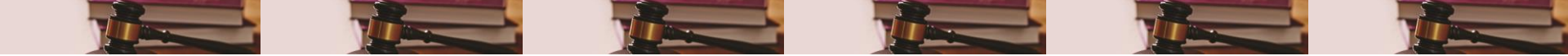

Tobacco: CTP Enforcement Challenges and Opportunities for Reform

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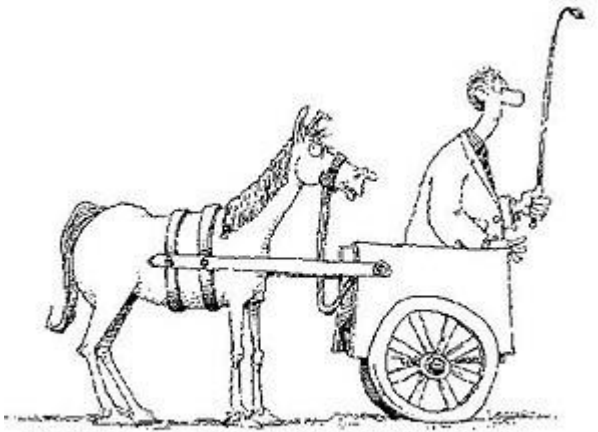
First Things First



Hang on.. I must be doing something wrong..
How does that saying go again?

Before We Can Talk About Enforcement We Need to Know What the Rules Are – and They are Still Being Made

- "And that's why today I'm directing our Center for Tobacco Products **to develop a comprehensive nicotine regulatory plan** premised on the need to confront and alter cigarette addiction."
- "[W]e **will advance rules** that will lay out what needs to be in applications for Substantial Equivalence, Modified Risk Tobacco Product, and Pre-Market Tobacco Product applications; . . . how to possibly regulate kid-appealing flavors in products like Electronic Nicotine Delivery Systems . . . "
- "[W]e must . . . **take a new and fresh look** at the noncombustible side of the house. And that is why part of CTP's task is to reconsider aspects of the implementation of the final deeming rule with an eye towards fostering innovation where innovation could truly make a public health difference, and **making sure we have the foundational regulations we need in place** to make the entire program transparent, predictable, and sustainable for the long run." (Scott Gottlieb, 7/28/17)

What are the Major Guideposts

- "[T]here's a **continuum of risk** for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other."
- "[W]e must recognize **the potential for innovation to lead to less harmful products**, which, under FDA's oversight, could be part of a solution."
- "Armed with the recognition of the risk continuum, and the reality that all roads lead back to cigarettes as the primary cause of the current problem, we need to envision **a world where** cigarettes lose their addictive potential through reduced nicotine levels. And a world where **less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them**." (Scott Gottlieb, 7/28/17)

How to Make Enforcement More Difficult

- Make the Rules Unreasonable
- Make the Rules Expensive

Shake and Vape/Nicotine Shots

- Europe and the “Shake and Vape” Problem
- The Unreasonable Rule – Under the TPD2, the maximum size for a bottle of e-liquid is 10 mL
- The “Expensive” Rule – TPD2 Notification Requirements cost approximately 10,000 GPB per SKU
- The Law-Evading Solution – “Shake and vape” – a 50 mL zero nicotine e-liquid bottle, sold separately from a 10 mL “nicotine shot”

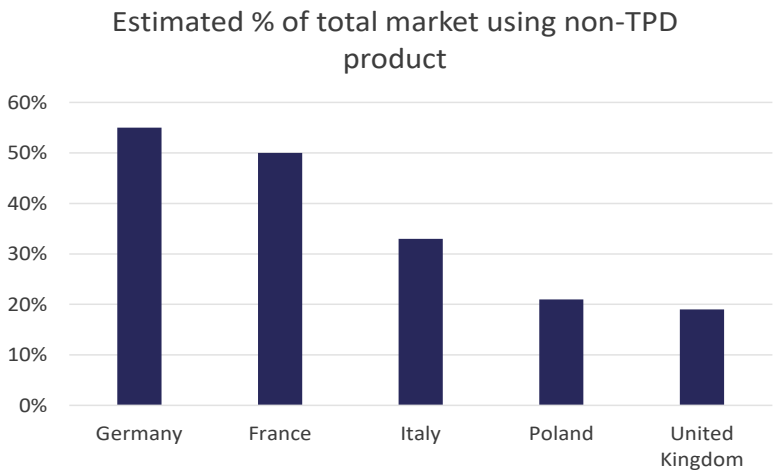
Nicotine Shots. What's the deal?

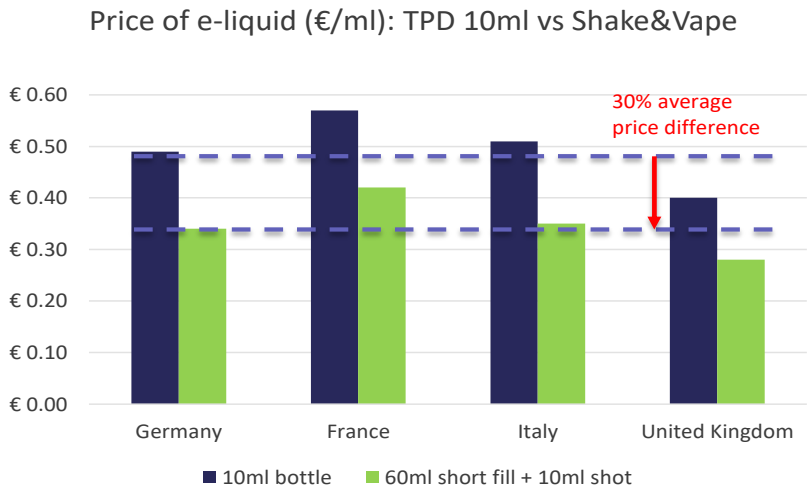
The TPD Legislation regulates the sale of nicotine containing liquids in the UK. This now means that every nicotine containing juice must pass a series of tests that can cost juice makers £10,000+ per flavour and per nicotine strength. For many juice makers, this is simply too expensive to be viable.
That's where nicotine shots come in.

How it works

Where a juice maker has opted to use nicotine shots, you will be able to add it to your order as an "Add-on" product. When you receive your order, you simply mix the shot with the juice, shake it and hey presto! You now have perfectly flavoured juice at the exact nicotine strength you love!

The Size of the Shake and Vape Problem





Requiring Burdensome Pre-Market Authorization

- Canada – The Law

To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada

Electronic smoking products (i.e., electronic products for the vaporization and administration of inhaled doses of nicotine including electronic cigarettes, cigars, cigarillos and pipes, as well as cartridges of nicotine solutions and related products) fall within the scope of the *Food and Drugs Act*. All of these products require market authorization prior to being imported, advertised or sold in Canada. Market authorization is granted by Health Canada following successful review of scientific evidence demonstrating safety, quality and efficacy with respect to the intended purpose of the health product. This evidence is provided by the sponsor seeking market authorization. To date, no electronic smoking product has been authorized for sale by Health Canada.

The Reality


Canada
E Juice
Premium Canadian E Juice


Tillsonburgs Vape Experts
Ontario Electronic
Vape Store
E-Liquid
Hardware

Not Just a Canada Problem

US Challenges – Getting the Cost/Burden Right

- Getting the PMTA right – current FDA estimate of PMTA cost – "a premarket tobacco application (PMTA) = in the low to mid hundreds of thousands of dollars (around $117,000 to around $466,000)" https://www.fda.gov/TobaccoProducts/AboutCTP/ucm378205.htm#1
- Is that number credible?
- Note that the TPD2 cost (10,000 GBP/$13,400) has been sufficiently high to generate evasion
- PMTA Guidance – currently being finalized, a key first test for the Gottlieb-led FDA, post the 7/28/17 Announcement

What is the Incentive to Comply – Need to Think About Both Carrots and Sticks

Carrots = Claims (1)

- "Safer Than/Reduced Harm Claim" - Broad agreement, across public health spectrum (including ENDS skeptics), that ENDS products deliver significantly fewer toxicants to the user than combustion cigarettes.
  - Stan Glantz – referring to the "widely-accepted fact that e-cigarettes deliver lower levels of most cancer-causing chemicals" https://tobacco.ucsf.edu/evidence-e-cigs-increase-cardiovascular-risk-keeps-piling-effects-heart-rhythm-and-oxidative-stress-1)(2/15/17

Carrots = Claims (2)

- "Quitting Smoking Claim" – ENDS products are the number one quit aid in the U.S. (CDC, 4/17), are the number one quit aid in the UK (STS), and led to the first statistically significant rise in the U.S. cessation rate in 15 years (Zhu, et al)
- Broad public health support for use as a quit aid as a second-line intervention
  - CDC - "E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products." (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm)
  - Stan Glantz – "If a patient has failed initial treatment, has been intolerant of or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt."
  - AHA Policy Statement - "If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt."
  - WHO Report - "In considering ENDS as a potential cessation aid, smokers should first be encouraged to quit smoking and nicotine addiction using a combination of already approved treatments. However, at the individual level, experts suggest that in some smokers who have failed treatment, have been intolerant to it or who refuse to use conventional smoking cessation medication, the use of appropriately-regulated ENDS may have a role to play in supporting attempts to quit."

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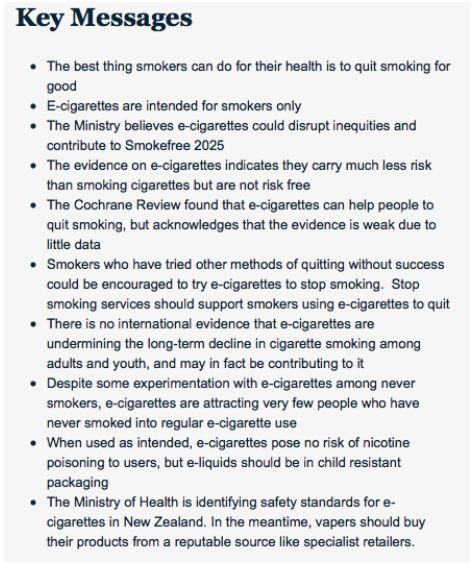
Getting the Carrots Right – Who Can Make Consensus Statements

- Claims – can a product that is the subject of an approved PMTA even be advertised as having been approved by FDA? Not clear from the statute. Can it be advertised as reduced harm? Presumably not. Can it be advertised as a quit aid? Presumably not.
- MRTP pathway – time, cost - Swedish Match, IQOS
- CDER pathway – time, cost
- Will the government make consensus statements?
- If the approval pathway is too time-consuming, too expensive, and not rewarded with a sufficient claims-making ability – there will be an incentive to evade compliance and the enforcement challenge will be greater

Is the Law an A**?

Can the Government Ameliorate the Problem by Making Consensus Statements – at least for PMTA Products?



Key Messages

- The best thing smokers can do for their health is to quit smoking for good
- E-cigarettes are intended for smokers only
- The Ministry believes e-cigarettes could disrupt inequities and contribute to Smokefree 2025
- The evidence on e-cigarettes indicates they carry much less risk than smoking cigarettes but are not risk free
- The Cochrane Review found that e-cigarettes can help people to quit smoking, but acknowledges that the evidence is weak due to little data
- Smokers who have tried other methods of quitting without success could be encouraged to try e-cigarettes to stop smoking. Stop smoking services should support smokers using e-cigarettes to quit
- There is no international evidence that e-cigarettes are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it
- Despite some experimentation with e-cigarettes among never smokers, e-cigarettes are attracting very few people who have never smoked into regular e-cigarette use
- When used as intended, e-cigarettes pose no risk of nicotine poisoning to users, but e-liquids should be in child resistant packaging
- The Ministry of Health is identifying safety standards for e-cigarettes in New Zealand. In the meantime, vapers should buy their products from a reputable source like specialist retailers.

Could it Happen Here?

tfn® Nicotine
Not derived from Tobacco
Leaf, Stem, or Waste Dust