CTP PERSPECTIVES ON NICOTINE POLICY

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September 20, 2016
OVERVIEW OF TODAY’S PRESENTATION

• **Nicotine: A Look Back**
  - The Particle Size Dilemma: Phillip Morris Research
  - What the Industry Knew and When They Knew it

• **Nicotine: A Look Forward**
  - Comprehensive FDA-wide Nicotine Policy
  - Altering Perceptions on Nicotine: Are We Having the Right Debate?
NICOTINE: A LOOK BACK

Through the Eyes of the Tobacco Industry
SIZE MATTERS: PHILIP MORRIS RESEARCH INTO THE PARTICLE SIZE DILEMMA
• Two Philip Morris officials “requested, during a visit to Battelle, that a proposal be prepared for a study of practical methods whereby the particle size of cigarette smoke might be altered to minimize lung retention.”

• “…this proposal describes the general plan of research that would be followed when attacking the problem of altering the particle size of cigarette smoke with a view to reducing lung retention.”

*From “Development of Practical Methods for Modifying Cigarette Smoke to Give Minimum Lung Retention” (Bates Number 1001800978-1001800989)
PARTICLE SIZE RESEARCH: WHY?

• “Cigarette smoke is comprised largely of particles approximately 1.0 micron in diameter, a size that is near the optimum for retention in the lungs.”

• “The particle size of about 1.0 micron is undesirable in that the retention of tar particles is high, but desirable in that there is maximum retention of physiologically active components.”

• “Moreover, one must preserve the physiological response. If the size of the smoke particles were to be changed, alternative means might be required to increase the alkaloid content in the smoke.”
• “If we can modify this system, which way should we modify it? Do we want the particle size larger, or do we want it smaller?”
• “The question is which way we want to go? I am not prepared to state which way we want to go at this point.”

*From “Formation of the Cigarette Aerosol” (Bates Number 2021656381-2021656394)
• “...consideration might be given to the concept of developing what might be termed an instant cigarette where the physiologically active components, along with the appropriate odoriferous constituents and other casing agents, might be dispersed in the form of an aerosol through a metered device in such a way as to simulate a puff of a cigarette.”

*Letter from Battelle’s Chief Chemical Consultant to Philip Morris’ Vice President for Research (Bates Number 1000325557-1000325558)
• “...such a technique *would require an understanding of some of the addictive aspects of nicotine and of the associated alkaloids.* With the background which is being built up on psychic drugs, I am sure that you will agree that *the important consideration is not tobacco but the reaction resulting from the nicotine.*”

• “Still another feature which may prove valuable in this consideration is the knowledge which your laboratory and ours have been accumulating on the size of the aerosol in smoke. *In order to get the physiological reaction, it will be extremely important to have the particle size such as to yield rapid absorption through the lung.*”

(*Emphasis added)
“Such a device naturally could be used to rationalize schemes on cutting down the number of cigarettes. As long as the system achieved its quota of nicotine, it would make little difference whether the alkaloid was secured from smoke or from a mist.”

(*Emphasis added)
WHEN WAS THIS?

• Battelle began the particle size research described here as early as 1957
• The Battelle proposal was submitted in 1959
• The Philip Morris internal discussion over which way to go was in 1959
• And the Battelle musings on something sounding very much like a prototype for the e-cigarette was in 1959
WHAT THE INDUSTRY KNEW ABOUT NICOTINE AND WHEN
“Nicotine is addictive. We are, then, in the business of selling nicotine – an addictive drug.”

- Brown and Williamson (1963)
“The cigarette should be conceived not as a product but as a package. The product is nicotine...Think of the cigarette pack as a storage container for a day’s supply of nicotine...Think of a cigarette as a dispenser for a dose unit of nicotine. Think of a puff of smoke as the vehicle of nicotine.”

- Phillip Morris (1972)
“In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects.”

- R. J. Reynolds (1972)
“BAT should learn to look at itself as a drug company rather than as a tobacco company.”

- British American Tobacco (1980)
“The entire matter of addiction is the most potent weapon a prosecuting attorney can have in a lung cancer/cigarette case. We can’t defend continued smoking as ‘free choice’ if the person was ‘addicted’.”

- The Tobacco Institute (1980)
How Should FDA and Society Think About Nicotine?
COMPREHENSIVE FDA NICOTINE REGULATORY POLICY
LOOKING AT TobACCO, DRUGS ANd DEVICES DIFFERENTLY

• 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:
  – Published Jurisdictional proposed rule to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product
  – Working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
  – Finalized Deeming regulation
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

So if Michael Russell was right 40 years ago, how should we be thinking about nicotine today?
ACKNOWLEDGING THE NICOTINE REALITY

Nicotine delivery to addicted adults can come in safer forms...

• 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 combusted tobacco
• The deadliest form of delivery (cigarettes) is legal and will remain legal
But 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 earlier a teen becomes addicted to nicotine, the harder it will be for them to quit
- 90% of the users of the deadliest nicotine-delivering products (cigarettes) start as kids
Our responsibility is to assess the “net” impact on the population...

• Potential benefit to currently addicted smokers unable or unwilling to quit who completely substitute
• Clear harm from any initiation by kids; unknown “gateway” effect of starting on “less harmful” product
• Unknown longer-term impact of dual use rather than complete substitution to lower risk products
• Unknown impact on cessation rates
ALTERING PERCEPTIONS OF NICOTINE: ARE WE HAVING THE RIGHT DEBATE?
OPINING ON NICOTINE

Smoking, Vaping and Nicotine

Joe Nocera  MAY 26, 2015

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?
  – Can longer-term use for those who need it be accepted?
  – What about recreational use for adults who may want it?
  – Can a short transitional period of dual use be ok? Or a long period?
  – How much youth initiation can we tolerate?
  – How much weight should diminished interest in quitting play?
  – Can we revise labeling and indications for medicinal nicotine to increase quitting?
  – 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 start, 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