Bluffer's guide to FDA regulation of tobacco and nicotine products

written by Clive Bates | 6 April 2016



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If you aren't American, or even if you are, the regulation of tobacco, nicotine, and vape products in the United States can seem bewildering but somehow important. So if you want to be on it, here's my bluffer's guide to the United States Food and Drug Administration (FDA) and its approach to tobacco and nicotine products.

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Regulatory framework and process

1. **What law gives the FDA the power to regulate tobacco or nicotine?** For tobacco, FDA operates under the Family Smoking Prevention and Tobacco Control Act of 2009 – usually shortened to 'Tobacco Control Act' (TCA) This is primary legislation made by Congress and it governs the institutional framework and regulatory regime for tobacco products. The TCA actually amends the Federal Food Drug and Cosmetic Act to create Chapter IX on tobacco products. For pharma nicotine, medical regulation under Chapter V applies.

2. **How is the FDA set up internally to deal with tobacco?** The TCA set up the Center for Tobacco Products (CTP) as the main regulatory body within the FDA, and this is currently headed by Mitch Zeller. Mr Zeller has made encouraging public statements indicating that he recognises that different tobacco products have different risks and should be regulated accordingly. However, we cannot assume that the FDA-CTP will act consistently with that view – it will be confined by law, by its interpretation of science, and by how others in FDA want to approach the issue.



Mitch Zeller JD

3. **Why is the FDA regulating vaping nicotine products as if they are tobacco products?** Like the UK and EU, the FDA originally tried to regulate e-cigarettes as medicines, which would have been a disaster. Thankfully, FDA was defeated in the appeal courts in 2010 in the 'Sottera case' in which the court found that unless a product derived from tobacco is marketed for therapeutic purposes, the FDA may regulate it only under the provisions of the Tobacco Control Act. This is because the TCA defines 'tobacco product' to mean '*any product made or derived from tobacco*

that is intended for human consumption' – and the nicotine in e-liquids is derived from tobacco.

4. **What does "deeming" mean and how is the FDA getting control of vape products?** The Tobacco Control Act did not initially cover e-cigarettes, so in April 2014 FDA announced it was initiating the process of 'deeming' e-cigarettes (as well as a several other tobacco products such as dissolvable tobacco, hookah, little and big cigars, and pipes) to be tobacco products under the definition used in the Act – and in May 2016 that process completed and FDA asserted it has powers over vape products. Now it has deemed vape products to be tobacco products under the TCA, the FDA will apply concepts from the TCA to regulate e-cigs and liquids. Under the deeming rule, the FDA will require age restrictions, a warning label, and registration, as well as mandate a pre-market approval process for e-cigarettes (see 6 PMTA below) from the outset. The FDA, companies and consumers all agree that the PMTA process is so burdensome that is will radically reshape the market, reducing the choice available and causing most firms to 'exit' – they differ by how much it will change, and how much this matters.

5. **What FDA is proposing sounds terrible, why can't they do something sensible?** Because it is operating under the Tobacco Control Act, FDA can only do what the TCA allows or requires, and no more or less. But the TCA was created when no-one had any idea about e-cigarettes. The TCA was designed with a couple of purposes in mind – to stop innovation in cigarette design on the basis that it might be harmful, and to create a very high bar for demonstrating 'reduced risk' claims for products in case these mislead smokers into a false sense of security. But these are objectives that if applied to products that are in reality likely to be at least 95% lower risk than smoking, amount to a stranglehold on the vastly improved alternative – the opposite of what a sensible regulator would want.

6. **What are the ways that vape or tobacco products can get on to the market?** The TCA allowed any product on the market on 15 February 2007 to remain on the market – this is called 'grandfathering', and amounts to a free pass for the most dangerous products. The vast majority of cigarettes on sale now were waved through because they were

on sale in 2007. For new products or variations on old products made after 2007, the TCA (and hence FDA) provides four routes to market:

6.1 *Substantial equivalence*. This is a supposed to be a straightforward route to market for products with characteristics that are 'substantially equivalent' to a 'predicate product' that was on the market on 15 Feb 2007. It might mean some change in formulation, packaging, colour etc. but essentially has same characteristics and doesn't raise new public health questions. Products announced before 22 March 2011 can stay on the market provided they have made a substantial equivalence application until FDA completes the evaluation. Given many tobacco products have changed in some way since 2007, there have been over 3,600 applications and there is now a large backlog, casting doubt on whether it is a straightforward route or whether FDA has regulatory capacity to deal with new categories, like e-cigarettes.

6.2 *Exemption from substantial equivalence*. For minor changes to existing products.

6.3. *Pre-Market Tobacco Application (PMTA)*. This is for products that are not substantially equivalent, and would apply to e-cigarettes. To issue an order, FDA must evaluate that product based on a public health standard that considers the risks and benefits of the product on the population as a whole, including tobacco product users as well as non-users. Note that this has to be done before the product is allowed on the market – and requires an assessment of the positive or negative impact on cessation and initiation.

…the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account–

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products

Just imagine what you would have to know to be able to answer this question. The test is virtually impossible to meet for a product that has never been on the market – so models are created to try to show what will happen. A much better way in my view would be to allow products onto market based on their individual risk controlled by a cross-industry standard, and then monitor for adverse population effects – but that is not what the TCA says.

6.4. *Modified Risk Tobacco Product (MRTP)*. This is the route used if the manufacturer wants to make a claim of reduced risk in some way. This is like the PMTA but with the added burden of showing that the health claim is true and will be positive for public health. There is only one product that has attempted this – Swedish Match has submitted 130,000 pages of evidence to show that snus is less harmful than smoking – something everyone knows. The main aim of SM is to get warnings removed for which there is no evidence and to change the generic warning:

Current label:
Warning: this product is not a safe alternative to smoking

Requested:
Warning: no tobacco product is safe, but this product presents substantially lower risks to health than cigarettes

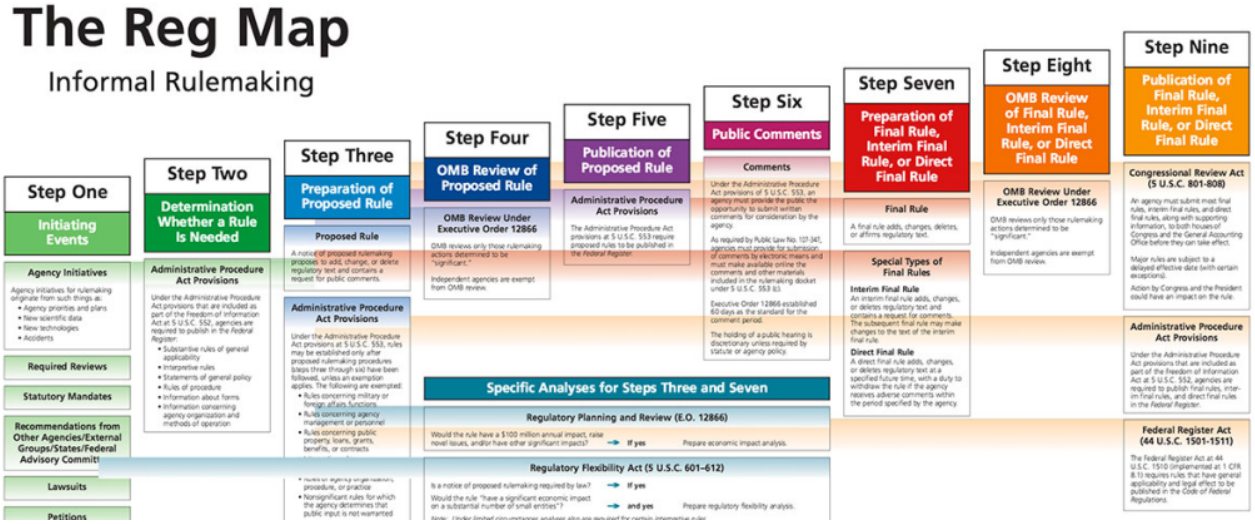
Amazingly, this change is totally opposed by the US public health establishment and FDA's 'independent' Tobacco Products Scientific Advisory Committee (TPSAC) and there is a legal consortium that has vowed to challenge it. In my view, the MRTP approach is nuts: it means consumers only get realistic risk information if a tobacco company finds it commercially worthwhile to go through this process, and then public health will always it. Nothing is done to check whether the existing warning is misleading or causing harm. It's nuts!

7. **And the problem for vape products is…?** The problem with this framework is that e-cigarettes barely existed in 2007 – so the substantial equivalence route is closed. That leaves them with PMTA. Consumer advocates argue that this route is so onerous and costly in terms of its evidence and paperwork requirements and compliance costs that it will

wipe out almost every product in the US market – see CASAA's most recent statement or for those with an iron will, Bill Godshall's comprehensive case. They are also concerned about the FDA using these rules to create a *de facto* ban on flavours simply by requiring impossible burdens of proof (that, of course, do not apply to cigarettes).

8. **Does anyone have a game-plan?** Advocates are trying various ideas – getting an amendment to the 15 Feb 2007 grandfathering date added to a Bill going through Congress (e.g. HR2058 – or an amendment to the Agricultural Appropriations Bill for 2017); suggesting easing off on enforcement (the proposed rule already included a 24-month delay in enforcement of the PMTA requirement). Some experts close to the FDA claim they have more flexibility and discretion than appears at first sight. Maybe this is right, but there is little sign of much flexibility in the deeming rule.

9. **Where are we in what seems like a never-ending process?** The process of regulatory scrutiny is very demanding in the US – and the FDA treads very carefully because it expects legal challenges and needs watertight decisions (nothing like the EU!). Stage 9 is complete and the final rule was published on 10 May 2016, and came into effect on 8 August 2016 (see below).



Central to the legal challenges that have now commenced is whether these regulations have correctly followed the requirements for making regulations and whether there has been adequate justification. In October 2015, the regulation was sent to the Office of Information and Regulatory Affairs (OIRA)

at the Office of Management and Budget (OMB) for review – these are the best thought of as the President's 'enforcers' on good quality regulation and sensible spending.

10. **What does OIRA/OMB do?** OIRA and OMB were supposed to apply the criteria in two presidential executive orders to decide if this is good regulation. These are:

    Executive Order 12866, "Regulatory Planning and Review" 1993 establishes and governs the process under which OIRA reviews agency draft and proposed final regulatory actions. It requires an analysis of the costs and benefits of rules and, to the extent permitted by law, action only on the basis of a reasoned determination that the benefits justify the costs.

    Executive Order 13563 "Improving Regulation and Regulatory Review" 2011 updates this, but does not fundamentally change the underlying principles: it points to the need for predictability and for certainty, and for use of the least burdensome tools for achieving regulatory ends. It indicates that agencies "*must take into account benefits and costs, both quantitative and qualitative*." It asks agencies "*to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." It also authorizes agencies to consider, and discuss qualitatively, "values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts*."

    These requirements form an important basis to challenge the rule.

11. **When will this all actually affect the businesses and products?** The rule was published in May 2016 and came into effect on 8 August 2016. From this point, new products or variants will need a PMTA approval. Existing products can stay on the market as long as they file a PMTA within two years and as long as the FDA has granted an approval within a further year. Note that even *improvements* (including in safety, ease of use, toxicity, consistency) can not be introduced from 8 August 2016 without a PMTA.

12. **Is there a better way?** Yes, there is.

12.1 **Do nothing.** Sticking with the status quo would be an enormous improvement on everything in the Final Rule. That is because there isn't actually a serious problem for regulators to address and benefits of the products are large. How about simply never publishing the deeming rule? Into the long grass, something for the next president to ignore. This is superior to all other strategies

12.2 **Move the predicate date**. At least do what was done for cigarettes and let everything already in the market continue. There are no problems and all is working well for health. Whether this needs a Congressional action or can be done within the existing TCA is a source of dispute.

12.3. **Consumer protection framework**. A variation on 'do nothing' is to regulate vape products as *consumer* products, at least until Congress had provided FDA a legal framework fit for purpose, which the current TCA isn't. This would have meant no deeming regulation and supervision by default by the Consumer Products Safety Commission, which has general product safety responsibilities – and could deal with electrical, mechanical, and thermal safety, child-resistant containers, warning labels etc – actually the more pressing issues.

CPSC is charged with protecting the public from unreasonable risks of injury or death associated with the use of the thousands of types of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than $1 trillion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard.

12.4. **Give FDA new law fit for purpose?** In an ideal world, health advocates would have lobbied Congress for a purpose-built legislation that would have secured a framework for proportionate and non-discriminatory risk-based regulation that wouldn't wipe the industry out as part of trying to make it safer – see my notes on regulating new and disruptive technologies. Instead, I think they actually *like* FDA regulation under the TCA *precisely because* it is so damaging. In that mindset, heavy regulatory burdens are a benefit, not a cost.

12.5. **Same law but FDA is smarter with it**. Optimists claim that FDA can

do it all under the TCA, just by 'being smarter' and finding a legally watertight way to reduce the pre-market burdens to some acceptable proportional level.

In all scenarios, CDC and its state-level equivalents should stop deceiving the American public and start communicating relative risk honestly – something they could learn from England.

13. **Can you just summarise all that?** The basic problem is that the Tobacco Control Act was set up to do something completely different – opposite in fact – to what consumers and public health need for e-cigarettes. The FDA has to apply it and can't do that much with it – even if it wanted to, which is far from clear. This form of regulations creates really high barriers to entry (suits the cigarette trade); puts a brake on innovation (suits the cigarette trade); will dramatically reduce competition in the e-cigarette industry (suits the cigarette trade); and favours the e-cigarette business model favoured by the tobacco industry – bricks and mortar high volume simple products (suits…).

Deeming regulation final rule announced

On 10 May 2016, FDA announced the long-awaited rule and related guidance, officially published 10 may 2016.

- Final rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and PDF (134 pages) To fully understand this, you may also need the proposed rule from 2014)
- Final Regulatory Impact Analysis FDA page (PDF of analysis)
- Guidance:
    - Guidance: Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide
    - Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems – the draft guidance in PDF

- Guidance: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Small Entity Compliance Guide
- Guidance: Tobacco Product Master Files
- Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

Commentary

My 2014 submission to FDA: Critical commentary on the public comments on the FDA deeming rule submitted by UCSF faculty and fellows – in which I focus on countering the multiple highly misleading submissions from Professor Glantz and his team at UCSF.

Reaction from the industry and legitimate public health advocates was swift and withering….

- Mike Siegel – The rest of the story: FDA e-cigarette deeming regulations are a disaster for public health and op-ed in WSJ ($)
- Mike Siegel – The rest of the story: FDA Draft Guidance Confirms that Deeming Regulations Will Decimate the E-Cigarette Industry
- Konstantinos Farsalinos: FDA deeming regulation on e-cigarettes: an effective ban on most (and on most effective) products
- CASAA: New FDA E-cigarette Regulations Condemned by CASAA
- Vapor Technology Association: FDA deeming regulation went from bad to worse for vapor industry
- SFATA: Largest Vapor Trade Association Says New Regulations Problematic
- White Cloud E-cigs: Florida Company Gears Up to Supply the Underground "Vaping Prohibition"

Legal challenges

A good summary by Mike Siegel on the cases brought by various litigants as of June 2016.

- First Lawsuit Filed Challenging FDA Deeming Regulations
- Four More Lawsuits Filed Against FDA to Block its E-Cigarette Deeming Regulations

1. Nicopure Labs

2. Right to be Smoke-free Coalition

The Nicopure Labs and Right to be Smokefree Coalition cases have been joined in the District Court of Washington DC.

Plaintiffs' case

- Nicopure News release: Nicopure Labs challenges FDA's deeming rule 10 May 2016.
- Nicopure initial filing: Nicopure Labs LLC vs FDA Robert Califf & Sylvia Mathews Burwell
- Nicopure commentary by Mike Siegel: First lawsuit filed challenging FDA deeming regulation
- Nicopure Motion for Summary Judgement (detailed argument 8 July 2016): Nicopure Labs et al vs Food and Drug Administration et al
- Right to be Smokefree Coalition website: r2bsmokefree.org and the coalition's lawyers, Keller and Heckman, information on the case
- Right to be Smokefree Coalition initial filing: Right to be Smoke-free Coalition vs FDA Robert Califf & Sylvia Mathews Burwell
- Right to be Smokefree Coalition Motion for Summary Judgement (detailed argument 25 July 2016): Right to be Smokefree Coalition vs Food and Drug Administration et al

Amicus Curiae briefs

These are briefs submitted by 'friends of the court' that add a further perspective for the benefit of the court. The following were filed support of the plaintiffs on 5 August 2016.

- Clive Bates and fifteen others – the tobacco harm reduction case
- Smoke-Free Alternatives Trade Association (SFATA)
- National Center for Public Policy Research and TechFreedom
- Vape A Vet

The following were filed in support of the FDA

- Campaign for Tobacco-Free Kid and other activist organisations – 19 August 2016.

FDA response

- FDA response to plaintiffs' motions and *amicus* briefs: Defendant's cross motion for summary judgement – 16 August 2016

Plaintiffs' response to FDA's defence

- Nicopure and Right to be Smokefree Coalition joint memorandum in opposition to FDA's cross motion – 26 August 2016

Court's decision 21 July 2017

The case was lost by Nicopure and Right to be Smokefree Coalition…

> *ORDER. Pursuant to Federal Rules of Civil Procedure 56 and 58, and for the reasons stated in the accompanying memorandum opinion, the [20] [21] motions for summary judgment filed by plaintiffs Nicopure Labs and the Right to be Smoke Free Coalition are DENIED, and defendants' [44] cross-motion for summary judgment is GRANTED. SO ORDERED. Signed by Judge Amy Berman Jackson on 7/21/2017.*

The reasoning is described in the Memorandum Opinion

3. Lost Art Liquids

- New release: Lost Art liquids file lawsuit against FDA
- Initial filing: Lost Art Liquids LLA vs FDA, Robert Califf, Sylvia Mathews Burwell

4. Larry W. Faircloth (State Representative West Virginia)

- Larry W Faircloth – State Representative West Virginia website Fight the FDA

- Initial filing: Larry W. Faircloth vs FDA, Robert Califf, Sylvia Mathews Burwell