

A Response to the MHRA

Gower Enterprises Ltd response to the MHRA consultation document.

Gower Enterprises Ltd is the owner of the website ECigaretteDirect.co.uk, the UK distributor of the NJOY brand of electronic cigarettes. NJOY, Inc. have very strict quality control procedures in place, and have independent test results from a leading USA laboratory showing the product is toxin free.

Position

While Gower Enterprises Ltd agrees that effective regulation is necessary, it also believes that the electronic cigarette should be regulated as an alternative to smoking, and not as a medicine.

To that effect, we propose that an alternative regulatory framework be implemented under which Trading Standards can operate and which will ensure the safety of the devices.

Current timelines for the application for the device to become a medicine (two weeks) are not feasible, and may represent an attempt by the MHRA to ban the device in favour of nicotine cessation aids, due to the close relationship with the pharmaceutical industry as identified by a 2004 Parliamentary Select Committee.¹

Gower Enterprises is committed to working and co-operating with whomever is necessary in order to ensure the effective regulation of electronic cigarettes.

1. Unfair Competition

Tobacco products are not currently regulated as medicines. E-Cigarettes are an alternative to smoking traditional tobacco cigarettes, delivering nicotine (which is a legally available drug) without tobacco. Imposing more onerous regulation upon electronic cigarettes than on tobacco cigarettes would place the considerably more dangerous tobacco cigarettes at an unfair competitive advantage. In particular, as we detail below in point 7, we believe the proposed timeline for licensing (two weeks) to be unrealistic, especially as no guidelines for the licensing have yet been proposed. If regulation which we believe is unfair or unwarranted is imposed by the MHRA, or if - due to the time scale involved - we are forced out of business and out of

House of Commons Select Committee The Influence of the Pharmaceutical Industry <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>

competition with the tobacco industry, we will be presenting our case against the MHRA as a business with the EU via SOLVIT. We will also be seeking judicial review of the MHRA's decision.

2. Viable Alternative to Cigarettes

We believe electronic cigarettes are an attractive and feasible alternative to the cigarettes which kill more than 100,000 Brits every year.

Experts such as Dr Joel Nitzkin estimate that the danger posed by electronic cigarettes is considerably less than 1% that of traditional cigarettes. ²

In contrast to the ingredients of tobacco cigarettes, FDA tests on the ingredients of the electronic cigarette showed that the electronic cigarettes tested contained nitrosamines hundreds of times lower than tobacco cigarettes and at similar levels to those contained in existing nicotine cessation aids. ³ Independent testing of the NJOY's vapour (as opposed to its ingredients) showed that no toxic nitrosamines at all were produced. ⁴

In contrast to cigarettes, combustion does not take place. According to scientific experts at tobacoharmreduction.org, combustion is the main cause of harm in the tobacco cigarette.

30% of house fire deaths in the UK are caused by tobacco smokers. A local fire service is considering offering free electronic cigarettes to elderly smokers at risk. In contrast, electronic cigarettes pose no fire hazard.

A survey of electronic cigarette users also found that e-cigarette users experienced numerous short term health benefits when compared to their previous experiences of smoking tobacco cigarettes. ⁵ This in no way implies that these products must be

² Nitzkin, J: <http://www.ecigarettdirect.co.uk/interviews/joel-nitzkin-electronic-cigarette.html>

³ Siegel M. Comparison of Carcinogen Levels Shows that Electronic Cigarettes are Much Safer Than Conventional Ones <http://tobaccoanalysis.blogspot.com/2009/07/comparison.html>

⁴ NJOY Tests <http://www.ecigarettdirect.co.uk/research/NJOY-analyze-report.pdf>

⁵ Electronic Cigarettes (E Cigarettes) As a Potential Harm Reduction Product <http://www.ecigarettdirect.co.uk/research/electronic-cigarette-working-paper.html>

considered medicines. (Similar health benefits would be felt by those taking more exercise, for example, which would not require a MHRA MA either.)

David Swenor, a former advisor on tobacco control to the WHO, informed us that:

"If there is anyone who believes cigarettes are no more hazardous than e-cigarettes I'd recommend a remedial course in basic sciences."

A comparison of the risks of smoking e-cigarettes and tobacco cigarettes, he told us, would be that between playing with a football and playing with a live grenade. ⁶

Given that tobacco cigarettes kill between 1/3 and 1/2 of long term users, we believe that the electronic cigarette should be available as widely as possible as a recreational alternative for smokers.

3. Use of the Electronic Cigarette

There are numerous uses of the electronic cigarette. Users purchase them for many reasons, including commonly: to save money; for health reasons; to increase the number of places where they can smoke. According to a Consumer Electronic Cigarette Survey, less than 8% of users buy the product to treat nicotine addiction. ⁷ By labelling it as a medicine, the use of the product may be decreased, with smokers continuing to smoke tobacco cigarettes estimated to be approximately 99% more harmful (as outlined in point 2 above).

4. EU Guidelines

The EU directive 2001/83/EC states "Electronic cigarettes may fall under the definition of a medicinal product if the product is presented as a remedy against nicotine addiction or if it is qualified as restoring correcting or modifying physiological functions" (emphasis added).

If the electronic cigarette or the nicotine cartridge are not classified as either medicinal product or medical device, Directive 2001/95/EC on general product safety applies by default. This Directive provides for restrictive or preventive measures to

⁶ Swenor, D: <http://www.ecigarettedirect.co.uk/interviews/david-swenor-2.html>

⁷ CASAA, Poll of Electronic Cigarette Users: Why Did You Start Vaping?, CASAA.org

be taken if the product is found to be dangerous to the health and safety of consumers.⁸

The NJOY electronic cigarette is not marketed as a smoking cessation device. It is an alternative method of nicotine delivery, without the attendant harms of tar, tobacco and hot smoke found in traditional nicotine delivery systems, and without the concomittent dangers of combustion and fire damage and death. It does not purport to be a nicotine replacement therapy. The component parts comply with EU and UK regulations, and the labelling is as required by Trading Standards officers in Keighley, where the company is based.

5. Reasonable Regulation

NJOY and Gower Enterprises Limited welcome reasonable regulation. Having invested a large amount of time, research and money into the quality and safety of their product, NJOY would like the industry's less responsible companies producing inferior and untested items at cheap prices to either leave the industry or compete on a level playing field. Such regulations should set a minimum standard to which companies must conform to gain approval, and presently this should come under the auspices of Trading Standards, who regulate the rest of the tobacco product industry. We understand that industry expert Katherine Devlin is suggesting guidelines for a minimum standard to be regulated by a dedicated tobacco regulation authority, and in principle we support this approach.

We suggest that the sale of electronic cigarettes as a recreational device be limited to adults over the age of 18 to bring them in line with the sale of tobacco. Suffice to say, we do not believe it would be appropriate to classify our products as tobacco products or medicines - we are entirely separate from these two industries.

NJOY and Gower Enterprises Ltd are ready and more than willing to work with a UK regulating body to comply with reasonable requirements should this be required, although we feel that Trading Standards officers have proven themselves to be more than capable of effectively regulating our products.

6. Consumer's Rights

Adding any restrictions on a product imposes on the rights of smokers, consumers and the public. Given that electronic cigarettes are a viable alternative to cigarettes

⁸ Answer given by Mr Dalli on behalf of the EU Commission.

(see point 2 above), the public should have the right to buy these products without being labelled as 'sick' in order to do so.

7. Time Scale

As already mentioned above, the two week timescale suggested in Option 1 for application to become a medicine is unfeasible and unjustified, and will cause the demise of many small companies and subsequent hardship, both to the users of the product and suppliers. This will lead to an influx of cheap, poor-quality, uncontrolled and unregulated products onto a black market, loss of import duty and VAT revenue, and a lack of support to the consumer, as well as the return of thousands of e-cigarette users to the cigarettes that kill over a hundred thousand British people a year.

8. Lack of Justifiable Reason

8.1 No justifiable reason has been given for the the MHRA's actions. To date, and despite over 800,000 kits being sold in the US, there has been no case of a user dying after use of an electronic cigarette. As we demonstrate in point 9.2 the evidence quoted in favour of the MHRA's position is not credible.

We believe that commercial interests are affecting this issue, including those of the tobacco industry, the government with its potential loss of lucrative cigarette-generated revenue and the pharmaceutical industry which itself largely funds the MHRA, and which earns very large sums through NHS-funded supply of nicotine cessation therapy products.

It is observed that the MHRA is ignoring the legal requirement of presentation and qualification or proof of purpose in order to close the commercial nicotine market. They have no evidence to show risk or a need to do this, and are breaking even their own mandate.

Nicotine itself does not cause tobacco-related disease or death (as is indeed acknowledged both in the MHRA's own consultation document and in the Royal College of Physicians' advice). It carries about the same health risk as another widely used addictive drug: caffeine.⁹

⁹ Tobacco Myths <http://www.oasas.state.ny.us/admed/documents/TobaccoMyths.pdf>

NJOY and Gower Enterprises Limited believe that smokers should be truthfully informed about comparable health risks and have unhindered access to less hazardous, smoke-free alternatives.

A recent study showed that switching to alternative non-medicinal nicotine products reduces health risks nearly as much as quitting totally, which emphasises that the product must remain freely and easily accessible to all. ¹⁰

8.2 MHRA Evidence

The MHRA based its call for the electronic cigarette to be regulated as a medicine on an FDA press release which stated that the electronic cigarette contains toxic chemicals.

- The FDA manipulated the findings of its researchers, pointing out the existence of nitrosamines in the e-cigarette liquid whilst failing to point out that levels were similar to those found in existing approved nicotine cessation aids. ¹¹

- The existence of one percent of diethylene glycol in one sample of one brand (Smoking Everywhere) should not be reason to punish all brands of electronic cigarette. In particular, the same analysis of the NJOY electronic cigarette found that the ingredients of the electronic cigarette contained no diethylene glycol at all. ¹²

- The FDA's position did not stand up in court, with Judge Leon pointing out that:

"While the FDA's interest in protecting public health and safety is, in the abstract, paramount to plaintiffs' purely economic interests, given the particular facts and circumstances of this case, I am not convinced that the threat to the public interest in general or to third parties in particular is as great as FDA suggests. Together, both Smoking Everywhere and NJOY have already sold hundreds of thousands of electronic cigarettes, yet FDA cites no evidence that those electronic cigarettes have endangered anyone. Nor has FDA cited any evidence that electronic cigarettes are

¹⁰ Phillips, C

Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments
<http://harmreductionjournal.com/content/6/1/29>

¹¹ Siegel, M <http://tobaccoanalysis.blogspot.com/2009/07/tobacco-specific-carcinogens-found-in.html>

¹² NJOY Tests <http://www.ecigarettedirect.co.uk/research/NJOY-analyze-report.pdf>

any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public." ¹³

Scientists have criticised the FDA's interpretation of their own study. Professor Carl Phillips argues that the FDA's announcements represented propaganda, not science ¹⁴, while Professor Michael Siegel has pointed out that banning the electronic cigarette based upon the findings of the FDA would also mean banning peanut butter. ¹⁵

ECigaretteDirect would also like to highlight that a press release issued by LACORS stating that electronic cigarettes contained up to 20% of nicotine was incorrect. The statement was based upon an elementary mathematical mistake which led to the quantity of nicotine being exaggerated by a factor of 10. For example, one cartridge was labelled at 18mg/ml, and could have been assumed by a non-mathematician to contain 18% nicotine. However, 18mg/ml would represent a nicotine concentration level of 1.8%, not 18%. ¹⁶ The lower quantity is far more in line with tests carried out by Health New Zealand, the FDA and others.

8.3. Legal Advice

The MHRA tells us that they have received legal advice that nicotine should be regulated as a medicine because it affects the metabolism of the body. (We note that cigarettes, alcohol and caffeine also affect the metabolism of the body and yet are not required to be regulated as medicines.) However, the MHRA has refused to disclose any more details regarding this advice, despite a freedom of information request. It is our view that the overwhelming public interest in a decision which could return tens of thousands of e-cigarette users to tobacco cigarettes clearly outweighs the legal professional privilege the MHRA is trying to claim as its excuse not to disclose the information.

8.4 Extension of Power

¹³ Judge Leon Memorandum p.30/31 <http://www.ecigarettedirect.co.uk/research/judge-leon-report.pdf>

¹⁴ Phillips, C <http://www.ecigarettedirect.co.uk/carl>

¹⁵ Siegel, M <http://tobaccoanalysis.blogspot.com/2009/08/action-on-smoking-and-health-warns.html>

¹⁶ Katherine Devlin: LACORS maths blunder threatens hundreds of thousands of UK lives (LACORS incorrect nicotine statement)

The MHRA told us in a recorded (with permission) telephone call that one reason they want to regulate the electronic cigarettes as medicines is that this is the only way that electronic cigarettes can be regulated. We do not believe this is a valid reason for regulation. We dispute that Trading Standards' officers unable to regulate these consumer products. Electronic cigarettes are already regulated perfectly adequately by Trading Standards with cooperation from our industry. We note that in Judge Leon's judgement against the FDA he also accused the FDA of attempting to extend its regulatory power, stating:

"This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the FDCA." ¹⁷

8.5 Conflict of Interest

A 2004 parliamentary select committee found that the MHRA had an "unhealthy" relationship with the pharmaceutical industry, was financed by the industry it regulated and was often staffed by that industry. ¹⁸ The electronic cigarette competes with the nicotine cessation products produced by the pharmaceutical industry, which often promotes them by funding studies designed to exaggerate claims of the success rate of nicotine cessation aids. ¹⁹ The electronic cigarette is regarded as a threat by the nicotine cessation industry, as shown by an industry report which stated: "E-Cigarettes Will Revolutionise the Face of Tobacco Smoking and Could Pose a Threat to the Smoking Cessation Market." ²⁰

9. Unfair Exemption

Nicotine is freely available in products which are exempt from regulation as medicines, in cigarettes as well as other readily available products such as aubergines and tomatoes. ²¹

¹⁷ Judge Leon Memorandum p.30/31 <http://www.ecigarettedirect.co.uk/research/judge-leon-report.pdf>

¹⁸ House of Commons Select Committee The Influence of the Pharmaceutical Industry <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>

¹⁹ House of Commons Select Committee The Influence of the Pharmaceutical Industry <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>

²⁰ (Webpage removed since we highlighted this on our website, but the table of contents have been published here: <http://velvetgloveironfist.blogspot.com/2010/02/talking-e-cigarettes-and-rest.html>.)

²¹ The Nicotine Content of Common Vegetables <http://content.nejm.org/cgi/content/extract/329/6/437>

In the event that nicotine-delivery devices are to be classed as medicines, then other products containing nicotine cannot fairly be exempted. We dispute the authority of the MHRA to reclassify general sales products as medicinal products.

10. An Alternative Solution

As stated before ECigaretteDirect, while objecting to labelling the electronic cigarette as a medicine, welcomes structured regulation ensuring that quality control and standards are met by all electronic cigarette retailers.

The product falls between two categories: it is neither a tobacco cigarette nor a smoking cessation product. All the research demonstrates that electronic cigarettes are an alternative and less harmful option for tobacco smokers to continue to enjoy nicotine, with no effect on other individuals by their usage. Most users of electronic cigarettes continue to use the electronic cigarette rather than ceasing to use nicotine.

There are risks involved in attempting to regulate electronic cigarettes as medicines. These risks include decreased availability and making the product less attractive to existing smokers. This will inevitably involve many current e-cigarette users switching back to smoking tobacco cigarettes, and many cigarette users failing to switch from smoking tobacco cigarettes to using electronic cigarettes.

As far as we know, no risk assessment has been carried out either of the inherent risks of the product or of the ramifications of making the product a medicine. Denial of access to this product will encourage people to return to tobacco cigarettes with their concomitant and fully-acknowledged dangers, leading to increased death and illness amongst nicotine users who will smoke cigarettes if unable to use this safer alternative.

In view of this, we suggest a middle way, where a regulatory framework is drawn up which will enable safe and effective regulation of the electronic cigarette by Trading Standards, thus avoiding the risks associated with regulating nicotine delivery devices as medicines (as outlined above).

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