

# Ethical issues raised by a ban on the sale of electronic nicotine devices

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## ABSTRACT

**Background** Some countries have banned the sale of electronic nicotine delivery systems (ENDS). **Aims** We analyse the ethical issues raised by this ban and various ways in which the sale of ENDS could be permitted. **Method** We examine the ban and alternative policies in terms of the degree to which they respect ethical principles of autonomy, beneficence, non-maleficence and justice, as follows. **Results** Respect for autonomy: prohibiting ENDS infringes on smokers' autonomy to use a less harmful nicotine product while inconsistently allowing individuals to begin and continue smoking cigarettes. Non-maleficence: prohibition is supposed to prevent ENDS recruiting new smokers and discouraging smokers from quitting, but it has not prevented uptake of ENDS. It also perpetuates harm by preventing addicted smokers from using a less harmful nicotine product. Beneficence: ENDS could benefit addicted smokers by reducing their health risks if they use them to quit and do not engage in dual use. Distributive justice: lack of access to ENDS disadvantages smokers who want to reduce their health risks. Different national policies create inequalities in the availability of products to smokers internationally. **Conclusions** We do not have to choose between a ban and an unregulated free market. We can ethically allow ENDS to be sold in ways that allow smokers to reduce the harms of smoking while minimizing the risks of deterring quitting and increasing smoking among youth.

**Keywords** E-cigarettes, ethics, tobacco harm reduction, regulation, snus, nicotine use.

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## INTRODUCTION

During the past 30 years developed countries at the forefront of tobacco control have reduced smoking prevalence very substantially to approximately 15% [1] by: imposing higher tobacco taxes; banning cigarette advertising; introducing smoke-free policies in all public spaces and workplaces; graphic health warnings; and plain packaging of cigarettes [1–3].

The persistence of smoking in a substantial minority of adults [4,5] has prompted some public health researchers to advocate for 'tobacco harm reduction' (THR) [6–8]. THR policies encourage smokers who do not want to quit, or are unable to do so, to obtain their nicotine in ways that do not involve smoking cigarettes [9]. Electronic Nicotine Delivery Systems (ENDS) have been the most controversial of the products advocated for THR [7,8,10]—which also include pharmaceutical nicotine [9], and the low nitrosamine smokeless tobacco product, snus [11,12].

All ENDS deliver nicotine in an aerosol that is inhaled and produces effects that smokers report feel more like smoking than nicotine replacement therapies (NRTs). The short-term health effects of ENDS when used for smoking cessation are minor, because the carcinogens and toxicants in the aerosol occur at much lower levels than in tobacco smoke [13,14]. This has been confirmed by urinary analyses of ENDS users' and smokers' exposures to toxicants and carcinogens [15]. The adverse effects of long-term use of ENDS are unknown, but are likely to be substantially less than those of daily cigarette smoking [13,16].

In this paper, we focus on the ethical issues raised by bans on the sale of ENDS that apply in 13 of 59 countries that regulate ENDS [17]. Leading international public health advocates have expressed support for sales bans [18]. In Australia, for example, sale and possession or use of ENDS containing nicotine for non-therapeutic purposes is banned under drugs and poisons legislation. Possession and use for therapeutic purposes is only legal with a medical prescription [19]. In future, ENDS could be sold as

smoking cessation aids if they are approved by pharmaceutical regulatory authorities, but none have been.

In market economies, companies and individuals have a right to manufacture and sell products, unless governments have a good reason to ban them. The current sales ban on ENDS reflects a policy of prohibiting new non-medicinal psychoactive substances, a position some governments are attempting to move away from [20]. In the case of ENDS, the extraction of nicotine from tobacco is not new, but its use in ENDS for non-medicinal purposes is. However, the use of much more dangerous tobacco cigarettes is not banned.

### **ARGUMENTS FOR AND AGAINST ALLOWING THE SALE OF ENDS**

THR advocates [21] argue that huge public health gains can be made if all current smokers switch to ENDS because their health risks are perhaps only 10% of those caused by cigarette smoking [22]. These gains would be achieved either if smokers use ENDS to quit, or they use ENDS as a long-term alternative to smoking cigarettes (e.g. [23]).

Those who favour a ban on ENDS do not believe that their use will produce public health benefits. Instead of helping smokers to quit smoking, they believe that smokers who use ENDS will continue to smoke and that this 'dual use' will have no health benefits. They would allow the use of ENDS for smoking cessation only if they are shown to be safe and effective for this purpose, and if they were approved by pharmaceutical regulatory authorities.

Critics of ENDS are opposed to them being sold in the same way as cigarettes [24–29] because they are convinced that the tobacco industry will use ENDS to: (1) discourage smokers from quitting, by encouraging dual use (i.e. using ENDS when smoking is not allowed and continuing to smoke when it is) and thereby undermine smoking bans; (2) re-normalize and glamourize a behaviour that resembles smoking; and (3) provide a gateway to smoking among young adults. Their fears have been heightened by the fact that multi-national tobacco companies have purchased leading ENDS producers [25].

#### **An ethical appraisal of the ENDS debate**

In pluralistic democracies there is rarely unanimous agreement on how to resolve conflicts between competing normative or ethical views such as those raised by ENDS. Ethical analyses of these issues rarely command universal assent. Advocates of different ethical theories offer advice on which course of action ought to be pursued [30,31]. These include: utilitarianism or consequentialism, which judges individual actions or moral rules by the net effects for good and ill that they have on all who are affected by them (e.g. [32]); deontological or duty-based theories that derive obligatory

rules for moral conduct from general ethical principles (e.g. [33,34]); and rights-based theories [31,35].

In the face of major disagreements about these different ethical theories, bioethicists have often used four influential moral principles (principlism) to analyse and frame debates about ethical issues in medicine and public health. Autonomy, non-maleficence, beneficence and justice are four clusters of moral principles that derive from a common morality, ethical principles often shared by people who support very different ethical theories [31]. These principles have been invoked in debates over ENDS. We use this approach to identify possible policy compromises that may attract majority support for politically acceptable trade-offs between these competing ethical principles.

#### *Respect for autonomy*

We respect autonomy when we do not interfere with the free and informed choices of rational adults [31]. Most ethical theories assume that rational people have the capacity to decide freely upon the course of action that they judge to be in their own best interests. Most theories would agree that we should not interfere in the exercise of autonomy by rational adults, e.g. by coercing them into behaving in a certain way, or encouraging them to act in ways that we think are in their best interests by providing false or misleading information.

There is disagreement about whether individuals decide autonomously to consume nicotine, either in the form of cigarettes or ENDS. Individuals are currently free to begin and to continue smoking cigarettes but, in countries where ENDS are banned, they are prevented from consuming nicotine in a way that has fewer negative health effects than smoking.

#### *Non-maleficence*

The principle of non-maleficence means that we should 'do no harm'. It generally requires us to refrain from acting in ways that will cause harm or injury to others, or that place others at risk of harm or injury. The challenge in applying this principle is that few, if any actions, are guaranteed to be harm free. Policymaking usually involves a choice between policies that produce a mix of harms and benefits, rather than selecting a policy that causes no harm.

Much of the discussion around ENDS focuses upon their aggregate effects on two types of harm: (1) the health risks for current smokers who may be helped to quit or reduce the harms of nicotine use; and (2) tobacco-related harm that may be increased if ENDS discourage smokers from quitting (via dual use) and recruit non-smokers who later become smokers.

#### *Beneficence*

Beauchamp & Childress [31] have identified 'positive beneficence' and 'utility' as two elements of beneficence. Positive

beneficence requires us to perform actions that benefit others. Utilitarian approaches to beneficence aim to maximize utility (or pleasure) by ensuring that the aggregate benefits of policies outweigh the costs incurred by all people who are affected by the policy. This involves aggregating the benefits and costs in the population across different types of individual, e.g. current smokers and possible future smokers.

Beneficent regulation of ENDS will depend upon whether regulators see their goal as fostering choice and reducing harm from smoking or eliminating all nicotine use. As we will explain below, ENDS provide significant advantages to smokers who are willing to switch but may pose risks to newly recruited smokers.

#### *Distributive justice*

'Distributive justice' requires policies to be fair in the ways that they treat everyone affected by them. This involves fairly sharing the resources, risks and benefits of different public health policies. Bans on ENDS raise issues of equity by disadvantaging smokers who want to reduce the health risks of using nicotine. Different national policies towards ENDS may create inequalities in access between smokers in different countries.

#### **Resolving conflicts between ethical principles**

In pluralistic liberal democracies, ethical conflicts arising in public health policy debates are resolved by the political system which produces legislative and regulatory responses. These responses enact consensus, when one exists, but more often reflect negotiated compromises that are acceptable to most members of the community. These compromises rarely involve a simple comparison of the costs and benefits of different policy options. Policy choices more often involve complex comparisons of different types of costs and benefits, many of which are difficult to quantify, in the absence of consensus on the relative weighting that should be attached to these competing values.

In debates about public health policy, the principles of autonomy and beneficence conflict when policies, such as a sales ban, infringe the autonomy of adults to act in ways that may harm themselves in order to protect the health of individuals and the whole population. For example, in most developed countries, criminal law denies adults the right to use heroin and cocaine in order to prevent addiction, fatal overdoses and blood-borne virus infections.

Our approach to analysing the ethical issues raised by ENDS is pragmatic. We evaluate the ethical implications of two broad policy options: retaining a ban on the sale of ENDS; and two very different ways of allowing ENDS to be sold.

#### **Ethical issues raised by a ban on the sale of ENDS**

##### *Autonomy*

Libertarians oppose bans on the sale of ENDS [36] because they do not believe that they respect the autonomy of adult smokers. In their view, smokers should be allowed to purchase ENDS as easily as cigarettes. One need not be a libertarian to believe that a ban on ENDS sales seriously infringes smokers' autonomy and that such infringements require a strong justification.

Tobacco control advocates often respond to libertarian arguments by arguing that smokers' choices are not autonomous because of their addiction. Whatever its merits, they selectively invoke this argument by using it to justify a ban only on ENDS and still allow smokers to exercise their impaired autonomy by purchasing cigarettes. Any argument in favour of a ban on ENDS based on an appeal to smokers' impaired autonomy would also logically entail supporting a ban on the sale of cigarettes, which are much more dangerous than ENDS.

##### *Non-maleficence and beneficence*

Disagreements about the net harms and benefits of ENDS are at the centre of the debate about bans on ENDS sales. Proponents of ENDS emphasize the potential health benefits for current smokers who switch to ENDS. Proponents of the ban are sceptical that these benefits will be realized for smokers and concerned about potential harms to future smokers.

Proponents of the ban on ENDS give a low priority to smoker autonomy and a high priority to beneficence by protecting public health. The interests of current smokers are given very little weight by those who support a ban on ENDS sales. They may want to argue that a sales ban serves smokers' interests by encouraging them to quit. They sometimes argue that ENDS are not as harmless as their proponents claim [10], in the process engaging in what critics of the ban claim is a misrepresentation of the evidence on the toxicology of ENDS vapour [37].

Proponents of a ban argue that it benefits public health by preventing the initiation of new smokers, especially adolescents. Allowing ENDS to be sold, in their view, will increase the number of new smokers: by re-normalizing a behaviour that resembles smoking; increasing uptake of ENDS by adolescents who would not otherwise smoke; and serving as a gateway to smoking among a substantial proportion of adolescent ENDS users. They claim to have evidence that this is happening in surveys of ENDS use by US youth, among whom substantial proportions of people who have ever used ENDS had never smoked a cigarette [38].

Proponents of allowing ENDS sales give a high priority to reducing the harms of smoking among current smokers who are unable or unwilling to quit. In their view, a ban on

sales prevents smokers from using ENDS to quit or to replace cigarette smoking by effectively forcing them to quit, if they can, and to smoke cigarettes, if they cannot. A ban has other adverse effects: it produces a black market for ENDS and it prevents ENDS products from being regulated to protect consumers, e.g. by ensuring that they deliver nicotine safely and protect children from nicotine poisoning.

Proponents of ENDS reject the claim that ENDS will re-normalize smoking and serve as a gateway to smoking. They criticize the Centers for Disease Control (USA) for confusing ever having used ENDS with regular use [37], and they cite UK survey data that ENDS are used by fewer than 1% of people who have never smoked cigarettes [39]. They also cite evidence that smoking prevalence has declined in the United Kingdom as a whole, and among youth, over the same time-period that ENDS use has increased among current and former UK smokers [37].

#### *Justice and fairness*

A policy that bans a less harmful form of nicotine while allowing the sale of cigarettes is inconsistent. This makes it difficult to justify. It is also unfair to addicted smokers who are denied access to a safer nicotine product and forced to continue to smoke cigarettes. It is also arguably unjust in giving a much higher priority to the interests of hypothetical future smokers at the expense of the interests of current, especially addicted, smokers.

#### **Ethical issues raised by allowing the sale of ENDS**

A policy that allows smokers to buy ENDS respects their autonomy. It does not inconsistently prohibit the use of a less harmful nicotine product while allowing the sale of the most harmful, tobacco cigarettes. Allowing smokers to use ENDS also benefits those smokers who quit or wholly switch to ENDS. It would also reduce the size of a black market and allow better regulation of ENDS products.

The critical question for advocates of allowing ENDS sales is: how can we allow smokers to buy ENDS in ways that minimize the public health risks of most concern to those who support a sales ban? We explore this question by considering the ethical issues raised by different ways in which smokers could be allowed to access ENDS.

#### *ENDS for medical use only*

Under the ban discussed above, ENDS will be available to smokers only as medicinal products for smoking cessation, if clinical trials show them to be safe and effective, and if they are approved for use as therapeutic goods. This policy is ethically problematic for two reasons. First, it is not clear how many ENDS manufacturers will have the funds required to have their products registered as cessation aids. This requirement may effectively confine approved ENDS products to those owned by the tobacco industry. Secondly,

a ban does not allow smokers who want to use ENDS from doing so before the pharmaceutical approval process has been completed. Until these products are approved, smokers who want to use ENDS must obtain them from an unregulated black market. Thirdly, limiting ENDS availability to prescription only is paternalistic in requiring medical approval for use of a product that is used in much the same way as cigarettes, which are sold legally.

#### *Allowing ENDS to compete with tobacco cigarettes*

Conceptually, there are two ways in which ENDS could be allowed to compete with cigarettes: 'levelling up' and 'levelling down' [40].

Levelling up would allow ENDS to be sold in the same way and at the same places as cigarettes (e.g. supermarkets, convenience stores, tobacconists). ENDS could be taxed at the same rate as cigarettes or taxed at a lower rate because they are less harmful than cigarettes. This would mean that ENDS would be regulated as lightly as cigarettes are now.

Levelling up is the preferred approach of advocates who want ENDS to replace cigarettes as quickly as possible. It also respects smoker autonomy, is fairer to addicted smokers and is consistent in allowing smokers to access a safer form of nicotine as easily as cigarettes [41]. Opponents of ENDS see levelling up as the approach most likely to increase ENDS uptake among non-smokers and to recruit new cigarette smokers.

Levelling down would increase restrictions on both the sale of tobacco cigarettes and ENDS. It would restrict sales of both products to a limited number of licensed sellers. It could include bans on advertising and promotion of ENDS and on their use in public spaces. A very restrictive variant of this policy would allow ENDS to be sold only by licensed suppliers to licensed users [42].

Levelling down is much less likely than levelling up to produce the adverse public health effects feared by proponents of a ban on ENDS. It is also consistent in allowing smokers to access both ENDS and tobacco cigarettes. It is mildly paternalistic in not allowing smokers to access ENDS as easily as they can buy cigarettes.

### **THE UNAVOIDABILITY OF ETHICAL TRADE-OFFS**

Any policy towards ENDS unavoidably involves trade-offs between respecting autonomy, beneficence, non-maleficence and fairness. These trade-offs have to be made in the face of some uncertainty about the future aggregate costs and benefits of either retaining a sales ban or allowing ENDS to be sold to smokers. These competing views about the ethics and public health consequences of banning or allowing ENDS sales are summarized in Table 1.

**Table 1** Competing ethical appraisals of those who support banning and permitting electronic nicotine delivery systems (ENDS) to be sold.

	<i>Ban ENDS sales</i>	<i>Permit ENDS sales</i>
Pro ban	Avoids increasing harm from: Allowing dual use Re-normalizing smoking Recruiting new smokers Long-term vaping	Risks increasing harm by: Deterring quitting Re-normalizing smoking Recruiting new smokers Encouraging long-term vaping
Con ban	Over-rides smoker autonomy Inconsistent in regulating risks Unfair to addicted smokers Produces a black market for ENDS Fails to regulate ENDS	Respects smoker autonomy Consistent policy on risks Fair to addicted smokers Avoids black market in ENDS Allows ENDS to be regulated

A sales ban on ENDS over-rides smokers' autonomy in order to protect public health against the projected long-term effects of ENDS on smoking recruitment. It is unjust to smokers who wish to reduce the harms of consuming nicotine. It is inconsistent in forbidding the use of less harmful nicotine products while allowing the unregulated sale of the most harmful, cigarettes. It also fails to regulate ENDS while allowing a black market to grow. Advocates of a ban would argue that these are acceptable costs to avoid undermining successful tobacco control policies and prevent the recruitment of new cigarette smokers.

Policies that would allow ENDS to be sold are more respectful of smokers' autonomy and fairer to smokers. They will reduce harm for those smokers who use ENDS to quit smoking or who switch completely from smoking to ENDS. The cost of securing these benefits is that we allow the recreational use of ENDS. The net effects of this policy on public health will depend upon how restrictive the regulations are on the ways in which ENDS can be sold.

The logically possible ways in which ENDS sales could be regulated suggest that levelling down approaches (1) may be more acceptable to advocates and opponents of THR using ENDS and (2) will make it easier to assess the public health consequences of allowing smokers to use ENDS.

## THE NEED FOR POLICY EVALUATION

If a ban on sales becomes the standard response to ENDS in most countries it will be more difficult to evaluate their impact. Research on ENDS use under a global sales ban will

encounter many of the same problems that arise in research on illicit drug use, drug-related harm [43] and the effectiveness of different illicit drug policies [44].

The Australian ban, for example, has made it difficult to conduct trials on the potential use of ENDS for harm reduction because they must be evaluated as smoking cessation devices, rather than as a less harmful competitor to cigarettes. The regulatory restrictions on ENDS have also limited the products that can be given to smokers.

## WHY NOT WAIT?

Supporters of the bans may suggest that countries with bans should retain them until studies have been conducted on the public health outcomes of ENDS in countries that allow their sale. This would allow countries that impose bans to avoid the risk of ENDS products in their own countries.

We see several problems with this proposal. First, it will take a decade or more before we know the outcome of the policy. During this time smokers will be denied access to a safer form of nicotine. Secondly, we doubt that any epidemiological evidence would be strong enough to change the minds of those who support a ban. Pre-emptive bans on the sale of low nitrosamine smokeless tobacco (snus) in Australia and the European Union remain in place, despite 20 years of epidemiological evidence showing that snus reduces harm to smokers and has not increased smoking among youth [45]. Advocates of a ban, and those who propose to wait, have an ethical obligation to specify what type of evidence would convince them to lift a ban on ENDS sales. Thirdly, a ban has not prevented ENDS use by smokers in Australia and other countries; it has abdicated responsibility for regulation of ENDS to the black market [46]. It has also not prevented child poisonings from ENDS, which could be reduced by regulating the packaging of ENDS [47].

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