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The following article is the second and final article in Life Sciences News about the Family Smoking Prevention and Tobacco Control Act of 2009. To read Part 1, [click here](#).

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It is important to note that this bill establishes the Center for Tobacco Products and tasks this group with creating the required regulations for control of tobacco. While these changes will increase government cost, the bill also implements user fees on tobacco product manufacturers and importers. Former Food & Drug Administration (FDA) Commissioner David Kessler stated that he believes the industry fees mandated by the bill to pay for FDA regulation, an estimated \$600 to \$700 million per year by 2013, will enable FDA to strictly enforce the new legislation.

Another interesting point in the bill is that, for the first time, industry will have to disclose the ingredients in its products. FDA could ban the most harmful of the estimated 6,000 chemicals used in cigarettes, cigars and other tobacco products. They could also reduce the amount of nicotine, perhaps to a point where tobacco is no longer addictive and smokers who want to quit can do so more easily. In addition to regulating the content of nicotine, the bill bans all additives except menthol. However, FDA is required to set up an advisory panel that will need to report, within a year, whether menthol should be banned or continued to be allowed.

The wording of the new bill indicates that the tobacco products, while technically combination products, will be regulated in a manner similar to devices. It would appear that, from a primary mode of action standpoint, the tobacco product is closer to a drug. However, terms such as “substantially equivalent” and “pre-market approval” appear in the Act. All new products require pre-market approvals unless substantially equivalent to a product marketed prior to February 15, 2007. To compensate for declining cigarette sales, many companies have aggressively moved into producing smokeless products. Several companies have begun developing snus (spit-free smokeless tobacco in pouches) and dissolvable tobacco pellets. Companies had hoped to advertise the lower risk of these smokeless products, but the new regulations don't allow smokeless-tobacco makers to say their products are healthier unless they can prove that to FDA. The Act also requires manufacturers to pull products from the market that were introduced after February 15, 2007 until a pre-market approval (PMA) is granted. This could affect some dissolvable tobacco pellets and strips; however, snus products will likely just need to demonstrate substantial equivalence as similar pouches were on sale before that date. The impact on cigarettes was previously unclear as they do not contain tobacco, but are nicotine replacement products. However, the Act does grant FDA the authority to regulate the content of nicotine ingredients in products.

One of the first steps noted for the new Center is to define appropriate good manufacturing practices to ensure consistent quality. Though, it is not clear at this point whether existing regulations will be referenced or new regulations will be implemented. Any product will be labeled as adulterated if any of the following applies:

- It is contaminated and/or prepared under unsanitary conditions
- The package contains a poisonous or deleterious substance
- Its manufacturer or importer fails to pay the user fee
- It doesn't meet specified standards
- It doesn't have PMA, or is marketed prior to February 15, 2007
- It fails to meet manufacturing, packaging or storage requirements
- It fails to conform to requirements for modified risk tobacco products

It will be interesting to see how industry defends that tobacco products do not contain poisonous or deleterious substances.

Marketing of tobacco products is another area of impact. FDA now has authority to impose restrictions on advertising. Many of the new restrictions are aimed at preventing children from starting to smoke. Cherry and other fruit flavorings that appeal to children will be banned, along with marketing aimed at younger smokers, such as the use of Joe Camel and other cartoon characters. Additionally, penalties for the sale and distribution to minors will be strictly enforced. There is precedence of FDA demanding the removal of nicotine-containing lollipops from the market. Further, tobacco manufacturers will be unable to use terms such as "light," "mild" and "low" unless they can scientifically prove that the product labeled as such is less harmful than standard tobacco. These marketing restrictions reflect further labeling oversight.

FDA also now has the authority to develop labeling regulations. The legislation requires tobacco companies to expand the size of warning labels so that they cover 50 percent of a pack, and to include graphic images of the health effects of tobacco, such as images of diseased lungs. This updates the warning label requirement for cigarette packs implemented by Congress in 1965 and revised in 1984. The tobacco product will be deemed misbranded if the labeling contains false or misleading information, fails to contain required information, and does not include the established name, manufacturer and contents with adequate directions and warnings. As already stated, it is not definite that the current Industry really knows the contents of the product. All label statements require prior approval. In short, failure of a manufacturer or importer to submit required information or any product which contains false and misleading information, fails to contain appropriate labeling or is manufactured prepared or processed in an unregistered establishment, will result in the product being considered misbranded.

While many, including the large tobacco companies support the bill, the ramifications are yet to be seen. A rise in cost can be expected. The small smokeless supply companies are likely to be impacted. The goal in mind is to improve the safety of the public health; only time will tell.

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