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Study finds that tobacco companies changed design of cigarettes without alerting smokers

Researchers call on FDA to require complete disclosure from tobacco companies of changes made to cigarettes

Boston, MA -- As President Obama prepares to sign a bill giving the Food and Drug Administration (FDA) oversight of the tobacco industry, a new study from Harvard School of Public Health (HSPH) researchers shows that tobacco manufacturers have continually changed the ingredients and the design of their cigarettes over time, even if those changes have exceeded acceptable product variance guidelines. The result, say the researchers, is that consumers who buy the same brand of product are not made aware of how that product has been altered and what effect those alterations might have on their levels of addiction or harm.

"I hope the FDA requires disclosure of any changes made to tobacco products and that the changes are disallowed if shown to increase appeal, addiction and harm," said Greg Connolly, director of the Tobacco Control Research Program at HSPH.

The study appears in the "Online First" section of the *Journal of Tobacco Control* and will appear in an upcoming print issue of the journal.

For their study, Connolly and lead author Geoffrey Ferris Wayne, an HSPH researcher, studied internal tobacco company documents released following the 1998 Master Settlement Agreement. These documents describe significant changes made to commercial products over time, including blend, processing, casing, flavoring and physical design features. For example, new methods were developed to process tobacco, altering the smoke chemistry and the form of nicotine delivery, and the levels of processed tobaccos were regularly adjusted within brands.

Despite the constant innovation of tobacco products, which in many cases have exceeded the levels of acceptable variance established within the tobacco industry, for the most part, these changes were not disclosed to consumers, say the researchers.

"Even incremental changes that occur over a period of years can result in significant design differences. The resulting product may have altered chemistry or delivery, yet the smoker is largely unaware of these changes. This underscores the need for industry transparency and accountability," said Ferris Wayne.

The study builds on earlier research done at HSPH on how products are designed to enhance appeal and addiction. At Senate hearings on the FDA bill last year, Connolly discussed that research, including how tobacco companies have increased nicotine content over time, manipulated menthol and added candy-like flavors to enhance appeal to children.

Until regulators have a system in place for assessing product revisions, Connolly and Ferris Wayne advise that all changes to tobacco products be reported to the FDA and that no changes be allowed until they have been scientifically shown to reduce addiction or harm.

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Read the abstract: <http://tobaccocontrol.bmj.com/cgi/content/abstract/tc.2009.030502v1>

"Regulatory Assessment of Brand Changes in the Commercial Tobacco Product Market," Geoffrey Ferris Wayne, Greg Connolly, *Journal of Tobacco Control*, online June 14, 2009.

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