
- Kids are using flavored e-cigarettes at alarming rates; and citing flavors as the Number One reason for usage
ACKNOWLEDGING THE NICOTINE REALITY

What about nicotine and people who are addicted?

• Nicotine has been marketed as a “safe and effective” medication for 30 years; so safe that a prescription is not required for gum, patch or lozenge forms
• So it’s not the drug...it’s the delivery mechanism
• The disease and death is primarily due to combustible tobacco
• So if Michael Russell was right 40 years ago, how should we be thinking about nicotine today?
ARE WE HAVING THE RIGHT DEBATE?
Smoking, Vaping and Nicotine

“We need a national debate on nicotine,” said Mitch Zeller.

Race to Deliver Nicotine’s Punch, With Less Risk

By BARRY MEIER   DEC. 24, 2014

The Opinion Pages

Nicotine Without Death
DEBATING THE WRONG THING?

• Current debate has been about e-cigarettes
  – Emotional
  – Divisive
  – Value-laden
  – Filled with misperceptions about nicotine safety
• Is the real need for society to grapple with profound questions about nicotine itself?
  – Longer-term use for those who may need it
  – Potential need for a transitional period of dual use; but for how long?
  – Unintended consequences (e.g. youth initiation, diminished interest in quitting because of dual use)
  – Revised labeling and indications for medicinal nicotine
• Where does the principle of harm reduction come in?
SEARCHING FOR COMMON GROUND

• Progress since the first Surgeon General’s Report 50 years ago
• But 90% of all smokers started before age of 18 and half become addicted before they are old enough to legally buy tobacco
• Tobacco use, overwhelmingly because of combustion, remains the leading cause of preventable disease and death in the country and the world
• What will it take to change this trajectory?
• Are there principles that could unify us rather than perpetuate the e-cigarette debate?
THANK YOU

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• HOW SCIENCE INFORMS FDA’S REGULATORY DECISIONS – TODAY @ 4:45 PM
• PUBLIC HEALTH THEME LECTURE – FRIDAY @4:30 PM