Addiction

Commentaries on Wagener *et al.* (2012)

E-CIGARETTES: A VULNERABLE PROMISE

Wagener, Siegel & Borrelli [1] provide a much-needed counterbalance to the generally negative response to e-cigarettes (EC) by most tobacco control activists. The calls to ban or at least to severely regulate EC, even in the absence of any clear evidence of harm or risk, may seem prudent and protecting public health from one perspective, or misguided and harmful to public health from another.

EC seem to have potential both as a smoking cessation treatment and as a consumer product, paving the way for nicotine delivery systems to compete with conventional cigarettes (CC) on the open market. The former is important, but the latter could have an even larger impact. The aim of this commentary is to expand the arguments of Wagener *et al.* in this less often-addressed direction.

The treatment potential of EC is clear. They seem more attractive to smokers than the existing nicotine replacement products (NRT), which are rarely used recreationally; they are cheaper; and in experienced users at least they probably provide better nicotine delivery [2]. To be marketed as treatment, EC will need to undergo the usual requirements regarding proof of efficacy and production and content controls. Wagener *et al.* make such points succinctly and well.

The consideration of EC as a consumer product is even more exciting. If a harmless nicotine delivery device appeared which would be capable of competing with tobacco products in the market-place, the public health benefit would be enormous. I personally do not think that the current versions of EC are as yet up to the task of replacing CC, but they can be seen as a trial run of a hugely promising new development. The first evidence is emerging that perhaps 20% of smokers who try EC become regular users [3]. Our reaction to this first dawn of a credible non-tobacco consumer nicotine product is likely to influence future developments profoundly. If we ban EC or make them jump through hoops and choke them in red tape, the deadly CC will continue to rule unchallenged.

The general approach to EC at the moment seems to be dictated by an a priori suspicion that they are bad. Wagener *et al.* show that the main objections to EC generated so far are largely spurious. Others can be added to the list. I have heard it argued that if EC are not regulated, some smokers may purchase brands which deliver little nicotine or deliver it inconsistently. No regulation is needed on how much caffeine different brands of teabags must deliver (the drug content is not even marked), or how tasty and consistent in taste a chocolate bar has to be, or how entertaining a film must be. Consumer products which are not very good will leave a few purchasers disappointed, this is true, but such products will not stay on the market for long, and their failure becomes a valuable benchmark for everyone else.

Since Russell's call for harmless alternatives to cigarettes to compete with the tobacco products on the open market [4], smokers who are unable or unwilling to quit have been waiting for a palatable alternative to conventional cigarettes which gives them what they want without killing them. EC are the first sign that such a product can be commercially viable. The public health community should support this development.

Declarations of interest

PH has received funding from manufacturers of stop-smoking medications but has no links with any manufacturers of e-cigarettes.

Keywords Electronic cigarettes, public health, smoking.

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E-CIGARETTES: ROOM FOR CAUTIOUS OPTIMISM

Wagener and colleagues examine concerns that have been raised about e-cigarettes, and argue that these have been overstated relative to the potential benefits of these

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new products [1]. Their paper raises important questions about the possible role of e-cigarettes in tobacco control, and in particular in tobacco harm reduction. What place might e-cigarettes have in efforts to reduce the harm from smoking and what further evidence is required before policy-makers and regulators can reach informed conclusions about their safety and efficacy?

A key consideration is whether e-cigarettes can serve as a substitute for tobacco smoking. In order to avoid the health risks that are associated with cigarettes smokers need to quit, but many find it hard to do so. Current alternative nicotine delivery devices such as nicotine replacement therapy (NRT) products fail to deliver nicotine in the way that a cigarette does. For this, and a range of other reasons, most smokers do not use them when trying to stop even though NRT, when used correctly, can double a smoker's chances of achieving abstinence [2]. In addition, most smokers do not use NRT as an aid to smoking reduction or temporary abstinence, even though recent evidence suggests that these products aid in cutting down and increase the chances of eventual cessation for those who engage in smoking reduction [3,4].

In contrast, the limited evidence we have about e-cigarettes suggests that users are treating them as a replacement for tobacco smoking and are using them to cut down and to quit, as outlined by Wagener and colleagues. This evidence should be treated with some caution, as it is drawn largely from surveys that may attract those who are positive rather than negative about the products [5,6]. However, if it can be confirmed in larger population studies or trials then these products may have a role to play in reducing smoking prevalence.

Where most of the remaining concerns lie is in relation to the safety and quality of e-cigarettes. There are also questions about the role of e-cigarettes as a potential gateway product into smoking for young people, and questions about the extent to which the tobacco industry may become involved in the manufacture of these products. By reviewing existing and forthcoming research and involving professionals and the public in their deliberations, these are questions that a range of organizations in different countries are now considering. This includes, for example, the Medicines Healthcare Regulatory Agency (MHRA) in the United Kingdom, which has recently completed a public consultation on nicotine-containing products that are not licensed as medicines [7]. Responses to the consultation indicated that there was clear support for regulation of these products, particularly from public health bodies, while the importers and users of e-cigarettes were opposed to regulation in case it results in a ban on the sale of existing products. The MHRA's response has been to coordinate a period of further research and information-seeking regarding, in particular, the doses of nicotine that have a significant pharmacological effect and the impact of potential regulation on businesses and for public health. A final decision on the regulation of e-cigarettes as medicinal products in the United Kingdom is expected in spring 2013.

Declarations of interest

None.

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Keywords electronic cigarette, harm reduction, nicotine.

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ELECTRONIC CIGARETTES – THE HOLY GRAIL OF NICOTINE REPLACEMENT?

Electronic cigarettes are an interesting innovation, a new way to administer vapourized substances to the bronchia, lung and bloodstream. This opens new perspectives for smoking cessation and other fields (e.g. pulmonary medicine). Electronic cigarettes are increasingly popular: Google searches for this term have increased by 5000% over the past 2 years [1], 18% of US smokers have ever

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used them and 6% have used them in the past 30 days [2]. E-cigarettes are probably more satisfactory than nicotine medications: they have tobacco flavours, visible inhaled and exhaled vapour, they resemble a cigarette and can deliver high amounts of nicotine [3,4]. Even e-cigarettes that do not contain nicotine decrease craving and tobacco withdrawal symptoms, and are perceived as helpful to quitting smoking [5]. Using e-cigarettes costs about 1$ a day, which is five to seven times cheaper than smoking a pack a day for the same number of puffs, or than using nicotine medications at the recommended dosage [5].

Older models were often of mediocre quality, but these products evolve rapidly and newer models are much more effective: compare the e-cigarette industry with the pharmaceutical industry, which has not marketed any new nicotine medication for a decade. The nicotine inhaler is the same today as it was 2 decades ago, when it was first launched; it is unattractive and requires a hard draw and many puffs to obtain nicotine [6]. In contrast, the e-cigarette industry is much more innovative and reactive, it regularly launches new products and is able to segment the market (e.g. brands for women). Additional technological innovations are needed, in particular to vapourize nicotine directly, without propylene glycol or glycerol. The e-cigarette industry would almost certainly be less innovative if it was regulated, but regulation is nevertheless needed to ensure that these products are safe and effective [7].

Even though e-cigarettes were invented almost a decade ago (in 1993), relatively few research reports have been published [7]. Researchers have lacked curiosity. Research is needed urgently *in vitro*, in animal models, in clinical and in public health settings to document the safety, toxicity, efficacy and public health impact of these products [7]. Randomized trials are under way and will soon show whether e-cigarettes help smokers to quit; but who will fund this research effort? E-cigarettes are manufactured and distributed by relatively small companies, not by Big Pharma or Big Tobacco. These companies have little interest in publishing research; they even probably fear that studies may document adverse effects. Thus, there is a need for independent research supported by governments or foundations. However, we cannot wait until the results are known, as this may take years. Thus, for some time it may not be possible to base regulations, clinical advice and recommendations on a sound body of science.

Regulation agencies should balance the positive and negative aspects of any regulation, and keep in mind that the priority is to help smokers to quit. Prohibition would be incompatible with legal quality control. These products are sold mainly over the internet, and it is almost impossible to stop internet sales: if a shipment were blocked the legal risk to users would be minimal, and the sales volume is too high for customs officials to check more than a fraction of shipments. Nevertheless, there is a need for reasonable regulation, starting with standards of good manufacturing practice.

Even if manufacturing standards were enforced, users would continue to modify the products ('mods'), adding larger batteries to produce more vapour, or adding substances of their choice to refill liquids [8]. Users should be informed that these 'mods' may convey some risk. Smokers often ask clinicians and smoking cessation counsellors about information on e-cigarettes, and clinicians should be trained to answer these questions adequately. Clinicians should inform users about the scarcity of relevant data on safety and efficacy, but they should also tell users that the risks are lower than for smoking. If users say that e-cigarettes help them to quit smoking, counsellors should focus on smoking cessation rather than on e-cigarette cessation [9]. Advising smokers to stop using e-cigarettes might be deleterious in many situations, in particular in people who failed to quit with other treatments. Hopefully, the timely paper by Wagener *et al.* will stimulate research and debate [10].

Declarations of interest

None.

Keywords Electronic nicotine delivery devices (ENDS), electronic cigarette, E-cigarette, nicotine, smoking, tobacco use disorder.

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LAISSEZ-FAIRE REGULATION: TURNING BACK THE CLOCK ON THE FOOD AND DRUG ADMINISTRATION AND PUBLIC HEALTH

In 1906, in an effort to end the sale of unsafe and ineffective patent medicines, the US Congress passed the Food and Drug Act, bringing regulation to what had been a chaotic and dangerous *laissez-faire* market-place. Thirty years later mass poisonings from a diethylene glycol antibiotic solution led to the subsequent creation of the Food and Drug Administration (FDA), and a move to proactive monitoring and oversight [1]. Wagener, Siegel & Borrelli appear to be in favor of turning back the clock, disputing selected arguments behind our call for the FDA to regulate 'e-cigarettes' in the United States [2] and claiming that, in the meantime, 'removing e-cigarettes from the market or discouraging their use could harm public health' [3]. However, there is no rigorous evidence for the additive benefit of 'e-cigarettes' over evidence-based nicotine replacement therapy (NRT) for cessation or harm reduction, and consumers are not in a good position to evaluate unregulated drugs and devices sold alongside regulated competitors. Moreover, no addictive and potentially lethal drug such as nicotine should ever be commercially marketed without formal regulatory oversight. This debate is timely, as in the United States the 2009 passage of the Family Smoking Protection Tobacco Control Act (FSPTCA) provides a regulatory pathway for potentially reduced-harm tobacco products [4]—but only after formal scrutiny and validation.

Given that the paper refers heavily to our previously published commentary in a US medical journal, we urge readers to read our original opinions [2,5] as well as the reviews by other authors and the World Health Organization [6,7]. The 'straw man' arguments framed by the authors bear little resemblance to our central concerns driving the call for regulation of the industry. Readers not familiar with our position might be surprised that we believe that refined nicotine has a substantial role to play in harm reduction and, like NRT, 'e-cigarettes' can in all likelihood be constructed and manufactured in a safe manner. Where we differ is on the specific question of whether a subset of nicotine products should remain on the market exempt from oversight, or if they should be withdrawn pending their regulation.

At the root of this issue is money. In the United States and some other countries, devices labeled 'e-cigarettes' are advertised and sold widely and without oversight, regardless of their origin, contents or construction. This contrasts starkly with heavy restrictions on traditional NRT, including physician prescription requirements for the e-cigarette's close cousin, the nicotine inhaler. Currently, e-cigarette manufacturers and distributers are taking venture capital to expand (e.g. Njoy [8]), seeking to establish market share during this unregulated period. For them, academic and political debate fosters delay in regulation, and delay gains time to grow while the tobacco and pharmaceutical industries are in limbo awaiting regulatory rule-making. While protagonists such as Professor Siegel [9,10] may seek to portray the US debate as one lacking balance, we believe it is a snapshot of aggressive corporate jockeying within a capitalist system to determine who will gain a cut of a lucrative market for an addictive drug. Meanwhile, tobacco companies are preparing for their own entry, not least by investing heavily in intellectual property to create more efficient devices [11,12]. The same companies that brought us decades of deception and manipulation will be the major beneficiaries of any limitation on regulation achieved by the current industry and its advocates.

Ultimately at issue is *not* the potential for refined nicotine products, including 'e-cigarettes', to be part of a comprehensive harm reduction strategy. Rather, the question is if this should occur under a regulatory framework such as the US FSPTCA—or whether harm reduction should evolve within the existing tobacco market-place unfettered by national regulatory agencies.

The authors present a limited view of the utility of regulation, comparing refined nicotine to flavored acetaminophen syrup (e.g. Tylenol): '. . . for consumer products that are hazardous to children, we simply warn adults to keep them out of their reach' [3]. The reality is complex—multiple laws, codified as regulations, exist and are enforced to ensure safety before and after sale. Acetaminophen, like refined nicotine, can be lethal in commonly dispensed sizes [13], yet can be purchased over the counter even when sold with flavorings. Such a risk would be unacceptable to modern consumers without the guardrails of FDA regulation; for example, labeling standards, tamper-resistant caps, evidence of safety of the drug supply and traceable identification of each batch.

In the absence of modern regulatory controls is the chaos of the early 1900s, and rarely seen in the developed

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world today. Like 'e-cigarette juice', acetaminophen solutions are usually sold in propylene glycol or glycerol solutions susceptible to contamination by diethylene glycol. In the mid-1990s scores of Haitian children were poisoned by acetaminophen syrup, resulting in more than 80 deaths. Because of Haiti and a half-dozen similar events [14], the public health community was critically concerned by contamination in 'only one of 18' samples tested by the FDA. Drugs, chemicals and devices sold outside the bounds of traditional regulation and scrutiny carry risks that are unfamiliar to consumers who trust in FDA oversight.

The authors conclude by noting that 'some e-cigarette manufacturers are attending to safety concerns by making their products safer, such as using distilled water and glycerin instead of propylene glycol' [3]. Such a *laissez-faire* approach emphasizes the responsibility of the tobacco industry in producing safe products, assuming that safer products will flourish while unsafe ones falter (or even explode [15]). However, it is difficult to reconcile the continued strict regulation of pharmaceutical nicotine and its competing delivery systems (inhalers, sprays, gums, lozenges, etc.) with the unregulated sale of nicotine in 'electronic' form. The end result of the current US system is that safe and effective nicotine is expensive and difficult to obtain, while unmonitored and unregulated nicotine is cheaper and more easily purchased.

A balanced argument would call for opening the market by loosening regulation on existing products, allowing safe and effective nicotine replacement to be available more widely to smokers but still preserving measures to prevent pediatric use. In the United States the FDA has the authority to regulate nicotine products (including 'e-cigarettes') [4] provided that it exercises its jurisdiction under the FSPTCA. We believe it is unwise to waive or delay regulation based on corporate expediency, a vocal consumer base or even academic opinion, however well intentioned. It would be inappropriate to use the cited self-selected online survey data [16], small convenience samples of users [17] or industry-funded [18] pilot studies [19] to exempt oversight for one particular product among many. We agree with the authors that more rigorous research will be informative, but efforts to use the current evidence to support ongoing sale of 'e-cigarettes' without regulation could result in a subversion of the FDA and a century of progress in public health, and in our opinion is profoundly unwise.

Declarations of interest

None.

Keywords Electronic cigarettes, electronic nicotine delivery systems, harm reduction, tobacco.

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LET'S KEEP OUR 'EYE ON THE BALL': REDUCING TOBACCO-RELATED HARM

We are very pleased that our recent For Debate article [1] stirred interest and thoughtful discussion related to the topic of electronic cigarettes (e-cigarettes). The commentaries provided by Drs Hajek [2], Bauld [3] and Etter [4] generally agree that e-cigarettes are promising, that there is a need for more research and that there is not enough scientific evidence to discourage their use at this time. All three commentaries also extended our original points: Dr Hajek examined the potential benefit of e-cigarettes as a consumer nicotine product that directly competes with conventional tobacco cigarettes and called for the public health community to support their development; Dr Bauld discussed the UK's Medicines Healthcare Regulatory Agency decision to respond to the differing views of the public health community and current e-cigarette users by coordinating a period of further research on the impact of potential e-cigarette regulation on public health; and Dr Etter discussed that healthcare providers should inform smokers interested in e-cigarettes that research is scarce but that compared to regular cigarettes the health risks appear to be lower, and that current e-cigarette users should not be deterred by healthcare providers from continued use if they are finding that it is helping them quit smoking.

We believe that our thesis was misconstrued by Cobb & Abrams [5]. The main goal of our article was a call for a more balanced perspective regarding the potential utility of e-cigarettes by researchers, tobacco control experts and the FDA. The current FDA website [6], for example, does not cite any of the potential promise of e-cigarettes and overstates some of the data on risk. We concluded our initial commentary by stating that the 'initial evidence suggests that e-cigarettes offer more promise than peril' and we called for future discussion to be 'based on a balanced view of the available science rather than an ideology that opposes harm reduction' [1]. At no point in the article did we call for 'turning back the clock' on the FDA and public health or an e-cigarette market 'unfettered by national regulatory agencies' [5].

We are strongly in favor of FDA regulation of e-cigarettes under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) through the Center for Tobacco Products (CTP). We are in agreement with Cobb and Abrams' call for the FDA to regulate e-cigarettes. We believe that the FDA should act quickly to exercise their regulatory authority over these products. Our academic debate should continue but should not, as Cobb & Abrams contend 'foster delay in regulations' [5]. The FDA has already been granted regulatory authority over tobacco products. We understand that Cobb & Abrams would prefer that e-cigarettes not be regulated as tobacco products but instead as drug delivery devices under the regulatory authority of the U.S. FDA's Center for Drug Evaluation and Research (CDER). However, this idea falls foul of the D.C. District Court decision [7] which prohibited the FDA from regulating e-cigarettes under the Food, Drug, and Cosmetics Act in the absence of therapeutic claims. Thus, the only option that the FDA has is to regulate e-cigarettes as tobacco products under the FSPTCA. However, if in the future, e-cigarette companies, tobacco companies, or refined nicotine companies want to put a health claim on their product or market it as 'modified risk', then they too should be required to demonstrate the necessary safety and efficacy standards to obtain the designation as a pharmaceutical product or modified risk tobacco product, through CDER or CTP, respectively.

What we *were* disputing was Cobb & Abrams presentation of the scientific information regarding the

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potential effectiveness of these products, concerns over repeated propylene glycol inhalation, and risks of potential child or adult overdose of nicotine liquid or 'e-juice'—selecting pieces of information from studies that supported their hypotheses while ignoring information that did not.

Cobb & Abrams report difficulty reconciling 'continued strict regulation of pharmaceutical nicotine and its competing delivery systems, with the unregulated sale of nicotine in "electronic" form' [5]. To us, it is more perplexing trying to reconcile why should the e-cigarette, a product that delivers nicotine without the harmful effects of combustion, be banned from the market until it can be proven safe and effective, while the tobacco cigarette, a product we know to be harmful and deadly, is allowed to stay? We continue to call for a balanced perspective on e-cigarettes and still find that the current evidence suggest that they offer more promise than peril. We agree with Drs Bauld, Etter and Hajek that e-cigarettes are likely to be safer than tobacco cigarettes but that more research is needed. We hope that the public health community will keep their 'eye on the ball' and embrace new approaches to harm reduction and smoking cessation.

Declarations of interest

None.

Keywords Electronic cigarettes, harm reduction, tobacco, nicotine.

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