

LIFE SCIENCES NEWS

Vol. 2, Issue 1

On June 22, 2009, President Barack Obama signed the most sweeping piece of tobacco regulation in the history of the United States – the Family Smoking Prevention and Tobacco Control Act of 2009 (“the Act”). The Act had a long and tumultuous journey coming into fruition. Based primarily on the tobacco industry’s large roots in the American economy, the U.S. government left tobacco products virtually unregulated for a number of years. After having expressly disavowed having the authority to regulate tobacco products, in August of 1996 the Food and Drug Administration (FDA) asserted jurisdiction in a final rule entitled, “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” 61 Fed. Reg. 44619-45318. In this regulation, the FDA concluded that nicotine was a “drug” within the meaning of the Federal Food, Drug and Cosmetic Act (FFDCA) cigarettes and smokeless tobacco products are “combination products” that deliver nicotine to the body. Pursuant to this declared authority, the FDA promulgated regulations concerning tobacco promotion, labeling and accessibility which were intended to reduce tobacco consumption among children and adolescents.

In response to the FDA’s action, a group of tobacco manufacturers, retailers, and advertisers filed suit in the United States District Court for the Middle District of North Carolina challenging the regulations. See *Coyne Beahm, Inc. v. FDA*, 966 F.Supp. 1374 (1997). Their argument was that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, the regulations exceeded the FDA’s authority granted to it by Congress, and the advertising restrictions violated the First Amendment. At the end of the appeal process, the United States Supreme Court, per Justice O’Connor, concluded that the Congress intended to exclude tobacco products from the FDA’s jurisdiction. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). After the Supreme Court ruled that the FDA did not have authority to regulate tobacco products, anti-tobacco forces began the long, nine year journey to enact legislation that would expressly give the FDA that power.

On April 2, 2009, anti-tobacco legislation sponsored by Rep. Henry A. Waxman (D-CA) and Rep. Todd Platts (R-PA) passed the House of Representatives by recorded vote 298:112. On June 11, 2009, the Senate passed a similar bill S. 982 sponsored by Senator Edward Kennedy (D-MA) by recorded vote 79-17. On June 12, 2009, the House voted 307-97 to accept the Senate’s version of the bill.

Simply stated, the Act gives the FDA broad regulatory authority over the manufacture, labeling and marketing of tobacco products. The Act, however, does not grant the FDA authority to ban tobacco products. By amending the FFDCA, the Act grants FDA authority to regulate tobacco products. Tobacco products, however, will not be regulated

under the “safe and effective” standard currently used for other products under the agency’s review such as food, dietary supplements and cosmetics, but under a new standard – “appropriate for the protection of public health.”

Some of the more notable highlights to the Act are the following:

1. Directs the Secretary of the Department of Health and Human Services (the “Secretary”) to establish within the FDA the Center for Tobacco Products to implement the Act;
2. Directs the Secretary to promulgate regulations to assure that tobacco products are manufactured in accordance with good manufacturing practices or hazard analysis or critical control point methodology;
3. Requires premarket approval of all new tobacco products (products not “substantially equivalent” to an existing tobacco product) commercially marketed after February 15, 2007. The Act defines “substantially equivalent” as having the same characteristics or having different characteristics but not raising different questions of public health;
4. Grants FDA the authority to regulate the content of nicotine and other harmful ingredients, and to ban additional herbs, spices or flavors (with the exception of menthol);
5. Grants FDA authority to develop regulations concerning the marketing of tobacco products. The Secretary has the authority now to develop regulations (in coordination with the Chairman of the Federal Trade Commission) that impose restrictions on the advertising of a tobacco product that are consistent with the Federal Trade Commission Act and the First Amendment to the United States Constitution. The key will be whether the proposed marketing regulations are appropriate for the protection of the public health;
6. Grants FDA the authority to promulgate regulations to prevent the sale and distribution of tobacco products to minors;
7. Grants FDA authority to develop regulations concerning the labeling of tobacco products. This includes the authority to require large, graphic warnings on packaging; and
8. Grants FDA authority to prohibit descriptive claims such as “light,” “mild,” and “low” which give consumers the false impression that these types of tobacco products are somehow better for them.

The Act deems a tobacco product to be “adulterated” if:

1. It contains any filthy, putrid, or decomposed substance or is contaminated by any added poisonous or deleterious substance that may render the product injurious to health;
2. It has been prepared, packed, or held under unsanitary conditions;
3. Its package is composed of any poisonous or deleterious substance;

4. The manufacturer or importer of the product fails to pay the assessed user fee;
5. It fails to meet specified tobacco product standards;
6. It does not have required premarket review;
7. It fails to meet applicable requirements or conditions on manufacturing, packing, or storage; or
8. It fails to conform to requirements for modified risk tobacco products.

The Act deems a tobacco product to be “misbranded” if:

1. Its labeling, packaging, or advertising contains any false or misleading information;
2. Its label or advertising fails to contain all required information displayed prominently and conspicuously, including its established name, manufacturer, and contents and adequate directions and warnings;
3. It was manufactured, prepared, or processed in an establishment not registered with the Secretary; or
4. There is any failure to submit the required information or notices to the Secretary. For example, the Act allows the Secretary to require prior approval of all label statements on tobacco products to ensure that such statement (1) do not violate misbranding provisions and (2) comply with other provisions of the Act.

The Act was supported by over 1,000 public health, faith-based and other organizations around the country and some former executive level federal public health officials. Skeptics, however, are concerned that the Act puts additional financial and human resources on an already struggling FDA. Part II of this article will address what effects we can expect from this new piece of anti-tobacco legislation.

For additional information on the above matters, please contact Julie Dykstra, a partner in the firm’s Business Department at 616-742-3976 or Julie.dykstra@btlaw.com

© 2009 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, is proprietary and the property of Barnes & Thornburg LLP. It may not be reproduced, in any form, without the express written consent of Barnes & Thornburg.

This Barnes & Thornburg LLP publication should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.