



FDA'S PROPOSED "DEEMING RULE" AND ELECTRONIC CIGARETTES

THE PUBLIC HEALTH CONSENSUS



THE MEANING OF “DEEMING”

- 2009 Family Smoking Prevention and Tobacco Control Act: FDA authority over cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco.
- FDA may “deem” other “tobacco products” subject to statute.
- Broad definition of “tobacco product”: “any product made or derived from tobacco that is intended for human consumption, including any component, part or accessory of a tobacco product”

PRODUCT REGULATION

- Manufacturer registration and product listing
- Reporting of product ingredients
- Reporting of harmful and potentially harmful constituents
- Reporting of company documents on health effects of products
- FDA authority to obtain documents on company research and marketing
- Prohibition of adulteration or misbranding
- Prohibits unsubstantiated claims of modified risk
- FDA authority to impose product standards
- Premarket review of new products

The screenshot shows the V2 CIGS website interface. At the top, the logo 'v2CIGS' is displayed. Below the logo, there are navigation links: 'Shop V2', 'The V2 Experience', 'Compare V2', 'The V2 Communit', and 'Image from 1/4/2011 /2'. The main content area is divided into two sections. On the left, under 'Our Products', there are links for 'V2 STARTER KITS', 'V2 CARTRIDGES', 'V2 BATTERIES', and 'V2 ACCESSORIES'. Below this, under 'Bestsellers', there is a product listing for 'V2 Vapor Cartridges (5 Pack)' with a price of '\$42.95 \$9.95' and a star rating. On the right, there is a large image of a man smiling and holding a lit cigarette. The text 'THE HEALTHIER ALTERNATIVE' is overlaid on the image. Below the image, there is a testimonial: '"Feels and Tastes just like the real thing. . . minus the guilt!" -Alex, San Diego CA'.

SALES AND MARKETING RESTRICTIONS

- Prohibits sales to persons under 18 and requires age verification by retailers
- Prohibits sales through vending machines except in adult-only facilities
- Bans free samples



SALES AND MARKETING: REGULATORY GAPS

- Allows Self-service Displays
- Allows Brand Sponsorship of Athletic and Musical Events
- Allows Distribution of Non-Tobacco Merchandise with Brand Logos
- Fails to Protect Against On-Line Sales to Kids



Self-service NJOY products in a store at Ronald Reagan Washington National Airport, Washington, DC, July 30, 2014.



www.facebook.com/FINCigs,
July 1, 2013

FAILURE TO ADDRESS FLAVORINGS

- Proliferation of flavored e-cigarette products
- No action proposed by FDA
- Need for product standard prohibiting characterizing flavors (other than tobacco flavor)



www.tenacious7vapor.com, June 20, 2014



FAILURE TO ADDRESS RISK OF NICOTINE POISONING OF CHILDREN

“It’s not a matter of if a child will be seriously poisoned or killed. It’s a matter of when.”

–Director of a poison control center in California

- FDA notes problem, but no proposal for action
- Need to mandate child-resistant containers





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