

## **Regulations and guidance**

I believe the FDA regulations in use now were intended to regulate tobacco companies as they existed before vaping, thus they are not even appropriate to regulate the small businesses and medium size producers of liquids/equipment.

Instead of showing flexibility in regulating a very different demographic than expected the FDA has tried to force the existing regulations on companies that are not the large multinationals the regulations were intended for.

All nicotine vaping products use the same technology, ingredients, and basic principal. The failure here is to adapt the regulations to the new product, a standards based approach would be more appropriate, considering as above, all new products in this space use the same technology. Standards would also be easier to regulate, updates can be made to incorporate innovations in the product, as required. Standards would also allow important safety updates to be applied to all manufacturers and products, should that be required, with a simple change to a single document. Consumers would be better protected, and innovations that provide better efficiency for people who smoke to make the switch, can be adopted very quickly, and easily.

The current approach favours products from big tobacco and large vape companies, while putting independent american owned companies out of business, possibly exactly the opposite of ideal!

### **Application review**

Please see above, the review process is unfit for purpose, and needs to be totally re-imagined. The vaping nicotine market is not the sort of product envisaged when the current regulations were made, unfortunately sticking to them has done more harm than good.

As noted above a more suitable regulatory framework, such as testing and inspection to ensure compliance with safety standards, would be more affordable, reasonable for businesses of any size, and better for consumer safety.

There appear very few downsides to a standards based approach, and many benefits, including agility, consumer protection, easy (less costly too) verification that products meet the required standard.

The FDA and manufactures are both put in an impossible situation, a new way of dealing with the problem is the only way out. Forcing a poor regulatory system on a regulator and industry harms them both, and the public too. The very worst of all possible outcomes!

### **Compliance and enforcement**

Inspections of manufacturing facilities, testing of samples, or batch testing should be adequate to ensure products are meeting the requirements.

Inspection of and monitoring of retailers to ensure that rules are followed, and customers are given the information required for safe use of the product, and the best advice for transitioning from combustible tobacco to these safer products. Such monitoring can also be used to confirm that retailers follow the law (e.g. T21), and do not sell to minors.

### **Communication with the public and other stakeholders**

The FDA has been woefully inadequate at communicating risk to appropriate members of the public. The so called 'laser targeted' education for youth went laughably off target, being broadcast to mainly adults, e.g. on social media, regular media. That simply hurts people who smoke, by giving the wrong message, often that vaping is worse than smoking (it is absolutely proven, and Brian King acknowledges that vaping is very much less harmful than smoking).

### **Strengths and challenges**

The FDA is quite good at distributing information. Sadly, they are utterly incapable of getting the correct information, to the audience that needs it. The 'demonic possession' campaign for example is most likely to result in the young people who seeing it, thinking the FDA below contempt / utterly ridiculous, while convincing some adults vaping is worse than smoking.

Urgent action is required, because this is not acceptable, or helpful to the public. The health of those who smoke is being damaged by putting them off switching to a vastly safer product, while young people are being encouraged to try vaping to rebel, or because the FDA is so utterly ridiculous as to be laughable.

It is hard to imagine a worse possible outcome.

I would like to see swift action to correct this, it is not acceptable for a regulator to act in this way, actively damaging public health.

### **Additional comments**

I have no additional comments.

### **Stakeholder Group**

Consumer/Consumer Advocate