Submission from Julian Morris of Reason Foundation to the Hong Kong Government Panel on Health Services Special meeting on Legislative proposals to strengthen tobacco control, regarding the safety, utility and legality of electronic cigarettes.

The Hong Kong department of health recently made a series of statements regarding electronic cigarettes. I examine these statements (highlighted in yellow) in turn as they were reported on the website of the tobacco control office.<sup>1</sup>

1. The Department of Health (DH) today (March 4) called on smokers not to use electronic cigarettes as the safety, efficacy and quality of this kind of product have to be established.

The safety of electronic cigarettes has been evaluated in numerous studies. A recent (2014) metaanalysis published in the journal *Therapeutic Advancements in Drug Safety* concluded that:

"Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes."<sup>2</sup>

Claims that some electronic cigarettes deliver toxic doses of formaldehyde, such as those made by Pankow et al. in a recent letter published by the New England Journal of Medicine (NEJM), are based on experiments that do not reflect actual use of these devices, as my colleague Jacob Sullum has noted:

The implication—that vapers in the real world are apt to generate levels of formaldehyde similar to those generated by Pankow et al.'s machine—is highly misleading. "By setting their machine to repeatedly take three-to-four-second puffs at 5.0 volts, the researchers overheated the vaporizer," says Bill Godshall, executive director of Smokefree Pennsylvania. "Vapers call this the 'dry puff phenomenon' and don't do it due to the very harsh and awful taste. By making a false assumption and by multiplying that false assumption over and over, the researchers got it all wrong. There is no scientific evidence that e-cigs increase risks for cancer or any other disease."

Moreover, even if e-cigarettes result in the inhalation of more formaldehyde than would be obtained from a conventional cigarette, that does not make them less safe than those products. Far from it: the carcinogenic and other adverse health effects from burning tobacco result from a

<sup>&</sup>lt;sup>1</sup> http://www.tco.gov.hk/textonly/english/infostation/infostation\_04032009.html

<sup>&</sup>lt;sup>2</sup> http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/

<sup>&</sup>lt;sup>3</sup> http://reason.com/blog/2015/01/22/does-formaldehyde-make-e-cigarettes-wors

wide range of particulates, polyaromatic hydrocarbons and other substances that are the direct consequence of burning tobacco. Since e-cigarettes don't contain tobacco (they typically contain liquid nicotine mixed with propylene glycol and flavourings), it is not possible for them to produce most of these toxic products. The lead author of the NEJM letter admitted as much, as Sullum reports:

Pankow told NBC "we are not saying e-cigarettes are more hazardous than cigarettes," although that is the impression left by the NEJM letter. He noted that "we are only looking at one chemical" out of the thousands that can be found in tobacco smoke, of which hundreds are toxic or carcinogenic. "The jury is really out on how safe these drugs are," he said. According to Reuters, "Pankow conceded that the study could have contained more context about overall relative risk, but said the authors 'just wanted to get it out."

E-cigarettes are probably not harmless but a report from Public Health England puts these concerns into context:

"Cigarettes deliver nicotine in conjunction with a wide range of carcinogens and other toxins contained in tar, including nitrosamines, acetone, acetylene, DDT, lead, radioactive polonium, hydrogen cyanide, methanol, arsenic and cadmium, [30] and vapour phase toxins such as carbon monoxide. [7] In contrast, electronic cigarettes do not burn tobacco, so any toxins in vapour arise either from constituents and contaminants of the nicotine solution, and products of heating to generate vapour. The principal component other than nicotine is usually propylene glycol, which is not known to have adverse effects on the lung[31] but has not to our knowledge been tested in models that approximate the repeated inhalation, sustained over many years, that electronic cigarettes involve. We are aware of two cases of lipoid pneumonia attributed to inhalation of electronic cigarette vapour, one in the peer-review literature[32] the other a news report. [33]

Despite some manufacturers' claims that electronic cigarettes are harmless there is also evidence that electronic cigarettes contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic to humans, [34] and that in some cases vapour contains traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead. [34] Although levels of these substances are much lower than those in conventional cigarettes, [34] regular exposure over many years is likely to

present some degree of health hazard, though the magnitude of this effect is difficult to estimate."<sup>4</sup>

In other words, e-cigarettes are almost certainly significantly less harmful than cigarettes. So, while it would certainly be desirable to continue to improve understanding of the health effects of e-cigarettes so that consumers can demand and manufacturers thereby encouraged to produce increasingly safer products, it seems wholly inappropriate at this point to prohibit their use.

2. A DH spokesman said initial laboratory analysis on a sample of electronic cigarettes revealed that it contained nicotine.

While most electronic cigarettes contain nicotine, not all do. Open vapor systems, for example, allow users to decide the level of nicotine being used, which can be zero if the user so chooses.

However, the ability to deliver nicotine through electronic cigarettes is a feature, not a bug. Studies show that nicotine delivered by an electronic cigarette more closely matches the pharmacokinetics of nicotine delivered by a conventional burnt tobacco cigarette than most smoking cessation devices, including patches and current non-electronic inhalers. Since most smokers choose to consume nicotine and many revert to smoking because alternatives fail adequately to deliver nicotine, <sup>5</sup> electronic cigarettes offer a desirable alternative that is safer than conventional cigarettes. <sup>6</sup>

As regards the toxicity of nicotine, a comprehensive report released in 2014 by Public Health England came to the following conclusion:

- "... aside from minor and transient adverse effects at the point of absorption, nicotine is not a significant health hazard. Nicotine does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease, [27, 28] and is not carcinogenic. [29] The doses of nicotine delivered by electronic cigarettes are therefore extremely unlikely to cause significant short or long-term adverse events."
- 3. The spokesman stressed that under the Pharmacy and Poisons Ordinance, electronic cigarettes containing nicotine and marketed as tobacco cessation products were classified as pharmaceutical product requiring registration in Hong Kong.

<sup>&</sup>lt;sup>4</sup> <u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/311887/Ecigarettes\_report.pdf</u> <sup>5</sup>E.g.: Henningfield, J.E. 1995. "Nicotine medications for smoking cessation." New England Journal of Medicine

<sup>33: 1196-203;</sup> Campling BG, Kuryatov A, Lindstrom J (2013) Acute Activation, Desensitization and Smoldering Activation of Human Acetylcholine Receptors. PLoS ONE 8(11): e79653. doi:10.1371/journal.pone.0079653; <a href="http://jpet.aspetjournals.org/content/287/3/958.long">http://jpet.aspetjournals.org/content/287/3/958.long</a>;

<sup>&</sup>lt;sup>6</sup> http://www.ncbi.nlm.nih.gov/pubmed/24830741; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/; http://www.ingentaconnect.com/content/png/ajhb/2014/00000038/00000002/art00012

<sup>&</sup>lt;sup>7</sup> https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/311887/Ecigarettes\_report.pdf

If true, this would be unfortunate, since registration is a time consuming and expensive process. Forcing electronic cigarette manufacturers to go through this process would likely result in a significant reduction in the availability of these products on the markets and an increase in their price. This would make it more difficult for smokers and former smokers to access the devices. The almost certain result is that more people in Hong Kong will continue to smoke, with adverse effects for their health.

Legally, the claim that electronic cigarettes should be treated as a pharmaceutical product is highly questionable. According to the Pharmacy and Poisons (Amendment) Ordinance 2015:

"pharmaceutical product" (藥劑製品) and "medicine" (藥物) mean any substance or combination of substances— (Amended 2 of 2015 s. 4)

- (a) presented as having properties for treating or preventing disease in human beings or animals; or
- (b) that may be used in, or administered to, human beings or animals, either with a view to—
- (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
  - (ii) making a medical diagnosis; (Replaced 50 of 1977 s. 2. Amended 2 of 2015 s. 4) $^8$

Since smoking is not in itself a disease, a product marketed as a means of ceasing consumption of tobacco does not qualify as a "pharmaceutical product" or "medicine" under (a). So, electronic cigarettes would only qualify if they are specifically presented as treating or preventing a disease, or are being used with a view to "restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action," per section (b)(i) above. But it is not clear that any electronic cigarettes are being used in this way.

Devices used with liquid that does *not* contain nicotine or other substances intended to exert a pharmacological, immunological or metabolic action are certainly not being used in this way.

To the extent that electronic cigarettes are being used in this way (e.g. arguably when they contain or are used with liquid containing nicotine), so are dozens of other devices. For example, espresso machines are used to produce a substance (coffee, which contains caffeine along with dozens of other chemicals) that is consumed at least in part in order to modify physiological functions by exerting a pharmacological, immunological and metabolic action. Kettles also are often used for a similar purpose when the substance they contain is poured onto coffee grounds or tea leaves. Is the DH also planning to regulate espresso machines and kettles as pharmaceutical devices?

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4. He said that investigations by DH had indicated that several brands of electronic cigarettes were found on sale on internet and in individual local shops.

This is likely good news for smokers, since it means they have a choice – making it more likely that they will find a device that helps them to quit smoking. Moreover, the evidence shows that over time choice and competition has resulted in a dramatic improvement in the quality of electronic cigarettes available to consumers. Reducing this choice artificially through regulation would be harmful.

5. DH raided a shop in Sham Shui Po earlier today, resulting in the seizure of nine types of electronic cigarettes. DH's investigations are in progress.

This is unfortunate, as it is likely to discourage that shop – and others – from stocking these beneficial devices.

6. DH has also instructed the parties concerned to remove electronic cigarettes advertisements and promotional materials from their websites.

Again, this is unfortunate. It is important that manufacturers and retailers of electronic cigarettes be permitted to advertise their products in a truthful way. So doing increases the chances that smokers will switch to this safer alternative.

7. The spokesman said possession or sale of unregistered pharmaceutical product, and possession of Part I poisons without authority were both liable on conviction to a \$100 000 fine and two years' imprisonment.

It is most unfortunate that the DH has chosen to view electronic cigarettes as an unregistered pharmaceutical product. It would seem far more logical to treat conventional cigarettes in this way, since the available evidence suggests that they represent a far greater threat to health than electronic cigarettes. (We should stress that we do *not* advocate this, as it would present a gross violation of personal liberty.)

Locking up and/or imposing fines on users of e-cigarettes would likely result in the following:

- a. Fewer people will switch to e-cigarettes. As a result, more people will continue to consume burnt tobacco products, with adverse health consequences.
- b. Some people will continue to use e-cigarettes illegally, relying upon products of uncertain quality purchased on the black market. These products may well be less safe than products sold openly, since there is less incentive to ensure the quality of the product and no legal recourse.
- c. E-cigarette manufacture and sale will become dominated by organized crime, with local control of distribution channels maintained through violence.
- d. The HK government will spend significant resources on law enforcement attempting to control sale and use of e-cigarettes but even so will fail to eliminate their use.

- e. Local law enforcement will be paid off with bribes by the criminal gangs who will come to dominate the sale of e-cigarettes. This will create a toxic culture of corruption within law enforcement.
- f. Law enforcement in Hong Kong will focus fewer resources on criminal activities that actually pose a threat to inhabitants and visitors.

Out of interest, is the DH proposing also to regulate other nicotine-containing products in this way? Eggplant and tomatoes, for example?

8. He urged members of the public who have been using electronic cigarette to stop using it immediately.

This is most unfortunate. Evidence suggests that warnings from government officials can be effective in discouraging use of tobacco products – for example in the U.S., the 1964 Surgeon General's warning concerning burnt tobacco products initiated a long-term decline in smoking. If this warning results in fewer people switching to electronic cigarettes, as seems likely, then more people will continue to smoke, which will result in an increase in the incidence of morbidity and mortality relative to what would have happened had those people switched to electronic cigarettes.

It seems unlikely that the spokesman for the DH intends to cause people to suffer and die, so it is unclear why he should have issued such a counterproductive statement.

9. They should destroy and dispose of the products or submit them to the DH's Pharmaceutical Service at 3/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon during office hours.

No comment.

10. Smokers who want to quit smoking should seek advice from medical professionals. Information on smoking cessation can be obtained at the Tobacco Control Office website.

Medical professionals from across the world agree that electronic cigarettes are a powerful tool for smokers who wish to quit. Here is the summary and conclusion from the Public Health England study mentioned earlier:

"Smoking kills, and millions of smokers alive today will die prematurely from their smoking unless they quit. This burden falls predominantly on the most disadvantaged in society. Preventing this death and disability requires measures that help as many of today's smokers to quit as possible. The option of switching to electronic cigarettes as an alternative and much safer source of nicotine, as a personal lifestyle choice rather than medical service, has enormous potential to reach smokers currently refractory to existing approaches. The emergence of electronic cigarettes and the likely arrival of more

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effective nicotine-containing devices currently in development provides a radical alternative to tobacco, and evidence to date suggests that smokers are willing to use these products in substantial numbers. Electronic cigarettes, and other nicotine devices, therefore offer vast potential health benefits, but maximising those benefits while minimising harms and risks to society requires appropriate regulation, careful monitoring, and risk management. However the opportunity to harness this potential into public health policy, complementing existing comprehensive tobacco control policies, should not be missed."<sup>10</sup>

<sup>10</sup> https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/311887/Ecigarettes\_report.pdf