FDA Regulation of Tobacco Products: Past, Present and Future

MDQuit Best Practices Conference
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Presentation Overview

- Overview of FDA Tobacco Control Authority
- FDA Proposed "Deeming Regulation"
- What Does the Proposed Rule Mean for Electronic Cigarettes?
- What's Next for the FDA?
- What's Left for State/Local Policymakers?

FDA and Tobacco Control

- Until 2009, tobacco was regulated by a handful of federal statutes and otherwise under the discretion of individual states
- Tobacco Control Act (2009) gave FDA authority over any **tobacco product**, meaning "*any product made or derived from tobacco that is intended for human use*." *FD&C Act*
- However, the Act, when passed, only immediately applied to four specific products:
  - Cigarettes,
  - Cigarette tobacco,
  - Roll-your-own tobacco and
  - Smokeless tobacco
- To regulate any other product FDA must assert jurisdiction through agency regulation, or "deem" the product as subject to the entire Act or any of its parts
- What is an agency regulation or rule? And what is its effect?

Federal Agency Rulemaking Process

- **What is an agency regulation? How does it differ from a statute?**
  - A regulation is a detailed rule, which has the effect of law, outlining how statutes will be implemented
  - Unlike a statute, which is a law passed by a democratically elected legislature (i.e. Congress), a regulation is created by unelected administrative agencies like FDA
  - Statutes are often vague or broad, and regulations represent an agency's interpretation of the statute
  - Tobacco Control Act → Congress gave FDA authority to regulate tobacco products, but gave very little substantive direction; left substantial discretion up to agency

Proposed "Deeming" Regulation

- After nearly 5 years, on April 24, 2014 FDA issued the Notice of Proposed Rulemaking (NPRM) that "deems" anything meeting the statutory definition of a tobacco product as subject to the Tobacco Control Act

- Products to now be regulated include:
  - electronic cigarettes,
  - cigars,
  - little cigars,
  - pipe tobacco,
  - nicotine gels,
  - waterpipe (or hookah) tobacco, and
  - dissolvables

- So what does it mean that these products will now be regulated?

FDA "Deeming" Regulation

- The Tobacco Control Act requires the FDA to adopt certain requirements for **ALL** tobacco products under its authority, but **MOST** authority is discretionary
- Essentially, short of banning these newly deemed tobacco products or completely removing nicotine from them, FDA may regulate as they see fit
- In the proposed rule, FDA extends the same regulations to **ALL** newly deemed products

Automatic Requirements

- A manufacturer of a deemed tobacco product **MUST**:
  - Register with the FDA and report product and ingredient listings;
  - **Only market new products after FDA review (unless on market before February 15, 2007)**
  - Not make reduced risk claims without scientific data and FDA approval
  - Not distribute free samples
  - Submit data on health effects of product
  - Pay user fees (CTP is user fee funded, not taxpayer funded)

Non-Automatic Requirements

- Non-Automatic Requirements extended to newly deemed tobacco products:
  - **Minimum age (18) and ID requirements**
    - Most states (including MD) already do this
  - **Packaging must contain health warnings**
    - FDA requested public comment on acceptable warnings
  - **Vending machine sales prohibited** (unless in 18+ facility)

What does this mean for E-Cigarettes?

- **Uncertain Long-term Status**
  - All tobacco products, including e-cigs subject to pre-market approval unless:
    - The product is identical to a product on the market prior to February 15, 2007, **OR**
    - Introduction of the product is appropriate for the protection of public health (i.e. reduced harm)
  - The "grandfather" date is problematic for e-cigs because they've only recently entered the domestic market
  - FDA proposed to delay premarket approval for 2 years after regs become effective, but unclear how e-cigs will qualify under either route even after the delay
- **Manufacturers/Retailers Prohibited from Making Health Claims Without FDA Approval**
  - *Sottera v. FDA* (2009) already prohibits health or cessation claims for manufacturers; law extends to retailers

What does this mean for E-Cigarettes?

- **Administrative Burdens of Premarket Application**
  - Premarket applications are extremely expensive and time-consuming, which could thin e-cig industry
  - FDA statement: the costs of submitting premarket applications for e-cigarettes "would be high enough to expect additional product exit, consolidation, and reduction in variety compared with baseline"
  - Deep pockets = tobacco manufacturers → very real concern that FDA regs will drive independent, non-tobacco companies from the market
- **What steps did FDA not take?**
  - Ban on flavored liquid nicotine favored by youth
  - Advertising/marketing restrictions

What steps must occur for FDA to implement the deeming regulation?

- A **proposed rule**, or **NPRM** is the official document that announces and explains the agency's plan to address a problem or accomplish a goal

- **Mandatory Public Comment** period follows the NPRM – public comment closed August 8, 2014
  - *FDA received more than 130,000 comments*

- **Post-Public Comment Period**
  - Agency must use rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages to reach a final rule
  - No time limit for agency review of public comments

- **Final Rule**
  - Agency may decide to extend comment period, scrap the proposed rule, amend (and re-open for comment) or issue a final rule

So what does it all mean?

- Final rule may take a year or more
- Rule exempts e-cigarette manufacturers from pre-market approval requirements, which could mean they don't have to comply with regulations for an additional 24 mos. following the final rule
- Many important regulations, such as pack sizes and flavored bans, were not extended to any of the newly deemed tobacco products
- Rule is a step in the right direction, but many in the public health community believe the FDA should have done more

Additional FDA Activities…

What is left for FDA?

Potential Next Steps

- Graphic Warning Labels
- Advertising/Marketing restrictions for newly deemed tobacco products (i.e. e-cigs)
- Flavored Cigar or OTP Ban (including e-cigs)
- Menthol Ban
- Child-Resistant Packaging (E-Cigarettes)
- Minimum Packaging Requirements

What is left for FDA?

Long-Term Goals

- Increase Age of Purchase
- Reduce nicotine content
- Reduce/Remove non-nicotine additives

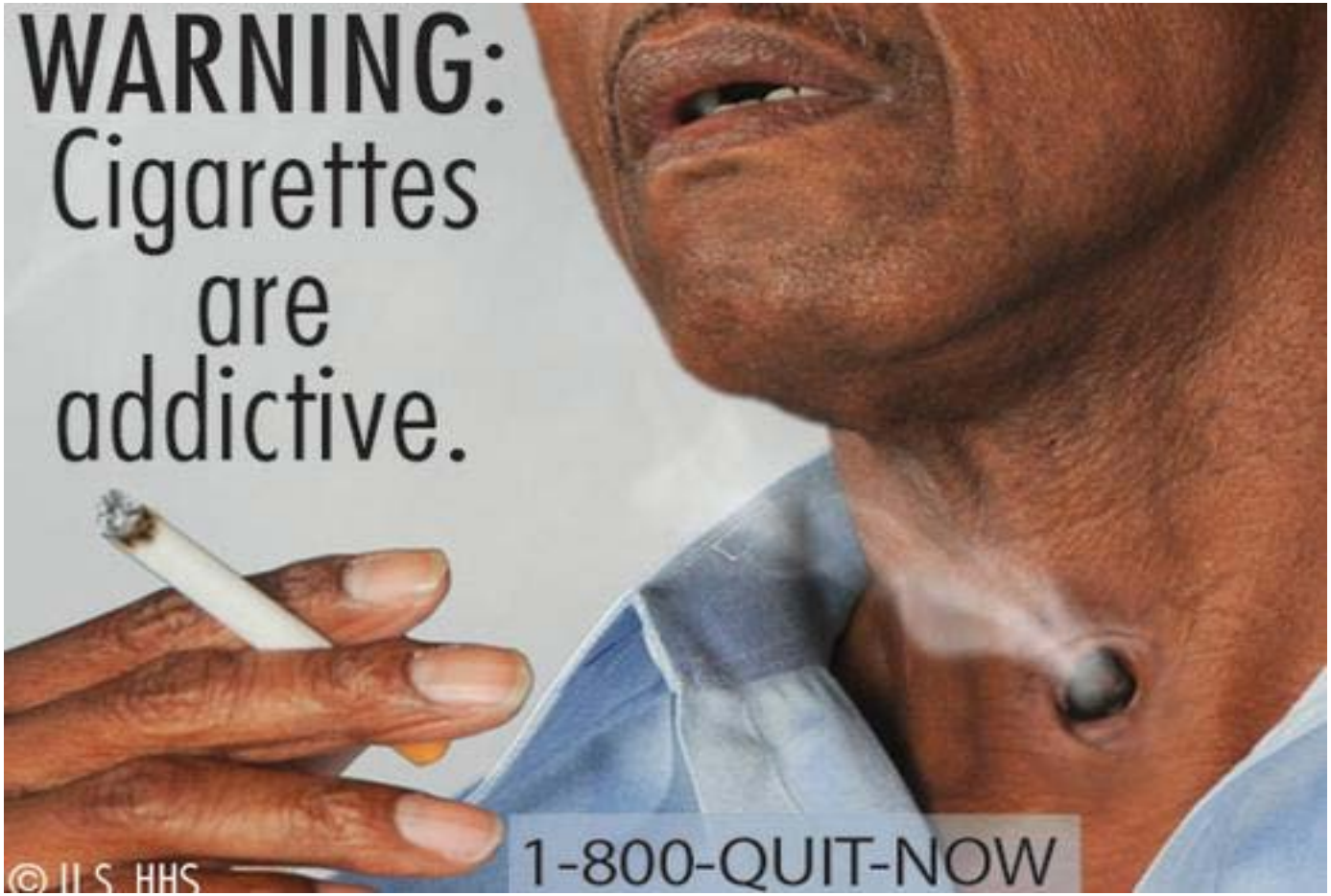
Cessation-Related Activities of the FDA

- Graphic Warning Labels
- Modified Risk Tobacco Products
- Real Cost Campaign

Graphic Warning Labels

- FSPTCA called upon the FDA to develop and mandate use of graphic warnings on ***cigarette*** packaging and advertising.

- In 2011, FDA proposed a series of graphic warnings:
  - Colored graphics;
  - 50% of package;
  - 20% of advertisements.


WARNING:
Cigarettes
are
addictive.
1-800-QUIT-NOW

WARNING:
Smoking can kill you.

WARNING:
Cigarettes cause cancer.


WARNING:
TOBACCO SMOKE CAN HARM YOUR CHILDREN.
1-800-QUIT-NOW

Graphic Warning Labels

- Sixth Circuit
  - Tobacco manufacturers challenged FSPTCA on grounds it was overly restrictive and violated 1st Amendment
  - District Court and 6th Circuit Court of Appeals held most provisions constitutional and valid, including graphic warning labels
- D.C. Circuit
  - R.J. Reynolds challenged constitutionality of FDA regulations and the specific graphic warning labels they created
  - District Court and Court of Appeals held specific warning labels chosen violate 1st Amendment rights of manufacturers
  - FDA may amend, but MUST link graphics with evidence-based effects

Graphic Warning Labels

- Expect the FDA to propose a new series of graphic warning labels perhaps sometime in 2015.

- Post-2011 research provides additional support of effectiveness of graphic warning labels.

Modified Risk Tobacco Products

- MRTP defined as “tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”
- Tobacco products may not be marketed as MRTP without FDA approval.
- FSPTCA sets forth the standard for review of an application to market a MRTP.

Standard for MRTP Approval

Application must demonstrate that the product, as used by consumers will:

- "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users;" and
- "benefit the health of the population as a whole taking into account tobacco products and persons who do not currently use tobacco products."

Factors FDA Considers

- The FDA must consider these factors in reviewing an application to market a product as an MRTP:
  - health risks of the tobacco product;
  - likelihood that users of tobacco who would otherwise stop using it would start using the product;
  - likelihood that people who do not use tobacco will start using the product;
  - risks and benefits of the product as compared to use of already-approved products to treat nicotine dependence; and
  - comments, data, and information submitted by interested persons.

MRTP Applications

- FDA has rejected many MRTP applications.
- FDA requested public feedback on the application of Swedish Match to market snus as MRTP.
  - Comments filed by LRC (Fall 2014);
  - Comment period closed in late February (though November 25 was date for commetns to be read by TPSAC);
  - TPSAC to review comments filed by many in support of and in opposition to the application and issue recommendation to CTP;
  - Anticipate decision by FDA; technically has one year to respond—but this will take some time.

Swedish Match Application

- SM requests that the company be permitted to market the listed snus products without including the two oral cancer-related labels.
- SM requests modification of another label so that it will read:
- **"No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes."**

Summary of LRC Comment

- SM's application:
  - fails to provide sufficient evidence that SM snus does not present significant health risks for individual tobacco users, particularly considering the increased health risks for dual users of snus and cigarettes and the likelihood of increased dual use in the United States;
  - fails to demonstrate that MRTP status will not increase dual use, particularly among youth users.
  - fails to establish sufficient evidence that MRTP approval will benefit the population as a whole.

FDA Action on SM Application

- FDA's response to the SM application will set the stage for the future.
- This is particularly of interest with respect to all smokeless tobacco products and to electronic cigarettes.
- Stay tuned . . .

FDA's "The Real Cost" Campaign

- FDA's first youth tobacco prevention campaign targets at-risk youth aged 12-17 who are open to smoking or already experimenting with cigarettes.
- Campaign launched nationally on February 11, 2014 via TV, radio, print, and online. The campaign will continue to air in more than 200 markets across the country for at least two years.

Real Cost Messages

- ***Loss of Control Due to Addiction***: Reframes addiction to cigarettes as a loss of control to disrupt the beliefs of independence-seeking youth who currently think they will not get addicted or feel they can quit at any time.
- ***Dangerous Chemicals:*** Depicts the dangers of the toxic mix of chemicals in cigarette smoke to motivate youth to learn about what's in each cigarette and reconsider the harms of smoking.
- ***Health Consequences:*** Dramatizes the negative health consequences of smoking in a meaningful way to demonstrate that every cigarette comes with a "cost" that is more than just financial.

TV Ads

https://www.youtube.com/watch?v=WnqZoKZuHCg&list=UUxg_kBtJtSclPreOEjRDweQ#t=17

- Amanda Green is not a kid anymore . . .
  - I agree to relinquish control to you.

https://www.youtube.com/watch?v=zhbXENhrkTA&list=UUxg_kBtJtSclPreOEjRDweQ#t=12

- Little bully

Digital Ads


See what your
SMILE COULD
LOOK LIKE...
...if you
SMOKE.
Smoking can cause yellow teeth and
serious gum disease that makes it mo
likely to lose your teeth than someone
who doesn't smoke.

Print Ads


EVEN WHEN YOU BUM A SMOKE YOU'RE STILL PAYING.
Smoking cigarettes can cause wrinkles that age you prematurely.
Find out what tobacco is costing you.
TheRealCost.gov
Brought to you by the FDA.
FDA
THE REAL COST

Full Campaign Materials

Campaign materials are available at:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/PublicEducationCampaigns/TheRealCostCampaign/default.htm

What is Outside FDA Control?

- FDA authority under the Tobacco Control Act is finite – product standards, manufacture, advertising/marketing, etc.

- So what actions are the exclusive domain of state/local governments?
  - Levy taxes on sale of tobacco products
  - License requirements
  - Ban sale, distribution or possession of tobacco products
  - Clean Indoor Air
  - Funding for tobacco prevention programs
  - Access to cessation treatment
  - Anti-smuggling/tax-evasion measures (MD criminal bill)

Presenter Information

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