

A Look Back: A Brief History of Tobacco Control



MDQuit Best Practices Conference

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January 23, 2014

History of FDA Regulation of Tobacco Products (pre-FSPTCA)

Pre-1996

No regulation.

1996

FDA Commissioner, David Kessler, issues regulations imposing sales and advertising restrictions on cigarettes and smokeless tobacco.

2000

Supreme Court decides *FDA v. Brown and Williamson*, holding that the agency lacked power to regulate tobacco products. 1996 regulations invalidated.

History of Tobacco Regulation

- ▶ Prior to FDA intervention, Congress and the states oversaw tobacco products.
- ▶ **Federal Cigarette Labeling and Advertising Act (1965)**
 - Warning Labels mandatory on all cigarette packs
 - *Caution: Cigarette Smoking May be Hazardous to Your Health*
 - **Note:** Other health warnings prohibited
 - Prohibited warning labels on cigarette advertisements (for three years)
 - State and local governments preempted from regulating the advertising or marketing of tobacco products

History of Tobacco Regulation

▶ Public Health Cigarette Smoking Act (1969)

- Required package warning label – *Warning: The Surgeon General Has Determined that Cigarette Smoking is Dangerous to Your Health* (other warnings prohibited)
- Prohibited cigarette advertising on TV and Radio
- Prevents states or localities from regulating or prohibiting cigarette advertising or promotion for health-related reasons

▶ Comprehensive Smoking Education Act (1984)

- Requires four rotating health warning labels:
 - Smoking causes lung cancer, heart disease and may complicate pregnancy
 - Quitting smoking now greatly reduces serious risks to your health
 - Smoking by pregnant women may result in fetal injury, premature birth, and low birth weight
 - Cigarette smoke contains carbon monoxide

▶ Comprehensive Smokeless Tobacco Health Education Act (1986)

- Prohibits smokeless advertising on television and radio
- Requires warning labels on smokeless packages and advertisements
- **Note:** First SGR on smokeless tobacco was also released in 1986

1996 FDA Regulations

- ▶ FDA claimed authority over cigarettes and smokeless tobacco because:
 - Nicotine is a drug within FDCA; AND
 - Cigarettes and smokeless tobacco are drug delivery devices
- ▶ FDA promulgated regulations restricting cigarette/smokeless tobacco advertising, labeling and youth access
- ▶ Summary of Regulations:
 - Must be 18 w/valid license to purchase
 - Cigarettes must be sold in packs of at least 20
 - No free samples
 - No self-service displays or vending machines

FDA v. Brown and Williamson

- ▶ Group of tobacco advertisers, manufacturers and retailers bring suit (in N.C. district court) challenging FDA authority to regulate tobacco products as customarily marketed. Also, claim advertising restrictions violate 1st Amendment
- ▶ **District Court** – found FDA had authority to regulate tobacco products, but advertising restrictions violated 1st Amendment
- ▶ **4th Circuit Court of Appeals** – Reversed decision stating Congress did not grant FDA jurisdiction to regulate tobacco products

FDA v. Brown and Williamson: Supreme Court Decision

“Viewing the FDCA as a whole, it is evident that one of the Act’s core objectives is to ensure that any product regulated by the FDA is ‘safe’ and ‘effective’ for its intended use.”

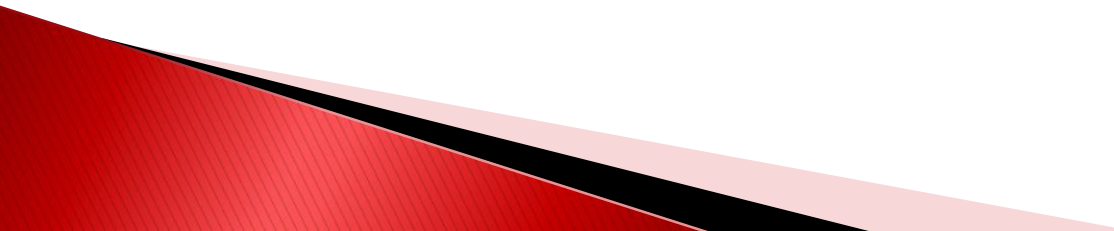
“[T]he Act generally requires the FDA to prevent the marketing of any drug or device where the ‘potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.’”

FDA v. Brown and Williamson: Supreme Court Decision

Court Reasoning:

- ▶ If the FDA had authority to regulate tobacco products, the agency would have to ban their marketing and sale because they are **not safe** and the **harm of use vastly outweighs any therapeutic benefit** (because there is none).
- ▶ Congress passed several laws relating to tobacco products (i.e. FCLAA—warning labels), and therefore did not intend for tobacco products to be banned.
- ▶ Congress considered and rejected several bills granting FDA authority over tobacco products
- ▶ Prior to 1995, FDA repeatedly stated it did not have jurisdiction to regulate tobacco products

Post-*Brown and Williamson*

- ▶ **2001**: Kennedy-DeWine Bill introduced in Congress; failed to get out of committee
 - ▶ **2004**: Kennedy-DeWine Bill PASSES SENATE
 - ▶ **2007**: Kennedy-DeWine Bill PASSES key House Committee
 - ▶ **2008**: House Bill passes but too late for Senate to pass
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Tobacco Control Act

- ▶ TCA grants FDA authority over tobacco and re-imposes 1996 regulations
 - Cigarettes must be sold in packs of at least 20
 - Must be 18 w/valid ID
 - No free samples
 - No self-service displays)
- ▶ **Additional Restrictions:**
 - Prohibits sale of flavored cigarettes
 - Eliminates use of terms Light, Mild, Low Tar, etc.
 - Allows for state and local regulation in most areas, reserving only certain products standards/new product approval/reduced harm product regulation exclusively for FDA. (**Note:** Reverses comprehensive preemption clause since 1965)