

Experts Address Criticism of FDA Regulation of Tobacco

National Conference on Tobacco or Health Wraps with Discussion of New Legislation

By Mary Theobald, MBA

You've undoubtedly heard by now that both the Senate and the House of Representatives voted to approve the Family Smoking Prevention and Tobacco Control Act of 2009, legislation that grants the Food and Drug Administration (FDA) authority to regulate the manufacturing, marketing and sale of tobacco products. The president signed the legislation into law on June 22, 2009. "Today... the decades long effort to protect our children from the harmful effects of tobacco has emerged victorious," President Obama said at a press conference. "It is a law that will save American lives and make Americans healthier."

The Family Smoking Prevention and Tobacco Control Act was endorsed by more than 1,000 organizations, including the American Academy of Family Physicians, but even supporters concede that it's not a silver bullet. "The bill isn't perfect, but it's a very strong bill," said Danny McGoldrick, Vice President, Research at Campaign for Tobacco-Free Kids. At the closing plenary of the June 2009 National Conference on Tobacco or Health in Phoenix, public health advocates, including McGoldrick, addressed some of the controversial language in the bill that was soon to be signed into law.

Legal Rights Loopholes

Doug Blanke, Director of the Tobacco Law Center and Executive Director of the Tobacco Control Legal Consortium, addressed the concern many have about the impact of the new legislation on tobacco-related litigation. He said the legislation preserves most legal rights the public has today, but "there are areas that are open to debate" and he expects the tobacco industry to try to use these to prevent litigation. According to Blanke, there is no language in the legislation that says litigation is preemptive, and the bill grandfathered in pending cases. The legislation also protects future cases filed under the product liability law of any state. This is where things get tricky. Blanke said the industry may try to exploit this language by arguing that many cases are barred because they are not product liability cases. Past litigation has traditionally focused on industry misconduct rather than the product itself.

Blanke went on to predict that the tobacco industry will argue that preemption is implied in the legislation, and may use the fact that they are compliant with FDA regulations as a defense in future trials. Blanke said the "overall impact [of the legislation] on litigation is good, but there's still room for dangerous interpretations."

Exclusion of Menthol

The new tobacco legislation bans most flavored cigarettes, but it specifically excludes those that are menthol-flavored. Phillip S. Gardiner, DrPh, Research Administrator, Tobacco Related Disease Research Program, University of

California Office of the President, said that menthol may have been a “sacrificial lamb.” He, and many others, speculate that proponents of the bill thought it was unlikely it would pass without the exclusion. Gardiner still insisted it “was a mistake to leave menthol out.” However, wording was placed in the bill mandating that an FDA scientific advisory committee study the effects of menthol flavoring and issue a recommendation within one year. The FDA must also produce an action plan on the advertising and promotion of menthol and other cigarettes to young people, particularly those in minority communities. Gardiner believes the public health community needs to keep a close eye on who is appointed to the committee. “The main problem,” he said, “was a lack of inclusivity (sic), transparency and accountability. We want to change that.”

Empowering Communities

While all the panel speakers advised public health advocates to stay abreast of actions by both the FDA and the tobacco industry, all were upbeat about the opportunities provided by what is “the strongest action Congress has ever taken to reduce tobacco use.”ⁱ Karla Sneegas, MPH, Executive Director, Indiana Tobacco Prevention and Cessation Agency, pointed out that the new legislation gives control back to communities. For the first time since 1969 states have the authority to prohibit or restrict the location, color, size, number and placement of cigarette advertisements. Sneegas said public health proponents need to make sure local legislators know that “their power is back.”

The Family Smoking Prevention and Tobacco Control Act of 2009 grants the FDA the authority to:

- Restrict tobacco advertising and promotion in order to promote overall public health.
- Stop illegal sales of tobacco products to children.
- Ban the use of all product flavorings, except for menthol.
- Require larger, more informative health warning labels, including color and graphics, on tobacco product packages and advertisements
- Ban misleading health claims such as “light” and “low-tar.”
- Prohibit health claims about purported reduced-risk products, where such claims are not scientifically proven. This includes prohibiting terms such as “light,” “mild” and “low-tar.”
- Require tobacco companies to disclose the contents of tobacco products, as well as changes in products and research about their health effects.
- Require changes in tobacco products, such as the removal or reduction of harmful ingredients or the reduction of nicotine levels.ⁱⁱ

Need resources to help your patients quit? Visit the AAFP’s Ask and Act website at www.askandact.org.

ⁱ Campaign for Tobacco Free Kids. *Special Report: FDA Authority Over Tobacco*. June 12, 2009. <http://www.tobaccofreekids.org/reports/fda/>

ⁱⁱ Tobacco Control Legal Consortium. *Proposed Regulation of Tobacco Products by the U.S. Food and Drug Administration*. <http://tclconline.org/documents/FDA-fact-sheets.pdf>