Tobacco Control: A Congressional Perspective

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Generating Science to Drive Comprehensive Tobacco Control Policy: Creating a Research Blueprint

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Background

- **Counsel, House Committee on Oversight and Government Reform**
- **Rep. Henry Waxman, Chairman**
- **Speaking in my personal capacity**

The Family Smoking Prevention and Tobacco Control Act of 2007

- **Legislation to give the Food and Drug Administration authority over tobacco products**
- **Introduced in the House (H.R. 1108) and Senate (S. 625) in February 2007**
- **Passed by the Senate committee (HELP) in August and currently pending in the House committee (Energy & Commerce)**

Basics of the Legislation

- **Amends the Federal Food Drug and Cosmetic Act (FFDCA)**
  - **Adds a new, separate chapter on tobacco**
- **Restores the regulatory authority asserted by FDA in the 1990s and found lacking by the Supreme Court in 2000, reinstating final FDA rule**
- **Complex, comprehensive legislation**

Core Components of the Bill (A Whirlwind Tour)

- **Sales and Promotion Restrictions**
- **Warning Labels**
- **Information Reporting**
- **Product Standards**
- **Modified Risk and Modified Exposure**
- **User Fees**
- **Limits on FDA authority**
- **Effect on state authorities**

New Chapter of the Act

- **Unlike the approach tried by FDA in the 1990s, does not regulate tobacco under drug or device sections of the Act**
- **Allows for a more appropriate regulatory standard, tailored to the tobacco context — a legal, lethal product to which millions are already addicted**

Sales and Marketing Restrictions (Sections 101, 102)

- **Drastically limits youth access**
- **Gives FDA authority over retail sales**
- **Means better enforcement, stronger penalties**
- **Bans outdoor advertising near schools and sponsorship of sports/entertainment events**
- **Bans vending machine and self-service sales, coupons and product giveaways**
- **Black-and-white text only in outdoor and point-of-sale advertising and in publications with significant youth readership**

Warning Labels (Section 201)

- Replaces existing warning labels, not updated in over 20 years
- Establishes nine new, stronger warnings on cigarette packs and in cigarette ads
- Dictates size and placement to ensure prominence
- Mandates quarterly rotation of warnings in cigarette advertisements, to preserve impact
- Authorizes FDA to require graphic warning labels
  - Senate bill as amended mandates graphic warning labels

Information Reporting (Section 904)

- **Key component — gets too little attention**
- **Requires manufacturers to submit information on product contents and emissions, by brand, by quantity**
- **Permits FDA to request information from manufacturers on research into health effects, modified risk products/technology, and marketing**
  - **Will complement and inform ongoing work of NIH, CDC and many others**

Product Standards (Section 907)

- **New regulatory approach: FDA may establish tobacco product standards as "appropriate for the protection of the public health"**
  - **Differs from traditional FDA standard for drugs and devices: "safe and effective"**
- **Bans flavorings in cigarettes, including fruit flavors, spices and cloves (but not menthol)**
- **Gives FDA authority to ban menthol**

Product Standards (cont'd)

- **Authority might be used by FDA in several ways:**
  - **Reduce addictiveness of products**
    - **Control levels of nicotine (including"free nicotine")**
  - **Reduce appeal of products**
    - **Restrict cooling agents, flavorings**
  - **Reduce toxicity of product constituents and emissions**
  - **Reduce product ignition propensity**

Claims of Reduced Harm and Reduced Exposure (Section 911)

- **Prohibits claims of reduced harm or reduced exposure unless specifically permitted by FDA on the basis of sound scientific evidence**
  - **Major departure from status quo**
  - **Covers both express and implied claims**
  - **Prohibits specific descriptors: "light," "mild," "low" and similar terms**
- **Requires analysis of both the scientific accuracy of a claim and its likely impact on public**
  - **FDA must assess population-wide impact, as well as individual**

Claims of Reduced Harm and Reduced Exposure (cont'd)

- **Imposes different standards for reduced harm and reduced exposure claims**
- **Allows for ongoing evaluation of emerging science and technologies**
- **Allows FDA to approve reduced harm or reduced exposure claims for existing products such as smokeless tobacco, but not automatic**

User Fees (Section 920)

- **Fully funds tobacco programs through industry user fees**
- **User fees apportioned based on market share, by product (cigarette, snuff, etc.) and by brand (Marlboro, Camel, etc.)**
- **$85, $175, $300 million in first three years, then amounts rise yearly based on automatic inflator**
  - **Amounts in Senate bill as amended slightly higher: $85, $235, $450 million**

Limitations on FDA Authority

- **FDA cannot ban tobacco products completely**
- **FDA cannot reduce the level of nicotine in tobacco products to zero**
- **FDA cannot raise the minimum age of purchase above 18**
- **FDA cannot ban all tobacco advertising and promotion (First Amendment)**

Effects on State and Local Authority (Section 917)

- **Expressly preserves most state authorities**
- **Restores states' authority to regulate time, place and manner of tobacco marketing and promotion, previously stripped by the courts**
- **Preserves states' authority to ban all tobacco sales**
- **Preserves states' authority to restrict tobacco sales to licensed retailers, cap the number of retailers and impose additional limits on access**
- **Prohibits conflicting performance standards or warning labels**

Criticism of the Bill and Responses

- **Inconsistent with FDA's mission — FDA should not oversee a product that is lethal when used as intended**
- **FDA's mission is to "protect and promote the public health" — regulation of tobacco falls squarely within that mission**
- **FDA lacks resources for the job — already overburdened and underpaid**
- **All tobacco activities at FDA will be fully funded by industry user fees and will not draw on existing resources**

Criticism and Responses (cont'd)

- **Regulating tobacco is too complex for FDA — risk of unintended consequences**
- **FDA has unparalleled expertise and experience. Moreover, FDA is the primary federal agency charged with protecting the public health. If FDA doesn't do this, it won't get done. If it doesn't get done, we continue with the status quo, which is unacceptable.**
- **The bill should make it easier/harder for products to be promoted as "reduced harm" or "reduced exposure"**
- **The bill strikes the right balance between encouraging harm reduction and protecting the public from misleading claims**

Criticism and Responses (cont'd)

- **Philip Morris supports it**
  - **PM supports the bill because it will lock in its dominant market share**
  - **PM supports the bill because it is a weak bill**
  - **PM supports the bill solely to improve its public image**
- **Whatever the reasons for PM's position, many experts, including the National Institute of Medicine, agree that FDA regulation is critical to reducing the toll of tobacco. It's not a perfect bill, but it's a good bill, and the alternative is unacceptable.**

Summary and Conclusions

- **Comprehensive federal oversight of the tobacco industry for the first time in history**
- **A tremendous achievement for the public health, but only the beginning of the next chapter on tobacco control**
- **Success will rely on experts like those in this room**
- **Not assured of passage but chances are good**
- **Possible House markup in December, then the House floor, Senate floor, conference, the White House….**
- **Every bit helps — contact your representatives (if you live outside the District of Columbia)**

Further Information

- **For more information on the bill, go to:**
  - http://thomas.loc.gov/ **(bill text and status)**
  - http://www.henrywaxman.house.gov/ **(background and related information)**

- **Contact information:**

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