

## Totally Wicked vs. the EU's tobacco directive

Written by Gilbert Ross on 13 October 2014



The EU's five-year process of revising the tobacco products directive (TPD) has resulted in a nearly-unmitigated disaster. Eschewing at every opportunity science-based (or even rational) policy, a conflicted, unaccountable bunch of commissars, (I mean commissioners) working in secret and in concert with like-minded petty mandarins, crafted a destructive, corrupt framework for dealing with tobacco. Many of us who are devoted to public health - specifically interested in reducing the dreadful toll of smoking via harm reduction and disgusted with this measure foisted on an unsuspecting populace - hoped some entity with credibility and resources would tackle the TPD legally.

At last, this has been addressed: the UK-based electronic cigarette (eCig) and vapour product company Totally Wicked (TW) has not only launched a formal legal challenge, but has passed two big hurdles: on 31 July their brief gained acceptance from the UK's administrative court to bring a judicial review action challenging the TPD's article 20 as to process and substance. And on 6 October, earlier this week, the administrative court judge acquiesced in furthering the TW litigation all the way towards a hearing in the EU court of justice (ECJ), next spring in Luxembourg.

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Everyone agrees that smoking is the most important, catastrophic - yet preventable - cause of disease and death in the western world: while 100 million lives were lost to tobacco in the last century, reliable estimates predict one billion were cut short in the 21<sup>st</sup>. The lethal use of tobacco derives almost entirely from the smoking of cigarettes. The ostensible goal of the TPD revision was to reduce the toll of smoking, an especially important issue in Europe, where about 30 percent of the population smokes, and where almost 700,000 die each year from it.

How did the current TPD version come to be so miserably wrong? The perverse requirements of the extraordinarily lengthy section dealing with electronic cigarettes and vapour products, now known as article 20, are more stringent than those applied to cigarettes. The Byzantine process of making legislative and regulatory policy in the EU cannot be understood, or even described, in an opinion piece of reasonable length. Suffice it to say that the three-headed lawmaking organs - the commission, the European council and the parliament - simply evaded (or when necessary, ignored) the legal framework mandated by the treaties which created the EU; many of the proposed regulations fly directly in the face of both the substance and the spirit of these pillars of the EU.

Saying it could have been worse is unacceptable as an explanation of the irresponsible measure facing European smokers and eCig users ('vapers') now. During much of the TPD debate, calls for requiring medicinal regulation seemed to hold sway - which would have surely removed these breakthrough devices from the market completely for years, perhaps permanently. When the parliament, encouraged by the accumulating evidence of eCigs benefits and small-to-negligible risks, and moved by a newly-voice outcry of consumers themselves, voted convincingly last October to regulate them as consumer products instead, it seemed that the sun had broken through the clouds of ignorance, agenda and corruption which enshrouded the issue.

In an astounding feat of legalistic broad-daylight larceny, the commission and council resolved - in secret - over the ensuing months to veto, in effect, the voice of the people and create a new eCig paradigm that amounted to creating an entirely new TPD as regarding eCigs. Flouting the law-making principles as well as the underlying science regarding reduced-risk nicotine delivery products, the resultant document was presented as basically a *fait accompli* to the parliament in January, with the threat of having to start the process all over again hanging over their heads.

Therefore, despite the clear evasion of the tenets of consultation, scrutiny by national parliaments, proportionality ('lightest touch'), impact assessment and effect on commerce and free movement of goods - all fundamental to the EU - the current iteration presents strictures on eCigs which will surely drive most (if not all) of them off the market, leaving those remaining far less effective in helping smokers quit. Vapour products will be especially hard hit, just as the market for these customised devices are taking over from the standardised 'cigalikes' mainly sold by 'big tobacco'.

What are the alleged bases of the severe restrictions on eCig marketing? Ignorance and fear account for some: the media and politicians benefit from fear-mongering and alarmism about eCig bogeymen; yet the evidence behind such concerns is absent. 'Nicotine poisoning' and an apocryphal 'gateway effect' of eCigs luring teens into smoking are two of the most common myths. Doing some actual

research - not a common activity among our lawmakers, unfortunately - would reveal these as the fictions they are.

Another factor is not so easily countered: brazen corruption. It has been suspected that 'big pharma', in an effort to protect their lucrative market for nearly-useless nicotine replacement products (patches, gum, etc.) and drugs (both ineffective and potentially toxic) have been supplying generous quantities of financial incentives to both regulators and 'public health' non-profits to spread the mantra of eCig hypothetical risks. Indeed, a few months ago, emails to members of parliament from a pharmaceutical company lobbying against eCigs by citing false and half-true allegations came to light.

Clearly, article 20 of the TPD, created in shadows and in haste, must be scrapped, having failed in all spheres: science, policy and process. It is to be fervently hoped that the Totally Wicked litigation will succeed in the upcoming months in the ECJ, and an intelligently and responsibly revised TPD can be made into a valid regulatory structure: protecting EU residents from poorly-made or contaminated nicotine-delivery products, protecting children (via packaging regulations and age restrictions on sales and marketing) from inadvertent exposure, and informative labelling. It is difficult, frankly, to be overly optimistic, despite the overwhelming evidence for change: remember that the EU's guiding lights have stubbornly maintained the perverse ban on snus despite numerous science-based calls for its revocation. Stringent regulations contained in the current TPD will merely drive ex-smokers back to deadly cigarettes and discourage desperate, addicted smokers from quitting at last.

### **About the author**

Gilbert Ross is the executive director and medical director of the American Council on Science and Health (ACSH)

[rossg@acsh.org](mailto:rossg@acsh.org) [1]

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