

**Intended Responses of 9,040 Current E-Cigarette Users to the U.S. Food and Drug Administration's Deeming Regulations of E-Cigarettes**

Christopher Russell (B.A., M.Res., Ph.D.) and Neil McKeganey (B.A., M.Sc., Ph.D.)

Centre for Substance Use Research, 19 Keith Street, Glasgow, G11 6QQ, United Kingdom.

Correspondence concerning this document should be addressed to Christopher Russell,  
Centre for Substance Use Research, 19 Keith Street, Glasgow, G11 6QQ. Email:

[russell@csures.org](mailto:russell@csures.org)

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## ABSTRACT

**Background:** On 5<sup>th</sup> May 2016, the U.S. Food and Drug Administration (FDA) finalized a rule that deemed vaporizers, e-cigarettes and all other electronic nicotine delivery systems (ENDS) as tobacco products and therefore subject to FDA's regulatory authority. This 'Deeming Rule' will likely mean that the vast majority of e-cigarette products that are on the U.S. market today will not be legally available for purchase, at least temporarily, in the United States after August 8<sup>th</sup> 2018. Investigation of the likely impact of the Deeming Rule on the U.S.' estimated 8.34 million current e-cigarette users' future use of nicotine and tobacco products is therefore critically important to evaluating the potential population health impact of the Deeming Rule.

**Method:** An online survey was conducted to ask adult current e-cigarette users in the United States what actions they believe they will take in regard to their use of nicotine and tobacco products if, as a result of the FDA's Deeming Rule coming into effect on August 8<sup>th</sup> 2018, they are no longer able to legally buy their preferred e-cigarette products.

**Results:** The majority (> 60%) of 9,040 current e-cigarette users surveyed expressed intentions to respond in four ways to the Deeming Rule coming into effect that would increase their risk for adverse health effects and fuel a 'black market' in e-cigarette products: (i) buy in bulk/stock up on e-cigarettes, liquids and other supplies prior to the regulations coming into effect; (ii) continue to use e-cigarettes by buying products and supplies from a local non-authorized vendor (i.e. buy from the 'black market'); (iii) continue to use e-cigarettes by importing products and supplies from an overseas vendor; and (iv) continue to use e-cigarettes by making their own liquids. With regard to tobacco smoking, an intention to restart smoking was expressed by 15% of 8,451 former smokers; an intention to start smoking was expressed by 9% of 307 never smokers; and an intention to smoke more tobacco than at present was expressed 33% of 282 current smokers.

**Conclusions:** These survey findings suggest FDA's Deeming Rule may have the effect of displacing a large proportion current users to a black market trade in e-cigarette products that would. Such displacement would increase the risk for three adverse outcomes: (i) an increased risk of consumers' using more toxic, poorly manufactured e-cigarette products; (ii) an increased risk of fuelling criminal activity associated with black market trading; and (iii) FDA's ability to reliably estimate the impact of the Deeming Rule on population toxicant

exposure would be significantly undermined by the notorious difficulty of measuring the size of the black market trade in tobacco products (i.e. prevalence, frequency and quantity of use; toxicology of products being used). Such a displacement of licit purchases to the black market would, therefore, leave FDA unable to reliably assess the effectiveness of the Deeming Rule against its stated objective.

## **Background**

On 5<sup>th</sup> May 2016, the U.S. Food and Drug Administration (FDA) finalized a rule on docket FDA-2014-N-0189 / RIN 0910-AG38 – known as the Deeming Rule – that extends FDA’s authority to regulate the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of all tobacco products, including vaporizers, e-cigarettes and all other electronic nicotine delivery systems (ENDS) (U.S. Food and Drug Administration, 2016). This Deeming Rule will likely mean that the vast majority of e-cigarettes, e-liquids and other vaping accessories that are on the market today will not be legally available for purchase, at least temporarily, in the United States after August 8<sup>th</sup> 2018. After this date, it is very likely that only a small number of closed-system e-cigarettes will be legally available to purchase, although companies that submit a complete Premarket Tobacco Product Application (PMTA) by this date will be permitted to continue selling their products while FDA is reviewing their applications, and it is expected that at least some companies will file PMTAs for open-system e-cigarette devices. Companies that do not have FDA approval to sell an e-cigarette or e-liquid after this date will not be legally allowed to continue selling the product, and no new vaping products or e-liquids will be allowed on the market after August 2018 unless the manufacturer applies for and obtains FDA approval to sell that product. Possession and personal use of e-cigarettes and liquids will still be legal after August 8<sup>th</sup> 2018, but the sale of any products that have not been approved by the FDA will be illegal. By requiring the majority of e-cigarette products to be removed from the market, coupled with the high financial cost required for companies to undertake or commission the research studies that are required to be submitted as part of a PMTA to allow a product to remain on the market, the likely impact of this Deeming Rule will be the closure of the vast majority of vape shops and a substantial reduction in trade conducted by companies involved in the licit manufacture and sale of e-cigarettes in the United States prior to or after August 2018.

The impact of the FDA Deeming Rule on the future behaviours of current e-cigarette users, however, is less clear. The Centers for Disease Control and Prevention’s 2015 National Health Interview Survey estimates there were approximately 8.34 million people in the United States who were using e-cigarettes every day or some days in 2015, of whom 4.9 million were also smoking regular cigarettes, 2.5 million were former smokers, and 0.95 million were never-smokers (Centers for Disease Control and Prevention, 2016). The Deeming Rule may result in the vast majority of these current e-cigarette users being unable to legally buy the products they

use currently. However, FDA has made no statement about what it expects these 8.34 million current e-cigarette users will do if and when they are no longer able to legally buy the e-cigarette products they currently use, and more importantly, whether these future behaviours will increase or decrease these individuals' risk for exposure to toxicants. That is, while FDA's pre-market tobacco application (PMTA) process will require manufacturers who wish to keep an e-cigarette product on the market after August 8<sup>th</sup> 2018 to provide estimates of how population toxicant exposure will change as a result of *introducing* the product into the market – by conducting research on the product's toxicity and likelihood of uptake by population sub-groups – FDA has not publicly stated the extent to which population toxicant exposure is anticipated to change as a result of *withdrawing* the majority of e-cigarette products from the licit market after August 8<sup>th</sup> 2018.

FDA's hope will be that the Deeming Rule will reduce population toxicant exposure by rationalizing current e-cigarette users' decisions to either cease using all e-cigarette products or by switching to exclusive use of FDA-approved e-cigarette products. However, FDA should also consider, and prepare for the possibility, that a proportion of current e-cigarettes users may respond in ways that would increase their toxicant exposure, or the difficulty for FDA to reliably measure their toxicant exposure. For example, it is reasonable to expect that a proportion of current e-cigarette users who have quit smoking regular cigarettes with the assistance of e-cigarettes will return to smoking when their preferred e-cigarette products are no longer available to buy legally. Or, in fear that they will relapse to cigarette smoking if they do not continue to use their preferred e-cigarette products, some may take actions that ensure their continued use of e-cigarettes, even if this requires they subvert the law. For example, individuals may decide to buy in bulk/stock up on their preferred products before they are taken off the market, or start to source their preferred e-cigarette products or comparable counterfeit products from unauthorised vendors (i.e. the 'black market'), or start to import e-cigarette products from abroad, or start to make or mix e-liquids on their own, using their own equipment on their own premises.

The magnitude and direction in which each of these four possible responses to the Deeming Rule would change current e-cigarette users' exposure to toxicant would be extremely difficult for FDA to measure, though there is a risk that overall toxicant exposure would be much higher in each of these four scenarios compared the current scenario in which a variety of e-cigarette products are widely available to purchase legally. Investigation of the likely impact of the

Deeming Rule on current e-cigarette users' use of nicotine and tobacco products is therefore critically important to evaluating the potential population impact of the Deeming Rule.

An online survey was conducted to ask adult current e-cigarette users in the United States what actions they believe they will take in regard to their use of nicotine and tobacco products once the FDA's Deeming Rule comes into effect on August 8<sup>th</sup> 2018. The survey also elicited other data that are relevant to evaluating the potential impact of the FDA deeming regulations on current e-cigarette users, including current e-cigarette users' perceptions of the likely impact of the Deeming Rule on various stakeholders, beliefs about the source of FDA's disagreement with Public Health England's (2015) conclusion that e-cigarettes are likely to be at least 95% less harmful than smoking regular cigarettes, and intentions to vote for political candidates who express opposition and support for FDA's Deeming Rule.

## Method

### Recruitment

A call for survey participants, survey web-link – <http://nicotinesurveys.org/united-states/responses-to-fda/> – and share request was tweeted from our Twitter account, @NicotineSurveys, on 27<sup>th</sup> May 2016. By clicking the web-link, individuals were directed to a page that gave some basic background information about the FDA’s Deeming Rule and explained that the purpose of this survey was to “give e-cigarette users an opportunity to express their views and likely responses to the FDA’s Deeming Rule”. This page also specified that this survey was open only to adults (aged 18 years and older) living in the United States who are currently using an e-cigarette. Potential participants were assured that their data would be kept confidential and anonymous, that only the named investigator would have access to their data, and confirmation that this survey is not funded by any tobacco, e-cigarette, pharmaceutical or any other company or organisation.

The initial recruitment tweet was then retweeted and shared by managers of the Twitter accounts and Facebook community pages of a number of people and organisations with access to a wider network of e-cigarette users, including e-cigarette advocacy groups (e.g. Consumer Advocates for Smoke-free Alternatives, American Vaping Association, Not Blowing Smoke); organisers and attendees of vape meets, vape fests, vape expos; owners and employees of vape shops; vaping advocates, bloggers and vloggers with large social media followings; vendors of e-cigarette devices, liquids and other accessories; and researchers, scientists and policy analysts known to be working in or interested in the fields of public health, tobacco control and tobacco harm reduction. The survey was live from May 27<sup>th</sup> to June 27<sup>th</sup> 2016.

### Survey Questions

The survey assessed participant demographics (age, gender, location), e-cigarette use status, smoking status, and actions intended to be taken by participants when the FDA Deeming Rule comes into effect.

Participants’ intended responses to the implementation of the Deeming Rule was assessed by the question: “At this moment, what do you think you will do when the FDA deeming regulations of e-cigarettes come into effect on August 8<sup>th</sup> 2018, meaning that most of the vapor

products that are available today will likely no longer be available to buy legally? Check all the responses that apply if you believe you would respond in several ways.” Participants were presented with a list of 13 responses (Figures 1, 2 and 3), with smoking-related responses varying according to whether the participant identified as a current, former or never smoker.



## Results

### E-Cigarette Use and Cigarette Smoking Status

The survey was completed by 9,229 U.S. adults (i.e. aged 18 years and older), of whom the vast majority (n = 8,451; 91.6%) were current e-cigarette users *and* former smokers; 282 (3.1%) were current e-cigarette users *and* current smokers; 307 (3.3%) were current e-cigarette users *and* never smokers; 104 (1.1%) identified themselves as ‘something else’; and 85 (0.9%) did not answer the question. Only the 9,040 respondents who reported being a current e-cigarette were retained for the following analyses.

### E-Cigarette Use and Smoking Status by Age

The mean age of respondents who were both current e-cigarette users and former smokers (M = 41 years, 0 months; SD = 14.04) was not significantly higher than the mean age of respondents who were both current e-cigarette users and current smokers (M = 38 years, 8 months; SD = 13.53). Respondents in these groups were, on average, significantly older than respondents who were current e-cigarette users and never smokers (M = 31 years, 4 months; SD = 13.34). Table 1 shows current e-cigarette users who had never smoked were significantly more likely to be younger (i.e. be aged 18-25 years) compared to current e-cigarette users who were also either current or former smokers.

Table 1. Age category of survey respondents, stratified by current e-cigarette use and ever smoking status.

EC + Smoking Status	Age Category					
	18-25 (%)	26-35 (%)	36-45 (%)	46-55 (%)	56-65 (%)	66-75 (%)
Current EC + Current Smoker (n = 282)	21.6	22.3	21.6	22.3	10.6	1.4
Current EC + Former Smoker (n =8,430)	12.3	25.7	25.9	20.8	12.8	2.5
Current EC + Never Smoker (n = 303)	44.9	27.4	10.9	9.2	5.3	2.3

## E-Cigarette Use and Smoking Status by Gender

Respondents who were both a current e-cigarette user and a current smoker were more likely to be female (37.9%) than were respondents who were both a current e-cigarette user and a former smoker (29.2%) and respondents who were both a current e-cigarette user and a never smoker (26.1%) (Table 2).

Table 2. Gender of survey respondents, stratified by current e-cigarette use and ever smoking status.

EC + Smoking Status	Male (%)	Female (%)	Transgender (%)	No Answer (%)
Current EC + Current Smoker (n = 282)	59.9	37.9	1.1	1.1
Current EC + Former Smoker (n =8,451)	70.3	29.2	0.3	0.2
Current EC + Never Smoker (n = 307)	73.3	26.1	0.7	0.0

## E-Cigarette Use and Smoking Status by U.S. State

Survey respondents represented all 50 U.S. States and four of six territories. The five most represented States were Texas (n = 748; 8.3%); California (n = 614; 6.8%); Florida (n = 497; 5.5%); Ohio (n = 489; 5.4%); and Pennsylvania (n = 443; 4.9%). Together, these States accounted for 30.9% of the survey sample. The five least represented States were Hawaii, Wyoming, North Dakota, South Dakota, and Vermont, together accounting for 1.1% of the survey sample.

## **What Do Current E-Cigarette Users Say They Will Do Once the FDA's Deeming Regulations of E-Cigarettes Come into Effect on August 8<sup>th</sup> 2018?**

### ***Current E-Cigarette Users and Former Smokers (n = 8,451)***

Current e-cigarette users who were also former smokers were asked to indicate, from a list of 11 options, all the actions they think they will take when the FDA's deeming regulations of e-cigarettes come into effect on August 8<sup>th</sup> 2018. Respondents were reminded that, as of this date, the vapor products they use today will no longer be available to buy legally, at least temporarily until the product manufacturer obtains approval from the FDA, or permanently if the manufacturer fails to gain, or doesn't apply for, FDA approval to sell the product. The majority of current e-cigarette users who are also former smokers said they would be likely to respond in four ways to the FDA deeming regulations coming into effect:

- i. 72.9% said they will buy in bulk/stock up on e-cigarettes, liquids and other supplies prior to the regulations coming into effect.
- ii. 69.4% said they will continue to use e-cigarettes by buying products and supplies from a local non-authorized vendor (i.e. buy from the 'black market').
- iii. 66.6% said they will continue to use e-cigarettes by importing products and supplies from an overseas vendor.
- iv. 65.0% said they will continue to use e-cigarettes by making their own liquids.

In contrast to the high rate at which respondents indicated their intention to continue using e-cigarettes and supplies that will not be purchased from a licensed vendor, only 17.5% of these current e-cigarette users and former smokers said they will continue to buy e-cigarette products that have been FDA-approved for sale. Only 6.2% of these respondents expressed an intention to stop using e-cigarettes *after* the regulations come into effect, and even fewer (1.2%) expressed an intention to stop using e-cigarettes *before* the regulations come into effect. There was also little indication that respondents intended to replace e-cigarettes with other nicotine products post-implementation; 3.1% said they would start using snus/smokeless tobacco, and 1.8% said they would start using or use more NRT products. Despite the high rate of intention among these former smokers to continue using e-cigarettes by some means post-regulations, 15.0% said they would likely go back to smoking tobacco once they are no longer able to legally buy the e-cigarette products they currently use.

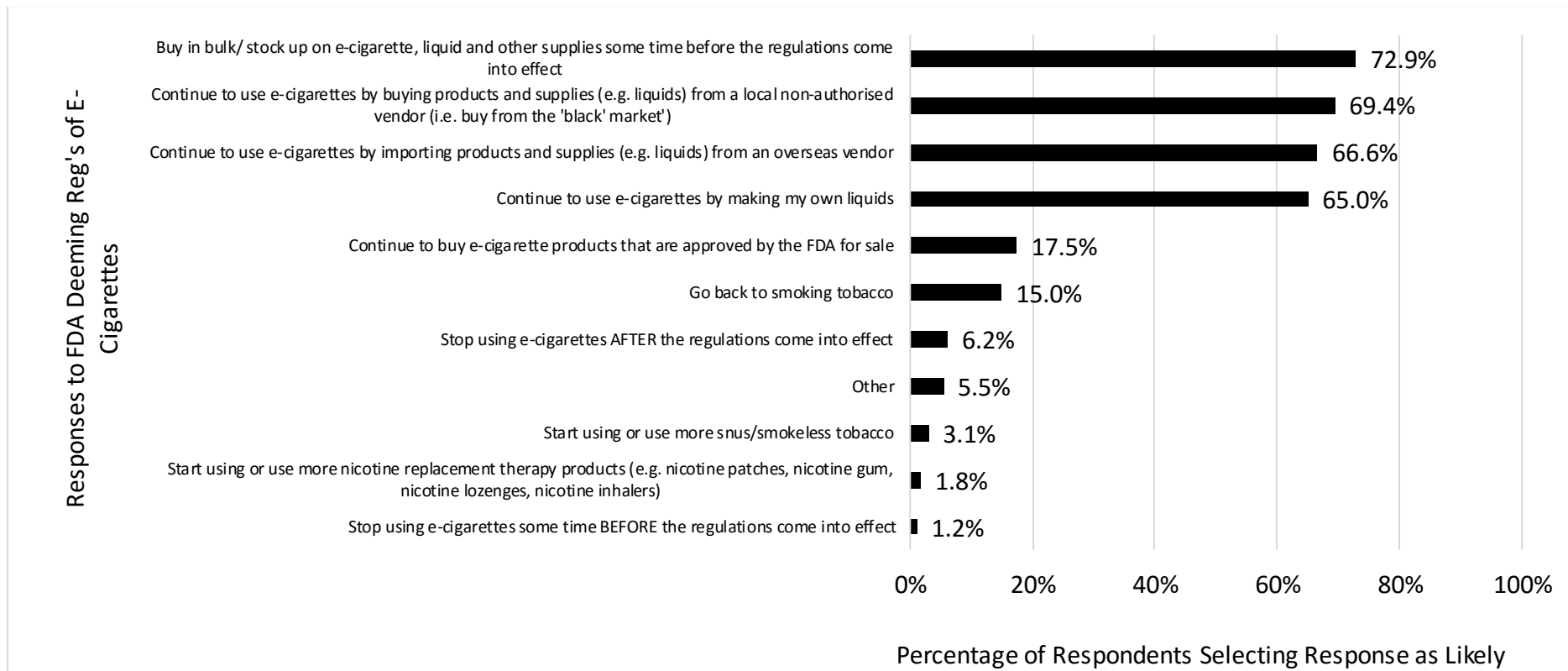


Figure 1. Actions indicated as likely to be taken by 8,451 current e-cigarette users who have stopped smoking in response to FDA's deeming regulations of e-cigarettes coming into effect on August 8<sup>th</sup> 2016.

***Dual Current E-Cigarette Users and Smokers (n = 282)***

The majority (i.e. >50%) of current dual e-cigarette users and tobacco smokers stated their intention to respond in the same four ways indicated by current e-cigarette users who have stopped smoking. Approximately 33% of dual users indicated they would likely smoke more tobacco than they do right now once they are no longer able to buy the e-cigarette products they use now. In contrast to the high rate of intention to find ways to continue using e-cigarettes without buying from approved vendors after the regulations are implemented, only 25.9% of dual users said they would be likely to continue to use only e-cigarette products that are approved by the FDA for sale.

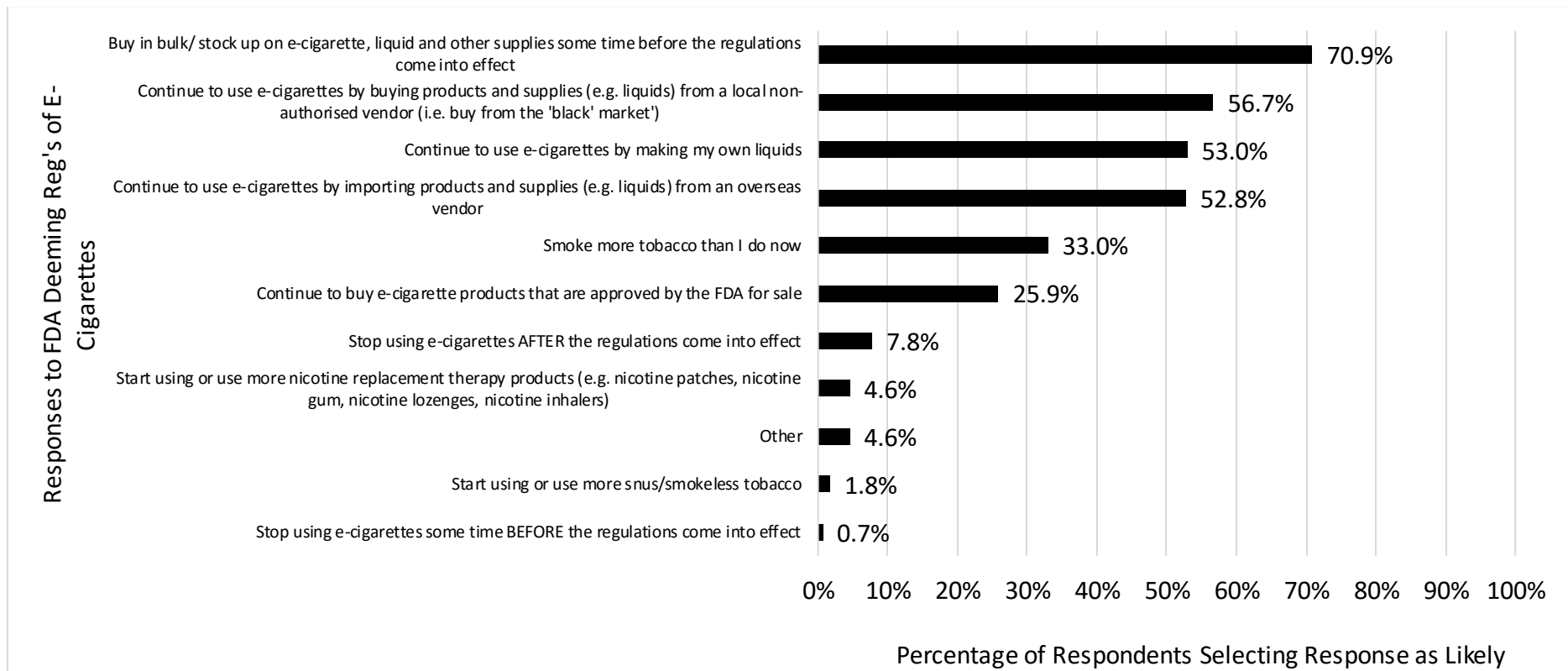


Figure 2. Actions indicated as likely to be taken by 282 dual current e-cigarette users and smokers in response to FDA's deeming regulations of e-cigarettes coming into effect on August 8<sup>th</sup> 2016.

***Current E-Cigarette Users and Never Smokers (n = 307)***

Figure 3 shows the four responses identified by the majority of current smokers who have stopped smoking were also identified by e-cigarette users who have never smoked. Approximately 10% of current e-cigarette users who have never smoked tobacco said they would likely start smoking tobacco once they are no longer able to legally buy the e-cigarette products they currently use. In contrast, only 2.0% said they would likely start using NRT products.

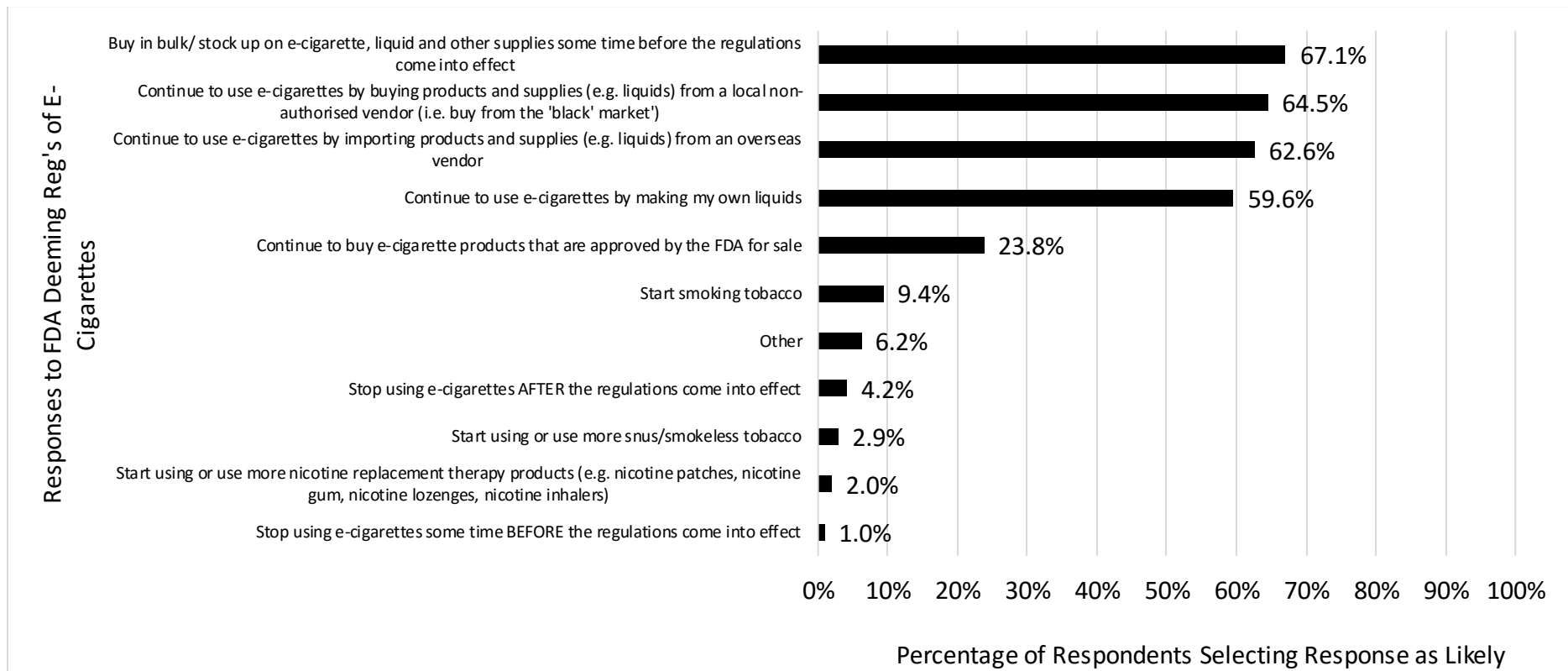


Figure 3. Actions indicated as likely to be taken by 307 current e-cigarette users who have never smoked in response to FDA's deeming regulations of e-cigarettes coming into effect on August 8<sup>th</sup> 2016.



## Discussion

The present study was undertaken to identify what actions may be taken by the 8.34 million estimated current e-cigarette users in the United States when FDA's Deeming Rule comes into effect on August 8<sup>th</sup> 2018, at which point the majority of vapor products on the market today will likely no longer be available for legal purchase. A survey of 9,040 current e-cigarette users suggested that, by prohibiting the legal sale of currently used e-cigarettes and related products, the FDA deeming regulations of e-cigarettes risks increasing current e-cigarette users' toxicant exposure in several ways. First, the vast majority of the 9,040 current e-cigarette users surveyed expressed intentions to circumvent the Deeming Rule by continuing to source, in at least one of four ways, e-cigarettes that will likely be removed, at least temporarily, from the licit market by the Deeming Rule: (i) bulk buying/ 'stocking up' on preferred e-cigarette products that are currently available but will likely be removed from the market post-implementation of the Deeming Rule; (ii) buying preferred e-cigarette products from unauthorised vendors – i.e. on the 'black market'; (iii) buying preferred e-cigarette products online from overseas vendors that export to the U.S. and (iv) making and mixing one's own e-liquids on one's own premises. By rationalising individuals' decisions to purchase e-cigarette products from unauthorised vendors – i.e. the 'black market' – and by rationalising decisions to begin manufacturing and mixing e-liquid on their own, the Deeming Rule may have the effect of displacing current users of available shop-bought products to clandestine black markets, and in turn, increasing, rather than reducing, these individuals' use of unlicensed e-cigarette products. Even if a small proportion of these individuals were motivated to source e-cigarettes from black markets, FDA's ability to monitor the prevalence, quantity and frequency of e-cigarette use post-implementation of the Deeming Rule, and to estimate the health risks associated with use of black market products, would be significantly undermined.

Second, findings suggest the Deeming Rule may increase the risk of relapse to smoking in approximately 15% of e-cigarette users who have stopped smoking, may increase consumption of smoked tobacco in approximately 33% of current e-cigarette users who also smoke, and may increase the risk for smoking initiation in approximately 10% of current e-cigarette users who have never smoked. This 15.0% figure for a perceived 'likely return to smoking' closely is just less than half of the approximately 27% of individuals who achieve long-term (i.e. six months) smoking abstinence in the U.S. with a combination of medication plus behavioural counselling [3]. If, then, 15.0% of former smokers were to relapse to smoking tobacco as a consequence of

the Deeming Rule, this would almost significantly diminish the net rate of smoking cessation being produced by the best combination of currently available FDA-approved products and methods for smoking cessation.

Only a small minority of current e-cigarette users in this survey expressed an intention to comply with the Deeming Rule by stopping use of e-cigarettes or by continuing to use only FDA-approved e-cigarettes products from licenced vendors. The lowest rate of intended compliance with the Deeming Rule was expressed by former smokers, who likely attribute their success in quitting smoking to e-cigarette products that will be taken off the market, at least temporarily, by the Deeming Rule.

## **Implications**

These expressed behavioural intentions are useful for estimating the likely impact of the Deeming Rule on millions of current e-cigarette users, and for estimating change in population toxicant exposure associated with these intended changes in behaviour. However, these stated intentions should only be read as suggestive of actions that may be taken, not as evidence of certain behaviour change. It is critical that all stakeholders recognise that these intentions, expressed by current e-cigarette users at one moment in time, are subject to change with personal circumstances and enthusiasm for vapor products. The fullness of time may well show that the intentions of only a small fraction of vapers manifest as concrete behaviours to circumvent the Deeming Rule. Nonetheless, it is vitally important that FDA and policy makers recognise the harms that would potentially be caused if, after August 8<sup>th</sup> 2018, the vast majority of current e-cigarette users sampled, who may represent many millions more, act on their expressed intentions to pursue ways to continue to using e-cigarette products after they have been taken off the licit market by the FDA's Deeming Rule.

First, by recourse to what may be a growing black market in e-cigarette products, individuals may find themselves buying and using counterfeit and poorly manufactured products that are more harmful than currently available products as a result of diminishing production quality standards associated with black market production. Second, individuals who seek products from the black market will find themselves engaged in a form of illegal transactions in which other illegal items may be offered to them, and in which the money being paid to unauthorised vendors for e-cigarette products is used to fuel other criminal activity – it is likely that a

criminal who profits from selling counterfeit e-cigarettes will at least seek to expand his/her business to the manufacture, distribution and sale of other counterfeit consumer goods. Third by sourcing e-cigarette products from the black market, individuals effectively become invisible to legitimate vendors and to health and regulatory authorities that wish to monitor use of e-cigarettes in the population. In effect, a sizeable proportion of the current vaper community and vapor product economy may be driven 'underground'. Fourth, a displacement of a sizeable proportion of the current economy in vapor products to the black market would mean a substantial loss of tax revenue to States, both in the form of taxes applied to the sale of products and in the form of income taxes lost as a result of substantial job losses owing to the closure and scaling back of small and large businesses involved in the vapor product supply chain. To re-iterate, this portion of the current economy in vapor products would not only be lost to States' treasuries, but displaced to the pockets of criminals both within and out-with the United States.

### ***Methodological Considerations***

The present survey was administered online to current e-cigarette users who were active on social media and internet discussion boards and websites that are relevant to e-cigarette use and, more broadly, to tobacco harm reduction. The sample of respondents are therefore best characterised not as representative of the general population of current e-cigarette users, but rather as a large sample drawn from the community of 'vaping enthusiasts', who actively take part in discussions about e-cigarettes and seek out information about e-cigarettes. Nevertheless, it is important to recognise that, as with all surveys conducted online, the views and intentions expressed here are those of individuals who were willing to take five minutes to complete the survey; those who turned down the invitation to participate may well have given entirely different responses. Relatedly, it may well also be true that the current respondents are the most committed to continuing their use of e-cigarettes, and so are the most motivated to participate in research that they feel will serve to preserve their access to e-cigarettes.

However, these are not good reasons to discount the views of the current e-cigarette users surveyed here. These findings provide an indication, at minimum, of how a sample of current e-cigarette users, drawn from all 50 U.S. States and who likely speak for at least one million current e-cigarette users in the United States, view the motivations for and likely effects of the FDA Deeming Rule, and intend to act in response to the Deeming Rule. At the present time,

we cannot know whether the anticipated reactions of this sample of current e-cigarette users will indeed come to pass. Indeed, it will only be possible to answer that question once the regulations have been operationalized. Nevertheless, every public policy intervention needs to be scrutinised not only in terms of what outcomes it is seeking to bring about, but also in terms of its risk for generating unintended outcomes. Data obtained by the present survey should point FDA and policy makers to several unintended health and criminal outcomes that would flow from current e-cigarette users' planned responses to the implementation of the Deeming Rule.

### **Conclusion and Possible Actions**

The vast majority of the 9,040 current e-cigarette users sampled in this survey expressed a current intention to circumvent FDA's Deeming Rule in several ways that increase their risk for adverse health effects and that would feed a black market in e-cigarette products. Respondents indicated their intention to continue using e-cigarettes beyond the implementation of the Deeming Rule by stocking up on e-cigarette products prior to the regulations coming into effect, by sourcing them from the 'black market', by importing from overseas, and by personally manufacturing and mixing e-liquids on their own premises.

The latter three of the four intended responses point to the possibility of a significant unintended consequence of the FDA deeming regulations of e-cigarettes – the displacement of current e-cigarette users to markets that are far more difficult to monitor and regulate. The consequence of such mass displacement of current e-cigarette users to these markets, as opposed to the market of FDA approved products, is an increased difficulty to reliably estimate the prevalence and volume of e-cigarettes use in society, and an increase in consumers' consumption of products that have not been subjected to anything close to the standards of quality control and safety stewardship as are to be required of e-cigarette products seeking approval via the PMTA pathway.

However, it must be accepted that no government body can allow itself to be paralysed into inaction on the basis of fears about the possible unintended consequences of the regulations they perceive as being important to the protection of human health. Equally, though, effective governance requires that any public body seeking to draft and implement new regulations take action to reduce the likelihood of adverse consequences, particularly when presented with data

that point to the possibility of such adverse consequences occurring on a broad scale. What then might FDA and other bodies involved in implementing the regulations consider doing in the light of these data pointing to a possible mass subversion of the Deeming Rule? There are a range of actions that FDA and affiliates may wish to consider.

First, there appears to be a pressing need for FDA to initiate a programme of communication with current e-cigarette users to explain, in basic terms, FDA's rationale for implementing the Deeming Rule and why alternative models of regulation are considered to be inadequate for protecting and improving health. Whilst engagement with the various organisations that represent the rights and interests of e-cigarette users, (given evidence reported here of the apparent anger and suspicion with which the majority of current e-cigarette users view FDA), the consequences of failing to better explain why the regulations are being implemented is likely to increase the risk that the various unintended consequences expressed in this survey actually come to fruition.

Second, the various unintended consequences identified in the present survey are so serious that a plan for closely monitoring the actual reaction of current e-cigarette users post-implementation of the Deeming Rule is a public health imperative. Clearly, in assessing whether the regulations are improving or harming public health, it will be important to obtain current information on the balance between the intended and unintended consequences of the regulations as these are occurring following implementation of the regulations. Where there is clear evidence that societal harms are being increased by the ways in which e-cigarette users are responding to the regulations, then there should be a willingness to consider reconfiguration of the regulations in the light of new outcome data.

Finally, the impact of the Deeming Rule will not be limited to individuals who use e-cigarettes. Rather, the impact will be felt throughout these individuals' networks of husbands, wives, parents, siblings and close friends. The people in these networks may have been instrumental in encouraging a person to stop smoking, and possibly to start using an e-cigarette as an alternative to smoking regular cigarettes, and so may be instrumental social influences for current e-cigarette users to comply with or to subvert the Deeming Rule if they believe that such a course of action will reduce their loved one's risk of disease and premature death. There is a need, therefore, for FDA to assess not only the extent to which implementation of the Deeming Rule displaces current e-cigarette users to other products, behaviours and activities

that may increase toxicant exposure, but also to assess the role of family and peer influences in rationalising behavioural responses to the Deeming Rule that are consistent with and counter to its purpose.

### **Conflict of Interest**

This study was not funded by any tobacco, e-cigarette, pharmaceutical or any other company or organisation. The Centre for Substance Use Research (CSUR) conducts research on factors associated with smoking cessation and tobacco harm reduction behaviours, and has received funding for other research studies from a range of public and commercial bodies, including on occasion companies linked to the tobacco industry and e-cigarette industry.

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