

FDA legislation

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A strong bill that represents a major step forward

In the United States and much of the world cigarettes and other tobacco products remain largely free from meaningful regulation. No national agency currently regulates the manufacture, marketing or sale of tobacco products. The tobacco industry has long taken advantage of the absence of regulation to hide the truth about the health effects of their products; manipulate the levels of toxic constituents and nicotine in its products; deceive consumers about so called reduced risk products; and engage in marketing that is deceptive and appealing to women, youths and vulnerable populations.

For at least the past 15 years there has been a consensus about the need to fill this gap by giving the US Food and Drug Administration authority over tobacco. Recently, the Institute of Medicine of the National Academy of Sciences and the President's Cancer Panel of the US National Cancer Institute both concluded that FDA authority is a critical component of the overall tobacco control effort.

Earlier this year legislation drafted by Senator Ted Kennedy and Congressman Henry Waxman was introduced to give the FDA such authority. Despite the vocal opposition of a few, never before has a single legislative proposal been supported by a broader cross section of the American public health community. This legislation is supported by 63 major American health organisations and more than 300 state and local health organisations. It is also sponsored by all of the members of Congress who have been the longest, strongest and most thoughtful tobacco control public health leaders as well as other health leaders, like former FDA Commissioner David Kessler.

The supporters of this legislation do not see it as a panacea. Those who support this legislation do so because they have concluded that it gives the FDA authority to bring about fundamental change in the tobacco industry. Some argue the bill will pre-empt important state tobacco control activities. However, it explicitly does not pre-empt states from engaging in any of the tobacco prevention and cessation activities that they have used to reduce tobacco use. If anything, it complements those efforts.

Despite this support there are a number of inaccurate perceptions about the origins of the bill and what it will and won't do. Some of the opposition is prompted by the fact that Philip Morris USA also supports the legislation. Indeed, Philip Morris's announcement prompted those who support the legislation to review the bill again.

In the end those who support the legislation do so because they have concluded that their position should be based on their assessment of whether the bill will save lives, not whether one tobacco company supports or opposes it.

The latest version also contains provisions to prevent the tobacco industry from using the FDA's regulation to make claims that its products are "FDA approved."

This is not a bill that anyone has attempted to slip through the legislative process without substantial debate and public scrutiny. The issue has been debated for close to 10 years. This bill was debated widely in 2004 when it twice passed the US Senate, and has been the subject of Congressional hearings and days of discussion in committee in the Senate.

The legislation that Senator Kennedy and Congressman Waxman introduced in 2004, and that forms the basis for the legislation now being considered, is stronger than the legislation introduced by Senator McCain in 1998 that was supported by the entire public health community. It also does not contain the loopholes that were in bills introduced in 2001, which were supported by Philip Morris and opposed by the same public health leaders who support the pending legislation. A number of provisions, including those relating to the establishment of standards for tobacco products and the prevention of unsubstantiated health claims, have been strengthened from the earlier versions of the legislation to make it easier for the FDA to act and harder for the tobacco industry to abuse. The latest version also contains provisions to prevent the tobacco industry from using the FDA's regulation to make claims that its products are "FDA approved."

An analysis of the legislation indicates that those who support this legislation have remained consistent, and that it is Philip Morris that has changed its position.

This legislation would grant the FDA unprecedented power. The legislation empowers the FDA to require the reduction of nicotine to levels below that which are addictive and the reduction or removal of any other constituents, including smoke constituents, or any of the known harmful constituents based solely on public health criteria without having to overcome the difficult hurdle of first proving that such a proposed action will reduce the risk of disease. The bill also allows the FDA to adjust its rules based on evolving available science.

In addition, the legislation significantly alters both the text and the visibility of the health warnings on tobacco packages and ads, gives the FDA authority over tobacco marketing to the maximum extent permitted by the US Constitutional guarantee of free speech, including the authority to prevent marketing that is deceptive, encourages tobacco use or makes tobacco appealing to children. The Bill requires the disclosure of what is in each tobacco product by brand and by quantity in each brand, including all smoke constituents, and of any changes to the product. The law also makes clear that it does not alter the tobacco companies' liability in court.

It has been argued that the bill will make it more difficult to introduce potentially less hazardous products. It does not. The bill permits the entry of new products that might reduce disease caused by tobacco, but prohibits explicit or implicit health claims until the manufacturer demonstrates to the FDA that the product as actually used will substantially reduce the risk of disease. Today the tobacco industry uses the terms "light" and "low tar" to keep people smoking. The legislation prohibits use of these terms.

The provision that has prompted the most attention—the one that grants the FDA broad authority to make changes to tobacco products but provides that as between FDA and Congress, only Congress can enact an outright ban of all cigarettes or all smokeless tobacco products or totally remove nicotine—will not impact the FDA's ability to require change or take any other action short of an outright ban. The change from the status quo is dramatic. Today no governmental agency can require that nicotine be altered or tobacco products changed. Further, no public health leader credibly recommends banning all cigarettes today. The bill gives the FDA broad authority to

require changes in tobacco products and how they are marketed and to cut nicotine to non-addictive levels and does not impact the right of states to ban tobacco products. It is an enormous step forward.

But what about Philip Morris's position? This is not the first time Philip Morris has taken a position that appears to support initiatives also supported by public health leaders, including the Framework Convention on Tobacco Control (FCTC) and restrictions on tobacco use in the

movies. No one altered their support for these measures when Philip Morris announced its position. Indeed, many questioned whether Philip Morris truly supported those measures. The fact that every other tobacco company opposes the legislation is an indication that most members of the tobacco industry think this bill is bad for the industry.

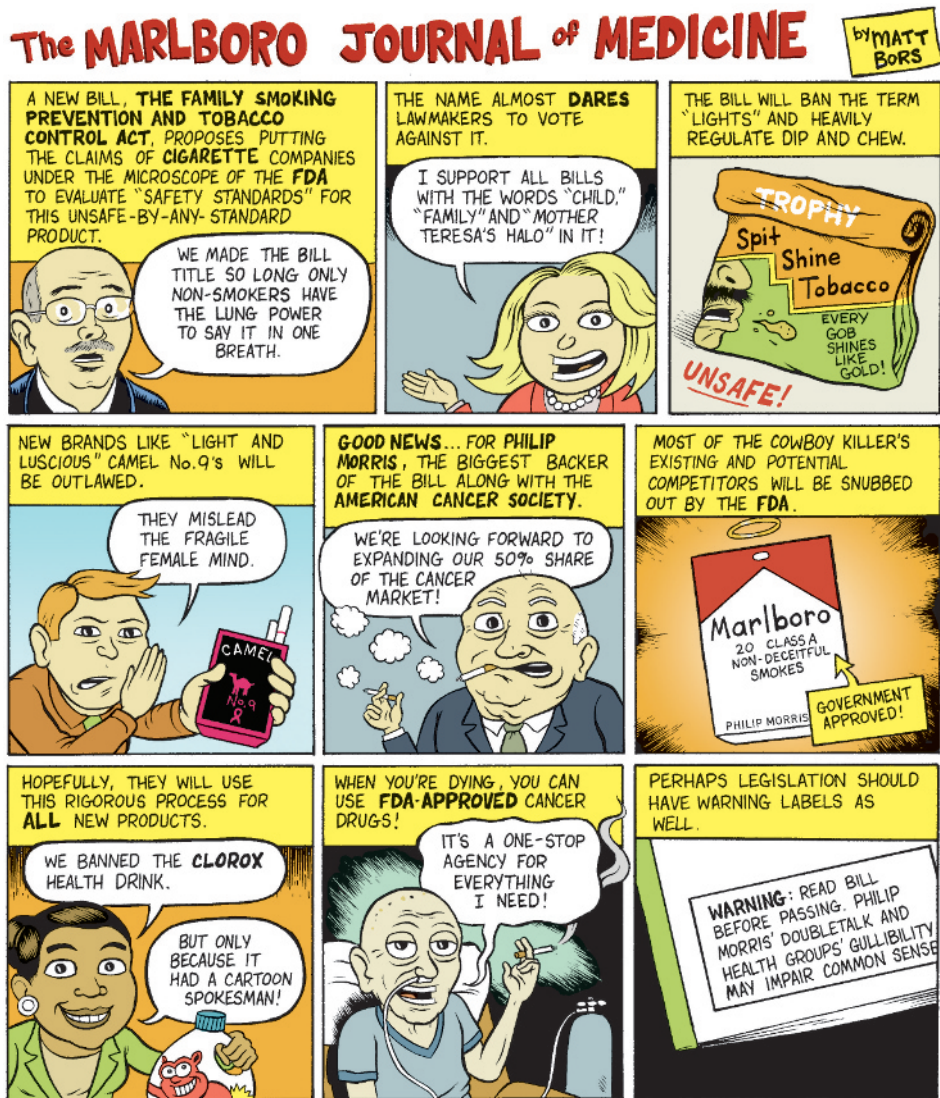
While it is possible to speculate why Philip Morris takes any particular action, ultimately whether the public health

community should support a specific proposal should be based on whether it is a good bill or a bad bill for public health, not whether Philip Morris supports it. We support this legislation because we believe it will save lives.

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The Lighter Side



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