

European Union making bad policy on nicotine - five ways to make it better



On 30 November, the draft EU Tobacco Products Directive was circulated for inter-service consultation (ie. sent round all other Directorates General in the European Commission). Its contents are not yet public, but it is widely thought to maintain the ban on snus and to impose strict restrictions or even bans on reduced risk non-combustible tobacco products, e-cigarettes and novel electronic nicotine devices. I cannot sufficiently stress how wrong and harmful that would be, given the role these products play as alternatives to smoking. I remain ever hopeful that good science, ethics and law (and common sense) will eventually prevail. To that end, I have written to the new Commissioner, Dr Tonio Borg, to suggest he makes five changes to the Commission's approach. Here's the letter:

*Dr Tonio Borg
Commissioner for Health and Consumer Policy
European Commission
B-1049 Brussels*

*CC: Chief Scientific Adviser, Dr Anne Glover
Chef De Cabinet, Ms Joanna Darmanin*

5 December 2012

*Dear Dr Borg
Re: Tobacco Product Directive - policy on snus and nicotine regulation*

May I congratulate you on your appointment as the new Commissioner for Health and Consumer Policy. It is a role in which a capable public servant can do a great deal of good for the health of European citizens. Alternatively, the wrong policies can cause a great deal of harm. With that in mind, I am writing to ask you urgently to reconsider those aspects of the draft Tobacco Products Directive that deal with snus and nicotine regulation. I was director of the UK health organisation Action on Smoking and Health (ASH-UK) between 1997 and 2003,

and I am concerned that the directive, as reportedly formulated for inter-service consultation, will cause more ill-health than it prevents by denying smokers access to products that are far less risky than cigarettes.

The ban on oral tobacco or 'snus'

The issue is straightforward: there is no scientific, ethical or legal justification for banning nicotine products that are much less hazardous than the dominant market leader, namely cigarettes, but that can act as effective substitutes for smoking. The risks arising from snus are of the order of 95-99% lower than those arising from cigarette smoking. The widespread use of snus as an alternative to smoking is, beyond doubt, the reason why Sweden has by far the lowest rates of tobacco-related cancer, respiratory illness and cardiovascular disease in Europe.

No scientific justification for a ban has been attempted - and much of the analysis of the Commission's [SCENIHR report on smokeless tobacco](#) supports a harm reduction strategy rather than a ban on snus. The ethics are just as clear: what sort of public authority would deny a smoker, at great risk of personal harm, a viable low-risk alternative? There are no precedents for denying citizens safer alternative products. As for legality, a ban clearly fails tests of discrimination and proportionality, and violates single market principles by protecting cigarettes from competition, indeed competition from far less dangerous products. I have summarised the arguments on snus in greater detail and with evidence at the following posting, [Death by regulation: the EU ban on low risk oral tobacco](#). I hope you will read this document or request advice on it, and form your own view.

Excessive regulation of novel nicotine devices and e-cigarettes

The scientific, ethical and legal arguments for new nicotine devices such as e-cigarettes are very similar to those for snus. These products are already proving very popular and have great potential to reduce the cancer, lung and heart disease caused by smoking. They give those who are unable or unwilling to quit smoking an alternative source of nicotine with negligible risk, and many users testify eloquently to the positive effect these products have had for them. The danger is that the new directive will impose excessive and ill-conceived regulation that marginalises these products by making them unattractive to smokers, by preventing clear communication about reduced risks, by making them hard to access, or by forcing product changes that make them inadequate substitutes for smoking, for example by limiting the nicotine delivery of these products. There is a place for regulation, but it should be to create an 'enabling framework' for these new, much less risky, alternatives to smoking to enter the market in a way that gives consumers confidence in switching from smoking.

The harm reduction philosophy

The underlying idea is 'tobacco harm reduction'. It is a key public health strategy, and it should be encouraged, not obstructed, by the new directive. I am not alone in believing this. I recently wrote an [open letter on tobacco harm reduction](#) to delegates of the WHO Framework Convention on Tobacco Control.

Twenty two of the most respected scientists, epidemiologists and tobacco policy experts in Europe and beyond followed up with supportive comments, giving their own views. It is simply not correct to assume that the entire public health community favours a ban on snus or obstructive regulation of nicotine products. I invite you to read this open letter and to consider the comments before proceeding further with a directive that embodies a 'quit or die' philosophy, with no middle ground to accommodate smokers who cannot or will not quit.

What should happen - five changes necessary

I believe the following policy changes are necessary to prevent the directive causing harm and to reorientate EU internal market policy on tobacco towards health.

1. The new directive should remove the ban on snus. On scientific, ethical and legal grounds it was not justified in 2001 and all the evidence that has accumulated since suggests it is even less justifiable now. No-one has provided an adequate justification for the ban, and no-one will. In effect, the ban protects the single market for the most harmful products of all.

2. Introduce regulatory toxicology standards for all smokeless tobacco products. WHO's expert committee ([TobReg](#)) advises this approach and many health organisations would support it. It would potentially remove from the market the worst forms of smokeless tobacco, whilst leaving better products, such as snus, to compete with cigarettes in the internal market, with health as a consumer driver.

3. Seek further advice and analysis before making any regulatory interventions concerning novel nicotine products and e-cigarettes. The major health benefits of these products for existing smokers should be given great weight in EU policy. If there is to be regulation, it should have the objective of creating an 'enabling framework' to build confidence in these products as alternatives to smoking. The 2001/37/EC directive has provisions to respond to emerging scientific understanding. It would be better to use a similar approach in the new directive to address novel nicotine products rather than rush to an ill-conceived and counter-productive regulatory intervention at this stage.

4. Publish the scientific and legal analysis underpinning the directive. Anyone should be able to see the advice on which credibility, lawfulness and expected health impact of the draft directive is based. This sort of transparency and openness to scrutiny is central to building citizen confidence in decision making and strengthening official accountability in the European Union.

5. Commission an assessment of the tobacco harm reduction potential for European public health. As the newly appointed Commissioner, you should expect high quality advice free from ideology and instinctive defence of past positions. You should insist on a better assessment of the potential for harm reduction strategies in tobacco control and then reorientate the underlying philosophy of European tobacco policy to embrace this approach if you are convinced. I believe you would be.

Your role has great responsibilities, with consequences measured in countless lives and much potential suffering. I hope the advice and links I have provided will help you to shape internal market policy for tobacco in a pro-health direction by encouraging competition for low risk alternatives to the dominance of cigarettes. I would welcome your views on these important issues, and I would like to request a meeting with you and your officials to discuss this issue in person, and to respond to concerns or objections you may have.

Yours sincerely

[Signed: Clive Bates]

Clive Bates
London, UK

Disclosure. I have no conflicting interests, in particular no financial or material links with the tobacco industry, nicotine device industry or pharmaceutical industry, or their agents. I am writing in a personal capacity.

Comments recovered

48 comments to European Union making bad policy on nicotine - five ways to make it better

Jean

December 5, 2012 at 1:48 pm · Reply · Edit

Excellent intervention.

It seems to have got worse: some press reports say that the directive also contains a provision that would force any tobacco product to be composed of at least 80% tobacco, which would in effect make snus illegal since it is about 50% tobacco and 50% flavours and water.

I don't know if it is true, and I don't know if Sweden could use its exception on snus to escape such an obligation. But that is worrying.

Overall, I think that this policy is not only absurd but also borders on criminal. Any objective impact study could show that banning snus costs lives. But while they can't possibly ignore the basic facts, they still go on with the ban no matter what. Whether it's ideology, incompetence or corruption I cannot tell, but whatever the reason, the decision makers have an enormous responsibility, and it must be made clear that they know it.

Clive Bates

December 5, 2012 at 4:47 pm · Reply · Edit

It is interesting to consider if the smokers' class actions of the future might be directed at Commission officials, politicians and European health groups who conspired to deny them much safer alternatives, with full knowledge of the relative risks, addictiveness of tobacco, and plenty of scientific advice showing that they knew or should have known the harm reduction benefits of these products.

I hope it doesn't come to this, but maybe a letter like this will be discoverable in a future court action and not acting on these five proposals may be regarded as negligent and actionable.

Anonymous

December 5, 2012 at 10:06 pm · Edit

That's exactly what I was thinking. In the same order, MP Engström addressed a question to the Commission asking them to produce the scientific evidence supporting the snus ban, which of course doesn't exist, which is why the answer from the Commission contains none.

nisakiman

December 5, 2012 at 2:40 pm · Reply · Edit

Once again Clive you have my applause for bringing this subject up. Although you and I will not see eye to eye on many aspects of the smoking issue, you have my respect because your stance is based on what you see as the scientific evidence rather than an ideologically driven hatred of smoking and smokers. But you are in the minority. Most people in the Tobacco Control Industry are zealots and fanatics. A paragraph from Michael Siegel's recent blog:

Perhaps the most telling statement in the paper is this one: "Due to its odourless and smokeless delivery system, the e-cigarette can be used in non-smoking areas, as suggested by some ENDS product inserts. This has the potential to allow people to satisfy the smoking urge despite being in areas where smoking is prohibited." (My emphasis).

So that is what worries the anti-tobacco mob. That someone might somehow be getting around the ostracisation, denormalisation and demonisation programme that has been devised for them by Those-Who-Know-Best. It matters not that they aren't actually smoking tobacco, so are not causing discomfort to anybody else. It matters not that they are not contravening the "no smoking" imposition. What matters is that they are enjoying a substitute that looks like smoking. And that cannot be allowed.

It's nothing to do with the science or health aspects Clive. It's to do with the mindset.

eCig News Item - Clive Bates Letter to EU

December 5, 2012 at 3:09 pm · Reply · Edit

[...] in an interview he wasn't going to focus on tobacco issues, former head of ASH UK Clive Bates posted another harm reduction article on his blog. The article was actually a copy of a letter Bates sent to the new head of the EU's tobacco [...]

Clive Bates letter urges new EU Commissioner Tonio Borg to not ban e-cigarettes or smokeless tobacco

December 5, 2012 at 5:51 pm · Reply · Edit

[...] [...]

Laccy Rowley

February 27, 2013 at 8:42 pm · Reply · Edit

Hello, I sat in a restaurant in France on Sunday 24TH FEB 2013 and had to

endure three people “vaping” as they call it AT A TABLE NEXT TO ME. As an ex smoker I found this annoying and to be honest disgusting. Imagine the whole restaurant filled with toxique vapours. If e cigs are not banned then you will be back to square one. I for one will NOT be eating in any more restaurants until this is sorted!!!!

L ?rOWLEY

Clive Bates

February 27, 2013 at 11:59 pm · Edit

Dear Laccy Rowley - this is interesting, and something vapers will increasingly face. Can you elaborate on what it was you found disgusting?

+ A genuine physical reaction to a smell or irritation?

+ The sense they were releasing toxic vapours that might be harming you (even if physically it wasn't that noticeable)?

+ That they were getting away with something like smoking, when smoking was banned?

+ As an ex-smoker, were you reminded of smoking and did it trigger cravings?

+ Did you think it was an injustice, because you had given up properly and they hadn't?

+ Was the irritation more than people talking too loudly at the next table?

Clive Bates letter urges new EU Commissioner Tonio Borg to not ban e-cigarettes or smokeless tobacco | Tececigs.Com

December 5, 2012 at 10:48 pm · Reply · Edit

[...] Clive Bates: European Union making bad policy on nicotine - five ways to make it better <http://clivebates.com:80/?p=697> For European vapers and e-cig companies who want to express their views, here are e-mail addresses [...]

Clive Bates writes letter to new EU Health Commissioner about Tobacco Harm Reduction

December 5, 2012 at 11:01 pm · Reply · Edit

[...] [...]

Clive Bates letter urges new EU Commissioner Tonio Borg to not ban e-cigarettes or smokeless tobacco | Vape Mongers

December 5, 2012 at 11:40 pm · Reply · Edit

[...] Clive Bates letter urges new EU Commissioner Tonio Borg to not ban e-

cigarettes or smokeless tobacco Posted on December 5, 2012 by admin Clive Bates: European Union making bad policy on nicotine - five ways to make it better <http://clivebates.com:80/?p=697> [...]

David Sweanor

December 6, 2012 at 1:19 am · Reply · Edit

The apparent new and draconian EU approach to products that are significantly less hazardous than smoking, and could be used in place of smoking, is deeply troubling. As you have articulated so clearly in your postings on this blog, the science and the ethics on this issue are clear (certainly no one within the EU - or elsewhere - has offered a credible alternative view). Strange that the very people entrusted with protecting the health of the citizens of the EU would ignore the science and would act as if ethics is something that need not influence their decision making.

Cigarette smoking is a huge cause of death due almost entirely to the repeated inhalation of the products of combustion. There are products currently available that can substitute for cigarettes without inhalation of smoke, and there would undoubtedly be many more (and better) ones if the regulatory gatekeepers would allow such product onto the market. Instead they seem determined to hand the cigarette industry a nicotine maintenance monopoly. Gee, I can remember when health officials sought to reduce smoking caused disease rather than protect the cigarette business from competition from massively less harmful alternatives.

This is not the first time that key players have acted so as to deprive smokers of the products and information that could save their lives. As a public interest lawyer I have battled on this topic for decades, albeit primarily against the longstanding negligence of the cigarette companies. For far too many years these companies fell far short of their duty of care for their consumers. They are now dealing with the inevitable court actions that seek to hold them accountable for their malfeasance.

But tobacco companies are not the only ones against whom an action in negligence, perhaps even a charge of criminal negligence causing death, can be a viable cause of action. Public officials have a professional, legal and ethical obligation to protect the health of citizens and an obligation to avoid acting in illogical and capricious ways when enacting regulations. The dereliction of duty by these officials is not just a cause of concern but a potential basis of future

litigation. They need reminding that the massive and numerous lawsuits against cigarette companies are not a result simply of them being cigarette companies, but rather a result of a failure to live up to their duty to consumers. It appears some senior EU officials are walking that same dangerous path.

David T. Sweanor
Adjunct Professor of Law
University of Ottawa

Peter Hajek
December 6, 2012 at 9:36 am · Reply · Edit
I have written to Commissioner Borg

Dear Dr. Borg and colleagues,

I am writing in support of Clive Bates' suggestions for the new Tobacco Product Directive.

I am a researcher in smoking and tobacco dependence with extensive track record.

I consider safer nicotine delivery devices, in particular the e-cigarette, the most important development in tobacco control over the last 50 years. E-cigarettes are not fully competitive with conventional cigarettes yet, but they are likely to develop into a real alternative relatively quickly. The promise of this development is that smokers will switch from conventional cigarettes to much safer alternatives on a population scale. This may actually end the tobacco epidemic within the next few years.

Attempts to stop this process are in effect helping to maintain the market monopoly of the deadly conventional cigarettes. If it is true that you are poised to ban or restrict this development, this would have massive detrimental effects on public health. It is hard to imagine an argument for this. Various potential dangers of the alternative nicotine delivery devices have been proposed, but these are negligible compared to the potential benefits. I would be happy to elaborate on this in case you seek expert input and evidence for your deliberations.

With best wishes,

Professor Peter Hajek

Wolfson Institute of Preventive Medicine
Barts and The London School of Medicine and Dentistry
Queen Mary, University of London
Turner Street, London E1 2AD

P.S. I have no links with any manufacturers of e-cigarettes

Jonathan Bagley

December 7, 2012 at 1:26 pm · Reply · Edit

Hi Clive, I guess you've seen yesterday's Times Raconteur section devoted to ecigs. Both the anti tobacco and the tobacco industries are in favour of strict regulation. My concerns are expressed in the comments below this post on Dick Puddlecoates blog:

<http://dickpuddlecote.blogspot.co.uk/2012/12/its-time-to-take-our-freedom-back.html>

e-Cigarette News Roundup 12-6 - Mad Men

December 7, 2012 at 2:35 pm · Reply · Edit

[...] in an interview he wasn't going to focus on tobacco issues, former head of ASH UK Clive Bates posted another harm reduction article on his blog. The article was actually a copy of a letter Bates sent to the new head of the EU's tobacco [...]

Bryan Davies

December 8, 2012 at 6:28 am · Reply · Edit

Electronic cigarettes are forming a vital part of my own cessation from smoking. I have tried gums (they gave me a sore throat) patches (I ended up with nasty weals due to an allergic reaction) and Champix (weird). These had little or no effect, excepting repetitive expenditure (personal and through the NHS) to the pharmaceutical companies that have published and sponsored all sorts of spurious information in their attempts to cause e-cigarettes to be banned, restricted or placed in their control, effectively protecting their revenues on ineffective treatments and maybe (being cynical) cancer, COPD and heart treatment medicines.

Electronic cigarettes, in contrast, in a few months have enabled me to cease smoking everywhere with the exception of work. I feel better, my lung function is better and I now have just one hurdle to overcome - the 'quick fix' cigarettes of work tea breaks. I am near to cracking this too with a 42 mg/ml strength mix -

which I will be reducing. I am looking forwards to a smoke free 2013 and hope during the year, to slowly reduce the nicotine content of my vaping.

The only 'fly in the ointment' is the possibility of an ill informed EU ban or excessive control of nicotine bases by MHRA. I would urge all concerned to help prevent these and concentrate their efforts on providing a workable framework within which electronic cigarettes can develop into mass market alternatives to smoking. Where controls are necessary (purity of nicotine bases, lack of harmful materials in flavourings, poor quality delivery devices) existing legislation exists that can be implemented - currently involvement by Trading Standard officers in policing this market is virtually non existent and would be welcomed by many users and the better retailers and manufacturers.

I urge the EU to heed the wise words of Clive Bates - his credentials are impeccable/

Clive Bates

December 8, 2012 at 6:58 am · Reply · Edit

Bryan... That's a powerful testimony. I hope the prohibitionists and regulators are paying attention. Very best wishes for your efforts to go smoke free in 2013.

jredheadgirl

December 10, 2012 at 3:24 am · Reply · Edit

Hi Clive,

Thanks to Christopher Snowden, I have just discovered this blog. First of all, I would like to commend you on your advocacy of THR; however, as a smoker I have become concerned with the lack of attention (amongst some THR advocates) being directed towards ALL forms of THR. While I applaud your pointing out the obvious difference in risk amongst combustible and non-combustible forms of tobacco use, I do believe that tobacco users (such as myself) have the right to be informed of the varying risks that exist amongst combustible tobacco products as well. Combustible cigarettes are not all created equally. The advent (and recent proliferation) of e-cigarettes is promising for sure, and I am equally certain that the technology will improve with time. With that said, 92% of tobacco users still prefer analog cigarettes. This is a fact that cannot be ignored. Many people do not realize that there has been a resurgence towards THR in this field as well. It is my sincere hope that you, as well as that of governing bodies and actors around the

world, will soon recognize ALL forms of tobacco harm reduction, one step at a time. For those of us who will continue to smoke, this is of paramount importance.

For example, there have been many advancements in cigarette technology; here are but a few:

Brand B-The World's Lowest Tar to Nicotine Cigarette

<http://jredheadgirl.blogspot.com/2012/12/brand-b-worlds-lowest-tar-to-nicotine.html>

Researchers Create Healthier Cigarette

<http://www.jove.com/about/press-releases/10/researchers-create-healthier-cigarette>

Designing A Safer Cigarette

<http://www.forbes.com/sites/donaldfrazier/2012/02/21/designing-a-safer-cigarette/>

It is clear to see that all cigarettes are not created equally, just as combustibles are not the same as compared to that of e-cigarettes or snus. We smokers deserve to know the truth with regards to all of our options; anything less than the whole truth will result in the continued suppression of science and progress.

Thanks for all that you do. I do hope that those with a conscience are listening.

Clive Bates

December 15, 2012 at 9:07 am · Reply · Edit

Thanks for this and sorry for the delay in moderating. This is a really interesting and difficult area. The harm reduction case is overwhelming for non-combustible nicotine products - 95-99.9% reduction in risk is where I'd place it. With modified combustibles, where the risk reduction would be much less, I'm much less sure. There are really two perspectives on it.

The public health view: the danger is that net health gain may be negated if these products provide a kind of false reassurance and the person continues to smoke (rather than quit, vape, chew or snus...). Tobacco companies have been at this for years as a strategy to keep people in the smoking franchise - filters, light & mild brands etc (see our report on the great low-tar scam). The public health view sees such products playing a role in diffusing 'cognitive dissonance' - that is the psychological discomfort arising from knowing something is crap and so needing

a rationale to continue doing it (my thoughts from 2003 on this here).

The consumer view: takes the perspective of the user, who of course isn't smoking for public health reasons. In this view, the smoking continues regardless of what public health people think - and that is realistic even if the non-combustible harm reduction strategies are wildly successful. Hundreds of millions of people worldwide will continue to smoke. For continuing smokers, I guess two questions arise: (1) can meaningful risk reductions be made? (2) Should these be a matter for consumer choice or 'product liability' regulation?

On the first of these, I suspect some progress can be made. Nigel Gray, for example, argues tobacco specific nitrosamines could be reduced by better curing and tobacco selection. As you suggest, raising nicotine concentrations, selective filters and a few other wheezes may help - and I think tobacco companies have been busy in their labs on this agenda. But much of the toxicity comes from newly created 'products of combustion' - the same stuff you'd get if you inhaled garden bonfire smoke or set fire to a plate of organic food. The difficulty with a voluntary, consumer-choice driven approach is how to frame claims about the risk reduction - both in knowing what (if any) the risk reduction is, and how to communicate it. Without some sort of health claim there is no reason to switch and no reason for anyone to bring the product to market. On the other hand, a danger with regulation is that it may be a barrier to innovation, it would inevitably come in at a minimal but broadly applicable level of risk reduction, and would be easily circumvented if it changed the character of familiar products too much. Maybe a bit of each is needed - a 'floor standard' for pre-existing toxins in any tobacco placed on the market, and on top of that some innovation with justified but not misleading claims?

All of which is to say... I don't really know! I just know it's a difficult area and small reductions in risk over large populations may be worthwhile. I'm more focussed on making space for non-combustible nicotine options, where the benefits are totally convincing, but regulators and various fools in the 'health community' are trying to close it down.

Clive

jredheadgirl

December 16, 2012 at 11:57 pm · Edit

Hi Clive,

Thanks for responding and for having an open mind on an issue that we all can agree is difficult. I applaud your setting a precedent for what I predict will become the future of tobacco harm reduction.

“The harm reduction case is overwhelming for non-combustible nicotine products – 95-99.9% reduction in risk is where I’d place it. With modified combustibles, where the risk reduction would be much less, I’m much less sure.”

While I think that the case for non-combustible nicotine products is promising and it is certainly meaningful in the sense that health agencies should (at the very least) publicly acknowledge the immense and varying differences in relative risk as compared with that of combustible tobacco products, smokeless tobacco is currently not a panacea for the majority of us tobacco users in the real world. As I pointed out above, 90+% of tobacco users still choose to use combustibles, and will mostly likely (myself included) continue to do so well into the foreseeable future; therefore, we (those of us from both the public health view and the consumer view) really have no choice (if we wish to make any significant dent in tobacco-related mortality rates around the world while preserving the concept of freedom and personal autonomy) but to embrace the idea of a safe(er) cigarette. The science is there and can no longer be ignored.

“For continuing smokers, I guess two questions arise: (1) can meaningful risk reductions be made? (2) Should these be a matter for consumer choice or ‘product liability’ regulation?”

Of course there can be meaningful reductions in risk:

Per Brand B-

“Studies of smokers using low tar-to-nicotine (LTN) research cigarettes such as BRAND B have demonstrated that smoking behavior changes and the dose of smoke inhaled by the smoker including “tar” is significantly reduced (Russell MAH 2000). Specifically, compensatory smoking (e.g., more and/or larger puffs per cigarette) of LTN research cigarettes is greatly curtailed.”

“Leading U.S. brands have an average tar-to-nicotine ratio of approximately 13 – meaning that approximately 13 parts “tar” is inhaled for every part nicotine. LTN

cigarettes with a tar-to-nicotine ratio of 7 or less have the potential to reduce smoke exposure by 50 percent. If smoke inhalation with LTN cigarettes is reduced by 50 percent on average, confirmed by biomarkers in exposure studies, reduced harm is expected. 22nd Century's CEO, Joseph Pandolfino explained, "A cigarette that reduces smoke exposure by an average of 50 percent is effectively a hybrid of a zero-tar e-cigarette and a Marlboro® Gold. How much would smoking-related disease decrease in the U.S. if all the cumulative smoke inhaled by smokers were cut in half?"

Per the Jove article-

"Using natural antioxidant extracts in cigarette filters, the researchers were able to demonstrate that lycopene and grape seed extract drastically reduced the amount of cancer-causing free radicals passing through the filter. The research will be the 1500th article published in the ground-breaking Journal of Visualized Experiments (JoVE), the only peer-reviewed, PubMed indexed video-journal."

"Haemoglobin (which transports oxygen in red blood cells) and activated carbon have been shown to reduce free-radicals in cigarette smoke by up to 90 percent, but because of the cost, the combination has not been successfully introduced to the market."

Per the Forbes article-

"The MicroBlue filter is different. It includes a biochemical substance that attracts and immobilizes the carcinogens while letting nicotine slip through. Says one Filligent customer, Canadian distributor Edward Roundpoint: "People normally hate reduced-harm cigarettes. But this is different: It does not affect the flavor or the nicotine experience at all."

Does the Filligent filter work? Not completely, but tests at labs in the U.S. and the U.K. did conclude that the Filligent Generation 3 filter reduces cancer-causing DNA mutations by 40% to 75%."

"But much of the toxicity comes from newly created 'products of combustion' - the same stuff you'd get if you inhaled garden bonfire smoke or set fire to a plate of organic food."

I do believe that the above examples have taken this into account.

“The difficulty with a voluntary, consumer-choice driven approach is how to frame claims about the risk reduction -”

How about we just start with telling the truth? ..And you are of course correct in pointing out that the lack/suppression of any real health claim acts as a de facto barrier to any meaningful progress with regards to harm reduction. As you have pointed out, the overzealous regulation of tobacco products in this case has impeded innovation. This is simply unacceptable. Surprisingly, I am beginning to realize that maybe there is something that we (smokers and proponents of harm reduction) can agree on. I think that your idea of a ‘floor standard’ coupled with that of scientific innovation-and freedom of speech-is a good place to start.

“I’m more focussed on making space for non-combustible nicotine options, where the benefits are totally convincing, but regulators and various fools in the ‘health community’ are trying to close it down.”

Of course they are trying to shut it down. Look at what happened to Dr. Gori so many years ago.

Imagine how far along we would have been by now had Dr. Gori’s Tobacco Working Group at the NCI not been so tragically abandoned in favor of what has become well known as the “quit or die” approach. As you and I both know, that approach has failed.

Maybe it’s time for a change?

Cheers:-)

Clive Bates

December 17, 2012 at 9:55 am · Edit

Very interesting response - thank you. Perhaps those who work in this area would also like to comment (anonymously if you prefer).

Rory Morrison

December 18, 2012 at 7:07 pm · Edit

PMI seems to be investing a bit in the hopes of producing a reduced risk ‘heat not burn’ type device - they did a series of biomarker-type studies on it with somewhat mixed results last month in regulatory toxicology and pharmacology

however, even with something like that, and even if after some years in development it had lots of optimistic and supportive-seeming biomarker data, there is a little bit of 'pick the fights you have some chance of winning' here, surely.

there is still a legacy of mistrust around light/low tar for combustibles, and we can see how that still echoes around out today, even on products that aren't based around combustion and that we have lots of epidemiology on.

so if we struggle to convince people of the merits of products that have one or more orders of magnitude of risk difference and lots of epi (and struggle we do), the prospect of trying to convince people to support reduced risk safety claims about a product that has no epidemiology, just a lot of vaguely positive biomarker data gives me a headache just contemplating.

jredheadgirl

December 24, 2012 at 2:28 am · Edit

Happy Holidays Clive. I apologize for misjudging your intentions:-)

Robert MOLIMARD

December 10, 2012 at 3:04 pm · Reply · Edit

I am very isolated in France to defend the urgent need for another policy against smoking. The economic war being waged by giant tobacco and pharmaceutical companies totally ignores the smoker. Better yet, they fight in their interest all that might reduce the risk of smoking, both for the smoker's health and budget. The tobacco industry will survive as long as it has to satisfy a demand. It has no interest in smokers giving up. Thus it is regarded as the devil and is in on a difficult defensive position, because of advertising and smoking bans. . Pharmaceutical companies want only to sell their drugs, especially if they are ineffective! Thus they have also no interest in what smokers stop. They dominate European politics because states wish to continue to collect taxes on tobacco. They seek to discredit those who speak out against the criminal policy actually they inspire, accusing them of being the henchmen of an industry of death. I am happy that people like Clive Bates have the courage to face these threats in the name of scientific rigor, and remember his 2003 paper in Tobacco Control. Even Fagerström, who signed this paper, now recognizes that tobacco addiction is not an addiction to nicotine. The myth of nicotine addiction bases the policy of the industry. I also wrote a letter to the President of the French High Health

Authority, to warn against potential conflicts of interest of the group to revise the directive of good practice in smoking cessation. See, unfortunately in French : <http://www.formindep.org/Le-mythe-de-l-addiction-a-la.html>

Jacques Le Houezec

December 14, 2012 at 6:50 pm · Reply · Edit

Unfortunately, Robert Molimard is mixing up things. He is not in the same dynamic we are.

I totally support Clive Bates proposal. We clearly need to change the way addiction is seen at the EU level.

Klaus K

February 9, 2013 at 2:26 am · Reply · Edit

There seem to be three powerful players in the game: The tobacco industry, the pharmaceutical industry and the governments. Who is the most likely supporter of a harm reduction strategy?

Answer: The tobacco industry! They have been long-time into snus, and now they are into E-cigarettes too: http://www.youtube.com/watch?v=VZishwAt_RM

Now isn't this interesting? The tables have turned. As Dr. Molimard remarks, neither the governments nor the pharma industry have any economical interest in smokers giving up. Well, the tobacco industry obviously could have such interest. Did yesterday's enemy suddenly become today's friend, and vice versa?

The EU's dangerous Tobacco Ban Experiment - Amy Ridenour's National Center Blog | Up to the hour news

December 10, 2012 at 3:06 pm · Reply · Edit

[...] would be. Clive Bates, the former head of London's Action on Smoking and Health has offered up a bold set of suggestions to improve the EU tobacco [...]

Dave Dorn

December 20, 2012 at 11:18 am · Reply · Edit

<https://www.youtube.com/watch?v=LAN8510tpSY> is where we've covered this - it is going to take concerted action to prevent the EU from becoming murderers - they are following a path that can only lead to trouble.

Clive Bates

December 21, 2012 at 3:36 pm · Reply · Edit

Dave - very good Vapour Trails... The proposal is absurd. I completely agree with

your call to arms - vapers have to put up a fight. My tips on writing lobbying letters:

1. Write your own - authenticity counts, so describe what it means to you and what you want to happen
2. Don't worry that you have to use technical or legal language. You don't - just put it in your own words
3. Always be polite and work on the assumption that the person you are writing to will want to do the right thing - ie. give them the benefit of the doubt
4. Short is good, but keep to a couple of pages max
5. Always ask for a reply insisting they give their position and respond to your suggestions
6. Ask for a meeting or say you will be going to their surgery (and go). Explain what vaping is and why it has made a difference to you and what would happen if banned
7. Try to make a constructive proposal. Obvious things you could ask for:
 - + remove the provisions on e-cigarettes from the directive completely because there is no evidence they are doing any harm and plenty that for you they are doing some good
 - + a 2-3 year delay in bringing the provisions on e-cigs into effect (at present greater than 4mg/ml products would come under medical regulation immediately - a delay would give the manufacturers some time to get medical approval (if that was possible));
 - + more study of the potential for tobacco harm reduction taking into account the people that are using e-cigs to get off cigarettes;
 - + labels that really inform people that these products are nothing like as dangerous as cigarettes, rather than try to scare people off them.
 - + assessment of the consequences of applying medicinal regulation and effectively banning e-cigs (ie. bad things that might happen).
8. Use writetothem.com to work out who to write to... MPs and MEPs should be your main targets
9. Start with MEPs - the directive will be scrutinised in the European Parliament at a session on 25 February - so that is an important date to work towards (see brief).
10. Directives also have to be agreed by the European Council (ie. national governments). So write to your MP and ask them to take the matter up with the Secretary of State for Health (Jeremy Hunt). This is better than writing directly to the Secretary of State or civil servants, or just to your MP. Not all MPs will

contact the Secretary of State, but many will do that on your behalf.

By the way, the draft directive bans vapour products above the thresholds in article 18.1 (>2mg/unit or 4mg/ml) at entry into force, not after 24 months (see article 26 on transitional provisions, which only applies to the irrelevant products below the threshold). It does that by requiring medical regulatory approval from day 1.

Adrian

December 20, 2012 at 7:53 pm · Reply · Edit

JReadhead Girl makes an extremely valid point. Even with the advent of smokeless products and e-cigarettes, for the foreseeable future, cigarettes will dominate the tobacco market. Granted, the search for a 'safer cigarette' has so far proved elusive. That's really not surprising given the complexities of tobacco smoke and the need for long-term studies products with, for example, ultra-low tar products. But it hasn't been helped by the moralistic attitude of some in the public health community to the effect that even if a combustible product was safer it would still be seen as a bad thing because it would likely promote a behaviour that is seen as being abnormal - no change there from the situation in the 16th Century! This attitude extends to wanting to ban e-cigarettes simply because they simulate the action of smoking (which ironically is probably why they are proving to be so popular). Many argue, and understandably so, that cigarettes are a unique product because of their public health impact. However I would argue that they are also a unique product because of the abject failure of regulators to evaluate objectively the potential impact of changes in cigarette design, particularly as regards the risk of lung cancer. Instead the default is to gravitate to a 'quit or die' mentality based on the mantra that 'there is no such thing as a safe cigarette'. Until this prejudiced mind set changes I fear that little can be achieved on combustibles. That the proposed new EU directive seeks to maintain the ban on snus and push most e-cigarettes off the market reinforces this view. At the end of the day it's consumers who are caught in the crossfire between anti-tobacco campaigners, openly aided and abetted by the pharmaceutical industry, and the tobacco industry. As such, in the EU they are deliberately denied access to proven safer tobacco products (e.g. snus, apart from in Sweden) and likely to be so in the case of e-cigarettes. What kind of perverse logic is this?? It is indeed time for a change!

Adrian

December 20, 2012 at 7:56 pm · Reply · Edit

Oops - sorry should have said JRedheadgirl -hope she will be forgiving :)

Jonathan Bagley

December 24, 2012 at 4:34 pm · Reply · Edit

Clive, in your reply to Dave Dorn, you write

“By the way, the draft directive bans vapour products above the thresholds in article 18.1 (>2mg/unit or 4mg/ml) at entry into force, not after 24 months (see article 26 on transitional provisions, which only applies to the irrelevant products below the threshold). It does that by requiring medical regulatory approval from day 1.”

You are the first I've heard mention this. When is “entry into force” likely to be. Is it 2014/2015, or do these date include the 24 months?

Clive Bates

December 24, 2012 at 6:40 pm · Reply · Edit

Jonathan - it's never possible to be sure how long it will take, but given they've been consulting since 2010 and the high level of support in the Commission, Council and Parliament, entry into force could be in 2013. The 24 months for transition in Article 26 starts from entry into force, but the transition doesn't apply to non-tobacco nicotine containing products above the very low threshold set in Article 18.1. It's possible that they'll realise how bad this might be, and that they will bring in some transitional provisions, but they are not there in Article 26 now [see Commission proposal - Article 26]. NCPs above the thresholds are subject to medicines regulation under directive 2001/83/EC relating to medicinal products for human use. That applies from the moment the new directive enters into force. The main feature of this system is set out in Article 6, namely that:

No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive...[or through the European Medicines Agency]

It then specifies in Article 8 requirements that must be satisfied before marketing authorisation is granted. These are demanding, and may be impossible for some e-cig makers, and for any company they would be tough to satisfy quickly. For example, regulators require (amongst other things):

Results of:

pharmaceutical (physico-chemical, biological or microbiological) tests,
pre-clinical (toxicological and pharmacological) tests,
clinical trials.

A summary of the applicant's pharmacovigilance system which shall include the following elements:

proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance,

the Member States in which the qualified person resides and carries out his/her tasks,

the contact details of the qualified person,

a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Title IX,

a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.

The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof.

A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Directive 2001/20/EC.

We will rely very heavily on medicines regulators like the UK's MHRA taking an enlightened view of this issue. But I also foresee lots of disputes between regulators taking different approaches in different member states, and therefore lots of procedural time consumed on that. The other troubling thing is the labelling requirements of the directive - Article 54-59. These will ensure that the products look like medicines - that is if they ever see the light of day.

Clive Bates

December 25, 2012 at 10:09 pm · Reply · Edit

The process by which the directive will be agreed is the Ordinary Legislative Procedure (previously known as the Co-Decision Process). It aims to give a greater say to the European Parliament and national parliaments. You can read a description [here](#).

The bottom line is that if everyone agrees, things go through quickly. If there is

dispute - they move slowly and require compromise.

Lesley Lawless

December 27, 2012 at 7:57 pm · Reply · Edit

I'm wondering if this can stand up in the courts, as three EU countries have banned and the ban has been reversed in the courts.

This is almost as crazy as the recent Maldives Tobacco Control Law which banned all plants of the same genus being grown, so outlawing growing tomatoes and potatoes!

Nicotine is not a tobacco product as it can be extracted from a number of other plants, it's just the easiest and cheapest to get it from. Nicotine is also used as a pesticide and some of the ideas I've heard if it is banned are horrifying, from using pesticide to deadly nightshade.

If it is a medicine then so are countless other consumer products. Never mind the coffee, I can even buy caffeine tablets at my local garage.

Personally I find the prospect of a ban frightening as I've only recently swapped to vaping, have tried NRT at least once a year for many years but eventually gave up, and I know I'll be back on the ciggies if I can't get a suitable concentration of eliquid in a flavour I like. I hate tobacco and I hate the menthol in NRT. In fact NRT has kept me off cigarettes with intense cravings and a nicotine overdose for a maximum of three days. I won't consider such as Champix and my doctor refuses to prescribe it as he says it's too dangerous. He does class vapers as non-smokers though after a few months without smoking and is very pleased that they've quit in spite of the fact that they aren't planning to stop using nicotine.

For me this is the worst and most retrograde step that could ever be made. I'd much rather that tobacco was banned, not that it will ever happen.

Judi Peachey

January 2, 2013 at 3:49 pm · Reply · Edit

Clive - Thank you for highlighting this misguided proposal. It seems to me that the only explanation for this idea must be to try and get more people to go back onto tobacco smoking! I was a 20 a day smoker for 25 years and had tried so many ways to give up, (patches, inhalators, hypnotism) none of which were successful. Then I discovered vaping and literally gave up tar and carbon-monoxide the day I tried my first e cigarette. I have now not had a smoking cigarette for over 2 years. I have felt so much fitter and several medical practitioners have told me that they think that e cigarettes are so much healthier

than smoking as it is the burning of the tobacco and the tar that causes cancer. E cigarettes are not heavily marketed as yet, but if they were I suspect that many more people would quit smoking cigarettes and many lives (and a great deal of tax payers money in the Health system) would be saved. If e cigarettes are effectively banned by the need for regulation, I am certain that I would go back to tobacco.....and I am sure I am not alone in this.

One question...would e cigarettes still be available outside the EU? Or would the required regulation be world wide?

I feel really strongly about this issue and cannot understand the motivation behind this proposal. It makes me cynically wonder whether the tobacco companies are behind it as the only consequence of this legislation will be more people buying cigarettes.

Judi

Clive Bates

January 2, 2013 at 4:27 pm · Reply · Edit

Hi Judi - this would be an 'internal market' measure and therefore apply within the European Union only. However, foolish public health policy isn't the sole preserve of the EU. The World Health Organisation has taken a very hostile approach to these products and is making noises about greater global regulation through the Framework Convention on Tobacco Control. You can read my blog posting on this here: [Open letter to the delegates of the WHO FCTC](#)

Clive Bates

January 2, 2013 at 6:18 pm · Reply · Edit

An interesting question: would the EU will be able to stop a vast internet mail order business developing to import e-cigarettes from third countries. My guess is that the black market response would overwhelm the regulators' willingness and means to police it.

V

January 3, 2013 at 2:26 am · Reply · Edit

Very recently, Hungary banned all e-cig products that contain nicotine. That did nothing really, it just takes half a day longer to get them in from Slovakia.

I don't know for how long it will work, but I guess it can go on forever.

What's hurtful is the willingness of governments to sell your health and happiness for the love of tax and corporate profit. It's straight out disgusting.

Judi Peachey

January 14, 2013 at 3:09 pm · Reply · Edit

This is the e mail that I have sent to my MP and MEP'sfollowed by the reply from MEP (none received yet from MP)

Dear Philip Bradbourn OBE, Michael Cashman, Nicole Sinclaire, Malcolm Harbour, Mike Natrass, Anthea McIntyre and Phil Bennion,

I am writing to you in connection with the EU draft Tobacco Products Directive and wondered if you would be able to help. I have no connection with the tobacco industry or e cigarettes, except that I am an ex smoker thanks to discovering e cigarettes. I am 52 years old and had been smoking 20 cigarettes a day from the age of 20. I had tried many times to give up, using patches, gum, inhalators and even hypnosis, but to no avail. Then two years ago I discovered e cigarettes and have not smoked a cigarette since. I have felt significantly fitter since giving up smoking. I now use vapour cigarettes daily and have been told by a number of medical practitioners that these are far less harmful than tobacco cigarettes as the most harmful part of smoking is the tar, the carbon monoxide and the fact that the cigarette is alight. I know that nicotine may have some harmful effects, but I genuinely feel that vaping is a far less harmful thing to do. It also has the benefit of not harming others through passive smoke.

I understand that the EU Directive will have the effect of denying or obstructing people like me from quitting. I would still be smoking if I could not get access to e cigarettes, and indeed I am worried that I would return to smoking if they are effectively banned by the need for medical regulation. I feel that this cannot make sense as surely it is better for people to be able to access a less harmful alternative to cigarettes and hence avoid the more catastrophic and expensive diseases that are caused by tobacco smoking. It seems to make even less sense that whilst calling for medical red tape to effectively ban e cigarettes, the more harmful tobacco cigarettes are freely available to all adults.

Even if medical regulation is seen to be absolutely necessary, surely there should be a long transitional period to allow the e cigarette industry to continue in business whilst it complies with the regulation. I understand that if this directive comes in there would be no such transitional period.

My final point is that if the EU brings in this effective ban, surely this will just adversely affect EU trade as presumably internet businesses outside the EU will step in unregulated.

I would be grateful if you could let me have your thoughts upon this directive. In particular please could you let me know whether you would be able to put forward my views during the scrutiny of this directive. Could you also let me know whether I am right in thinking that as it stands there would be no transitional period and that the existing e cigarette companies (in the EU) would disappear.

As I said at the beginning of this letter I have no connection whatsoever with the tobacco or e cigarette industry and am a Solicitor and law lecturer who is very grateful to e cigarettes for enabling me to feel fitter and to give up smoking.

I am most grateful to you for taking the time to read this. I do hope that you will be able to help by raising my concerns with the commission as it is very important for my health and the health of others in my position. I would be happy to meet with you and explain more fully why this is so important to me.

I look forward to hearing from you.

Kind regards

Reply:-

Dear Judi

Thank you for your recent email concerning possible proposals to introduce MORE EU regulations on tobacco/smoking alternative related products. We would oppose this in the EU Parliament, thus Nikki will be vote against any proposed directive or amendment that would legislate goods such as these sold in the UK .

These proposals if passed would only add to the growing already very BIG list of reasons why we'd be better off out the EU!!

The smoking community needs EU intervention like a fish needs a bicycle - If changes need to be made, those changes should be taken by our democratically elected politicians in Westminster, not by faceless bureaucrats in Brussels.

Yours sincerely,

Josh O'Nyons

Office of Nikki Sinclair MEP - We DEMAND A REFERENDUM MEP for the West Midlands Region

Wilson

February 22, 2013 at 12:53 am · Reply · Edit

Hello, this weekend is fastidious for me, for the reason that this point in time i am reading this great informative piece of writing here at my residence.

dm

April 21, 2013 at 9:23 pm · Reply · Edit

If they ban e cigs cause they are harmful ,then cigarettes should be top of the list to be banned

dm

April 21, 2013 at 9:31 pm · Reply · Edit

Doctor chris steele was on the programe This morning and was promoting e cigs the other day,perhaps if we all wrote to him telling him what the eu is up to..it might get some air time,

dm

April 23, 2013 at 5:20 pm · Reply · Edit

I bet you a few weeks before our goverment votes to legistate it,there will be a big story in the news saying someone was seriously hurt through using a vaping device, i might be wrong ,but thats just me being paranoid with all goverments ,if theres no money to be made then they dont care,look at 24 hour drinking ect,what idiot thought that was a good idea.the chancelor maybe, I am now ranting as well as being paranoid.

Geoff

May 21, 2013 at 9:30 pm · Reply · Edit

I believe people have rights. However did you Know that Christians in the UK have been fighting for the right to have there own Radio station, for about twenty years. Our Government has Band Christians from the airwaves.

I totally believe and thank God for people who fought and have taken a stand. for what they believe in. And now there is UCB united christian broadcasting DAB Radio. I believe in freedom of choice. So I call on ever person who Vapours to think more positive and stand up and fight for your rights. People all over the world drink coffee which has caffeine in, which is a drug. Will the EU ban coffee. The EU has in the past tried to ban bent bananas. To me this and many more stupid ideas the EU thinks up. I hope it will be the last nail in the coffin for the EU. When Britton votes NO to joining the EU in the referendum. Then the word great will be put back on the front of "Great Britton" Amen.

Maz

May 23, 2013 at 5:10 pm · Reply · Edit

THIS IS ABOUT THE BIG TOBACCO COMPANIES, THEY WANT EVERYONE BACK ON TOBACCO AND ARE LINING THE POCKETS OF THOSE IN POSITIONS OF POWER. THE TOBACCO GIANTS KNEW FOR DECADES THAT THEIR PRODUCTS CAUSED CANCER, BUT KEPT IT SECRET.

THE OTHER CULPRITS ARE THE GOVERNMENTS WHO EARN VAST TAX REVENUE FROM SO-CALLED MEASURES TO CUT SMOKING BY MAKING IT TOO EXPENSIVE.. E CIGS ARE NOT A CASH COW FOR THEM....

DEATH DEALERS, THE LOT OF THEM. BUT THEN THERE'S BIG MONEY IN IT FOR ALL OF THEM SO WHAT DOES IT MATTER IF PEOPLE GET LUNG CANCER,

Maz

May 23, 2013 at 5:13 pm · Reply · Edit

PS. I'M sick of UKIP MEP'S AND SUPPORTERS USING EVERY ISSUE AS A PROPOGANDA PLATFORM FOR THEIR POXY PARTY

randy cox

November 29, 2013 at 1:39 pm · Reply · Edit

Good post! Electronic Cigarette was more popular, since it was safer one and helps to live healthier. It protects from harmful diseases which traditional cigarette will cause.