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FDA Regulation of Tobacco Called 'Death Sentence'

by GoozNews ~ 14 Jun 2009 11:07am

Legislation headed for President Obama's desk that would give the Food and Drug Administration regulatory authority over tobacco was called a "death sentence" for agency morale by longtime FDA observer Jim Dickinson, editor of *FDA Webview* (subscription required).

> The impact of this bill internally will be like a death sentence, steadily killing the agency's old public health spirit and replacing it with a strange hybrid. This new ethos will have to blend public health and safety with toleration for and husbandry of death-dealing products that have no plausible relationship to the diverse family of other products regulated by FDA.

Dickinson predicts the fate of tobacco regulation at the agency will be the same as control of narcotics, which was first subjected to FDA regulation in 1966. The short-lived Bureau of Drug Abuse Control (BDAC) was only at the FDA for two years before authority was shifted to the Treasury's Bureau of Narcotics, which was later merged into the Drug Enforcement Administration.

Last week, criticism of the Waxman-Kennedy legislation came largely from the right, with the Cato Institute leading the charge on behalf of small tobacco companies who claim FDA regulation will cement Philip Morris' stranglehold on the cigarette market by making introduction of new products nearly impossible. From a public health perspective, who cares?

But it would be significant if career staff at FDA share Dickinson's concerns. Anyone inside the agency who wants to write me at merrill@gooznews.com to share their thoughts is welcome. Anonymity assured if any get published here.

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Mon, 06/15/2009 - 23:53 — Steven Grossman

Jim Dickinson is legendary in his knowledge and understanding of FDA, so I would normally defer to his judgment. On this one, we disagree. With Drs. Hamburg and Sharfstein at the helm and new dollars to re-build the agency, I don't fear for the public health spirit at FDA. The real danger is that human resources and the Commissioner's time may be drained away from meeting FDA's traditional responsibilities. The key is to build the new Center with the leadership and capacity to handle its own problems. A fuller analysis is on my blog, FDA Matters, at: http://www.fdamatters.com/?p=303 (no subscription required). I would add that FDA needs to make the new center work; there is no hope of a transfer elsewhere in a couple of years if things are rocky.

Merrill, I know we are all interested in what feedback you receive from within FDA.

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