The role of regulatory science in reducing the public health impact of tobacco use

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American Chemical Society Fall Meeting, Indianapolis, September 9th, 2013
Overview

• Tobacco use and health

• Potential for reducing the public health impact of tobacco use

• Regulatory science

• The role of the regulated industry
Tobacco use and health

• Smoking is a major cause of many fatal diseases, including lung cancer, chronic obstructive pulmonary disease and cardiovascular disease

• Epidemiologic studies show dose-response relationships

• Smoking is addictive
The British Doctors

“…smoking is a factor, an important factor, in the production of carcinoma of the lung…”

1950
Doll-Peto curves for smoking cessation
The public health impact of tobacco and nicotine use

“Over the course of the 21st Century, tobacco use could kill a billion people or more unless urgent action is taken” WHO report on the global tobacco epidemic, 2011: warning about the dangers of tobacco

Prof Michael Russell wrote in 1976: "People smoke for nicotine but they die from the tar." M. Russell, British Medical Journal 1:1430-33, 1976

“Extensive experience with nicotine replacement therapy in clinical trial and observational study settings demonstrates that medicinal nicotine is a very safe drug.” Royal College of Physicians, Harm reduction in nicotine addiction, 2007

“Nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death.” UK National Institute for Health and Care Excellence (NICE): Tobacco: Harm reduction approaches to smoking, June 2013
Lung Cancer Deaths, Men Age 40+, Europe 2000

WHO-IARC Worldwide Cancer Mortality Database

Deaths per 100,000 men-years
Nicotine harm continuum

Combustible tobacco products

Cigarettes
Cigars
Pipes

Chewing tobacco
Tobacco gum
Snus

E-cigarettes
NRTs

Most dangerous

Least dangerous

US FDA and the Family Smoking Prevention and Tobacco Control Act

• Introduced June 22, 2009
• Regulates the manufacture, distribution and marketing of tobacco products to protect public health
• Regulates to a population health standard
• Has set up and staffed an Office of Science, and has set research priorities
• Funding, with NIH, a large body of regulatory science
US FDA Center for Tobacco Products (CTP) research priorities 2012/13

“Although a vast and sound science base exists with regard to numerous areas of the TCA, new research will provide scientific evidence in several areas. Research areas include:

- understanding the diversity of tobacco products,
- reducing addiction to tobacco products,
- reducing toxicity and carcinogenicity of tobacco products and smoke,
- understanding the adverse health consequences of tobacco use,
- understanding communications about tobacco products,
- understanding tobacco product marketing, and
- understanding how economics and policies affect tobacco product use.”
Some of the science-based issues being considered by FDA CTP

• Mentholated cigarettes

• Harmful and potentially harmful constituents

• Regulating other tobacco products, including e-cigarettes

• Modified risk tobacco products (MRTPs)
FDA CTP method of collecting and using science

• Know what’s known
  – Public comment opportunities
  – Workshops

• Distil what is known into useable information
  – Tobacco Products Scientific Advisory Committee
  – CTP science reviews, eg menthol

• Identify and fund new research
  – Population assessment of tobacco and health (PATH)
  – Research into communicating harmful and potentially harmful constituents
  – Tobacco regulatory science programme (with NIH)
US FDA workshop on MRTPs

- In August 2011 the US FDA held a public workshop on MRTPs

Panel 2: Comparisons of MRTPs to other Products

David Burns, M.D.
Timothy McAfee, M.D., M.P.H.
Christopher Proctor, Ph.D.
Lars E. Rutqvist, M.D., Ph.D.
Karla Sneegas, M.P.H.
Role of the regulated industry in the development of regulatory science

• Contribute knowledge

• Help develop standard test materials

• Fund research, and be part of funded research
Conclusions

• US FDA support the use of science in regulatory decision making

• In the case of tobacco, FDA Center for Tobacco Products are investing considerable resources into building a science base

• The regulated industry should assist the regulator in this effort