10 ways to improve Matt Myers' letter to the New York Times

written by Clive Bates | 30 October 2015



Joe Nocera



Matt Myers

In a recent column, New York Times columnist Joe Nocera invited Matt Myers, President of the Campaign for Tobacco-Free Kids, to change direction and lead a campaign to exploit the public health potential of e-cigarettes by finding a better form of regulation than that in preparation at the FDA. In a response letter to the NYT, Matt declined this genuine and flattering invitation. Here I take a look at the exchange and then suggest 10 ways Matt Myers' response letter could be improved.

1. The Joe Nocera New York Times commentary

In an excellent commentary on Oct 17th, Can E-Cigarettes Save Lives?, the New York Times columnist Joe Nocera invited the tobacco control community to support a reality-based campaign to realise the public health benefits of e-cigarettes. Nocera argued that hoping that the US FDA would come up with regulation that sensitively strikes proportionate balances between risk and opportunity, between burdens and freedoms, between bureaucratic sclerosis and disruptive innovation was, well, *not that likely*.

> *It seems to me that if the tobacco-control community wants to start saving lives by employing the reduced-harm strategy that e-cigarettes offer, it needs to forget about the F.D.A. and take matters into its own hands.*
>
> *That means engaging with companies like NJOY that profess to be trying to do the right thing. Instead of demonizing them, the tobacco control community needs to find common ground, and come up with a set of standards — for marketing, manufacturing, and keeping e-cigarettes away from kids — that both sides can agree to. If such a deal were put in place, perhaps with state attorneys general to oversee it, anti-tobacco advocates could talk about the reduced harm potential of e-cigarettes with a clear conscience, without the involvement of the federal government. They then could describe the benefits of e-cigarettes for smokers that the companies themselves can't.*

Good advice, something to look into perhaps…

Nocera also identified, correctly, that a key player is Matt Myers, President of the Campaign for Tobacco-Free Kids, the most active and influential of the national tobacco control organisations in the United States.

> *The undisputed leader of the tobacco-control community is Matt Myers, who helped found and is the president of the Campaign for Tobacco-Free Kids. Unlike many of his anti-tobacco peers, Myers is on the record as saying that if "responsibly marketed and properly regulated, e-cigarettes could benefit the public health."*

…and suggested that Matt Myers might pluck up the courage to lead a new approach focussed on realising the opportunity to disrupt the market for cigarettes.

> *I believe the time has come for Myers to screw up his courage again. It could be the beginning of the end for one of the greatest scourges on earth.*

I agree and urged Matt Myers to take this suggestion seriously.

2. The Matt Myers response letter

Sadly, Matt Myers didn't respond all that enthusiastically to this invitation. Instead, he wrote a letter to the New York Times, The Uncertainties about E-cigarettes, published 23 October 2015. Here it is in full.

> *To the Editor:*
>
> *In "Can E-Cigarettes Save Lives?" (column, Oct. 17), Joe Nocera expresses certainty about the health benefits of e-cigarettes and argues that it is time to "forget about the F.D.A." in regulating these products.*
>
> *Whether e-cigarettes can reduce the number of Americans who die from tobacco use is far from certain. E-cigarettes may reduce the risk of disease for addicted cigarette smokers, but any benefit will come only if they are shown to be effective at helping smokers stop using cigarettes completely and if they are marketed so they do not re-glamorize smoking among young people. These goals can be achieved only through effective oversight by the Food and Drug Administration, not by circumventing it.*
>
> *The concern about youth use is serious. In 2013, over a quarter of a million youths who had never smoked a cigarette had used e-cigarettes.*
>
> *For more than 75 years, the Food, Drug and Cosmetic Act has required manufacturers, including manufacturers of products that claim to help people quit smoking, to present their scientific evidence to the F.D.A. To our knowledge, not one e-cigarette manufacturer has done so.*
>
> *The 2009 law giving the F.D.A. authority over tobacco products also sets out common-sense standards to govern the relative safety claims of tobacco products, including e-cigarettes. No other manufacturer of products regulated by the F.D.A. is allowed to make safety claims without first conducting the science to demonstrate the accuracy of their statements; neither should e-cigarette makers.*
>
> *The skyrocketing youth use and irresponsible marketing of e-cigarettes show what happens in the absence of meaningful rules. To realize any potential benefits of e-cigarettes and minimize their risks, the Obama administration must promptly issue an effective final rule asserting F.D.A. authority over e-*

cigarettes.

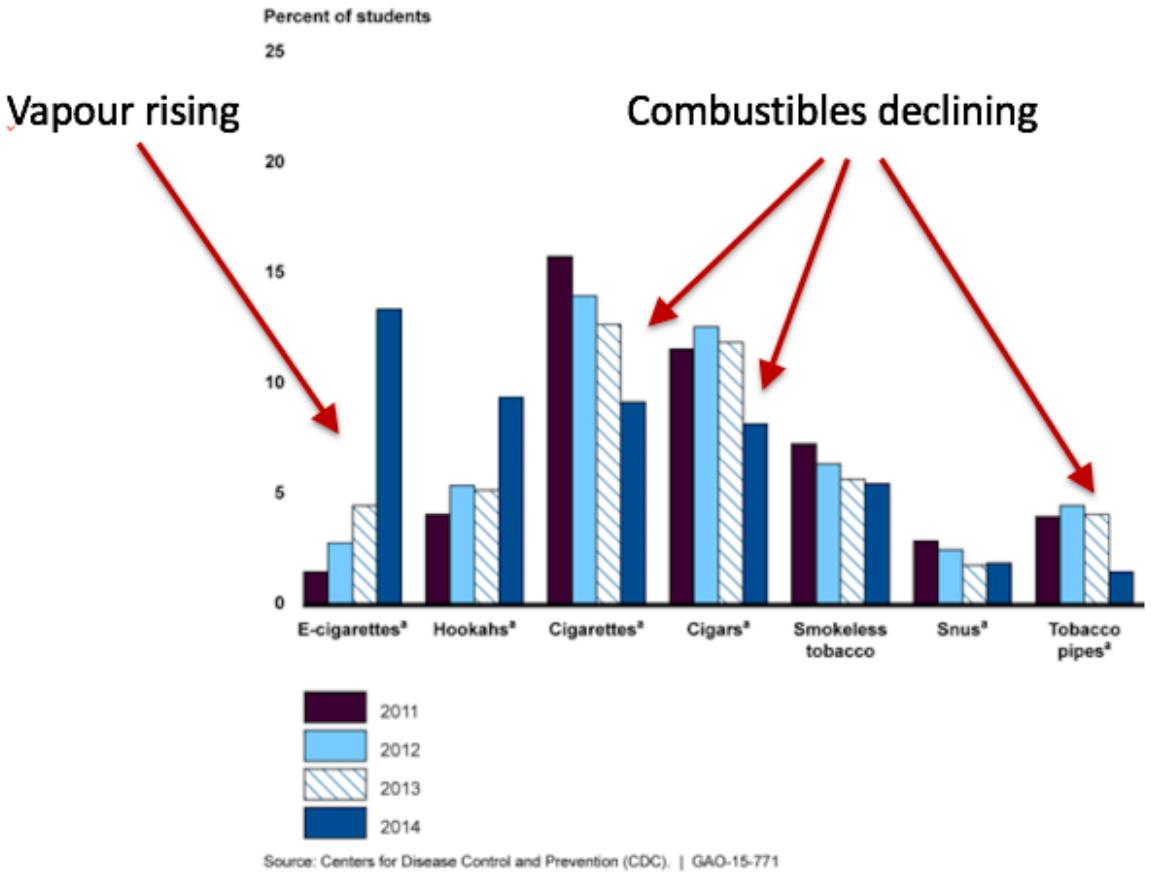
MATTHEW L. MYERS
President
Campaign for Tobacco-Free Kids
Washington

There is also an extended version on the CTFK blog: FDA Oversight is Key to Minimizing Risks of E-Cigarettes, Especially to Kids, and Realizing Potential Benefits: A Response to Joe Nocera

3. Ten ways to improve the Matt Myers response letter

I know one can't say everything you would like to say in newspaper letter, but that is why we have to take great care with what we do say to faithfully reflect reality. I think Matt's letter is a little short on context, a little selective with data and does not quite convey the full picture. Allow me to make ten suggestions that would have improved the letter (or blog).

1. Mention the decline in teenage smoking. No one in tobacco control should discuss the rise in adolescent e-cigarette use without also discussing the marked decline in the adolescent use of cigarettes and other combustible tobacco that has happened concurrently. This is the recent CDC data with my annotation…



Source: High school tobacco use. CDC data, annotation added

If you want to see it put even more dramatically, look at Brad Rodu's visualisation of the CDC data: [The CDC Buries the Lead: Teen E-cigarette Use Rises as More Dangerous Cigarette Use Plummets]

2. Acknowledge that vaping virgins may otherwise have smoked. Myers notes with great gravity that "*over a quarter of a million youths who had never smoked a cigarette had used e-cigarettes*". It might have been worth mentioning that there were 1.96 million current high school e-cigarette users in 2014, 90% of whom were current or previous users of tobacco products, mostly cigarettes. For these young people, the vast majority of adolescent vapers, it is quite possible that e-cigarettes are helping them reduce the impact of smoking or to quit. Harm reduction doesn't have to wait until after age-18.

But let's join Matt Myers in discussing the other 10% – those that have never used tobacco before vaping… He's kind of implying that these young people may be new recruits to nicotine addiction. But what counts is what they'd have done *in the absence of e-cigarettes*. Here again, the story may not be as grave as he

implies: at least some of those never-smokers would have gone straight to smoking had there been no e-cigarettes. Furthermore, some who would have become smokers may yet be diverted away from cigarettes and never become the smokers they would otherwise have become. Both positive results.

I have to keep repeating this because people mistakenly think it is somehow important, but **the sequence in which kids experiment with cigs or e-cigs or other stuff is not a relevant concern**. Three things matter with so-called gateway effects. Firstly, does youthful experimentation consolidate into harmful long-term smoking habits? Secondly, does a period of vaping *cause* a harmful consolidated smoking habit that would otherwise not have happened – a quite implausible idea? Thirdly, how much does it have to happen, before it is a material concern? If this happens to one individual somewhere in the world, do we call a 'gateway effect'? How prevalent does this have to be – bearing in mind the potential benefits in diverting young people from smoking – before it is a legitimate concern? It is no surprise that young people both vape and smoke – the same 'risk factors' (parental smoking, educational attainment, rebellious nature etc) predict for both behaviours given the similiarities (other than the radical difference in harm). If first-time vapers are vaping instead of smoking first, *then that's a good thing*. One would expect an organisation that specialises in 'kids' to understand all this mild complexity – so it's hard to see how such naïve (or alarmist) presentation of data is justified.

3. Not all vaping is the same. *Some vaping doesn't include nicotine.* Although CDC purports to be measuring 'tobacco use', in which it (absurdly) includes e-cigarettes because they contain nicotine, it doesn't actually ask if the e-cigarettes used contain nicotine. But CDC really should ask: a survey of school students in Connecticut found high proportions of adolescents vaping non-nicotine liquids… See table 3 showing 30-40% of e-cigarette use is non-nicotine (highlight added).

E-cigarette Use Among High School and Middle School Adolescents in Connecticut

Table 3.
Percentage of Students Using Various Electronic Cigarette (E-Cigarette) Battery Types and E-Cigarettes With Nicotine by Cigarette Smoking Status

	First e-cigarette use				Typical e-cigarette use			
	Total (n = 953)	Never-smoker (n = 405)	Ever-smoker (n = 253)	Current smoker (n = 295)	Total (n = 451)	Never-smoker (n = 144)	Ever-smoker (n = 97)	Current smoker (n = 210)
Battery type		$\chi^2(4) = 32.09$, $p < .001$				$\chi^2(6) = 20.80$, $p = .002$		
Disposable	20.8	17.8[a]	21.3[a]	24.4[a]	11.3	15.3[a]	13.4[a,b]	7.6[b]
Rechargeable	61.6	57.0[a]	62.9[a,b]	66.8[b]	60.1	45.8[a]	61.9[b]	69.1[b]
Uncertain	17.2	24.4[a]	15.8[b]	8.5[c]	10.6	16.7[a]	6.2[b]	8.6[b]
Both	–	–	–	–	6.0	6.9[a]	4.1[a]	6.2[a]
Nicotine content		$\chi^2(4) = 154.47$, $p < .001$				$\chi^2(6) = 67.45$, $p < .001$		
Nicotine	38.6	19.3[a]	38.3[b]	65.4[c]	22.4	4.2[a]	16.5[b]	37.6[c]
No nicotine	40.6	55.6[a]	39.1[b]	21.4[c]	22.0	27.8[a]	30.1[a]	13.8[b]
Uncertain	20.4	24.4[a]	22.1[a]	13.2[b]	12.0	18.1[a]	10.3[a,b]	8.6[b]
Both	–	–	–	–	17.1	22.9[a]	13.4[a]	14.8[a]

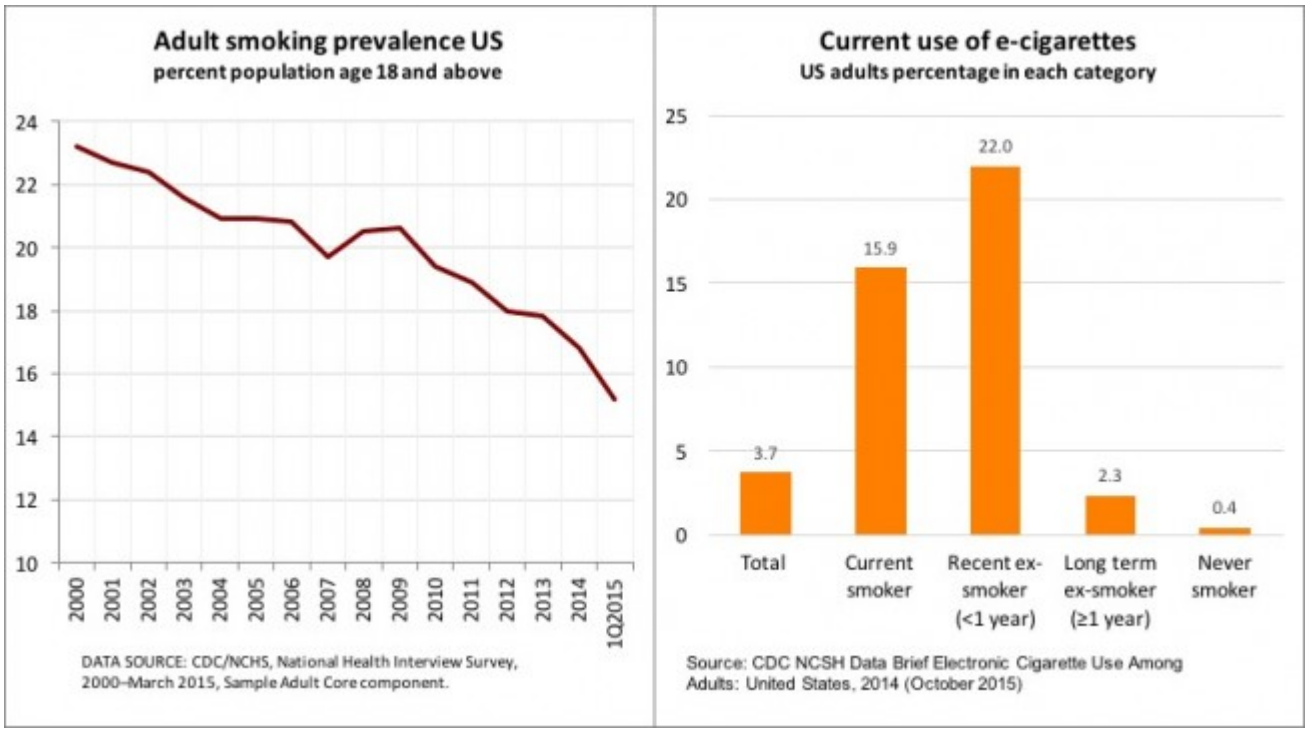
In weird circular logic, e-cigarettes are defined as *tobacco products* and problematic because they contain nicotine. But if they don't contain nicotine, they are still e-cigarettes, still added to the CDC stats as tobacco products and by implication still seen as problematic.

...and some vaping isn't that much vaping. Although the CDC stats show 13.4% of high school students using e-cigarettes, this is the proportion that has used them at least once in the last 30 days. A lot of that is basically just adolescents messing about... or what is known in polite society as 'experimentation'. 45% of these 13.4% high-school age e-cigarette users were using the products on only 1 or 2 days per month. The 200,000 that Matt Myers refers to are likely to be highly represented in this group because they have not been smokers, and therefore nicotine users. In fact, the overall pattern of use shows a lower intensity of use for e-cigarettes, with less than 10 percent of adolescents using e-cigs daily, compared to 22.6 percent of young smokers who are smoking daily (CDC Data).

Frequency of use in last 30 days (High School students)		
% using	Cigarettes	E-cigarettes
1–2 days	37.0	45.4
3–5 days	12.3	16.2
6–9 days	9.7	12.0
10–19 days	9.4	10.9
20–29 days	9.0	5.8

All 30 days	22.6	9.7
	100.0	100.0

4. Spare a thought for the adults – and cheer up… it's good news! It is not exactly going wrong in the adult world. Smoking has been in rapid decline as vaping has risen and vaping is concentrated in smokers and, importantly, in recent ex-smokers. The use of e-cigarettes by 22% of recent ex-smokers is a good sign – we can't know from this data if they are ex-smokers *because* of vaping, but it is possible that is the case for many of them and also possible that vaping is preventing relapse for some.



- Adult smoking prevalence: Early Release of Selected Estimates Based on Data From the January-March 2015 National Health Interview Survey
- Use of e-cigarettes: Electronic Cigarette Use Among Adults: United States, 2014

But statistics can be tiresome and dry, especially if they don't reveal the story you are expecting. As a more human alternative, I recommend anyone wishing to empathise with the positive experience of vaping should read some vaping testimonies – for example, see these thousands of brilliant CASAA testimonies *and just be inspired – this is what public health ought to be about.*

5. Don't dwell on what we don't know at the expense of what we do know. We now have thousands of toxicology measurements and assessments and know

beyond any doubt that e-cigarettes are far safer than smoking. They simply do not contain the harmful products of combustion in cigarette smoke or, if they contain detectable toxins, they are at levels far below cigarette smoke or concentrations not generally regarded as dangerous. According to the expert review for Public Health England, vaping is likely to be at least 95% lower risk than smoking. So far, we know of no reason why e-cigarettes would cause serious disease or death. So even the residual risk 5 percent is an allowance for uncertainty – a workable guideline for smokers, who should not assume they are proven risk-free. To become better acquainted with what is known, I recommend four reviews:

- Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health*2014;**14**:18. [Link]
- Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;**5**:67–86. [Link]
- Hajek P, Etter J-F, Benowitz N, *et al*. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* 2014;**109**:1801–10. [link]
- McRobbie H, Bullen C, Hartmann-Boyce J, *et al.* Electronic cigarettes for smoking cessation and reduction. *Cochrane database Syst Rev* 2014;**12** :CD010216. [link]

The remarkable thing about the last of these, the Cochrane Review, is that it gives a positive assessment of e-cigarettes for smoking cessation, but based on products that are now obsolete and even though these products are not used like medical interventions tested in these trials.

"Dual use". Somehow tobacco controllers have managed to convince themselves that there is no benefit to 'dual use' (both smoking and vaping) and Myers asserts there are no benefits unless smokers "*stop using cigarettes completely*". This is obviously wrong. The problem starts with classification: someone who smokes once a month and vapes the rest of the time is a dual user, but so is someone who vapes once a month and pumps through two packs a day – but they clearly don't have the same behaviour or health prognosis. Smokers who vape are likely to reduce their exposure to smoke because they are taking nicotine from another source – all the studies used to measure health impacts of cutting down are worthless guides to cutting down with e-cigs unless they have a replacement

nicotine source. Dual use also predicts for eventual quitting and may be a behaviour change pathway to quitting cigarettes over time.

6. Don't suggest American businesses waste $$millions in pointless supplication before the FDA. The complaint that companies are not voluntarily subjecting themselves to FDA approvals is baseless. There is no reason why any manufacturer should present evidence to the FDA, and if they did, it would be a never-ending and draining process. In 2010, the courts ruled that the products cannot be classified as medicines unless therapeutic claims are made. However, e-cigarettes are not sold as smoking cessation aids but as alternatives to smoking – and it should be uncontroversial to say they are safer. The FDA has not yet issued a final rule deeming them to be tobacco products – so e-cig companies have no need to approach the FDA as "tobacco manufacturers". So the letter makes it sound as though the manufacturers are being irresponsible or lawless, but they aren't. If CTFK thinks they are, they can always complain to the FDA.

7. Actually find the irresponsible marketing. There is little evidence of marketing to children, only assertions that certain ads or brands are designed to appeal to children but with no empirical evidence, and apparently minimal understanding of modern advertising. It remains unclear why CTFK believes that adolescents would seek to reinforce their status as children – most are experimenting with adult behaviour. For example, it is often asserted that certain flavours are aimed at kids. The one study that has looked at the appeal of flavours to teens found minimal interest and that the most interest was in 'Single Malt Scotch' flavour, though this preference was not statistically significant.

E-cigarette advertising should be understood as disruptive anti-smoking pro-health advertising, with potentially negative unintended consequences from over-zealously restricting it. A lot of what is purportedly irresponsible advertising is just well-executed advertising that could be for anything:



Found on the internet – thanks to the creator of this

8. Accept that FDA regulation will destroy most vapour businesses, remove the most effective products and gift the vapour category to the tobacco industry. The FDA's approach to regulating tobacco products is inappropriately restrictive and excessively burdensome if applied to the e-cigarette category, given the very low risk of these products. The Family Smoking Prevention and Tobacco Control Act, 2009 was designed to throttle innovation of harm-causing tobacco products. As such, it is not an appropriate regulatory regime for a rapidly-evolving, harm-reducing disruptive alternatives to smoking. Unless something creative is done in the FDA's deeming regulation, and there is no sign of that or that Myers is encouraging this (quite the contrary), most products favoured by vapers and most successful as alternatives to smoking will be driven off the market. Most firms will close, leaving the vapour category mainly or exclusively to the tobacco industry and its commoditised, high-volume,

low-diversity products that can be made to appeal to regulators more easily. If you are in Big Tobacco you may not worry too much about FDA slowing down the growth of e-cigs and exquisitely shaping the vapour market to favour the Big Tobacco business model, but if you are President of CTFK, I'd say that's something to lose sleep over.

9. Don't pretend to support fair communication of risk via the FDA. It is a little disingenuous to argue that the FDA should be the place where reduced risk claims are approved. We know this because of what happened when Swedish Match made a 130,000-page application to the FDA for a 'Modified Risk Tobacco Product' approval to remove some warnings for which there is no evidence and to change the main warning on snus (smokeless tobacco pouches, probably >98% lower risk than smoking), as follows:

> *From: WARNING: This product is not a safe alternative to smoking*
>
> *To: WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.*

In response to the apparently deadly threat from this entirely reasonable and cautious wording change, the Campaign for Tobacco-Free Kids participated in a "legal consortium" which produced a weighty 110-page submission dedicated to blocking the sensible proposed changes with some tortured legal reasoning. Here's an alternative theory: they don't actually want any consumer-friendly communication of the orders of magnitude difference in risks between cigarettes and e-cigarettes or snus – they want an unambiguous 'quit or die' proposition. To this end, the immensely ponderous risk-aversion and bureaucratic burdens of the FDA's MRTP process are an *advantage* – it is likely no e-cigarette will ever get through this process. Not because there is the slightest doubt they are much safer, but because of the bureaucratic burdens and high barriers to change.

10. Take some responsibility for unintended consequences – or at least look worried that you might be making things worse. Regulatory activists need to think harder about whether their ideas for protecting young people, non-smokers or even smokers from vaping simply expose these people to more smoking by making vaping relatively less attractive. We have just seen the first evidence of the potential harmful unintended consequences of even modest e-cigarette regulation: *youth smoking increased where youth access to e-cigarettes*

was banned.

- Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* October 2015. [Link]

Friedman took advantage of a natural 'controlled' experiment: using regression analysis to compare changing smoking rates in US states with and without bans on e-cigarette sales to minors. The study found that smoking was increased in the 12-17-year-old age group in states where bans on selling e-cigarettes to under-18s are in place (emphasis added).

> ***Abstract:*** *Understanding electronic cigarettes' effect on tobacco smoking is a central economic and policy issue. This paper examines the causal impact of e-cigarette access on conventional cigarette use by adolescents. Regression analyses consider how state bans on e-cigarette sales to minors influence smoking rates among 12 to 17 year olds. Such bans yield a statistically significant 0.9 percentage point increase in recent smoking in this age group, relative to states without such bans. Results are robust to multiple specifications as well as several falsification and placebo checks. This effect is both consistent with e-cigarette access reducing smoking among minors, and large: banning electronic cigarette sales to minors counteracts 70 percent of the downward pre-trend in teen cigarette smoking in the states that implemented such bans.*

This is not an implausible finding. If e-cigarettes are made harder to access, more expensive or risky to buy or sell, or state legislation implicitly signals they are harmful, then their value relative to smoking could be degraded. It may not be a definitive study, but it raises the question of unintended consequences and shifts the burden of proof to regulatory activists – are you really sure you aren't making things worse?

This observed unintended consequence with youth access regulation is a specific case of a general problem. All the e-cigarette policies proposed by tobacco control advocates and regulators are vulnerable to this problem: banning advertising; banning flavours; imposing big warnings; limiting nicotine strength; setting demanding or restrictive technical specifications; imposing paperwork burdens that slow innovation and reduce diversity etc – all of these can be manifest as more smoking. Are the regulatory activists at CTFK really paying enough

attention to this? All their hard work may be leading to more smoking. Can the regulatory activists provide some assurance that their plans for grand regulatory schemes administered by the FDA will not do more harm than good, will not simply harm harm-reduction and increase smoking, and will not mean that more adult *and kids* are smoking, getting sick and dying early? What may appear to be precautionary regulation might actually be reckless meddling.

4. Conclusion

Nocera was right and Myers should show renewed courage and accept his *de facto* responsibility to lead a campaign to exploit the huge potential of e-cigarettes and tobacco harm reduction – I for one would be delighted if he did, despite what is written here. There is an emerging highly positive story about vaping both for adults and youth in the United States. The free market of innovative companies and discerning consumers is serving public health quite well right now in Europe and the United States. But the clouds are gathering: in the next 2-3 years we shall face implementation of bad ideas hatched in ignorance and a measure of panic in 2011-12. Today's marketplace could be improved with some modest regulation designed to provide greater consumer confidence and to knock out any rogue traders and the odd unsafe product, and it would benefit from truthful communication of risks and opportunities by trusted figures in public health. But taken as a whole, the market is working well. The heavy duty FDA tobacco regulation favoured by Myers and much of the U.S. public health establishment and the impossibility of communicating risks candidly is a framework that is not fit for purpose and was designed for something else – crushing any innovation in the tobacco sector. Now is the time for the chief proponent of FDA regulation of e-cigarettes to call a halt – *or at least say what size of catastrophe would be needed to change his mind* – and to start the change of course.

I'll end with a quote (falsely) attributed to John Maynard Keynes:

> *"When the facts change, I change my mind. What do you do, sir?"*