Unable to take any more, I write to Dr Nathanson of the BMA (updated)

written by Clive Bates | 25 February 2014



Apex of the public health establishment – but are their views on e-cigarettes coherent and well-informed?

I powered up the iPlayer to listen to Chris Snowdon of IEA (and a vaper) and Vivienne Nathanson of the BMA debate e-cigarettes on *You and Yours* 21 February 2014. This was on the occasion of Vype e-cigarettes beginning an advertising campaign on TV. Vype is made by Nicoventures, the e-cigarette subsidiary of BAT – British American Tobacco – so it is of course controversial. I was depressed and disappointed by some of the arguments made by Dr Nathanson, though sadly these are all too typical in the public health establishment.

… unable to take any more, I decided to email Dr Nathanson to 'pick up on a few points' made in the interview.

22 February 2014

Dear Dr Nathanson

I have just listened to your Friday interview on e-cigarettes on *You and Yours* via BBC iPlayer (from 1′ 25).

I would like to pick up on a few points you made in the interview… I am writing this so that you can consider these arguments and evidence and decide if you wish to continue to make these points in the media.

1. Doubt about whether e-cigarettes are safer than cigarettes. You left an opening for doubt that e-cigarettes may not be safer than smoking: "*…almost certainly… but we cannot tell for sure*" were the words used. Actually we do know for sure. The reason we are sure is down to basic physics and chemistry. The primary risk from smoking arises from combustion of organic material, which is then inhaled as smoke particulates and toxic gases into the lungs. We know with certainty that process is completely absent from all e-cigarettes. There is no conceivable mechanism in e-cigarettes that could create similar risks and no-one to my knowledge has proposed one. The more realistic question is whether the reduction in risk is 99% or 99.9%. Contrived equivocation over what is known beyond dispute is a disreputable tactic – it adds to public confusion and creates baseless concern.

2. Scientific uncertainty. While it may have been acceptable in 2008 to play on how little was known, that really is not credible today. We know a considerable amount about these products and there is an ever growing body of literature and commentary. As a general introduction, I recommend this review and all the sources it draws together: *A fresh look at tobacco harm reduction: the case for the electronic cigarette*.

3. Unknown toxicity. On the specific point you raised about toxicity, this has also been extensively studied. The products are usually a simple mix of nicotine, excipient, water and a flavouring, and these are not subject to high temperature processes that would create products of combustion. It is possible that there are residual contaminants and some breakdown products, but these have so far been found at an extremely low level. One detailed survey assessed 9000 observations. It concluded exposure to active e-cigarette users for almost all contaminants was below 1% of the threshold limit values used for involuntary workplace exposure, which is in itself an exacting standard.

> *There was no evidence of potential for exposures of e-cigarette users to contaminants that are associated with risk to health at a level that would warrant attention if it were an involuntary workplace exposure. The vast majority of predicted exposures are <1% of TLV. Predicted exposures to*

> *acrolein and formaldehyde are typically <5% TLV.*
> *Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks*

This is not to argue for no regulation, but for some basic standards that govern purity of ingredients and operating parameters of devices. Sadly, in the misguided attempt to have these non-medical products regulated as medicines, the public health community has failed to contribute to development of such standards that would actually be useful and proportionate.

4. Cancer causing agents. You raised the spectre of 'cancer causing agents' being present in e-cigarettes. I am sure you know that it is emotive and misleading to imply that the presence of a hazardous substance represents a material risk to health. Risk depends on exposure. Cancer causing agents are present in pretty well everything, including ambient air. If you have this approach to e-cigarettes, how would the BMA cope with coffee, for example? It is literally the case that we do not know what is in each cup – the roasting process is chemically uncontrolled and creates many *de novo* chemicals, including numerous carcinogens – see this statement from one of the pioneers in the field:

> *Over a thousand chemicals have been reported in roasted coffee: more than half of those tested (19/28) are rodent carcinogens. There are more rodent carcinogens in a single cup of coffee than potentially carcinogenic pesticide residues in the average American diet in a year, and there are still a thousand chemicals left to test in roasted coffee.*
> *The causes and prevention of cancer: the role of environment (1998).*

5. Quit rates. You assert that the quit rate with e-cigarettes is about the same as patches and gum. But that is based on a single RCT (Bullen et al 2013) using old products and with none of the real world advantages of e-cigarettes built in (eg. higher consumer preference, experimentation with different devices, learning over time, and of course the better products that have evolved since the study was conducted etc). Even so, raw data showed higher quit rates for e-cigs than the NRT arm, but the study did not have the power to show these with 95% confidence. If, instead of relying on the most pessimistic interpretation of one study using technology that is now obsolete, you took all the evidence into account I think you would come to a different conclusion, especially when you

consider efficacy in a real world setting rather than in an RCT. You might find this survey from Robert West's group interesting in that regard:

> *Conclusion: Among smokers stopping without professional support, those who use e-cigarettes appear more likely to be able to remain abstinent than those who use a licensed NRT product bought over-the-counter or no aid to cessation.*
> *Real world effectiveness of e-cigarettes – a population study*

If you look at the detailed numbers in the abstract, e-cigarettes are substantially more effective in this survey.

6. Gateway effect. You drew on the idea of a gateway effect and 'renormalisation' of smoking, or that e-cigarette users would somehow progress from vaping to smoking. This argument was used to justify banning snus in 1992 in the EU (other than Sweden), but the effect never materialised and in fact in both Sweden and Norway, snus acts as an exit gateway from smoking, and diverts young people from smoking onset. I think everyone who comments on e-cigarettes needs to understand the snus story, and I recommend this letter to Jeremy Hunt from a dozen experts as good starting point. This is important because harmful regulation (a ban) followed from irresponsible population-effect arguments and, as a result, many smokers have been denied access to these much-safer products. There was no scientific, ethical or legal basis for that, and there is a danger that restrictions on e-cigarettes will repeat this lethal error leading to thousands of unnecessary smoking related deaths. Your assertions about progression from vaping to smoking were quite rightly challenged on the programme: there is no evidence to suggest this pathway exists in reality or is any more than a theoretical construct created for campaigning purposes. If you know of any, please share it. Far more likely is that e-cigarettes will create *beneficial* pathways out of smoking for existing smokers or divert people who would otherwise have become smokers into vaping. When the BMA campaigns aggressively, but without evidence of a harmful gateway, it risks diminishing the health benefits that would arise from the beneficial gateways and thereby contributing to more death and disease. I have written about the gateway effect in some detail here: *We need to talk about the children – the gateway effect examined*. I would advise much greater care about protecting the health-positive pathways that introduction of a vastly reduced risk product creates.

7. Medicine regulation. You continue to press for these products to be subject to compulsory medical licensing, as if that is the only way that 'safety' can be guaranteed. There are so many objections to this reasoning that I am unable to list them all here, but let me try a few:

- The products are not medicines – they are not sold or bought as medicines any more than cigarettes are.
- Six courts in EU member states and the US courts have so far rejected medicines designations for these products, for largely the same reasons. If you would like to understand why this happened, the some of the reasoning is available in this: *Are e-cigarettes medicines?*
- Medicine regulation does not give assurance that products are 'safe' – it makes a judgement on risks and benefits, and authorises products like Bupropion and Varenicline that are definitely not 'safe'.
- It is perfectly possible to regulate these products without classifying them as medicines – there are standards set for many non-medical products under consumer protection regulation. Sadly, the public health establishment ignored this option.
- Medical regulation is complex, burdensome and restrictive. It would create high barriers to entry, reduce competition, protect incumbents and favour the industry with the deepest pockets. It would favour big tobacco – a view shared by many investment analysts.

For more on why regulating these products as medicines is a bad idea, please take a look at this critique of the pro-medicine regulation case as argued by the European Parliament's *rapporteur*. The optimum regulation for these products has to balance control of risks arising from e-cigarettes with realisation of benefits through smokers switching to e-cigarette use.

8. Advertising ban. You want e-cigarette advertising banned. On what basis? Tobacco advertising is banned in the EU because smoking kills over 500,000 people in Europe annually, and this justification is coded into the tobacco advertising directive 2003/33/EC at recital 3. There is no equivalent justification for banning e-cigarette advertising, and no conceivable reason to protect the cigarette market from challenge by a disruptive entrant that appears to be reducing cigarette sales significantly, at least while it is still allowed to advertise. If controls beyond the standard advertising code are necessary at all, they can be of the form used to control alcohol advertising in non-broadcast and broadcast

media. Some commentators seem shocked that e-cigarette advertising sometimes looks glamorous or reminds them of vintage cigarette adverts… they should not be. This is the important work of appealing to smokers to switch from smoking to vaping, and they will not achieve that with ads that look like ads for athletes foot cream. Again, your preferred approach of a ban assists tobacco companies to two ways: firstly by reducing e-cigarette category competition with cigarettes, secondly because advertising bans favour businesses with established distribution chains and experience of promoting their products without the benefit of advertising – namely tobacco companies.

9. Tobacco industry. I realise the involvement of the tobacco industry is a cause of concern, and I too am cautious. But I am cautiously optimistic. It is actually better if these companies offer their customers options that do not cause death and disease The idea that they are doing this to protect the cigarette industry falls at the first fence. The combined tobacco-owned e-cigarette companies have less than 10% of UK market share and there is no conceivable way they could protect cigarette sales in a competitive e-cigarette market. There is no homogenous Big Tobacco in the marketplace: each company will try to sell e-cigarettes as hard as possible. If they do not produce attractive products that smokers like they will lose out to their competitors – other tobacco companies or non-tobacco e-cigarette companies. Competition will drive innovation that will make e-cigarettes increasingly attractive as an alternative to smoking and will take more of the cigarette market as a result. The biggest risk to this market place is excessive regulation, not the involvement of tobacco companies *per se*.

10. Missing empathy. I wish that the health and medical establishment, of which you are part of the apex, would find time to listen to what the users of these products say and to understand the experience they have had. There are now thousands of moving and visceral testimonies from people whose lives have been transformed by these products. These experiences should be what inspires public health professionals – and in rare cases it actually does (see this initiative at an NHS stop smoking clinic). However, the public health establishment has largely responded to the rise of e-cigarettes with an obsessive aversion to minor or implausible risks and casual disregard for the great life-enhancing opportunities. It is a depressing, prudish, prohibitionist outlook, when there is room to be far more positive. I would like to invite you to contrast the comments from vapers in this posting with the sour and lazy cynicism of public health

establishment: Where is the humility? Where is the empathy?

This also starts with a quote from one of the nation's best loved GPs. I think this doctor has it right and the doctors' trade union has it wrong.

> *For the record: I wholeheartedly support use of E-cigs and think banning them would sound the death knell for smokers everywhere.*
> *Dr Christian Jensen*

I have tried to provide responses to most of the points you made on the radio in good faith and with good intentions. I hope you will not just dismiss these comments but consider them seriously and rethink the BMA's approach to this important public health opportunity. I think the organisation is now out of step with evidence, ethics and experience.

Best regards

Clive Bates

Update: 4 March 2014 reply from Dr Nathanson

> *From: Vivienne Nathanson*
> *Date: 4 March 2014 15:26*
> *Subject: Re: What we do know about e-cigarettes*
> *To: Clive Bates*
>
> *Clive*
>
> *Thank you for your email.*
>
> *I shall take the points you raise to a future meeting of the Board of Science which writes /defines BMA policy in this area.*
>
> *Best wishes*
>
> *Vivienne*
>
> *Professor Vivienne Nathanson*
> *Director of Professional Activities*
> *British Medical Association*

I replied, with hope and exhortation.

> *From:* ***Clive Bates***
> *Date: 4 March 2014 16:33*
> *Subject: Re: What we do know about e-cigarettes*
> *To: Vivienne Nathanson*
>
> *Dear Vivienne – that's a very welcome move. I hope they approach the issue with open minds. BMA could make a big difference here.*
>
> *Clive Bates*