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Current Issues Affecting FDA-Regulated Companies

FDA Law Update

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Congress Passes Legislation Giving FDA Authority Over Tobacco Products

On June 12, 2009, Congress passed a legislation empowering the Food and Drug Administration to regulate cigarettes and tobacco products. Just one day after the Senate approved the bill, the House decided to forgo its own version of the bill and passed the Senate bill with a final vote of 307-97. President Obama stated he will promptly sign the bill into law. Enactment of such legislation will end a long battle over the years to give FDA the authority to regulate the manufacturing, marketing and sale of cigarettes and other tobacco products. The bill, authorizes sweeping regulation of the tobacco industry.

Under its new authority over tobacco products, the FDA will be able to regulate cigarette content, including flavorings and the maximum amount of nicotine that may contain. FDA will also be able to regulate the promotion of tobacco products by limiting advertising, requiring agency review of all new products before they are introduced to the market, and strictly limiting youth access and marketing. Additionally, the bill prohibits the use of descriptors, such as "light", "mild" and "low," to describe a product and will require a manufacturer to receive agency authorization before marketing any tobacco product as presenting a "modified risk." In addition, the FDA will have significant authority over the content and format of warning labels on tobacco products and in print advertisements.

Matthew L. Myers, president of Campaign for Tobacco-Free Kids, has supported the bill through all stages and stated this bill will fundamentally change the way tobacco products are marketed and advertised. However, the bill did face opposition. For example, Senator Richard Burr (R-NC) opposed the bill because he believes FDA is the wrong entity to regulate a “dangerous commodity”. He stated that the bill will prevent efforts to develop new and less harmful tobacco products.

To accommodate this additional regulatory authority, a new office will be set up in the FDA, with administrative costs paid for by a fee imposed on tobacco companies.

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