Integrating Science into the FDA Center for Tobacco Products

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Disclosures

Since leaving Federal Service, I have received funds for work done

- as a research professor at Georgia State University
- as an independent contractor for CDC through McKing Consulting and Cherokee National Operational Systems
- for the World Health Organization Tobacco Free Initiative
- as a Special Government Employee of the U.S. Food and Drug Administration
- and as a consultant for Pfizer

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Background

- Family Smoking Prevention and Tobacco Control Act signed into force in June 2009
- I joined CTP as Director of the Office of Science in June 2010
- When I joined, CTP had about 40 employees, 15 in Office of Science
- When I retired in 2017, CTP had about 800 employees, 325 in Office of Science

The starting point

Regulatory language in the Family Smoking Prevention and Tobacco Control Act (TCA)

Timeline of required deliverables

Adequate funding, Insufficient staff

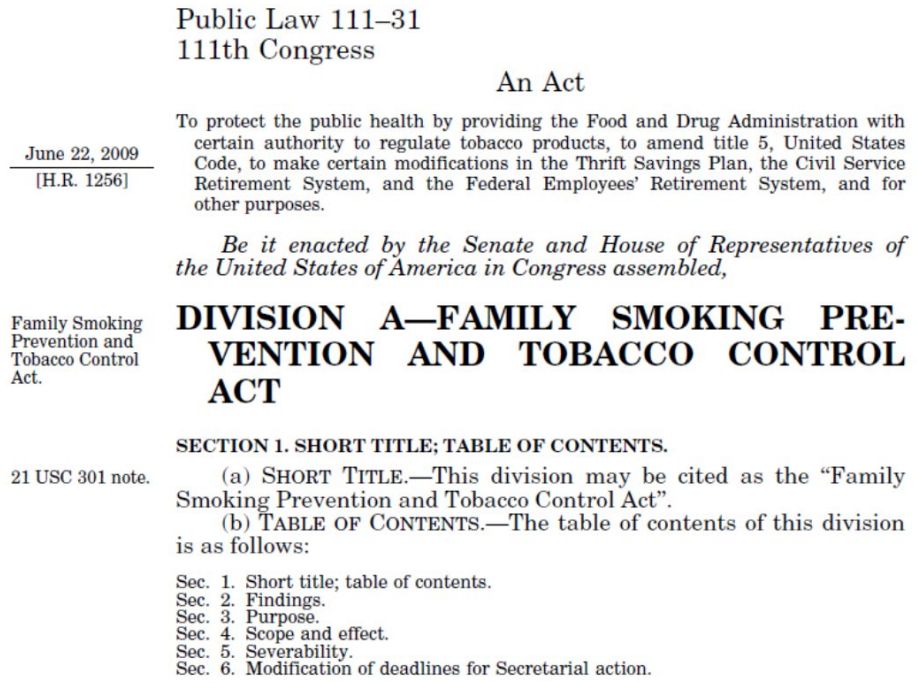
A few limitations to authority

- Cannot ban certain products
- Cannot require nicotine be reduced to zero
- Cannot set indoor air policies
- Cannot set tax rates
- Cannot regulate tobacco growing

Scientific foundation in Tobacco Control

Accessible scientific expertise

Complex policy questions



Public Law 111–31
111th Congress

An Act

June 22, 2009
[H.R. 1256]

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Family Smoking Prevention and Tobacco Control Act.

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

21 USC 301 note.

(a) SHORT TITLE.—This division may be cited as the "Family Smoking Prevention and Tobacco Control Act".

(b) TABLE OF CONTENTS.—The table of contents of this division is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Scope and effect.
Sec. 5. Severability.
Sec. 6. Modification of deadlines for Secretarial action.

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The TCA Outlined Primary Tasks for CTP

Conduct research to understand the regulated product

Disseminate guidance to explain FDA thinking

Develop product standards to reduce harm

Conduct product review to restrict product changes and limit modified risk claims

Carry out compliance and enforcement to require adherence with the law

Educate the public on the hazards of tobacco use

Approach to meeting the objectives

Long-term objective – keep this set as the target

Appropriate for the Protection of Public Health

Short term goals – sketch out timeline

Balance long-term and short-term objectives while not allowing the immediate to overly distract from the long-term objective

Utilize all scientific expertise together to inform questions

Establish a research program and encourage new experts to generate evidence beyond what had been done before

OS Structure

Research
Knowledge Development
Regulatory Management

- Product
  - Chemistry
  - Engineering
  - Microbiology

Substantial equivalence

- Tobacco Product User
  - Toxicology
  - Pharmacology
  - Clinical medicine
  - Addiction
  - Product use behavior

New product review

- Population as a Whole
  - Environmental assessment
  - Epidemiology
  - Consumer perception
  - Statistical analysis
  - Evaluation

Modified risk products

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Resource utilization

Partner with others to maximize scope of impact

- National Institutes of Health – Research administration
- CDC – Epidemiological surveys
- Sandia National lab – Population modeling

Impact on tobacco regulatory science research

- Population Assessment of Tobacco and Health Study
- Society for Research on Nicotine and Tobacco
- Tobacco Regulatory Science Conferences

Personnel Integration

Tobacco science, Regulatory science, Scientific disciplines

CDC

FDA

NIH

Other agencies

Multi-functional assignments:

Product standards, product review, knowledge development, research

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Policy Development Growing Pains

Other agencies - Other FDA centers, CDC, NIH, EPA

Use the experiences of others to inform CTP decision-making

Creating a CTP/OS culture

Set the policy bar for authorization and other decisions to meet the primary objective

Tobacco Products Scientific Advisory Committee

Utilize outside expertise to provide a fuller perspective and avoid groupthink

FDA Office of Chief Counsel

Treat lawyers as partners to integrate public health science and law maximizing effectiveness while still meeting the requirements of the law

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Building toward the goal

Remain focused on the long-term objective

Create partnerships

Make every decision based on evidence

Encourage excellence

Create a team culture

Learn from mistakes

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Questions?

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