

Overcautious FDA has lost its way

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Five years after the passage of the Family Smoking Prevention and Tobacco Control Act, little progress has been made in the effort to regulate the US tobacco industry and advance the public health goals of tobacco control. Legal challenges by the tobacco industry, and evidence of political interference from the White House have resulted in the US Food and Drug Administration's (FDA) overcautious approach toward advancing a meaningful regulatory agenda. While the White House bears final responsibility, it is incumbent upon the FDA and its Center for Tobacco Products to become more aggressive and seize the extraordinary opportunity to save lives that the Family Smoking Prevention and Tobacco Control Act has created.

When the Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into law, some in the tobacco control movement expressed scepticism that a piece of legislation with compromises and provisions, reportedly included at the behest of Philip Morris, could result in meaningful regulatory action. After five disappointing years with little regulatory progress, those sceptics might very well feel even more convinced that the legislation itself is the problem.

Some features of the law are indeed troubling, such as the provisions preventing the US Food and Drug Administration (FDA) from ever banning cigarettes and requiring industry representatives to sit on the Tobacco Products Scientific Advisory Committee, however there is no reason to think that they have contributed meaningfully to the FDA's inaction. The solid regulatory framework itself, built around a public health standard, is extremely powerful and should result in potentially transformative actions, such as (1) eliminating menthol; (2) regulating nicotine levels to reduce dramatically abuse liability and toxic exposure; (3) implementing arresting and effective graphic warnings; (4) facilitating an increase of the national minimum tobacco sales age to 21; and (5) responsibly controlling new tobacco products' entry into the market.

The reason none of these actions or anything else of great significance has happened has little to do with the FSPTCA, but rather, has much to do with a fundamentally overcautious approach by the FDA and its Center for Tobacco Products. The reasons for this overabundance of caution are understandable. Every important step taken by the FDA has been met with legal challenges or political interference.

The FDA's authority was broadly attacked less than 3 months after the FSPTCA was signed into law, when the tobacco industry filed a lawsuit to challenge numerous provisions of the law. While a federal district court in Kentucky issued a mostly favourable decision for the agency, which was upheld on appeal in *Discount Tobacco City and Lottery v. FDA*, this was just the first of several obstacles that the industry placed in the path of regulatory progress.¹

Implementing large graphic warnings on cigarette packaging was a key mandate of the FSPTCA.² While the *Discount Tobacco City and Lottery* decision upheld this provision of the FSPTCA, the specific graphic warnings selected by the FDA were challenged in a separate lawsuit and found to violate the manufacturers' right to free speech.³

The FDA lost this case, in part, due to vastly understating the public health benefits of the warnings.⁴ More alarmingly was their consideration in their analysis of the lost 'pleasure' of smokers maintaining nicotine dependence as a cost associated with reducing smoking.⁵ While the free speech protections of the First Amendment to the US Constitution might protect the tobacco industry from Australian-styled plain packaging someday, it need not have shielded the industry from warnings of the sort used successfully in dozens of nations around the world.⁶

The FSPTCA required the FDA to appoint a scientific advisory committee and, as its first order of business, to evaluate the public health impact of mentholated cigarettes.⁷ As the FDA's Tobacco Products Scientific Advisory Committee was developing its report in 2011, Lorillard, the menthol market leader, along with RJ Reynolds, sued the FDA on the basis that some of the Committee's members had potential conflicts of interest that should have barred their

participation under federal law.⁸ This lawsuit, which is still pending, may have been the cause for the FDA to produce a second, staff-written, peer-reviewed menthol report, reaching similar conclusions to the first report, to ensure that the evidence base for action was not clouded by the potential impact of the *Lorillard* lawsuit. Although the peer review was reportedly completed in early 2012, the FDA did not issue the second report until mid-2013.

Researchers at the Center for Tobacco Control Research and Education at the University of California, San Francisco, examined documents obtained through a Freedom of Information Act request, and concluded that the White House Office of Management and Budget (OMB) delayed acting on the report for more than a year, possibly to ensure that there would not be a proposed menthol rule issued before the 2012 Presidential election.⁹

Since October, 2013, OMB has been reviewing the FDA's proposed 'deeming' regulation which would expand the agency's rulemaking authority to include products such as cigars and electronic cigarettes. A deeming regulation must be finalised before the FDA can begin to regulate electronic cigarettes, a process that was delayed due to a lawsuit that the agency lost to an e-cigarette company in 2010.¹⁰ In the meantime, e-cigarette companies advertise in ways that seem designed to appeal blatantly to youth.¹¹

The slow pace of responsiveness from a White House office suggests the possibility that the FDA is facing political as well as difficult legal hurdles.

This is not a typical regulatory environment. Every move that the FDA makes has been met with a vigorous legal challenge by the tobacco industry and its allies and, possibly, some form of political interference as well. This is not to say that regulating the pharmaceutical industry or medical device companies is free from confrontation, but the inevitability of well-coordinated attacks designed to deny and delay any meaningful regulation of tobacco products calls for a more aggressive course of action.

The FDA and, in particular, the legal team that has charted this cautious approach, might do well to consider how Sharon Eubanks, the lead attorney in *U. S. v. Philip Morris*, and her colleagues at the US Department of Justice successfully surmounted similar legal and political challenges.¹²

Eubanks faced several legal setbacks in the same appeals court that reviews most FDA litigation. Her group was working

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under a presidential administration which included a top advisor, Karl Rove, who spent years on the payroll of Philip Morris.¹³ It was an extraordinarily difficult 6 years, but by staying aggressive, quickly making adjustments when confronted with setbacks, and remaining focused on winning the battle, the trial team achieved a historic victory that resulted in the finding that the cigarette manufacturer defendants were racketeers under US law.¹⁴

No, this is definitely not a typical regulatory environment. The industry being regulated is a ruthless cartel of adjudicated racketeers that takes no prisoners, and not merely a regulatory stakeholder.

To have a meaningful impact on reducing tobacco's toll, the FDA must execute bold and decisive regulatory actions in rapid succession. Delaying such action only serves to benefit the tobacco industry and harm the public.

Although a great deal of exciting and important research is underway, the FDA needs to rely on the best available extant evidence whenever it demonstrates the need for regulatory intervention. Reliance on the best available science is supposed to be the cornerstone of the Regulatory Science approach adopted by the FDA's Center for Tobacco Products.¹⁵ The Center should not postpone action awaiting potentially better or newer science that simply confirms or adds to the evidence base.

The FDA must push forward knowing that some actions will be rejected by the courts or held up for political reasons. It is critically important for the agency to understand that most such setbacks will occur regardless of regulatory speed. Consequently, the best public health regulatory practice is to drive the process forward as fast as the law will allow. Ultimately, some of the regulations will succeed and begin to fulfil the great promise of the public health-focused

approach envisioned by the FSPTCA. The fact that such victories are likely to have global implications only amplifies the importance of this work.

Excessive deliberation and caution literally costs lives, and it is time for the FDA's Commissioner, the Center, and its staff to commit to pursue a bold agenda and accelerating dramatically the regulatory pace.

If the indications of political interference by the White House Office of Management and Budget prove to be real, then the President is personally accountable for the lives lost or destroyed by the FDA's inaction. The FDA is a branch of his administration and it is within the purview of the president to push forward the regulatory agenda or to push back against it.

It logically follows that a president who has invested vast political capital in American health and healthcare should empower the FDA and the Center for Tobacco Products to take swift and decisive action. There exists no better public health opportunity of any kind than this one, now in the hands of the FDA. They should run with it, not from it.

Acknowledgements The author is grateful for the assistance of Richard A Daynard, JD, PhD, for providing valuable initial feedback, Lissy C Friedman, JD, for editorial assistance, and his wife Julie T Viens, for final editing.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.



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To cite Gottlieb M. *Tob Control* 2014;**23**:187–188.

Tob Control 2014;**23**:187–188.
doi:10.1136/tobaccocontrol-2014-051695

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