BRITISH AMERICAN TOBACCO NEDERLAND SUBMISSION TO THE MINISTRY OF HEALTH, WELLBEING AND SPORTS

COMMENTS ON THE REGULATION OF E-CIGARETTE FLAVOURS

IN

THE DRAFT DECREE AMENDING THE TOBACCO AND TOBACCO PRODUCTS DECREE

19 JANUARY 2021

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1. INTRODUCTION

1.1 This submission by British American Tobacco Nederland ("**BAT Nederland**") (the "**Response**") responds to the consultation on the draft decree amending The Tobacco and Tobacco Products Decree, issued by the Ministry of Health, Wellbeing and Sports. In particular, this document responds to the proposal to regulate the available flavours for e-cigarettes and to only allow flavourings that are mainly found in tobacco flavours (the "**Proposal**").

1.2 BAT Nederland is a member of the British American Tobacco group of companies ("**BAT**") and is engaged in the development and commercialisation of BAT's range of potentially reduced risk nicotine and smoke-free tobacco products.

1.3 BAT is at the forefront of the development and sale of a whole range of potentially reduced risk products ("**PRRPs**") that provide an alternative to smoking without burning tobacco. BAT has a significant R&D presence, having had an R&D facility since 1956. Over 1,000 people are employed at our main UK R&D hub; including scientists and engineers from multiple disciplines. These are employees who have been recruited both from within the UK, some as graduates, and also worldwide, to ensure we attract and retain the best talent. BAT expenditure on research and development was £376 million in 2019. BAT's growing portfolio of PRRPs includes e-cigarettes, tobacco heating products ("**THPs**"), and oral nicotine pouches.

1.4 As an initial point, we note that the timing and unreasonable duration of the consultation (a period of only 4 weeks across the Christmas period and when companies are faced with the complexities of dealing with the COVID-19 pandemic) fails to provide any meaningful level of participation in the process. Instead, the consultation has all the appearances of a desire to push through the Proposal without proper scrutiny.

1.5 BAT Nederland is strongly opposed to the Proposal to severely restrict e-cigarette flavours to tobacco flavours. E-cigarettes do not contain tobacco, do not involve combustion, and only contain a fraction of the toxicants contained in tobacco smoke. For those reasons, many Public Health Authorities ("**PHAs**") have endorsed the reduced risk profile of these products, for instance Public Health England deemed e-cigarettes to be "*at least 95% less harmful than smoking*"[1]. A copy of a Scientific Assessment of Electronic Nicotine Delivery Systems British American Tobacco Appendix 1 is provided with this Response, which demonstrates the potential of e-cigarettes as an instrument to support tobacco harm reduction.

1.6 We believe that the Proposal is contrary to the Government's objective of improving public health. Banning e-cigarette flavours as proposed, cannot be justified on the evidence, will undermine the potential public health benefits that e-cigarettes can provide, and risks

[1] Public Health England (2018), McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18.

foreclosing the legal market altogether, while boosting the illicit trade of such products[2]. A ban on all flavours in e-cigarettes except tobacco flavours would destroy the user experience of e-cigarettes for many adult smokers that have switched to vaping – with the likely impact of encouraging exactly the opposite of what the Government is trying to achieve (i.e. a return to or continuation of smoking). Moreover, irrespective of the comprehensive scientific evidence referred to in this response, it is clear on its face that a Proposal which limits e-cigarettes solely to the flavour of tobacco must be counter-productive to facilitating lasting and complete transitions away from smoking.

1.7 The proposed regulations will create absurd inconsistencies whereby more harmful products, such as cigarillos and cannabis, are regulated less restrictively with regards to flavour than e-cigarettes which are potentially significantly reduced risk products in the eyes of revered PHAs and leading scientists. This will have very serious adverse effects on tobacco harm reduction particularly when considered in combination with the proposed introduction of plain packaging for e-cigarettes. E-cigarettes, which are almost universally acknowledged to be a key pillar in tobacco harm reduction, are being unjustifiably and disproportionately regulated which will no doubt undermine public health.

1.8 We acknowledge concerns regarding potential youth nicotine and tobacco use and we agree that nicotine and tobacco products should be restricted to adults only. However, the sale of e-cigarettes to youth is already banned, and there are alternative regulatory policies that are more properly targeted to reducing youth access and use than a ban on all non-tobacco e-cigarette flavours, which is not proven to have any significant effect on youth usage and runs counter to tobacco harm reduction aims.

1.9 To be clear, we are not opposed to regulations. In fact, just the opposite. Regulation is critical to ensuring responsible growth and consumer access, and to support smokers to switch. What we call for is proportionate - not arbitrary or ill-informed - regulation, which takes account of the relative risks and does not treat these products in the same way as combustible tobacco products, let alone more restrictively. As a group of public health experts recently commented: **”[p]*olicies that fail to differentiate will fail public health*”**.[3]

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[2] For instance, notwithstanding that e-cigarettes are legally prohibited in Australia, government data shows that almost one third (31%) of smokers reported in 2016 having tried e-cigarettes in their lifetime and 4.4% of smokers and 21% of ex-smokers reported current use of e-cigarettes in 2016; Australian Institute of Health and Welfare 2017. National Drug Strategy Household Survey 2016: detailed findings. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.

[3] Fairchild et al (2019) Evidence, alarm, and the debate over e-cigarettes, Science13 Dec 2019: 1318-1320.

2. SAMENVATTING

2.1 BAT Nederland verzet zich tegen het Voorstel op een aantal punten:

2.1.1 HET MINISTERIE HEEFT EEN GEBREKKIG EN INADEQUAAT PROCES GEVOLGD

2.1.2 Het ministerie heeft de belanghebbenden niet gevraagd om hun mening te geven of hen in de gelegenheid gesteld om commentaar te geven op de analyse en het bewijsmateriaal dat werd gebruikt om de voorgestelde beperking op e-sigarettensmaken te rechtvaardigen voordat het Voorstel werd gepubliceerd. Bovendien is de consultatie die nu loopt nadat het Voorstel al is gepubliceerd, slechts 4 weken, waarvan een deel in de kerstperiode. Dit wijst op de intentie om door te gaan en zet vraagtekens bij de legitimiteit van deze raadpleging.

2.1.3 Om het Parlement in staat te stellen het Voorstel naar behoren te onderzoeken, is een grondige, op feiten gebaseerde analyse van het Voorstel nodig. De Aanwijzingen voor de regelgeving (2.2) vereisen dat de noodzaak van enige regelgeving duidelijk wordt vastgesteld. Dit vereist dat er voldoende zekerheid is dat de voorgestelde regeling een maatschappelijk probleem daadwerkelijk zal oplossen of verminderen, dat er geen minder belastende alternatieven zijn en dat de kosten en lasten die ermee gepaard gaan, gerechtvaardigd zijn door de ernst van het probleem. Het Integraal Afwegingskader voor beleid en regelgeving en de Nota van Toelichting daarbij bevatten niet de nodige bewijzen en analyses om aan deze eis te voldoen en vormen geen adequate basis om te concluderen dat het Voorstel noodzakelijk, adequaat en proportioneel is.

2.1.4 HET VOORSTEL IS IN STRIJD MET DE VOLKSGEZONDHEID

2.1.5 Het ministerie heeft verzuimd de gevolgen van haar besluit voor de volksgezondheid in het algemeen te beoordelen of rekening te houden met de rechten van rokers en vapers. Het ministerie heeft met name nagelaten het voordeel van e-sigaretten voor de volksgezondheid als een potentieel aanzienlijk minder risicovol alternatief voor rokers te beschouwen, zoals door veel volksgezondheidsinstanties wordt erkend:

(A) Aroma's spelen een belangrijke rol bij het helpen van volwassen rokers bij de overgang naar e-sigaretten en dragen ertoe bij dat rokers e-sigaretten een bevredigend alternatief vinden voor conventionele sigaretten. Studies tonen aan dat volwassen rokers gebruik maken van gearomatiseerde e-vloeistoffen om volledig van het roken af te stappen.

(B) Het ministerie beweert ten onrechte dat alle smaken, behalve de tabakssmaak, 'aantrekkelijk' zijn en betrokken zijn bij de werving van niet-rokers, met name jongeren, om te gaan dampen.

(C) Een aantal studies concludeert dat jongeren die experimenteren met e-sigaretten, niet aangetrokken worden door smaakjes.

(D) Gezondheidsdeskundigen zijn het er in toenemende mate over eens dat het exclusieve gebruik van e-sigaretten minder risico's op schade met zich meebrengt dan het roken van conventionele sigaretten.

(E) Er is overtuigend bewijs dat e-sigaretten het roken verdringen. Het bewijs van “gerandomiseerd onderzoek met controlegroep” (“randomized controlled trial”), observationele studies en bevolkingsgegevens geven aan dat voor veel rokers e-sigaretten een bevredigend alternatief zijn voor traditionele sigaretten en dat ze hebben bijgedragen aan een aanzienlijke vermindering van het aantal rokers na hun introductie. In jurisdicties waar er redelijke middelen zijn voor productdistributie en -communicatie en waar er geen beperkingen zijn voor smaken, in combinatie met de steun van de overheid en de volksgezondheidsinstanties, is er een aanzienlijke daling van het aantal rokers na de introductie van e-sigaretten. Empirische modellering suggereert ook een algeheel gunstig effect op de beperking van tabaksschade door e-sigaretten.

(F) De in de toelichting aan de orde gestelde punten van zorg met betrekking tot het duaal gebruik moeten naar behoren worden beoordeeld. Duaal gebruik maakt vaak deel uit van een overgang van het roken naar een volledige overstap naar e-sigaretten. Uit studies blijkt dat duaal gebruikers meer kans hebben om te stoppen met roken. Het ministerie levert geen enkel bewijs dat gearomatiseerde e-sigaretten duaal gebruik in stand houden.

(G) Er is geen bewijs voor de stelling van het ministerie dat er "*toenemend*" wetenschappelijk bewijs is dat e-sigaretten fungeren als een "poort" naar het roken (“gateway”). Sterker nog: er is bewijs dat dat effect niet optreedt. Bovendien is in een aantal uitgebreide beoordelingen door onafhankelijke organisaties kritiek geuit op de argumenten die zijn aangevoerd met betrekking tot e-sigaretten en is geconcludeerd dat er geen betrouwbaar bewijs is voor het gateway effect.

(H) Het ministerie heeft geen goede evaluatie gedaan van het dampen onder jongeren om inzicht te krijgen in de producten die zij gebruiken (of het nu gaat om nicotine- of nicotinevrije producten), de kenmerken van de jongeren die aan het dampen zijn (met inbegrip van de vraag of het rokers, ex-rokers of niet-rokers zijn) en de redenen waarom zij dampen.

2.1.6 **HET VOORSTEL ZOU EEN AANTAL ONBEDOELDE GEVOLGEN HEBBEN DIE DE VOLKSGEZONDHEID EERDER ONDERMIJNEN DAN VERBETEREN.**

2.1.7 Het Voorstel zou ertoe kunnen leiden dat voormalige rokers die nu e-sigaretten gebruiken, weer gaan roken, dat minder rokers volledig overstappen op e-sigaretten en het zou ertoe kunnen leiden dat de huidige dampers illegale producten gaan gebruiken. Een verbod op smaken zou er ook toe kunnen leiden dat een deel van de smaakzoekende dampers hun eigen gearomatiseerde vloeistoffen maken van ingrediënten die op het internet of uit illegale bronnen kunnen worden gekocht, met alle risico's van dien. De potentiële risico's van illegale producten en geknoei met vloeistoffen worden aangetoond door de recente EVALI-zaken in de VS. Deze gevallen zijn sterk gerelateerd aan producten die vitamine E-acetaat en/of THC bevatten (en niet in het bijzonder aan smaakstoffen), en in het bijzonder aan producten die uit illegale bronnen zijn verkregen. Bovendien zou het opleggen van dezelfde smaakverboden voor e-sigaretten zoals die bestaan voor traditionele sigaretten, de huidige misvattingen over de relatieve risico's van deze producten bestendigen en rokers ontmoedigen om volledig op e-sigaretten over te schakelen.

2.1.8 **HET VOORSTEL IS ONWERKBAAR.**

2.1.9 Het Voorstel is op meerdere fronten onwerkbaar. Een positieve lijst kan niet worden opgesteld aan de hand van de informatie die wordt verstrekt over het EU-Common Entry Gate System ("**EU-CEG**"), aangezien niet alle ingrediënten zijn opgenomen in de bij de EU-CEG in te dienen documenten. Het zou buitengewoon moeilijk, zo niet onmogelijk, zijn om tot een positieve lijst te komen die het juiste evenwicht vindt tussen het niet beperken van de tabakssmaak en het niet toestaan van smaken anders dan tabak. Tabak en verschillende soorten bladeren hebben op zich een rijk en samengesteld scala aan smaakeigenschappen en om te proberen dit te karakteriseren om een werkbare lijst van toegestane aroma-additieven te produceren zou veel tijd, specifieke deskundigheid en voortdurende actualisering vergen om te voorkomen dat er verschillende soorten niet-tabaksaroma's worden gebruikt. Vloeistoffen met tabaksaroma's zijn samengesteld uit complexe smaakcombinaties van een breed scala aan ingrediënten die op verschillende inclusie-niveaus kunnen worden gemengd om verschillende smaakprofielen te creëren. Smaakprofielen zijn ook handelsgeheimen die bescherming behoeven (zoals erkend in de EU-TPD). Als alle ingrediënten die momenteel in de samenstelling van de verschillende tabaksaroma's op de markt worden gebruikt, openbaar zouden moeten worden gemaakt, zouden deze handelsgeheimen, die eigendomsrechten zijn, worden geschonden en zou de markt worden verstoord. Als een lijst van additieven te strikt wordt vastgesteld, bestaat het risico dat het

ministerie het gebruik van sommige bestaande tabakssmaakprofielen verhindert en daardoor een discriminerend effect heeft.

2.1.10 Het huidige Voorstel is om een limitatieve lijst op te stellen op basis van aroma additieven die aanwezig zijn in vloeistoffen die op 1 juni 2020 voor de Nederlandse markt zijn geregistreerd, en het Voorstel bevat onvoldoende informatie over de wijze waarop nieuwe ingrediënten aan de limitatieve lijst kunnen worden toegevoegd. Een langdurig proces zou een negatief effect hebben op de innovatie en op zijn beurt een negatief effect hebben op de concurrentie op de markt.

2.1.11 De regelingen zullen ook niet effectief kunnen worden gehandhaafd zonder gedetailleerd en tijdrovend onderzoek en chemische tests. Het is niet realistisch te verwachten dat de fabrikanten alle ingrediënten en het niveau van die ingrediënten op de verpakking van de producten of bij de bekendmaking aan het EU-CEG notificatiesysteem zullen vermelden (niet in de laatste plaats om redenen van handelsgeheim).

2.1.12 **HET VOORSTEL BEVAT EEN GEBREK AAN DUIDELIJKHEID EN ONDERMIJNT DE BEDRIJFSZEKERHEID**

2.1.13 Het Voorstel bevat een alarmerend gebrek aan duidelijkheid over het proces om te bepalen welke additieven in de limitatievelijst zullen worden opgenomen, op welke niveaus ze zullen worden opgenomen en hoe nieuwe ingrediënten zullen worden toegevoegd. De discretionaire bevoegdheid van het ministerie is dan ook zeer ruim en het is verontrustend dat het ministerie niet verplicht is om nog een zinvol overleg met de belanghebbenden te voeren over de samenstelling van de voorgestelde lijst voordat deze definitief wordt vastgesteld. Dit is met name van belang in het licht van de seismische gevolgen die de voorgestelde lijst zou hebben voor de industrie, met inbegrip van een mogelijk verbod op producten met tabakssmaak als de limitatieve lijst niet volledig of accuraat is.

2.1.14 De EU is begonnen met de herziening van de huidige EU-regels voor tabak en e-sigaretten, die zou moeten leiden tot de goedkeuring van een nieuw stuk EU-wetgeving, de zogenaamde TPD3. Onder deze omstandigheden zou het duidelijk verkeerd zijn als Nederland doorgaat met het vaststellen van eigen nationale regels. Dit is met name het geval gezien het feit dat de Voorstellen onderworpen zullen zijn aan TRIS-kennisgevingstermijnen, wat ertoe zal leiden dat de nieuwe regelgeving op korte termijn zal worden gevolgd door TPD3.

2.1.15 De combinatie van het gebrek aan duidelijkheid binnen de Voorstellen en de mogelijke verdere wijziging van TPD3 zal de rechtszekerheid voor het bedrijfsleven ondermijnen, het rechtszekerheidsbeginsel schenden en de fabrikanten van e-

sigaretten onevenredig zwaar belasten. Deze onzekerheid vormt dan ook een onrechtmatige inbreuk op het recht van de fabrikanten om zaken te doen.

2.1.16 **HET VOORSTEL IS ONWETTIG.**

2.1.17 Het Voorstel is in strijd met de beginselen van het Nederlandse recht, het EU-recht en het EVRM. Daaronder valt ook dat:

(A) het Voorstel geen rechtsgrondslag heeft op grond van artikel 24, lid 3, van de TPD2 en ook al zou dat artikel kunnen worden toegepast, dan nog voldoet de Nederlandse regering in het geheel niet aan het vereiste rechtvaardigingscriterium;

(B) het Voorstel gaat het toepassingsgebied van de TPD2 ernstig te buiten en vormt een ongerechtvaardigde beperking van het vrije verkeer van goederen tussen Nederland en andere EU-lidstaten, die in strijd is met het EU-recht; en

(C) het Voorstel zou inbreuk maken op de persoonlijke keuze van de consument en het recht op privacy, alsmede op het recht van fabrikanten en detailhandelaren om een bedrijf te voeren, op eigendomsrechten, met inbegrip van handelsmerkrechten, en op het recht op vrije meningsuiting zoals dat beschermd wordt door de Nederlandse grondwet, het Europees Verdrag tot bescherming van de rechten van de mens ("**EVRM**") en het Handvest van de grondrechten.

2.1.18 **HET VOORSTEL IS IN STRIJD MET DE INTERNATIONALE VERPLICHTINGEN VAN NEDERLAND.**

2.1.19 Het Voorstel is in strijd zijn met de internationale verplichtingen die voortvloeien uit overeenkomsten van de Wereldhandelsorganisatie ("**WTO**"), zoals de Overeenkomst inzake technische handelsbelemmeringen ("**TBT-overeenkomst**") en de Algemene Overeenkomst inzake tarieven en handel van 1994 ("**GATT**").

2.1.20 **ER ZIJN ALTERNATIEVEN**

2.1.21 Er is een aantal alternatieve opties voor regulering die beter zijn om de toegang en het gebruik door jongeren te verminderen, terwijl er toch voor wordt gezorgd dat volwassen rokers voldoende toegang hebben tot een reeks smaken om aan hun uiteenlopende voorkeuren tegemoet te komen en zodat zij worden ondersteund in de volledige overstap naar de e-sigaret. Ook andere maatregelen moeten worden overwogen:

(A) Het verbieden van elke aanduiding of illustratie van een smaakbenaming of -omschrijving die aantrekkelijk is voor jongeren (zoals het gebruik van descriptoren voor alcoholische dranken, dat in de toelichting als een punt

van zorg aan de orde wordt gesteld). Dit zou bescherming bieden tegen productnamen die mogelijk aantrekkelijk zijn voor jongeren, terwijl volwassen rokers en vapers toch toegang zouden krijgen tot een breed scala aan e-sigaretten die aan hun uiteenlopende voorkeuren voldoen.

(B) Handhaving van kwaliteits- en veiligheidsnormen, ook met betrekking tot smaken. Wij zijn van mening dat de smaken die in e-sigaretten worden gebruikt, onderworpen moeten worden aan een grondige toxicologische risicobeoordeling en wij steunen het verbod op additieven waarvan is aangetoond dat ze de toxicologische effecten van het product vergroten.

(C) Implementeren van een negatieve lijst van additieven waarvan wetenschappelijk is vastgesteld dat zij schadelijk zijn.

(D) Het uitvoeren van gerichte educatieve programma's voor de jeugd, gericht op het voorkomen van het gebruik van rook- en nicotineproducten door jongeren;

(E) Verplichte opleidingsprogramma's voor alle retailers die elektronische sigaretten verkopen;

(F) Handhaving van de bestaande wetgeving die detailhandelaren verbiedt om e-sigaretten aan minderjarigen te verkopen en de uitvoering van aanvullende maatregelen voor leeftijdscontrole;

(G) Strenge handhaving van het verbod op 'proxy verkoop' van e-sigaretten door volwassenen voor minderjarigen; en

(H) Verbod op grote online bestellingen van dampproducten die een bedrag overschrijden dat redelijkerwijs nodig is voor persoonlijk gebruik of het gebruik van volwassen familieleden.

2.1.22 De volksgezondheid zou veel beter gediend zijn met de uitvoering van een van de bovengenoemde alternatieve maatregelen, of een combinatie daarvan, dan met de onwerkbare en ongefundeerde maatregelen zoals opgenomen in het Voorstel.

3. EXECUTIVE SUMMARY

3.1 BAT Nederland opposes the Proposal on a number of grounds, including:

3.1.1 **THE MINISTRY HAS FOLLOWED A FLAWED AND INADEQUATE PROCESS**

3.1.2 The Ministry did not seek any views from stakeholders or allow them the opportunity to comment on the analysis and evidence used to justify the imposition of the proposed restriction on e-cigarette flavours before the Proposal was published. Furthermore, the consultation now being run after the Proposal has already been published, with a period of only 4 weeks across the Christmas period to respond, indicates an intent to press ahead and calls into question the legitimacy of the Consultation.

3.1.3 A thorough evidence-based impact analysis of the Proposal is required to enable Parliament to properly scrutinise the Proposal. The Regulatory Instructions (2.2) ("Aanwijzingen voor de regelgeving (2.2)") require that the need for any regulation must be clearly established. This requires that there is sufficient certainty that the proposed regulation will actually solve or reduce a social problem, that there are no less onerous alternatives, and that the costs and burdens involved are justified by the seriousness of the problem. The Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum for this Proposal do not include the necessary evidence and analysis to meet this requirement and are not an adequate basis to conclude that the Proposal is justified as necessary, adequate and proportionate.

3.1.4 **THE PROPOSAL IS CONTRARY TO PUBLIC HEALTH**

3.1.5 The Ministry has failed to assess the impact of its decision on public health overall or to consider the rights of smokers and vapers. Specifically, the Ministry has failed to consider the public health benefit of e-cigarettes as a potentially significantly reduced risk alternative for smokers, as acknowledged by many PHAs:

(A) Flavours play an important role in helping adult smokers transition to e-cigarettes and contribute to smokers finding e-cigarettes a satisfactory alternative to conventional cigarettes. Studies show that adult smokers are using flavoured e-liquids to transition away from smoking completely.

(B) The Ministry wrongly asserts that all flavours, other than tobacco flavour, are 'attractive' and are implicated in the recruitment of non-smokers, particularly youth, into vaping.

(C) A number of studies have concluded that flavours are not a determinative factor in youth vaping initiation.

(D) There is increasing agreement amongst health experts that exclusive use of e-cigarettes confers reduced risks of harm as compared to smoking conventional cigarettes.

(E) There is compelling evidence that e-cigarettes are displacing smoking. The evidence from randomized controlled trials, observational studies, and population data indicate that e-cigarettes are a satisfactory alternative to conventional cigarettes for many smokers and that they have contributed to substantial reductions in smoking prevalence following their introduction. In jurisdictions where there are reasonable means of product distribution and communication, and no restriction on flavours, coupled with the support of the Government and public health authorities, there has been a significant decline in smoking prevalence following the introduction of e-cigarettes. Empirical modelling also suggests an overall beneficial tobacco harm reduction effect from e-cigarettes.

(F) Concerns regarding dual use which are raised in the Explanatory Memorandum, need to be properly assessed. Dual use is often part of a transition away from smoking completely. Studies indicate that dual users are more likely to stop smoking. The Ministry provides no evidence suggesting that flavoured e-liquids cause or otherwise perpetuate dual use of e-cigarettes and traditional cigarettes.

(G) The weight of the evidence does not support the Ministry's proposition that there is "*increasing*" scientific evidence that e-cigarettes act as a 'gateway', to smoking but rather the evidence suggests to the contrary that e-cigarettes have provided a gateway out of smoking. Moreover, a number of comprehensive reviews by independent organisations have criticised 'gateway' arguments that have been made in relation to e-cigarettes and concluded that there is no reliable evidence of a gateway effect.

(H) The Ministry has not provided a proper assessment of youth vaping in order to understand the products they are using (whether they are nicotine or nicotine free products), the characteristics of those youth that are vaping (including whether they are smokers, former smokers or non-smokers) and the reasons why they are vaping.

3.1.6 **THE PROPOSAL WOULD HAVE A NUMBER OF UNINTENDED CONSEQUENCES THAT WOULD UNDERMINE, RATHER THAN IMPROVE PUBLIC HEALTH**

3.1.7 The Proposal could result in relapse to smoking amongst former smokers who currently use e-cigarettes, fewer smokers switching completely to e-cigarettes, and could result in current vapers using illicit products. Banning flavours could also lead to a proportion of flavour-seeking vapers making their own flavoured e-liquids from ingredients that can be purchased on the internet or from informal sources, with all the associated risks. The potential risks of illicit products and tampering with e-liquids are demonstrated by the recent EVALI cases in the US. These cases have been strongly linked to products containing vitamin E acetate and/or THC (and not particularly to flavours), and in particular products obtained from informal sources. Moreover, imposing the same flavour bans for e-cigarettes that exist for combustible cigarettes would also perpetuate current misperceptions regarding the comparative risks of these products and discourage smokers from switching completely to e-cigarettes.

3.1.8 **THE PROPOSAL IS UNWORKABLE**

3.1.9 The Proposal is unworkable on multiple fronts. A positive list cannot be created simply by means of the information provided on the EU-Common Entry Gate system ("EU-CEG") as not all ingredients are included in submissions to the EU-CEG. Achieving a positive list that strikes the correct balance between not restricting tobacco flavours and not permitting other non-tobacco flavour profiles would be exceptionally difficult, if not impossible. Tobacco and different leaf-types have a rich and composite range of flavour attributes and to try to characterise this to produce a workable list of permitted flavour ingredients would take considerable time, specific expertise and continuous maintenance to avoid encompassing different non-tobacco flavour-types. Tobacco flavours e-liquids are composed of complex flavour compositions from a broad variety of ingredients that can be mixed at different inclusion levels to create different flavour profiles. Flavour profiles are also trade secrets which require protection (as recognised in the EU TPD). Requiring the disclosure of all the ingredients currently used in the composition of the different tobacco flavours on the market would violate these trade secrets, which are property rights, and create market distortion. Fixing an ingredients list too narrowly risks that the Ministry would prevent the use of some existing tobacco flavour profiles and thereby create a discriminatory impact.

3.1.10 The current proposal is to create a positive list based on flavouring ingredients present in liquids registered for the Dutch market on 1 June 2020 and the Proposal

does not contain sufficient information concerning how new ingredients could be added to the positive list. A protracted process would result in a negative impact on innovation and in turn have an adverse impact on market competition.

3.1.11 The regulations will also be incapable of effective enforcement without detailed, time-consuming investigations and chemical testing. It is unrealistic to expect that manufacturers will list all ingredients and the level of those ingredients on product packaging or in disclosure to the EU-CEG reporting system (not least for trade confidentiality reasons).

3.1.12 **THE PROPOSAL CONTAINS A CONCERNING LACK OF CLARITY AND UNDERMINES BUSINESS CERTAINTY**

3.1.13 The Proposal contains an alarming lack of clarity around the process of determining which ingredients will be set out in the positive list, at what inclusion levels and how new ingredients would be added. The breadth of the Ministry's discretion is therefore extremely broad and it is alarming that there is not a requirement for the Ministry to undertake meaningful consultation with stakeholders in relation to the preparation of the proposed list before it is finalised. This is particularly concerning in light of the seismic impact the proposed list would have on the industry, including potentially banning tobacco flavoured products if the positive list is not complete or accurate.

3.1.14 The EU has commenced the process for the revision of the current EU tobacco and e-cigarette rules which should result in the adoption of a new piece of EU legislation, the so-called TPD3. In these circumstances, it would be clearly wrong for the Netherlands to proceed with the adoption of their own national rules. This is particularly the case given the Proposal will be subject to TRIS notification delays which will result in the new regulations being imminently followed by TPD3.

3.1.15 The combination of the lack of clarity within the Proposal and the potential further change from TPD3 will undermine business certainty, infringing the principle of certainty under the law, and impose a disproportionate burden on e-cigarettes manufacturers. Accordingly, this uncertainty represents an unlawful interference with manufacturers' right to conduct business.

3.1.16 **THE PROPOSAL IS UNLAWFUL**

3.1.17 The Proposal would violate principles of Dutch, EU and ECHR law. These include that:

(A) the Proposal has no legal basis under Article 24(3) of the TPD2 and, even if that Article could be engaged, the Dutch government has completely failed to meet the requisite standard of justification under it;

(B) the Proposal severely exceeds the scope of TPD2 and constitutes an unjustifiable restriction of the free movement of goods between the Netherlands and other EU Member States contrary to EU law; and

(C) the Proposal would infringe on consumers' personal choice and right to privacy, as well as manufacturers' and retailers right to conduct a business, property rights, including trademark rights, and free speech rights as protected under the Constitution of the Netherlands, and the European Convention on Human Rights ("**ECHR**"), and the Charter of Fundamental Rights.

3.1.18 **THE PROPOSAL WOULD VIOLATE THE NETHERLANDS' INTERNATIONAL OBLIGATIONS**

3.1.19 The Proposal would violate international obligations under World Trade Organization ("**WTO**") Agreements such as the Agreement on Technical Barriers to Trade ("**TBT Agreement**") and the General Agreement on Tariffs and Trade 1994 ("**GATT**").

3.1.20 **THERE ARE A NUMBER OF ALTERNATIVE REGULATORY OPTIONS**

3.1.21 There are a number of alternative regulatory options that are more properly targeted to reducing youth access and use while still ensuring that adult smokers have appropriate access to a range of flavours to meet their varying preferences and so that they are supported to switch to potentially reduced risk alternatives to combustible cigarettes. Other measures that should also be considered include:

(A) Banning any indication or illustration of a flavour name or descriptor that would be appealing to youth (such as the use of descriptors for alcoholic drinks which is raised as a concern in the Explanatory Memorandum). This would protect against flavour descriptors and labelling that are targeted at youth while still allowing adult smokers and vapers access to a broad range of e-cigarettes to suit their varying preferences.

(B) Enforcing quality and safety standards, including with respect to flavours. Our view is that flavours used in e-cigarettes should be subject to a thorough toxicological risk assessment and we support the ban of ingredients that are shown to increase the toxicological effects of the product.

(C) Implementing a negative list of additives that has been scientifically established to be harmful;

(D) Implementing targeted youth education programmes aimed at preventing young people from taking up smoking and nicotine products;

(E) Mandatory training programs for all vaping retailers;

(F) Enforcing existing laws forbidding retailers to sell e-cigarettes to minors and the implementation of additional age verification measures;

(G) Rigorous enforcement of the ban on 'proxy purchasing' of e-cigarettes by adults for minors; and

(H) Prohibition of large online orders of vaping products which exceed an amount reasonably required for personal use or the use of adult family members.

3.1.22 Public health would be far better served by implementing any of the above measures, or a combination of these, as opposed to the unworkable and unsubstantiated measures contained in the Proposal.

4. THE MINISTRY HAS FOLLOWED A FLAWED AND INADEQUATE PROCESS

4.1 The procedure followed by the Ministry to-date raises serious concerns.

4.2 The Proposal is proceeding without a proper impact assessment

4.3 The failure to undertake and/or publish a proper regulatory impact assessment or undertake any meaningful consultation before the substantive decisions were made means that the decisions were taken without proper analysis of the costs and benefits of the Proposal and without consideration of alternative policy options.

4.4 The enactment of effective and evidence-based regulation which meets public health objectives and respects the Netherlands' legal framework and international obligations is central to the development of evidence-based, transparent and effective regulation.

4.5 The need for a regulatory impact assessment is reflected in the Instructions for Regulations ("aanwijzing 2.2. van de Aanwijzingen voor de regelgeving):

> "Regelgeving is noodzakelijk indien aannemelijk is dat het concrete voorstel een effectieve, efficiënte en evenredige reactie vormt op het maatschappelijke probleem dat aanleiding geeft voor die regelgeving. Daarvoor is dus vereist dat voldoende zekerheid bestaat dat de voorgestelde regeling werkelijk zal leiden tot het oplossen of verminderen van dat probleem, dat er geen minder bezwarende alternatieven zijn, en dat de kosten en lasten daarvan gerechtvaardigd worden door de ernst van het probleem. Indien niet aan elke van deze voorwaarden is voldaan, bestaat onvoldoende grond om tot regelgeving (in de voorgenomen vorm) over te gaan. Eventueel kan in zo'n geval een alternatief, minder bezwarend sturingsinstrument worden ingezet, of dient simpelweg van overheidsingrijpen te worden afgezien."

4.6 The Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum for this Proposal do not include the necessary evidence and analysis to meet this requirement and are not an adequate basis to conclude that the Proposal is justified as necessary, adequate and proportionate.

4.7 The Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum merely present a narrative statement supporting the Proposal, based on selected evidence and assumptions. The documents are neither objective nor adequate to provide proportionate, evidence-based policy recommendations. In particular, the Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum:

4.7.1 Do not provide a proper assessment of the use of e-cigarettes in the Netherlands, including by smokers as alternatives to combustible cigarettes, and the nature and extent of use by youth in order to understand the extent of use, the products they are using (whether they are nicotine or nicotine free products), the characteristics of those youth that are vaping (including whether they are smokers, former

smokers or non-smokers) and the reasons why they are vaping. The Explanatory Memorandum refers to data that shows that in 2019 25% of young people between 12 and 16 years old have ever used an e-cigarette. However, 'have ever used' can include a range of behaviours, including single use and experimentation, and it does not give any meaningful information on the frequency of current use. Indeed, the Explanatory Memorandum fails to note that the data also shows that of those e-cigarette users amongst young people in the Netherlands (i.e. the 25% of 12-16 year olds) more than half (55%) have not vaped recently, and only one in ten reported 'users' use the e-cigarette almost every week or more often. It is also noteworthy that this percentage of 'sometimes use' has decreased from 34% in 2015 and that youth smoking rates are low and continue to decline, from 2.1% in 2017 to 1.8% in 2019. This suggests a very different situation regarding youth e-cigarette use and calls into question the basis for the Proposal.

4.7.2 Do not demonstrate that any particular flavours cause the uptake of e-cigarettes where there would otherwise be no use. The Ministry simply asserts that all flavours, other than tobacco flavour, are 'attractive' and are implicated in the recruitment of non-smokers, particularly youth, into vaping. The Explanatory Memorandum refers to research undertaken by RIVM regarding the different flavours available in the Netherlands.[4] However, this research only reported on the flavour descriptions of e-liquids marketed in the Netherlands in 2017. Thus it is a list of descriptors, not a list of flavour additives. This study does nothing to define, much less provide any testing to establish those flavour additives that are alleged to appeal to youth. Consumer control tests would also be required using different unbranded additives, thereby overcoming brand loyalty and the impact of any marketing. Accordingly, this study provides no basis for designating any flavour additives as 'attractive' or otherwise banning flavoured e-liquids.

4.7.3 Do not demonstrate that the Proposal would have a beneficial public health impact, including considering the impact of the Proposal on adult smokers and former smokers that are using e-cigarettes; or considering the potential impact of the Proposal on diverting youth away from smoking;

4.7.4 Do not consider any possible unintended consequences associated with the Proposal, including increases in smoking and incentivising 'do it yourself' (DIY) and black-market flavours;

4.7.5 Do not even attempt to identify, let alone monetise or quantify the substantive costs of the Proposal on e-cigarette manufacturers and retailers who will lose almost their

[4] A. Havermans, E.J.Z. Krüsemann, J. Pennings, et al. '20 000 e-liquids and 250 unique flavour descriptions: an overview of the Dutch market based on information from manufacturers', Tobacco Control 2019.

entire business. Indeed, the Proposal will likely shut down a number of legitimate manufacturers and retailers, particularly small to medium-sized businesses (vape stores and manufacturers) that make and sell predominantly flavoured products; and

4.7.6 Provide no consideration of less restrictive alternative options and further, introduces the Proposal concurrently with a plain packaging proposal for e-cigarettes.

4.8 Since the Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum for this Proposal do not include the elements required for an adequate a regulatory impact assessment. Therefore they cannot fulfil the purpose of an impact assessment and cannot be relied on to provide proportionate, evidence-based policy recommendations.

4.9 The need for a proper evidence based regulatory impact assessment is even more pressing in this case given the Ministry's purported reliance on Article 24(3) of the EU Tobacco products Directive ("**TPD**") as a basis to implement the measure. Mandatory conditions must be satisfied before Article 24(3) can be invoked. In particular, Article 24(3) only permits the introduction of an additional measure to "*prohibit a certain category of tobacco or related products*" (not certain flavours within a category of products), "*provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive*" and it is proportionate.

4.10 The Ministry's failure to undertake an evidence-based impact assessment, including meaningful consultation with stakeholders, means that the Proposal cannot be shown to be justified as necessary, appropriate and proportionate, or to comply with the obligations under the TPD and the TFEU; and WTO Agreements such as the TRIPS Agreement and the TBT Agreement to "*ensure*" that requirements do not violate internationally protected intellectual property rights or constitute an "*unnecessary obstacle to trade*".

4.11 Accordingly, even if the Proposal could proceed, a proper objective, evidence based, impact assessment should be carried out before proceeding further with the Proposal.

4.12 **Lack of meaningful consultation**

4.13 The Government did not seek any views from stakeholders or allow them the opportunity to comment on the analysis and evidence used to justify the imposition of the Proposal before the regulations were published. Furthermore, the consultation now being run after the decision has already been made indicates an intent to press ahead and calls into question the purpose and legitimacy of the Consultation. The timing, content and unreasonable duration of the Consultation fails to provide any meaningful level of transparency or participation in the process.

4.13.1 The purpose of internet consultations is to ensure that more people, companies and organisations receive information on legislative acts that are being prepared (Government position on internet consultations of 17 June 2011). Internet consultation is also intended to increase transparency of the legislative process, improve possibilities for public participation and enhance the quality of legislation and regulation. This Consultation completely fails to meet those objectives.

4.13.2 The Consultation was published on Saturday 19 December 2020, which was the first day of the Christmas holiday (which, for schools lasted for 2 weeks and for Parliament lasted for 3 weeks). The deadline to respond to the Consultation is four weeks. It follows from the Government's position on internet consultations of 17 June 2011 that the minimum time to respond is four weeks. In this case, the consultation period overlapped with Christmas holidays resulting in an effective period during which the public was able to respond of not more than 2 weeks. Moreover, the entire consultation period falls in a period of lockdown due to the COVID-19 pandemic. During this lockdown, vaping shops are closed upon governmental order. Vaping shops and their customers are particularly affected by the Proposal, but due to the lockdown they do not have proper possibilities to be made aware of the proposal, gather and discuss their views on the Proposal and respond to the Consultation.

4.13.3 It is furthermore noted that several website links of the Consultation do not work properly: the link 11975 under "Keten-ID" does not work at all; the link "Gezondheidsrisico's Jongeren" under "Onderwerpen" refers to an amendment in the Opium Act; and the link to the source eur-lex.europ.eu under "Externe bronnen" refers to an empty website.

4.13.4 This timing as well as the errors on the website suggest that the Government did not truly intend to increase transparency, enhance quality and improve public participation by more people, companies and organisations.

4.13.5 It is a fundamental principle of consultation that it takes place at a time when proposals are still at a formative stage, and that the product of the Consultation is given conscientious consideration. This is highlighted by the European Commission Impact Assessment Guidelines, which also note that the consultation process should engage all affected stakeholders; ensure that stakeholders can comment on a clear problem definition, description of the possible options and their impacts; maintain contact with stakeholders throughout the process and provide feedback; and analyse stakeholders' contributions for the decision-making process

and report fully in the impact assessment report on how the input was used.[5] The process being conducted by the Ministry doesn't meet any of these standards.

5. THE PROPOSAL IS CONTRARY TO PUBLIC HEALTH

5.1 The Ministry has failed to assess the impact of its decision on public health overall or to consider appropriately the rights of smokers and vapers. Specifically, the Ministry has failed to consider the public health benefit of e-cigarettes as a potentially significantly reduced risk alternative for smokers. In this context, it is worth noting that:

5.1.1 Flavours play an important role in helping adult smokers transition to e-cigarettes and contribute to smokers finding e-cigarettes a satisfactory alternative to conventional cigarettes. Studies show that adult smokers are using flavoured e-liquids to transition away from smoking, as set out below.

5.1.2 The Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum for this Proposal refer to research undertaken by RIVM[6] and the Trimbos Institute[7] which it is stated show that regulating flavours would reduce the attractiveness of e-cigarettes. However, these papers are based on limited and selective references only, and they fail to consider other evidence which demonstrates the important role that flavoured e-cigarettes can have in reducing the use of combustible cigarettes. These papers do not show that a ban on flavours is appropriate for the protection of public health, including that any benefits would outweigh the harms, which include the harms caused by adult and youth usage of cigarettes which are a far more harmful product.

5.1.3 Research that is not referred to in Integral Policy and Regulatory Assessment Framework, and Explanatory Memorandum or relied on by the Ministry, show that flavours are central to the smoke-free proposition offered to smokers and that they are important in preventing relapse back to smoking as users make a transition away from smoking over time. For example:

(A) A recent peer reviewed study published in JAMA[8] concludes that "*adults who began vaping non-tobacco flavoured e-cigarettes were more likely to quit smoking than those who vaped tobacco flavours*." The same study also found that flavours are not associated with youth smoking initiation: "*Relative to vaping tobacco flavours, vaping non tobacco-flavoured e-*

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5 European Commission Impact Assessment Guidelines at page 19, http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf.

6 RIVM, 'E-cigarette attractiveness for smokers and non-smokers', March 2018.

7 S. Troelstra, E. Croes, J. Bommelé, M. Willemsen, 'Factsheet elektronische sigaretten', Trimbos institute, division: National Expertise Centre for Tobacco Control, April 2020.

8 Friedman AS, Xu S. Associations of Flavoured e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. *JAMA Netw Open.* 2020;3(6):e203826. doi:10.1001/jamanetworkopen.2020.3826

cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation."

(B) A study by Farsalinos et al., found that "[t]*he average score for importance of flavours variability in reducing or quitting smoking was…'very important'"* and that *"the majority of participants stated that restricting variability of flavours would make the* [e-cigarette] *experience less enjoyable while almost half of them answered that it would increase craving for tobacco cigarettes and would make reducing or completely substituting smoking less likely."* The study concluded that "[e-cigarette] *liquid flavourings play a major role in the overall experience of dedicated users and support the hypothesis that they are important contributors in reducing or eliminating smoking consumption.*"[9]

(C) Recent survey data from 15,456 US adult smokers, found that after 3 months, participants who had exclusively used non-tobacco flavours (mango, cucumber, fruit, crème, menthol, and mint) were 30% more likely to have abstained from smoking for the last 30 days, compared to those who exclusively used tobacco flavours.[10]

(D) An internet survey of 20,836 adult frequent vapers in the US investigated trends in the first flavour used across time of e-cigarette use initiation.[11] Amongst those who had fully switched from smoking to vaping (76.4% of the participants), the proportion of first e-cigarette purchases that were fruit-flavoured increased from 17.8% of first purchases made before 2011 to 33.5% of first purchases made between June 2015 and June 2016. In contrast, tobacco-flavoured first purchases almost halved during this time. Based on the observed trend, the study concluded that restricting the availability of e-cigarette flavours could reduce adult smokers' interest in switching to e-cigarettes and raises the possibility that e-cigarette users could return to combustible tobacco products. Specifically, the authors stated: ""[t]*he findings suggest that access to a variety of non-tobacco flavoured e-liquid may be important for encouraging and assisting adults to use e-cigarettes in place of conventional cigarettes. Restricting the*

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9 See e.g. Farsalinos, Konstantinos *et al.* "Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey." International Journal of Environmental Research and Public Health. December 17, 2013.

10 Russell, C., et al. (2019) Factors associated with past 30-day abstinence from cigarette smoking in a non-probabilistic sample of 15,456 adult established current smokers in the United States who used JUUL vapor products for three months. Harm Reduction Journal. Available at: https://doi.org/10.1186/s12954-019-0293-7

11 Russell, C., McKeganey, N., Dickson, T. *et al.* Changing patterns of first e-cigarette flavour used and current flavours used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* **15,** 33 (2018). https://doi.org/10.1186/s12954-018-0238-6.

availability of non-tobacco flavours could reduce adult smokers' interest in switching to e-cigarettes or rationalize a return to cigarette smoking among frequent END users whose journey towards smoking abstinence started with, progressed to, and is being sustained by frequent use of e-cigarettes containing non-tobacco flavours. ***A tobacco products regulatory framework that balances adult smokers' increasingly common preference to try to quit smoking by using e-cigarettes that do not taste like cigarettes, with measures that reduce the appeal and use of e-cigarettes by non-smokers and youth, may accelerate the US progress towards the end of the tobacco smoking epidemic that causes the premature death of approximately 480,000 Americans each year***". (emphasis added)"

(E) An analysis of data from the US Population Assessment of Tobacco and Health ("**PATH**") survey[12], found that those young adult smokers who used a single flavoured (non-tobacco/non-menthol) e-cigarette were 2.5 times more likely to quit smoking in comparison to non-e-cigarette users, and those who used a variety of flavoured (non-tobacco/ non-menthol) e-cigarettes were 3.0 times more likely to quit smoking.

5.1.4 Public health experts have also recognised the important role that flavours can and do play in increasing the potential for e-cigarettes to act as a satisfactory alternative to cigarette smoking. For example:

(A) Clive Bates, ex-director of UK anti-smoking charity Action on Smoking and Health (ASH UK) has stated that "[n]*on-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours often as part of a permanent switch from smoking*".[13]

(B) Jeff Stier, Senior Fellow at the National Center for Public Policy Research in Washington and an industry consultant has said: "[W]*e're also beginning to see scientific data pointing to the benefits of flavours helping people not only quit smoking, but more importantly, stay off cigarettes."* He added that *"[h]umans learn by association. When we associate the pleasure of nicotine with the burnt tobacco, we think we like burnt tobacco. What*

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12 Chen, J., (2018) Flavoured E-cigarette Use and Cigarette Smoking Reduction and Cessation—A Large National Study among Young Adult Smokers. Substance Use & Misuse, 53:12, 2017-2031, DOI: 10.1080/10826084.2018.1455704

13 Bates, C. "E-cigarettes, vaping and public health: A summary for policy-makers." Counterfactual Consulting and Advocacy, February 2015. Available at http://www.casaa.org/e-cigarettes-vaping-and-public-health/

flavours help us do is disassociate the pleasure of the nicotine with the burnt tobacco".[14]

(C) Associate Professor Colin Mendelsohn of the School of Public Health and Community Medicine, University of New South Wales (Australia) and a Tobacco Treatment Specialist, has stated: "[f]*lavours are an important part of the appeal of vaping for adult smokers and make the products attractive as an alternative to smoking, just as flavours are also used to enhance the appeal of nicotine gum. Banning flavours would likely undermine the use of e-cigarettes and the public health benefits*."[15]

(D) Ann McNeill, Professor of Tobacco addiction at King's College, London stated: "*Many adult smokers say they need the flavours if they're going to use e-cigarettes—it's the flavours that make them palatable. Banning flavours might therefore prolong the smoking habit for many*".[16]

(E) Raymond Niaura, Professor of Social and Behavioral Sciences, NYU College of Global Public Health identified: "*A lot of people who want to switch away from tobacco don't want to be reminded of the taste and smell of smoking cigarettes*".[17]

(F) The World Health Organisation (WHO) has acknowledged that "[f]*lavours also seem to play a role among adults and experienced ENDS [electronic nicotine delivery systems]/ENNDS [electronic non-nicotine delivery systems] users in helping migration away from tobacco*".[18]

5.1.5 A number of studies have also concluded that flavours are not a determinative factor in youth vaping initiation. For example:

(A) In a study by Shiffman et al., (2015)[19] teenagers were asked to rate their interest on a scale of 0-10 in using e-cigarettes and were offered a list of flavours. They reported minimal interest in flavours (average = 0.41 out of

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14 Stier, Jeff. "Q&A: Defending Electronic Cigarettes to the White House." Interview by Melissa Vonder Haar. CSP News. July 08, 2016. Accessed March 21, 2018. http://www.cspdailynews.com/category-news/tobacco/articles/qa-defending-electronic-cigarettes-white-house

15 Submission 258 to the "Inquiry into the use and marketing of electronic cigarettes and personal vaporisers" in Australia, by Colin Mendelsohn, 5 July 2017. Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Submissions

16 https://www.planetofthevapes.co.uk/news/vaping-news/2019-10-18_prof-counters-dame-sally-s-ban-proposal.html

17 "Trump move on flavoured e-cigarettes may hit adults trying to quit" The Hill, 14 September 2019, available at: https://thehill.com/policy/healthcare/461361-trump-move-on-flavoured-e-cigarettes-may-hit-adults-trying-to-quit

18 FCTC/COP/7/11, WHO (2016), Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report by WHO. Available at: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1%22&ua=1

19 Shiffman S, Sembower MA, Pillitteri JL, Gerlach KK, Gitchell JG. (2015) *The impact of flavour descriptors on non-smoking teens' and adult smokers' interest in electronic cigarettes*. Nicotine Tob Res 17(10).

10), much less so than adult smokers (1.73 out of 10). Further, their interest did not vary much across flavours.

(B) This is further supported by a study by Pepper et al., (2013)[20] which analysed whether adolescent males were willing to try e-cigarettes, and specifically looked at whether there was a difference in respondents' willingness to try plain versus flavoured varieties. The study found that "[t]*he same proportion of respondents were willing to try plain e-cigarettes or to try flavoured e-cigarettes.*"

(C) The UK House of Commons Science and Technology Committee also studied the issue of e-cigarettes flavours and youth initiation. Consistent with prior studies, the Committee's E-Cigarettes Report, published in 2018, came to the same conclusion, namely, that "*the risk of the variety and type of flavours being attractive to young non-smokers, who would be drawn into* [e-cigarette] *use, also appears to be negligible.*"[21]

5.1.6 Research also suggests broader causes for youth vaping uptake than flavours, in line with reasons why youth engage in other illegal and risky behaviours. Nicksic et al., (2019)[22] undertook an analysis of the PATH study data to assess the reasons to use e-cigarettes among adults and youth. The authors concluded that there were two broad factors driving of e-cigarette use by both adults and adolescents – with several sub-factors organised under these:

"*This study found two overarching factors, "alternative to cigarettes" and "larger social environment", which combine sub-categories to explain main motivators of e-cigarette use.*"[23]

"*For example, this study found that sub-categories, including peer influences and social norms, were strongly related to one another through* [exploratory factor analysis]*, and are part of a larger, latent organizing factor that we called the "larger social environment". This factor also included media, advertising, and socializing influences, a category of responses that speaks to ways in which youth and adults look for cues to use and integrate information from many sources to make decisions about tobacco use. The larger category of "alternative to cigarettes" encompasses not just goal-directed use (e.g., to quit cigarette smoking), but also*

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20 Pepper et al., (2013) *Adolescent Males' Awareness of and Willingness to Try Electronic Cigarettes* Adolesc Health, 52(2): 144–150.

21 House of Commons Science and Technology Committee, E-Cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018.

22 Nicksic NE, Snell LM, Barnes AJ. Reasons to use e-cigarettes among adults and youth in the Population Assessment of Tobacco and Health (PATH) study. Addict Behav. 2019;93:93–99. doi:10.1016/j.addbeh.2019.01.037.

23 Ibid at p9.

perceptions about where the product could be used, how acceptable use is, and how use might affect health."[24]

In this analysis of PATH data, "*It comes in flavours I like*" was merely the sixth most prominent factor in the "alternative to cigarettes" category and flavours were of little importance to youth in the wider social environment category.[25]

5.1.7 BAT has also commissioned an expert report from Professor Irvine, a Professor of Economics at Concordia University, Montreal, Canada with expertise in Public Economics, Public Policy, Health Economics. **A copy of Professor Irvine's report is provided at Appendix 2 to this Response.** Professor Irvine discusses the potential impact of restrictive vaping policies such as banning flavours. Professor Irvine refers in his expert report to a recent study published in the journal Addictive Behaviors (Landry et al., 2019), which surveyed 1492 current e-cigarette users aged 18 or older with the aim of establishing the role that flavours play in adopting e-cigarettes. He notes that the dominant two reasons given by respondents for initiating vaping were because e-cigarettes were perceived to be less harmful, and they are an alternative to cigarettes.

5.1.8 Flavours were the third most popular reason. Professor Irvine states: *"[t]hese results are consistent with the thesis that a sizable number of respondents indicated that they switched to or initiated e-cigarettes for health reasons and that flavours at the same time played a key role in facilitating that decision.*" (emphasis added) Thus: "*flavours can be a contributing secondary factor, and that secondary role may at the same time be very important in helping a smoker to switch and stay with the e-cigarette*."

5.1.9 We are aware that some concerns have been raised in relation to the potential health risks of flavours. Our view is that flavours used in e-cigarettes should be subject to a thorough toxicological risk assessment and we support the ban of ingredients that are shown by sound scientific evidence to increase the toxicological effects of the product. Our approach to ingredients (including flavours) is to (i) use only pharmaceutical or food grade ingredients; (ii) exclude any ingredients with carcinogenic, mutagenic or reproductive toxicity (CMR) properties or respiratory sensitisation properties; and (iii) risk assess all ingredients that pass this initial screening process taking into account published data on ingredients to help determine suitability of particular compounds. We have published detailed articles in peer reviewed journals setting out our approach to

[24] Ibid at p6.
[25] Ibid, at Table 1.

the use of flavours[26] and allergens[27] in e-liquids. As discussed below, such an approach is a far more proportionate, more effective, and less restrictive approach to the protection of public health.

5.1.10 **There is increasing agreement amongst health experts that exclusive use of e-cigarettes confers reduced risks of harm as compared to smoking conventional cigarettes.**

5.1.11 As already mentioned, e-cigarettes do not contain tobacco and there is no combustion of the e-liquid, which dramatically reduces users' exposure to carcinogens and toxicants relative to conventional cigarettes and provides a real potential for tobacco harm reduction for those who switch completely from traditional combustible cigarettes to e-cigarettes. A growing number of scientific and public health organisations have concluded that e-cigarettes are significantly reduced risk compared to combustible cigarettes[28], for instance Public Health England has deemed e-cigarettes to be "*at least 95% less harmful than smoking*"[29]. Health Canada, which is understood to be one of the most conservative and precautionary tobacco regulators in the world, has also recently adopted an estimate of the mortality/morbidity risks associated with vaping of 20% of that of cigarettes. This estimate was developed in consultation with members of an expert panel.[30] Indeed, it is also widely understood that the risks associated with smoking do not derive from nicotine but mainly from the toxicants produced in combustion and contained in the resulting tobacco smoke.[31]

5.1.12 A large-scale systematic review of the scientific literature undertaken by the US National Academies of Sciences, Engineering, and Medicine ("**NASEM**") for the Food and Drug Administration[32] concluded, inter alia, that:

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26 Costigan, S., et al., An approach to ingredient screening and toxicological risk assessment of flavours in e-liquids, Regul Toxicol Pharmacol. Epub 2015 May 27

27 Costigan, S., et al., An approach to allergy risk assessment for e-liquid ingredients, , Regul Toxicol Pharmacol. Epub 2017 April 5

28 **A list of scientific and public health organisations that have concluded that electronic cigarettes are reduced risk compared to combustible cigarettes is provided at Appendix 3 to this Response.**

29 Public Health England (2018), McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18.

30 See Canada Gazette, Part I, Volume 154, Number 51: Concentration of Nicotine in Vaping Products Regulations - Regulatory Impact Assessment Statement (http://www.gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html)

31 Royal College of Physicians. *Harm reduction in nicotine addiction: helping people who can't quit*. A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom; 2007: "[i]*n this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved*."

32 NASEM (2018), Public Health Consequences of E-Cigarettes.

"*There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes*."

"*The evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes*".

5.1.13 **A copy of a Scientific Assessment of Electronic Nicotine Delivery Systems British American Tobacco, January 2021 is also provided at Appendix 1 to this Response.** This describes the peer-reviewed scientific data generated by British American Tobacco suggesting the potential of e-cigarettes as an instrument to support tobacco harm reduction. This scientific evidence includes:

(A) an overall reduction in emission toxicant levels for e-cigarettes in the order of 99% relative to the scientific reference cigarette, focusing on the list of nine priority toxicants proposed for reduction via product regulation by the WHO Study Group on Tobacco Product Regulation ("**WHO TobReg**").[33]

(B) Reduced toxicity across a series of toxicological tests, which findings are in accordance with Public Health England's and the UK Royal College of Physicians' predictions of the significantly reduced relative risk of e-cigarette use compared to smoking.

(C) Reduced biomarkers of tobacco exposure in the blood, breath and urine of e-cigarette users relative to levels found in smokers.

(D) Empirical modelling suggesting an overall beneficial effect from launching e-cigarettes.

(E) Reduced impact on indoor air quality– with Public Health England noting "*the risk to the health of bystanders from exposure to vapour from nicotine vapourisers is extremely low*"[34].

5.1.14 Published peer-reviewed research by BAT which is referred to in the document, includes an examination of 150 chemical emissions from the BAT's e-cigarette (Vype ePen), a reference tobacco cigarette (Ky3R4F) and laboratory air/method

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33 The nine specific toxicants are: CO, formaldehyde, acetaldehyde, acrolein, 1,3-butadiene, benzene, benzo[a]pyrene, N-nitrosonornicotine ("NNN"), and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone ("NNK"). See Burns DM, Dybing E, Gray N, et al., (2008) Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal Tobacco Control 2008;17:132-141. Available here.

34 Public Health England. 2015. Policies and practice on use of e-cigarettes in enclosed public places: towards a consensus. Public Health England. Available at: <www.ukctas.ac.uk/ukctas/documents/e-cigarettes-in-enclosed-public-places-final-survey.pdf>

blanks.[35] All measurements were conducted by an independent, contract research laboratory, using ISO 17025 accredited methods. The data and figure below show the comparisons between cigarette smoke and Vype ePen aerosol, organized by four public health priority toxicant lists:

(A) the nine WHO TobReg constituents proposed for mandated lowering in cigarette smoke;[36]

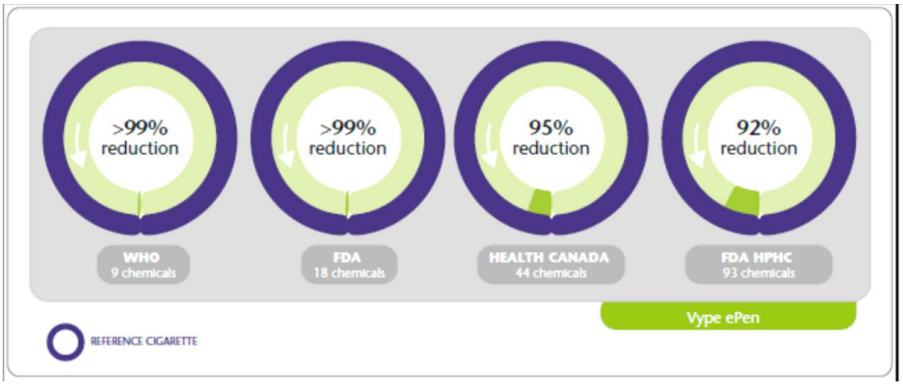
(B) the 18 constituents on the US Food and Drug Administration ("**FDA**") abbreviated harmful and potentially harmful constituents reporting list;[37]

(C) the Health Canada list of 44 tobacco smoke toxicants;[38] and

(D) the full FDA list of 96 HPHCs (other than the three species for which no analytical method was available).

5.1.15 As shown, toxicant levels in the emissions from Vype ePen were from 92% to >99% lower compared to those from the reference cigarette.

Comparison of percent reduction in e-cigarette emissions in comparison to those from a reference tobacco cigarette (Ky3R4F) under HCI puffing conditions



5.1.16 BAT has also commissioned an expert report from Dr. Fagerström, a renowned expert in the study of tobacco, nicotine dependence, smoking cessation, and harm reduction, who states that: "*e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in*

35 J Margham, K McAdam, M Forster, C Liu, C Wright, D Mariner, C Proctor. Chemical composition of an e-cigarette aerosol – a quantitative comparison with cigarette smoke, Chem. Res. Toxicol. 29 (2016) 1662–1678.

36 Burns DM, Dybing E, Gray N*, et al.,* (2008) Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal Tobacco Control 2008;17:132-141. Available here

37 Food and Drug Administration (2012) Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List, April 2012, available here

38 Liu, C., McAdam, K. G., and Perfetti, T. A. (2011) Some recent topics in cigarette smoke science. Mini-Rev. Mini-Rev. Org. Chem. 8, 349−359.

cigarette smoke," and instead "*deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke.*"[39]

5.1.17 Dr. Fagerström also explains in his report that: "*[…] while long term epidemiological data with respect to e-cigarettes is not yet available […] evidence to date indicates that e-cigarettes are unlikely to present significant health risks to both users and non-users. The available evidence indicates that e-cigarette use is not a gateway to the uptake of cigarette smoking. The scientific evidence further demonstrates that e-cigarettes are as effective as nicotine replacement products in helping cigarettes smokers to quit smoking. It is my view, therefore, that the weight of the scientific evidence to date demonstrates that e-cigarettes are an important component of a public health and harm reduction strategy*." **A copy of Dr. Fagerström's report is provided at Appendix 4 to this Response.**

5.1.18 There is general agreement in the scientific community that there is sufficient evidence to support the fact that exclusive use of e-cigarettes that are manufactured to robust quality and safety standards is likely to be substantially less hazardous than smoking conventional cigarettes and that these products have a significant potential to contribute to public health harm reduction. They are able to deliver nicotine to consumers without the vast majority of the hazardous constituents of tobacco smoke whilst simultaneously providing behavioural and sensory aspects of the smoking ritual.

5.1.19 Fairchild *et al* (2018)[40] opine that:

"[h]*arm reduction recognizes that the proposed alternatives carry uncertainties. It involves making a strategic determination: when the risks are considerable – as they surely are with cigarette smoking – moving forward in the face of uncertainty is unavoidable. But the extent to which policies actually reduce harm matters.* ***Opting for a harm-reduction approach in name isn't enough if the specific policies employed are so restrictive that e-cigarettes contribute very little to reducing smoking-related risks in the long term****. To be sure, a permissive approach demands continuous health and safety monitoring along with the will to change course if necessary. Yet if policymakers are serious about mounting a largescale attack on smoking, we believe they must be willing to consider strategies, by any name, that are true to the spirit of harm reduction and could have a population-level effect.*" (emphasis added)

5.1.20 **The Proposal cannot be justified on the basis of the precautionary principle**

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39 See Fagerström Report at ¶ 18

40 Fairchild, A. L., Lee, J. S. Bayer, R., Curran, J. (2018). E-Cigarettes and the harm-reduction continuum. New England Journal of Medicine, 378:216–219.

5.1.21 Contrary to the conclusion reached in the Trimbos Institute Factsheet which is relied on in the Explanatory Memorandum, the lack of scientific certainty as to the absolute level of risk of e-cigarettes is not a justification for taking excessive preventive measures, such as those envisaged by the Proposal, based on the precautionary principle. The application of the precautionary principle must be reasoned and involve an examination of the full range of impacts, which in this case includes denying smokers access to acceptable potentially reduced risk products with the potential public health benefits that this carries.This is underscored by Professor John Britton, the Director of the UK Centre for Tobacco and Alcohol Studies, University of Nottingham, who has stated: "[t]*hose who cite the precautionary principle as justification to discourage or prohibit electronic cigarettes ignore the fact that for the great majority of users, the counterfactual is premature death from tobacco smoking. Smoking kills. So does denying smokers opportunities to quit*."[41]

5.1.22 Moreover, the Court of Justice of the European Union ("**CJEU**") has recently highlighted in Case C-663/18 (the "**Kanavape Case**") that the precautionary principle should only be applied in circumstances where there is a clear understanding of the likelihood and seriousness of harm, stating "*the assessment of the risk cannot be based on purely hypothetical considerations*"[42] and that *"[a] correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of the substance at issue and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research*"[43].

5.1.23 It is simply not sufficient to attempt to justify the Proposal on a vaguely articulated precautionary principle. The Ministry has wholly failed to meet the requirements as set out under EU law: (i) there has been a total failure to identify the negative consequences for health of non-tobacco flavoured e-cigarettes and (ii) there has been no comprehensive assessment of the risk to health based on the most reliable scientific data. To the contrary, as BAT has demonstrated in this response, the overwhelming available scientific evidence does not support the grounds on which the Proposal is made and demonstrates that it will in fact have a detrimental health impact. In this way, the Ministry's Proposal falls squarely into regulation based on 'purely hypothetical considerations' and should not proceed.

41 John Britton: Electronic cigarettes and the precautionary principle.
42 Case C663/18 at 90.
43 Case C663/18 at 91.

5.1.24 **The current evidence also does not establish a significant risk to bystanders from second-hand e-cigarette vapour**.

5.1.25 There are no 'sidestream' emissions (these arise from the tip of the lit cigarette) from vaping. A systematic review of the evidence conducted by Glasser et al (2017)[44] found that: "[s]*econdhand vapor studies to date show that non-users may be exposed to nicotine in ENDS vapor but the level of exposure is low, and exposure to other compounds also appears very low, or at trace or non-detectable levels when compared with secondhand smoke. It is unclear if any levels are sufficient to be of biological concern to humans. More-definitive studies are needed before conclusions about harm can be made*." Indeed Public Health England notes that "*[e-cigarette] use releases negligible levels of nicotine into ambient air with no identified health risks to bystanders*"[45] and that "b*ased on the available evidence, the risk to the health of bystanders from exposure to vapour from nicotine vapourisers is extremely low."*[46]

5.1.26 **There is compelling evidence that e-cigarettes are displacing smoking**.

5.1.27 The evidence from randomized controlled trials, observational studies, and population data indicate that e-cigarettes are a satisfactory alternative to conventional cigarettes for many smokers and that they have contributed to substantial reductions in smoking prevalence following their introduction. Farsalinos *et al*., (2020)[47] examined the association between e-cigarette use and smoking in the Eurobarometer 2017 survey data (which was commissioned by the European Commission). They found that current daily e-cigarette use in the EU in 2017 was rare among former smokers of >10 years and was positively associated with recent (≤5 years) smoking cessation. Former daily e-cigarette use was also positively associated with recent (≤2 years) smoking cessation. Commenting on the study, Dr Farsalinos stated: "*we found a strong association between current daily e-cigarette use and being a former (rather than a current) smoker. Specifically, we found that daily e-cigarette use was associated with 5-fold higher odds of having quit smoking in 2015-2017, and with 3-fold higher odds of having quit smoking in 2012-2015. Another important finding of the study was that e-*

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44 Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of electronic nicotine delivery systems: A systematic review. Am J Prev Med. 2017;52(2):e33-e66.

45 Public Health England, *E-cigarettes: an evidence update*, A report commissioned by Public Health England, p. 65. Available at <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454516/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England.pdf>

46 Public Health England. 2015. *Policies and practice on use of e-cigarettes in enclosed public places: towards a consensus.* Public Health England. Available at: <www.ukctas.ac.uk/ukctas/documents/e-cigarettes-in-enclosed-public-places-final-survey.pdf>

47 Farsalinos KE, Barbouni A., Association between electronic cigarette use and smoking cessation in the European Union in 2017: analysis of a representative sample of 13 057 Europeans from 28 countries *Tobacco Control* Published Online First: 03 February 2020. doi: 10.1136/tobaccocontrol-2019-055190.

cigarette use was extremely rare among former smokers who had quit before the availability of e-cigarettes, showing that e-cigarettes do not result in relapse to an inhalational habit for these former smokers."[48]

5.1.28 In the UK, where there is reasonable means of product distribution and communication, and no restriction on flavours, coupled with the support of the Government and public health authorities, there has been a significant decline in smoking prevalence following the introduction of e-cigarettes:

(A) West et al. (2014)[49] estimated that the availability of e-cigarettes resulted in between 16,000 and 22,000 long-term quitters in England during 2014;

(B) Similarly, Beard et al. (2016)[50] estimated that e-cigarettes may have contributed about 18,000 additional long-term ex-smokers in the England in 2015;

Referring to these studies, the 2018 Public Health England Report concluded that: *"[w]hile caution is needed with these figures, the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England*".[51]

5.1.29 A factsheet by UK Action on Smoking and Health ("**ASH**") on the use of vaping products among adults in Great Britain found that in 2020: "*for the first time, current e-cigarette use has declined year-on-year, from 7.1% to 6.3% of the adult population in Great Britain, amounting to 3.2 million people… Over half (58.9%) of current vapers are ex-smokers and the proportion has grown year-on-year*" and "[a]*s in previous years the main reason given by ex-smokers for vaping is to help them quit (41%) and prevent relapse (20%)*". The report also noted: "*The Annual Population Survey found that smoking prevalence among adults aged 18 and over in England declined by 5.9 percentage points from 2011 to 2019. In 2011, 19.8% of adults smoked, falling to 13.9% in 2019; equivalent to a drop from 7.7 million smokers in 2011 to 5.7 million in 2019*."[52] Zhu *et al*., (2017)[53] assessed the relationship between e-cigarette use and smoking cessation in a representative sample of the US population. They found that e-cigarette users were more likely than non-users to make a quit attempt (65.1% v 40.1%), and 70% more likely to

48 http://www.ecigarette-research.org/research/index.php/research/2020/277-ecig-cess.
49 West R, Shahab L, Brown J. Estimating the population impact of e-cigarettes on smoking cessation in England. Addiction. 2016;111(6):1118-9.
50 Beard E, West R, Michie S, Brown J. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. BMJ Brit Med J. 2016;354:i4645-i.
51 Public Health England (2018), Public Health Matters (Blog) - Turning the tide on tobacco: Smoking in England hits a new low. Available at: https://publichealthmatters.blog.gov.uk/2018/07/03/turning-the-tide-on-tobacco-smoking-in-england-hits-a-new-low/.
52 ASH (2020), Use of e-cigarettes (vapes) among adults in Great Britain.
53 Zhu *et al*., (2017) E-Cigarette use and associated changes in population smoking cessation: evidence from US current population surveys.

succeed in quitting (8.2% v 4.8%); and the overall population smoking cessation rate increased between 2010-2011 (4.5%) and 2014-15 (5.6%) representing approximately 350,000 additional US smokers who quit in 2014-15.

5.1.30 A study by Levy *et al*., (2018)[54] also found that tobacco use among youth is declining as e-cigarette use increases, stating that their findings "*paint a consistent picture of accelerated reductions in youth and young adult smoking prevalence as vaping became more widespread*."

5.1.31 More recently, Kalkhoran *et al*., (2019)[55] found in a longitudinal cohort study of U.S. adult cigarette smokers, that daily e-cigarette use was associated with higher odds of prolonged cigarette smoking abstinence over two years, compared to no e-cigarette use. The authors concluded: "*Daily use of e-cigarettes may help some smokers to stop smoking combustible cigarettes*".

5.1.32 In October 2020, the *Cochrane Collaboration* published an update to its 2014 review into the effect and safety of using e-cigarettes to help smokers achieve long-term smoking abstinence.[56] It assessed the results of 50 studies from across 13 jurisdictions, representing 12,430 participants, of which 26 studies are randomized controlled trials. The authors concluded that "*nicotine e-cigarettes probably do help people to stop smoking for at least six months*". This was based on their findings that "*there is moderate-certainty evidence that* [electronic cigarettes] *with nicotine increase quit rates compared to* [electronic cigarettes] *without nicotine and compared to* [nicotine replacement therapy]". It further noted that "*there was no clear evidence of harm from nicotine* [electronic cigarettes]" based on a two-year follow-up period.

5.1.33 Empirical modelling also suggests an overall beneficial population effect from e-cigarettes. For example, a study by Levy *et al*., (2018)[57] modelled the future population impact if more smokers in the US switched to e-cigarettes. They estimated that taking into account several parameters such as cessation, initiation and relative harm, switching cigarette smokers to e-cigarette use over a 10-year period would lead to 1.6 to 6.6 million fewer premature deaths in the US under pessimistic and optimistic scenarios respectively. The authors concluded that "*a*

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54 Levy *et al*., (2018) Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check.

55 Sara Kalkhoran, Yuchiao Chang, Nancy A Rigotti, Electronic Cigarette Use and Cigarette Abstinence Over 2 Years Among U.S. Smokers in the Population Assessment of Tobacco and Health Study*, Nicotine & Tobacco Research*, , ntz114, https://doi.org/10.1093/ntr/ntz114

56 Hartmann-Boyce et al (*2020*)*, Electronic cigarettes for smoking cessation*, Cochrane Systematic Review – Intervention: https://doi.org/10.1002/14651858.CD010216.pub4

57 Levy DT, Borland R, Lindblom EN, *et al* Potential deaths averted in USA by replacing cigarettes with e-cigarettes Tobacco Control 2018;27:18-25.

strategy of replacing cigarette by e-cigarette use can yield substantial gains, even with conservative assumptions about related risks."

5.1.34 **Concerns regarding dual use which are raised in the Explanatory Memorandum, need to be properly assessed**.

5.1.35 'Dual use' can encompass a wide range of smoking and e-cigarette use patterns, including those who smoke many cigarettes per day and use e-cigarettes only occasionally, those who predominantly use e-cigarettes and smoke only occasionally, and all other combinations of smoking/vaping behaviours. These variations in use and the multiple definitions of 'dual use' used by researchers' compromise the ability to draw accurate and meaningful comparisons and correlations about 'dual users.'[58]

5.1.36 The view, stated in the Explanatory Memorandum, that dual use is more harmful that smoking alone is based on a study by Goniewicz et at. (2018)[59], which is fundamentally flawed and unreliable. There are a number of design issues with this study which undermine its conclusions. For example, there were significant differences in the number of individuals within each group (e.g. ten times as many cigarette smokers compared to e-cigarette users), the make-up of each group varied (i.e. sex, age, race, education level) and the level of cigarette or e-cigarette use was merely based upon a recall questionnaire, which may not represent the true level of use for an individual. Further, the study failed to consider whether levels of any particular chemical were due to smoking, or from another source.[60]

5.1.37 The position regarding dual use stated in the Explanatory Memorandum also fails to take account of a growing body of scientific evidence suggesting that partial substitution of cigarettes with e-cigarettes can reduce smokers exposure to toxicants and ultimately increase movement away from cigarette use completely,

58 Maglia et al (2017) Dual use of electronic cigarettes and classis cigarettes: a systematic review.

59 (M.L. Goniewicz, D.M Smith, K.C Edwards et al., 'Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes.', JAMA Network Open 14 December 2018

60 https://www.sciencemediacentre.org/expert-reaction-to-report-on-nicotine-and-toxicant-exposure-in-vapers-and-smokers/

including Mc Robbie et al, (2014)[61], Abrams et al (2014)[62], O'Connell et al. (2016)[63] and Czoli et al. (2019)[64]

5.1.38 Dual use is often part of a transition away from smoking which can take some time for some smokers. Studies indicate that dual users are more likely to stop smoking. For example:

(A) A study by Etter et al., (2014) [65] which followed vapers over a 12-month period found that 22% of dual tobacco and e-cigarette users had stopped smoking after one month and 46% after one year.

(B) A study by Zhuang et al., (2016)[66] also concluded that: "*This study found that those who used e-cigarettes longer term were more likely to quit smoking. Moreover, those who used short term were no less likely to quit smoking. This suggests that e-cigarette use is more likely, overall, to have a positive rather than a negative impact on smoking cessation*."

5.1.39 A systematic review of the literature on dual use of electronic cigarettes and conventional cigarettes[67] also found that: "*there is an evolving evidence-base to suggest e-cigarette use may promote cessation and reduction among dual users with and without mental illness. This research is important in light of the substantial body of evidence demonstrating that gradual reduction in cigarette consumption aids future quit attempts*." The authors concluded that: "[t]*aken together, the findings indicate a potential role for e-cigarettes in tobacco harm reduction programs, in addition to a possible role as an intervention for smoking cessation. It also suggests that in the studies presented in this review at least, dual use of tobacco and e-cigarettes does not necessarily perpetuate or exacerbate smokers' tobacco addiction and use, as some public health researchers have warned*."

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61 McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub

62 Abrams et al (2014) Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives Annu Rev Public Health. 2018 April 01; 39: 193–213. doi:10.1146/annurev-publhealth-040617-013849

63 O'Connell et al (2016) Reductions in biomarkers of exposure (BoE) to harmful or potentially harmful constituents (HPHCs) following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers Toxicology Mechanisms and Methods, 26:6, 453-464, DOI: 10.1080/15376516.2016.1196282

64 Czoli et al. (2019) Biomarkers of Exposure Among "Dual Users" of Tobacco Cigarettes and Electronic Cigarettes in Canada, Nicotine & Tobacco Research, 2019, 1259–1266 doi:10.1093/ntr/nty174)

65 Etter et al., (2014) *A longitudinal study of electronic cigarette users.* Addict Behav. 2014 Feb;39(2):491-4. doi: 10.1016/j.addbeh.2013.10.028.

66 Zhuang YL et al., (2016) *Long-term e-cigarette use and smoking cessation: a longitudinal study with US populatio*n. *Tobacco control, 25(Suppl 1):i90-5.*. See also Brose LS et al., (2015) *Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with 1-year follow-up.* Addiction,110(7):1160-8.

67 Maglia et al (2017) Dual use of electronic cigarettes and classis cigarettes: a systematic review.

5.1.40 Finally, it is worth noting that the Explanatory Memorandum provides no evidence to support the proposition that flavoured e-liquids cause or otherwise perpetuate dual use of e-cigarettes and traditional cigarettes, and with this submission we have provided positive evidence that disproportionate restrictions in terms of e-liquids' flavours are detrimental to e-cigarette usage and are more likely to lead to consumers resuming smoking/dual use.

5.1.41 **The overall weight of the evidence does not support the Ministry's proposition that there is "increasing" scientific evidence that e-cigarettes act as 'gateway' into smoking**.

5.1.42 We acknowledge concerns regarding youth nicotine and tobacco use and we agree that nicotine and tobacco products should be restricted to adults only. However, the evidence does not support the claim that the use of e-cigarettes causes widespread established nicotine use among non-smokers (including youth) and/or leads to increased smoking.

5.1.43 As noted above, the Ministry has not provided a proper assessment of youth vaping in the Netherlands in order to understand the products they are using (whether they are nicotine or nicotine free products), the characteristics of those youth that are vaping (including whether they are smokers, former smokers or non-smokers), the reasons why they are vaping and whether vaping is causing increased smoking. Without such an assessment, any assertions regarding e-cigarettes impact on youth smoking are merely speculative and unfounded.

5.1.44 Furthermore, as discussed below, data from other jurisdictions does not support claims that e-cigarettes are causing an increase in consumption of combustible tobacco products.

5.1.45 A study by Levy et al., (2018)[68] examined the temporal relationship between vaping and youth smoking using multiple data sets to explore the question of whether vaping promotes smoking initiation in the US. The authors found that "[a] *long-term decline in smoking prevalence among US youth accelerated after 2013 when vaping became more widespread. These findings were also observed for US young adults, especially those ages 18-21. We also found that the decline in more established smoking, as measured by daily smoking, smoking half pack a day or having smoked at least 100 cigarettes and currently smoking some days or every day, markedly accelerated when vaping increased. Like previous analyses, the proportion of daily to past 30-day smoking decreased slowly through 2012, but the extent of the decline in this measure of smoking intensity increased once vaping*

[68] Levy et al., (2018) Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check

became popular. The results were consistent across different surveys, suggesting that the results are robust across different methods of data collection."

5.1.46 In England, where flavours have not been restricted, a 2018 report by Public Health England[69] found that "*[d]espite some experimentation with these devices among never smokers,* [e-cigarettes] *are attracting very few young people who have never smoked into regular use*" and that "*EC use among never smokers in GB remains very rare at less than 1%, similar to the level of use of NRT. Among never smokers who have ever used EC, a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use*."

5.1.47 While the Trimbos Institute Factsheet[70] which is relied on by the Ministry refers to the conclusion in the NASEM Report that there is substantial evidence that e-cigarette use by youth and young adults increases their risk of ever using conventional cigarettes, this is not a finding of causation. Maciej Gonievicz, a member of the NAS committee which conducted the study, stated: **"[t]*he relationship is just correlation. We did not make any conclusion that electronic cigarettes cause smoking…*"**[71] (emphasis added). Levy et al., (2018)[72], also critiques the NASEM Report's conclusion, noting that "[i]*n examining population-level trends in youth smoking, the NASEM Report was limited by its reliance on a single data source, its failure to incorporate past trends in smoking before vaping became popular, and failure to examine trends in established smoking among young adults where the progression to more established smoking is likely to be more apparent*." As discussed above, when Levy et al., (2018) control for previous trends, they find that the downward trend in both current use and more established cigarette use substantially accelerated among US youth and young adults once vaping became popular.

5.1.48 A number of other comprehensive reviews by independent organisations have also criticised 'gateway' arguments that have been made in relation to e-cigarettes and concluded that there is no reliable evidence of a gateway effect.[73]

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69 McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England.* London: Public Health England, 2018

70 S. Troelstra, E. Croes, J. Bommelé, M. Willemsen, 'Factsheet elektronische sigaretten', Trimbos institute, division: National Expertise Centre for Tobacco Control, April 2020.

71 https://globalnews.ca/news/3984754/are-e-cigarettes-harmful-or-helpful/

72 Levy et al., (2018) Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check

73 Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016; *E-cigarettes: an evidence update*: a report commissioned by Public Health England; O'Leary *et al.* (2017*), Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices:* Victoria, BC: Centre for Addictions Research of BC.

5.1.49 Claims that there is an 'epidemic' of youth vaping in the US, which are referred to in the Explanatory Memorandum, have also been shown to be unsubstantiated. West et al (2019)[74] also analysed the US National Youth Tobacco Survey data and found that in never-smokers, regular vaping was rare, nicotine addiction was minimal and the great majority of smokers used tobacco before trying vaping. The authors concluded: **"[d]*ata from the NYTS do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes*** *, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence*." (emphasis added).

5.1.50 A group of independent UK public health professionals also recently stated:[75]

> " […] *experimentation with e-cigarettes occurs predominantly among young people who have already started smoking or are at increased risk of smoking, thus representing a rational choice over the far more hazardous tobacco product. Most importantly, smoking rates among teenagers in the US and UK are falling. The same is true of adult smoking, which is falling in both countries, particularly rapidly in the UK as increasing numbers of adult smokers switch to e-cigarettes. Moreover, parental smoking is one of the main drivers of child smoking uptake, so as e-cigarette use enables more adults to quit so fewer children will have smoking parents as role models and more children will be protected from in utero and passive smoke exposure*."

5.1.51 In light of the above-mentioned comprehensive scientific evidence, it is clear that the overall weight of the evidence does not support the Ministry's proposition that there is "increasing" scientific evidence that e-cigarettes act as 'gateway' into smoking.

6. THE PROPOSAL WOULD HAVE A NUMBER OF UNINTENDED CONSEQUENCES THAT WOULD UNDERMINE, RATHER THAN IMPROVE PUBLIC HEALTH

6.1 Evidence suggests that the Proposal would have a number of unintended consequences that would undermine, not improve, public health.

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74 Robert West, Jamie Brown, Martin Jarvis. (2019). Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios. doi:10.32388/745076.3.

75 Britton et al. (2020) A rational approach to e-cigarettes - challenging ERS policy on tobacco harm reduction. Eur Respir J 2020; in press (https://doi.org/10.1183/13993003.00166-2020).

6.2 **A ban on nearly all flavours in vaping products would severely limit the availability of potentially less harmful alternatives for adult smokers seeking to transition or stay away from combustible cigarettes**.

6.3 The effect of a ban on flavoured e-liquids was explored in the ASH Smokefree Great Britain 2019 Survey[76] where participants were asked what they thought they would do if flavours were no longer available. Around a quarter said they would still try to get flavours. Less than 1 in 10 vapers who use flavoured liquids said they would stop vaping, just under 1 in 5 said they would either smoke more tobacco or return to smoking tobacco. 1 in 10 said they would make their own flavoured e-liquids. This data demonstrates the potential negative consequences that could result from a ban on flavours.

6.4 A US 2017 survey of young adults who use both e-cigarettes and combustible cigarettes also indicated that bans on e-liquid flavours would lead to reductions in e-cigarette use and simultaneous increases in combustible cigarette use.[77]

6.5 As discussed above, a 2018 study[78] which examined 20,836 e-cigarettes users in the US concluded that: "*Restricting the availability of non-tobacco flavours could reduce adult smokers' interest in switching to e-cigarettes or rationalize a return to cigarette smoking among frequent e-cigarette users whose journey towards smoking abstinence started with, progressed to, and is being sustained by frequent use of e-cigarettes containing non-tobacco flavours*."

6.6 The most recent March 2020 PHE evidence update report[79] also found: "*vapers said that banning flavoured liquids would deter them from using vaping products to help them quit or reduce their smoking. It could also push current vapers towards illicit products*." The report concluded: "*a ban on flavoured e-liquids could have adverse effects and unintended consequences for smokers using vaping products to quit. It should only be considered with caution.*"

6.7 A recent expert report commissioned by ASH New Zealand[80] notes: "[t]*here is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black-market flavours – which may be more*

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76 https://ash.org.uk/wp-content/uploads/2019/09/Use-of-e-cigarettes-among-adults-2019.pdf.

77 Lauren R. Pacek, "What Would You Do If…?: Analysis of Young Adult Dual User's Anticipated Responses to Hypothetical E-cigarette Market Restrictions," Duke University, 2017, https://www.rti.org/sites/default/files/related-content-files/pacek_ppt.pdf.

78 Russell, C., McKeganey, N., Dickson, T. *et al.* Changing patterns of first e-cigarette flavour used and current flavours used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* **15,** 33 (2018). https://doi.org/10.1186/s12954-018-0238-6

79 McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England

80 Bates C, Beaglehole R, Laking G, Sweanor D, Youdan B. 2019. A Surge Strategy for Smokefree Aotearoa 2025: The role and regulation of vaping and other low-risk smokefree nicotine products. Auckland: ASH New Zealand and End Smoking New Zealand.

dangerous. Even with young people, there is the possibility that any attraction to flavours is an attraction away from cigarette smoking and may be beneficial, meaning a ban would be harmful."

6.8 **The flavour ban is also likely to be ineffective with consumers resorting to the black market or DIY flavours in order to maintain their current vaping preferences.**

6.9 The risk of a flavour ban incentivising the illicit trade has also been recognised by the United States Food and Drug Administration. In its January 2020 guidance document entitled "*Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*",[81] the FDA stated that it is aware that "*removal of some of the most popular products from the market may be accompanied by an increase in black market versions of these products that may pose additional health and safety risks to consumers beyond those of the authentic products*".[82]

6.10 The banning of flavours could also lead to a proportion of flavour-seeking vapers to move to making their own flavoured e-liquids from ingredients that can be purchased on the internet or from informal sources, with all the risks that this entails. The potential risks of illicit products and tampering with e-liquids are amply demonstrated by the recent spate of EVALI cases in the US, which is referred to in the Explanatory Memorandum. These cases have been strongly linked to products containing vitamin E acetate and/or THC (and not particularly to flavours), and in particular products obtained from informal sources like friends, family, or online dealers.

6.11 **Imposing the same regulation for combustible products to e-cigarettes, as proposed, would also perpetuate current misperceptions regarding the comparative risks of these products and discouraging smokers from switching**.

6.12 Restricting e-cigarette flavours only to tobacco flavours will exacerbate existing misconceptions of the relative risks of e-cigarettes compared to combustible tobacco and is therefore liable to deter consumers from switching from smoking to e-cigarettes, or from using e-cigarettes in preference to combustible tobacco. The Explanatory Memorandum states that "*[b]y regulating flavours for e-cigarettes, the attractiveness of e-cigarettes is reduced and the ability to differentiate the product from other tobacco and related products is reduced. This also reduces the possibility of advertising these products. Use is discouraged and awareness of the harmfulness is increased. This will improve health*." This demonstrates the Ministry's flawed thinking since it has failed to consider the public health benefit of e-cigarettes as a reduced risk alternative to combustible tobacco. Rather than being evidence based, these regulations are being driven by a political ideology of an 'abstinence-only' approach to tobacco that devalues individual autonomy and health literacy.

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81 https://www.fda.gov/media/133880/download

82 Id. at 28.

6.13 Studies show that a substantial portion of the public believes that e-cigarettes are just as dangerous as cigarettes. For example, BAT has also commissioned an expert report from Professor Winer, the William Joyce Professor of Marketing and Deputy Chair of the Marketing Department at the Stern School of Business, New York University. Professor Winer provides his opinions regarding how imposing stringent marketing regulations on potentially reduced risk products ("**PRRPs**"), such as e-cigarettes, may affect awareness of these products and their potential to reduce rates of smoking and smoking-related diseases for existing adult tobacco users who do not want to stop using tobacco and/or nicotine**. A copy of Professor Winer's expert report is provided with this Response at Appendix 5**. In examining these issues, Professor Winer noted that "*There is an increasing body of literature that consumers are confused and ill-informed about the relative risks of PRRPs in relation to combustible cigarettes, and that those misperceptions are growing. For example, a large number of consumers in many markets believe that PRRPs such as e-cigarettes and snus are as risky, if not more risky, than combustible cigarettes.*"[83]

6.14 Even more troubling is that the public's views are growing less accurate as time goes by. Research from King's College London found that smokers and ex-smokers in the UK overestimate the harm from vaping, with fewer than 6 out of 10 accurately believing that e-cigarettes are less harmful than tobacco cigarettes. Lead researcher Dr Leonie Brose from the Institute of Psychiatry, Psychology & Neuroscience at King's College London stated: "[i]*t is possible that smokers may not try e-cigarettes or NRT [nicotine replacement therapy] due to inaccurate beliefs about nicotine and vaping. A lot of public discussion and media reporting focuses on harms from vaping, but we rarely see any reports on how deadly smoking is – 1500 people die from smoking-related illness every week in England alone. Correcting misperceptions around nicotine may help smokers move towards less harmful nicotine delivery methods*."

6.15 A recent study carried out by Perski et al. (2020) reviewed the association between changes in harm perceptions and e-cigarette use among current tobacco smokers in England between 2014 and 2019. The authors found that between 2014 and 2019, at the population level, there was a decline in the proportion of tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes. There was also a decline in the proportion of tobacco smokers who reported the use of e-cigarettes during this time period. After adjusting for potential confounders and underlying trends, the decline in the belief among current smokers that e-cigarettes are less harmful than combustible cigarettes was strongly associated with declines in the use of e-cigarettes among current tobacco smokers in England. For every 1% decrease in the mean prevalence of current tobacco smokers who

[83] Winer Report at ¶14.

endorsed the belief that e-cigarettes are less harmful than combustible cigarettes, the mean prevalence of e-cigarette use decreased by 0.48%.

6.16 BAT has also commissioned an expert report from Professor Kip Viscusi, that examines the evidence on consumers perceptions of the risk of e-cigarettes and other potentially reduced risk nicotine products compared to cigarettes, and the relationship of these beliefs with the use of these alternative nicotine products. Professor Viscusi is the Distinguished Professor of Law, Economics and Management, Vanderbilt University Law School, Nashville, United States and is a renowned expert on risk perceptions and how they affect consumer behaviour. He has published more than 400 articles and 30 books dealing primarily with health and safety risks, and has been ranked among the top 25 economists in the world based on citations in economics journals. **A copy of Professor Viscusi's expert report is provided at Appendix 6 to this Response.**

6.17 In his report, Professor Viscusi examines the current literature regarding consumers perceptions of the risks of e-cigarettes and presents an analysis of data from a new survey conducted in 2020 in seven European markets, including the Netherlands[84]. Professor Viscusi notes that numerous studies and comprehensive reviews by public health authorities have stated that e-cigarettes are less harmful than conventional tobacco cigarettes. Nevertheless, independent surveys in the UK and the US which Professor Viscusi discusses in his report, show that many people believe that e-cigarettes are as harmful or more harmful than cigarettes. These misperceptions of the estimated harms of e-cigarettes are increasing over time. Furthermore, there is evidence that these misperceptions are closely associated with stringent regulatory restrictions on e-cigarette use, with respondents who have these views being less likely to use e-cigarettes instead of cigarettes.

6.18 Analysis by Professor Viscusi of the data from the new survey conducted in seven European markets, is consistent with this evidence, and finds, *inter alia*:

6.18.1 43% of the sample view e-cigarettes as being the same as or more harmful than cigarettes.

6.18.2 For current cigarette smokers who consider the harm levels from e-cigarettes to be the same or more harmful compared to cigarettes, 37% currently use e-cigarettes. This is strongly reversed for current cigarette smokers who consider e-cigarettes to be less harmful than cigarettes, with 65% of this group currently using e-cigarettes.

6.18.3 For those who use e-cigarettes, having low levels of comparative harm beliefs is also associated with not smoking cigarettes. For those e-cigarette users who consider that e-cigarettes are less harmful than cigarettes, 54% do not smoke

[84] The countries included in the sample are the United Kingdom, Belgium, Denmark, the Netherlands, France, Germany, and Italy.

cigarettes. The pattern is strongly reversed for those who consider the risks to be just as harmful or more harmful, as 63% of this group currently smoke cigarettes.

6.19 Regression analysis undertaken by Professor Viscusi also found that those who consider e-cigarettes to be less harmful than cigarettes are 33% more likely to currently use e-cigarettes.[85]

6.20 Professor Viscusi concludes that non-combustible tobacco and nicotine products merit quite different treatment than conventional cigarettes, and that this principle should be carried over across all dimensions of government and regulatory policies. These efforts include, among others, advertising bans and limitations, retail display bans, and requirements regarding the use of plain or standardized packaging as well as restrictions on ingredients/flavours and the imposition of taxes. Efforts that adopt the same regulatory approach as is used for tobacco cigarettes will continue to reinforce consumers' misperceptions regarding the comparative estimated risk of these products. In fact, in this specific context, the use of an exhaustive positive list of ingredients even exceeds the restrictions currently imposed vis-à-vis combustible tobacco products which is likely to have a serious adverse impact on consumer perceptions of risk regarding the different products, thus undermining tobacco harm reduction and negatively affecting public health accordingly – clearly illustrating the lack of basis for the Proposal.

6.21 The danger of excessive regulation like the proposed flavour ban was also recognised by the U.K. Royal College of Physicians in its 2016 Report, in which it stated:

"*A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However,* ***if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking***."[86] (emphasis added).

6.22 This risk of excessive regulation was also underscored in a recent independent, peer-reviewed research publication which found that:

"[w]*ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and by country income" and* "[i]*n contrast to many of the* [less restrictive policies] *and* [restrictive policies*] countries, rates of use were quite low in the* [most restrictive policies] *countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of* [nicotine

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85 This relationship is statistically significant with a 95% confidence level.

86 Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction.

vaping products] *laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them*".[87]

This study thus confirms the relationship between restrictions on e-cigarettes and the levels of switching to these products by adult tobacco consumers – that is, between highly restrictive regulatory regimes and low uptake on the one hand, and between less restrictive regimes and higher switching on the other.

6.23 BAT has also commissioned an expert report from Professor Kessler, a tenured professor at Stanford Law School and the Stanford Graduate School of Business. Professor Kessler assesses, based on available empirical evidence, whether public health law should impose tobacco-like regulatory restrictions or outright bans on the sale of e-cigarettes and other PRRPs. **A copy of Professor Kessler's expert report is provided with this Response at Appendix 7.** In this report, he concluded:

"*Given that the availability of PRRPs creates significant health benefits that outweigh any potential health harms, and that accepted international public-health principles require States to devise policies that weigh health benefits and harms, States should regulate PRRPs less stringently than CT* [combustible tobacco]. *This conclusion is strengthened by evidence that the health benefits from PRRP availability accrue disproportionately to disadvantaged groups: people from disadvantaged groups are not only more likely to use EC* [e-cigarettes]*, but also more likely to successfully quit smoking using EC. Moreover, because restrictions on PRRPs generally increase smoking – thereby resulting in net harm to the population – such restrictions should be adopted only after analysis to ensure that their net benefits, in terms of harm reduction, exceed their costs, in terms of restricting access to a proven tool for smoking reduction and cessation*".[88]

6.24 Further, BAT has commissioned an expert report from Professor Jan Wouters (Professor of International Law at the University of Leuven, Belgium), which examines whether the FCTC applies to Alternative Nicotine Delivery Systems ("ANDS"), including e-cigarettes, THPs and modern oral nicotine products. Professor Wouters in concluding that these products do not fall within the scope of application of the FCTC, notes "*The harm reduction approach to tobacco control in the context of ANDS has much support from a range of stakeholders. The letter of 72 health experts to the WHO referred to earlier in this opinion emphasizes that authorities should "adopt a more positive approach to new technologies and innovations that have the potential to bring the epidemic of smoking-caused disease to a more rapid*

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87 Gravely, et al (2019) Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project, Addiction. doi: https://doi.org/10.1111/add.14558.

88 Kessler Report at ¶26.

conclusion[89]". **A copy of Professor Wouter's expert report is provided with this Response at Appendix 8.**

6.25 Commenting on a flavour ban in the US, the former director of UK ASH, Clive Bates opines that the likely consequences include[90]:

- The closure of thousands of small to medium-sized businesses (vape stores and manufacturers) as the products they make and sell are predominantly flavoured.
- A transfer of the supply of flavoured products from legitimate American businesses to highly professional consumer-facing Chinese internet-based suppliers;
- The development of a new and flourishing black market in flavoured nicotine e-liquids manufactured by amateurs, opportunists, and criminal enterprise;
- Migration of users to the existing unregulated sub-culture of DIY mixing of nicotine and food flavours; and
- Vapers or dual users possibly reverting to smoking or the use of other tobacco products and current smokers who would otherwise switch to vaping in the future possibly remaining as smokers.

Similar consequences are likely also in the Netherlands if the Proposal proceeds and these were not assessed at all by the Ministry, which renders the Proposal flawed, unjustified and disproportionate.

7. THE PROPOSAL IS UNWORKABLE

7.1 The Proposal seeks to ban non-tobacco flavours in e-cigarettes by creating an exhaustive list (a positive list) of additives/ingredients that can be used to impart flavour in e-cigarette liquids or components. This approach in the Proposal, however, is unworkable for a number of reasons.

7.1.1 **It is not possible to compose a workable positive list of flavour additives solely using disclosures made in the EU-CEG reporting system.**

7.1.2 Each flavour is a unique and often commercially/trade secret formulation. Within the EU-CEG reporting system there is no express field to describe a product's flavour and nor is it evident from a product descriptor. The chemical name of the ingredient and the weight of the ingredient used (according to the recipe) that is

89 See https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf, at p. 1.
90 Bates (2019) The US vaping flavour ban: twenty things you should, https://www.clivebates.com/documents/Flavours20Nov2019.pdf

submitted to the EU-CEG system by the manufacturer or importer is likely to occur in an inconsistent fashion and with varying levels of detail. For instance, markets such as the UK and France have said that ingredients below 0.1% can be grouped together under a handle name. These informational issues with the EU-CEG database are well-attested to by Kruseman[91] who states "*2586 e-liquids (15% of the entire dataset) could not be classified as flavour-related information was unspecific, incomplete or even unavailable. For example, it was not possible to classify e-liquids with generic brand names that are unrelated to a flavour (eg, 'Spaceship' or 'Purple Unicorn', hypothetically*)." Similarly, Havemans also notes "*Because of limited or unspecific flavour-related information from EU-CEG, classification of approximately one-third of the e-liquids required an internet search*".[92]

7.1.3 Whilst BAT provides ingredient disclosures into the EU-CEG reporting system at the individual ingredient level. This level of detail may not be the case for all manufacturers or importers, particularly for users of 'proprietary flavour blocks' that are often purchased as "off the shelf-formulations" from Flavour Houses, who will also need to protect commercially sensitive information. In these instances, for intellectual property reasons, the manufacturer or importer may be unlikely to have access to all the individual, and levels of, ingredients that create the flavour block. They should, however, at a minimum be able to verify the quality of the ingredients and that they meet safety standards for e-liquids.

7.1.4 Without provision of all ingredient information to the Ministry, the composition of a complete and accurate positive list would not be possible. What has been disclosed in the EU-CEG reporting system at 1 June 2020 (i.e. the point in time that the Ministry intents to capture its data) is unlikely to be concise or comprehensive enough to be able to construct a workable flavour list that is built on scientific principles and rigour.

7.1.5 **Supportive sensory research would be required**.

7.1.6 Most of the time it is impossible to define and distinguish a flavour based on its chemical name only. Flavours have a unique composition of multiple flavouring ingredients to give rise to a sensorial flavour note. Information submitted by manufacturers or importers to the EU-CEG reporting system, does not necessarily represent the flavour description or flavour as perceived by consumers sensorially. Irrespective of how long or short the list is from EU- CEG, this approach could result in legitimate tobacco flavourings being prohibited because they can impart a non-

91 Krüsemann EJZ, et al. Tob Control 2020;0:1–7. doi:10.1136/tobaccocontrol-2019-055447.
92 Havermans A, et al. Tob Control 2021;30:57–62. doi:10.1136/tobaccocontrol-2019-055303.

tobacco flavour on their own or in a combination with another ingredient. Selecting flavours because of frequency of presence in e-liquids is an example of cherry-picking without following any sound scientific principle.

7.1.7 In Canada, the federal regulation prevents the use of flavours that are confectionary, dessert, cannabis, or that relate to soft drinks or energy drinks. By prohibiting the use of such flavours, manufacturers cannot use flavours that clearly impart a flavour attribute listed above. Taking this more targeted approach is a far more appropriate way to achieve the aims that the Government seeks to achieve and would be more straightforward to define and implement.

7.1.8 **Inclusion levels for ingredients (if they are to be used) can have a significant impact on the variety of tobacco flavours that would be permitted but there is no detail in the Proposal on how these will be set.**

7.1.9 The Proposal sets out that not only will specific ingredients be listed, but the Ministry will also have the power to prescribe the maximum inclusion levels of such flavourings and / or ingredients. There is, however, no explanation as to how the hugely technical task of analysing the ingredients on a proposed positive list and setting any maximum inclusion limits will be carried out. For example, the flavouring "X" at a high concentration level might not impart a specific flavour attribute but will be more complementary to balance the overall composition. Conversely, a flavouring "Y" at a low concentration level may have a low sensorial threshold by imparting a more intense and specific flavour attribute.

7.1.10 **Achieving the correct balance between not restricting tobacco flavours and not permitting other non-tobacco flavour profiles is unlikely to be possible, at least without considerable time and specific expertise.**

7.1.11 Further, when characterising "tobacco" it is not as simple a single flavouring. In fact tobacco imparts a broad range of flavour attributes. If the Ministry is wanting to limit to a single flavour type then it merits flavourist expertise to generate a tobacco flavour wheel / library. This will set a framework to categorise "tobacco" flavour notes, the ingredients used, and prevent overspill into other flavour types or territories. In 2016, Krussmann et al highlighted the importance of establishing a methodology that will assist "*to detect flavour additives that are characteristic for a certain flavour, and thus can be useful for regulation of flavours in tobacco and related products …"*[93]

[93] Identification of flavour additives in tobacco products to develop a flavour library Erna JZ Krüsemann, Wouter F Visser, Johannes WJM Cremers, Jeroen LA Pennings, Reinskje Talhout. (http://dx.doi.org/10.1136/ tobaccocontrol-2016-052961)

7.1.12 The Proposal is likely either to result in a positive list, drawn up from chemical ingredient information and not necessarily representative of the flavour perceived by the consumer, which is too narrow or too broad. A list that is too narrow will provide an unsatisfactory product, and may risk smokers reverting to cigarettes to see satisfaction from a tobacco 'flavoured' product. Conversely, a list that is too expansive will not guarantee non-tobacco flavours are not produced given the complexity of flavour compositions whereby different ingredients can be mixed in different proportions to create significantly different flavour profiles.

7.1.13 Removing and adding specific flavouring ingredients will have the effect of augmenting or attenuating different tobacco or non-tobacco attributes. Tobacco flavour ingredients have specific attributes but are also core to other non-tobacco flavourings. In 2017, Krussmann et al identified 8 common flavouring ingredients that supposedly make up a tobacco flavour. However, these 8 tobacco flavours are made up from a composition of many other ingredients. Furthermore, Krussmann identified the top five flavouring ingredients across 16 flavour categories (e.g. nuts, tobacco, candy, fruits etc). Four of the top five tobacco flavouring ingredients, were also found to be predominant flavouring ingredients in 12 other flavour categories.[94]

7.1.14 **Flavour profiles are highly commercially sensitive trade secrets**.

7.1.15 Flavour profiles are trade secrets which require protection. Requiring the disclosure of all the ingredients currently used in the composition of the different tobacco flavours on the market would violate these trade secrets, which are property rights, and create market distortion. This is reflected in the fact that elements of ingredient disclosures/notifications via the EU-CEG reporting system are made confidential to preserve business/supplier information. For example, as a result of the publicly available list, a flavour house could potentially consider using an ingredient in a tobacco profile which had not previously been considered.

7.1.16 **The Proposal provides no mechanism for keeping the positive list up to date in a developing market**

7.1.17 The Proposal is to create a positive list based on flavouring ingredients present in liquids registered for the Dutch market on 1 June 2020. However, manufacturers are constantly researching and innovating their flavour profiles based on an ever-changing combination of ingredients/additives at varying inclusion levels. The idea of a fixed ingredients list therefore fundamentally misunderstands the dynamism of the market as it represents a snapshot at a single point in time. Additionally, as products are notified at least 6 months prior to being placed on the market, it is possible that some products, which have entered the market after 1 June 2020,

94 Krüsemann EJZ, et al. Tob Control 2020;0:1–7. doi:10.1136/tobaccocontrol-2019-055447

were not on the market when the original data was collated from the EU-CEG reporting system. The proposal contains insufficient information or processes concerning how new or old ingredients could be added or removed from the positive list.

7.1.18 **The proposed methods of enforcement will not work in practice**

7.1.19 The proposed monitoring of compliance with the regulation by cross-referring ingredients lists provided on packaging in the EU-CEG reporting system against a positive list will be ineffective. Product packaging and/or leaflets do not contain full ingredients lists with inclusion levels. In reality, some manufacturers or importers are unlikely to list an ingredient that they know is not on a positive list or they may not be aware that an ingredient on the positive list is present in the flavour block that they are using. For the reasons stated above, the detail of submissions to the EU-CEG reporting system will continue to have an element of confidentiality around this sensitive information which even if available to enforcement agencies may not be in sufficient detail. It would therefore not be possible to enforce the restrictions without a full analysis of each product.

7.1.20 The alternative regulatory options identified in 11.3 below are better targeted to reducing youth access and initiation and will be more effectively enforced in practice.

7.1.21 Whilst it is stated that the Proposal seeks to make the requirements unambiguous and easy to monitor, it leaves uncertainty around a number of elements. First, it is not clear how a tobacco flavour will be interpreted, for instance, if some fruit flavour is detected in natural tobacco, will fruit flavours accordingly be permitted? Second, whilst it is stated that the Proposal seeks to make the requirements unambiguous and easy to monitor, it leaves uncertainty around the determination of the “purpose” of inclusion of specific ingredients. Under the Proposal it is permissible to add substances that generate a flavour - but which are not included for the purpose of generating a flavour. To determine the "purpose" behind the inclusion of ingredients would require an evidential inquiry and potentially expert analysis. This creates similar issues to those regarding the use of sensory expert panels, including costs and delays, which the Ministry states it wants to avoid; and calls into question the claim that enforcement of the Proposal will be efficient and effective.

8. THE PROPOSAL CONTAINS A CONCERNING LACK OF CLARITY AND UNDERMINES BUSINESS CERTAINTY

8.1 The Proposal contains a concerning lack of clarity and will create uncertainty for the industry, undermining investment in operations:

8.1.1 **The Proposal contains an alarming lack of clarity concerning the process of creation and maintenance of the positive list.**

8.1.2 The Proposal contains wholly insufficient detail around the process of determining which ingredients will be set out in the positive list, at what inclusion levels and how new ingredients would be added. The breadth of the Ministry's discretion is therefore extremely broad and it is alarming that there is not a requirement for the Ministry to undertake meaningful consultation with stakeholders in relation to the preparation of the proposed list before it is finalised. This is particularly concerning in light of the seismic impact the proposed list would have on the industry, banning large proportions of e-cigarettes.

8.1.3 **There is a risk of contradiction with impending EU-level Regulation**

8.1.4 The EU has commenced the process for the revision of the current EU tobacco and e-cigarette rules which should result in the adoption of a new piece of EU legislation, the so-called TPD3. It is well understood that – as part of this process – the EU is considering whether or not to introduce restrictions on the use of flavours in e-cigarettes.[95]

8.1.5 In these circumstances, it would be clearly wrong for the Netherlands to proceed with the adoption of their own national rules regulating the same topic as these would likely be inconsistent with the coming EU rules and would, therefore, have to be changed rapidly following the adoption of TPD3.

8.1.6 **This risk of conflicting legislation is increased pursuant to the need to comply with the TRIS Directive**

8.1.7 Before any Dutch legislation banning e-cigarette flavours is adopted, a draft will have to be notified to the European Commission under the TRIS Directive. This is to allow the Commission and other Member States to assess whether it creates obstacles to the free movement of goods within the internal market.

8.1.8 The notification will trigger a 3 to 6 months standstill period during which the Netherlands will have to refrain from adopting the new legislation. Moreover, as the regulation of e-cigarette flavours is currently being considered at EU level, the standstill period could be extended to 12 or even 18 months from the date of the notification. During this time, the Netherlands will be prevented from adopting the legislation pursuant to Article 6(3) and 6(5) of the TRIS Directive. Thus increasing the prospect that conflicting EU-level regulation could be implemented imminently after the Dutch legislation.

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95 See, e.g., the SCHEER Preliminary Opinion on Electronic Cigarettes which was prepared in the context of the TPD revision and specifically discusses the impact of flavours.

8.1.9 This strengthens the view that the appropriate and efficient course of action is to await the outcome of the ongoing EU process.

8.1.10 **The above combination of factors create uncertainty which will have an adverse impact on the industry**

8.1.11 Not only would this be an inefficient approach to legislating, it would also further undermine business certainty, infringing the principles of legal certainty as enshrined in Dutch law, and impose a disproportionate burden on e-cigarette manufacturers and retailers to comply with such ever-changing rules.

8.1.12 Manufacturers are investing in constant research and development concerning flavour profiles and ingredients which could be rendered void by the Proposal or TPD3. This uncertainty has the potential to undermine innovation.

8.1.13 Accordingly, this uncertainty also represents an unlawful interference with manufacturers' right to conduct business and contradicts their legitimate expectations.

9. THE PROPOSAL IS UNLAWFUL

9.1 The Proposal engages a number of legal rights which call into question their legality. These include that:

9.1.1 **The Proposal has no legal basis under Article 24(3) of TPD2.**

9.1.2 The Proposal exceeds the scope of the TPD2 which contains no such restriction on flavours in e-cigarettes. The provisions of the TPD2 illustrate that the EU considers these provisions to adequately and proportionately pursue the objective of protection of public health. To the extent a Member State wishes to diverge from this regulation, this is only lawful in limited and exceptional circumstances either on the basis of Article 24(3) or if the regulations are "justified" and notified pursuant to Directive 2015/1535 on Technical Regulations ("TRIS Directive). The Proposal is not permissible under either of these, the latter of which is discussed further below.

9.1.3 Article 24(3) TPD allows Member States to prohibit "*a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive*". This is clearly not available in these circumstances.

(A) Article 24(3) only authorises the prohibition of a category, not the ban of flavours within a certain category.

(B) Divergence from the scope of the TPD must be justified on the basis of some exception circumstances in the Member State. Article 24(3) states that a Member State may prohibit a certain category of tobacco or related products "*on grounds relating to the specific situation in that Member State*". The Ministry has wholly failed to particularise any specific exceptional circumstances which affect the Netherlands thus warranting the need for divergence from the TPD2 provisions.

(C) Article 24(3) requires that the measures must also be justified by the need to protect public health taking into account the high level of protection of human health already achieved through the Directive and the Commission must be notified for the purposes of approving Member State divergence. This illustrates the exceptionally high threshold which must be met in these circumstances. As set out above, it is evident that this threshold has not been met - there is no justification on public health grounds, and in fact the Proposal is likely to have an adverse impact on public health.

9.1.4 **The Proposal would restrict the free movement of goods between the Netherlands and other EU Member States.**

9.1.5 In addition to the lack of legal basis under Article 24(3) the introduction of the Proposal also violates the free movement of goods within the EU and is therefore unlawful.

9.1.6 It is self-evidently the case, as acknowledged in the Explanatory Memorandum, that the Proposal will restrict the movement of goods within the EU. The Proposal will partition the internal market by imposing purely national conditions and requirements on the ingredients in the Netherlands. In doing so, it will prevent the access of many flavoured e-cigarettes in the Netherlands.

9.1.7 Whilst, as noted in the Explanatory Memorandum, it is open to a Member State to restrict free movement on the grounds of protection of public health, it is settled law that any measure inconsistent with Article 34 TFEU may only be justified on Article 36 TFEU grounds (including for the protection of human health) – if the measure complies with a strictly-applied test of proportionality.

9.1.8 The Dutch ban cannot be justified under the exceptions set out in Article 36 TFEU. As recently confirmed by the CJEU in the Kanavape Case, [96] even where, as in the

[96] Case C-663/18 *B S and C A (Commercialisation du cannabidiol - CBD)* ECLI:EU:C:2020:938.

present case, the justification for a ban is the protection of public health, the Member State has a high bar to meet, requiring more than a bare assertion of public health objectives. The CJEU held that where a product is lawfully produced and marketed in one Member State, it can only be banned in another Member State if such a restriction of free movement can be justified on the basis of "available scientific data" that (a) a real risk for public health was sufficiently established, (b) the restriction was proportionate and (c) the public interest is being pursued in a consistent and systematic manner[97]". The CJEU further emphasised that "*the assessment of the risk cannot be based on purely hypothetical considerations"*[98].

9.1.9 This high threshold is particularly the case in light of Article 24(3) of the EU TPD2, which, as discussed above, creates a de facto presumption that, save for detailed and specific justification, restrictions on free movement arising from divergence from the TPD2 shall not be lawful.

9.1.10 Moreover, as discussed above, the precautionary principle cannot render lawful this otherwise unlawful Proposal. The CJEU judgment in the Kanavape Case makes clear that the precautionary principle is only applicable in limited circumstances where there is a clear understanding of the likelihood and seriousness of harm, based on scientific data, and cannot be cited merely on the basis of purely hypothetical considerations.

9.1.11 It is manifestly clear that the Netherlands has wholly failed to discharge its burden of justifying an infringement to free movement. The Ministry has failed to conduct an adequate proportionality analysis, nor has it provided evidence substantiating the efficacy of the Proposal. As outlined in this consultation response, the Proposal will undermine public health, is unworkable, unenforceable and there is a myriad of less restrictive alternative measures. The Proposal is unjustified, non-sensical and manifestly disproportionate.

9.1.12 Further, the prohibition on flavours would not pursue the stated public health objective in a consistent and systematic manner. To the contrary, the Proposal would create bizarre inconsistencies. For instance, the Proposal would create the absurd result that the use of some flavours would be allowed in more harmful tobacco products such as cigarillos and other tobacco products but would be banned in e-cigarettes that can be expected to pose significantly less risk to human health. Moreover, individuals would be prevented from using potentially significantly reduced risk flavoured e-cigarettes whilst simultaneously being able to

97 Case C663/18 at 87.
98 Ibid at 90.

freely use more harmful, psychotropic cannabis with all manner of flavours in coffeeshops.

9.1.13 Accordingly, the Proposal does not satisfy the general conditions allowing the restriction of the free movement of goods under the TFEU and must be quashed as unlawful.

9.1.14 **The Proposal would infringe on consumers' personal choice and right to privacy**.

9.1.15 The Proposal would deny adult smokers' access to certain potentially reduced risk products that they prefer, including in private, for the purpose of switching away from smoking combustible cigarettes. The Proposal is also inconsistent with the internationally protected right to health, as it deprives smokers of access to products that are likely to be less harmful to health (as endorsed by leading health regulators and experts around the world).

9.1.16 The right to privacy also enshrines the right to individual self-determination with regards to one's own health. For example, commenting on the right to privacy in Article 8 of the ECHR, the European Court of Human Rights has confirmed:

> "*The Court would observe that the ability to conduct one's life in a manner of one's own choosing may also include the opportunity to pursue activities perceived to be of a physically or morally harmful or dangerous nature for the individual concerned. The extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and jurisprudential discussion, the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate. However, even where the conduct poses a danger to health, or arguably, where it is of a life-threatening nature, the case-law of the Convention institutions has regarded the State's imposition of compulsory or criminal measures as impinging on the private life of the applicant within the scope of Article 8(1) and requiring justification in terms of the second paragraph*".[99]

9.1.17 In this case, the Proposal cannot be justified in any way because, in imposing the Proposal, the Government is depriving smokers of access to potentially significantly reduced risk alternatives.

9.1.18 **The Proposal violates manufacturers' and retailers right to conduct a business, property rights, including trademark rights, and free speech rights**.

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99 *Pretty v United Kingdom* (2002) 35 EHRR 1.

9.1.19 The Explanatory Memorandum acknowledges that these rights are engaged by the Proposal. Whilst, as noted in the Explanatory Memorandum, governments can restrict the above rights on the grounds of protection of public health, any measure must comply with a strictly-applied test of proportionality. However, since the evidence shows that the Proposal would be likely to undermine public health rather than improve it, there is no basis – and certainly no proportionate basis – to justify the Proposal.

9.1.20 The Proposal is also discriminatory in that it regulates fundamentally different product categories from the same or similar perspective, irrespective of the fact that this is inappropriate given the reduced risk potential of e-cigarettes relative to combustible cigarettes. In fact, in this context, e-cigarettes would be subject to restrictions which exceed those imposed against combustible tobacco products, which, as discussed above, risks perpetuating misconceptions regarding the different products' risk profiles and adversely impacting tobacco harm reduction.

9.1.21 Further, the Proposal will likely result in the insolvency of a number of legitimate manufacturers and retailers, particularly having a disproportionate and discriminatory impact on small to medium-sized businesses (vape stores and manufacturers) that make and sell predominantly flavoured products. In light of the economic strain arising from the coronavirus pandemic, the Ministry should be extremely cautious in introducing legislation with such severe economic consequences particularly in the absence of compelling justifying evidence.

10. THE PROPOSAL WOULD VIOLATE THE NETHERLANDS' INTERNATIONAL OBLIGATIONS

10.1 The Proposal would violate international obligations under World Trade Organization Agreements. A ban on flavours would amount to technical regulations that are more trade restrictive than necessary to achieve the legitimate policy objective of protecting public health and thus violate obligations under Article 2.2 of the WTO TBT Agreement. The Proposal would also effectively restrict imports in violation of GATT Article XI which forbids the imposition of any prohibition or restriction on importation other than duties, taxes or other charges. The "prohibition" on importation of flavoured e-liquids represents an absolute numerical limit (of zero) on the amount of imports that can be made, and thus serves as the ultimate quantitative restriction. This is comparable to a ban imposed on the importation of certain periodicals in Canada – Periodicals, where the WTO panel found that "[s]*ince the importation of certain foreign products into Canada is completely denied…, it appears that this provision by its terms is inconsistent with Article XI:1 of the GATT 1994*."[100]

[100] Panel Report, *Canada – Periodicals* (1997) WT/DS31/R, para. 5.5.

10.2 BAT has commissioned an expert report from Professor Petros C. Mavroidis (professor of WTO Law at Columbia Law School, New York and at the University of Neuchâtel) which examines the consistency with WTO law of a measure that would ban the importation and sale “Alternative Nicotine Delivery Systems” ("ANDS") including e-cigarettes (“ENDS”). Professor Mavroidis concludes that an import ban on ANDS violates Article XI of GATT, since it constitutes a prohibition on importation, and thus a prohibited zero import quota. He also considers that there are good reasons to believe that the regulating Member will not meet the necessity-requirement under the general exceptions of Article XX of GATT, as is required, in order to mount a successful defence of its otherwise GATT-inconsistent measure. He states:

"*The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary, it seems. In any case, even if the regulating Member were to be successful in demonstrating the “necessity” of the ban on ANDS, its measure will fail the requirements of the chapeau of Article XX of GATT. This is so because, the ban is a disguised restriction on trade and applied in a manner that constitutes unjustifiable discrimination: in the name of protecting human health (and/or public morals), the regulator will be banning the sale of certain goods while not banning the sale of like goods* [i.e. traditional cigarettes] *that are at least as harmful to health and probably much more harmful to health. Thus, it will find it impossible to explain why its decision to ban some and not other (more harmful) products, is rationally connected with the health objective of the measure*."

A copy of Professor Mavroidis' report is provided with this response at Appendix 9.

10.3 Although Professor Mavroidis was considering a ban on the category, the circumstance at issue in this consultation is not dissimilar, entailing a ban on large proportions of the e-cigarette category. This same reasoning would also apply to a ban on non-tobacco flavoured e-cigarettes. As explained above, the measure does not contribute to the protection of health and there are a multitude of alternative less restrictive measures. Further, the measures create unjustifiable discrimination whereby less harmful e-cigarettes are regulated more restrictively than more harmful tobacco products and psychotropic drugs.

11. THERE ARE ALSO NUMBER OF ALTERNATIVE REGULATORY OPTIONS THAT ARE MORE PROPERLY TARGETED TO REDUCING YOUTH ACCESS AND INITIATION.

11.1 As discussed above, because flavours play an important role in helping adult smokers transition to e-cigarettes and contribute to smokers finding e-cigarettes satisfactory alternatives to conventional cigarettes, the continued availability of flavours in e-cigarettes is vital.

11.2 The (misplaced) concern regarding non-tobacco flavours and youth initiation would also be more effectively targeted by the introduction of restrictions on certain labelling and

descriptors that are targeted at youth. For example the Ministry could consider a ban on using any indication or illustration of a flavour that would be appealing to youth (such as the use of descriptors like 'bubble gum' or descriptors for alcoholic drinks which is raised as a concern in the Explanatory Memorandum). This would protect against flavour descriptors and labelling that are targeted at youth while still allowing adult smokers and vapers access to a broad range of e-cigarettes to suit their varying preferences. Moreover, such a measure would be capable of enforcement without recourse to additional, time-consuming scientific ingredient-based investigations

11.3 Other measures that should also be considered are:

11.3.1 Enforcing quality and safety standards, including with respect to flavours. Such standards should be followed to minimise the risk of potentially hazardous contaminants being used in flavours. In particular:

(A) All ingredients should be of the highest quality: only pharmaceutical grade nicotine and humectants should be used and flavourings should be food grade. Ingredients classified as CMRs (carcinogenic, mutagenic and reprotoxic) and respiratory allergens should be prohibited in e-liquids, including ingredients on the negative list considered in the EU Tobacco Products Directive, and as outlined in national vaping standards.[101]

(B) Toxicological risk assessments should be conducted in accordance with the framework for the risk assessment of flavours in e-cigarettes set by the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment ("COT"). This provides a framework that all responsible producers should adhere to when conducting their vaping scientific toxicological risk assessment.[102] We support the ban of ingredients that are shown to increase the toxicological effects of the product.

11.3.2 Enforcing product labelling and information standards, including potential (food) allergens and banned ingredients (see, for example, the Global Harmonized System (GHS) for classification and labelling of contact and respiratory allergens).

11.3.3 Implementing a negative list of additives that has been scientifically established to be harmful. This would constitute a far more proportionate and effective measure to safeguard public health with regards to e-cigarette use. Moreover, such an

[101] PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products – Manufacture, importation, testing and labelling – Guide, Table 2 – List of substances which should be controlled in e-liquids.

[102] Framework for risk assessment of flavouring compounds in electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), March 2020 https://cot.food.gov.uk/sites/default/files/frameworkforriskassessingflavourings_0.pdf

approach has already been adopted by other EU Member States, see, for example, Germany in respect of FMC products;

11.3.4 Implementing targeted youth education programmes aimed at preventing young people from taking up smoking and nicotine products;

11.3.5 Mandatory training programs for all vaping retailers;

11.3.6 Enforcing existing laws forbidding retailers to sell e-cigarettes to minors and the implementation of additional age verification measures;

11.3.7 Rigorous enforcement of the ban on 'proxy purchasing' of e-cigarettes by adults for minors; and

11.3.8 Prohibition of large online orders of vaping products which exceed an amount reasonably required for personal use or the use of adult family members.

12. CONCLUSION

12.1 For the reasons set out above, BAT Nederland believes that the Proposal should be rejected. In summary, those reasons include:

12.1.1 The Ministry has failed to follow an adequate process. A proper evidence based regulatory impact assessment has not been undertaken, in order to identify the need for the Proposal and to properly consider the impacts, costs and benefits of the Proposal. Further, the legitimacy of the consultation process has been wholly undermined in light of the timing, content and unreasonable duration of the Consultation.

12.1.2 The Proposal will undermine public health rather than improve it. The Ministry's failure to consider evidence demonstrating the role that flavoured e-cigarettes can play in public health underscores that the Proposal is not evidence based. The Proposal would prevent adult smokers from accessing a range of e-cigarette flavours that they prefer and discourage them from switching away from cigarettes.

12.1.3 The Proposal would have a number of unintended consequences that would also undermine, rather than improve public health. The Proposal could result in relapse amongst former smokers who currently use e-cigarettes users, fewer smokers switching completely to e-cigarettes, and could result in current vapers using illicit products. Banning flavours could also lead to a proportion of flavour-seeking vapers making their own flavoured e-liquids from ingredients that can be purchased on the internet or from informal sources, with all the associated risks. Imposing the same flavour bans for e-cigarettes that exist for combustible cigarettes would perpetuate current misperceptions regarding the comparative risks of these

products and also discourage smokers from switching completely to e-cigarettes. Indeed, the Proposal treats more restrictively e-cigarettes than tobacco products

12.1.4 The Proposal would effectively destroy the vaping market which will likely shut down a number of legitimate businesses, as well as amount to a wholesale expropriation of manufactures' lines of products, brands and trademarks; with no demonstrable benefit to public health. The Ministry should be extremely cautious to adopt disproportionate measures with such severe economic consequences in the absence of compelling evidence justifying the measures in question, particularly in light of the important judgment of the CJEU in the Kanavape Case.

12.1.5 The Proposal is simply unworkable. A positive list cannot be created by means of the information provided on the EU-CEG database and it will be difficult, if not impossible, to strike the correct balancing point between not restricting tobacco flavours and prohibiting non-tobacco flavours. There is a real risk that the positive list will result in disclosure of trade secrets which would entail an absurd violation of intellectual property rights. The proposed regulations will also be incapable of effective enforcement without detailed, time-consuming investigations.

12.1.6 The Proposal contains concerning an alarming amount of uncertainty with regards to the manner in which the positive list will be prepared and the process for any future additions to the positive list. Given the serious impact of the Proposal on market participants, this is unacceptable and undermines the ability of operators to plan their business operations, in particular their ongoing flavour research and development. This is exacerbated by the additional uncertainty of potential conflicting EU-level regulation in this area imminently following the Dutch regulations.

12.1.7 The Proposal is unlawful. The Proposal exceeds the scope of the TPD and is not justified under the TPD. The Proposal also infringes the free movement of goods between the Netherlands and other EU Member States and the Ministry has wholly failed to demonstrate that the Proposal is justified and the weight of evidence shows that the Proposal is not necessary, appropriate or proportionate.

12.1.8 The Proposal would violate consumers' personal choice and right to privacy; and manufacturers' and retailers' freedom to conduct a business and fundamental property rights and freedom of expression as enshrined in the Dutch Constitution and ECHR. In addition, the Proposal would violate the Netherlands's international obligations under WTO Agreements.

12.1.9 There are a number of alternative regulatory options that are more properly targeted to reducing youth access and initiation, and which could provide significant public health gains through tobacco harm reduction.

12.2 Rather than stifling the e-cigarette category and likely eliminating it altogether, the Government should focus on developing a balanced regulatory regime that supports the e-cigarette market, so that adult smokers have awareness of, and appropriate access to, a wide range of potentially reduced risk alternatives to conventional tobacco, while protecting against youth usage of any tobacco or nicotine products. The Government should do so immediately, rather than undermining the harm reduction potential of e-cigarettes by regulating them in the same way as combustible tobacco products.

12.3 We strongly urge the Government to consider our comments on the Proposal. We would also welcome the opportunity to work with the Government in establishing an appropriate framework for the regulation of e-cigarettes. We are also able to make our research and development scientists available for any further questions or comments regarding smoke and tobacco free alternatives.

Appendix 1

Scientific assessment of electronic nicotine delivery systems manufactured by British American Tobacco

Prepared by British American Tobacco – January 2021

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1 Introduction

Smoking is a key risk factor for many diseases including cardiovascular disease, chronic obstructive pulmonary disease and cancer, and its impact on population health is well established[1]. In cigarettes, the tobacco burns at temperatures in excess of 900°C, forming smoke comprising more than 7000 compounds[2], of which approximately 150 are known toxicants[3]. It is generally accepted that nicotine is not the primary cause of smoking-related disease but other constituents contained in cigarette smoke[4].

In 2001, the US Institute of Medicine proposed that a tobacco harm reduction approach could reduce the burden of smoking on health at a population level through the development of Potentially Reduced Exposure Products (PREPs), which (i) result in a substantial reduction in exposure to one or more tobacco toxicants, and (ii) could be reasonably expected to reduce the risk of one or more specific diseases or other adverse health effects[5]. More recently, the Food and Drug Administration (FDA) introduced a framework outlining the US approach to permitting the sale or distribution for use of Modified Risk Tobacco Products (MRTP), to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products[6]. British American Tobacco scientists have outlined a framework for the assessment of potentially reduced risk products, such as e-cigarettes. This integrated approach proposes the use of pre-clinical[7], clinical[8] and population studies[9] to assess the risk reduction potential of new tobacco and nicotine products at the individual and population level[10].

E-cigarettes, which can replicate many of the sensorial, ritualistic and pharmacological aspects of cigarette smoking, are used in many countries around the world. E-cigarettes which, do not normally contain tobacco and do not involve combustion, have the potential to contribute to a reduction in the health risks associated with cigarette smoking for smokers who switch completely. The original e-cigarettes were simple devices, consisting of a battery, a microprocessor and an e-liquid tank that wicks e-liquid to a heating coil, which heats the e-liquid into an inhalable aerosol[11]. Today, e-cigarettes are available in numerous formats with varied battery power and heating coil resistance. In some devices, the traditional heating coil has been replaced with technology that reduces the potential for over-heating[12]. E-liquids may be supplied via a single use closed pod, refillable pods or cartridge system, or via a built-in refillable tank. E-liquids in general consist of propylene glycol, vegetable glycerol, water and flavours, and may be purchased with or without nicotine.

On account of their potential as a substitute for tobacco smoking, e-cigarettes present a unique opportunity for tobacco harm reduction. In 2015, Public Health England (PHE), an executive agency of the UK Department of Health, reported their findings from a review of more than 180 multidisciplinary studies, concluding that 'best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes'[13]. A subsequent report from the UK Royal College of Physicians (RCP), in 2016 concluded that, while long-term harm could not be dismissed, the available data suggest that harmful effects are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower. The RCP also concluded that e-cigarettes are not a gateway to smoking, do not normalize smoking, and are likely to lead to quit attempts that may not otherwise happen[4].

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[1] US Department of Health & Human Services. 2014 Surgeon General's Report: The health consequences of smoking – 50 years of progress. Atlanta, GA: Centres for Disease Control and Prevention; 2014. Available from https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm (accessed 26 November 2020).

[2] Rodgman A, Perfetti TA. *The chemical components of tobacco and tobacco smoke*. CRC Press: New York; 2013.

[3] Fowles J, Dybing E. Application of toxicological risk assessment principles to the chemical constituents of cigarette smoke. *Tobacco Control*. 2003:12(4): 424–430

[4] Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. London: Royal College of Physicians; 2016. Available from https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction (accessed 26 November 2020). See also Royal College of Physicians, Promote e-cigarettes widely as substitute for smoking says new RCP report

[5] Institute of Medicine Committee to Assess the Science Base for Tobacco Harm Reduction. *Clearing the smoke: assessing the science base for tobacco harm reduction*. Stratton K, Shetty P, Wallace R, Bondurant S (Eds). Washington, DC: National Academy Press; 2001

[6] Food and Drug Administration Guidance for industry. Modified risk tobacco product applications. Draft guidance. Silver Spring: FDA; 2012. Available from https://www.fda.gov/media/83300/download (accessed 26 November 2020).

[7] Laboratory based studies in cells or three dimensional tissue that are performed before assessment in humans (clinical study). Pre-clinical studies are routinely performed by the pharmaceutical industry to understand product responses or damage (toxicity) to cells and to determine a safe dose for a clinical study.

[8] Clinical trials are research studies performed in human volunteers that evaluate a medical, surgical, or behavioural intervention to understand if a new treatment/drug, or diet or medical device is safe and effective in people.

[9] Studies which assess the health of a population, at specific time points and over longer periods of time, to uncover patterns, trends, and outcomes that may be applicable to the general population. These studies can also assess the effect over time of the introduction of an external factor (drug, diet, environmental exposure etc) to these specific populations.

[10] Murphy J, Gaça M, Lowe F, Minet E, Breheny D, Prasad K, Camacho O, Fearon IM, Liu C, Wright C, McAdam K. Assessing modified risk tobacco and nicotine products: Description of the scientific framework and assessment of a closed modular electronic cigarette. *Regulatory Toxicology and Pharmacology*. 2017;90:342–357.

[11] Papaefstathiou E, Stylianou M, Agapiou A. Main and side stream effects of electronic cigarettes. *Journal of Environmental Management*. 2019;238:10–17

[12] Breheny D, Thorne D, Baxter A, Bozhilova S, Jaunky T, Santopietro S, Taylor M, Terry A, Gaça M. The in vitro assessment of a novel vaping technology. *Toxicology Reports*. 2020;7:1145–1156.

[13] McNeill A, Brose LS, Calder R, Hitchman SC, Hajek P, McRobbie . E-cigarettes: an evidence update A report commissioned by Public Health England. London: Public Health England; 2015. Available from https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update (accessed 26 November 2020).

In an updated report in 2018, PHE[14] concluded that "vaping poses only a small fraction of the risks of smoking, and that switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate unambiguously the large difference in relative health risks, so that more smokers will be encouraged to switch from smoking to vaping. It should be noted that this does not mean that e-cigarettes are safe". In 2018 the US National Academies of Sciences (NAS) also reviewed the available scientific data and concluded that, "while e-cigarettes are not without health risks, they are likely to be far less harmful than conventional cigarettes"[15].

The consensus that, relative to smoking, e-cigarettes represent a reduced risk product for smokers (who switch completely) and bystanders has continued to build in 2020. First, the most recent report from PHE states that "vaping regulated nicotine products has a small fraction of the risks of smoking, but this does not mean it is 'safe'"[16]. Second, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) reported that "the evidence on the toxicity of E(N)NDS [electronic nicotine (and non-nicotine) delivery systems] aerosol indicates that use of E(N)NDS products may be associated with a reduced risk compared with [conventional cigarettes], but this should not be taken as meaning that these products are risk-free"[17]. COT also concluded that the "relative risk of adverse health effects would be expected to be substantially lower from E(N)NDS than from conventional cigarettes". Third, a Cochrane review on use of e-cigarettes as a smoking cessation aid found "moderate-certainty evidence that e-cigarettes with nicotine increase quit rates quit rates compared to EC without nicotine and compared to NRT" [18]. The review did not detect clear evidence of harm from nicotine e-cigarettes; however, the longest follow-up in the included studies was 2 years. Furthermore, the review found that, in some studies, reductions in biomarkers observed in smokers who switched to vaping, were consistent with those seen among individuals who quit[18].

In this document, we describe peer-reviewed scientific data generated by British American Tobacco to facilitate the risk profiling of e-cigarettes relative to cigarettes. The described studies have assessed a number of e-cigarette devices manufactured by British American Tobacco; specific product details are included in the corresponding references. For laboratory studies, University of Kentucky 3R4F[19] or 1R6F[20] scientific reference cigarettes were adopted as controls because they have a history of application in tobacco product assessment studies and are used by academic, regulatory and public health scientists globally. In clinical and consumer tests, commercial cigarettes were used as a control; the specific cigarette brand is detailed in the referenced publication.

When assessing any consumer product, it is important to assess the product as recommended by the manufacturer and as used by the consumer. Internationally recognized methods should also be used, in addition to good laboratory practice if available and appropriate. Our laboratory assessments, and those conducted at contracted third party suppliers, used commercially available equipment manufactured for the testing of e-cigarettes. Specific puffing regimes were used for aerosol generation in the laboratory: namely, Health Canada Intense for scientific reference cigarettes[21], and CORESTA recommended method No. 81 for e-cigarettes[22]. Standard methods enable data from different studies, laboratories and research groups to be compared, our own studies to be replicated and also ensure that the e-cigarette does not overheat during testing. Lastly, all our clinical studies are performed to good clinical practice and follow the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which enforces tight guidelines on ethical aspects of clinical research.

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[14] McNeill A, Brose LS, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England. London: Public Health England; 2018. Available from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf (accessed 26 November 2020).

[15] National Academies of Sciences, Engineering, and Medicine. Public health consequences of e-cigarettes. Washington, DC: National Academies Press; 2018. Available from https://doi.org/10.17226/24952 (accessed 26 November 2020).

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2 E-cigarette emissions

Emission assessment is the first step in our product assessment framework[10]. E-cigarettes produce an aerosol or vapour upon heating of the e-liquid; this aerosol is also known as the product "emissions". The composition of the aerosol generated by e-cigarettes is fundamentally different from that of cigarette smoke. The aerosol mainly comprises the ingredients used to produce the e-liquid: propylene glycol, vegetable glycerol, water, flavours and nicotine. The toxicants of concern in e-cigarette aerosols are typically carbonyl-containing compounds (aldehydes and ketones) and metals[23]. The levels of carbonyls and metals are measured routinely and published data show these compounds are significantly lower in e-cigarette product emissions than in scientific reference cigarette smoke[23]. We also assess panels of constituents prioritised by national and international agencies for monitoring and reporting of constituents in tobacco products, the TobReg9 list[24], 18 substances prioritized by US FDA for reporting in tobacco products and smoke[25], substances prioritized by Health Canada[26] and HPHCs of tobacco and smoke identified by the FDA[25]. These compounds have been shown to be present in cigarette smoke but are significantly reduced in the e-cigarette emissions. Calculation of the overall reduction in toxicant levels in e-cigarette emissions showed that all toxicants/compounds analysed, depending on the product being assessed, were 95-99% reduced relative to the scientific reference cigarette[23],[27].

As each new e-cigarette variant is produced, we repeat the above experiments to ensure that toxicant levels are comparable to or lower than those in previously launched products. In a recent study comparing toxicant emissions from five BAT manufactured e-cigarettes with smoke from a reference cigarette, levels of the nine WHO TobReg priority cigarette smoke toxicants were more than 99% lower in the e-cigarette aerosols[27]. This study confirms that, despite the continuing evolution in device design, components and ingredients, our e-cigarettes continue to produce aerosols/emissions with significantly lower levels of toxicants as compared with cigarette smoke.

3 Laboratory pre-clinical assessment

Pre-clinical in vitro studies are widely used to determine the extent to which chemicals and complex mixtures including cigarette smoke negatively affect physiological functions. Standard regulatory-approved methods are available for some toxicological testing and are routinely applied by the tobacco industry; ICH[28], COT[17], Health Canada[26], CORESTA[29]. We have assessed e-cigarette aerosols by numerous laboratory assays[10],[30],[31],[32],[33],[34],[35],[36],[37]. In all tests conducted[38], e-cigarette aerosols caused no or little biological effect, whereas the reference cigarettes induced dose-dependent responses in the numerous cell types that were assessed. In addition, a series of dosimetric studies were undertaken to ensure that equivalent amounts of aerosol were delivered to the cellular systems during both cigarette and e-cigarettes exposure[39]. Collectively, these results are consistent with the chemical analysis of e-

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cigarette emissions[23],[27] and demonstrate that the emissions of e-cigarettes are associated with reduced toxicity in laboratory tests as compared with cigarette smoke.

Furthermore, smoking disease pathways have been investigated in commercially available human lung tissue. In these studies, lung tissue is exposed to reference cigarette smoke or e-cigarette aerosol, and the genes and disease pathways activated are identified[40],[41]. We found that genes and cytokines associated with disease-relevant endpoints, such as tissue damage, inflammation and respiratory damage, showed an increased response after exposure to cigarette smoke, but substantially smaller responses after exposure to e-cigarette aerosol.

4 Impact on indoor air quality and odour and surface staining

When used indoors, cigarette smoke may affect air quality and cause surface staining and odour. Reduced air quality, higher room toxicant levels, staining and odour result from side stream smoke, which is emitted from cigarettes mainly between puffs and also exhaled smoke. E-cigarette use differs considerably from cigarette smoking: there is no tobacco and no combustion, and the products operate only under user actuation, meaning that no side stream aerosol is produced. The only impact that e-cigarette use may have on air quality will come from the aerosol exhaled by the user, and much of this comprises glycerol and/or propylene glycol, water, nicotine or flavours from the heated e-liquid. Thus, the aerosol exhaled after e-cigarette use has low odour and toxicant levels and dissipates quickly in air.

We have tested indoor air quality during e-cigarette use in an environmentally controlled room, showing that toxicant levels and particulate matter emitted from e-cigarettes are more than 90% reduced relative to cigarette smoke[42]. These findings were confirmed in a subsequent study testing the impact of a range of potentially reduced risk products on indoor air quality at an independent laboratory[43], where the air levels of particulate matter during e-cigarette use did not exceed WHO outdoor air quality standards[44],[45]. E-cigarette use also has a reduced impact on room odour, as well as hand, hair and fabric odour compared with cigarettes[42]. The impact of e-cigarette aerosols on staining of wallpaper and furnishings is also significantly less than that of cigarette smoking[46].

5 Human usage, behaviour and consumption studies

Consumer studies are also part of our product assessment framework[10],[47],[48]. For cigarette smokers to switch to potentially reduced risk products, it is important to understand how consumers use the product and what factors increase acceptability. How individuals use an e-cigarette also has strong implications for nicotine intake and exposure to potential toxicants. Consumer use and behaviour is also central to standardising protocols for product laboratory testing. Particularly, where choice of puffing parameters (puff duration, interval, volume and profile) has a substantial impact on the magnitude of emissions, with significant differences between e-cigarettes and conventional cigarettes[49]. The amount of aerosol generated can be influenced by a number of factors, including product design, vaping topography, and device setting[50].

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A wider comparison of use behaviour across several different product categories, including e-cigarettes has demonstrated the need to further understand consumer product behaviour and consumption, and indicates that toxicological risk should be assessed as exposure/use *per day* when conducting cross-category evaluations[51],[52],[53].

6 Short-term clinical assessment

Clinical trials are studies conducted among human volunteers to assess new drugs, consumer products, devices and other forms of treatments and form part of our product assessment framework[10.] All our clinical studies are performed to good clinical practice and follow the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which enforces tight guidelines on ethical aspects of clinical research.

For consumers to be more likely to switch from smoking, e-cigarettes should deliver nicotine in a manner similar to/as close to that of a cigarette. We have therefore performed pharmacokinetic clinical studies to assess product effectiveness in terms of nicotine delivery[54],[55],[56]. As e-cigarette devices evolve or e-liquids formulations are developed, we will continue to carry out further pharmacokinetic studies.

We also perform short-term (5 days) product switching clinical studies to enable the assessment of exposure to tobacco toxicants after product switching. In these studies, biomarkers of tobacco exposure (BoE) were measured in consumers' blood, breath and urine after they switched completely from cigarettes to e-cigarettes for 5 days[57],[58],[59]. As compared with levels in smokers, biomarkers of tobacco exposure were significantly reduced in the blood, breath and urine of e-cigarette users. A recent study measured "biomarkers of potential harm" (BoPH) linked to inflammatory responses and early pathophysiologic events in cardiovascular and pulmonary disease. BoPH levels were significantly changed after exclusive use of an e-cigarette[59]. After 5 days of exclusive switching to an e-cigarette, some BoPH were at the level observed in individuals who had quit smoking. In summary, data from our clinical studies suggest that e-cigarettes have the potential to be reduced risk products.

7 Modelling population effects

Historically, epidemiological studies are the gold standard and have been used to substantiate the effects of smoking on population health; however, it can take up to a generation (i.e., 25 years or more) to gather the required datasets. In the absence of epidemiology, the impact of e-cigarettes on population health may be assessed by mathematical modelling. Using publicly available data from the United Kingdom, we have used a mathematical model to project the potential population health outcomes of introducing e-cigarettes into the marketplace[60]. Overall mortality over a 50-year period (2000–2050) – the health outcome of interest – was compared between two scenarios, with and without the availability of e-cigarettes. The model projected that smoking prevalence among adults would be 12.4% without e-cigarettes and 9.7% with e-cigarettes (including dual users) by 2050; the current prevalence of smoking in the United Kingdom is 14.1%. Smoking-related mortality was projected to fall to 8.4% without the introduction of e-cigarettes compared to 8.1% in the counterfactual scenario with the introduction of e-cigaettes[60]. The projections suggest that launching e-cigarettes will have an overall beneficial effect on public health.

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8 Overall conclusions

International public health authorities have reported that, based on available data, a switch by smokers to exclusive e-cigarette use results in reduced exposure to tobacco toxicants and thus should have a beneficial health impact for those individuals and a wider public health benefit as a result. We have conducted a series of studies assessing the chemical emissions, laboratory and clinical assessments of e-cigarettes in comparison to scientific reference cigarettes and commercial cigarettes. When considered in their totality, as a weight of evidence approach, and in line with our assessment framework, the results demonstrate that the e-cigarette category has the potential to be reduced risk in comparison to cigarettes. Longer-term clinical studies will help to further substantiate the potential of e-cigarettes to contribute to harm reduction on a population level.

Appendix 2

Guidelines to Good Policy for Vaping

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Abstract

In this commentary I explore the potential impact of the array of vaping policies currently under consideration by a number of regulators and governments.

In order to contextualise my discussion, I first draw upon publicly-available data series from Statistics Canada to illustrate the recent dramatic decline in cigarette sales that has coincided with the expansion of the e-cigarette market in Canada.

This decline is much larger than the prior declining trend in smoking consumption. Furthermore, this decline cannot readily be explained by other forces in the marketplace, such as an increase in cigarette taxes or heavier regulations on smokers.

This decline will potentially yield a major reduction in future harm to the health of smokers who have switched completely to vaping. Furthermore, since it has taken place in an environment that did not place undue restrictions on the access to, and use of, e-cigarettes, governments should be wary of implementing such undue restrictions on e-cigarette access and use of the type currently being proposed by some provincial governments in Canada – for example, in British Columbia and Nova Scotia, and in a number of other jurisdictions. I explore the consequences of several of these proposed measures and argue that they are not in the best interests of generating a switch from smoking to vaping. While my data analysis is focused on Canada, where there is available published data with monthly frequency to enable an assessment to be undertaken, my comments on policy development and the potential impact of proposed regulations also apply to other jurisdictions. For example, Denmark has recently proposed restrictive regulations on vaping products that resemble those proposed in several of Canada's province.

Youth behaviors are a significant concern because youth experimentation rates in some jurisdictions are elevated. However, the key to successful health policy in this area is to strike a balance in deterring youth vaping, including through strictly limiting access to nicotine products for youth and increasing youth education programmes, while supporting adult smokers who

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will not otherwise quit smoking to adopt a switching (harm-reduction) approach to nicotine consumption.

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1. Cigarette sales and e-cigarette use – a disruptive force

Introduction

The arrival of vaping in the Canadian market place has been a disruptive force, in that it has had a major causative impact on the reduction in consumption of cigarettes in Canada. This is true for both youth and adults. In this section I marshal some publicly available data to demonstrate this impact.

Nicotine consumption can be quantified in several ways. One is to query individuals on their consumption patterns through surveys. A second is to examine sales related data, such as shipments from suppliers or retail sales data.

The data used in this report are of the second type – i.e. shipments data from manufacturers in Canada. While surveys are useful insofar as they elicit a lot of information from individual consumers, there is inevitably a delay between the time of survey and the present time period. And if consumption patterns in a very recent period need examining, then surveys may not be ideal. Furthermore, survey data relies on consumers accurately recalling their level of consumption.

Sales – shipments data

Shipments data are reliable because they are a good proxy for actual consumer consumption. Statistics Canada asks each producer on a monthly basis to supply information of production, sales and inventories, measured in sticks of tobacco. The data are made available to the public with a short time lag – usually no more than three months.

Figure 1 contains annualized legal domestic quantity shipments of cigarettes to vendors in Canada for the period 2011-2019. Since the raw monthly data display substantial month-to-month variability, each data point in the figure 1 represents the sum of sales in the preceding 12 months. For example, the August 2019 number is the sum of shipments for the period September 2018 – August 2019. The inclusion of 12 months results in a relatively smooth series, and since every month of the year is included, seasonal effects are effectively washed out.

Two features of this graphic stand out. One is that the annual decline between the beginning of the period and September 2018 is small. The second is that the decline between September 2018 and September 2019 is, by comparison, substantial. September is used because the latest data available at the time of writing are for Sept 2019. September is also a good assessment point, for other reasons explained below.

The shipments figures for the three September months (2011, 2018 and 2019) are 21.964b, 20.360b, and 18.849b. The decline between 2011 and 2018 was 7.3%, making for an annual decline of about 1%. In contrast, the decline for the single year from September 2018 to September 2019 was dramatically higher at 7.4%.[2]

This decline could have occurred for several reasons. First, price increases might have driven down consumption. A second possibility is that more users switched to the illegal sector, away from the legal sector in the period 2018-2019, and thus the registered decline in legal sales might not reflect an actual consumption decline. A third possibility is that new regulations came into play that depressed sales. A fourth is that the legalization of cannabis in Canada may have diverted expenditures away from cigarettes. Finally, the decline may represent a shock to the market place by a new disruptive force or technology. I consider each of these in turn.

Consider first the role of prices. The price elasticity of demand for cigarettes is generally believed to be in the neighborhood of -0.3. This means that a 10% price increase results in a decline in the quantity consumed of 3%. Hence, in terms of the decline registered in the final year of the data, if price increases were to explain the decline it would be necessary for prices to have increased by about 25%. This is calculated as the actual decline (7.4%) divided by the elasticity value (-0.3). Elasticities are measured using changes in the real price of a good, that is, after extracting the increase in the consumer price index (CPI). If the elasticity were larger, for example -0.6, then a price increase of 12.5% (half of the 25%) would be required to bring about the observed change in quantity.[3]

[2] On a per-person basis the declines were slightly more, given that the population increases by about 1% per annum.

[3] Taurus et al (2016), in their study of how elasticity values vary in different US states, find that elasticities in higher price states are generally larger than in lower-price states. This is consistent with theory: the elasticity

To assess a possible role of prices, figure 2 contains a real (net of CPI inflation) price series for cigarettes in Canada for the period corresponding to figure 1. The real price index also accounts for price movements in the preceding 12 months in order that it be comparable with the sales data series. Between September 2011 and 2018 the price index increased by 22.8% and in the period September 2018-September 2019 by 3.2%. With an assumed elasticity value of -0.3, this means that in the most recent year, the price increase accounted for a single percentage point of the total 7.4% decline (if the elasticity value were -0.6, the price decline would account for two percentage points in the quantity decline). Thus, price changes do not explain the substantial decline in cigarette consumption.

To determine if smokers in the period Sept 2018 – Sept 2019 might have switched their consumption to the illegal market as a result of the real price increase in legal cigarettes, we can observe how shipments behaved in the preceding several years in response to price increases. The five-year period encompassing January 2013-December 2017 saw a real price increase of approximately 17%, or about 3.4% each year on an arithmetic basis. The corresponding sales data for this five-year period show a decline of about 6%, or 1.2% per annum. This quantity decline, assuming an elasticity value in the neighborhood of -0.3, is consistent with the price changes explaining most of the quantity movement. If the price increase of 3% in the period September 2018-September 2019 were to have caused a migration of smokers to the illegal market, then we would have expected a substantially greater decline in legal shipments for the five-year period 2013-2017.

It is possible to invoke the idea of tipping points in much behavioral analysis, and it might be proposed that in late 2018 smokers in the aggregate reached a price-tipping point and moved in large numbers to the illegal market. However, to accept that view, one would have to believe both that a 'herd instinct' came into play and that there was no alternative plausible explanation for this behavior. Accordingly, the evidence does not suggest that the substantial

formula is (ΔQ/ΔP)* (P/Q), so a higher P value in the numerator (associated with a corresponding lower Q value in the denominator) increases the value of the (P/Q) term. At higher prices it is possible that the population of smokers is less responsive to price changes, because a smaller population of smokers will contain more habituated smokers who respond less to price increases. Consequently the first term (ΔQ/ΔP) may be smaller at higher prices. What Taurus find is that the first of these effects generally dominates.

decline in cigarette sales in the most recent year is due to smokers' shifting their purchases to the illegal market.

As for new regulations governing smoking, Canada has been heavily regulated for two decades (in the form of smoking bans at work and in public places, in bars and in restaurants, within a given radius of buildings, display bans in stores, advertising and sponsorship restrictions etc.) that there is really little left to regulate. While plain packaging of tobacco products has been introduced in Canada, this did not come into force until November 2019. One substantial policy change in the recent past has been the banning of menthol flavors in cigarettes. The menthol market in Canada differs from the menthol market in the U.S. In the latter, menthol accounts for almost 30% of the total market. The U.S. Centers for Disease Control (CDC) reports that it accounts for more than one half of all youth smoking and approximately three quarters of African American smoking.

In Canada, the Canadian Tobacco, Alcohol and Drugs Survey (CTADS) of 2017 reports that 9% of smokers aged 15 and above smoked a menthol cigarette in the preceding 30 days. However, the percentage of smokers for whom menthol is a 'usual' choice was 2.7%. In turn this implies that menthol cigarettes in Canada accounted for about 5% of sales during 2017.

Following on from menthol bans already implemented by several provinces (including three of Canada's four large-population provinces – Ontario, Quebec and Alberta), the federal government banned menthol in early 2017, to take effect in October 2017.

The impact of the nationwide banning of menthol was limited on account of several provinces having introduced their own bans, at different dates, prior to the federal ban. The federal ban at the end of 2017, in a way, performed a mopping up operation – it hit menthol smokers in provinces that had not already banned menthol, and these provinces accounted for no more than 30% of Canada's population. Furthermore, smokers who may have quit in response to the ban likely did so long before the Fall of 2018. Chaiton et al (2018) report upon a prospective survey designed to capture the effects of Ontario's menthol ban which became effective in January 2017. They interviewed 325 smokers just prior to the ban and re-interviewed 205 of the same group one month after the ban date. Participants had smoked in the month prior to

the ban and had also smoked at least one menthol cigarette during the preceding year. The authors report that more smokers attempted to quit after the ban came into effect than who thought they might quit prior to the ban, and conversely more smokers actually switched to alternative products after the ban than had intended to prior to the ban.

The post ban survey was conducted just one month after the ban and it would be of interest to see if the intentions to quit were actually borne out in practice, and to see if actual attempts to quit were sustained. The evaluation of quit attempts in the month of January also needs careful interpretation, since January comes with New Year resolutions, and the CTADS data generally registers higher quit rates in January than in any other month. Accordingly, the evidence does not suggest that the introduction of bans on menthol were the cause of the substantial decline in cigarette sales in the most recent year.

Another possible explanation for the recent substantial decline in cigarette consumption is that cannabis legalization in Canada redirected expenditure from tobacco to legal cannabis. Cannabis became legal in Canada in October of 2018, just at the time when the shipments series begins to demonstrate a steeper decline. Statistics Canada has an on-line 'cannabis hub' that presents data on cannabis expenditures, cannabis prices, sales by quarter, cannabis use prevalence rates by quarter that come from an almost continuous user survey, and several other data series .[4]

Miller and Seo, 2018 suggest that some consumers may use cannabis in place of, rather than in addition to, cigarettes and thus if the price of one rises the quantity purchased of the other rises also. More broadly, this suggests that the greater consumption of one may reduce the consumption of the other. It is to be expected that total demand for cannabis would increase following legalization: legalization should lead to an increase in experimentation on the part of previous non-users, and should induce some existing users to transit to the legal market from the illegal market.

[4] https://www150.statcan.gc.ca/n1/pub/13-610-x/13-610-x2018001-eng.htm.

The critical question is then how cannabis users allocate their budget. In the aggregate they spend more on cannabis because (a) some users are new and (b) the switchers will pay a higher price per unit in the legal sector.

The new users tend to purchase very small amounts. Orens et al (2018) report that cannabis users who are 'daily' or 'almost daily' account for over 80% of total sales in Colorado. Cannabis survey data available on the Statistics Canada web site points to a similar high concentration in Canada. The importance of this observation is that daily or almost daily users did not wait for legalization to become regular users. Consequently, even though cannabis use prevalence rose between mid-2018 and mid 2019 by several percent, the new users accounted for a small addition to the total volume of cannabis consumed legally on account of their low usage.

Legal sales of recreational use cannabis in the 12 months following legalization amounted to $908m.[5]

Assuming that almost all of this $908m figure represents expenditure by existing users switching from the lower priced illicit market, it is straightforward to estimate new expenditure on cannabis. The Hub contains information on typical prices for legal and illegal cannabis, and an analysis of those numbers indicates that the illegal sector price is approximately 60% of the legal sector price. Hence, we can estimate that roughly 40% of the $908m or $363.2m, represents additional expenditure on cannabis by existing users switching from the illicit market to the legal market.

We do not know what part of that additional expenditure on cannabis came from expenditure on tobacco, or from other prior expenditures, e.g., alcohol, gaming, or restaurant meals. However if we assume that the fraction coming from tobacco expenditure was one third, then smokers would have redirected $121.1m away from tobacco to legal cannabis.

The final stage of the estimation involves taking the $121.1m figure as a percentage of total economy wide expenditures on tobacco. Statistics Canada reports in its data base (Table: 36-10-

[5] Medical cannabis sales prior to legalization were slightly higher than one year later. They accounted for almost 30% of total legal sales for the period. They are excluded from this $908m number.

0225-01; formerly CANSIM 384-0041) that the total expenditures on tobacco was $18b in 2018. The figure of $121.1m represents approximately 0.67% of this total expenditure.

The result then is that a reasonable estimate is that cannabis legalization might account for slightly less than a 1% decline in cigarette sales. To the extent that not all of the expenditure represents switching from the illegal sector, this fraction might move above 1%.

It seems safe, therefore, to conclude that the substantial decline in cigarette consumption witnessed in the period of interest is substantially attributable to something other than higher prices, a flight to illegal sales, additional regulations or redirected expenditure from tobacco to legal cannabis.

Consider now a role for e-cigarettes. E-cigarettes have been available in Canada for several years, but have taken off in the marketplace in the most recent two years. The arrival of a new generation of e-cigarettes in Canada marketed primarily by the JUUL Corporation is the most likely factor to have disrupted the traditional cigarette market. JUUL also began to sell its products starting September 2018. This is one of the reasons why September is a good month to consider as a pivot point. In my view, the arrival of vaping in the nicotine market place has had a major causative impact on the reduction in consumption of cigarettes in Canada.

The Take-away: Potential Harm Reduction Benefits

To conclude this review of the data, the past year plus has seen a massive decline in smoking among Canadians which is associated with an expansion of the e-cigarette market. A decline of this magnitude may ultimately result in thousands of Canadians avoiding early mortality.

The potential public health benefits of e-cigarettes have been recognised by a number of experts and public health authorities. For example an independent expert review commissioned by Public Health England (2018)[6] found that: "[v]*aping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that*

[6] McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18. A report commissioned by Public Health England. London: Public Health England, 2018

vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping." A large-scale systematic review of the scientific literature undertaken by the US National Academies of Sciences, Engineering, and Medicine for the Food and Drug Administration[7], also concluded that: "[t]*here is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes*" and "*[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes*". The potential benefits of switching to e-cigarettes for smokers who can't or don't want to quit using nicotine are also recognised by Health Canada in its advice on vaping and quitting smoking.[8]

Two aspects of recent experience in Canada should be emphasized: first, the substitution away from cigarettes to less toxic e-cigarettes has been achieved in an environment that to date has not been subject to unnecessarily heavy regulation. Should that regulatory approach change, as a result of the implementation of misguided regulation unduly restricting e-cigarettes, then the potential for further tobacco harm reduction will be diluted.

This observation can also be applied to other jurisdictions. For example, a recent multi-country study based upon the International Tobacco Control Policy Evaluation Project (Gravely et al, 2019), concluded that countries with the most restrictive policies on nicotine vaping products registered lower product awareness, ever use, current use and daily use, than countries that were classified as simply 'restrictive' or 'less restrictive' in their policy framework. Among the 14 countries examined, the authors highlight the very different experiences of China, Australia and the UK. China scores low on the use and awareness measures and the authors attribute this to the fact that China has a state-owned monopoly, in the form of the China National Tobacco Company, that has little interest in seeing competing lower-harm products in the market place. Australia has banned the availability and use of ENDS on the grounds that they 'should be subject to evidentiary review and should be restricted or banned until more evidence about

[7]NASEM (2018), Public Health Consequences of E-Cigarettes.
[8] https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/smokers.html.

their safety and efficacy are available'. This stance does not equate with the precautionary principle as I explain below. In the UK, in contrast, the prevalence of ENDS "was highest, compared to all other EU countries, therefore indicating that when governments and large public health organizations support using e-cigarettes for smoking cessation, there is an additional effect on usage rates". Many of the 25 authors on this paper have a long history of being public health advocates and advocating strongly against the use of tobacco.

Second, while e-cigarettes may be substituted for cigarettes by smokers who want to switch to a potentially less risky product, many smokers have not yet made the switch. This is likely due, in part, to a lack of knowledge about this new product category and its potential lower risk compared to combustible cigarettes. Accordingly, policy should be directed to educating smokers about the comparative risks of different tobacco and nicotine products and facilitating a switch to potentially less risky substitutes, and not be such as to discourage or make that switch more difficult.

In the following section I address the recent concerns regarding youth experimentation with vaping. I then explore the potential impact of the array of policies currently under consideration by provincial governments in Canada and regulators in other jurisdictions (e.g., Denmark) in section 3.

2. Youth vaping and youth smoking

The data

The data presented in the previous section provide evidence of a disruptive force in the market for traditional cigarettes – i.e., vaping products.

However, while e-cigarettes are a potentially reduced-risk product, they are addictive and are not 'safe.' Accordingly, concerns are rightly being raised regarding youth access to such products.

With this in mind, in this section I present somewhat comparable data focussing specifically on youth behaviors. Very recent data have become available for both the US and Canadian economies right at the end of 2019. It is instructive to examine youth behaviors in each economy, so I present data for each. The focus will be upon 'past-30 day' activity, rather than past-12-month activity, in order to focus upon regular users.

Data on past 30-day smoking and vaping rates for US high school students that come from the Monitoring the Future surveys are presented in table 1 below. Survey questions on vaping began in the year 2014. Several patterns emerge from this table: First, smoking has been dropping steadily and precipitously for several years. Second, vaping rates increased substantially in 2018, and again in 2019.

The rate of use of smokeless tobacco has more than halved in the most recent five year period, and that is consistent with the theory that students switch between different tobacco-based products. It is of particular interest that the smoking rate among grade 12 students dropped by 22% between 2017 and 2018, and again by 25% between 2018 and 2019.

These declines in prevalence are historic, and are all the more surprising given that they have been achieved when prevalence rates were already low (smoking in particular). With low prevalence rates, the difficulty in further reducing use becomes progressively more challenging.

These recent declines in tobacco use cannot be fully attributed to a shift to e-cigarettes. Indeed, it has been well-documented in the sociology literature that teens now have lower rates of risky behavior than in the past, and that the arrival of social media and new communications

methods, such as smart phones, has meant that youths 'venture out' less and consequently encounter fewer situations where risky behavior might be engaged. However, new technology has characterized the youth social environment for two decades and thus it would be unreasonable to attribute the enormous reduction in risky behavior in the period since say 2014, or even 2011 solely to electronic communications and social media.

Comparable data on cigarette use are also available for Ontario high school students from the Ontario Student Drug Use Survey (OSDUS), over a long period of time, and from the Canadian Student Tobacco and Drug use surveys (CSTADS) for the more recent period. Tables 2 and 3 below contain data for vaping and smoking, respectively, for Canadian youth. The smoking rates are from the OSDUS and the vaping rates are from Hammond et al, 2019. Like the US, smoking rates in Canada among youth have fallen, and they have continued to fall substantially even having attained very low levels. The OSDUS 2019 survey results are not yet available.

The 'almost daily' vaping rate for Canadian 16-19 year olds in Hammond et al, 2019 is 3.6% in 2018, which lies between the rate for England and the US.

Table 2a contains data that come from the Canadian Student Tobacco Alcohol and Drugs surveys for the years 2016-17 and 2018-19. I focus upon the grade 10-12 results, as those results are more likely to determine post-school behaviors than the rates for the lower grades. The survey questions are not exactly the same in each wave, but a clear pattern emerges for students who are regular users. In the early period the use rate for students using between 21 and 30 days per month was 2.5% (sum of 0.7 and 1.8). In the recent period the 'daily or almost daily' use rate of vaping products involving nicotine was 11.6%, which marks approximately a four-fold increase.

Complementary to this increase has been a continued and substantial decline in the smoking of traditional cigarettes, cigars and smokeless tobacco. This is displayed in the third and fourth panels of the table. Recent current smoking rates have declined and there has been an increase in the percentage of former smokers. The rate of daily smoking among students in grades 7-12 declined from 3.2% to 0.9%. Even the percentage of students who are occasional current smokers has dropped from 4.5% to 1.9%.

So, just as current vaping rates have increased among high-school students, current smoking rates have dropped substantially. This is more evidence that the availability of vaping products can push down smoking rates. However, strict regulations on youth access to e-cigarette products are nonetheless still justified.

Perspective and policy

Nicotine is an addictive substance. It is what primarily addicts smokers to cigarettes or some other manner of consuming tobacco. The standard smoking adage has been 'smoke for the nicotine, but die from the tar'. While e-cigarettes do not produce tobacco tar, due to the absence of tobacco combustion, it is also recognised that nicotine might have adverse effects during adolescent and young adult brain development. Accordingly, legislative policy and enforcement, should seek to keep youth away from addictive substances to the extent possible. In the case of nicotine products including e-cigarettes, retail outlets need to be visited and monitored to ensure that youth are not being sold nicotine in any form, and policy should criminalize purchase on behalf of under-age consumers.

The policy challenge for governments, which I take up in the following section, is to deter youth initiation, while supporting smokers who will not otherwise quit to switch to a less toxic option.

At the same time as we continue deterrence policies for youth, it is important to keep in mind the major gains that have been achieved through the reduction in risky behavior on the part of teens in the past several years. We have seen dramatic reductions in alcohol use, reductions in binge drinking, reductions in smoking, reductions in smokeless tobacco and cigar use, reductions in unwanted pregnancies, declines in the use of opioids, methamphetamine, prescription drugs and heroin (for details see OSDUS).

However, while on average, there has been a major recent decline in the consumption of substances and in risky behavior more generally, it must be recognized at the same time that there is an element of substitution associated with these reductions. For example, while the advent of electronic communications and social media has led to more teens staying 'closer to home', leading to reductions in vehicle accidents and drunkenness, there have also been increases in teenage mental health issues associated with social media. Likewise, the continued

reductions in smoking have been contributed to by the availability of an alternative, potentially reduced risk product – the e-cigarette.

3. Anti-vaping policies: science, inference and guiding principles

A number of vaping-related measures have been recently implemented or proposed by governments in a number of jurisdictions. An example of an extreme form of limitation policy is that undertaken by the city of San Francisco in its decision to ban the sale of vaping products completely. Other restrictions, recommended or enacted, are higher taxes, forbidding flavors other than tobacco, raising the age of legal purchase to 21, restricting the availability of vaping products to age-restricted shops, forbidding endorsements and testimonials, and requiring plain packaging on all tobacco and nicotine products.

As of December 2019, several of Canada's provinces are planning more stringent laws in relation to vaping. The Canadian Federal Government is also considering a number of measures aimed at reducing the youth appeal and access of vaping products. Several US states have already implemented measures designed to reduce youth use, and the US federal government has recently passed a law to increase the legal age in the US to purchase tobacco products, including e-cigarettes, to 21. The US Food and Drug Administration has also recently issued a policy that effectively bans flavored cartridge-based e-cigarette products (other than tobacco or menthol-flavored products). Similar policies are also being implemented or considered in a number of other jurisdictions.

In this section, I explore the value and likely impact of several policy measures currently under consideration. Several considerations or principles guide this discussion:

(i) E-cigarettes and traditional cigarettes differ dramatically in their toxicity and e-cigarettes are considered by multiple public health authorities to have dramatically lower risk profiles. Consequently policies that treat the two products the same way, as if they were identical, are anti-scientific and unlikely to contribute to public health.

(ii) Restrictive policies must consider the likely incentives that accompany their implementation. In particular, we must examine the likelihood that the law will be broken if it is unnecessarily severe. The likely counterfactual must be kept in view.

There is widespread evidence on how high taxes on cigarettes, accompanied by low monitoring rates, can lead to vigorous illegal markets.

(iii) Using a precautionary principle approach to regulation does not equate with, or result in, minimum societal risk. When society is uncertain as to the ultimate cost-benefit outcome of a new product, society may err by being excessively cautious, such as in the context of e-cigarettes, where there are important potential benefits to the population because of the harm reduction potential for adult smokers. This point has been emphasised by the UK Royal College of Physicians, for example, which stated: "[a] *risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm… if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking*." [9]

(iv) New technologies are disruptive, and they frequently introduce (sometimes reasonable) fear. New technologies may have consequences that are unknown at the time they are presented for adoption, and best-effort scientific research on new technologies may not yield unambiguous findings or prescriptions. But where findings do appear conclusive, it is important to incorporate this into policy.

(v) The formation of policy is heavily influenced by the writings of non-scientists, in part through influencing voters. Science can be challenging for non-scientists, as illustrated in the following sections. While papers published in the major health and medical journals may be presented in clear terms, the findings can be misrepresented (including by disregarding the limitations of the study), particularly in the broader mainstream media, and consequently generate an unjustified public clamor, which in turns pressures governments to take counter-productive action. I present a particularly apposite pair of examples in the sub-section on ‘flavors’

[9]Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction.

below. The misrepresentation of scientific findings is emphasized by McNeill et al, 2018.

(vi) The Instruments and Objectives approach to policy formation states that it is difficult to implement good policy in relation to two objectives unless one has at hand two instruments. In the case we are considering here, the two objectives are (a) to prevent youth uptake, and (b) to encourage smokers who will not otherwise quit to switch to a potentially less dangerous form of nicotine consumption.

Taxes and economics

Objectives and instruments: When choosing an appropriate tax rate for a good or service, we should ask what the purpose of the product is, and whether its consumption generates any externalities. Food, for example, is defined as a necessity and many economies exempt food from sales tax, since the impact of the tax is regressive – it is burdensome for low-income households who spend a disproportionate share of their budget on food. Taxes on luxury vehicles, in contrast, or on vehicles with high carbon dioxide emissions would be progressive and corrective at the same time, since they would fall on higher income groups and make the emitter of carbon dioxide pay for the externality generated.

The choice of an appropriate tax rate for cigarettes constitutes a dilemma. On the one hand, a high tax rate deters purchase; on the other, for low-income individuals who smoke, a high tax is regressive. In Canada, for example, the average tax component of the price of a cigarette is about two thirds of the final retail price (author's calculations).

The choice of a tax rate on e-cigarettes presents its own particular dilemma, because from a public health standpoint we should want smokers to switch to e-cigarettes in place of cigarettes, but we should equally want youth and never-smokers to avoid them. If we were solely concerned about deterring youth we would set a high tax, and if we were solely interested in encouraging smokers to move to vaping we should set a low tax.

A recent paper by Saffer et al (2019) analyzed the impact of a large increase in the tax on e-cigarettes in the state of Minnesota on adult (19 years and older) smoking cessation. Minnesota was the first state to impose a tax on e-cigarettes by expanding its definition of "tobacco products" to include e-cigarettes. The taxation began on August 1st 2010 with a tax rate of 35 percent. This tax was raised by another 60 percentage points to a total tax rate of 95 percent of the wholesale price on July 1st. 2013. The authors estimated that the e-cigarette tax deterred about 32,400 adult smokers in Minnesota from quitting. They also estimated that if the Minnesota tax had been a national one, it would have deterred around 1.83 million smokers from quitting. The authors state: "[s]*ome have suggested that e-cigs should be taxed at the same rate as cigarettes. Implementation of that policy would raise the price of e-cigs by*

approximately 62 percent, increase smoking participation by 8.1 percent, and deter approximately 2.75 million smokers from quitting." They add that if actual recent trends towards reduced smoking were to continue for the next decade, this tax policy would reduce the number of quitters by about one quarter.

Fortunately, there exists more than one policy instrument to address the public health objectives. We can simultaneously set a lower tax rate in order to induce switching from smoking, and implement strict (non-price) regulations on e-cigarette access for youth to deter them from initiating. Consequently, a punitive tax is not necessary.

The UK House of Commons Science and Technology Committee report on e-cigarettes in 2018[10] reached a similar conclusion, stating: "[t]he *level of taxation on smoking-related products should directly correspond to the health risks that they present, to encourage less harmful consumption. Applying that logic, e-cigarettes should remain the least-taxed and conventional cigarettes the most, with heat-not-burn products falling between the two*".

Regressivity: Smoking is heavily concentrated among lower income households. Consequently, when taxes are raised on cigarettes, the distributive effects are adverse: they hit low-income smoking households more severely than high-income smoking households.

In Canada, the Canadian Institute for Health Information (2019) provides data on smoking rates by income quintile. They find that, drawing upon data from the Canadian Community Health Survey of 2016, among the highest income quintile, 12% smoke, while among the lowest quintile 23% smoke. Statistics Canada (2019) reports that the average income of households in the bottom quintile is $26,513, and the average for the highest quintile of households is $164,117.

Excise taxes in Canada are relatively uniform across the provinces (in contrast to the United States). Depending upon whether a pack is regular or premium, prices are concentrated in the range between $11 to $15, with sales taxes included.

[10] House of Commons Science and Technology Committee, E-cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018.

An internet search on the pricing of e-liquid suggests that clip-in e-liquid pods, typically containing 0.7 ml of e-liquid, sold by market leaders such as JUUL, Vype or Blu, cost about $25, tax-included for a pack of four. Since each pod is designed to yield approximately the same nicotine as a pack of cigarettes, a move from cigarettes saves approximately $6 per 'pack'. A switch from cigarettes to a tank-based e-cigarette system such as Uwell, where the consumer buys the e-liquid in bulk and fills the tank periodically, yields a further reduction in cost of about $3 per 'pack'.

In consequence, the cost savings on an annual basis to a pack-a-day smoker are high: of the order of $2,000 per annum ($6 * 365 = $2,190) with a switch to an e-cigarette pod system, and $3,000 per annum with a tank-based system ($9 * 365 = $3,285).

These are significant gains to low-income smokers. Public policy should recognize the major financial benefits, as well as the potential health benefits to these users that would accrue from switching. The maintenance of a significant price differential between the two forms of product should encourage switching.

The efficiency of e-cigarettes in helping people quit smoking

E-cigarettes are frequently evaluated in terms of their efficiency – gauged by how effective they are in helping smokers quit. Two articles published recently in prestigious journals are frequently cited in this discussion: Walker et al, 2013, and Hajek et al, 2019.

The findings that are emerging from research studies indicate that while quitting smoking is difficult, e-cigarettes are effective in increasing the success of quitting. For example, Walker et al 2013 found that, in a randomized trial, quit rates associated with the use of e-cigarettes plus patches was 7%, whereas it was 2% for patches alone. In Hajek et al, 2019, e-cigarettes outperformed other nicotine replacement therapies with quit rates of 18% versus 9.9% after one year (though most of the quitters using e-cigarettes continued to vape).

The differentials here are enormous, but commentators frequently confuse low absolute success rates with ineffectiveness. For example, in a recent commentary, a well-known

cardiologist and epidemiologist claimed, “e-cigarettes didn’t improve the performance of nicotine patches”[11].

However, an improvement from 2% to 7% represents a change of 250%. To claim that e-cigarettes are not an improvement is a reflection of how easy it is to violate the principle of not misinterpreting science.

The doctor in question also describes as “underwhelming” the additional efficiency of e-cigarettes over patches in the second study. Again, this is the wrong conclusion in view of the potential reduced risk from the adoption of vaping. The additional use of e-cigarettes represented an 82% improvement in success rates (18%/9.9% = 1.82). In this latter study, participants were permitted to switch between several different replacement products, and so the additional effectiveness of e-cigarettes relative to any single other quitting device might be a multiple of the 82% improvement cited in the paper.

The risk of not understanding simple statistical inference is that such errors can get translated into public policy, given the enormous faith that the public and legislators have in doctors. However, doctors are not biostatisticians, no matter how well intentioned they may be in influencing public policy. The consequences can be serious when bad policy causes harm by perpetuating smoking.

Flavors

Perhaps the most emotive element in the debate about regulating access to e-cigarettes by minors is the role of flavors. The Canadian Federal Tobacco and Vaping Products Act ("TVPA") already bans the promotion of vaping products through any indication or illustration of flavour that could be appealing to youth, as well as certain flavours including confectionary, dessert, cannabis, soft drinks and energy drinks. This provides an approach that limits products being marketed to youth, while maintaining the availability of a limited range of flavors to encourage

[11] Christopher Labos (December 2019) in *The Conversation*. Dr. Labos is a fellow of McGill’s Office for Science and Society.

adult smokers to switch and avoiding the potential negative consequences of a complete ban on flavors.

Notwithstanding these existing restrictions, some provincial governments in Canada are currently considering, or have moved to ban the sale of all flavored e-liquids or restrict the sale of flavored e-cigarette products to age-restricted stores only.

For example, the Province of British Columbia has recently proposed legislation that will limit the availability of flavored products to age-restricted shops. This will dramatically limit availability, since vapers will not be able to purchase their preferred brand easily, and has the potential to send some former smokers back to cigarettes. Nova Scotia also plans to ban flavors altogether based on putative appeal to youth. In that scenario, flavors will not be available to adults who benefit from the existence of flavors in their efforts to transition to vaping and away from smoking. Restrictions on flavors have also been recently implemented in the U.S and are being implemented or proposed in a number of other jurisdictions as well.

An extreme view on flavors is that presented in an editorial in the New England Journal of Medicine (Drazen et al 2019). It advocated that only tobacco flavors be permitted in e-cigarettes, in the belief that if tobacco is the flavor generated in traditional cigarettes then potential switchers should be content with just a tobacco flavor in an e-cigarette. They stated:

> "*We think the FDA should simply ban the sale of flavored nicotine products for use in e-cigarettes. The public health problem that e-cigarettes can help solve — by helping people who are users of combustible tobacco products stop smoking by switching to vaping — is adequately addressed by liquids that are not flavored to appeal to adolescents. We urge the FDA to use its statutory powers in regulating nicotine delivery devices to take the bold step of removing these flavored products from the market."*

This statement proposes that prospective switchers would be minimally impacted by the absence of the most popular flavors, and that youth would be disincentivized from experimenting with e-cigarettes in the absence of flavors.

It would be foolhardy to pretend that we know the answers to these suppositions with any degree of exactness at this point in our state of knowledge. What we do know is that most users prefer flavors such as fruit, spice, mint or menthol to just plain 'tobacco'. It is important to recognize that adults use flavors; flavors are not restricted to youth, even though some youth may prefer certain specific flavors.

A number of published peer-reviewed research papers point to the important role played by flavors in helping some people quit smoking. Russell et al. (2018) found that access to a variety of non-tobacco flavoured e-liquid may be important for encouraging and assisting adults to use e-cigarettes in place of conventional cigarettes. The authors stated: "[r]*estricting the availability of non-tobacco flavours could reduce adult smokers' interest in switching to e-cigarettes or rationalize a return to cigarette smoking among frequent e-cigarette users whose journey towards smoking abstinence started with, progressed to, and is being sustained by frequent use of e-cigarettes containing non-tobacco flavours.*"

However, some papers and commentators suggest that flavours cause youth uptake. Again, inference is on occasion faulty, and interpretations of surveys and sentiments can depend upon the nature of questions posed to interviewees in surveys about the role of flavors.

The 2019 ASH UK Smokefree GB Youth Survey of 11-18 year olds[12] asks respondents who had ever used an e-cigarette (including current, ex-users and those who had tried at least once) what reason best described why they use or used an e-cigarette. Of ten possible answers, the six with the highest frequencies were (a) 'just to give it a try', (b) 'I like the flavors', (c) 'other people use them so I join in', (d) 'I use them instead of smoking', (e) 'I am trying to quit smoking', (f) 'I enjoy the experience'.

Response (a) 'just to give it a try', generated by far the highest frequency. Among never-smoking youth it had a 70% response rate among mutually exclusive answers. Response (b) on flavors received a 10% response rate among the same group. Relative differences among former smokers and current smokers were smaller. This survey indicates that flavours were

[12] Reported in ASH UK, Use of e-cigarettes among young people in Great Britain, June 2019

only a reason for use amongst a small percentage of respondents and there is no way of knowing which of these are current users or ex-users or those who had tried e-cigarettes only once. Thus, an important element of inference is to understand the nature of the survey question and the survey respondents.

The second caveat concerns, again, the interpretation of scientific results. A very recent study published in the journal Addictive Behaviors (Landry et al, 2019) surveyed 1492 current e-cigarette users aged 18 or older with the aim of establishing the role that flavors play in adopting e-cigarettes. Table 4 below is taken from the article.

In this sample 74% were either current or former smokers. Respondents in the survey were asked to state the major reasons (plural) for initiating vaping. Respondents listed an average of two reasons. The dominant two reasons were because e-cigarettes were perceived to be less harmful, and they are an alternative to cigarettes. Flavors were the third most popular reason. These results are consistent with the thesis that a sizable number of respondents indicated that they switched to or initiated e-cigarettes for health reasons and that flavors at the same time played a key role in facilitating that decision.

Returning to the final column in table 4, the percentages reflect the percentage of respondents who chose that response among their responses. It states that 29.5% of respondents chose 'I like the flavors' as one contributor to their decision, not that they initiated vaping because of flavors. As explained above, flavors can be a contributing secondary factor, and that secondary role may at the same time be very important in helping a smoker to switch and stay with the e-cigarette.

The data do not say that 29.5% of the sample initiated because of flavors. Yet, that is the incorrect interpretation placed upon the numbers by the epidemiologist cited above (footnote 11). He claimed that "nearly one third of users said they started vaping because of e-cigarette flavors."

Incorrect interpretation of scientific work is detrimental to good policy.

The banning of flavors also has a number of unattractive counterfactuals to those intended by its proponents, including that a proportion of flavor-seeking vapers would likely move to making their own flavored e-liquids from ingredients that can be purchased on the internet and that a substantial illegal market in flavored e-cigarettes will be likely to develop. Underground suppliers could easily buy the flavored pods in another jurisdiction, drive across the border and sell them on the street. The measure is therefore likely to lead to a large illegal sector that will avoid paying taxes.

The most concerning outcome of the absence of legal flavored products is that illicit products will start showing up on the street with contents that may increase toxicity. This is what appears to have happened with some cannabis vaping products in North America, which resulted in a number of deaths in 2019.

This point has been recognised by the United States Food and Drug Administration (FDA). In its January 2020 guidance document entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization",[13] the FDA states that it is aware that "removal of some of the most popular products from the market may be accompanied by an increase in black market versions of these products that may pose additional health and safety risks to consumers beyond those of the authentic products".[14] Considering the additional risks of these black market products and the need for increased enforcement efforts, the FDA notes "the potential that they contain harmful chemicals or constituents that are not present in other products, that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users—all of which increase the risk of adverse events".[15] These concerns are already manifest in the US market. Recently, Delnevo et al (2020) have documented that following the withdrawal of a range of flavored products by JUUL Labs, other companies quickly capitalised on these actions and produced JUUL-compatible pods in a variety of flavours.

[13] https://www.fda.gov/media/133880/download
[14] Id. at 28.
[15] Id.

Plain packaging

Many public health analysts believe that plain packaging takes the potential glamor from the packaging of products and thus should be required on harmful products such as cannabis, cigarettes and e-cigarettes. It is claimed that de-glamorizing cigarettes should reduce consumption. But both the likelihood of this being true, and the size of the impact, conditional upon there being one, are empirical issues.

The biggest plain packaging experiment in recent years was the requirement for plain packaging of cigarettes in Australia, which was implemented in December 2012. While public health advocates like to look upon the experiment as a success, because overall cigarette sales declined in subsequent years, there is little credible statistical evidence to sustain that belief.

The most optimistic view on plain packaging is contained in Chipty's research (2016), which was commissioned by the Australian federal government to assess the magnitude of the decline in smoking prevalence. Dr. Chipty concluded that smoking prevalence might have fallen by about one half of one percentage point. However, even this small decline is called into question by several other researchers (see Viscusi, 2018, and Oriani et al,, 2019). There are two reasons to doubt that the Australia experiment resulted in any declines in smoking at all. The first has to do with behavior in competitive market places; and the second has to do with the policy environment.

Plain packaging diminishes the power of branding, and thus a buyer may more easily 'stray' from her preferred, or historically purchased, brand. Goods become more homogeneous, or at least appear so. With differentiated products, it is well understood in economic theory that producers can raise their price to a level higher than would be the case if the differentiation declines. In economic terms the price elasticity of demand is more inelastic with greater product differentiation.

Consequently, producers may see the need to lower prices in the presence of plain packaging, in order to maintain their market share. This lower price (on the part of all suppliers in the

product category) may mean that consumers purchase greater quantities. Hence the intended impact of plain packaging may be offset.

The second aspect of the Australia plain packaging event is that it was accompanied by a vigorous public health anti-smoking drive in the period preceding the introduction of plain packaging, plus a series of major tax increases following its implementation. Econometrically, it then becomes a challenge to disentangle the impacts of the tax increases from the impact of the almost simultaneous additional policy events.

Dryden, 2017 also provides an econometric analysis which controls for prices and finds, consistently with the economic theory discussed above, that plain packaging is associated with a reduction in the average retail prices and with an increase in the per capita consumption of cigarettes in Australia compared to the counterfactual (i.e. the position that would have prevailed had plain packaging not been implemented in Australia).

Viscusi, 2018 analyzed the same data used by Chipty, except in an extended time framework: he had an additional three years of data. His econometric modelling focussed upon Chipty's specification of (a) the time trend variable in her regressions, and (b) the tax variable. Time trends are used to proxy unobservable variables that might explain behaviors, or the evolution of culture towards smoking. Viscusi proposed that a non-linear time trend better represents the data than Chipty's linear time trend. He also recommended treating the tax variable in dollar form, rather than as a dummy variable. Viscusi's models, using additional data and incorporating these changes, yield coefficients that could not support even the half point decrease in prevalence proposed by Chipty.

Oriani et al 2019, studied the issue in a context similar to Viscusi's, except that they had further additional data. They ran a number of econometric models of prevalence and use, using suitable control variables, and arrived at the same broad conclusion as Viscusi: there is no statistically significant evidence that plain packaging reduced smoking prevalence or tobacco consumption in Australia. They also found in one of their models, that plain packaging has had a counterproductive effect, resulting in an increase in cigarette consumption rather than a decrease, in line with Dryden, 2017.

To summarize so far: research commissioned by the Australian Federal Government proposed that prevalence may have fallen by one half of one percentage point following the imposition of plain packaging, but research commissioned by producers found fault with the government-commissioned research, and, when events such as tax rates or prices are properly controlled for, there was no evidence supporting a decline that might be attributable to plain packaging.

It is relevant in the Canadian context to also note that Canada's TVPA already places a number of limits on what can appear on vaping product packaging which further calls into question the likely added benefit of implementing plain packaging. These existing prohibitions include:

- Testimonials or endorsements;
- Promotions that could cause a person to have false impressions about the vaping product or its emissions or believe that it is contributing to health benefits;
- Comparisons to a tobacco product;
- Content (including an illustration or brand element) related to flavours that could be appealing to youth; and
- Tobacco brand elements.

Advertising bans

Advocates for a ban on advertising argue that vaping ads can encourage uptake by youth and renormalize smoking. However, advertising for relatively newer products, such as e-cigarettes, is important if these products are to compete with cigarettes which are well known, including to raise product awareness and to communicate the characteristics and value proposition of e-cigarettes to smokers.

The need for accurate communication regarding vaping is particularly important where there appears to a significant level of misperceptions regarding e-cigarettes. For example, Huang et al., (2019) found that: "the proportion of adults who perceived e-cigarettes as equally harmful as cigarettes more than tripled from 11.5%...in 2012 to 36.4%...in 2017." The authors also found that "the proportion of adults who perceived e-cigarettes to be more harmful than cigarettes also more than tripled from 1.3%...in 2012 to 4.3%...in 2017." The authors concluded

that their results "imply that at least some smokers may have been deterred from using or switching to e-cigarettes due to the growing perception that e-cigarettes are equally harmful or more harmful than cigarettes. Our results underscore the urgent need for accurate communication of the scientific evidence on the health risks of e-cigarettes and the importance of clearly differentiating the absolute harm from the relative harm of e-cigarettes." The independent expert review commissioned by Public Health England (2018)[16] also concluded that: "[m]isperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the PHE report in 2015 which called for clear and accurate information on relative harms."

There is some evidence that also suggests that e-cigarette advertising may reduce the demand for traditional cigarettes. For example, Tuchman, 2019 presents an empirical analysis on the effects of e-cigarette advertising on demand for traditional cigarettes, e-cigarettes, and smoking cessation products. Using both descriptive and structural methods, Tuchman shows that e-cigarette advertising decreases demand for cigarettes and smoking cessation products. She finds that in the absence of e-cigarette advertising, demand for traditional cigarettes would increase, suggesting that a ban on e-cigarette advertising may have unintended consequences.

The prohibition of advertising that is directed to youth or is misleading, is undoubtedly justified. Nor should advertising of a life style variety be permitted that would encourage new users of tobacco or nicotine products. However, overly restrictive regulations on advertising aimed at adult smokers restricts consumer information and awareness and could have unintended consequences, including exacerbating misperceptions regarding the relative risk of products and potentially deterring some smokers from considering vaping products as an alternative to combustible cigarettes.

In particular, I favor a publicity program of the type adopted by the smoking cessation program in Leicester City in the UK in 2014. That program produced a "Time to Switch" poster as part of its smoking reduction objectives (see below). As Shapiro (2018) reports, the poster went viral

[16] McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18. A report commissioned by Public Health England. London: Public Health England, 2018

immediately. If such a campaign were to be considered by health agencies, it would seem reasonable that manufacturers of vaping products should be permitted to signal to the public that they produce products which are compatible with the objectives of health agencies.

Time to Switch poster

Source: Source: http://www.stopsmokingleic.co.uk/resources/

Retail Display Bans

Retail display bans are another policy that is applied to combustible tobacco products, which some regulators are considering extending to vaping products.

However, there is little empirical evidence suggesting that retail display bans are effective in changing smoking behaviours. For example in a paper which I prepared with my colleague, Dr Hai Nguyen (Irvine, Ian J and Van Hai Nguyen, 2014) we note that there are few, if any, population-based econometric studies on the impact of retail display bans. In order to full this gap we analysed annual Canadian Tobacco Use Monitoring Survey data from 1999 to 2011 for eight of the ten Canadian provinces to assess the impact of retail display bans of cigarettes in Canada. In our analysis, we found no systematic support for a significant impact of the retail

bans on participation or quit intentions, and just limited support (among youth) for a reduction in intensity.

Furthermore, the retail display of vaping products is another factor that is important to raising the awareness of vaping products so that they are become known to smokers and are perceived by them as a viable alternative to cigarettes. Because vaping products are still relatively new compared to cigarettes, adult smokers' awareness of their availability and attributes will be inhibited if they are hidden at points of sale. Accordingly, banning the retail display of vapour products could have the unintended consequences of perpetuating misperceptions regarding the relative risk of products and discouraging smokers from switching, as well as adversely impacting the business of many small and medium size retailers.

Displays obviously come in different forms. As with advertising more generally, I do not propose that displays be unrestricted. However, if health agencies are to encourage switching, then it would be incongruous if retail outlets were prevented from indicating to the public that they sell a range of potentially reduced harm products that are consistent with health agency goals.

Age limits

A popular policy for preventing youth access is to limit the age of purchase to individuals aged 21 and over. The Canadian Province of Prince Edward Island has already proposed such a change. Recently, the US Federal government has passed a law to increase the purchase age for tobacco products, including e-cigarettes, to 21. Similar policies are also being considered in a number of other jurisdictions. The first of the several principles I outlined above proposes that products that are potentially less harmful to health should not be bundled up with products that are more harmful to health. But that is the result of such a measure, where cigarettes are likely an order of magnitude more toxic than e-cigarettes.

It is also incompatible with our social philosophy that 18 is the 'normal' age of majority. At this age, individuals in most jurisdictions may vote, buy firearms, hunt, drive vehicles, frequent gaming establishments, legally consume alcohol, kill opponents in war, fly aircraft, and engage in prostitution in some jurisdictions. It is therefore incongruous to deny individuals who are older than this the choice to consume nicotine.

Furthermore, while it is easy to legislate a higher threshold, it is costly to monitor it. Unless additional resources are directed to monitoring and enforcement, higher age thresholds may herald little change. This is the standard argument brought to bear in the national discussions over a permissible blood-alcohol content of drivers. A campaign to reduce alcohol levels every time a youth dies in a traffic accident carries an unassailable appeal, but unless it is accompanied by enforcement, it may have little impact.

The legal age of smoking in every province in Canada has to this point been either 18 or 19. This is consistent with the age eligibility associated with other cognate activities. It is well established that youth who initiate smoking almost always do so before the age of 19, meaning that if young adults are free to experiment above the age of 19 very few will likely choose to exercise that right. This indicates that increasing the legal age to 21 may not have as significant an effect as argued by its proponents.

The cannabis benchmark

In Canada, rules governing the consumption of cannabis also provide a comparison point for nicotine vaping. Cannabis may be purchased and consumed legally at the age of 19 in most Canadian provinces. When consumed in leaf form, cannabis produces a number of carcinogens as it involves combustion. It is also specifically designed to introduce an altered state of mind in the user. In contrast to cannabis in past decades, the THC content of the modern product is enormously elevated. Concentrations in the 20% plus range are now commonplace.

Rules of access should not be based upon false equivalences. Cigarettes, e-cigarettes and cannabis consumption carry different risks. Accordingly, the relative dangers of the products should be a consideration in setting different age thresholds. If the government sets the same legal access age for e-cigarettes and cigarettes it implies that these products are equally harmful. This is false and anti-scientific.

The formation of nicotine vaping policy in Canada cannot easily be separated from the formation of cannabis policy. If the legal age to vape is increased to 21, in most provinces, 19-year olds will be permitted to purchase cannabis that is intoxicating, but will be prohibited from vaping nicotine e-liquid that is not. This approach is unjustifiable.

Nicotine content

Limits on nicotine content for e-liquids are also being considered by a number of regulators. In Canada, for example, Federal policy under the *Consumer Product Safety Act*, will limit nicotine concentration in liquids for vaping products to 66 mg/ml. This policy is due to come into effect on 1 July 2020 under the new *Vaping Products Packaging and Labelling Regulations.* This policy reflects a comprehensive effort to establish a reasonable concentration limit. The limit reflects due consideration by the Federal Government to concerns over nicotine toxicity and the risk of accidental poisoning and also constitutes a federal limit that will encourage consistency and enforcement efficiencies.

However, it has recently been contended (for example, by authorities in British Columbia) that the concentration limit should be dramatically lower, proposing a 20 mg/ml limit. For the reasons stated herein, such a low nicotine concentration limit would likely be a counterproductive measure and would not constitute sound regulatory policy. In fact, it may perpetuate harm if smokers cannot achieve the nicotine delivery they want, which in turn may discourage switching to e-cigarettes or increase relapse.

For example, a group of leading authorities on nicotine and tobacco policy, (including noted tobacco and nicotine researcher Professor Lynn Kozlowski) has stated that the 20 mg/ml limit as adopted by the European Union is not supported by sound regulatory policy, finding that at least 50 mg/ml concentration is necessary to match nicotine delivery smokers obtain from conventional cigarettes in order to provide a satisfactory, potentially reduced risk alternative for smokers.[17]

Furthermore, a reduced limit would also encourage some users to self-assemble higher concentrations by purchasing liquid nicotine, flavoring and suspension agents independently.

The 66 mg/ml limit reflects consideration of harm reduction goals and an intention to limit accidental nicotine poisoning. A 20 mg/ml limit could lead to a demand for illicit products with

[17] See January 16, 2014 letter to EU authorities at http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/149-tpd-errors.

higher concentration, the production and marketing of which would result in an unregulated market that would perversely increase chances of accidental nicotine poisoning.

Furthermore, the 66 mg/ml concentration limit is a federal standard that provides consistent regulation nationally. If individual provinces set differing limits, products from other provinces with higher limits may be brought into provinces with lower limits to satisfy consumer demand, creating a new range of technically illicit products under particular provincial regulations. Such a situation would breed general disregard for regulations of vaping and tobacco products and pose dilemmas for the various police and other authorities tasked with enforcing such laws.

4. The need for balanced, proportionate policy

Public policy on vaping is being driven by a valid concern for the well-being of youth who are experimenting in large numbers in some jurisdictions. However, the potential public health gains that could be achieved with an effective vaping policy that encourages smokers to switch to vaping, have been substantially lost sight of by many advocates.

The Instruments and Objectives approach to policy formation, described above, is an important principle of policy making. If there are two objectives, then there should be more than one instrument. A distinction must be drawn between policies aimed at youth and policies aimed at potential adult switchers. In particular, to stem, or at least reduce, the widespread experimentation with e-cigarettes, rigorous access policies need to be put in place where youth are concerned.

However, the adoption of the policies discussed in the previous section, were they successfully implemented, and not undermined by an illegal market, means that as a society we may forego the opportunity to reduce the projected harm from tobacco use on a significant scale by encouraging smokers to move to a potentially reduced-risk product with characteristics that will enable them to avoid returning to smoking.

In Canada, in the nineties, we had daily smoking rates of 35% among high-school students in an environment where the legal age of smoking was 18. Smoking rates fell when a series of measures were adopted that collectively changed the public's cultural consciousness, and that were enforced.

In addition to the strong enforcement of youth access policies, society must continue to present youth education programs that promote an understanding of the risks of tobacco and nicotine use. Youth should be informed that the young brain is still being formed until individuals are in their twenties, and that any nicotine use may be detrimental to that development.

Public health authorities in the US have proclaimed that social marketing campaigns are effective tools at reaching youth audiences. For example, the US FDA has touted a study (Sharples, 2019) asserting that its Real Cost youth anti-smoking campaign has “prevented up to

587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers."

An informative analog in monitoring and regulating harmful products, is the cannabis market in Colorado. Colorado was one of the first US states to legalize recreational marijuana. A recent report (Marijuana Policy Group, 2018) indicates that the legal market has almost completely wiped out the illegal market, as a result of a series of policies. One of the policies relates to regulation monitoring and enforcement. The Marijuana Enforcement Division of Colorado's Department of Revenue is extremely active. It visits retail outlets to ensure that minors are not being served; and it takes samples of product from suppliers and retailers and sends them to laboratories to ensure both that the chemical compound claims on the product are true and that contaminants are absent. In all the MED in 2018 implemented 160,000 tests, and recorded 'passing' grades in the high 90s percentiles.

The combination of rigorous enforcement of rules, and the ability of the market place to function with a high degree of independence, means that consumers have access to a broad spectrum of legal products at competitive prices – a product that they can be confident is not contaminated and that contains the combination of CBD and THC stated on the label. A philosophy and approach that advocates truthful messages and ensures product quality has reduced the illegal market to a small fraction of the legal market.

5. Conclusion

E-cigarettes are a disruptive technology. They provide smokers with an alternative means of consuming nicotine that is potentially less harmful to health than smoking. So too are new products that heat rather than burn tobacco.

At the same time, youth are experimenting with vaping and, in Canada, recent data also indicates an increase on the number of youth vaping almost daily. However, it must be recognized at the same time that there is an element of substitution associated with this increase, with continued reductions in smoking having been contributed to by the availability of potentially reduced risk e-cigarettes.

The arrival of new technologies is inevitably associated with disruption. A new technology may disrupt the producers of products that may be displaced; it may disrupt long-established consumption patterns; it may disrupt the workplace; it will probably raise issues of safety on account of its unknown aspects. Rarely in history has a new technology been adopted by society that has not disrupted, caused anxiety and led to disputes. Juma, 2016, develops the theme of new-technology resistance.

The challenge for policy makers at the present moment is to recognize the potential for vaping products to reduce harm for adults, while still creating a physical, cultural and market-place environment in which the consumption of nicotine in any form is not attractive to youth.

The daily barrage of bad news on vaping frequency in high schools ignores the simultaneous dramatic changes in other youth behaviors, including that their smoking is dropping precipitously. There is also no evidence of vaping leading to more smoking. Alcohol consumption and drunkenness are also plummeting, as is the consumption of a number of other serious drugs.

Regulators require a two pronged approach to vaping. On the one hand, smokers who will not otherwise quit should be encouraged and helped to switch to potentially reduced risk products. There is growing evidence indicating that vaping is more effective in helping smokers to quit smoking than any of the existing medical technologies. Unfortunately, that evidence too has been misinterpreted in the public domain. The second approach involves increased youth

education programs, combined with intensive scrutiny of retail practices. The State of Colorado was able to do this in the field of marijuana, and governments can do it in the field of vaping.

But policies and enforcement should not be such as to prevent the dissemination of accurate information on e-cigarettes that enable adult consumers to make informed choices.

Raising the legal age of purchase to 21 and banning flavors may indeed reduce vaping among some individuals. But it will send some vapers back to smoking and most surely invite an illegal market. A balanced policy would leave non-youth oriented flavors in the market-place as well as prohibiting the marketing of flavors aimed at youth, as Canada's TVPA currently provides, and increase enforcement of restrictions on youth access.

Taxes may seem attractive on the surface, but government needs to consider the impact of increasing costs and in treating cigarettes and e-cigarettes in the same way. A favorable price of an alternative to cigarettes will provide a greater inducement for smokers to switch, particularly for those on low incomes.

The scientific evidence on plain packaging for cigarettes indicates that it had little if any discernable impact on smoking when introduced in Australia, and this begs the question of why there might be a different outcome in the case of vaping. Treating e-cigarettes in the same way as combustible tobacco products, including by banning all advertising and banning the retail display of products can also undermine consumer awareness and perceptions of the different risks of products, and thus deter some consumers who smoke tobacco from switching.

It is important that society avoid implementing an excess menu of measures that will undermine the harm-reducing potential of this new technology. The precautionary principle is attractive on the surface only; excessive limitation of new technologies that incorporate both positive and negative elements may kill the positive as well as the negative.

On the political front, politicians are under pressure to ‘do something for our children’ as a result of the non-stop media coverage of vaping among youth. It is unfortunate that the public is not more aware of the comparative risks of e-cigarettes compared to smoking; that it is not

fully aware of the simultaneous dramatic declines in other risky behaviors among youth and of the number of individuals that e-cigarettes have already aided in quitting cigarettes.

It is an irony of the era that, while thousands of people die per day in the form of premature mortality associated with smoking, the potential for this new technology to ameliorate this situation is either unrecognized, ignored or underappreciated.

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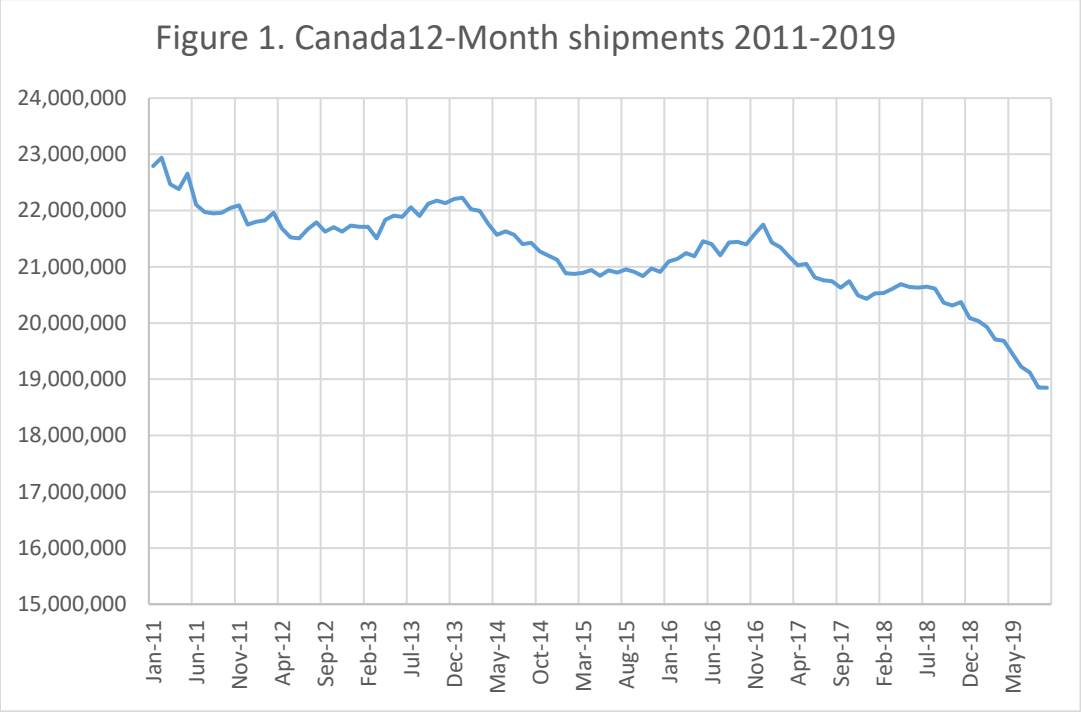
Professor Ian Irvine

13 February 2020

Graphics and Tables



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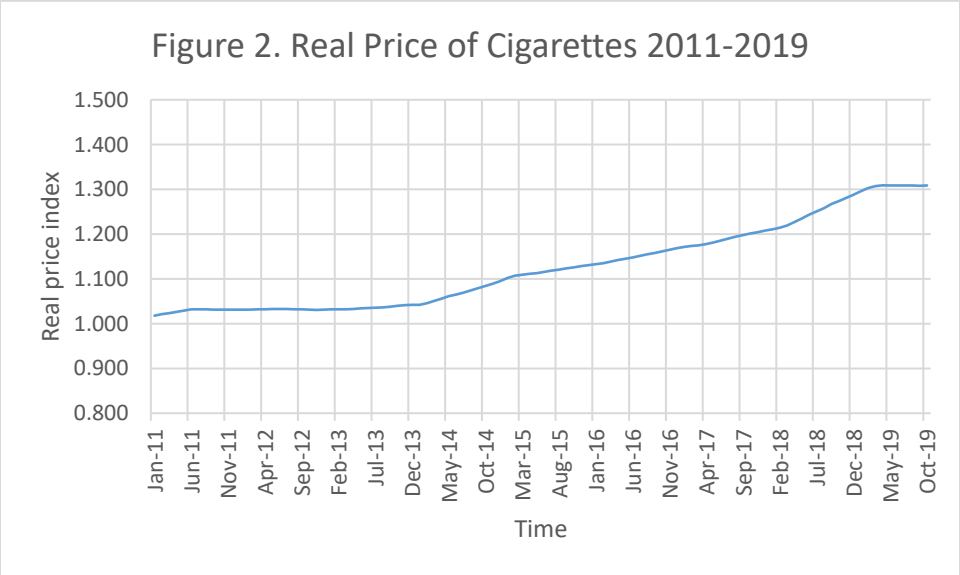

Data sources:

https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1810000201

https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=1810000401

Table 1. Smoking and vaping rates US high school past 30-day use						
	Gr 10 smoking	Gr 12 smoking		Gr 10 vaping	Gr 12 vaping	Gr 12 smokeless
1997	29.8	36.5				9.7
1998	27.6	35.1				8.8
1999	25.7	34.6				8.4
2000	23.9	31.4				7.6
2001	21.3	29.5				7.8
2002	17.7	26.7				6.5
2003	16.7	24.4				6.7
2004	16	25				6.7
2005	14.9	23.2				7.6
2006	14.5	21.6				6.1
2007	14	21.6				6.6
2008	12.3	20.4				6.5
2009	13.1	20.1				8.4
2010	13.6	19.2				8.5
2011	11.8	18.7				8.3
2012	10.8	17.1				7.9
2013	9.1	16.3				8.1
2014	7.2	13.6		16.3	17.2	8.4
2015	6.3	11.4		14.2	16.3	6.1
2016	4.9	10.5		11	12.5	6.6
2017	5	9.7		13.1	16.6	4.9
2018	4.2	7.6		21.7	26.7	4.2
2019	3.4	5.7		25.0	30.9	3.5
Source: MTF tables and Levy *et al* 2018.						

Table 2. Vaping rates in Canada, England and the US among 16-19 year olds, 2017-2018						
	Canada		England		United States	
	2017	2018	2017	2018	2017	2018
>15 days /past 30 days	2.1	3.6	2.0	2.2	3.0	5.2
During past 30 days	8.4	14.6	8.7	8.9	11.1	16.2
Source: Hammond et al, British Medical Journal 2019						

Table 2a Past 30-day e-cigarette use Canada 2016-17 CSTADS surveys								
	None	1 day	2-3 days	4-5 days	6-10 days	11-20 days	21-29 days	30 days
Grade 10-12	88.4	5.0	3.8	1.8	1.5	1.0	0.7	1.8
Past 30-day e-cigarette use Canada 2018-19 CSTADS surveys								
	Never tried	Not in last 30 days	< weekly	< daily and > weekly	Daily or almost daily			
Grade 10-12	59.0	14.2	8.7	6.4	11.6			
Smoker status Canada CSTADS 2016-17								
	Current smoker	Daily smoker	Occasional smoker	Former or experimental	Experimental smoker	Puffer	Never tried	
Grade 10-12	5.4	2.2	3.2	6.6	4.6	11.4	71.9	
Smoker status Canada CSTADS 2018-19								
Grade 10-12	4.6	1.3	3.2	7.9	4.1	12.2	71.2	

Table 3. Daily smoking rates among Ontario grade 11 students									
1999	2001	2003	2005	2007	2009	2011	2013	2015	2017
34.7	29.4	18.4	14.7	9.9	8.6	6.2	4.9	3.9	3.4
Source: Ontario Student Drug Use Survey, Centre for Addiction and Mental Health									

Table 4. Primary reasons for starting vaping		
	N = 1492	%
Just an alternative to cigs	652	43.7
Healthier/less harmful than other tobacco products	465	31.2
I like the flavors	440	29.5
Trying to quit smoking cigs or other tobacco products	277	18.6
Nicer smell than tobacco smoke	276	18.5
When I can't smoke cigarettes	275	18.4
My friends vape	126	8.5
I like trying new products	114	7.6
Cheaper than other tobacco products	113	7.6
I like the nicotine	94	6.3
More places allow vaping that do not allow cigarettes or cigars	75	5.0
Makes me feel good about myself	70	4.7
I'm a cloud chaser – I like big clouds	69	4.6
A healthcare professional recommended it	54	3.6
My family members vape	32	2.1
Other	38	2.6
Source: Landry et al, 2019.		

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Appendix 3

Growing list of respected scientific and public health organizations that have reviewed all the evidence and concluded that nicotine vaping is safer than smoking (and helps smokers quit)

All statements are hyperlinked to original documents. >35 organizations say "SAFER than smoking."

World Health Organization
REGIONAL OFFICE FOR Europe

World Health Organization EURO Office: "There is conclusive evidence that: Completely substituting electronic nicotine and non-nicotine delivery systems for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."

International Agency for Research on Cancer
World Health Organization

International Agency for Research on Cancer: "The use of e-cigarettes is expected to have a lower risk of disease and death than tobacco smoking… E-cigarettes have the potential to reduce the enormous burden of disease and death caused by tobacco smoking if most smokers switch to e-cigarettes."

Cochrane

Cochrane systematic review: "We found 50 studies in 12,430 adults who smoked… The studies took place in the USA (21 studies), UK (9), Italy (7), Australia (2), New Zealand (2), Greece (2) and one study each in Belgium, Canada, Poland, South Korea, South Africa, Switzerland and Turkey."
FINDINGS: "Moderate certainty" that "e-cigarettes with nicotine increase quit rates compared to e-cigarettes without nicotine, and compared to nicotine replacement therapy [nicotine patches & gum]… We did not detect any clear evidence of harm from nicotine e-cigarettes" [up to 2 years]."

Public Health England

Public Health England: "Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know."

Royal College of Physicians

Royal College of Physicians: "Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure… E-cigarettes are effective in helping people to stop smoking."

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence: "The evidence suggests that e-cigarettes are substantially less harmful to health than smoking but are not risk free. Many people have found them helpful to quit smoking cigarettes."

BMA

British Medical Association: "Significant numbers of smokers are using e-cigarettes (electronic cigarettes), with many reporting that they are helpful in quitting or cutting down cigarette use. There

are clear potential benefits to their use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use."

Cancer Research UK: "While the long-term health consequences of e-cigarette use are uncertain, the evidence so far suggests that e-cigarettes are far less harmful than smoking. ...There is also growing evidence to suggest that e-cigarettes can work successfully as an aid to cessation. …There is insufficient evidence to support a blanket indoor ban on e-cigarette use, either on the basis of renormalisation of smoking or harm to bystanders from second-hand vapour."

British Lung Foundation: "Experts have reviewed all the research done on e-cigarettes over the past few years, and found no significant risks for people using e-cigarettes. ...Swapping cigarettes for an e-cig can improve your symptoms of lung conditions like asthma and COPD."

Royal College of General Practitioners: "The evidence so far shows that e-cigarettes have significantly reduced levels of key toxicants compared to cigarettes, with average levels of exposure falling well below the thresholds for concern."

Royal Society for Public Health: "RSPH has welcomed a new comprehensive evidence review on e-cigarettes published by Public Health England (PHE). The report reflects an up-to-date evidence base that is increasingly pointing in the same direction: not only that vaping is at least 95% less harmful than smoking, but also that it is helping increasing numbers of smokers to quit."

Stroke Association UK: "Current evidence shows that the risk to health posed by e-cigarettes in the short term is likely to be considerably less compared to smoking."

Action on Smoking and Health UK: "It has been estimated that e-cigarettes are 95% less harmful than ordinary cigarettes. There is negligible risk to others from second-hand e-cigarette vapour. ...The lifetime cancer risk of vaping has been assessed to be under 0.5% of the risk of smoking. [But] Public understanding of the relative harms of e-cigarettes [vs smoking cigarettes] have worsened over time and are less accurate today than they were in 2014."

National Centre for Smoking Cessation and Training: "Experts estimate that e-cigarettes are, based on what we know so far, around 95% safer than cigarettes. Smoking is associated with a number of very serious health risks to both the smoker and to others around them. Therefore, smokers who switch

from smoking tobacco to e-cigarettes substantially reduce a major risk to their health. ...Nicotine does not cause smoking related diseases, such as cancers and heart disease."

National Health Service Scotland consensus statement on e-cigarettes: "Smoking kills. Helping people to stop smoking completely is our priority. …There is now agreement based on the current evidence that vaping e-cigarettes is definitely less harmful than smoking tobacco."

> This statement was created and endorsed by: Action on Smoking & Health Scotland • Cancer Research UK • Chest Heart & Stroke Scotland • Chief Medical Officer for Scotland • NHS Ayrshire and Arran • NHS Greater Glasgow and Clyde • NHS Lothian • NHS Tayside • Roy Castle Lung Cancer Foundation • Royal College of General Practitioners • Royal College of Physicians of Edinburgh • Royal College of Physicians and Surgeons of Glasgow • Royal Environmental Health Institute of Scotland • Scottish Collaboration for Public Health Research and Policy • Scottish Consultants in Dental Health • Scottish Thoracic Society • UK Centre for Tobacco & Alcohol Studies • University of Edinburgh • University of Stirling

New Zealand Ministry of Health: "The Ministry considers vaping products could disrupt inequities and contribute to Smokefree 2025. The evidence on vaping products indicates they carry much less risk than smoking cigarettes but are not risk free. Evidence is growing that vaping can help people to quit smoking. There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it."

Cancer Society of New Zealand: "E-cigarettes and smokeless tobacco products are less harmful than tobacco smoking."

Royal Australian & New Zealand College of Psychiatrists (RANZCP): "Research in Australia shows that 70% of people with schizophrenia and 61% of people with bipolar disorder smoke compared to 16% of those without mental illness. …RANZCP recognises the potential harm reduction benefits presented by e-cigarettes and vaporisers for people living with mental illness, and the need for legislative reform for these to be realised. The RANZCP therefore recommends: Exemption of nicotine-containing e-cigarettes and vaporisers from the restrictions imposed under the Poisons Standard so that they may be subject to stringent and suitable regulations as consumer products [and] lower rates of taxation for e-cigarettes and vaporisers compared to smokable tobacco products to ensure affordability for low-income smokers, and to provide a financial incentive to switch."

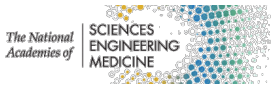
Drug and Alcohol Nurses of Australasia: "People with drug and alcohol dependence have high smoking rates [and] are more likely to die from a tobacco-related disease than from their primary drug problem. E-cigarettes are battery-operated devices that heat a liquid solution, which may or may not contain nicotine into a vapour for inhalation, simulating the behavioural and sensory aspects of smoking, and they are currently seen as a legitimate form of tobacco harm reduction."

Royal Australian College of Physicians: "The RACP acknowledges that e-cigarettes may have a potential role in tobacco harm reduction and smoking cessation for smokers unable or unwilling to quit."

German Federal Institute for Risk Assessment: "According to current knowledge, e-cigarettes are less harmful than conventional tobacco products when used as intended."

French National Academy of Medicine: "It is established that the vaporette is less dangerous than the cigarette… It is therefore preferable for a smoker to vape. Since 2016, the High Authority for Health (HAS) considers it 'as an aid to stop or reduce the consumption of tobacco by smokers.' Santé Publique France indicates that at least 700,000 [French] smokers have quit using electronic cigarettes. ...Smokers who were about to switch to vaporizing instead of tobacco should not hesitate…" [Google Translate from original French]

French National Academy of Pharmacy: "The World Health Organization's [anti-e-cigarette] position is incomprehensible. Tobacco is responsible for 73,000 deaths in France. The e-cigarette helps people quit smoking. Its components are obviously less harmful than tobacco." [NOTE: This is a Tweet from the Académie Nationale de Pharmacie. Not an official position statement.]



US National Academies of Sciences, Engineering and Medicine: "While e-cigarettes are not without health risks, they are likely to be far less harmful than combustible tobacco cigarettes. There is substantial evidence that... exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes."

US Food & Drug Administration: "Make no mistake. We see the possibility for ENDS products like e-cigarettes to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco."

US Centers for Disease Control: "E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products."

American Cancer Society: "Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes." [NOTE: This was the official statement from 2018-2019. As of

November 2019, ACS no longer recommends e-cigarettes as a smoking cessation tool. Their stated reason for this change was "e-cigarette use by young people." Yet their new statement still says, "former smokers now using e-cigarettes should not revert to smoking." So, obviously, ecigs are LESS HARMFUL.]

American Heart Association: "Participants who vaped exclusively showed a similar inflammatory and oxidative stress profile as people who did not smoke cigarettes or use e-cigarettes. ...Compared to participants who smoked exclusively, those who vaped exclusively had significantly lower levels of almost all inflammatory and oxidative stress biomarkers."

American Association of Public Health Physicians: "Smoke-free tobacco/nicotine products, as available on the American market, while not risk-free, carry substantially less risk of death and may be easier to quit than cigarettes. ...Smokers who have tried, but failed to quit using medical guidance and pharmaceutical products, and smokers unable or uninterested in quitting, should consider switching to a less hazardous smoke-free tobacco/nicotine product for as long as they feel the need. Such products include pharmaceutical Nicotine Replacement Therapy (NRT) products used, off-label, on a long term basis, electronic "e" cigarettes, dissolvables (sticks, strips and orbs), snus, other forms of moist snuff, and chewing tobacco."

Campaign for Tobacco-Free Kids: "E-cigarettes could benefit public health if they help significantly reduce the number of people who use combustible cigarettes and die of tobacco-related disease."

Government of Canada: "Vaping is less harmful than smoking. Completely replacing cigarette smoking with vaping will reduce your exposure to harmful chemicals. There are short-term general health improvements if you completely switch from smoking cigarettes to vaping products."

Canadian Heart & Stroke Foundation: "Emerging evidence demonstrates that e-cigarettes are less harmful than conventional cigarettes. Through the legalization of e-cigarettes containing nicotine, there is improved access to e-cigarettes for current smokers, therefore allowing adults more choice around alternative methods of nicotine intake and/or tobacco cessation. ...Those unable to quit smoking would be better off using e-cigarettes over the long-term, rather than continuing to smoke regular cigarettes."

Appendix 4

Expert Report of Karl Olov Fagerström, Ph.D.

BACKGROUND AND QUALIFICATIONS

1. My name is Karl Olov Fagerström. I studied at the University of Uppsala and graduated as a licensed clinical psychologist in 1975. Since 1975, my work has focused on behavioural medicine, nicotine dependence and smoking cessation. I received a Ph.D. in Medical Psychology (with a dissertation in nicotine dependence and smoking cessation) from the University of Uppsala in 1981.

2. I have over 150 publications in the scientific literature in the field of tobacco, nicotine dependence and smoking cessation. I developed the Fagerström Test for Nicotine Dependence, which continues to be the most widely used test. I was editor of the Scandinavian Journal for Behaviour Therapy from 1975 to 1977, and from 1978 to 1982 I served as editor-in-chief of this Journal. I was Manager, Research and Development, Nicotine Replacement Products, for Pharmacia AB, from 1983 to 1997, and I worked in smoking cessation clinical trials for Pharmacia/Pfizer from 1985 to 1997. I have worked with and contributed to the development of nicotine replacement therapy products such as nicotine gum, patches, sprays and inhalers. Since 1997, I have been working with my private consultancy, Fagerström Consulting AB. I am a consultant to companies with an interest in nicotine dependence treatment products. From 1998 to 2010, I was Director and owner of The Smokers Information Center in Sweden. I am also a founding member of the Society for Research on Nicotine and Tobacco and Chairman of the European Society for Research on Nicotine and Tobacco.

3. In 1999, I was awarded the World Health Organisation's medal for outstanding work in tobacco control. I am also the recipient of the 2013 Award on Clinical Science from the Society for Research on Tobacco and Nicotine. Further details of my publications and affiliations may be found in my attached curriculum vitae.

SCOPE AND SUMMARY OF OPINIONS

4. At the request of Nicoventures Holdings Limited, and having seen its prior regulatory submissions, I have reviewed the paper of the Hong Kong Legislative Counsel, Panel on Health Services, entitled "Progress of Tobacco Control Measures" (LC Paper No. CB(2)1456/14-15/(07)) and in particular its proposal to prohibit the import, manufacture, sale, distribution and advertising of electronic cigarettes ("e-cigarettes") in Hong Kong, which I refer to here as the "Proposal".

5. The Proposal seeks to justify a ban on e-cigarettes through assertions that (1) e-cigarettes present health risks both to users, including, for example, from the formation of formaldehyde during vaporisation, and to non-users, purportedly from "exposure to nicotine and other toxicants from passive smoking" (Proposal, ¶ 24); (2) e-cigarettes may act as a "gateway" to eventual cigarette smoking, after e-cigarette users, and in particular youth, have become "addicted to nicotine through e-cigarettes" (Proposal, ¶ 25); and that (3) there is only "limited and inconclusive" evidence that e-cigarettes help smokers to stop cigarette smoking (Proposal, ¶ 30).

6. As I explain below, and based on my medical and scientific background and expertise, there is insufficient scientific evidence to support the Proposal's assertions regarding e-cigarettes. Rather, while long term epidemiological data with respect to e-cigarettes is not yet available, and contrary to the suggestions in the Proposal, evidence to date indicates that e-cigarettes are unlikely to present significant health risks to both users and non-users. The available evidence indicates that e-cigarette use is not a gateway to the uptake of cigarette smoking. The scientific evidence further demonstrates that e-cigarettes are as effective as

nicotine replacement products in helping cigarette smokers to quit smoking. It is my view, therefore, that the weight of the scientific evidence to date demonstrates that e-cigarettes are an important component of a public health and harm reduction strategy. The e-cigarette category should be regulated appropriately so as to ensure that products meet high quality and safety standards expected from such consumer goods. The toxicity of the major compounds of e-cigarette vapour are well known and not of concern. Effective regulation should ensure product components are safe and that flavours used are not toxic or degradable to toxic compounds in use. A complete prohibition on e-cigarettes would benefit the traditional cigarettes and rather than leading to a public health benefit, would instead likely result in significant adverse public health effects.

THE SCIENTIFIC EVIDENCE DOES NOT SUPPORT THE PROPOSAL'S CONTENTIONS

7. E-cigarettes typically consist of a battery, a heating coil and a liquid. These liquids generally contain nicotine, water, a "diluent" such as propylene glycol and/or glycerol, and sometimes flavourings. They do not contain tobacco. The liquid is pulled into the coil by a wicking mechanism. Drawing on the e-cigarette or pressing a switch activates the battery to heat the coil, which vaporises the liquid. This vapour is then inhaled by the e-cigarette user. There is no combustion, so the user inhales vapour, not smoke, and no tobacco "tar" is produced. E-cigarettes and the liquids can be sold as integrated units or with liquids sold separately.

A. Claimed Health Risks Regarding E-Cigarettes

8. As set forth above, the Proposal contends that e-cigarettes present health risks to users, including, for example, from the formation of formaldehyde during vaporization) as well as to non-users, due to (in the Proposal's view) the exposure to nicotine and other toxicants from passive exposure to e-cigarette vapour (Proposal, ¶ 24).

9. The scientific evidence does not support this contention.

10. The only study cited in the Proposal regarding health effects is a single (non-peer reviewed) letter to the editor of the New England Journal of Medicine suggesting that high levels of certain formaldehyde-releasing agents could be formed during vaporisation of e-liquid[1]. The results reported in this letter have not been verified, duplicated or validated. In fact, this letter and its conclusions have subsequently been called into serious question. One commentator, for example, noted that the experimental conditions employed for the e-cigarette analysis described in the letter bear no resemblance to how people actually use e-cigarettes[2]. Another recent study directly refuted the findings of the letter, leading to the conclusion that far lower and minimal amounts of aldehydes are released in the e-cigarette aerosol at normal vaping conditions[3].

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[1] Jensen, R P, et al. Hidden Formaldehyde in E-Cigarette Aerosols, N. Engl J Med 2015; 372:392-392 (January 22, 2015) (see Proposal, ¶ 7).
[2] Nitzkin JL, Farsalinos K, Siegel M. More on hidden formaldehyde in e-cigarette aerosols. N Engl J Med. 2015 Apr 16;372(16):1575. doi: 10.1056/NEJMc1502242#SA1.
[3] Farsalinos KE, Voudris V, Poulas K. E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions. Addiction. 2015 May 20. doi:10.1111/add.12942.

11. As to formaldehyde, it has been reported that formaldehyde is present in the vapour from e-cigarettes, but where found this is at levels 6-50 times lower than found in conventional cigarette smoke[4].

12. It should be noted that low levels of carcinogens are found almost everywhere in the environment and the air that we breathe and the food that we eat. It is not merely the presence of trace amounts of carcinogens, but whether these carcinogens cause exposures at levels and via pathways that pose material risk. The largest study to date on toxicants in e-cigarette vapour concluded: "The levels of the toxicants were 9-450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference [pharmaceutical nicotine] product"[5].

13. While formaldehyde can be generated in small quantities in e-cigarettes, a systematic review of e-cigarette vapour composition published in 2014 concluded that: "Current state of knowledge about chemistry of liquids and aerosols associated with e-cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces"[6].

14. With respect to nicotine, while it has the potential to cause dependence, exposure to nicotine is not generally believed to be associated with any long term health effects such as cancer, heart disease or pulmonary disease[7]. The Medicines and Healthcare products Regulatory Agency ("MHRA") assessed the health effects of nicotine and stated "there is a large body of evidence that medicinal nicotine (in current licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease"[8].

15. The Proposal also asserts that "most e-cigarettes contain propylene glycol which is a known irritant when inhaled" (Proposal, ¶ 24). However, it has been reported that "[t]he results of extensive studies on animals, reviewed elsewhere, suggest that PG [propylene glycol] should be safe for inhalation in humans, although in children, chronic exposure to PG in indoor air may exacerbate or induce rhinitis, asthma, eczema and allergic symptoms. Acute and chronic respiratory effects, including reduced lung function, were reported in people chronically exposed to theatre fogs containing PG"[9]. The authors' concluded that "PG and glycerol inhalation is likely to

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[4] Farsalinos K. E-Cigarette Research Blog, 27 November 2014, available at http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/188-frm-jp.

[5] Goniewicz M, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 2014 Mar;23(2):133-9.

[6] Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. Igor Burstyn. BMC Public Health (2014).

[7] Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007.

[8] UK MHRA Public assessment report: The use of nicotine replacement therapy to reduce harm in smokers, February 2010, available at http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/es-policy/documents/publication/con068571.pdf.

[9] Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 3.

pose a low risk, although their long-term effects as well as the effects of long-term inhalation of EC flavourings and additives need to be studied"[10].

16. As to "passive vaping," it is noteworthy that the proposed ban on public place vaping recently suggested in Wales (UK) was opposed by a number of highly reputable health organisations and public health bodies as detailed in the quotations reported below:

    a. "There isn't enough evidence to justify a ban on using e-cigarettes indoors. The measure could create more barriers for smokers trying to quit tobacco." Cancer Research UK[11].

    b. "[I]n the absence of evidence of significant harm to bystanders, ASH does not support the inclusion of electronic cigarettes in smokefree laws which would completely prohibit their use in enclosed public places." Action on Smoking and Health UK[12].

    c. "To date, we can see no suggestion in the existing evidence base that would support an outright ban on the use of e-cigarettes." Action on Smoking and Health Wales[13].

17. The foregoing quotations sum up the clear conclusion that there is no known risk to health from being exposed to second hand vapour from e-cigarettes, and it is evidenced scientifically by expert analysis of air quality in a vaping environment. For example, one study concluded that "[f]or all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed"[14].

18. Ultimately, the Proposal asserts that the claimed health effects from e-cigarettes are a significant concern (Proposal, ¶ 30). However, there is good evidence that the toxicant yield of e-cigarettes is low, because e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in cigarette smoke. Instead, e-cigarettes deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke. As reported by the UK Royal College of Physicians: "Cigarette smoke is harmful primarily because it delivers nicotine in conjunction with an extensive range of toxins and carcinogens"[15]. The UK National Institute for Health and Care Excellence concludes similarly: "Most health problems are caused by other components in tobacco smoke, not by the nicotine"[16].

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[10] Id.

[11] George Butterworth, Tobacco Policy Manager at Cancer Research UK, available at http://www.cancerresearchuk.org/about-us/cancer-news/news-report/2015-06-09-welsh-government-proposes-banning-e-cigarettes-in-public-places.

[12] ASH Briefing, Electronic Cigarettes, Nov. 2014, available at http://www.ash.org.uk/files/documents/ASH_715.pdf.

[13] Electronic cigarettes ASH Wales Cymru, available at http://ashwales.org.uk/en/information-resources/topics/electronic-cigarettes.

[14] Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. McAuley et al, Inhal Toxicol. 2012 Oct:24(12):850-7. doi: 10.3109/08958378.2012.724728.

[15] Harm reduction in nicotine addiction. Helping people who can't quit. A report by the Tobacco Advisory group of the Royal College of Physicians. London RCP, 2007, at 220.

[16] Tobacco: Harm reduction approaches to smoking, a report by the UK National Institute for Health and Care Excellence (NICE), 2013.

19. A recent review of available research on content and safety of e-cigarettes, and their potential harm or benefit, concluded that the e-liquids and aerosols tested contain toxicants in concentrations far lower than that of tobacco smoke, and also contain negligible concentrations of carcinogens. In terms of the potential for e-cigarettes to cause excess morbidity and mortality, the authors stated: "[H]ealth effects of long-term EC [e-cigarette] use are currently not known and a degree of risk may yet emerge. However, based on the data available regarding the toxicant content of EC liquid and aerosol, long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders. This is because unlike cigarettes, EC do not deliver combustion generated toxicants that are linked to cancer, chronic lung disease and cardiovascular disease (CVD)"[17].

20. Another review of published e-cigarette vapour composition studies conducted in 2014 found that the "[c]urrent state of knowledge about chemistry of liquids and aerosols associated with electronic cigarettes indicates that there is no evidence that vaping produces inhalable exposures to *contaminants* of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces. . . . Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern"[18].

21. In 2014, an open letter to WHO Director-General, Margaret Chan, undersigned by 53 leading scientists and public health officials, summarised the risk to public health in banning e-cigarettes on the basis of the precautionary principle: "regulators should avoid support for measures that could have the perverse effect of prolonging cigarette consumption. Policies that are excessively restrictive or burdensome on lower risk products can have the unintended consequence of protecting cigarettes from competition from less hazardous alternatives, and cause harm as a result. Every policy related to low risk, non-combustible nicotine products should be assessed for this risk"[19]. Accordingly, because evidence to date indicates that e-cigarettes present minimal health risks to both users and non-users of e-cigarettes (recognising that long term epidemiological data with respect to e-cigarettes is not yet available), it is my opinion that e-cigarettes are an important part of the public health strategy for harm reduction, and a ban on e-cigarettes will work against that strategy.

B. The Purported "Gateway" Effect

22. The Proposal further contends that e-cigarettes are a "gateway" to eventual cigarette smoking, after e-cigarette users, and in particular youth, have become "addicted to nicotine through e-cigarettes" (Proposal, ¶ 25).

23. There is no meaningful data to support such concerns.

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[17] Hajek, P, Etter, JF, Benowitz, N, Eissenberg, T, and McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Addiction, 109(11), 1801-1810, at 6.

[18] Burstyn, I. (2014). Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC public health, 14(1), at 1. See also Nutt et al, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach.* Eur Addict Res 2014;20:218–225 (attributing a relative harm score of 100 % for conventional cigarettes, while giving a score of 4% for electronic cigarettes (also known as "Electronic Nicotine Delivery Systems")).

[19] Letter to WHO Director from 53 Specialists in nicotine science and public health policy, 26th May 2014, available at http://nicotinepolicy.net/documents/letters/MargaretChan.pdf.

24. Current evidence from the UK suggests this phenomenon is not occurring. Rather, the evidence shows that "[r]egular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible," and that "[r]egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked"[20]. Nationally representative survey data from the UK anti-smoking organisation ASH show that even having tried e-cigarettes is rare among children, particularly those under the age of 15[21].

25. The UK's ASH 2013 Fact Sheet on e-cigarettes states:

> "Among children regular use of e-cigarettes is extremely rare. Children who had heard of e-cigarettes were asked about their use and knowledge of them. What little use that is reported is confined almost entirely to children who currently smoke or used to smoke.
>
> - 1 in 10 16-18 year olds who had heard of e-cigarettes (1 in 20 among 11-15 year olds) has "tried e-cigarettes once or twice".
>
> - 1 in 100 16-18 year olds (0% 11-15 year olds) uses e-cigarettes more than once a week."

26. The ASH survey data also indicate that:

    - Among young people who have never smoked 1% have "tried e-cigarettes once or twice", 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon.

    - Among adults e-cigarette current use has grown among smokers and ex-smokers and remains at 0% among those who have never smoked. Ex-smokers report having used e-cigarettes to help a quit attempt (48%) to prevent relapse to tobacco use (32%).

27. Further studies tracking the use of e-cigarettes in the population and especially among children and youth are being published. At present, there is no indication that e-cigarettes are acting as a gateway into smoking; however this needs to be continuously monitored in the future.

28. In their paper published in the British Journal of General Practice, Professor Robert West and Jamie Brown from the University College London state that "[t]o date, studies that have been claimed as addressing the gateway issue in relation to e-cigarettes have not in fact done so. Moreover, warnings about a rapid rise in e-cigarette use among the young have been based on the proportion of young people who report ever having tried an e-cigarette, not the proportion of current users. In

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[20] ASH UK Fact Sheet May 2015, Use of electronic cigarettes (vapourisers) among adults in Great Britain; see also ASH UK Fact Sheet May 2015, Use of electronic cigarettes among children in Great Britain).

[21] ASH UK survey conducted by YouGov. ASH Briefing, November 2014, available at www.ash.org.uk.

England, the proportion of current users in people who have not smoked regularly remains extremely small at 0.2%"[22].

29. The concerns around a potential gateway effect and the current evidence base are well summarised by the report on e-cigarettes by Public Health England: "Experimentation with electronic cigarettes among nonsmoking children in the UK is currently rare, and only about 1% of 16 to 18-year-old never smokers have experimented to electronic cigarettes and few if any progress to sustained use. Furthermore, experimentation with electronic cigarettes should be considered in the context of current levels of experimentation with tobacco cigarettes, which in Great Britain currently generates a prevalence of smoking of 15% among 16 to 19-year olds, and 29% in 20 to 24-year olds. Experimentation with electronic cigarettes is most likely to occur predominantly in the same group that currently experiment with tobacco, as indeed is suggested by recent US data. It is therefore relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present"[23]. At this point, I see no evidence to suggest that this would be different in different cultures.

C. E-Cigarettes And Cessation

30. The Proposal also asserts that there is only "limited and inconclusive" evidence that e-cigarettes help smokers to quit cigarette smoking (Proposal, ¶ 30).

31. There is emerging evidence from around the world regarding growing use of e-cigarettes by smokers as a substitute for conventional cigarettes. This evidence is based on population level surveys of representative samples (e.g. ASH UK surveys, Professor Robert West's Smoking Toolkit Study data) and randomised controlled clinical trials using e-cigarettes for smoking cessation (e.g. Dr Bullen's clinical trial in New Zealand, Prof Polosa's ECLAT study in Italy).

32. Large sample-sized surveys from e-cigarette forums (e.g., a worldwide survey of over 19,000 e-cigarette users published by Dr Farsalinos) also confirm that e-cigarettes are indeed proving effective as a substitute for conventional tobacco cigarettes.

1. Representative population surveys

a. The ASH UK surveys[24]

33. Action on Smoking and Health, UK has conducted annual surveys for the past four years using representative samples of thousands of adults and children.

34. According to ASH, the increase in the numbers of people using e-cigarettes in the UK between 2014 and 2015 came almost entirely from "ex-smokers" (i.e. smokers who have substituted e-cigarettes for cigarettes). The proportion of ex-smokers using e-cigarettes rose from 4.5% in 2014 to 6.7% in 2015.

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[22] West, R, Brown, J. Electronic cigarettes: fact and faction, 1 September 2014. DOI: 10.3399/bjgp14X681253.

[23] Electronic Cigarettes: A report commissioned by Public Health England, John Britton and Ilze Bogdanovica, May 2014, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf.

[24] Action on Smoking and Health, UK, Surveys, generally available at www.ash.org.uk.

35. Among current "vapers" (e-cigarette users), the principal reasons given by ex-smokers are "to help me stop smoking entirely" (61%) and "to help me keep off tobacco" (53%). The principal reasons given by current vapers who still smoking are to "to help me reduce the amount of tobacco I smoke, but not stop completely" (43%) and "help me stop smoking entirely" (41%)[25].

b. The Smoking Toolkit Study[26]

36. The Cancer Research UK sponsored Smoking Toolkit Study is headed by Professor Robert West at the University College London. Worldwide, the Smoking Toolkit Study is considered important for tobacco control policymaking purposes and for establishing efficacy of smoking cessation therapies in a real world setting.

37. The recently published findings from this study used data collected from 2009 onwards of 5,863 adults who had smoked within the previous 12 months (from the date of survey). They found that people attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum[27].

38. These findings are a strong endorsement of e-cigarettes' potential in reducing smoking prevalence in the population.

2. Randomised controlled clinical trials

39. There are already two published randomised controlled clinical trials that suggest that e-cigarettes may prove efficacious as a smoking cessation aid.

a. Dr Chris Bullen's e-cigarette clinical trial in New Zealand[28]

40. A team at the University of Auckland, New Zealand, led by smoking cessation expert Dr Chris Bullen, conducted a clinical trial comparing e-cigarettes with nicotine patches in 657 people. The results published in the Lancet, a very prestigious medical journal, showed 7.3% using e-cigarettes had quit after six months compared with 5.8% using patches.

41. Also, after six months, 57% of e-cigarette users had halved the number of cigarettes smoked each day compared with 41% in those using patches.

b. Professor Riccardo Polosa's ECLAT trial in Italy[29]

42. In a prospective 12-month randomised, controlled trial that evaluated smoking reduction/abstinence in 300 smokers not intending to quit smoking, Prof Polosa

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[25] ASH Fact Sheet, May 2015 Use of electronic cigarettes (vapourisers) among adults in Great Britain.
[26] Cancer Research UK, Smoking Toolkit Study, available at http://www.smokinginengland.info/.
[27] Brown J, Beard E, Kotz D, Michie S, and West R. (2014). Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. Addiction 109: doi: 10.1111/add.12623; see also Press Release, available at http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates.
[28] Electronic cigarettes for smoking cessation: a randomised controlled trial. Bullen et al, Volume 382, No. 9905, p1629–1637, 16 November 2013.
[29] Caponnetto, P, Campagna, D, Cibella, F, Morjaria, JB, Caruso, M, Russo, C, & Polosa, R. (2013). EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomised control design study. PloS one, 8(6), e66317.

found that the use of e-cigarettes, with or without nicotine, decreased cigarette consumption and elicited enduring tobacco abstinence without causing significant side effects.

43. In this study, smoking reduction was documented in 22.3% and 10.3% at week-12 and week-52 respectively. Complete abstinence from tobacco smoking was documented in 10.7% and 8.7% at week-12 and week-52 respectively. Also, a substantial decrease in adverse events from baseline was observed and withdrawal symptoms were infrequently reported during the study. Participants' perception and acceptance of the product under investigation was satisfactory.

44. The findings from published clinical trials of e-cigarettes are summarised in the Cochrane Review led by Prof Peter Hajek: "Combined results from two studies... showed that using an [e-cigarette] containing nicotine increased the chances of stopping smoking long-term compared to using an [e-cigarette] without nicotine. Using an [e-cigarette] with nicotine also helped more smokers reduce the amount they smoked by at least half compared to using an [e-cigarette] without nicotine... This study showed that people who used [e-cigarettes] were more likely to cut down the amount they smoked by at least half than people using a patch. The other studies were of lower quality, but they supported these findings. There was no evidence that using [e-cigarettes] at the same time as using regular cigarettes made people less likely to quit smoking"[30].

3. Worldwide survey of e-cigarette users[31]

45. Dr Farsalinos' team conducted an online questionnaire in 10 languages and had a total of 19,441 participants from around the world. This was the first such globally comprehensive survey of e-cigarette users, and confirmed findings from national surveys and randomised controlled clinical trials. The key finding from this survey was that over 15,000 vapers (80%) of the respondents had quit smoking altogether using e-cigarettes.

46. One key finding was the improvement in the quality of life of the smokers who had quit using e-cigarettes, and e-cigarettes helped these former smokers remain smoke free.

47. Although the survey was not designed to be representative due to the nature of sampling from e-cigarette users' fora, given the sample size, the findings give a compelling insight into the real-world safety and effectiveness of e-cigarettes as a smoking substitute.

48. Although these studies indicate an emerging trend in use among smokers and impact on smoking prevalence, they will need to be supported by more in depth, better designed studies, to confirm the longer term individual and population level impact of e-cigarettes on public health.

49. Some of the abovementioned studies and survey findings are based on older products, and as the quality and performance of e-cigarettes keep on improving in

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[30] McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub2.

[31] Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers. Farsalinos et al. Int. J. Environ. Res. Public Health 2014, *11*(4), 4356-4373.

newer generations of products, it is expected that their effectiveness as a cigarette substitute will improve even further.

CONCLUSION

50. Based on the foregoing, I hold the following opinions with respect to e-cigarettes and their role as part of a public health and tobacco harm reduction strategy:

51. E-cigarettes do not contain tobacco, and because there is no combustion during e-cigarette use, tobacco "tar" is not formed. E-cigarettes do not expose users to any significant level of toxicants, and nicotine itself is not related to chronic health effects such as cancer, heart disease or pulmonary disease. If e-cigarettes are appropriately regulated to ensure standards exist for devices and liquids then they should not contain any significant levels of toxicants.

52. The scientific evidence does not support the conclusions contained in the Proposal regarding the health risks of e-cigarettes. Rather, while the long-term health effects of e-cigarettes are not yet known, there is increasing consensus in the scientific literature and although less so among anti-smoking advocates that e-cigarettes are unlikely to present significant health risks to users. There is also little evidence to suggest that e-cigarette vapour is harmful to non-users or bystanders.

53. The evidence does not indicate a "gateway" effect with respect to e-cigarettes. While e-cigarette use is increasing among adults, there is little evidence of regular e-cigarette use by people with no history of cigarette smoking. Recent evidence indicates that regular e-cigarette use is limited to current and former cigarette smokers. E-cigarette use by never smokers is negligible, and regular e-cigarette use by children and young people is rare.

54. The scientific evidence to date shows that consumers use e-cigarettes as a substitute for conventional cigarettes. Such evidence also indicates that e-cigarettes aid in facilitating successful smoking cessation, and can aid cessation at least as effectively as medical nicotine as e-cigarettes address not only pharmacological dependence, but also the behavioural component.

55. In conclusion, it is my opinion that there is insufficient evidence to support the Proposal's assertions regarding the health, "gateway" or smoking cessation effects of e-cigarettes. Moreover, the Proposal fails to recognise that the weight of the scientific evidence to date strongly points in favour of allowing consumers access to e-cigarettes that seem to be able to compete with cigarettes as an important component of a public health and harm reduction strategy, and that a ban on e-cigarettes would have significant adverse public health effects.

Karl Olov Fagerström
Ph.D.

JUNE 19 2015.
Date

Appendix 5

Report of Russell S. Winer

I. INTRODUCTION

A. Qualifications

1. I am the William Joyce Professor of Marketing and Deputy Chair of the Marketing Department at the Stern School of Business, New York University. I received my Ph.D. in Industrial Administration from Carnegie Mellon University in 1977.

2. At the Stern School, I teach marketing management courses to graduate students in our executive, part-time, and full-time MBA programs. I have also taught in MBA and executive programs around the world. Topics I teach in these courses include strategic frameworks such as the product life cycle and what are called the "4Ps" of marketing—price, new products and other issues related to products such as branding, distribution channels and retailing, and advertising and other communications issues, particularly new digital methods.

3. Prior to joining NYU, I have been on the faculties of the University of California at Berkeley, Vanderbilt University, and Columbia University. I have also been a visiting faculty member at the Massachusetts Institute of Technology, Stanford University, the Helsinki School of Economics, the University of Tokyo, École Nationale des Ponts et Chaussées (France), Cranfield School of Management (U.K.), Henley Management College (U.K.), and Singapore Management University.

4. I am the author of over 80 articles and four books in the area of marketing. Over the span of my career, I have made methodological and other substantive contributions to the field of marketing in the areas of pricing, advertising, consumer choice and decision-making, and a number of other areas. In my textbook, *Marketing Management*, a textbook that is used by leading business schools around the world, I cover all the major issues involved with marketing decision-making.

5. I have been given a number of awards for my research including a lifetime achievement award in pricing from Fordham Graduate School of Business Administration's Pricing Center which is dedicated to developing a better understanding of prices and pricing and the inaugural long-term research contribution award from the Institute for Operations Research and the Management Sciences ("INFORMS") Society of Marketing Science ("ISMS"). I was named as an inaugural ISMS Fellow. ISMS is the leading organization for marketing academics whose work involves quantitative modeling. I was also named an inaugural Fellow of the American Marketing Association, the leading organization for marketing academics in the world. In 2016, I was named a Legend of Marketing by the American Marketing Association.

6. I have extensive academic editorial experience. I have been the editor of the *Journal of Marketing Research* ("JMR") twice. *JMR* is widely considered to be among the most prestigious two or three journals in the field of marketing. I have been a Senior Editor for the journal *Marketing Science*, the leading quantitative journal in marketing. I am currently an Area Editor of the *International Journal of Research in Marketing* and an Associate Editor of the *Journal of Consumer Research*. In addition, I have served on

numerous editorial boards, acted as associate editor, and generally been involved with the peer review process both as a reviewer and editor for over 40 years.

7. I have served as an expert witness in a number of cases involving brands and brand/trademark infringement, survey methodology, corrective advertising, and a number of other areas.

B. Assignment

8. I have been asked to provide my opinions regarding how imposing stringent marketing regulations for Potentially Reduced Risk Products, specifically (i) modern oral products including tobacco-free nicotine pouches and pouches containing tobacco; (ii) snus; (iii) vapor products (also referred to as e-cigarettes); and tobacco heating products ("THPs") (collectively referred to as "PRRPs") may affect awareness of these products and their potential to reduce rates of smoking and smoking-related diseases for existing adult tobacco and nicotine users who do not want to stop using tobacco and/or nicotine (also referred to as "consumers").

9. In preparing this report, I reviewed and considered a wide range of marketing texts and articles, some authored by me. This report contains my findings and opinions as of February 14, 2020.

10. Before providing my opinions, it is important to first define two key terms for this assignment: (1) marketing, and (2) PRRPs.

11. Marketing, broadly defined, is comprised of firm activities that present products' and brands' selling points to the marketplace. Typically, marketing is broken down into four key functions: activities concerning **the product** (e.g., features and benefits), **price** (e.g., price points, discounts, price perceptions), **placement** (e.g., distribution channels such as direct-to-consumer and retailers), and **promotion** (e.g., traditional and digital advertising, sponsorship, etc.). For the purposes of this report, I will discuss the elements of marketing relating to non-price promotion.

12. PRRPs are alternative nicotine and tobacco products that do not burn tobacco to deliver nicotine to the user. While I am not an expert in these products or their health risks, it is my understanding that there is a growing consensus among public health authorities and governments that the exclusive use of these PRRPs is significantly less harmful than combustible cigarettes. I will discuss the following PRRPs:

    - **Modern oral products.** Modern oral products include both tobacco-free nicotine pouches and pouches that contain tobacco. These products are offered in a range of flavors and nicotine levels and are intended to be placed under the lip for nicotine absorption.[1] While there is scant data on the relative risk profile of modern oral products compared with combustible cigarettes, it stands to reason that such products likely would have lower risk profiles because there is no

[1] https://www.bat.com/snus

combustion, some of the products are tobacco-free and those that do contain tobacco have significantly less tobacco than snus (discussed below).[2]

- **Snus.** Snus is a moist powdered tobacco pouch that is placed under the lip so that nicotine can be absorbed. Public health authorities including the US FDA and the UK Royal College of Physicians have stated that the relative risk of using snus exclusively is significantly lower than the risks posed by combustible cigarettes. In fact, in late 2019, the FDA announced "that exclusive use of the eight General Snus products [by Swedish Match] will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users. . . [and] exclusive use of these products poses lower risks than cigarette smoking for many of the major causes of tobacco-related disease."[3] The FDA determined that these snus products can be marketed with the claim "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."[4] Previously, the Royal College of Physicians 2007 Report also noted that, "in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favourable."[5]

- **Vapor products.** These tobacco-free products are battery-powered devices that aerosolize a liquid that typically contains flavors and nicotine that users then inhale or "vape."[6] There appear to be two types of vapor products, open system vapor products and closed system vapor products but for purposes of this report, I will focus on closed vapor products ("vapor products") which employ pre-filled eliquid pods that generally contain nicotine and flavorings providing users with an array of flavor choices. It is my understanding that vapor products' risk profile stands in stark contrast to that of combustible cigarettes. For example, an independent expert review commissioned by Public Health England (2018) found, among other things, that: "[v]aping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping."[7] Similarly, a large scale systematic review of the scientific literature undertaken by the National Academies of Sciences, Engineering, and Medicine ("NASEM") for the FDA (the "NASEM Report") found, among other things, that "[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."[8] Given the reduced risk posed by vapor products compared with combustible cigarettes, public health authorities have suggested that such products can

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2 Robichaud, M.O., Seidenberg, A.B., Byron, M.J. Tobacco companies introduce 'tobacco-free' nicotine pouches. Tobacco Control Published Online First: 21 November 2019. doi: 10.1136/tobaccocontrol-2019-055321

3 Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

4 Id.

5 Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007 at 160-161.

6 https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DO9DCGT9

7 McNeill, A., Brose, L., Calder, R., Bauld, L. & Robson, D. (2018), Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England (2018).

8 NASEM (2018) Public Health Consequences of E-Cigarettes.

contribute to harm reduction by offering adult smokers who do not want to stop smoking a potentially less harmful alternative to smoking.

- **Tobacco Heating Products.** THPs are devices that heat tobacco to generate a nicotine-containing aerosol with a tobacco taste which the user inhales. I understand that THPs have potential reduced risk properties compared with combustible cigarettes because the tobacco is heated and not burned and the resulting aerosol potentially can contain substantially lower levels of the toxicants found in the smoke produced when tobacco is burned. In fact, the FDA recently announced in its Premarket Tobacco Product Order for IQOS, a THP product, that the "marketing of [this product] is appropriate for the protection of public health" because, among other things, the products produce fewer or lower levels of some toxins than combustible cigarettes, and that "the current evidence indicated that CC [combustible cigarette] smokers who switch completely to [this THP] will have reduced toxic exposures and this is likely to lead to less risk of tobacco-related diseases."[9] In addition, peer-reviewed evidence on THPs indicates that they are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes.[10]

13. If the harm reduction promise of PRRPs is to be fulfilled, it is critically important, in my view, that manufacturers of PRRPs are given broad and robust freedom to communicate with existing adult tobacco and nicotine users about their products, their attributes, how to use them and their availability among other things. Without such freedoms, there will be less awareness and use of PRRPs, as predicted in the marketing literature and theory and as can be seen in real world data from across the world where (not surprisingly) markets with greater marketing resources spent on marketing PRRPs have higher rates of PRRP awareness and use and lower rates of combustible cigarette use.

C. Summary of Opinions

14. Based on the analyses and findings described in more detail later in this report, it is my opinion that:

- Marketing communications including traditional advertising (TV, print, radio and outdoor media), new/digital marketing (internet, etc.), point-of-sale advertising, packaging, and establishing retail channels including direct marketing are essential to create awareness about a product or brand, impart knowledge about the product and/or brand attributes, build a relationship with consumers and respond to consumers' pre-existing preferences such that they will consider using the product or brand.

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9 US Food & Drug Administration, PMTA Marketing Order PM0000479 dated April 29, 2019 at 10-11 https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders; https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

10 Simonavicius, E., McNeill A., Shahab, L., et al., Heat-not-burn tobacco products: a systematic literature review, Tobacco Control Published Online First: 04 September 2018. doi: 10.1136/tobaccocontrol-2018-054419

- Marketing serves different functions at different points in time depending on the stage of the product life cycle -- that is, whether it is a new, growing, mature or declining product market. PRRPs would constitute new and growing product categories unlike combustible cigarettes. Other examples of new products include Nestle's Nespresso, a one-cup-at-a-time pod-style brewing system, and music streaming. While coffee and caffeine are not new products, Nestlé developed a new product to deliver traditionally brewed coffee. Similarly, although music streaming started with Napster in the late 1990s, the category did not significantly expand until Spotify started and marketed its service in 2006. As with these products, while the ingestion of nicotine is not new, the delivery of nicotine via modern oral products and THPs are new products and via vapor product and snus are growing product categories.

- In new and growing product markets, such as the PRRP market, the first objective of marketing is to make consumers aware of the product including its function, how to use it, where to buy it and its cost. Simply put, the success of new and growing product categories rests and falls on the ability of firms to communicate with potential consumers (here, existing adult tobacco and nicotine users) about the existence of the product, its features and potential benefits. Without such communications, these consumers will remain "in the dark" about new products, and not avail themselves of these products due to their lack of awareness, information or confusion about them.

- Marketing freedoms for PRRPs are critical to a firm's ability to inform existing adult tobacco and nicotine users about PRRPs and their unique attributes and potential benefits. Through firm communications, advertising and other forms of promotion, firms can create awareness of PRRPs amongst existing tobacco and nicotine users, inform them of the products' and brands' features and generate interest and trial use among these consumers by tapping into their pre-existing preferences, which for many adult tobacco and nicotine users may include wanting to enjoy the sensorial and pharmacological effects of nicotine but in ways that may pose lower health risks than from smoking combustible cigarettes.

- Because the marketing communication environment has changed dramatically over the past 10-20 years with the rise of the digital economy, firms need to avail themselves of more varied marketing communication platforms including, among other things, a wide mix of digital marketing as well as more traditional advertising channels such as television, radio, print and outdoor media, direct marketing and point-of-sale advertising, to effectively inform consumers about new and growing products. Digital marketing provides certain benefits to firms and consumers over traditional advertising because it allows firms to better target the intended consumers and to provide those consumers with marketing that serves their interests. In fact, as the FDA has recognized, digital marketing technologies have evolved such that firms using a variety of data management tools can more accurately target digital advertising to their intended adult audience and restrict youth access to a minimum.

- In addition, marketing is important for the development of strong brands and brand identities which in turn provides other benefits to consumers by dramatically cutting down on consumer search costs, allowing for easy

comparisons across brands and enabling consumers to efficiently locate products and brands that meet their needs.

- Beyond conveying information about new products and brands, advertising, other promotional efforts and packaging can, particularly over the longer term, help firms build brand awareness and positive brand images and associations in the minds of consumers. In addition, building brands is important to differentiate a firm's brands from those of competitors and create goodwill. Allowing firms to advertise and thereby compete on the basis of their respective brands fosters a competitive market, which leads to better consumer welfare by forcing competitors to compete for market share through prices and/or higher quality or more innovative products.

- Along with the importance of communications in the new and growing product diffusion process, establishing retail channels is critical to the success of new products. Consumers need to be able to buy the products they hear about from communications or word-of-mouth. Often, communications and retail channels are linked as stores will not carry a new product unless there is a promise of significant advertising support. Thus, limiting the freedom PRRP marketers have to communicate the features and benefits to consumers can have a secondary effect on their ability to gain shelf space in retail outlets.

- It stands to reason that restrictions on marketing for new and growing product categories for PRRPs will have an impact on consumer awareness and use of such products. For example, real world evidence indicates, not surprisingly, that there is higher awareness and use of e-cigarettes in jurisdictions with less restrictive marketing regimes and lower awareness and use of e-cigarettes in more restrictive marketing regimes. Real world data also suggest that jurisdictions with higher rates of e-cigarette use are seeing higher rates of decline in smoking initiation and overall smoking prevalence.

- Similarly, marketing communications are necessary to prevent and clear up consumer confusion and misperceptions about PRRPs. There is an increasing body of literature that consumers are confused and ill-informed about the relative risks of PRRPs in relation to combustible cigarettes, and that those misperceptions are growing. For example, a large number of consumers in many markets believe that PRRPs such as e-cigarettes and snus are as risky, if not more risky, than combustible cigarettes. Allowing firms that sell PRRPs to provide accurate information about the relative risks of these products compared to combustible cigarettes could serve a very important educational function and better align consumer beliefs about these products with the available scientific evidence. Moreover, restricting firms' abilities to market such products and inform consumers of their attributes have real potential to undermine public health efforts to move smokers who do not want to stop using nicotine towards PRRP use.

- Similarly, use of PRRPs has been associated with increased smoking cessation. These data confirm what the marketing literature and theory predict, which is that marketing freedoms are important for growing the e-cigarette market and

the entire PRRP category, and thus, for achieving harm reduction goals of reducing rates of smoking and smoking-related diseases.

- One legitimate concern with allowing PRRPs robust marketing freedoms (including the ability to use digital marketing) is the risk that such marketing could have "spillover" appeal to youth. This is an important risk that needs to be balanced against the harm reduction benefit to existing adult tobacco and nicotine users that may be obtained by allowing PRRPs marketing freedoms. There are sensible ways to regulate the marketing of PRRPs to reduce the risks of youth "spillover" while still allowing marketing freedoms that facilitate the ability of PRRPs to reduce rates of smoking and smoking-related diseases. Indeed, digital marketing, in particular, can be quite narrowly tailored to adult audiences in ways that reduce the risk of spillover exposure or appeal to youth.

- In sum, stringent restrictions on marketing communications would threaten the commercial viability of the PRRP market and risk foreclosing the market in such products and undermining if not eliminating the potential for the products to play a role in harm reduction.

II. MARKETING

A. Fundamentals of Marketing and the Product Life Cycle

15. Marketing is a set of activities taken by firms and other organizations to facilitate transactions in the marketplace. A distinction can be made between marketing strategy and marketing tactics or programs. The former is a conceptualization of how the firm wants to approach the market and typically involves identifying, among other things, which customers the firm wants target. A marketing strategy always begins with the set(s) of customers on which the marketer wants to focus, those that have the greatest proclivity to purchase the product. Here, for example, I understand that PRRPs are intended for existing adult tobacco and nicotine users who do not want to stop using nicotine. In addition, a marketing strategy would involve identifying competitors and determining what information the marketer wants consumers to have about its products and brands.

16. Once the strategy is established, decisions are made about the specific marketing programs to implement the strategy. These are the classic "4Ps" of marketing: price, promotion (communications/advertising), place (distribution channels), and product (specific product specifications to meet customer needs, benefits). As noted above, I will be discussing the elements of marketing related to non-price promotion.

17. It is generally understood among marketing scholars that marketing serves different functions at different points in time over the life of the product. This concept is referred to in the marketing science literature as the product life cycle ("PLC") and explains the process a product goes through when it is first introduced into the market until it declines or is no longer sold. Understanding the PLC and identifying what stage the product is in is critical to determine the most effective marketing strategies needed to educate and inform existing adult tobacco and nicotine users about PRRPs to achieve the promise of harm reduction.

18. There are four stages of the PLC:

    - Introduction (New): In this phase, the product is brand new. Consumers are unaware of the new product and its attributes and marketing efforts focus on creating awareness for the new product and gaining distribution in stores or other appropriate outlets.

    - Growth: At this stage, sales volume is increasing rapidly and, if the market for the new product looks attractive, competitors are starting to enter. The marketing efforts of both the innovator and the later entrants help to propel the sales. Due to the increased competition, there is greater focus on brand building to differentiate.

    - Maturity: During the mature phase, competitors are competing for market share and with that, price competition is increasing as are sales promotions (discounts).

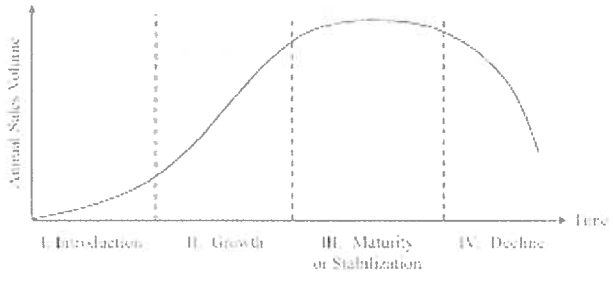
    - Decline: At some point, the sales of many product categories start to decline and even disappear (e.g., music cassettes).

19. New products are those that differ significantly in their characteristics than products currently on the market. New products are intended to meet a consumer demand or preference and can replace a current product or take over an existing product, such as the case with PRRPs and combustible cigarettes. Many new products have been launched in the last 20 years; examples are streaming music (mentioned earlier), smartphones (e.g., Apple's iPhone), ip telephony (e.g., Skype), digital payments (e.g., Paypal, Venmo), and many others.

20. The sales of these new and growing product categories typically follow the PLC. The shape of the PLC follows the model shown in Figure 1. The two dimensions of the PLC are annual sales volume (vertical axis) and time (horizontal axis). The time dimension is purposely vague as different new products' sales follow the curve at different rates of speed.

Figure 1

The Product Life Cycle

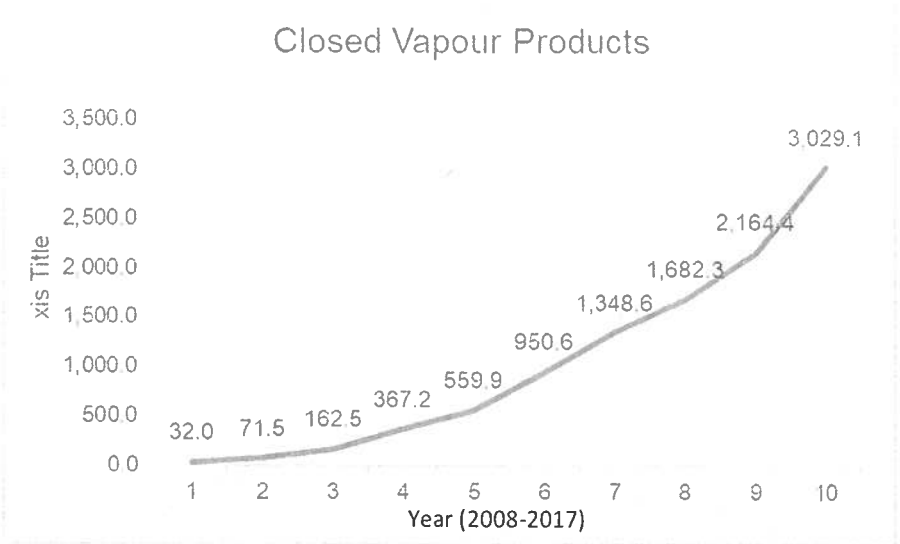


21. From the consumer side, the process that is causing the PLC to take its shape is called *diffusion*.[11] New product purchases come from two groups of consumers: *innovators* who want to be among the first to try a new product and hear about the new product through communications, and *imitators* who learn about the product from word-of-mouth, blogs, etc. from the innovators. I will elaborate below on the importance of marketing on this diffusion process.

22. To determine where the PRRPs are in the PLC I performed a PLC analysis for these products based on data I obtained from the 2018 report on Smokeless Tobacco and Vapor Products in the US produced by Euromonitor International, a leading global marketing research firm.[12] I note however that modern oral products were not included in the Euromonitor report because it appears that these products were not introduced in the US market until 2019.[13] I have used the US data as an illustrative example of the PRRP PLC in a jurisdiction where these products have not been heavily regulated.

Closed Vapor Products

23. For this category, I used retail sales in constant 2011 dollars covering the period 2008-17.[14] The graph of these data is below:



11 See, for example, Ofek, E., Muller, E., and Libai, B. (2016), Innovation Equity. Chicago: The University of Chicago Press.

12 *Passport: Tobacco 2018* (July 18, 2018), Euromonitor International.

13 Robichaud, M.O., Seidenberg, A.B., Byron, M.J. Tobacco companies introduce 'tobacco-free' nicotine pouches. Tobacco Control Published Online First: 21 November 2019. doi: 10.1136/tobaccocontrol-2019-055321

14 *Passport: Tobacco 2018* (July 18, 2018), Euromonitor International.

24. This category is still clearly in the growth phase of the PLC with the sales curve still sloping upwards. An examination of the forecasts for the next several years beyond 2017 supports the fact that the category will continue to grow.[15]

THPs

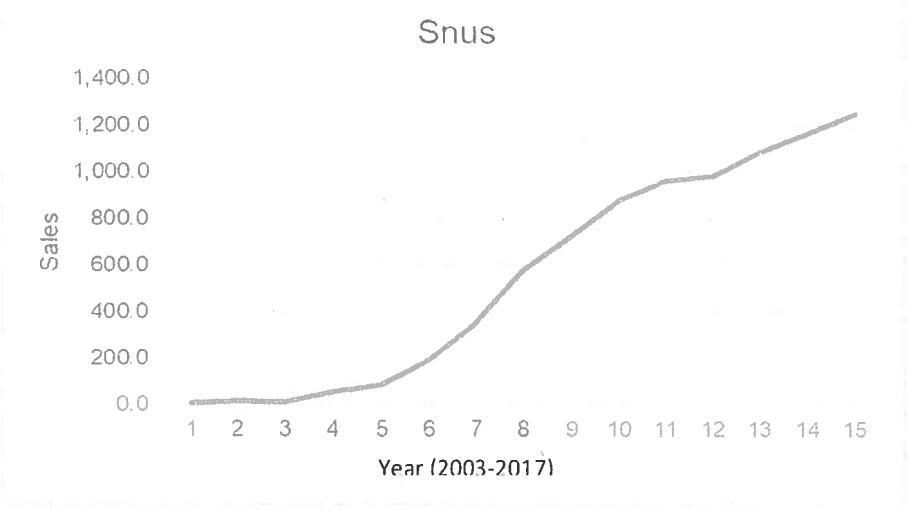
25. Due to the fact that the category is new, there are no historical figures through 2017. This is evidence that the category is at the very early stage of the PLC. Forecasts indicate very rapid growth for this new product.[16]

Modern Oral Products

26. Similarly, it is my understanding that modern oral products are new products that were introduced in the US in 2019.[17] Accordingly, the data is not sufficient to conduct an analysis but it stands to reason that these products are new products.

Snus

27. As can be seen from the graph below, we can capture the PLC for snus virtually from its introduction in the U.S. from 2003-2017:[18]



28. Snus has had a remarkable rate of growth in the U.S. Except for a period around 2013-14, the growth rate has been continually positive thus indicating that snus is still in the growth phase of the PLC. This is also supported by the forecasts.

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15 Based on interviews with Euromonitor staff and information documented in the report, the forecasts were developed using a combination of statistical methods and interviews with industry participants. I am satisfied that the forecasts can be used, at least in the short run, say, through 2020.

16 *Passport: Tobacco 2018* (July 18, 2018), Euromonitor International.

17 Robichaud, M.O., Seidenberg, A.B., Byron, M.J. Tob Control Nov. 19, 2019(0):1-2. doi:10.1136/tobaccocontrol-2019-055321; see also https://www.reuters.com/article/us-swedish-match-results/swedish-match-rolls-out-non-tobacco-nicotine-pouch-in-u-s-idUSKCN1Q20SM

18 *Passport: Tobacco 2018* (July 18, 2018), Euromonitor International.

29. In sum, based on their stages in their PLCs, I conclude that closed vapor products, THPs, modern oral products and snus are most vulnerable to restrictions on the marketing activities that can be undertaken to support brands in those categories.

III. MARKETING FREEDOMS ARE CRITICAL TO THE GROWTH OF PRRPS

30. Key marketing communications for PRRPs, new and growing product categories, broadly include advertising in traditional advertising media (e.g., television, print, radio and outdoor platforms), new/digital media (e.g., internet, search, banners/display ads), point-of-sale advertising, packaging, and the establishment of retail chains including direct marketing (e.g., direct communications with targeted consumers via a variety of media including mail, email, brochures, etc.), packaging and the establishment of retail channels. Below I will discuss marketing communications generally and then address the different forms of marketing communication and their importance to PRRPs.

31. These various marketing communications are the voice of the company and the means through which firms can inform and remind consumers about their products, services or brands and establish a relationship and discourse with their customers. This latter point is particularly important today with the increased use of digital media where communication is more of a conversation with consumers as opposed to the old "one to many" model of communications. This also allows firms to communicate with their target market better, here existing adult tobacco and nicotine users.

32. Marketing communications, particularly for new and growing product categories work by informing consumers that the product exists and showing consumers how and why a product is used, by whom, where, and when. With respect to PRRPs for example, these communications can provide the following essential factual information including (i) the names of the product, (ii) a description of the product components including, where applicable, how to open and how refill the device, if applicable, (iii) the price, (iv) instructions on how to use and store the product, (v) product ingredients, (vi) factual descriptions of the flavors, vapors, etc., (vii) nicotine content and delivery per dose, and (viii) a warning that the product contains nicotine, an addictive substance and is not intended for use by young people.

33. In addition to providing information about the product's attributes, marketing communications can alert consumers about relevant product or brand options that may be oriented to remove a problem, avoid a problem, more fully satisfy a pre-existing preference or for other reasons such as to provide pleasure, social approval, intellectual stimulation, etc. Here for example, with respect to PRRPs, making existing adult tobacco and nicotine users aware of PRRPs could tap into a desire to switch from smoking combustible cigarettes to a potentially reduced risk product insofar as those consumers want to continue to use nicotine.

34. In addition to creating product awareness, marketing communications can instill brand awareness by reminding the consumer about the brand and strengthening consumers' loyalty. Brand awareness refers to how strongly consumers recall or recognize the brand under different circumstances. Brand image refers to consumers' perceptions of and preferences for a brand, as reflected by the various types of brand associations held in consumers' memory. In this way, brand awareness and brand

image can create brand equity.[19] Brand equity refers to the brands' value as a function of brand awareness and brand image.

35. Developing a strong brand offers a range of important benefits to the firm and consumers. For the consumer, strong brands help identify a preferred brand and provide reassurance regarding the origin and quality of the preferred brand. Brands also provide consumers with a level of comfort in their choice of products. [20]

36. For firms, a strong brand offers a variety of benefits, including improved perceptions of product performance, greater customer loyalty, less vulnerability to competitive marketing actions and marketing crises, larger margins, more elastic customer response to price decreases and inelastic customer response to price increases, greater trade or intermediary cooperation and support, increased marketing communication effectiveness, and additional licensing and brand extension opportunities.[21] Research indicates that branded products typically command price premiums because consumers will pay more for the same product if it has a stronger brand.[22]

37. In addition, building strong brand equity can increase the effectiveness of marketing communications because consumers may be more inclined to attend to additional communications for a brand, process these communications more favorably and have a greater ability to later recall the communications.

Traditional Advertising

38. Advertising is a paid form of communication to inform consumers about a product or service. It is one of the most important platforms for marketing communications. The ability to advertise across a variety of traditional media channels (TV, print, radio and outdoor media) is vital to new and emerging PRRPs growth because consumers likely know little about the products and brands, have not formed preferences, and may be misinformed about the products and their attributes.

39. During the new and emerging growth stage, advertising is vital to help induce trial and promote word of mouth and diffusion, that is how a new product is accepted by the market. Here for example, real world data demonstrate that consumer awareness of e-cigarettes in countries that tightly regulate marketing communications about, and access to, e-cigarettes are significantly lower than in countries that allow for greater access and marketing freedoms.[23]

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19 Keller, K.L. and Lehmann, D.R. (2003), How Do Brands Create Value, Marketing Management, 12, 26-31.

20 Winer, R. and Dhar, R. (2011), Marketing Management, Fourth Ed. Upper Saddle River, NJ: Pearson Education, at 179.

21 Id. at 179-180; Keller, K.L. and Lehman, D.R. (2003), How Do Brands Create Value, Marketing Management 12, 26-31; Hoeffler, S. and Keller, K.L. (2003), The Marketing Advantages of Strong Brands, Brand Management 10, 421-445.

22 Lindermann, J., The Economy of Brands (2011), Basingstoke: Palgrave MacMillan, at 15.

23 Gravely, S., Driezen, P., Ouimet, J., Quah, A. C. K., et al., (2019), Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project. Addiction 114: 1060– 1073. https://doi.org/10.1111/add.14558

40. In addition, when consumers are unfamiliar with a new product and its attributes, they are often less efficient at incorporating important advertising information into memory. For example, consumers who are unfamiliar with PRRPs may take longer to digest critical messaging information than consumers in older markets. As such, advertising elasticity, that is the effect of an increase or decrease in advertising on the market, will be higher for products in the early stage of the life cycle than in the mature stage.[24] This has been supported by a number of other studies as well.[25]

Digital Marketing

41. To communicate effectively with consumers, "marketing communications must go where consumers are, and, over the past ten to twenty years, that is increasingly online."[26] Indeed, the rise of digital marketing (e.g., display ads including banner and pop-ups, search ads (e.g. Google Ads), search engine optimization, ad retargeting, mobile, etc.) has changed fundamentally the means and method of communication between people and between a customer and a brand or organization.[27]

42. Digital marketing, that is the marketing of products using digital technologies mainly on the internet in different channels (desktop, laptop, mobile devices), has become an increasingly important and central component of a company's marketing mix. Indeed, the IAB Internet Advertising Revenue Report found that "[d]igital revenues for full year 2018 surpassed $100 billion for the first time. Internet advertising revenues in the United States totaled $107.5 billion for the full year ("FY") of 2018, with Q4 2018 accounting for approximately $31.4 billion and Q3 2018 accounting for approximately $26.6 billion. Revenues for FY 2018 increased 21.8% over FY 2017."[28] Digital marketing is now an integral part of a firm's relationship with consumers and continues to show more rapid growth than traditional media.[29]

43. In addition, digital marketing provides certain benefits over traditional advertising because it allows firms to better target their intended audience. Indeed, the FDA Public Health Rationale for Recommended Restrictions on New Tobacco Product

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24 Sethuraman, R., Tellis, G., & Briesch, R. (2011), How Well Does Advertising Work? Generalizations from Meta-Analysis of Brand Advertising Elasticities. *Journal of Marketing Research*, *48*(3), 457-471. https://doi.org/10.1509/jmkr.48.3.457; Misra, S. (2015) Price and Advertising Effort Over the Product Life Cycle: The B.C.G. and Dorfman-Steiner Approaches. In: Hawes, J.M., Glisan, G.B. (eds) Proceedings of the 1987 Academy of Marketing Science (AMS) Annual Conference. Developments in Marketing Science: Proceedings of the Academy of Marketing Science. Springer.

25 See, for example, Parson, L. (1975), The Product Life Cycle and Time-Varying Elasticities. Journal of Marketing Research, 12, 476-80.

26 Keller, K. (2009), Building strong brands in a modern marketing communications environment. Journal of Marketing Communications Vol. 15, Nos. 2 – 3, April– July 2009, 139–155, at 147.

27 Banner ads are small, rectangular ads that run along the top or side bar of a web page. Popup ads are another form of paid online advertising methods and are intended to capture email addresses or attract traffic to a website. Ad retargeting is a strategy that utilizes cookies on a website to anonymously track users' activities as they move across the Web. These data can then be used to show ads that are relevant to them based on their prior search activities.

28 IAB internet advertising revenue report 2018 full year results, prepared by PWC (May 2019). https://www.iab.com/wp-content/uploads/2019/05/Full-Year-2018-IAB-Internet-Advertising-Revenue-Report.pdf

29 Keller, K. (2009), Building strong brands in a modern marketing communications environment. Journal of Marketing Communications Vol. 15, Nos. 2 – 3, April– July 2009, 139–155.

Labeling, Advertising, Marketing, and Promotion ("FDA Public Health Rationale") notes that

> "the data sources, methodologies, and technologies used to deliver and track digital media consumption have also evolved, enabling product marketers to create sophisticated, highly targeted digital marketing plans and paid media buys designed to reach their intended audiences based on specific demographics, psychographics, and media passion-points while also limiting reach or 'spill' to unintended audiences. Thus, it is possible, efficient, and necessary for firms to take advantage of these technologies to help ensure that tobacco product marketing is targeted to adults and that 'spill' to youth audiences is minimal."[30]

44. Indeed, there are many ways in which digital technologies can be used to better target consumers and prevent spillover to unintended recipients. These include, among others, behavioral targeting where advertisements are targeted at users based on their past purchase activity, day parting which allows firms to specify what time of the day an ad is to be shown, and interest-based targeting which refers to the ability to advertise to customers with a specific interest or hobby. For instance, services such as Google's Advanced Audiences technology provides marketers with tools that allow them to identify people based on their interests ("pre-built affinity audiences"), to create their own groups of audiences based on specific interests tailored to their brands ("custom affinity audiences"), and to reach people who are actively researching certain products or services ("in-market audiences").[31]

45. The FDA Public Health Rationale also recognizes that paid digital advertising targeting capabilities offer PRRP marketers with the ability to target adults who meet specific age criteria through the use of first- and/or second-part age-verified data on any digital property accepting paid advertising relating to PRRPs, while also restricting youth-access to such advertising.[32] As the FDA acknowledges, "this precision marketing ... represents an opportunity to limit youth exposure to digital marketing" of PRRPs."[33]

46. Social media marketing has become an important component of digital marketing. Social media marketing primarily covers activities involving social sharing of content, videos, and images for marketing purposes. Unlike more traditional marketing platforms such as TV or print media, social media provides consumers a forum where they can learn more about companies and their products and allows consumers to interact with branded content.

47. The FDA Public Health Rationale further notes that, while there are no universal age restriction controls on social media platforms, many social media platforms have

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30 FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

31 Diddarms, H. and Behmke, T. We Analyzed 75,000 YouTube Campaigns – Here's What We Learned About Using Demographic Data, Ad Week (November 4, 2019) https://www.zinio.com/read/readsvg/442856/G1

32 FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

33 Id.

started to offer firms the option to place age restrictions on some or all of their account pages, followers, and content including specific posts.[34]

48. Increasingly digital technologies have shifted companies' focus from mass communications to a more targeted, two-way communication with consumers.[35] This form of communication is often perceived by consumers as more interesting and relevant. With social media sites, companies can enhance the customer interaction that has already been established through traditional media (i.e., TV ads, print ads) to a more personal level.[36]

49. The importance of digital marketing, including social media platforms, is further underscored by the fact that more and more consumers use social media and rely on it for making shopping decisions. Firms can develop and grow closer relationships with new and existing customers through social media and can expand the market to the customers they could not reach before.

Point-of-Sale ("POS") Communication

50. POS communication "is a form of retailer promotion that includes information related displays and other company-paid advertising inside the store."[37] With POS communication, brands can be represented in a cohesive, attractive and appealing way at the point where the shopper can directly interact with the product. POS communication offer the opportunity to educate and help shoppers to choose the right product for them. POS communications are sometimes referred to as "shopper marketing."

Packaging

51. Packaging, particularly with respect to new and growing products, plays an important role in consumer decisions because it builds and maintains brand equity.[38] For new and growing products such as PRRPs, packaging can convey important information about the products that will help inform consumers of the products and aid in their purchase decisions.[39]

Retail Channels and Direct Marketing

52. The establishment of retail channels is also critical to the success of new and growing products. Of course, consumers need a place to purchase the new product. Today, many of these purchases take place online. However, in the U.S., for example, it is still the case that 90% of retail buying takes place in "bricks and mortar" locations. Thus, the ability to find retail space is critical to the success of a new product.

53. At the same time, there are a number of barriers to obtaining retail space. Even for established channels, the retailer's scarce resource is shelf space and displaying a new

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34 Id.

35 Winer, R. and Dhar, R. Marketing Management (4th Ed. 2011) at 615.

36 Rautela, S. and Singhal, T. (2017), Leveraging Social Media for New Product Development: A Review at 94.

37 Winer, R. and Dhar, R. Marketing Management (4th Ed. 2011) at 326.

38 Keller, K. Strategic Brand Management. 3rd Ed, Upper Saddle River, NJ Prentice Hall 2008, at 172.

39 Underwood, R.I., Klein, N.M. and Burke, R.R. (2001), Packaging communication: attentional effects of product imagery, J Product and Brand Management, 10(7):413-22.

product often means something else has to be replaced. As a result, competition for shelf space can often be fierce. To give retailers the incentive to do that, new products offer both marketing support (advertising) and, in some cases, what are called "slotting" fees, that is, direct payments for the space.

54. A channel that is often used is called direct marketing. Direct marketing is any form of direct communication that gives the consumer access to the firm's products without any intermediary. Traditional methods of direct marketing include telemarketing, infomercials on radio and TV, and teleconferencing. With the rise of digital marketing however, the nature of direct marketing has changed as well. [40]

55. Given that consumers are buying more goods through the internet, direct marketing via the internet (such as email direct marketing) has become increasingly important for firms to market new products. As with digital marketing, digital direct marketing has increased exponentially because technologies have increased firms' ability to target consumers more efficiently.[41]

IV. ANALYSIS OF LIKELY IMPACT OF MARKETING RESTRICTIONS ON THE PRRP MARKET

A. Marketing Restrictions Will Likely Undermine Public Health Efforts to Get Smokers to Switch From Combustible Cigarettes to PRRPs

56. There is a growing body of research that e-cigarettes, THPs and snus are considered to be significantly less harmful than combustible cigarettes. For example, as the UK Royal College of Physicians Report states, "[a]lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoking tobacco products, and may well be substantially lower than this figure." And, as noted above, the FDA has announced in its Premarket Tobacco Product Order for IQOS, a THP product, that the "marketing of [this product] is appropriate for the protection of public health" because "the current evidence indicated that CC [combustible cigarette] smokers who switch completely to [this THP] will have reduced toxic exposures and this is likely to lead to less risk of tobacco-related diseases."[42] Similarly, the FDA has recently permitted Swedish Match USA, a manufacturer of snus, to advertise its products through the modified risk tobacco product pathway and is allowed to claim that its snus products are less harmful than combustible cigarettes.[43] Specifically, the FDA found that Swedish Match "has demonstrated that, as actually used by consumers, the eight General Snus products sold or distributed with the proposed modified risk information, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and

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40 Winer, R and Dhar, R. Marketing Management (4th Ed. 2011).

41 Id.

42 US Food & Drug Administration, PMTA Marketing Order PM0000479 dated April 29, 2019 at 10-11 https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders; https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

43 Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

persons who do not currently use tobacco products."[44] Given that modern oral products do not burn tobacco and are either tobacco free or contain less tobacco than snus, it stands to reason that they likely have a reduced risk profile compared with combustible cigarettes.

57. In light of this evidence base, several public health authorities have encouraged smokers to switch to certain PRRPs, specifically e-cigarettes and snus, if they do not want to stop ingesting nicotine. In order to facilitate this goal, some public health authorities have recognized the need to have balanced regulations including marketing regulations (regarding e-cigarettes, in particular) because of their potential to reduce smoking prevalence.

58. As one study noted, the most restrictive policies would effectively eliminate e-cigarettes as a viable alternative to smoking.[45] The authors noted that "[h]arm reduction recognizes that the proposed alternatives carry uncertainties. It involves making a strategic determination: when the risks are considerable – as they surely are with cigarette smoking – moving forward in the face of uncertainty is unavoidable.... Opting for a harm-reduction approach in name isn't enough if the specific policies employed are so restrictive that e-cigarettes contribute very little to reducing smoking-related risks in the long term. To be sure, a permissive approach demands continuous health and safety monitoring along with the will to change course if necessary. Yet if policymakers are serious about mounting a largescale attack on smoking, we believe they must be willing to consider strategies, by any name, that are true to the spirit of harm reduction and could have a population-level effect."[46]

59. Similarly, in its 2016 report the Royal College of Physicians ("2016 RCP") urged smokers who did not want to quit to switch to e-cigarettes. The 2016 RCP found that whilst "[a] risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm... if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking."[47]

60. Moreover, in October 2017 the British Psychological Society published a briefing on e-cigarettes, which recommended that regulators should "[f]or e-cigarettes, avoid taxation and 'vape-free' legislation and promote unrestricted advertising of factual information"; and that they should "[r]egulate to promote product development" so as to "allow e-cigarettes to further evolve and improve so they are safer, more appealing and satisfying for more smokers. This means allowing higher nicotine strength e-liquid to remain on the market where there is no evidence to suggest

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44 Id.

45 Fairchild, A. L., Lee, J. S. Bayer, R., Curran, J. (2018), E-Cigarettes and the harm-reduction continuum. New England Journal of Medicine, 378:216–219.

46 Id.

47 Royal College of Physicians of London. Nicotine without smoke tobacco harm reduction. Royal College of Physicians of London; 2016.

harm, and avoid unnecessary burdensome and costly procedures for manufacturers so they can focus on improving the safety and efficacy of their products."[48]

B. Marketing Restrictions Would Reduce Consumers' Awareness and Use of PRRPs

61. Given the importance of marketing to the commercial viability of new and growing products, onerous restrictions on the marketing of PRRPs likely would threaten the overall viability of the PRRP market. If smokers do not have sufficient information about PRRPs and their attributes, they are unlikely to switch to these products. In addition, if significant marketing restrictions are put in place that would limit the retail distribution possibilities for PRRPs, this would also significantly reduce the market potential of the product.

62. For example, there is consistent real world data from large national surveys that provide evidence that e-cigarette awareness and use is correlated with a country's marketing regulations insofar as there is greater awareness and use of e-cigarettes in countries with more liberal marketing regimes compared with more restrictive marketing regimes.[49] For example, a 2019 cross-sectional analysis of adult current and former smokers from 14 countries participating in the International Tobacco Control Policy Evaluation Project "(ITC Project") found that, on the whole, there was higher awareness and use of e-cigarettes among current and ex-smokers in countries with less restrictive marketing policies (e.g., UK and US) and lower awareness and rates of use in countries with more restrictive policies (Australia) or no policies (Bangladesh).[50] This study provides evidence that patterns of e-cigarette use are likely to be influenced by the e-cigarette regulatory policy environment including regulations surrounding marketing. In short, this literature shows that real world data support the marketing theory and predictions – to wit, marketing has a significant impact on awareness and use of e-cigarettes among adult smokers and ex-smokers. Moreover, it stands to reason that awareness of and use of other PRRPs similarly would be influenced by the PRRP regulatory environment including regulations surrounding marketing.

65. In sum, imposing strict limits on marketing would be counterproductive to the harm reduction goal of reducing rates of smoking and smoking-related diseases because it would prevent smokers from becoming aware of and moving to PRRPs.

C. Restricting Marketing Communications Would Contribute to Consumers' Confusion and Misperceptions About the Relative Risks of PRRPs

66. Overly restrictive marketing regulations would restrict consumer information and awareness and would likely exacerbate existing misperceptions and undermine the ability of consumers to make informed choices; and are liable to deter smokers from

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43 British Psychological Society (2017), Changing Behaviour: Electronic Cigarettes. Available at: https://beta.bps.org.uk/sites/beta.bps.org.uk/files/Policy%20-%20Files/Changing%20behaviour%20-%20electronic%20cigarettes.pdf

49 Gravely, S, et al., (2019), Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project, Addiction]; Gravely, S, et al., (2014) Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project, Int. J. Environ. Res. Public Health 11:11691-11704; doi:10.3390/ijerph111111691;

50 Id.

considering PRRPs as an alternative to combustible products. This will make it harder for smokers to know of their availability and attributes and limit the potential for smokers to transition away from cigarettes. Accurate consumer education and widespread availability are key to enhancing smokers' awareness of PRRPs as an alternative to combustible cigarettes and facilitating the transition from cigarettes for those smokers that want to switch.

67. There is a real risk of consumer confusion and misinformation about PRRPs when there are restrictions on what firms can say in their advertising and other marketing communications about these products. For example, studies of consumer perceptions about the relative risk of e-cigarette use compared with combustible cigarettes demonstrate that consumers are ill-informed about the health risks of e-cigarettes compared with combustible cigarettes.[51] Along these lines, surveys have shown that a large percent of "the public and smokers fail to recognize that e-cigarettes are less harmful than smoking."[52]

68. In fact, it is my understanding that public health authorities have expressed concern over consumers' misperceptions about the relative risks of e-cigarettes and THPs compared to combustible cigarettes.[53] The Public Health England 2018 Report observed that "misperceptions of nicotine and different nicotine-containing products need to be addressed" and that these misperceptions have deteriorated since the prior Public Health England 2015 Report.[54]

69. Restricting a firms' ability to communicate with consumers about the attributes of PRRPs may also perpetuate the fallacy that PRRPs have a similar risk profile to combustible cigarettes and will further discourage consumers from quitting combustible cigarettes and migrating to PRRPs. For example, the evidence shows that a substantial portion of the public believes that e-cigarettes are just as hazardous as combustible cigarettes. For example, a 2016 study by Majeed et al., found that a higher percentage of US adults misperceived e-cigarettes to be equally or more harmful to combustible cigarettes between 2012 and 2015 and that these "[h]igher risk perceptions ... could deter current smokers from using e-cigarettes as a cessation aid of smoking combustible cigarettes and preventing a potential public health benefit."[55] Moreover, according to the Action on Smoking and Health ("ASH"), a UK anti-tobacco action group, "[b]etween 2013 and 2017 a growing proportion of both the general public and smokers failed to recognise that e-cigarette use is much less harmful than smoking. In 2017 only 13% of adults correctly identified that e-cigarettes are much less harmful, compared to 21% in 2013. The proportion of adults thinking that e-cigarettes are at least as dangerous as smoking nearly quadrupled from 2013 to 2017 from 7% to 26%."[56] Similarly, studies have found that smokers

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51 Majeed, B., et al., (2016), Changing Perceptions of Harm of E-Cigarettes among US Adults 2012-2015.

52 http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-report-e-cigarettes/

53 McNeill, A., Brose, L., Calder, R., Bauld, L., Robson, D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England, London: Public Health England, 2018.

54 Id.

55 Majeed, B., et al., (2016), Changing Perceptions of Harm of E-Cigarettes among US Adults 2012-2015.

56 https://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-report-e-cigarettes/

misperceive snus to be as or more harmful than smoking cigarettes and will likely need more accurate information about the relative risk of snus compared with combustible cigarettes before making the switch to products such as snus.[57]

70. In sum, regulating marketing communications of PRRPs similar to marketing regulations of combustible cigarettes may perpetuate the misleading message that PRRPs and combustible cigarettes confer similar risks.

D. Restricting Marketing Freedoms May Undermine the Ability of PRRPs to Reduce Smoking Prevalence By Increasing Smoking Cessation and Reducing Smoking Initiation

71. It is my understanding that there is a growing body of scientific research suggesting that e-cigarette use has contributed to reduced smoking prevalence. In the UK for example where there is a flexible regulatory environment that allows public vaping, reasonable access to e-cigarettes, retail displays and consumer communications, there was a significant 23% decline in smoking prevalence, dropping from 20.4% (2012) to 15.8% in 2016, following the introduction of e-cigarettes.[58] Similarly, smoking rates among adults in the US have dropped significantly with the introduction of PRRPs, declining from close to 20.6% in 2009 to around 14% in 2017.[59] Moreover, the 2018 Public Health England Report concluded that "[w]hile caution is needed ... the evidence suggests that e-cigarettes have contributed to tens of thousands of additional quitters in England."[60]

72. In addition, studies have shown that e-cigarette users are more likely to try to quit smoking and to successfully quit smoking.[61] For example, a study assessing the relationship between e-cigarette use and smoking cessation in a representative sample of the US population found that e-cigarette users were more likely than non-users to make a quit attempt and 70% more likely to successfully quit smoking.[62]

E. Balancing Marketing Freedoms for PRRPs with the Need to Reduce Youth Exposure to Marketing to the Greatest Extent Possible

73. It is important that firms take all feasible steps to try to prevent marketing spillover to adolescent smokers. Many industries deal with this issue and the tools of marketing, especially with regard to digital marketing and social media, have improved tremendously allowing firms to better target their intended audience.

74. For example, in early 2018, Diageo pulled all ad spending from Snapchat due to concerns that underage drinkers were being exposed to their products' ads. Since then, a number of advertisers including Heineken have started advertising on Snapchat when the latter moved away from users' self-declared ages to utilizing other

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57 Wackowski, O, et al., (2019), Smokers' perceptions of risks and harm from snus relative to cigarettes: A latent profile analysis study, Addict Behav 91:171-174.

58 Institute for Economic Affairs. (2017), Vaping Solutions: An easy Brexit win.

59 https://www.medpagetoday.com/pulmonology/smoking/73568, accessed 7 July 2019.

60 McNeill, A., Brose, L., Calder, R., Bauld, L. & Robson, D. (2018), Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018.

61 Zhu Shu-Hong, Zhuang Yue-Lin, Wong Shiushing, Cummins Sharon E, Tedeschi Gary J. (2017), E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys *BMJ* 358 :j3262

62 Id.

data such as how long someone has been a user, the age of their closest friends, and the content that they view. Facebook and YouTube have been similarly aggressive in changing the way they age-gate viewers of advertising targeting 21 and over consumers.[63]

75. A second example is from Diageo's 2018 UK Twitter campaign for its Captain Morgan brand. Although there were issues raised about the copy of the promoted tweets, the relevant issue is whether the use of Twitter included consumers under 18 years of age (the UK's legal drinking age) in violation of the UK's Committee of Advertising Practice guidelines, the CAP Code. It was ruled that Diageo had taken reasonable steps to ensure that consumers under 18 years old would not be exposed to the promoted tweet because (1) Twitter can select users 18 and over due to registration information and match their interests to the product as well, and (2) that, in fact, Twitter is not a popular social medium among the younger age group. Therefore, Diageo had taken all reasonable steps to prevent its promoted tweets to be seen by young consumers.[64]

76. While it is not possible to screen out underage users of products with minimum age restrictions with 100% effectiveness, these two examples with different social media demonstrate that marketers of products that have legal age restrictions can, in fact, use modern digital marketing techniques to target legal users far more effectively than traditional media such as TV, radio, print, and outdoor.

77. In the US, the FDA Public Health Rationale provides guidance on how marketing spillover can be limited through sensible marketing regulations that balance the harm reduction benefits of allowing marketing to reach smokers while limiting the potential for youth and other nicotine-naïve consumers to be exposed/influenced to use PRRPs by PRRP marketing. Indeed, the FDA notes that digital marketing offers some distinct advantages over traditional advertising that allow firms to more accurately target their intended audiences through data mining technologies and age restriction. Employing data management systems and algorithms can connect individuals to a "range of data points, including their demographic characteristics, purchase behaviors, preferences political opinions, internet search terms, browsing history, interactions with digital content ... digital accounts, connected devices, physical location, and information about other members of their household."[65] Moreover, paid digital advertising targeting capabilities offer firms "the ability to target adults who meet specific age criteria through the use of first- and/or second-party age-verified data ... on any digital property accepting paid tobacco advertising, while also restricting youth-access to such advertising." The FDA also reports that "marketers can also layer on additional demographic and psychographic data (e.g., tobacco product purchase behaviors) to further enhance the efficiency of their paid digital media buys."[66]

78. In addition, the FDA in its Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead for Swedish Match notes that "many social media platforms are beginning to offer

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63 Ilyse Liffreing, "Snapchat Lures Back Alcohol Brands," Digiday, October 31, 2018.

64 ASA ruling on Diageo Great Britain Ltd (June 6, 2018).

65 FDA, The Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion (April 2019).

66 Id.

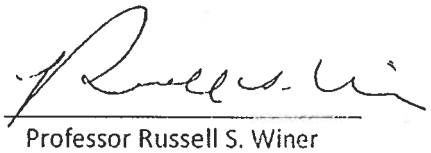
branded-account owners the option to age-restrict some or all of their account pages, followers, and content, including even specific posts, photos, videos, events, etc."[67] Moreover, the FDA recognizes that, while these have some limitations, "users are increasingly prompted to "link" digital profiles and accounts (e.g., option to sign-up for a new account using an existing email account or social media account), increasing the likelihood of more accurate self-reporting."[68] These safeguards demonstrate the many ways in which companies can minimize the risk of digital marketing spillover to youth.

V. CONCLUSION

79. Marketing for new and growing products, here PRRPs, is critical to inform existing adult tobacco and nicotine users who otherwise may have been unaware of the products that the products exist, and in so doing, can provide these consumers with essential information about the product's function and attributes such as where to buy them, price, how to use them, etc.

80. The success of PRRPs in potentially contributing to reductions in projected tobacco-related diseases depends on their acceptance by a critical mass of existing adult tobacco and nicotine users as a satisfactory alternative to combustible tobacco products. To achieve this, it is essential that the regulatory framework for PRRPs provides effective measures such as appropriate advertising and marketing freedoms to enable firms that sell PRRPs to inform consumers of about these products. Indeed, overly strict marketing restrictions will – as real-world data already show – lead to lower consumer awareness and use of PRRPs, along with consumer misperceptions about these products and their attributes, including their relative health risks compared to combustible cigarettes. While there are legitimate concerns about the importance of preventing "spill-over" of PRRP marketing communications to youth, there are sensible ways to reduce this risk so that PRRPs can fulfil their harm reduction promise to smokers.

81. In sum, imposing stringent marketing restrictions could severely limit the growth of the PRRP market, and the corresponding harm reduction promise of PRRPs to reduce rates of smoking initiation and consumption and to support increased rates of smoking cessation. Overly restrictive marketing regulations would, in effect, eliminate PRRPs as a possible reduced risk alternative to smoking combustible cigarettes since existing adult tobacco and nicotine users will not be aware of these products, learn about their offerings, and be motivated to switch. In this case, the potential for harm reduction will be lost.



Professor Russell S. Winer
18 February 2020

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[67] Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911 (d) of the FD&C Act – Technical Project Lead.

[68] Id.

Appendix 6

Analysis of Risk Beliefs and Usage of E-Cigarettes and other Potentially Reduced Risk Nicotine Products in Europe

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December 17, 2020

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I. INTRODUCTION

1. I am the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University. I hold a bachelor's degree in Economics, two master's degrees, and a Ph.D. in economics, all from Harvard University. I have published almost 400 articles and over 30 books dealing primarily with health and safety risks, and I have been ranked among the top 25 economists in the world based on citations in economics journals. I worked extensively with the U.S. Environmental Protection Agency ("EPA") on a continuous basis from 1983 to 2012, where much of my work was focused on the development of guidelines for hazard warnings for dangerous pesticides and chemicals.

2. In addition to my extensive work for EPA, I have consulted for several other governmental entities on a variety of issues, including the U.S. Department of Transportation, the U.S. Department of Labor, the U.S. Department of Justice, the U.S. General Accounting Office, the U.S. Department of Health and Human Services, the U.S. Office of Management and Budget, and the National Oceanic and Atmospheric Administration. I have also taught courses about risk, uncertainty, risk analysis, and hazard warnings to hundreds of Food and Drug Administration officials, congressional staff, and federal and state judges. I served as the Associate Reporter on The American Law Institute Study on Enterprise Responsibility for Personal Injury and co-wrote the chapter on Product Defects and Warnings. I have also testified before the U.S. Congress on nine occasions as an expert in economics and risk analysis. This testimony addressed such topics as, for example, alcoholic beverage warnings.

3. Apart from my academic and governmental work, I have consulted on matters such as risk perception, hazard warnings design, and safety devices for large companies,

including Bic, DuPont, Becton Dickinson, R.J. Reynolds, Bristol-Meyers Squibb, Anheuser-Busch, Black & Decker, and Medline Industries. I have submitted several expert reports on behalf of British American Tobacco group companies in relation to proposed tobacco regulation, including the introduction of graphic health warning requirements and legal challenges to such regulation. I have also served as a consultant/expert witness for the United States Department of Justice in a variety of cases. These include an analysis of natural resource damages issues in connection with the Exxon Valdez oil spill. I have also testified on behalf of the Province of Quebec on risks and warnings for video lottery terminals.

4. I am a founding editor of two journals: the Journal of Risk and Uncertainty, which publishes peer reviewed articles on issues relating to risk perception and analysis; and Foundations and Trends: Microeconomics. I am currently on the board of several other academic journals, including Regulation; Journal of Law, Economics and Policy; Journal of Tort Law; Contemporary Economic Policy; Regulation and Governance; Managerial and Decision Economics; Journal of Risk and Insurance; Journal of Benefit-Cost Analysis; and The Geneva Risk and Insurance Review. I have also held editorial positions with such journals as American Economic Review, which is the official journal of the American Economic Association; Review of Economics and Statistics, a journal specializing in quantitative applied economics and based at Harvard University; Journal of Environmental Economics & Management; Public Policy; International Review of Law and Economics; and Journal of Regulatory Economics. I have served as a peer reviewer for dozens of other publications and for government agencies in countries throughout the world.

5. I have won several awards for my books and articles. These include the "Article of the Year" award from the Western Economic Association for an article on the valuation of life; the "Article of the Year" award from the Royal Economic Society, an international economic society based in England, for an analysis of how ambiguous risk information influences decision-making; the "Article of the Year" award from the American Risk and Insurance Association for an article on automobile insurance regulation; and two "Article of the Year" awards from the Society for Benefit-Cost Analysis. I am also a five-time winner of the Kulp-Wright Award for "Book of the Year," given out by the American Risk and Insurance Association. Other recent professional awards include being named an Honorary Member of the Academy of Economics and Finance; winning the University of Chicago Law School's Ronald H. Coase Prize for an article on risk perception; and winning the 2019 Vanderbilt University Earl Sutherland prize, which is the school's most prestigious university-wide award for scholarly accomplishment.

6. Much of my scholarly research and writing has focused on issues of risk and health relating to smoking. My work on risk analysis, risk perception, consumer behavior, and regulation as it relates to smoking has included extensive research into the history of the tobacco industry and the related public health discussions, as well as current events as they pertain to these issues. These articles have been widely disseminated and subject to peer review.

7. I have also written two books exclusively related to smoking. The first, *Smoking: Making the Risky Decision* (Oxford University Press, 1992) is about smoking and smoking risks, and analyzes how the available information about smoking has changed over time, how people have assessed the risks of smoking, and how those risk perceptions

affect smoking behavior. The book also explains how changes in the price of cigarettes affect cigarette consumption. The second book, *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (University of Chicago Press, 2002), includes chapters on risk perceptions and addiction, youth smoking, environmental tobacco smoke, the promotion of potentially safer cigarettes, the settlement of the U.S. state litigation against the tobacco industry, the U.S. Master Settlement Agreement, and the financial costs of smoking. Both books were subject to peer review. A full copy of my Curriculum Vitae is available at https://law.vanderbilt.edu/phd/faculty/w-kip-viscusi/ViscusiCV.pdf.

8. I have been asked by British American Tobacco to provide a report that examines the evidence on e-cigarette risk beliefs and the relationship of these beliefs to e-cigarette usage, as well as presenting an analysis of data from a new survey conducted in selected European markets. I assisted in the design of this survey, which examines the e-cigarette risk beliefs of a sample of smokers, dual users, and exclusive e-cigarette users, as well as their risk beliefs for heated tobacco products and oral nicotine pouch products. In this report, I present an analysis of the risk beliefs regarding these different products and the impact of those beliefs on product usage. I also consider the implications of current risk beliefs for informed consumer choice and the potential public health benefits that these alternative potentially reduced risk products offer. Drawing on the implications of these empirical results, I propose several policy recommendations for Governments/regulators.

II. EXECUTIVE SUMMARY

9. Numerous studies and comprehensive reviews by public health authorities have stated that e-cigarettes are less harmful than conventional tobacco cigarettes. Nevertheless,

surveys in the UK and the US report that many people believe that e-cigarettes are as harmful or more harmful than cigarettes. Failure to understand the lower estimated risks associated with e-cigarettes will discourage e-cigarette use.

10. The trend in survey reports indicating beliefs that e-cigarettes are as harmful or more harmful than cigarettes is not favorable. The percentage of the population who regard e-cigarettes as being as harmful or more harmful than cigarettes has been increasing over time, particularly in recent survey waves.

11. This report analyzes data from a survey in 2020 of adults who currently smoke cigarettes exclusively, currently smoke cigarettes and use e-cigarettes, or use e-cigarettes but do not currently smoke cigarettes. The countries included in the sample are the United Kingdom, Belgium, Denmark, the Netherlands, France, Germany, and Italy.

12. The focus of the survey was on respondents' perceptions of the estimated harm of e-cigarettes compared to conventional cigarettes, and their usage of e-cigarettes. In addition, the survey also obtained information on other potentially reduced risk alternatives to cigarettes, specifically heated tobacco products,[1] and oral nicotine pouches.[2]

[1] Heated tobacco products (also known as 'heat-not-burn' tobacco products) are devices that heat tobacco to generate a nicotine-containing aerosol which the user inhales. Because the tobacco is only heated and not burned, the resulting aerosol can potentially contain substantially lower levels of the toxicants found in the smoke produced when tobacco is burned. In a review of the available evidence carried out for Public Health England in 2018, the authors, while noting the need for further research, concluded that "[t]*he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes*." and that "[c]*ompared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction found varies between studies*." McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England.

[2] Oral nicotine pouches are pre-portioned porous pouches containing nicotine (but no tobacco). The user puts a pouch between the upper lip and gum and leaves it there while the nicotine and taste are released. No combustion is involved. As oral nicotine pouches do not contain any tobacco, they contain far fewer and lower levels of toxicants than cigarettes and other tobacco products like snus.

13. Beliefs that e-cigarettes are less harmful than tobacco burning cigarettes are positively correlated with e-cigarette use. Those who consider e-cigarettes to be less harmful than cigarettes are 33% more likely to currently use e-cigarettes. For nonsmokers who formerly smoked, those who consider e-cigarettes to be less harmful than cigarettes are 9% more likely to currently use e-cigarettes and not smoke conventional cigarettes.

14. Respondents in the UK, a market that has taken a more progressive approach to the regulation of e-cigarettes than many of the other European countries analyzed in this study, are significantly more likely to believe that e-cigarettes are less harmful than respondents in any other country other than Italy, for which the difference in the levels of beliefs compared to the UK is not statistically significant.

15. Controlling for personal characteristics and the respondents' country, e-cigarette use is negatively related to being a cigarette smoker, with e-cigarette users being 48% less likely to also be a current smoker.

16. Not knowing enough about e-cigarettes and not believing that they are less harmful are the two principal reasons that people cite for not using e-cigarettes, while beliefs that they will help cut down or stop smoking are the main reasons given for using e-cigarettes.

17. A substantial number of the survey respondents were unfamiliar with heated tobacco products and oral nicotine pouches, with 35% of respondents stating that they had not heard of a heated tobacco product and 53% of respondents stating that they had not heard of oral nicotine pouches.

18. Beliefs that heated tobacco products and nicotine pouches are less harmful than cigarettes are positively correlated with usage of these products. Respondents who perceive heated tobacco products as being less harmful than cigarettes are 15% more likely to currently

use heated tobacco products, while the comparable increase in the use of oral nicotine pouches for those who perceive them as being less harmful is 4%.

19. The use of heated tobacco products and oral nicotine pouches is also negatively related to being a current smoker. Users of heated tobacco are 4% less likely to also be a current smoker, and users of oral nicotine pouches are 9% less likely to also be a current smoker.

20. Substantial opportunities remain for more effective risk communication efforts. The current failure by consumers to appreciate the estimated lower risk of these alternative products compared to cigarettes is a major shortfall of consumer knowledge. These beliefs in turn play an instrumental role in consumer decisions regarding the use of these products.

21. Recommended policy changes include both a more vigorous role for informational initiatives by governments as well as framing warnings information so that they facilitate informed consumer choices. Reducing the restrictions that manufacturers face in communicating the comparative estimated risks of these products would also facilitate efforts to inform consumers about the product risks.

III. THE ESTIMATED RISKS OF E-CIGARETTES

22. A principal driver of interest in e-cigarettes (EC) is their estimated risk levels compared to conventional cigarettes that burn tobacco. Because e-cigarettes have been available for a relatively short time compared to cigarettes and other traditional tobacco products, there are no epidemiological studies that have assessed their possible long-term health consequences. There is, however, a substantial literature that has analyzed the chemical composition of e-cigarette vapors and assessed the possible short-term health effects.

The general consensus is that e-cigarettes are estimated to be much less risky than conventional cigarettes.

23. Public Health England has commissioned reviews of the literature in 2015[3] and 2018,[4] each of which provided an extensive assessment of the literature. The 2015 report provided an update of Public Health England's earlier reports on e-cigarettes in the light of new evidence, stating (p. 12): "It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate." Public Health England (2018, p. 150) reiterated the principal conclusion of the 2015 report: "Since the 2015 Public Health England report, the Royal College of Physicians (RCP) has also reviewed evidence on the safety of EC and concluded that they were 'unlikely to exceed 5% of the harm from smoking to tobacco.'" With respect to the cancer risks posed by e-cigarettes, Public Health England (2018, p. 157) report concluded: "In summary, a study of cancer potencies of EC emissions suggested that these are largely less than 0.4% of smoking." The Public Health England (2018, p. 162) report similarly noted that there was no evidence of significant health risks from passive vaping.

24. The 2018 Public Health England report also included a discussion of what is known at this point about the risks posed by heated tobacco products. While noting that the current evidence for heated tobacco products was limited, the report concluded that compared to conventional cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful compounds, but pose more risk than e-cigarettes (p. 23). Their overall assessment (p. 24) is that heated tobacco products

[3] Ann McNeill, et al. Evidence Review of E-Cigarettes and Heated Tobacco Products 2015: A Report Commissioned by Public Health England. London: Public Health England, 2015.
[4] Ann McNeill, et al., Evidence Review of E-Cigarettes and Heated Tobacco Products 2018: A Report Commissioned by Public Health England. London: Public Health England, 2018.

"…may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes."

25. The 2020 Public Health England evidence update[5] included some cautionary information regarding the absolute risk of e-cigarettes along with the lower comparative risk message from its previous reports (p. 27), noting that "vaping regulated nicotine products has a small fraction of the risks of smoking, but this does not mean it is 'safe'."

26. The US National Academies of Sciences, Engineering, and Medicine (NASEM) undertook a large-scale systematic review of the scientific literature for the US Food and Drug Administration in 2018.[6] While noting the need for studies of the long-run effects of e-cigarettes, the report concludes (p.1) that the current evidence, based on laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies, suggests that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes. The report also concluded (p. 11): "The evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."

27. Other prominent studies have reached similar conclusions. Farsalinos and Polosa (2014) also undertook a systematic review of the literature and concluded that the currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes.[7]

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[5] A. McNeill, L.S. Brose, R. Calder, L. Bauld, and D. Robson. Vaping in England: An Evidence update Including Mental Health and Pregnancy March 2020: A Report Commissioned by Public Health England. London: Public Health England, 2020

[6] National Academies of Sciences, Engineering, and Medicine. 2018. Public Health Consequences of E-Cigarettes. Washington, D.C.: National Academies Press.

[7] K. E. Farsalinos, and R. Polosa. 2014. "Safety Evaluation and Risk Assessment of Electronic Cigarettes as Tobacco Substitutes: A Systematic Review," *Therapeutic Advances in Drug Safety*, 5(2), 67-86.

28. A more recent study by Stephens (2018) found that the cancer potencies of e-cigarettes were less than 1% of tobacco smoke.[8] Heat-not-burn devices were found to have an order of magnitude lower level of potency than tobacco cigarettes but had a higher level of potency than e- cigarettes.

29. Estimates of the health benefits that may result by switching from conventional tobacco cigarettes to e-cigarettes are substantial. Abrams et al. (2018, p. 205) provided the following estimates for the United States smoking population: "Replacement of most cigarette use by e-cigarette use over a 10-year period yields up to 6.6 million fewer premature deaths with 86.7 million fewer life years lost."[9]

30. Recently, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) concluded that the current evidence indicates that electronic cigarettes are substantially reduced risk compared with combustible cigarettes. COT, which is made up of independent experts, was commissioned by the UK Department of Health and Social Care and Public Health England to review the potential toxicological risks from electronic cigarettes.[10] The review concluded that, although the magnitude of the decrease will depend on the effect in question, the relative risk of adverse health effects would be expected to be substantially lower from e-cigarettes for smokers who completely switch to e-cigarettes, or if e-cigarettes are taken up instead of combustible cigarettes.[11]

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[8] William E. Stephens, "Comparing the Cancer Potencies of Emissions from Vapourised Nicotine Products Including E-Cigarettes with Those of Tobacco Smoke," *Tobacco Control*, Vol. 27, 2018, pp. 10-17.
[9] David B. Abrams, et al. 2018. "Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives," *Annual Review of Public Health*, Vol. 39, pp. 193-213.
[10] The review included electronic nicotine delivery systems and devices that use an e-liquid that does not contain any nicotine, collectively abbreviated as E(N)NDS
[11] The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment., *Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes)* July 2020 - A report commissioned by the Department of Health and Social Care and Public Health England.

IV. PREVIOUS STUDIES OF THE PERCEPTION OF E-CIGARETTE RISKS

31. There has been an extensive analysis of the perceived harm of e-cigarettes based on surveys of beliefs in the UK and the US. These studies have framed this assessment on a comparative basis using tobacco-burning cigarettes as the reference point. The wording used has usually been in terms of whether e-cigarettes are less harmful, more harmful, or just as harmful as conventional cigarettes. A couple of studies have framed the question in terms of whether e-cigarettes pose less risk, more risk, or just as much risk as conventional cigarettes. For both survey wordings, a substantial segment of the population either does not know whether e-cigarettes pose less harm or believes that e-cigarettes are either just as harmful or more harmful than conventional cigarettes. There has also been evidence of an increase over time in the fraction of the population who regard e-cigarettes as just as harmful or more harmful than conventional cigarettes. Comparison of the survey results in the different studies is sometimes hindered by the fact that some respondents may not be familiar with e-cigarettes, which would lead to a "don't know" response in many surveys. Such "don't know" responses are quite different than that of informed respondents who are not willing to make a judgment on whether e-cigarettes are less harmful. These "don't know" respondents may be similar to viewing the products as being equally harmful.

E-Cigarette Perceptions in the UK

32. Assessing the degree to which the population regards e-cigarettes as less harmful is potentially important from the standpoint of the number of smokers who might switch to e- cigarettes. In a study in England from 2014 to 2019 that followed the behavior of 300

smokers who were surveyed monthly, Perski et al. (2020)[12] found that declines in the belief among current smokers that e-cigarettes are less harmful than combustible cigarettes were strongly associated with declines in the use of e-cigarettes among current tobacco smokers. For every 1% decrease in the mean prevalence of current tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes, the mean prevalence of e-cigarette use decreased by 0.48%. The authors state:

> "*The reduction in the proportion of tobacco smokers who perceive e-cigarettes to be less harmful than combustible cigarettes from 2014 to 2019 and the associated reduction in the use of e-cigarettes may reflect smokers' concerns about the uncertainty about the long-term health effects of e-cigarettes. These concerns may have been amplified by frequent media reports focusing on the absolute (as opposed to relative) health risks of e-cigarettes or graphic, highly emotive depictions of e-cigarette explosions or e-cigarette or vaping product use-associated lung injury (EVALI) in the US. In line with Huang and colleagues' call for an increase in the availability of accurate risk information about e-cigarettes in mainstream media, our results highlight the need for an increase in media portrayals and public health campaigns focusing on the reduced health harms by switching from combustible tobacco to e-cigarettes and a reduction in alarmist media coverage of events such as EVALI*.".

33. Some studies of beliefs in the UK also include more than one country in the sample. The summaries below present them in rough chronological order of the survey years. The

[12] Olga Perski, Emma Beard, and Jamie Brown. 2020. "Association between Changes in Harm Perceptions and E-Cigarette Use among Current Tobacco Smokers in England: A Time Series Analysis," *BMC Medicine*, 18:98, pp. 1-10. In this study, each 1% decrease in the belief that e-cigarettes are less harmful is associated with a 0.5% decrease in e-cigarette use.

article by Adkinson et al. (2013) used a sample of current and former smokers from mid-2010 to mid-2011 and found that the percentage of respondents who viewed e-cigarettes as being less harmful than conventional cigarettes was 82% in the UK, 71% in Australia, 66% in the US, and 64% in Canada.[13] The average percentage across these studies was 70%. Most respondents--80%-- indicated that they used e-cigarettes because they were less harmful than conventional cigarettes, 75% said that they did so to reduce their smoking, and 85% said it was to help them quit smoking.

34. Another result from UK samples over two years reported that, excluding "don't know" responses, the percentage of the population who viewed e-cigarettes as less harmful than cigarettes decreased from 86.4% in 2013 to 78.2% in 2014.[14]

35. Public Health England (2015) reported the results of a series of surveys for the UK and Europe, noting that the trend in risk beliefs displayed a disturbing pattern (p. 6): "There has been an overall shift towards the inaccurate perception of e-cigarettes being as harmful as cigarettes over the last year in contrast to the current expert estimate that using e-cigarettes is around 95% safer than smoking." The Internet Cohort Great Britain Surveys reported by Public Health England (2015) covered the years from 2012 to 2014. The percentage who viewed e-cigarettes as less harmful than cigarettes was 67% in 2012, 67% in 2013, and 60% in 2014. The beliefs that the products are equally harmful rose from 9% in 2012 to 11% in 2013 and to 17% in 2014. The percentage who viewed e-cigarettes as more harmful than cigarettes remained at 2% throughout that period, while the "don't know" percentage declined from 23% in 2012 and to 21% in 2013 and 2014.

[13] Sarah E. Adkinson, et al. 2013. "Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey," *Am. J. Prev. Med.,* Vol. 44, No. 3, pp. 207-215.
[14] Leonie S. Brose, et al. 2015. "Perceived Relative Harm of Electronic Cigarettes over Time and Impact on Subsequent Use. A Survey with 1-Year and 2-Year Follow-ups," *Drug and Alcohol Dependence,* Vol. 157, 106-111.

The ASH Smokefree Great Britain Surveys reported by Public Health England (2015) show somewhat different levels of harm beliefs. The percentage who viewed e-cigarettes as less harmful than cigarettes rose from 52% in 2013 to 54% in 2014 and 2015. The equally harmful beliefs rose from 6% in 2013 to 14% in 2014 and 20% in 2015. The percentage who viewed e-cigarettes as more harmful than cigarettes remained low at 1% in 2013 and 2% in 2014 and 2015. There was a decline over time in the "don't know" percentage from 40% in 2013 to 30% in 2014 and 23% in 2015. However, the ASH Smokefree Great Britain Youth Surveys reported a decline in the belief that e-cigarettes are less risky than cigarettes from 74% in 2013 to 66% in 2014 and 67% in 2015, coupled with an almost doubling of the equally-risky beliefs from 12% in 2013 to 21% in 2015.

36. Action on Smoking and Health (ASH 2019) reported survey results among adults in Great Britain who have heard of e-cigarettes.[15] Those who viewed e-cigarettes as equally harmful or more harmful rose from 7% in 2013 to 15% in 2014, and subsequently to 26% in 2019. Among adult smokers, the percent who viewed e-cigarettes as equally harmful or more harmful was 8% in 2013 and 10% in 2014, rising to the much higher value of 22% in 2019.

37. The Public Health England (2020) report by A. McNeill et al. presented survey results for 2019 and compared them with results for an adult sample in 2014 (p. 97). The percentage of respondents who regarded e-cigarettes as less harmful than cigarettes dropped from 45% in 2014 to 34% in 2019. The report stated these misperceptions are particularly common among smokers who do not vape. The response group exhibiting the greatest change was that in which e-cigarettes and conventional tobacco-burning

[16] Action on Smoking and Health (ASH). 2020. "Use of E-Cigarettes (Vapes) among Adults in Great Britain, October 2020."

cigarettes are viewed as being equally harmful, as that fraction rose from 26% in 2014 to 42% in 2019. The remaining categories in 2019 consisted of 14% who viewed e-cigarettes as more harmful than cigarettes and 10% who indicated that they did not know. Similar changes in harm beliefs were also evident for the ASH-Y data for youths, as two-thirds of respondents viewed e-cigarettes as less harmful than cigarettes in 2014 and just over one-half did so in 2019 (p. 53).

38. An article by Wilson, et al. (2019) reported perception of harm results for a longitudinal UK sample interviewed in 2017. Overall, 57% believed that e-cigarettes are less harmful than cigarettes, 22% believed that e-cigarettes and cigarettes are equally harmful, 3% believed that e-cigarettes are more harmful than cigarettes, and 18% indicated that they did not know.

39. Perhaps influenced in part by the e-cigarette, or vaping, product use associated lung injury (EVALI) illnesses in the US, respondents to the 2020 Action on Smoking and Health Survey viewed e-cigarettes even less favorably compared to cigarettes.[16] Particularly striking is that 37% of adults and 34% of smokers regarded e-cigarettes as more harmful than or as harmful as cigarettes. Reporting on the Survey, ASH states: '[t]he proportion of the adult population thinking that e-cigarettes are more or equally harmful as smoking is five times higher than in 2013, increasing from 7% in 2013 to 37% in 2020' and '… in 2020 perceptions have shifted markedly with the highest proportion of people reporting inaccurate misperceptions that e-cigarettes are more harmful than smoking (37%) and the lowest proportion reporting that e-cigarettes are less or a lot less harmful (39%).'

[16] Action on Smoking and Health (ASH). 2020. "Use of E-Cigarettes (Vapes) among Adults in Great Britain, October 2020."

E-Cigarette Perceptions in the US

40. The pattern of harm beliefs in the United States also indicates that a substantial part of the population is not aware of the estimated comparative harm of e-cigarettes and conventional cigarettes. Richardson, et al. (2014) reported that in a 2011 survey of current and former smokers, the percentage distribution of comparative beliefs regarding harms of e-cigarettes was 21% don't know, 65% less harmful, 10% about the same harm, and 3% more harmful.[17] The less harmful belief percentages were lower for snus (12%), chewing tobacco, snuff, and dip (10%), and dissolvables (17%).

41. Results reported by Kiviniemi and Kozlowski (2015) using data from the US Health Information National Trends Survey (HINTS), a population-representative survey of US adults, for 2012-2013 were that 11% viewed e-cigarettes as much less harmful than cigarettes, 40% viewed them as less harmful than cigarettes, 46% viewed them as just as harmful as cigarettes, 1.6% viewed them as more harmful than cigarettes, and 1.2% viewed them to be much more harmful than cigarettes.[18] Combining the as harmful and more harmful groups, 49% believed that e-cigarettes are as harmful as or more harmful than cigarettes.

42. Persoskie, et al. (2019) reported trends of declining beliefs that e-cigarettes are less harmful than cigarettes from 45% in 2012 to 34% in 2017.[19] In wave two of the US National Population Assessment of Tobacco and Health (PATH) Study, 59% of those

[17] Amanda Richardson, et al. 2014. "Prevalence, Harm Perceptions, and Reasons for Using Noncombustible Tobacco Products Among Current and Former Smokers," *Am. J. of Public Health*, Vol. 104, No. 8, pp. 1437-1444.
[18] Marc T. Kiviniemi and Lynn T. Kozlowski. 2015. "Deficiencies in Public Understanding about Tobacco Harm Reduction: Results from a United States National Survey," *Harm Reduction Journal*, Vol. 12, No. 21, pp. 1-7.
[19] Alexander Persoskie, Erin Keely O'Brien, and Karl Poonai. 2019. "Perceived Relative Harm of Using E-Cigarettes Predicts Future Product Switching among U.S. Adult Cigarette and E-Cigarette Dual Users," *Addiction*, Vol. 114, pp. 2197-2205.

who used both e-cigarettes and cigarettes perceive the former as being less harmful, 35% considered the harms to be about the same, 4% viewed e-cigarettes as more harmful than cigarettes, and 1% did not know. Compared with those with other perceptions of e-cigarette harm, dual users who perceived e-cigarettes as less harmful were more likely to switch to exclusive e-cigarette use and were less likely to switch to exclusive cigarette use one year later.

43. Majeed, et al. (2017) considered results in 2012 and 2015 for both non-smokers and an over-sampled group of smokers.[20] The percentage of adults who viewed e-cigarettes as less harmful than cigarettes was 39% in 2012 and 31% in 2015, and for smokers these percentages were 45% in 2012 and 36% in 2015. There was a large change in the percentage of adults who believed the risks to be about the same, from 12% in 2012 up to 36% in 2015. For smokers, that increase was from 11% in 2012 to 31% in 2015. There was a drop in the "don't know" percentages from 48% to 30% overall, and from 44% to 29% for smokers. The percentage of those who believed that e-cigarettes cause more harm than cigarettes remained low at 1% in 2012 and 4% in 2015 for both the full sample and for smokers.

44. Huang et al. (2019) found that in two nationally representative multiyear cross-sectional surveys of US adults, the percentage who viewed e-cigarettes as being as harmful as or more harmful than cigarettes increased from 2012 to 2017.[21] In the Tobacco Products and Risk Perceptions Survey (TPRPS) data, the proportion of adults who perceived e-

[20] Ban A. Majeed, et al. 2017. "Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012-2015," *Am J. Prev. Med*., Vol 52, No. 3, pp. 331-338.
[21] Jidong Huang, et al. 2019. "Changing Perceptions of Harm of E-Cigarette vs. Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, Tobacco Products and Risk Perceptions Survey and Health Information National Trends Survey," *JAMA Network Open*, Vol. 2, No. 3, pp. 1-12.

cigarettes to be as harmful as cigarettes increased from 11.5% in 2012 to 36.4% in 2017 and the percentage of those who perceived e-cigarettes to be more harmful than cigarettes increased from 1.3% in 2012 to 4.3% in 2017. For the Health Information National Trends Survey (HINTS) data, the proportion of adults who perceived e-cigarettes to be as harmful as cigarettes increased from 46.4% in 2012 to 55.6% in 2017; and those who perceived e-cigarettes to be more harmful than cigarettes increased from 2.8% in 2012 to 9.9% in 2017. One difference in the surveys is that there is a "don't know" option in TPRPS but not in HINTS.

45. Nyman (2019) reported harm beliefs in 2017 and 2018 based on the U.S. Tobacco Products and Risk Perceptions Survey (TPRPS).[22] Between 2017 and 2018, the percentage of adults perceiving e-cigarettes to be as harmful as cigarettes increased from 36.4% to 43.0%. The percentage of adults perceiving e-cigarettes to be more harmful than cigarettes also increased from 2.4% to 4.4% and the percentage perceiving e-cigarettes to be much more harmful than cigarettes increased from 1.9% to 3.7%.

46. Malt, et al. (2020) provide a review of the harm beliefs of US adults for e-cigarettes in three waves of the nationally representative Population Assessment of Tobacco and Health (PATH) study data.[23] In wave 1 from September 2013 to December 2014, 54% regarded e-cigarettes as being as harmful as or more harmful than cigarettes, and 41% viewed them as less harmful than cigarettes. In wave 2 from October 2014 to October 2015, 65% regarded e-cigarettes as being as harmful as or more harmful than cigarettes,

[22] Amy L. Nyman. 2019. "Perceived Comparative Harm of Cigarettes and Electronic Nicotine Delivery Systems," JAMA Network Open, Vol. 2, No. 11, pp. 1-4.
[23] Layla Malt, et al. 2020. "Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data," *Harm Reduction Journal,* Vol. 17, No. 65, pp. 1-12.

and 32% considered them to be less harmful than cigarettes. The degree of beliefs that e-cigarettes are less harmful than cigarettes continued to decline to 25% in wave 3 from October 2015 to October 2016, with the percentage considering e-cigarettes as being as harmful as or more harmful than cigarettes increasing to 73% in October 2015. The "don't know" responses constituted the residual for each of these surveys. The authors conclude: "in this study, the proportion of US adults who incorrectly perceived e-cigarettes as equal to, or more, harmful than cigarettes increased steadily regardless of smoking or vaping status. Current adult smokers appear to be poorly informed about the relative risks of e-cigarettes yet have potentially the most to gain from transitioning to these products. The findings of this study emphasize the urgent need to accurately communicate the reduced relative risk of e-cigarettes compared to continued cigarette smoking and clearly differentiate absolute and relative harms. Further research is required to elucidate why the relative harm of e-cigarettes is misunderstood and continues to deteriorate."

47. Viscusi (2016, 2020) framed the question in terms of whether e-cigarettes pose lower risks than conventional cigarettes rather than lower levels of harm.[24] The results in both 2014 and 2019 were that 52% viewed e-cigarettes as being somewhat less risky or much less risky. The fraction who believed that e-cigarettes are more risky rose from 2% in 2014 to 11% in 2019, and the fraction who viewed e-cigarettes as just as risky was 44% in 2014 and 34% in 2019. In each case there was strong dependence of risk beliefs for e-cigarettes on respondents' risk assessment for conventional cigarettes. In particular,

[24] W. Kip Viscusi. 2016. "Risk Beliefs and Preferences for E-Cigarettes," *American Journal of Health Economics*, Vol. 2, No. 2, pp. 213-240. W. Kip Viscusi. 2020. "Electronic Cigarette Risk Beliefs and Usage after the Vaping Illness Outbreak," *Journal of Risk and Uncertainty*, Vol. 60, No. 3, pp. 259-279.

consumers' beliefs reflected a weight of about two-thirds on their cigarette risk beliefs when forming their e-cigarette risk beliefs.

Implications of the UK and US E-Cigarette Perception Studies

48. The percentage of the respondents who perceive e-cigarettes as being less harmful than cigarettes depends on the time period, the sample group, and the structure of the survey question. Including a "don't know" response decreases the percentage of respondents who commit to making a comparison. Surveys that are restricted to those who are familiar with e-cigarettes generate higher levels of comparative responses.

49. There are three principal implications of the survey results. First, a substantial segment of the population view e-cigarettes as posing equivalent risks to conventional cigarettes or even greater risks, which is inconsistent with the current scientific evidence and the prevailing public health opinions. Second, both in the UK and in the US, the proportion of the population who consider e-cigarettes to be as harmful or more harmful than conventional cigarettes has been increasing over time. Third, there is evidence that these continued misperceptions of the estimated risk of e-cigarettes are negatively correlated with e-cigarette use, with respondents who have these views being less likely to use e-cigarettes.

V. NEW EVIDENCE ON E-CIGARETTE PERCEPTIONS

50. A series of surveys were commissioned by British American Tobacco in 2020 to analyze the current level of harm beliefs in selected European markets. The principal objectives of the surveys were to ascertain the harm beliefs regarding e-cigarettes and the relationship of these beliefs to e-cigarette usage. In addition, the survey also asked

respondents' questions regarding their awareness, use and perceptions of heated tobacco products and oral nicotine pouches. I assisted in the design of the survey questions. The samples consisted of adult members of online survey panels. The countries included were the UK, Belgium, Denmark, the Netherlands, France, Germany, and Italy.

51. To be included in the sample, the respondent had to answer affirmatively to all of the following: (1) that they had smoked more than 100 cigarettes in their lifetime; (2) that they had heard of e-cigarettes; and (3) that they were either a current smoker, a current smoker and vaper, or a former smoker that currently vapes. As noted above, while not included as part of the screening of the sample (so as to avoid potentially limiting the sample size, given that these products are newer to the market and generally less used than e-cigarettes), the survey also asked questions regarding respondents' awareness, use and perceptions of heated tobacco products and oral nicotine pouches. After limiting the multi-country sample to those who passed these sample screens, the sample consisted of 1,073 respondents in Denmark, 1,477 respondents in Germany, and 1,500 respondents in each of the other five countries. The analysis below focuses on the pooled sample. Appendix A presents the demographic characteristics of the sample.

52. Table 1 provides overview statistics regarding product use and harm beliefs. Almost two-thirds of the sample use e-cigarettes currently, and 88% have either tried or currently use e-cigarettes. This high rate of product usage is a consequence of the sample screen. The harm perceptions reflect the beliefs of these groups. As also indicated in Figure 1, 57% of the sample view e-cigarettes as less harmful than cigarettes, and 43% consider them to be the same as or more harmful than cigarettes. For simplicity, all figures below will have numbers that correspond to the table of results that they are illustrating.

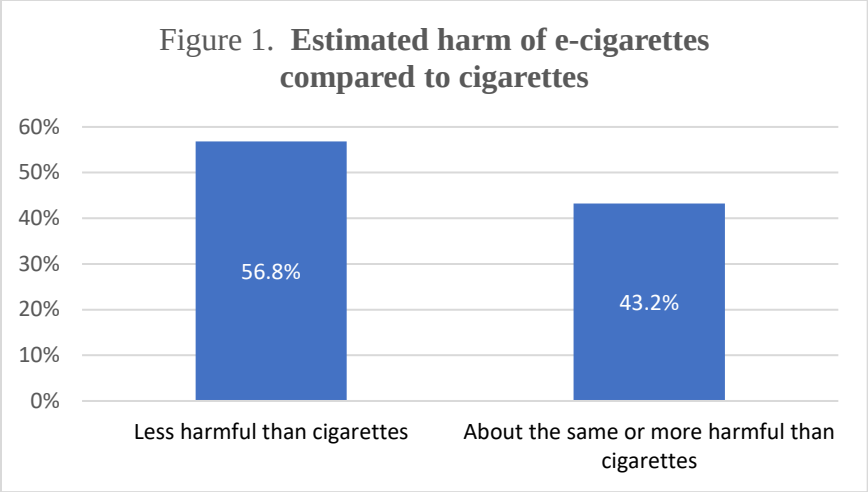
Table 1. **Product use and relative harm belief percentage**

	E-Cigarettes
Ever heard of the product *	100
Description of use **	
- Never tried the product	11.5
- Tried, but never use now	22.3
- Use the product currently	66.2
- Tried, regardless of current use	88.5
Harm relative to cigarettes ***	
- Less harmful than cigarettes	56.8
- About the same as cigarettes	35.5
- More harmful than cigarettes	7.7
- Same or more harmful	43.2

* Knowledge of e-cigarettes was required to participate in the survey.
** Those who have never heard of the product are assumed never to have tried it.
*** Harm beliefs are percentages of the subset of respondents who have heard of the product.

53. Table 1 indicates that a substantial portion of respondents perceive e-cigarettes to be the same as or more harmful than cigarettes. Since the sample consists of a disproportionate share of e-cigarette users, who would be expected to choose this behavior based on perceived lower levels of harm of the product, these results are likely to understate these perceptions for the general population.

Figure 1. **Estimated harm of e-cigarettes compared to cigarettes**

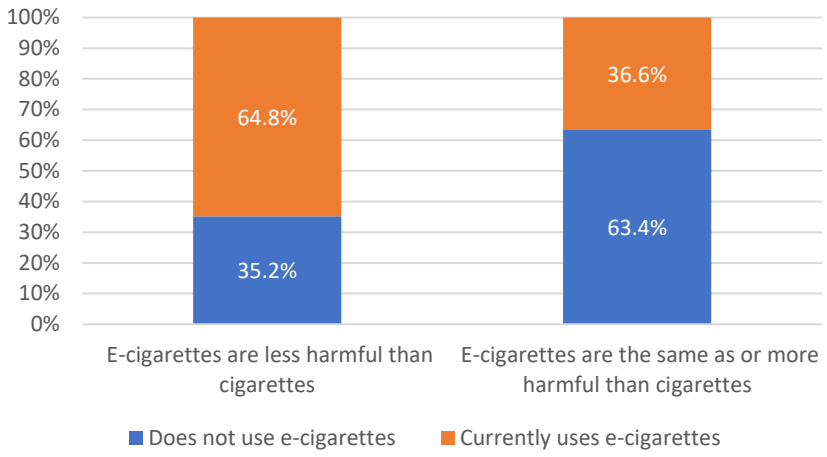


54. The relationship between product use and harm beliefs is examined in Table 2. The first two columns pertain to the beliefs of cigarette smokers. Half of the smokers in the sample use e-cigarettes and half of them do not. For cigarette smokers who consider e-cigarettes to be less harmful than cigarettes, 65% currently use e-cigarettes and 35% do not. In contrast, for current cigarette smokers who consider the harm levels from e-cigarettes to be the same or more harmful compared to cigarettes, 37% currently use e-cigarettes and 63% do not. Figure 2 also summarizes these harm belief results. The results for current non-smokers in the final two columns of Table 2 are less instructive, as all those who are non-smokers necessarily use e-cigarettes regardless of their harm beliefs or they will not be included in the sample.

Table 2. **Current or former cigarette smokers and their e-cigarette use percentage**

	Results for Current cigarette smokers		Results for Current non-smokers	
	Does not use product	Currently uses product	Does not use product	Currently uses product
E-Cigarette users	50.0	50.0	0	100
- Less harmful than cigarettes	35.2	64.8	0	100
- Same or more harmful	63.4	36.6	0	100

Figure 2. **Harm Beliefs of Current Cigarette Smokers**

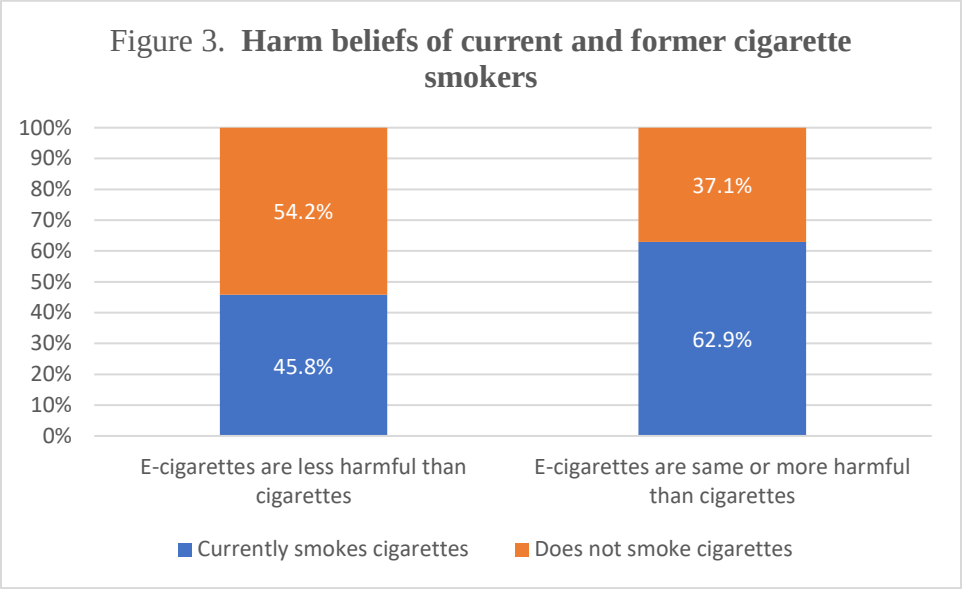


55. Table 3 and Figure 3 present the distribution of usage of cigarettes for e-cigarette users based on their level of harm beliefs. Overall, 51% of e-cigarette users in the sample currently smoke cigarettes, and 49% do not. For those who use e-cigarettes, having low levels of comparative harm beliefs is associated with not smoking cigarettes. The largest harm belief category among e-cigarette users is the less harmful group, for which 54% do not smoke cigarettes and 46% do. The pattern is strongly reversed for those who consider the risks to be just as harmful or more harmful, as 63% of this group currently smoke cigarettes and 37% do not smoke cigarettes.

Table 3. **Current or former cigarette smokers percentage, by use and harm perceptions of e-cigarettes**

	Observations	Currently smokes cigarettes	Does not smoke cigarettes
E-Cigarette users	6,650	51.1	48.9
- Less harmful than cigarettes	4,573	45.8	54.2
- About the same as cigarettes	1,634	73.3	26.7
- More harmful than cigarettes	443	24.4	75.6

E-Cigarette non-users	3,400	100	0
Distribution for all respondents	10,050	67.6	32.4

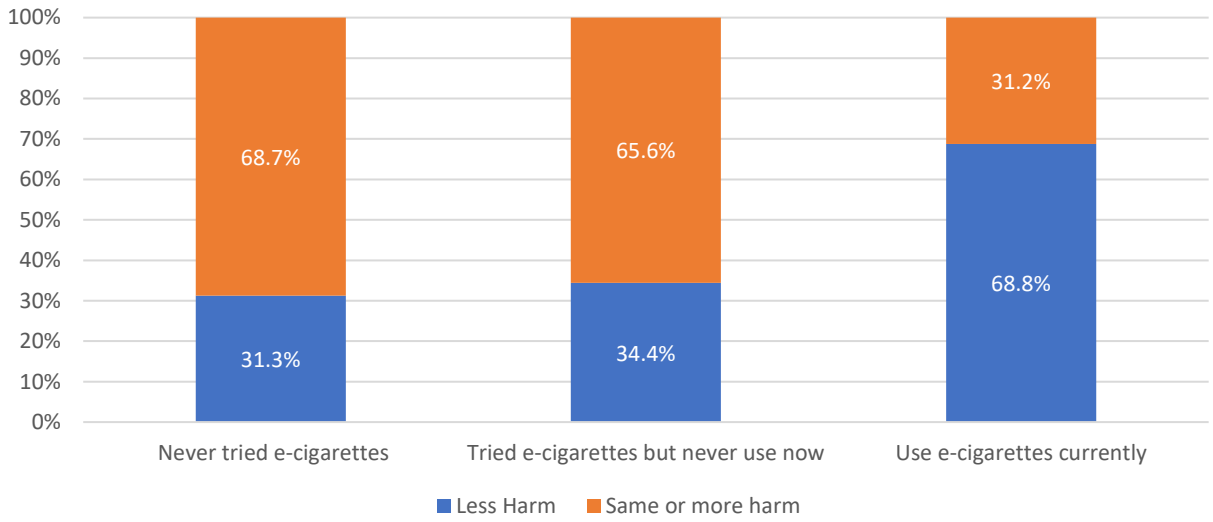


56. An alternative perspective on these relationships is the distribution of harm beliefs shown in Table 4 and Figure 4, conditional on different levels of e-cigarette usage. Those who currently use e-cigarettes are most likely to perceive that they are less harmful than cigarettes, with 69% of current e-cigarette users perceiving them to be less harmful than cigarettes and 31% of current e-cigarette users perceiving e-cigarettes to be just as harmful or more harmful than cigarettes. The least favorable assessments of the harmfulness of e-cigarettes are by those who have never tried the product, with only 31% of this group of those who have never used e-cigarettes considering e-cigarettes to be less harmful than cigarettes, and 69% considering e-cigarettes to be just as harmful or more harmful than cigarettes.

Table 4. **Harm beliefs relative to cigarettes percentage, by e-cigarette use**

	Observations	Less harm	Same harm	More harm	Same or More
E-Cigarettes	10,050				
- Never tried the product	1,155	31.3	55.8	12.8	68.7
- Tried, but never use now	2,245	34.4	57.5	8.1	65.6
- Use the product currently	6,650	68.8	24.6	6.7	31.2
- Tried, regardless of current use	8,895	60.1	32.9	7.0	39.9

Figure 4. **Estimated harm of e-cigarettes compared to cigarettes by use of product**



57. The linkage of harm beliefs to more measures of product usage is examined in Table 5 and Figures 5a, 5b, and 5c. Among those who smoke cigarettes but do not use e-cigarettes, 67% view e-cigarettes as the same as or more harmful than cigarettes. However, 76% of those who use e-cigarettes but not cigarettes consider e-cigarettes to be less harmful than cigarettes. By comparison, among those who both smoke cigarettes and use e-cigarettes, 62% consider e-cigarettes to be less harmful than cigarettes.

Cigarette smokers who do not use e-cigarettes are more likely to believe that e-cigarettes are at least as harmful as cigarettes, by a two-to-one margin.

Table 5. **Percentage distribution of harm beliefs for different groups of usage of cigarettes and e-cigarettes**

E-Cigarettes are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not e-cig	33.4	66.6	3,400
- E-Cigarettes, not cigarettes	76.3	23.7	3,252
- Both e-cigarettes and cigarettes	61.6	38.4	3,398

Figure 5A. **Estimated comparative harm beliefs of smokers of cigarettes and/or e-cigarette users**

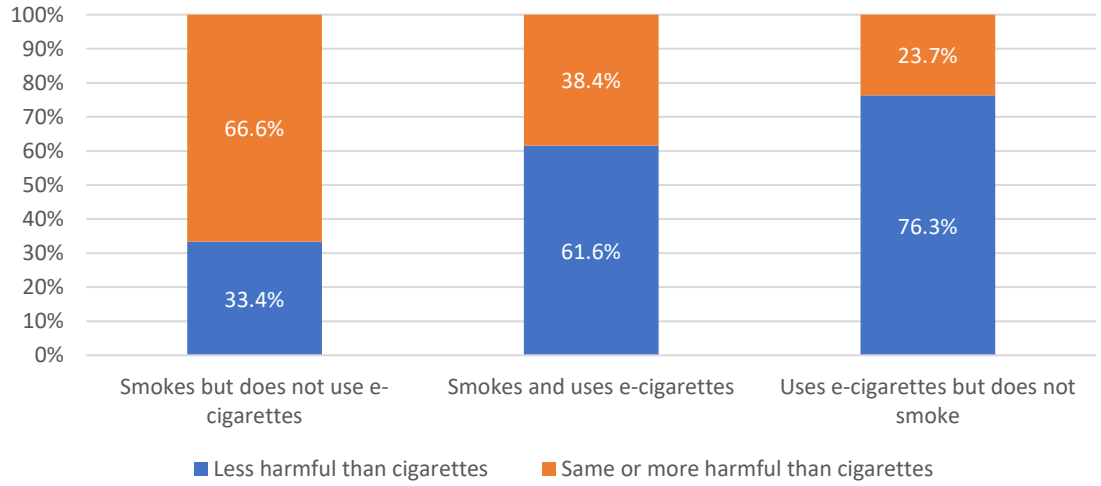


Figure 5B. **Harm beliefs of those who use e-cigarettes but do not smoke cigarettes**

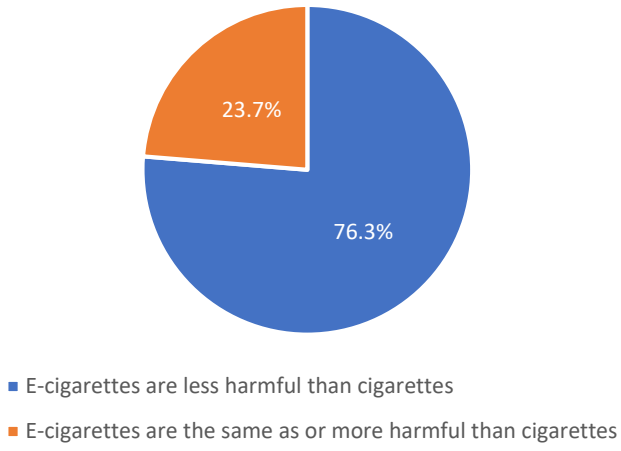
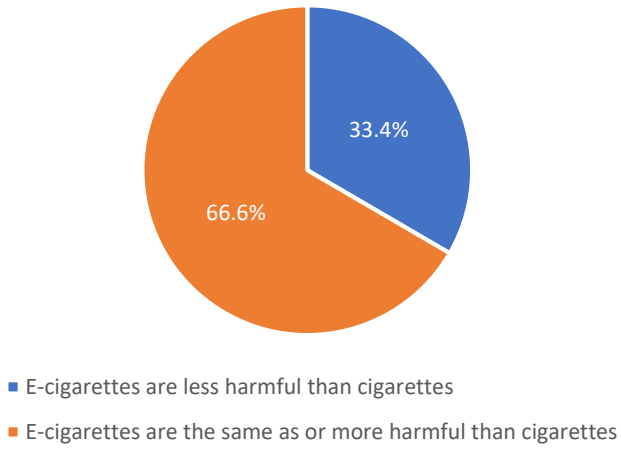


Figure 5C. **Harm beliefs of those who smoke cigarettes and do not use e-cigarettes**



58. The implication of Tables 1-5 and their figure counterparts is that beliefs that e-cigarettes are less harmful than cigarettes are correlated with e-cigarette usage, as well as with the combination of e-cigarette usage and not smoking cigarettes.

59. To better analyze the impact of risk perceptions on current e-cigarette use, Table 6 presents regression results in which the dependent variable is a 0-1 indicator for current product use, and the explanatory variables consist of harm beliefs, countries, and

demographic factors. These regressions in effect analyze factors that affect the probability that the respondent currently uses e-cigarettes. For some demographic variables, such as income and gender, a small number of respondents did not answer the question (Appendix A lists the missing data percentages for each variable). For these observations for which the respondent did not answer the question, I followed the standard statistical practice of including these responses in the statistical analysis but creating a 0-1 indicator variable to address the fact that an observation on this particular variable is missing for the particular respondent.

60. Controlling for the variables included in the regression in Table 6, those who consider e-cigarettes to be less harmful than cigarettes are 33% more likely to currently use e-cigarettes. This relationship is statistically significant with a 95% confidence level, a test that is noted by at least two asterisks in the regression results in this report (three asterisks reflect a 99% level). There are no statistically significant country effects. For this and in subsequent regressions, the UK is the excluded country, which means that any country effects are measured relative to the UK. Usage of e-cigarettes rises with age, but then declines for those age 60+.

Table 6. **Regressions predicting the probability that respondent CURRENTLY USES e-cigarettes, based on harm beliefs, country, and demographics**

	E-Cigarette yes use
E-cigarette less harmful	0.3260***
	(0.0090)
Belgium	0.0066
	(0.0170)
Denmark	0.0090
	(0.0177)
Netherlands	-0.0210

	(0.0163)
France	0.0213
	(0.0161)
Germany	0.0174
	(0.0161)
Italy	0.0014
	(0.0162)
Age	0.0011**
	(0.0005)
Age 60+	-0.0360**
	(0.0159)
Income	0.0010***
	(0.0002)
Income €150,000+	0.1087***
	(0.0242)
Years education	0.0127***
	(0.0020)
Black	-0.1276***
	(0.0300)
Asian	-0.0440
	(0.0294)
Other	-0.0098
	(0.0268)
Female	-0.0255***
	(0.0091)
Married	0.0114
	(0.0128)
Widowed	-0.0175
	(0.0296)
Divorced	-0.0301
	(0.0186)
Separated	-0.0042
	(0.0279)
Partner	0.0217
	(0.0147)
Missing income	0.0187
	(0.0177)
Missing education	0.2332***
	(0.0511)
Missing race	0.0714*
	(0.0399)
Missing female	-0.1824*
	(0.1065)
Missing relationship	-0.0283
	(0.0438)
Constant	0.1959***

	(0.0373)
Observations	10,050
R-squared	0.15

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

61. Given the pivotal role of whether the respondent believes that e-cigarettes are less harmful than cigarettes, the regressions in Table 7 analyze the relationship of the 0-1 variable for whether the respondent perceives e-cigarettes as less harmful than cigarettes. Also included are the variables for the different countries and demographic groups. Relative to the UK sample, respondents in Belgium, Denmark, the Netherlands, France, and Germany are significantly less likely to believe that e-cigarettes are less harmful than cigarettes. Given the efforts by Public Health England and other public health organizations in the UK to communicate the relative risk profile of e-cigarettes as compared to cigarettes, this pattern is consistent with a possible impact of these efforts on harm beliefs. The greatest disparity is for respondents in Belgium, as they are 25% less likely to regard e-cigarettes as less harmful. Respondents also are more likely to regard e-cigarettes as less harmful if they are age 60+ or have high income but are not in the top income group.

Table 7. **Regressions predicting the probability that the respondent believes e-cigarettes are LESS HARMFUL than cigarettes, based on country and demographics**

	E-Cigarettes less harmful
Belgium	-0.2596***
	(0.0188)
Denmark	-0.1356***
	(0.0197)
Netherlands	-0.0862***
	(0.0182)
France	-0.0513***
	(0.0179)
Germany	-0.1216***

	(0.0179)
Italy	-0.0029
	(0.0181)
Age	-0.0009*
	(0.0005)
Age 60+	0.0813***
	(0.0177)
Income	0.0008***
	(0.0002)
Income €150,000+	-0.0903***
	(0.0269)
Years education	-0.0031
	(0.0022)
Black	-0.0528
	(0.0335)
Asian	-0.1280***
	(0.0327)
Other	-0.0394
	(0.0299)
Female	-0.0723***
	(0.0101)
Married	-0.0034
	(0.0143)
Widowed	-0.0228
	(0.0330)
Divorced	0.0154
	(0.0208)
Separated	0.0072
	(0.0311)
Partner	0.0393**
	(0.0164)
Missing income	0.0126
	(0.0197)
Missing education	-0.0386
	(0.0570)
Missing race	-0.0138
	(0.0445)
Missing female	-0.3318***
	(0.1187)
Missing relationship	0.0619
	(0.0489)
Constant	0.7316***
	(0.0409)
Observations	10,050
R-squared	0.04

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

62. Whether e-cigarette use is related to smoking status is examined in the regressions in Table 8, where the dependent variable is the 0-1 indicator variable for whether the respondent is a current smoker. If the respondent currently uses e-cigarettes, he or she is 48% less likely to also be a current smoker. These results are consistent with e-cigarettes serving as an alternative for conventional cigarettes given the sample screens that required all people to be a current or former smoker. Given the cross-sectional nature of the data, the timing of the transition to use of e-cigarettes cannot be determined.

Table 8. **Regressions predicting the probability that the respondent is a CURRENT CIGARETTE SMOKER, based on e-cigarette USE, country, and demographics**

	Smoker
E-cigarette yes use	-0.4814***
	(0.0085)
Belgium	0.0337**
	(0.0153)
Denmark	0.0730***
	(0.0161)
Netherlands	0.0064
	(0.0148)
France	0.0024
	(0.0146)
Germany	0.0014
	(0.0146)
Italy	-0.0217
	(0.0147)
Age	-0.0054***
	(0.0004)
Age 60+	-0.0612***
	(0.0144)
Income	0.0000
	(0.0002)
Income €150,000+	-0.2013***
	(0.0219)
Years education	0.0095***
	(0.0018)
Black	-0.0229

	(0.0273)
Asian	0.0611**
	(0.0267)
Other	0.0207
	(0.0244)
Female	-0.0101
	(0.0083)
Married	0.0212*
	(0.0116)
Widowed	0.0295
	(0.0269)
Divorced	0.0021
	(0.0169)
Separated	-0.0180
	(0.0254)
Partner	-0.0544***
	(0.0133)
Missing income	-0.0569***
	(0.0160)
Missing education	0.1229***
	(0.0465)
Missing race	-0.0077
	(0.0363)
Missing female	0.0037
	(0.0968)
Missing relationship	-0.0539
	(0.0398)
Constant	1.1053***
	(0.0336)
Observations	10,050
R-squared	0.29

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

63. Table 9 reports a regression on a closely related matter regarding exclusive e-cigarette usage. The dependent variable is a 0-1 variable for whether the respondent currently uses e-cigarettes and also does not smoke cigarettes. The principal variable of interest is whether the respondent considers e-cigarettes to be less harmful than cigarettes. Those who have this belief are 9% more likely to be an e-cigarette user and not smoke conventional cigarettes. The country effects relative to the UK are also interesting. All

effects that are statistically significant are negative. The four statistically significant relationships are for Belgium, the Netherlands, Germany, and Italy, all of which have a lower likelihood of respondents using e-cigarettes and not also smoking compared to the UK. Together with the earlier results on risk beliefs, these findings indicate that in the UK people are more likely to perceive e-cigarettes as less harmful than cigarettes and are also more likely to use e-cigarettes and not also smoke even after controlling for this difference in beliefs, compared to these other countries.

Table 9. **Regressions predicting the probability that the respondent CURRENTLY USES e-cigarettes for the subsample that DOES NOT SMOKE CIGARETTES, for exclusive use of product**

	E-Cigarette yes only
E-cig less harmful	0.0935***
	(0.0167)
Belgium	-0.1904***
	(0.0264)
Denmark	0.0200
	(0.0259)
Netherlands	-0.0758***
	(0.0232)
France	-0.0268
	(0.0215)
Germany	-0.1053***
	(0.0221)
Italy	-0.2933***
	(0.0220)
Age	-0.0017**
	(0.0007)
Age 60+	-0.0018
	(0.0206)
Income	-0.0029***
	(0.0002)
Income €150,000+	-0.2022***
	(0.0334)
Years education	-0.0078***
	(0.0029)
Black	0.0990**
	(0.0485)

Asian	-0.0035
	(0.0554)
Other	-0.0314
	(0.0431)
Female	-0.0090
	(0.0130)
Married	-0.0076
	(0.0191)
Widowed	-0.0163
	(0.0421)
Divorced	-0.0304
	(0.0261)
Separated	-0.0469
	(0.0393)
Partner	-0.0239
	(0.0208)
Missing income	-0.0631***
	(0.0238)
Missing education	-0.0754
	(0.0698)
Missing race	-0.0323
	(0.0527)
Missing female	-0.5457
	(0.3379)
Missing relationship	-0.0459
	(0.0594)
Constant	1.1903***
	(0.0560)
Observations	3,252
R-squared	0.37

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

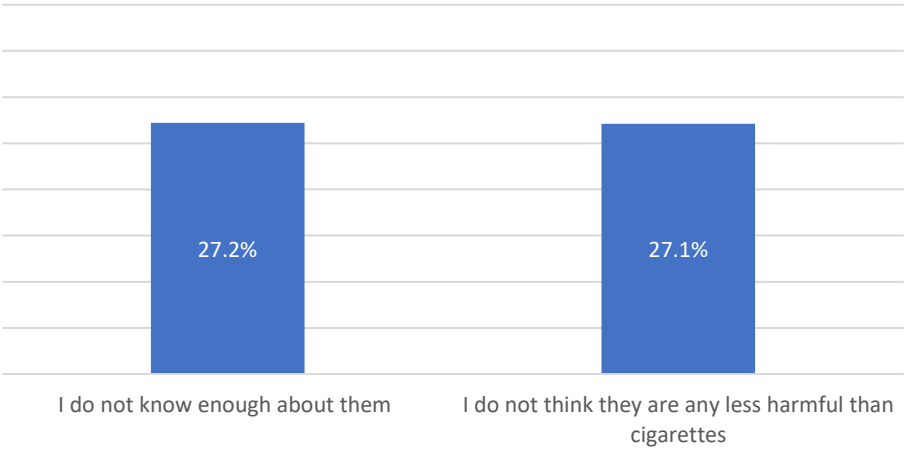
64. The surveys also elicited respondents' reasons for never trying e-cigarettes. For the sample of respondents in Table 10 who have never tried the product, the main reasons given are that they do not know enough about e-cigarettes or do not think that e-cigarettes are any less harmful than cigarettes, each of which were mentioned by 27% of the respondents. Just under 17% of the sample indicate that they do not want to quit smoking, and 16% believe that e-cigarettes will not help them quit. Cost is a minor

concern voiced by 10% of respondents. Figure 10 summarizes the most prominent main reasons for never trying e-cigarettes.

Table 10. **Percentage distribution of the main reason for decision to have NEVER TRIED e-cigarettes**

What is the main reason for you not trying	E-Cigarette
I do not know enough about them	27.2
I do not want to quit smoking	16.9
I do not think that they are any less harmful than cigarettes	27.1
They cost too much	9.7
I do not think that they would help me to quit or cut down smoking	15.8
Other	3.3
Number of observations	1,155

Figure 10. **Main reason given by respondents for never having tried e-cigarettes**



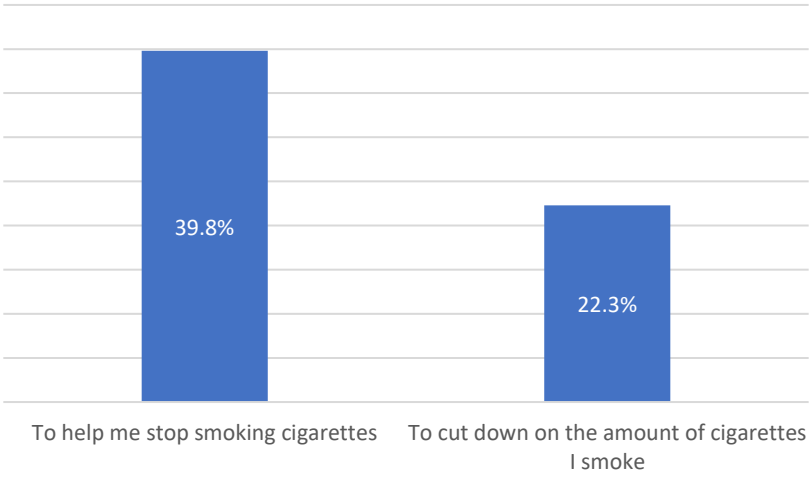
65. The stated reasons for currently using e-cigarettes shown in Table 11 are consistent with e-cigarettes serving as an alternative for conventional cigarettes. A combined total of 62% of the current users indicate that they are using e-cigarettes to either help them stop

smoking cigarettes (40%) or to cut down on the number of cigarettes smoked (22%). Figure 11 illustrates these key results. Saving money and the availability of a variety of flavors rank next in importance. Lower on the list are responses more closely related to exposure to others and acceptability of using e-cigarettes, as 8% indicate that e-cigarettes can be used in more places and 6% reference the absence of environmental tobacco smoke.

Table 11. **Percentage distribution of the main reason for decision to CURRENTLY USE e-cigarettes**

What is the main reason for you using	E-Cigarette
To help me stop smoking cigarettes	39.8
To cut down on the amount of cigarettes that I smoke	22.3
[To help me stop or to cut down]	62.0
To save money	11.6
Because they are available in better flavors than cigarettes	10.2
Convenience, e-cigarettes can be used in more places	8.1
To not expose people nearby me to cigarette smoke	5.5
Other	2.6
Number of observations	6,650

Figure 11. **Main reason for decisions to currently use e-cigarettes**



VI. NEW EVIDENCE ON HARM PERCEPTIONS FOR HEATED TOBACCO PRODUCTS AND ORAL NICOTINE POUCHES

66. The respondents to the surveys also answered questions regarding heated tobacco products and oral nicotine pouches. Both because of the sample screens and the lower overall usage of these products, the results often pertain to a subset of the overall sample.

Table 12. **Product use and relative harm belief percentage, for each of two products**

	Heated tobacco products	Oral nicotine pouches
Ever heard of the product*	64.8	47.2
Description of use **		
- Never tried the product	61.9	75.3
- Tried, but never use now	21.2	15.7
- Use the product currently	16.9	9.0
- Tried, regardless of current use	38.1	24.7

Harm relative to cigarettes ***		
- Less harmful than cigarettes	43.6	48.7
- About the same as cigarettes	48.7	40.3
- More harmful than cigarettes	7.7	11.0
- Same or more harmful	56.4	51.3

* Knowledge of e-cigarettes was required to participate in the survey.
** Those who have never heard of the product are assumed never to have tried it.
*** Harm beliefs are percentages of the subset of respondents who have heard of the product.

67. As indicated in Table 12, 66% of respondents had heard of heated tobacco products, and only 47% had heard of oral nicotine pouches. The data in Table 12 and Figures 12A and 12B regarding the respondent's use of the product and harm perceptions only pertain to the subsample of respondents who indicated that they had heard of each of the products. Among these groups, 38% had tried heated tobacco products, and 25% had tried oral nicotine pouches. Beliefs are roughly evenly divided between perceptions that the product is less harmful than cigarettes and perceptions that the product is just as harmful or more harmful. For heated tobacco products, 44% view them as less harmful than cigarettes, and 56% consider them to be the same or more harmful than cigarettes. For oral nicotine products, 49% consider them to be less harmful than cigarettes, and 51% consider them to be the same or more harmful than cigarettes.

Figure 12A. **Estimated harm of heated tobacco products compared to cigarettes**

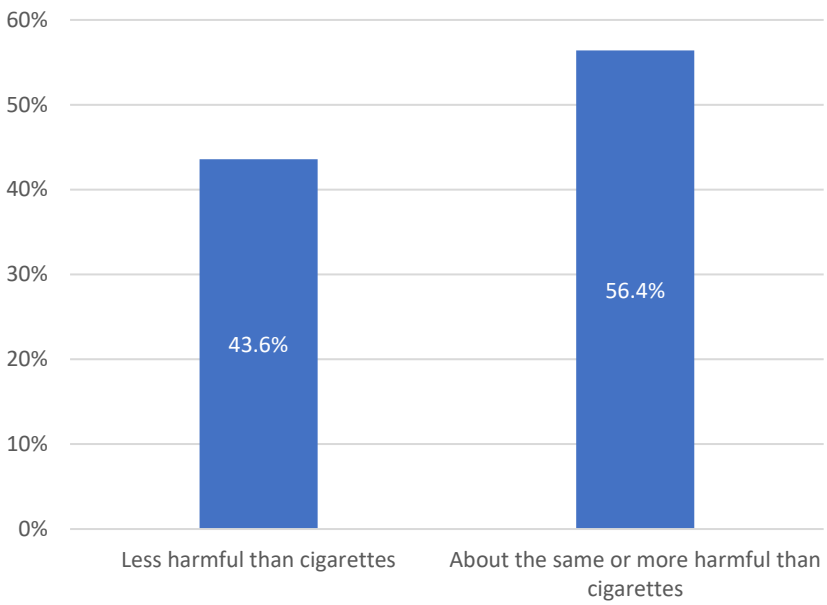
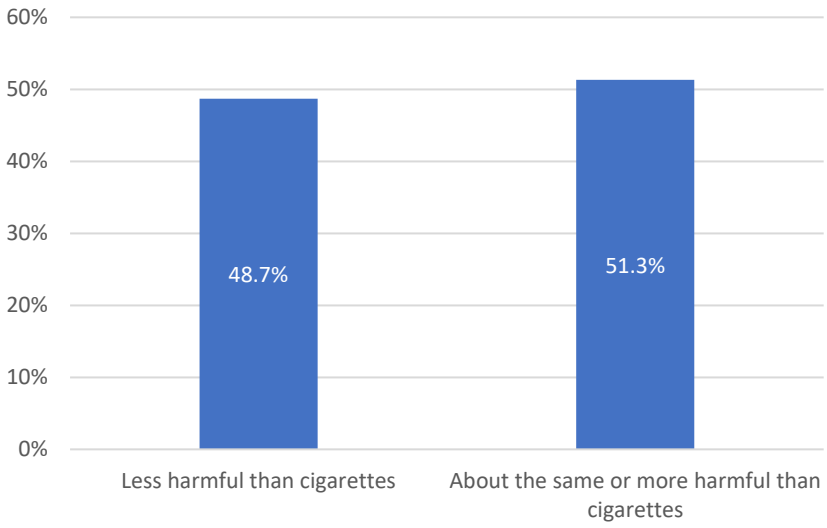


Figure 12B. **Estimated harm of oral nicotine pouches compared to cigarettes**



68. The distribution of harm perceptions varies depending on product usage, as indicated in Table 13 and Figures 13A and 13B. The product usage statistics are at the top of each

panel of Table 13. Overall, 14% of current cigarette smokers currently use heated tobacco products, and 22% of former smokers currently use heated tobacco products. Among those who believe that heated tobacco products are less harmful than cigarettes, 67% of current smokers currently use heated tobacco products, and 33% do not, while for former smokers who believe that heated tobacco products are less harmful than cigarettes, 51% currently use heated tobacco products and 49% do not. Usage among those who believe that heated tobacco products are the same as or more harmful than cigarettes is much lower—only 15% among smokers and 16% among former smokers in this belief group use heated tobacco products. Only 7% of current smokers currently use oral nicotine pouches and 14% of former smokers currently use oral nicotine pouches. For those who believe that oral nicotine pouches are less harmful than cigarettes, the rate of usage is 19% for current smokers and 42% for former smokers. For those who believe that oral nicotine pouches are the same as or more harmful than cigarettes, the rate of product usage is 10% among current smokers and 16% among former smokers.

Table 13. **Current or former cigarette smokers and their alternative product use percentage, by product and harm belief for that product**

	Results for Current cigarette smokers		Results for former smokers	
	Does not use product	Currently uses product	Does not use product	Currently uses product
Heated tobacco users	85.6	14.4	78.0	22.0
- Less harmful than cigarettes	67.4	32.6	48.7	51.3
- Same or more harmful	84.8	15.2	84.0	16.0
Oral nicotine users	93.2	6.8	86.4	13.6
- Less harmful than cigarettes	80.8	19.2	58.0	42.0
- Same or more harmful	90.1	9.9	84.5	15.5

Figure 13A. **Harm Beliefs of Current Cigarette Smokers**

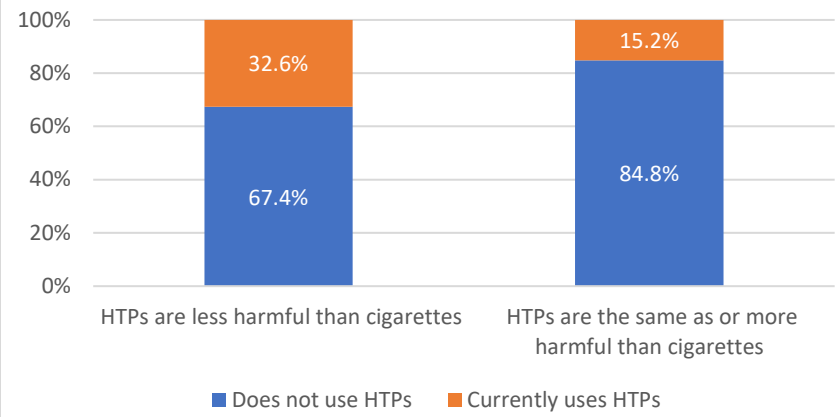
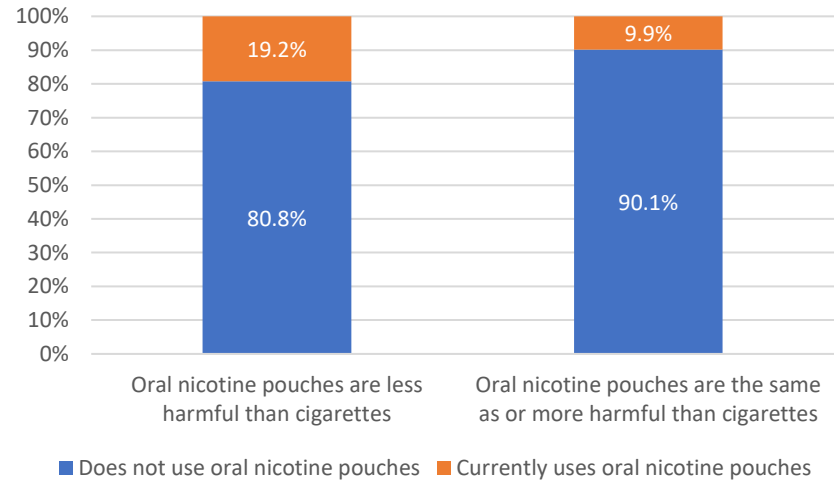


Figure 13B. **Harm Beliefs of Current Cigarette Smokers**



69. To explore the linkage between usage of these products and whether the respondent currently smokes cigarettes, Table 14 reports these statistics both overall as well as conditional on harm beliefs. The table and the Figures 14A and 14B illustrate the key results. Users of heated tobacco products and oral nicotine pouches are more likely to be former smokers. Among heated tobacco product users 42% do not currently smoke

cigarettes, as compared to 30% of non-users of heated tobacco products who do not currently smoke cigarettes; and 49% of oral nicotine pouch users do not currently smoke cigarettes, as compared to 31% of non-users of oral nicotine pouches who do not smoke cigarettes. Similarly, users of both heated tobacco and oral nicotine products have a 57% non-smoking rate.

70. For those who use heated tobacco products and oral nicotine pouches, perceiving these products as being less harmful than cigarettes is also associated with not smoking cigarettes. Among heated tobacco product users who believe that heated tobacco is less harmful than cigarettes, 49% do not currently smoke cigarettes; and 55% of oral nicotine pouch users who believe that the product is less harmful than cigarettes do not currently smoke cigarettes. This effect is diminished for those who believe that these products are the same or more harmful than cigarettes, such that 28% do not currently smoke cigarettes if they believe this about heated tobacco products and 36% do not currently smoke cigarettes if they believe this about nicotine pouches, as shown in Figure 14B.

Table 14. **Current or former cigarette smokers percentage, by use and harm perceptions of products, including multiple product users**

	Observations	Currently smokes cigarettes	Does not smoke cigarettes
Heated tobacco users	1,696	57.9	42.1
- Less harmful than cigarettes	1,130	50.6	49.4
- About the same as cigarettes	438	80.6	19.4
- More harmful than cigarettes	127	44.1	55.9
Heated tobacco non-users	8,354	69.6	30.4
Oral nicotine users	906	51.2	48.8
- Less harmful than cigarettes	629	45.5	54.5
- About the same as cigarettes	172	84.3	15.7
- More harmful than cigarettes	104	30.8	69.2
Oral nicotine non-users	9,144	69.3	30.7
Users of multiple products - Heated & Pouches	709	43.4	56.6
Distribution for all respondents	10,050	67.6	32.4

Figure 14A. **Harm beliefs of current and former cigarette smokers**

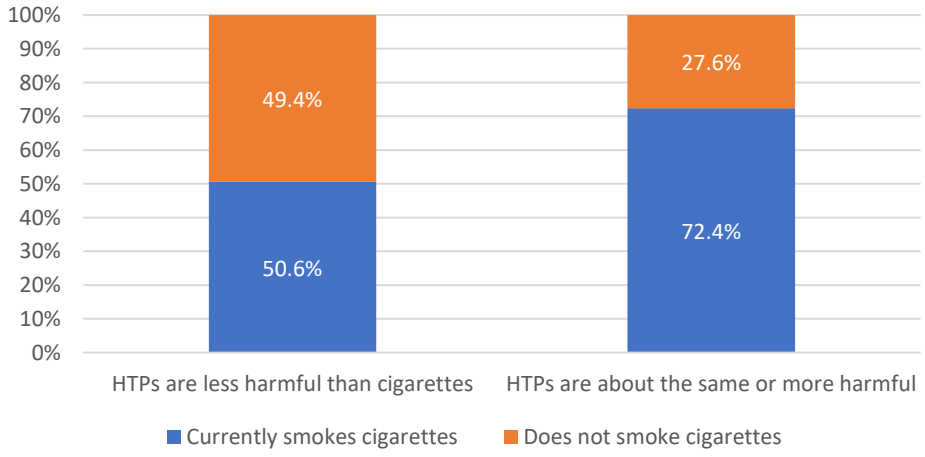
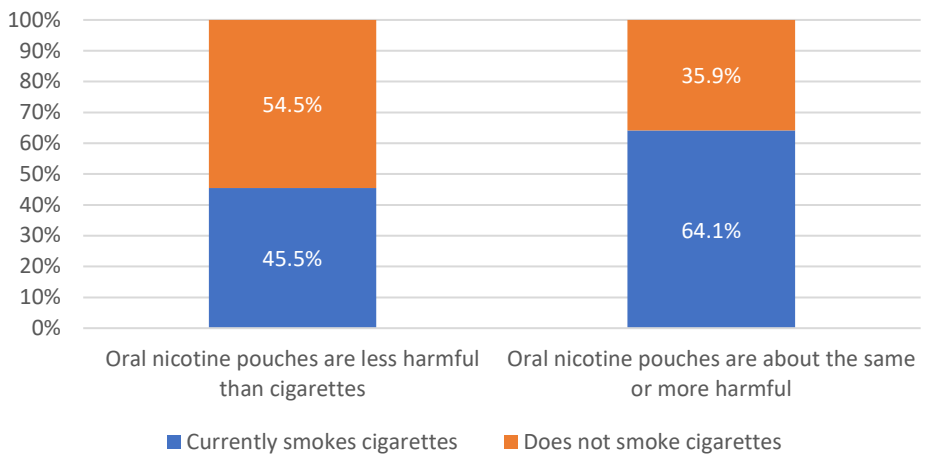


Figure 14B. **Harm beliefs of current and former cigarette smokers**



71. Table 15 and Figures 15A and 15B show the distribution of harm beliefs conditional on different levels of heated tobacco and oral nicotine products usage. In the case of heated tobacco products, 67% of those who use the product perceive that they are less harmful than cigarettes and 33% perceive that they are the same as or more harmful than cigarettes. In the case of oral nicotine pouches, 69.5% of those who use the product perceive that they are less harmful than cigarettes and 30.5% perceive that they are the same as or more harmful than cigarettes.

Table 15. **Harm beliefs relative to cigarettes percentage, by product use for each product**

	Observations	Less harm	Same harm	More harm	Same or More
Heated tobacco products	6,511				
- Never tried the product	2,685	34.7	57.7	7.6	65.3
- Tried, but never use now	2,131	36.6	55.7	7.9	63.4
- Use the product currently	1,695	66.7	25.8	7.5	33.3
- Tried, regardless of current use	3,826	49.9	43.4	7.7	50.1
Oral nicotine pouches	4,739				

- Never tried the product	2,256	46.9	43.4	9.8	53.1
- Tried, but never use now	1,578	39.4	48.3	12.3	60.6
- Use the product currently	905	69.5	19.0	14.5	30.5
- Tried, regardless of current use	2,483	50.4	37.6	12.0	49.6

Figure 15A. **Estimated harm of heated tobacco products compared to cigarettes by use of product**

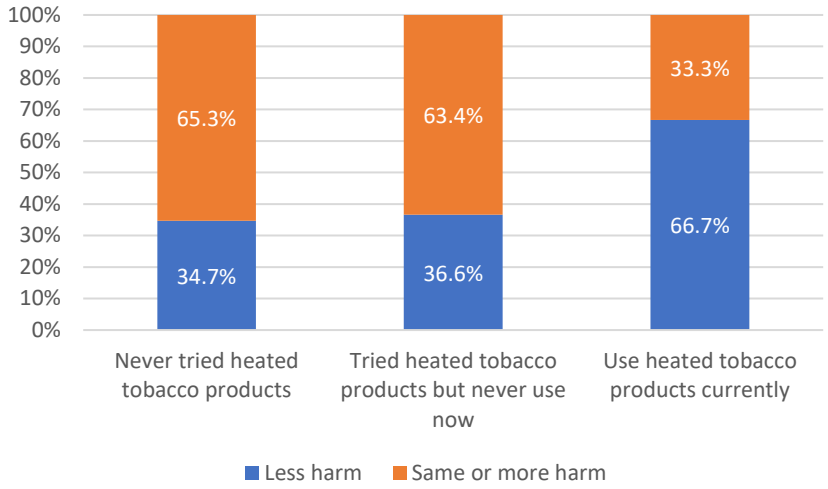
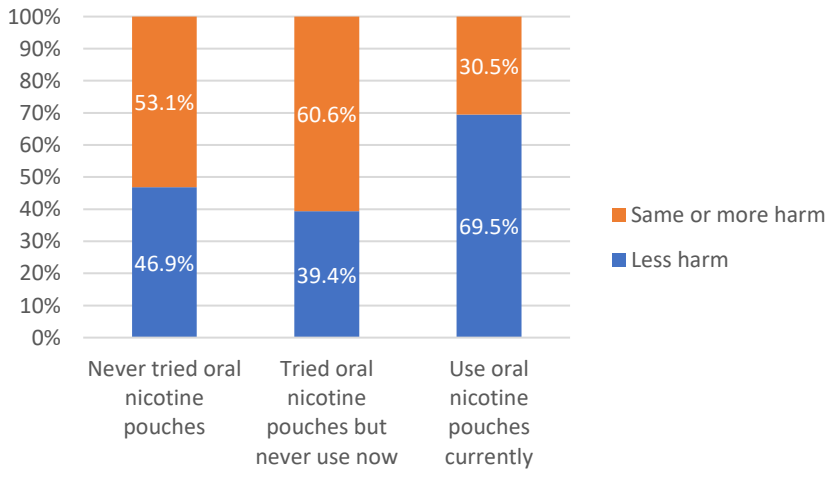


Figure 15B. **Estimated harm of oral nicotine pouches compared to cigarettes by use of product**



72. The final set of overall harm belief statistics in Table 16 analyzes the product use groups in conjunction with the harm beliefs. In the case of heated tobacco products, the percentage who believe that they are as harmful as or more harmful than cigarettes is 66% for those who smoke cigarettes and do not use heated tobacco products, 22% for those who use heated tobacco products and do not smoke cigarettes, 42% if they use both heated tobacco products and cigarettes, and 61% if they use neither heated tobacco products nor cigarettes. The remainder in each group believe that heated tobacco products are less harmful than cigarettes. In the case of oral nicotine products, the percentage who believe that they are as harmful as or more harmful than cigarettes is 57% for those who smoke cigarettes but do not use oral nicotine pouches, 22% for those who use oral nicotine pouches but do not smoke cigarettes, 38% for those who use both oral nicotine pouches and smoke cigarettes, and 53% for those who use neither oral nicotine pouches nor cigarettes.

Table 16. **Percentage distribution of harm beliefs for different groups of usage of cigarettes and other products**

Heated products are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not heated	34.1	65.9	3,467
- Heated, not cigarettes	78.2	21.8	714
- Both heated and cigarettes	58.3	41.7	981
- Neither heated nor cigarettes	39.2	60.8	1,349
Oral nicotine pouches are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not pouches	42.8	57.2	2,821
- Pouches, not cigarettes	77.6	22.4	442

- Both pouches and cigarettes	61.8	38.2	463
- Neither pouches nor cigarettes	46.7	53.3	1,013

73. Given the nature of the sampling screens, usage of heated tobacco products and oral nicotine pouch products is less common than is e-cigarette usage in this sample. Nevertheless, the patterns regarding the usage of these products and the relationship of product usage to perceptions of their degree of harm are instructive. Each of the products faces substantial barriers with respect to accurate understanding of the estimated risks that these alternative products pose as compared to the risks posed by conventional cigarettes that burn tobacco. Just over half of all respondents believe that these products pose risks of harm that are the same as or greater than those posed by cigarettes. The perceptions of harm are correlated with product usage in the expected manner, as respondents who believe that the products are less harmful than cigarettes are more likely to use them than are respondents who believe that they are just as harmful as cigarettes or more harmful. People who do not believe that these products pose less harm are less likely to try these products or to currently use them. This relationship also holds for cigarette smokers, as the failure to understand the comparative risk reduction that scientists estimate is provided by these products may deter their usage as an alternative to smoking cigarettes.

74. Table 17 presents regression results in which the dependent variable is a 0-1 indicator for current product use, and the explanatory variables consist of harm beliefs, country, and demographic factors. Those who perceive that heated tobacco products are less harmful than cigarettes are 15% more likely to be using heated tobacco products, while those who perceive nicotine pouches as being less harmful than cigarettes are 4% more likely to be

using them. There are several differences across countries in the usage of these products. All statistically significant effects reflect higher levels of usage than in the UK. Higher income and better educated respondents are also more likely to use each of these products.

Table 17. **Regressions predicting the probability that respondent CURRENTLY USES each of the products, based on harm beliefs, country, and demographics**

	Heated yes use	Pouch yes use
Heated less harmful	0.1473***	
	(0.0102)	
Pouch less harmful		0.0390***
		(0.0098)
Belgium	0.1755***	0.2034***
	(0.0211)	(0.0179)
Denmark	0.0132	0.0251
	(0.0216)	(0.0186)
Netherlands	0.0242	0.0464***
	(0.0181)	(0.0172)
France	0.0264	0.0339**
	(0.0184)	(0.0167)
Germany	0.1023***	0.0322*
	(0.0170)	(0.0168)
Italy	0.1550***	-0.0138
	(0.0167)	(0.0174)
Age	-0.0002	0.0006
	(0.0005)	(0.0005)
Age 60+	-0.0328*	-0.0295
	(0.0191)	(0.0198)
Income	0.0017***	0.0015***
	(0.0002)	(0.0002)
Income €150,000+	0.1976***	0.3044***
	(0.0247)	(0.0218)
Years education	0.0160***	0.0122***
	(0.0022)	(0.0021)
Black	-0.0932***	-0.0866***
	(0.0309)	(0.0260)
Asian	-0.0162	0.0566**
	(0.0304)	(0.0267)
Other	0.0063	0.0202
	(0.0291)	(0.0243)
Female	0.0080	0.0134

	(0.0101)	(0.0099)
Married	0.0370***	0.0076
	(0.0141)	(0.0142)
Widowed	-0.0268	-0.0126
	(0.0334)	(0.0317)
Divorced	0.0144	-0.0350
	(0.0221)	(0.0223)
Separated	0.0032	0.0825***
	(0.0317)	(0.0310)
Partner	-0.0039	-0.0160
	(0.0168)	(0.0165)
Missing income	0.0412*	0.0191
	(0.0232)	(0.0241)
Missing education	0.2838***	0.1371**
	(0.0670)	(0.0639)
Missing race	-0.0028	-0.0074
	(0.0475)	(0.0434)
Missing female	0.0782	-0.0535
	(0.1170)	(0.0825)
Missing relationship	-0.0405	-0.0301
	(0.0585)	(0.0525)
Constant	-0.2442***	-0.2289***
	(0.0412)	(0.0384)
Observations	6,511	4,739
R-squared	0.23	0.36

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

75. The regression results in Table 18 analyze the determinants of whether the respondent believes that the product is less harmful than cigarettes. The results of greatest interest are the differences across countries, all of which are relative to the UK. With a few exceptions, all country effects are negative and statistically significant, meaning that relative to the UK, the residents of these countries are less likely to perceive these two products as being less harmful than cigarettes.

Table 18. **Regressions predicting the probability that the respondent believes the product is LESS HARMFUL than cigarettes, based on country and demographics**

	Heated less harmful	Pouch less harmful
Belgium	-0.0313	-0.0076
	(0.0256)	(0.0267)
Denmark	-0.0470*	-0.1190***
	(0.0262)	(0.0277)
Netherlands	-0.1482***	-0.2388***
	(0.0219)	(0.0253)
France	-0.0928***	-0.1621***
	(0.0223)	(0.0248)
Germany	-0.0350*	-0.1541***
	(0.0206)	(0.0249)
Italy	0.1513***	-0.1238***
	(0.0202)	(0.0258)
Age	0.0023***	0.0020***
	(0.0006)	(0.0007)
Age 60+	-0.0409*	-0.0763***
	(0.0231)	(0.0295)
Income	0.0008***	0.0000
	(0.0002)	(0.0002)
Income €150,000+	0.3189***	0.3249***
	(0.0298)	(0.0322)
Years education	-0.0042	-0.0041
	(0.0027)	(0.0032)
Black	-0.1196***	-0.1056***
	(0.0375)	(0.0387)
Asian	-0.0148	-0.0563
	(0.0369)	(0.0397)
Other	-0.0031	-0.0928**
	(0.0353)	(0.0362)
Female	-0.0736***	-0.0570***
	(0.0123)	(0.0147)
Married	0.0266	0.0128
	(0.0171)	(0.0212)
Widowed	0.0432	0.0666
	(0.0405)	(0.0473)
Divorced	-0.0156	0.0142
	(0.0268)	(0.0332)
Separated	-0.0077	-0.0880*
	(0.0385)	(0.0461)
Partner	-0.0478**	-0.0252
	(0.0204)	(0.0246)
Missing income	-0.0293	-0.0300

	(0.0281)	(0.0359)
Missing education	0.0243	-0.1074
	(0.0813)	(0.0951)
Missing race	-0.0833	0.0607
	(0.0576)	(0.0646)
Missing female	-0.2186	-0.0328
	(0.1419)	(0.1230)
Missing relationship	-0.0226	-0.0066
	(0.0710)	(0.0783)
Constant	0.3762***	0.5648***
	(0.0498)	(0.0567)
Observations	6,511	4,739
R-squared	0.12	0.12

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

76. Whether the respondent is a current smoker is the dependent variable in the regression results in Table 19. These results for the full sample find that users of both heated tobacco products and oral nicotine pouches are less likely to be a current smoker, whether these products are included in the regression results individually or jointly. When both products are included in the final regression, heated tobacco users are 4% less likely to be a current smoker and users of oral pouches are 9% less likely to be a current smoker.

Table 19. **Regressions predicting the probability that the respondent is a CURRENT CIGARETTE SMOKER, based on alternative product USE, country, and demographics**

	Smoker	Smoker	Smoker
Heat yes use	-0.0685***		-0.0438***
	(0.0137)		(0.0148)
Pouch yes use		-0.1162***	-0.0926***
		(0.0195)	(0.0211)
Belgium	0.0758***	0.0827***	0.0833***
	(0.0176)	(0.0176)	(0.0176)
Denmark	0.0893***	0.0908***	0.0902***
	(0.0184)	(0.0184)	(0.0184)
Netherlands	0.0296*	0.0304*	0.0300*

	(0.0170)	(0.0170)	(0.0170)
France	0.0004	0.0012	0.0012
	(0.0167)	(0.0167)	(0.0167)
Germany	0.0180	0.0120	0.0158
	(0.0168)	(0.0167)	(0.0168)
Italy	-0.0094	-0.0236	-0.0152
	(0.0171)	(0.0169)	(0.0171)
Age	-0.0058***	-0.0058***	-0.0058***
	(0.0005)	(0.0005)	(0.0005)
Age 60+	-0.0593***	-0.0586***	-0.0599***
	(0.0165)	(0.0165)	(0.0165)
Income	-0.0005***	-0.0005***	-0.0004**
	(0.0002)	(0.0002)	(0.0002)
Income €150,000+	-0.2171***	-0.1912***	-0.1867***
	(0.0256)	(0.0264)	(0.0264)
Years education	0.0048**	0.0048**	0.0052**
	(0.0021)	(0.0021)	(0.0021)
Black	0.0420	0.0405	0.0387
	(0.0313)	(0.0313)	(0.0313)
Asian	0.1020***	0.1073***	0.1061***
	(0.0306)	(0.0306)	(0.0306)
Other	0.0321	0.0346	0.0343
	(0.0280)	(0.0279)	(0.0279)
Female	0.0125	0.0131	0.0125
	(0.0095)	(0.0095)	(0.0095)
Married	0.0186	0.0184	0.0195
	(0.0134)	(0.0133)	(0.0133)
Widowed	0.0417	0.0431	0.0430
	(0.0308)	(0.0308)	(0.0308)
Divorced	0.0148	0.0134	0.0140
	(0.0194)	(0.0194)	(0.0194)
Separated	-0.0164	-0.0118	-0.0125
	(0.0291)	(0.0291)	(0.0291)
Partner	-0.0721***	-0.0720***	-0.0726***
	(0.0153)	(0.0153)	(0.0153)
Missing income	-0.0664***	-0.0667***	-0.0660***
	(0.0184)	(0.0184)	(0.0184)
Missing education	0.0307	0.0273	0.0341
	(0.0533)	(0.0533)	(0.0533)
Missing race	-0.0401	-0.0397	-0.0398
	(0.0416)	(0.0416)	(0.0415)
Missing female	0.1488	0.1466	0.1493
	(0.1109)	(0.1108)	(0.1108)
Missing relationship	-0.0517	-0.0515	-0.0523
	(0.0457)	(0.0456)	(0.0456)
Constant	0.8847***	0.8832***	0.8785***

	(0.0383)	(0.0383)	(0.0383)
Observations	10,050	10,050	10,050
R-squared	0.06	0.06	0.06

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

77. Table 20 reports a regression on the use of heated tobacco products, the use of oral nicotine pouches, or the use of both heated tobacco products and oral nicotine pouches, for those respondents that do not smoke cigarettes. The dependent variable is a 0-1 variable for whether the respondent currently uses a heated tobacco product, an oral nicotine pouch product, or both heated tobacco products and oral nicotine pouches and also does not smoke cigarettes. The principal explanatory variable of interest is whether the respondent considers heated tobacco products or oral nicotine pouches to be less harmful. Those who believe heated tobacco products are less harmful than cigarettes are 19% more likely to use a heated tobacco product and not smoke conventional cigarettes. Those who believe oral nicotine pouch products are less harmful than cigarettes are 5% more likely to use an oral nicotine pouch product and not smoke conventional cigarettes

78. In the third regression in Table 20, beliefs regarding whether the product is less harmful than cigarettes are included for both products. In this case, respondents are 15% more likely to be using heated tobacco products or oral nicotine pouches if they perceive heated tobacco products as being less harmful than cigarettes; while the effect of oral nicotine pouch beliefs is not statistically significant once the heated tobacco beliefs variable is included.

Table 20. **Regressions predicting the probability that the respondent CURRENTLY USES product for subsample that DOES NOT SMOKE CIGARETTES, for each or any of two products, based on harm beliefs, country, and demographics**

	Heated yes use	Pouch yes use	Heated or Pouch yes use
Heated less harmful	0.1905***		0.1502***
	(0.0186)		(0.0285)
Pouch less harmful		0.0500***	-0.0390
		(0.0182)	(0.0290)
Belgium	0.4872***	0.4440***	0.5754***
	(0.0443)	(0.0358)	(0.0558)
Denmark	0.0087	-0.0053	0.0499
	(0.0434)	(0.0379)	(0.0604)
Netherlands	0.1335***	0.1453***	0.1360***
	(0.0342)	(0.0329)	(0.0482)
France	0.0820**	0.0616**	0.1377***
	(0.0348)	(0.0303)	(0.0488)
Germany	0.1361***	0.0889***	0.1645***
	(0.0310)	(0.0320)	(0.0463)
Italy	0.2760***	-0.0004	0.3390***
	(0.0301)	(0.0326)	(0.0462)
Age	0.0010	0.0059***	0.0033**
	(0.0010)	(0.0010)	(0.0015)
Age 60+	-0.0073	-0.0785**	0.0659
	(0.0307)	(0.0314)	(0.0460)
Income	0.0030***	0.0029***	0.0042***
	(0.0003)	(0.0003)	(0.0005)
Income €150,000+	-0.0049	0.0885**	-0.1687***
	(0.0448)	(0.0380)	(0.0523)
Years education	0.0040	0.0127***	0.0097
	(0.0043)	(0.0042)	(0.0064)
Black	-0.0604	-0.2043***	-0.0879
	(0.0634)	(0.0495)	(0.0698)
Asian	-0.0785	0.1553**	0.0887
	(0.0805)	(0.0633)	(0.0868)
Other	0.0543	-0.0322	0.1181*
	(0.0624)	(0.0468)	(0.0707)
Female	0.1010***	0.0721***	0.1886***
	(0.0188)	(0.0187)	(0.0282)
Married	0.0090	-0.0511*	-0.0009
	(0.0274)	(0.0285)	(0.0422)
Widowed	-0.0378	-0.0098	-0.0531
	(0.0586)	(0.0578)	(0.0808)
Divorced	0.0646*	-0.0017	0.0789
	(0.0389)	(0.0401)	(0.0571)

Separated	0.0255	0.0858	0.1316
	(0.0560)	(0.0574)	(0.0853)
Partner	0.0484	0.0863***	0.0551
	(0.0304)	(0.0308)	(0.0467)
Missing income	0.1009***	0.0528	0.0714
	(0.0382)	(0.0413)	(0.0663)
Missing education	-0.0283	0.2184*	0.0381
	(0.1199)	(0.1217)	(0.1930)
Missing race	0.0501	0.0836	0.4845***
	(0.0844)	(0.0756)	(0.1288)
Missing female	0.7447**	0.1060	0.6967*
	(0.3717)	(0.2917)	(0.3692)
Missing relationship	0.0809	0.0329	0.0873
	(0.0971)	(0.1004)	(0.1705)
Constant	-0.3044***	-0.5862***	-0.5370***
	(0.0796)	(0.0750)	(0.1163)
Observations	2,063	1,455	1,195
R-squared	0.40	0.61	0.48

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

79. Table 21 and Figures 21A and 21B summarize the reported reasons for not using heated tobacco products and oral nicotine pouches. The most important reason given is that they do not know enough about the products, which is cited by 44% of respondents who had not tried heated tobacco products and by 46% of respondents who had not tried oral nicotine pouches. Belief that the products are not less harmful than regular cigarettes or not believing that the products will be effective in helping the respondent quit smoking are also common responses.

Table 21. **Percentage distribution of the main reason for decision to have NEVER TRIED product for each product**

What is the main reason for you not trying	Heated	Pouch
I do not know enough about them	43.5	45.7
I do not want to quit smoking	8.1	11.8
I do not think that they are any less harmful than cigarettes	17.8	12.3
They cost too much	11.7	6.3
I do not think that they would help me to quit or cut down smoking	12.9	16.6
Other	6.0	7.2
Number of observations	2,685	2,256

Figure 21A. **Main reason given by respondents for never having tried heated tobacco products**

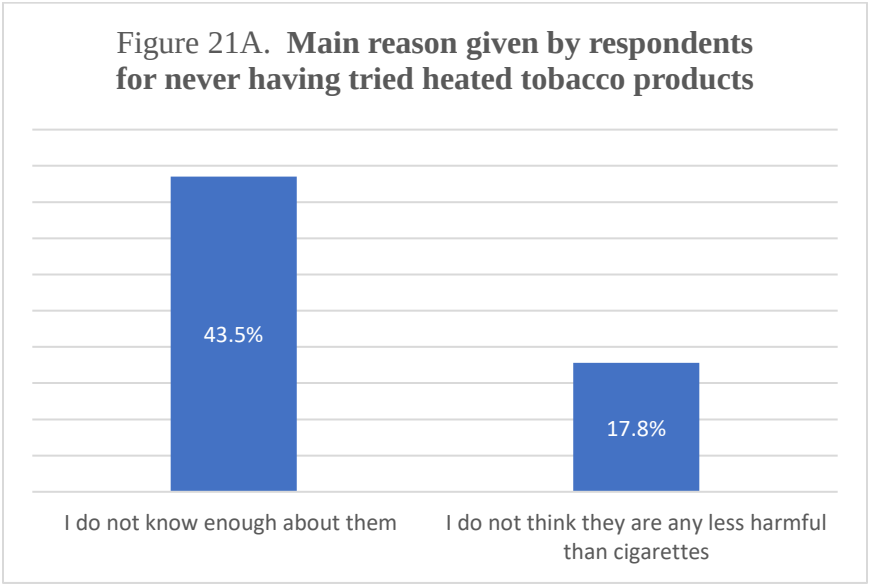
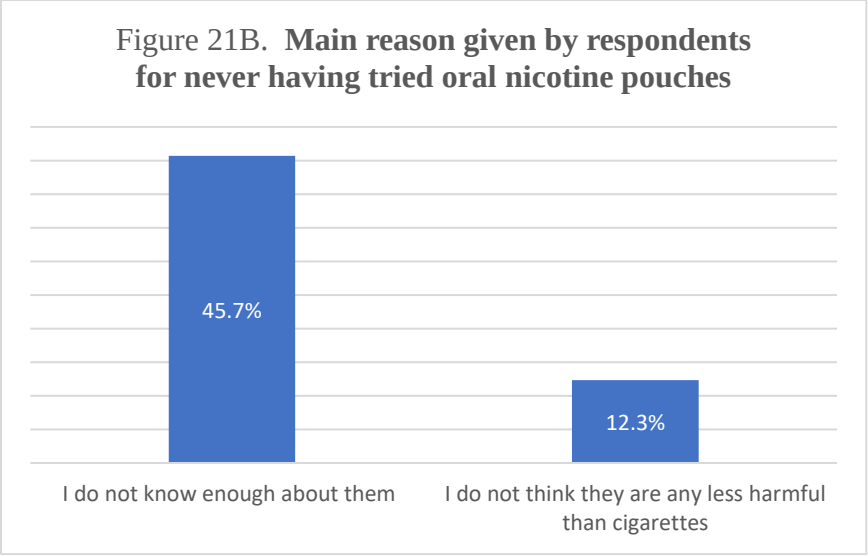


Figure 21B. **Main reason given by respondents for never having tried oral nicotine pouches**



80. The reasons that respondents gave for currently using heated tobacco products and oral nicotine pouches are summarized in Table 22 and Figures 22A and 22B. The dominant response for 58% of heated tobacco users and 70% of pouch users is that the product would help them stop or cut down on their smoking.

Table 22. **Percentage distribution of the main reason for decision to CURRENTLY USE product for each product**

What is the main reason for you using	Heated	Pouch
To help me stop smoking cigarettes	41.1	59.4
To cut down on the amount of cigarettes that I smoke	16.5	11.0
[To help me stop or to cut down]	57.5	70.4
To save money	8.4	7.0
Because they are available in better flavors than cigarettes	12.3	8.2
Convenience, e-cigarettes can be used in more places	11.9	9.6
To not expose people nearby me to cigarette smoke	7.8	4.2
Other	2.1	0.7
Number of observations	1,696	906

Figure 22A. **Main reason for decisions to currently use heated tobacco products**

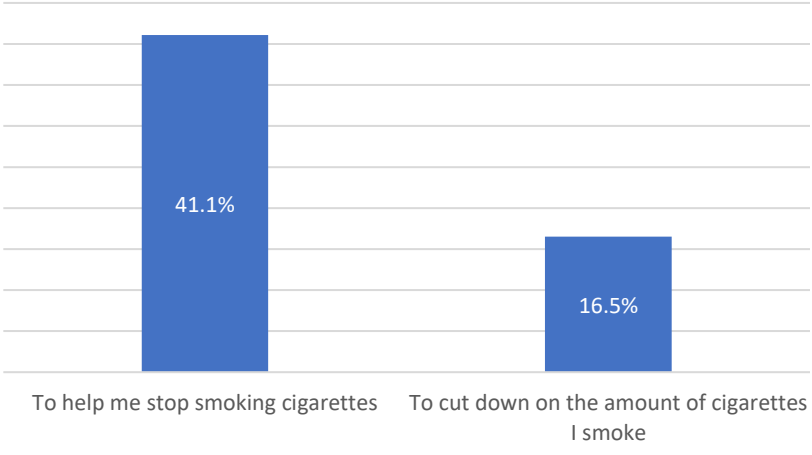
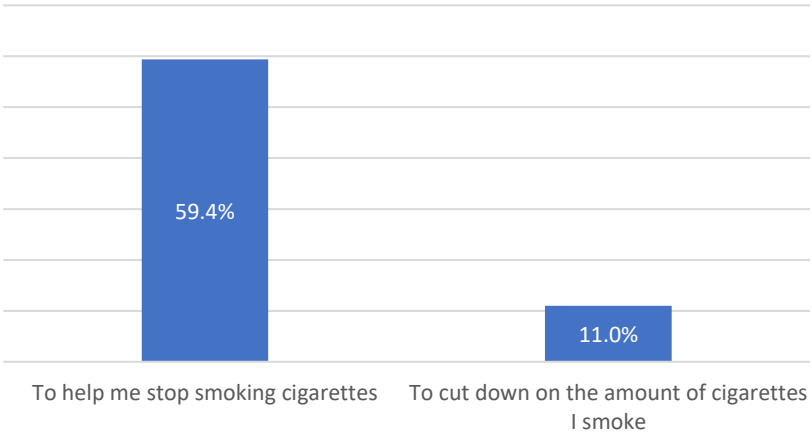


Figure 22B. **Main reason for decisions to currently use oral nicotine pouches**



81. The demographic characteristics of the sample used in the analysis of heated tobacco products and oral pouches are identical to Appendix A, Table Full Sample Characteristics below, since the sample is the same.

VII. COUNTRY-SPECIFIC RESULTS

82. Although a comprehensive discussion of the specific country effects is not included in this report, there are some results that were particularly striking, in addition to the effects of the country variables in the regressions above.

83. The data in Table 23 regarding current product usage and those who do not use cigarettes reflect the influence of the sample screens. The first two columns reflect how respondents were recruited to participate in the survey, where two-thirds were intended to be smokers and two-thirds were intended to be e-cigarette users, with an overlap such that one-third of respondents currently use both cigarettes and e-cigarettes.

84. The last two columns show product usage by country for heated tobacco products and oral nicotine pouches, which were not part of whether the respondent would be included for the sample or screened. As a result of the screening process, the usage of all products in Table 23 is unlikely to be representative of the entire population. Amongst the sample there are significant differences in the use of these products across the different countries.

Table 23. **Percentage who currently use product.**

	Cigarettes	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	66.7	66.7	30.0	28.6
Denmark	74.5	62.7	6.3	3.7
Netherlands	66.7	66.7	16.3	12.4
United Kingdom	66.7	66.7	8.7	4.3
France	66.7	66.7	8.1	4.7
Germany	67.6	66.1	18.8	5.1
Italy	66.7	66.7	26.9	2.7
Total	67.6	66.2	16.9	9.0

85. The distribution of the percentage of those who currently use the product and do not use cigarettes appears in Table 24. The first column again reflects how the sample was recruited, so all respondents who do not currently smoke cigarettes currently use e-cigarettes. In this sample, Belgium and the Netherlands have higher rates of use for heated tobacco products and nicotine pouches. Germany and Italy also have comparatively higher rates of use for heated tobacco products, but this distribution may be a consequence of the sampling procedure.

Table 24. **Percent who currently use product and do not use cigarettes**

	N	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	500	100	60.6	59.6
Denmark	274	100	3.6	1.1
Netherlands	500	100	23.8	20.2
United Kingdom	500	100	3.6	1.0
France	500	100	5.8	2.8
Germany	478	100	15.5	3.8
Italy	500	100	32.2	0.6
Total	3,252	100	22.0	13.6

86. The pivotal measure of risk beliefs is whether the respondent believes that the product is less harmful. This variable is summarized for the different countries in Table 25. The UK and Italy have a comparatively higher proportion of respondents who regard e-cigarettes to be less harmful than cigarettes. Beliefs vary for the other products, but across all countries there is a significant proportion of respondents that do not perceive these products as being less harmful than cigarettes.

Table 25. **Percent who believe product less harmful than cigarettes**

	E-Cigarettes Less Harmful than Cigarettes	Heated Tobacco Products Less Harmful	Oral Nicotine Pouches Less Harmful
Belgium	40.0	61.8	73.5
Denmark	52.0	35.5	43.4
Netherlands	58.5	33.0	37.0
United Kingdom	65.7	41.9	56.0
France	60.0	31.8	39.2
Germany	54.5	39.0	40.8
Italy	65.4	56.8	44.3
Total	56.8	43.6	48.7

87. Table 26 reports for each of the three products, the percentage of current cigarette smokers who believe that the product is the same or more harmful than cigarettes, by country. The perceptions across countries are relatively consistent, where most often at least half of current smokers believe the other products to be as harmful or more harmful compared to cigarettes.

Table 26. **Percent who believe product the same or harmful than cigarettes, current smokers**

	E-Cigarettes Same or More Harmful than Cigarettes	Heated Tobacco Products Same or More Harmful	Oral Nicotine Pouches Same or More Harmful
Belgium	54.9	60.5	41.0
Denmark	59.3	65.0	59.1
Netherlands	53.2	64.2	52.2
United Kingdom	47.7	59.9	48.3
France	53.6	69.6	63.5
Germany	55.8	62.6	60.1
Italy	44.5	48.4	58.4
Total	52.5	60.5	54.6

88. Table 27 reports, for each of the products, the percentage of those who do not use that product who believe that the product is just as harmful or more harmful than cigarettes, by country. A high percentage among non-users of each product regard it as just as

harmful or more harmful than conventional cigarettes. The average across all countries is greater than half for each product. This is the case for each product in every country with the exception of oral nicotine pouches in the United Kingdom.

Table 27. **Percent who believe product same or more harmful than cigarettes, among those who do not currently use the product**

	E-Cigarettes Same or More Harmful than Cigarettes	Heated Tobacco Products Same or More Harmful	Oral Nicotine Pouches Same or More Harmful
Belgium	75.6	77.0	53.9
Denmark	74.8	67.3	57.5
Netherlands	66.6	69.4	63.1
United Kingdom	60.8	59.5	43.9
France	65.6	71.7	60.9
Germany	67.4	66.3	60.4
Italy	57.2	51.7	56.8
Total	66.6	64.5	56.2

89. Table 28 summarizes the country differences in the percentage who give as their reason for not using the product that they do not know enough about the product or they do not think that the product is less harmful. These perceptions are relatively consistent across surveyed countries, where lack of information or a belief that the products are at least as harmful as cigarettes account for between 46% and 71% of respondents' primary reasons for not using the product.

Table 28. **Percent whose main reasons for not using product is do not know enough about them or do not think that they are any less harmful than cigarettes**

	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	56.8	59.5	53.7
Denmark	55.7	59.2	45.7
Netherlands	50.6	62.9	68.1

United Kingdom	49.3	67.9	55.9
France	48.4	67.3	58.9
Germany	58.1	51.9	54.2
Italy	68.1	57.1	70.7
Total	54.3	61.3	58.1

90. The country analyses in the appendices also yielded regression estimates for several key relationships of interest. The coefficients summarized in the first column of Table 29 correspond to the effect of harm beliefs on e-cigarette usage. On average, the belief that e-cigarettes are less harmful than cigarettes increases that the probability of e-cigarette usage by 33%. For all countries, e-cigarette usage is negatively related to being a current smoker, as shown in the second column 2. While the linkage between e-cigarettes being perceived as less harmful than cigarettes and exclusive e-cigarette usage is not statistically significant for the individual countries, it is for the entire sample.

Table 29. **E-cigarettes, comparative country regressions by product use and harm beliefs**

	Table A6	Table A8	Table A9
	E-cigarette less harmful *Predicting* Yes e-cigarette use	E-cigarette yes use *Predicting* Smoker	E-cigarette less harmful *Predicting* Only e-cigarette use
Belgium	0.2864***	-0.3803***	0.0092
Denmark	0.3772***	-0.4181***	-0.0254
Netherlands	0.2955***	-0.4406***	0.0263
United Kingdom	0.3932***	-0.4891***	0.0364
France	0.3514***	-0.4946***	0.0578*
Germany	0.2976***	-0.5034***	0.0082
Italy	0.3182***	-0.5041***	0.0317
Total	0.3260***	-0.4814***	0.0935***

VIII. DISCUSSION

91. Understanding of the attributes of products is an essential input to consumers being able to make efficient decisions with respect to using the product. One such attribute is the potential health risk that the product poses to users of the product. The number of alternative nicotine products on the market has grown to include e-cigarettes, heated tobacco products, and oral nicotine pouches. Available scientific evidence indicates that each of these products offers potential risk reductions as compared to conventional cigarettes. As a result, policies that lead consumers to switch from smoking cigarettes to these products offer potential public health gains.

92. Consumers must make the decision whether to switch from cigarettes to these products. These are individual consumer choices made on a decentralized basis. Understanding of the risks of these alternative products as compared to cigarettes is essential for consumers to make informed decisions with respect to using these alternative products. Understanding of the risk is not only important from the standpoint of potential health consequences but also in terms of matching the product choice to the consumer's preferences.

93. In recognition of the importance of understanding the comparative risks, Public Health England in particular has taken a prominent role in communicating its conclusion that e-cigarettes provide a risk reduction compared to tobacco burning cigarettes of at least 95%.

94. Unfortunately, the available evidence indicates that many consumers have not grasped the extent of the estimated risk reduction provided by alternatives to conventional cigarettes.

95. This study provides new survey results from respondents in seven European countries. The current study provides further evidence, consistent with a number of other studies, that a substantial portion of the public believes that e-cigarettes and other potentially reduced risk nicotine products, are just as harmful or more harmful than cigarettes. This gap in consumer knowledge is consequential, as the results in this report and other studies demonstrate that these risk perceptions are strongly correlated with the non-use of these products. These findings suggest that more needs to be done to improve consumers understanding of the comparative risks of these products.

96. Foregoing consumption of a product that the consumer would choose if adequately informed of the risk of the product, produces a loss for consumers. Consumers would be better off if they understood the potentially lower risks of the alternative products and then made product decisions that matched their preferences. Even if informed of the risk attributes, some consumers may choose to smoke conventional cigarettes than switch to e-cigarettes. But some smokers may be deterred from switching because they do not realize the potential risk reductions that such products offer. These consumers will be worse off than if they had the information to be able to make a more informed choice.

97. The gaps in consumer knowledge, also may lead to a public health loss to the extent that people who would have switched from conventional cigarettes to e-cigarettes or other potentially reduced risk nicotine products are discouraged from doing so because of a misunderstanding of the risks.

98. These misperceptions exist notwithstanding the generally held view by many public health experts and public health authorities that e-cigarettes and other non-combustible tobacco and nicotine products are likely to pose substantially reduced risks compared to

combustible cigarettes. However, some opponents to these products continue to raise concerns regarding the absolute risk of e-cigarettes and the absence of long-term epidemiological evidence regarding these products. A particular example of this approach is that of the World Health Organization (WHO), which emphasizes that e-cigarettes are not safe, and continues to advocate in favor of bans on e-cigarettes, or, if they are not banned, that these products should be regulated in a similar way to traditional tobacco products.[25] The WHO also takes a similar approach to heated tobacco products.[26] However, this approach to communicating the risk of these products, denies current smokers accurate information on the risk of these products compared to cigarettes and contributes to existing misperceptions.

99. Risk perceptions can also be heavily influenced by inaccurate media reporting regarding these products and related research. This misinformation phenomenon was an issue highlighted in the 2018 PHE report, where the authors noted the problem with inaccurate reporting and stated:

> "*The consequences of this inaccurate or inadequate reporting are that the general public is misled. This could induce smokers to carry on smoking rather than switching and EC users to relapse to smoking. While such inaccurate reporting is not confined to the tobacco harm reduction and EC field, the impact is rarely as large. Smoking is uniquely dangerous and each year in England around 80,000 smokers die because of tobacco use (2) . There are few other scientific areas where the gains and losses to public health are so high. It is very likely that these*

[25] See World Health Organization, E-Cigarettes, Q&A, 29 January 2020.
[26] See World Health Organization, Heated tobacco products: a brief (2020).

reports and headlines are playing a key role in the persistent misperceptions that the public have about the relative risks of EC and tobacco cigarettes."[27]

100. A particular example of this is in the case of the reporting of the EVALI cases in the US. While most of the cases in the U.S. have been associated with inhalation of vitamin E acetate, an additive found in some tetrahydrocannabinol ('**THC**') vaping products, news reports often failed to distinguish THC vaping products from standard nicotine-based e-cigarettes.[28] There is some evidence suggesting that this inaccurate reporting has contributed to increasing misperceptions regarding the risk of e-cigarettes.[29]

101. The regulatory regime for these alternative nicotine products is a critical factor for communicating risk and facilitating awareness and trial of these products. Research shows that regulation can affect awareness and use of nicotine vaping products. For example, Gravely, et al (2019) found that:

> "[w]*ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and by country income" and* "[i]*n contrast to many of the* [less restrictive policies] *and* [restrictive policies] *countries, rates of use were quite low in the* [most restrictive policies] *countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of* [nicotine vaping products]

[27] McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, at p173.
[28] See Wayne Hall, Billie Bonevski, Coral Gartner, Policy-based evidence on e-cigarette, or vaping product, use–associated lung injury, Drug and Alcohol Review, 10.1111/dar.13072, **39**, 4, (426-427), (2020).
[29] Tattan-Birch H, Brown J, Shahab L, Jackson SE. Association of the US Outbreak of Vaping-Associated Lung Injury With Perceived Harm of e-Cigarettes Compared With Cigarettes. *JAMA Netw Open.* 2020;3(6):e206981. doi:10.1001/jamanetworkopen.2020.6981.

laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them".[30]

102. Regulating potentially reduced risk alternative tobacco and nicotine products in the same way as combustible products conveys the message that these products pose the same potential health risks as combustible tobacco products and undermines the communication of the comparative risks of products. The anchoring of the presentation and communication regarding new potentially reduced products with existing more risky products has more general implications for the performance of consumer markets for potentially reduced risk products. If new, potentially reduced risk products become available, these products will encounter the hurdle of overcoming consumers' prior risk beliefs associated with the product class to the extent that consumers are reluctant to alter their high risk beliefs. The dominant market failure may involve overestimation of the new product's riskiness. This influence will impede consumers' response to new, potentially less risky alternative products introduced in the market.

103. For example, requiring e-cigarettes and other potentially reduced risk products to carry the same style warnings and look the same as combustible tobacco products (for example by imposing the same plain or standardized packaging requirements); and applying the same restrictions on product display, will reinforce current beliefs that the risks of these products are comparable in character and magnitude to the risks of cigarettes. The particular challenge for informational policies is to convey the properties of e-cigarettes or and other smoking non-combustible tobacco and nicotine alternatives like heated

[30] Gravely, et al (2019) Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project, Addiction. doi: https://doi.org/10.1111/add.14558.

tobacco products and oral nicotine pouches, which are estimated to pose significantly lower health risks than conventional cigarettes but are more comparable in terms of the nicotine levels. Cigarette style warnings and packaging policies are not designed to foster lower risk beliefs with respect to e-cigarettes or to promote accurate comparative risk beliefs. Warnings should frame risk information that allows users to make informed choices.

104. Advertising bans and prohibitions on comparative risk claims prevent manufactures from communicating the attributes of these products and potential benefits for smokers, thereby impeding informed consumer decision making. Imposing advertising bans may also have negative consequences in increasing demand for traditional cigarettes.[31]

IX. CONCLUSION

105. Analysis of the survey results for seven European countries yields differences across countries in terms of the public's perception of alternative nicotine delivery devices. Four conclusions are most noteworthy. First, the perceptions of a substantial segment of the population are not in line with the estimated lower levels of harm posed by e-cigarettes and other non-combustible tobacco and nicotine alternatives like heated tobacco products and oral nicotine pouches, based on prevailing public health opinions. Second, the evidence is strongly consistent with e-cigarettes and other non-combustible tobacco and nicotine products serving as an alternative for conventional cigarettes. Third, the main reasons given by respondents for not using e-cigarettes and other potentially reduced risk products are that they do not know enough about them or they do

[31] See Tuchman, Anna E. 2017. "Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising." Working Paper, Northwestern University Kellogg School of Management

not think that they are less harmful than cigarettes. Fourth, the decisions to use e-cigarettes and other potentially reduced risk products are strongly correlated with perceptions that these products pose less harm than smoking conventional cigarettes, so that continued misperceptions of the estimated harms from non-combustible tobacco and nicotine products have adverse implications for informed consumer decision making.

106. These findings, in combination with the studies reviewed in this report, lead to the following observations and policy recommendations for governments and regulators:

a. The results of the European surveys discussed in this report and other studies, find that consumers are misinformed about the estimated reduced harms of non-combustible tobacco and nicotine products compared to combustible tobacco products.

b. The policy challenge is to address the shortfall in consumer knowledge so that current cigarette smokers can make a comparison between cigarettes and these alternative products that reflects the estimated substantial reduction in the risk of harm that they are expected to provide. Improving the perceptions of harm for non-combustible tobacco and nicotine products in line with their estimated reduced harm compared to conventional cigarettes will likely lead to more smokers switching to these products as an alternative to smoking.

c. To reduce the continued misperception of the estimated harm posed by non-combustible tobacco and nicotine products compared to conventional cigarettes, governments and regulators should treat these products differently than cigarettes and should undertake sustained efforts to communicate the estimated lower risk that they pose compared to cigarettes.

d. Such policies might include efforts along the following lines:

i. Undertaking risk communication efforts that credibly convey to consumers accurate information about the estimated lower risk posed by these non-combustible products.

ii. Adopting warnings for these products that are not patterned on cigarette warnings but rather are reflective of the lower degree of estimated risk that they pose and providing information that facilitates informed consumer decision making. Warnings and other information efforts should not be policies of persuasion designed to discourage smokers' usage of non-combustible tobacco and nicotine products.

iii. Allowing marketing freedoms for companies selling alternative tobacco and nicotine products so that they can create awareness of these products and the estimated risk reduction that they offer to smokers who choose these products instead of cigarettes.

107. The underlying principle of these recommendations, which is that non-combustible tobacco and nicotine products merit quite different treatment than conventional cigarettes, should be carried over across all dimensions of government and regulatory policies. These efforts include, among others, advertising bans and limitations, retail display bans, and requirements regarding the use of plain or standardized packaging as well as restrictions on ingredients and the imposition of taxes. Efforts that adopt the same regulatory approach as is used for tobacco cigarettes will continue to reinforce consumers' misperceptions regarding the comparative estimated risk of these products. There is evidence that consumer beliefs have become more out of line with the estimated

risk that these products pose compared to cigarettes. Given the increase in risk beliefs for e-cigarettes that has been observed in several recent surveys, it is possible that recent regulatory efforts that treat these alternative products in the same way as combustible tobacco products may have even increased the degree of misperception regarding non-combustible tobacco and nicotine products.

W. Kip Viscusi

17 December 2020

Appendix A. Sample Characteristics and Survey Text

Appendix Table Full Sample Characteristics. **Full sample demographic percentages**

Age

	18-20	21-29	30-39	40-49	50-59	60+
Age	2.3	138	27.8	21.6	20.7	13.8

Gender

	Male	Female	Other	No Answer
Gender	52.7	46.4	0.7	0.2

Race or ethnicity

	White	Black	Asian	Multiple	Other	No Answer
Race	91.4	2.2	2.3	2.1	0.6	1.3

Relationship

	Married	Widowed	Divorced	Separated	Never Married	Live-in Partner	No Answer
Relationship	48.6	2.6	8.6	2.8	18.9	17.4	1.1

Education

	Less than High School	High School	Trade / Tech / Vocational	Bachelor	Post-Graduate	No Answer
Education	7.1	25.3	23.4	23.9	19.1	1.1

Income in Euros*

	0-10	10-30	30-49	50-75	75-100	100-125	125-150	150+	No Answer
Income	7.1	25.6	24.3	13.9	10.4	0.7	2.2	7.2	8.6

* United Kingdom and Denmark respondents were adjusted based on their currencies' exchange rate relative to the euro on July 22, 2020 which is the date when half of all surveys were complete. Top income for the United Kingdom is the equivalent of €165,000 or more in pounds. Top income for Denmark is the equivalent €167,500 or more in kroner.

Country

	N	Percentage
Belgium	1,500	14.9
Denmark	1,073	10.7
Netherlands	1,500	14.9
United Kingdom	1,500	14.9
France	1,500	14.9
Germany	1,477	14.7
Italy	1,500	14.9

Appendix 7

The Regulation of Alternative Nicotine Delivery Systems Under International Public-Health Law

Daniel P. Kessler
20 December 2020

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I. Qualifications

I am a tenured professor at Stanford Law School and the Stanford Graduate School of Business; a Senior Fellow at Stanford's Hoover Institution and its Institute for Economic Policy Research; and a Research Associate at the National Bureau of Economic Research, the country's leading nonprofit, nonpartisan economic research organization. I teach a University-wide course in health care law, finance, and regulation at Stanford. I have also taught courses in health law and policy at the Wharton School of the University of Pennsylvania and Harvard Law School. I have served as a consultant to the US Federal Trade Commission and US states as well as hospitals, health systems, and insurers in the US and internationally. I currently serve on Stanford's Committee on Faculty and Staff Human Resources, which oversees the University's health insurance plans and reports to its Chief Financial Officer. I obtained a J.D. from Stanford Law School in 1993 and a Ph.D. in economics from MIT in 1994, specializing in law-and-economics and health economics.

I study the empirical effects of health law and policy. I have published numerous books and papers in peer-reviewed journals on health economics, health insurance, and regulation. In particular, I have published a book and several articles examining the causes and consequences of technological change in health care internationally. I have received grant support from the US National Science Foundation, the US National Institutes of Health, the US Agency for Healthcare Research and Quality, the California Health Care Foundation, and the American Cancer Society. My full curriculum vitae is attached as Appendix A.

II. Introduction and Executive Summary

Counsel[1] asked me to assess, based on available empirical evidence, whether international public-health law should impose tobacco-like regulatory restrictions or outright bans on the sale of e-cigarettes (ECs) and other Alternative Nicotine Delivery Systems (ANDS).[2] I conclude that public-health law should regulate ANDS less stringently than combustible tobacco (CT).[3]

To make this assessment, I reviewed the literature about the effects of ANDS on smoking, the health risks of ANDS, and the principles of public-health law. The remainder of this report proceeds in five sections.

§ III discusses the health benefits from ANDS. § III concludes that at the population level the health benefits from ANDS are significant, because ANDS facilitate smoking cessation and reduction. § III also concludes that the health benefits from ANDS availability accrue disproportionately to disadvantaged groups.

§ IV investigates the potential health harms from ANDS, including potential direct health harms (i.e., harms from toxic substances in ANDS) and potential indirect health harms (i.e., harms from ANDS allegedly providing a gateway to smoking). § IV concludes the following:

[1] This report was commissioned on behalf of British American Tobacco. The views expressed herein are entirely my own.

[2] ECs are devices that heat a liquid, usually containing nicotine, to create an aerosol vapor that is inhaled. They contain no tobacco and do not involve combustion of any type. Other ANDS include snus, an oral tobacco product; heated tobacco products (HTPs) devices that heat but do not combust tobacco to generate a nicotine-containing aerosol with a tobacco flavor; and non-tobacco nicotine pouch products, which are consumed in the same way as snus, but contain no tobacco at all, only nicotine, flavorings, and fillers.

[3] I use the term "regulate" to include product standards and taxation as well as other forms of regulation (e.g., on advertising).

1. The potential direct health harms from ANDS are much smaller than the direct health harms from smoking, so any direct health harms from ANDS are outweighed by their health benefits; and
2. There is no convincing empirical evidence of indirect health harms from ANDS; thus
3. The health benefits from ANDS outweigh the potential (direct plus indirect) health harms.

§ V discusses the principles of public-health law and their origins and implications, given the findings of §§ III – IV. § V concludes the following:

1. According to the World Health Organization and the US Centers for Disease Control, the key principle of public-health law is "to provide the maximum possible benefit to the largest number of people"[4];
2. In the case of ANDS, the basic principles of public-health law all point in the same direction: public-health law should regulate ANDS less stringently than CT; and
3. If international law is to embody these basic principles, then it requires States to regulate ANDS less stringently than CT. In particular, the harm-reduction objective of the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) requires States to regulate ANDS less stringently than CT.

§ VI reviews research on specific policies that restrict availability of ANDS. According to these studies, increases in taxes on, expansions in regulations of, or decreases in exposure to product communications about ANDS generally increase smoking.

[4] https://www.who.int/violenceprevention/approach/public_health/en/; https://www.cdc.gov/publichealth101/documents/introduction-to-public-health.pdf, p.6.

§ VII concludes.

III. Availability of ANDS Creates Health Benefits

Evidence of the health benefits of the availability of ANDS comes from several sources. In § III.A, I present two international comparisons of the availability of ANDS, rates of smoking, and prevalence of smoking-related illnesses. § III.A shows that smokers transition to alternative, less-harmful products in markets where ANDS are available, leading to less smoking-related illness. In § III.B, I discuss other empirical evidence on ANDS availability, which shows conclusively that ANDS facilitate smoking cessation and reduction.

A. International Comparisons

Different countries have taken dramatically different approaches to the regulation of ANDS. In this section, I consider two case studies: the availability of snus in Sweden[5] and Norway, and the contrast in EC regulation in Australia, the UK, and the US.

1. Snus in Sweden and Norway

Sweden has a long history of use of snus. Snus was introduced there in the 1600s and reached record levels of use by 1919, but then declined with the introduction of cigarettes.[6] However, by the 1970s, new methods for manufacturing snus led to significantly lower levels of tobacco-related toxic substances in the product, which was also taxed at a lower rate than

[5] Sweden is the only EU country in which snus is lawfully available. It is also lawfully available in Norway, which is not part of the EU.

[6] Clarke E, Thompson K, Weaver S, et al, Snus: a compelling harm reduction alternative to cigarettes, Harm Reduction Journal 2019;16:62.

cigarettes.[7] The WHO has specifically recognized snus as considerably less hazardous than cigarettes.[8]

Contemporaneous with these changes, Swedish men shifted from CT to snus. By 2017, Swedes had by far the lowest daily smoking rates in Europe: 5 percent as compared to 24 percent in the EU as a whole.[9] Norway has experienced similar results with its more recent growth in snus consumption, which coincided with a dramatic reduction in smoking and tobacco use as a whole. In 2010, 26 percent of Norwegians used CT or snus daily, with 19 percent smoking daily and 7 percent using snus; by 2019, 23 percent of Norwegians used CT or snus daily, with only 9 percent smoking daily and 14 percent using snus.[10]

As with all international comparisons, it is impossible to attribute causality to a single factor – the availability of snus – as Sweden and Norway differ from other countries in the EU along many dimensions. Nonetheless, several studies conclude the availability of snus has played a significant role in reducing smoking in the Nordic countries.[11] In turn, these countries have also shown very low rates of tobacco-related mortality. For example, in 2004, the death rate for Swedish men aged 60-69 attributable to tobacco was 222 per 100,000, as compared to a median death rate for men aged 60-69 attributable to tobacco in the EU (except Sweden) of 550

[7] Ramstrom L, Borland R, Wikmans T, Patterns of Smoking and Snus Use in Sweden: Implications for Public Health, International Journal of Environmental Research and Public Health 2016;13:1110-24.

[8] WHO, The scientific basis of tobacco product regulation: second report of a WHO study group (WHO technical report series; no. 951), p273 available at https://www.who.int/tobacco/publications/prod_regulation/trs_951/en/.

[9] Eurobarometer, report 458, issued May 2017: March 2017 survey data, p. 6.

[10] https://www.ssb.no/en/helse/artikler-og-publikasjoner/less-norwegians-smoke-more-use-snus.

[11] Lund I and Lund EK, How Has the Availability of Snus Influenced Cigarette Smoking in Norway? International Journal of Environmental Research and Public Health 2014;11: 11705-17.

per 100,000 – more than twice as much.[12] According to a recent study, "the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe."[13]

2. Vaping in Australia, the UK, and the US

The sale and use of nicotine for EC use (vaping) is effectively banned in Australia.[14] As a result, the rate of vaping there is extremely low – only 1.2 percent of the adult population. By contrast, ECs are widely available in the UK and the US: in those countries, 6.3 and 3.2 percent of the adult population, respectively, report vaping. Indeed, in the UK, vaping is an important component of a harm-reduction policy to facilitate switching away from smoking. For example, in 2017, the British Medical Association published a position paper on ECs reporting "clear potential benefits to their use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use."[15] An independent expert review commissioned by Public Health England,[16] which updates the evidence from its landmark 2015 report, found that "[v]aping poses only a small fraction of the risks of smoking

[12] Ramstrom L and Wikmans T, Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report, Tobacco Induced Diseases 2014;12:14.

[13] Ramstrom L, Borland R, Wikmans T, Patterns of Smoking and Snus Use in Sweden: Implications for Public Health, International Journal of Environmental Research and Public Health 2016;13:1110-24.

[14] The details in this section are from Mendelsohn C, Hall W, Borland R, Could vaping help lower smoking rates in Australia? Drug and Alcohol Review 2020;39:415-8.

[15] E-cigarettes: Balancing risks and opportunities, British Medical Association, November 2017.

[16] Public Health England was established on 1 April 2013 and brings together public health specialists from more than 70 organisations. It works with national and local government, industry and the UK National Health Service. http://www.nhs.uk/NHSEngland/thenhs/healthregulators/Pages/public-health-england.aspx.

and switching completely from smoking to vaping conveys substantial health benefits over continued smoking."[17]

Contemporaneous with Australia's ban on ECs, smoking rates in the UK and the US – which were higher than those in Australia in 2010 – fell below those in Australia by 2017. This rapid flip is all the more striking, given that Australia has among the highest-priced and most stringently regulated cigarettes in the world. Although it is impossible to attribute causality for this flip to Australia's ban on ECs, an editorial in the Medical Journal of Australia about the country's smoking rate concludes that "Regulation of EC in Australia should be liberalized to allow smokers the opportunity to benefit from their use."[18]

B. Other Empirical Evidence

The negative association in international comparisons between ANDS availability and smoking rates suggests that ANDS availability has a causal effect on smoking reduction and cessation. An extensive empirical literature seeks to identify the causal effect of the most common ANDS, ECs. This literature concludes that EC availability creates significant health benefits by facilitating smoking reduction and cessation.

Randomized Controlled Trials (RCTs) have long been the gold standard for evaluating the effects of health interventions, including the effect of vaping, because they eliminate "confounding." Confounding occurs when the treated and untreated groups differ in terms of characteristics that are not observed by the researcher but are associated with better or worse

[17] McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18. A report commissioned by Public Health England. London: Public Health England, 2018

[18] Mendelsohn CP, Electronic cigarettes: what can we learn from the UK experience? Medical Journal of Australia 2016:204(1):14-16.

outcomes. RCTs eliminate confounding because, by definition, they assign subjects to treatment by a coin flip.

Evidence from RCTs indicates that vaping facilitates smoking cessation. According to a 2016 Review of RCTs by the Cochrane Collaboration,[19] smokers who used ECs were more likely to have abstained from smoking for at least six months compared with those using placebo ECs (i.e., those without nicotine).[20] A recent RCT conducted by the UK National Health Service found that smokers who used ECs were more likely to have abstained from smoking for one year compared with those using a nicotine-replacement product of their choice. This finding is particularly striking given that the nicotine-replacement products were used under expert guidance.[21]

Consistent with the RCT evidence, observational studies find a positive association between vaping and smoking reduction, quit attempts, and cessation, after adjusting for differences in the characteristics of EC users and non-users.[22] For example:

[19] The Cochrane Collaboration is the most influential international organization devoted to evidence-based medicine and health policy. Cochrane Reviews are systematic investigations of the scholarly literature that include a comprehensive search of all potentially relevant studies; the use of explicit, reproducible criteria in the selection of studies for review; appraisal of studies' research design, characteristics, and data; and peer evaluation of ultimate conclusions. Cochrane Collaboration, Cochrane Reviews, available at http://www.cochrane.org/cochrane-reviews.

[20] Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P, Electronic cigarettes for smoking cessation, Cochrane Database of Systematic Reviews 2016;9.

[21] Hajek P, Phillips-Waller A, Przulj D, et al, A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy, New England Journal of Medicine 2019;380:629-37.

[22] In addition to the studies quoted below, see Johnson L, Ma Y, Fisher S, et al, E-cigarette Usage Is Associated With Increased Past-12-Month Quit Attempts and Successful Smoking Cessation in Two US Population-Based Surveys, Nicotine & Tobacco Research 2019;21(10):1331-1338; Biener L, Hargraves JL, A Longitudinal Study of Electronic Cigarette Use Among a Population-Based Sample of Adult Smokers: Association With Smoking Cessation and Motivation to Quit, Nicotine & Tobacco Research 2015;17(2):127-33; Brose LS, Hitchman SC, Brown J, et al, Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with 1-year follow-up, Addiction 2015;110:1160-8.

1. In a representative sample of EU citizens, 35.1 percent of EC users reported using ECs to quit smoking, with an additional 32.2 reporting using ECs to reduce smoking, after adjusting for covariates. Based on this, the authors conclude that "[a]n estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the help of EC, respectively";[23]
2. In a representative sample of US smokers from the Population Assessment of Tobacco and Health Study, daily vaping was associated with 77 percent greater odds of prolonged smoking abstinence, after adjusting for covariates;[24]
3. In a representative sample of US smokers from the National Health Interview Survey, over half of daily EC users (52.2 percent) quit smoking in the last 5 years, a higher prevalence than any other demographic or behavioral subgroup. After adjusting for covariates, this group was three times more likely than never-EC users to quit;[25]
4. In a representative sample of English smokers, EC users were 2.23 times more likely to report abstinence than either those who used nicotine-replacement therapy or no aid (1.38 times more likely), after adjusting for covariates;[26]
5. In representative samples of US smokers from the Current Population Survey from 2000-2015, EC users in 2014-15 accounted for almost all of the additional

[23] Farsalinos KE, Poulas K, Voudris V, et al, Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries, Addiction 2016;111:2032-40.

[24] Kalkhoran S, Chang Y, Rigotti NA, Electronic Cigarette Use and Cigarette Abstinence Over 2 Years Among US Smokers in the Population Assessment of Tobacco and Health Study, Nicotine & Tobacco Research 2019;

[25] Giovenco DP, Delnevo CD, Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers, Addictive Behaviors 2018;76:129-34.

[26] Brown J, Beard E, Kotz D, et al, Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study, Addiction 2014;109:1531-40.

smoking cessation as compared to previous years. Unless EC users quit because of forces not encountered by non-EC users – which is unlikely – EC availability contributed to the population increase in smoking cessation in the US.[27]

One review and meta-analysis catalogues studies that report a negative association between vaping and smoking cessation.[28] However, many of the studies with this finding have serious limitations.[29] Most important, in contrast to the studies finding a positive association between vaping and smoking cessation, they fail to control for *any* confounding factors that may be associated with EC use and smoking cessation. Even those studies that do control for some confounding factors do not control for the fact that several of them exclude subjects who have tried ECs in the past and successfully quit smoking.[30] Disproportionately including EC users who have failed to quit without controlling for their past will bias downward these studies' assessment of the association between EC use and smoking cessation.[31]

C. Availability of ANDS Promotes Health Equity

Other observational studies analyze differences in ANDS use by socioeconomic status. This work finds that ANDS users are disproportionately from socioeconomically-disadvantaged groups. In a representative sample of EC users in the US in 2016-17, people with incomes below

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[27] Zhu SH, Zhuang YL, Wong S, et al, E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys, BMJ 2017;358:j3262.

[28] Kalkoran S, Glantz SA, E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis, Lancet Respiratory Med 2016;4:116-28.

[29] Glasser AM, Collins L, Pearson JL, Overview of Electronic Nicotine Delivery Systems: A Systematic Review, American Journal of Preventive Medicine 2017;52(2):e33-66,e40; Villanti AC, Feirman SP, Niaura RS, et al, How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor, Addiction 2017;113:391-404.

[30] Hajek P, McRobbie H, Bullen C, E-cigarettes and smoking cessation, Lancet Respiratory Med 2016;4:e23.

[31] Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P, Electronic cigarettes for smoking cessation, Cochrane Database of Systematic Reviews 2016;9,19.

the US poverty line were almost twice as likely to use EC as those with incomes at or above poverty.[32] Along these lines, those with high school education or less were also more likely to use EC as those with at least some college education, and sexual minorities were more than twice as likely to use EC as heterosexuals.[33] This makes sense, because people from disadvantaged groups are much more likely to smoke,[34] and people use EC to quit smoking.

People from disadvantaged groups are not only more likely to use EC, but also more likely to successfully quit using EC. In particular, in England in 2019, people with low socioeconomic status who had quit smoking for more than 1 year were more likely than those with high socioeconomic status to have used EC.[35] Because (as § IV shows) the health benefits of EC use exceed the potential health harms, these studies show that ANDS availability contributes to health equity.

IV. Any Health Harms From ANDS Are Much Smaller Than Their Benefits

Because ANDS may themselves cause some harm to health, any evaluation of the net benefits of ANDS availability must consider both their benefits and risks. Potential health harms of ANDS fall into one of two categories: potential direct health harms (i.e., harms from toxic substances in ANDS) and potential indirect health harms (i.e., harms from ANDS allegedly providing a gateway to smoking). In § IV.A, I discuss research on the potential direct health harms of ANDS. These studies universally find that any direct health harms of ANDS are much

[32] Spears CA, Jones DM, Weaver SR, et al, Sociodemographic Correlates of Electronic Nicotine Delivery Systems (ENDS) Use in the United States, 2016-2017, American Journal of Public Health 2019;109(9):1224-32, Table 4, 1.83 = 11.9 / 6.5

[33] Id., Table 4, 8.4 vs. 6.1, and 2.05 = 13.3 / 6.5, respectively.

[34] Id., Table 1, 34.2 vs. 11.9.

[35] Kock L, Brown J, Shahab L, Association of Socioeconomic Position With e-Cigarette Use Among Individuals Who Quit Smoking in England, 2014 to 2019, JAMA Network Open 2020;3(6):e204207.

smaller than the direct health harms from smoking – so much smaller that ANDS availability creates net direct health benefits. In § IV.B, I discuss research on the potential indirect health harms of ANDS. Although some of these studies show a positive *association* between EC use by young people and subsequent smoking, this work does not provide evidence of a *causal link* between EC use and smoking, because of their inability to account for the characteristics of individuals that affect their likelihood of using both EC and CT. Thus, § IV.C concludes that the health benefits of ANDS outweigh the potential (direct plus indirect) health harms.

A. Potential Direct Health Harms

The best evidence of potential direct health harms from ANDS use would be based on the actual health outcomes of cohorts of ANDS users as compared to those of cohorts of current smokers, ever smokers, and never smokers. However, as Public Health England has observed, such evidence is not yet available, because ANDS use has been prevalent for less than a decade.[36] In addition, because almost all ANDS users are current or former smokers, and smoking-related health harms may manifest with delay, separating the potential health harms from ANDS use and those from smoking will be difficult.

In the absence of data on health outcomes and a method to separate the health harms from ANDS use with those from smoking, most of the evidence of the effects of ANDS use on health comes from studies of the volumes of tobacco-related toxicants in ANDS. These studies universally find that ANDS use is likely to be significantly less harmful than smoking.[37]

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[36] McNeill A, Brose LS, Calder R, et al., Evidence review of e-cigarettes and heated tobacco products 2018, Public Health England 2018, available at https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review.

[37] The recent occurrences of vaping-associated lung injury in the US have been linked to products from informal sources that contain tetrahydrocannabinol and Vitamin E acetate (an additive to products containing tetrahydrocannabinol). Although the US CDC cannot rule out the contribution of other chemicals of concern,

One review focuses on the carcinogenicity of EC vapor as compared to tobacco smoke. It finds that tobacco smoke is between 100 and 10,000 times as carcinogenic as EC vapor.[38] A second review focuses on adverse cardiovascular effects ECs. It finds that "although ECs might pose some cardiovascular risk to users, particularly those with existing cardiovascular disease, the risk is thought to be less than that of cigarette smoking based on qualitative and quantitative comparisons of EC aerosol versus cigarette smoke constituents."[39] The Royal College of Physicians review studies of the potential adverse respiratory effects of ECs, and find that "e-cigarettes deliver a much smaller range of toxins at much lower concentrations than cigarettes" and although they allow for a "possibility that some harm from long-term e-cigarette use cannot be dismissed," nonetheless conclude that "harm from e-cigarette use is likely to be far less than that from smoking" and "very small in absolute terms."[40]

Two recent studies investigate the extent of biomarkers of tobacco-related toxicants in EC users. These studies confirm the findings of the studies discussed above. One study based on data from the UK compares biomarkers for toxicants in smokers, smokers who also use EC and non-EC nicotine-replacement therapy (NRT), former smokers with long-term EC use only,

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tetrahydrocannabinol and Vitamin E acetate are not used in commercial EC products. See https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

[38] Stephens WE, Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke, Tobacco Control 2018;27:10-17, Figure 1.

[39] Benowitz NL, Fraiman JB, Cardiovascular effects of electronic cigarettes, Nature Reviews: Cardiology 2017;14:447-56.

[40] Royal College of Physicians, Nicotine without smoke 2016 § 5.3.3, 5.3.3.6, available at https://www.rcplondon.ac.uk/file/3563/download. Another review (Gotts JE, Jordt SE, McConnell R, et al, What are the respiratory effects of e-cigarettes?, BMJ 2019;366:l5275) finds "current knowledge insufficient to determine wither the respiratory health effects of e-cigarettes are less than those of combustible tobacco products," but concedes that it will not be possible to know whether EC use is safer than smoking until health outcomes data are available (p. 11).

and former smokers with long-term NRT use only.[41] It finds that all groups had similar levels of nicotine metabolites in their urine or saliva, but that the EC-only and NRT-only users had significantly lower levels of metabolites of other toxicants than all types of smokers. It also finds that the EC-only and NRT-only groups were generally statistically indistinguishable from one another, except that the EC-only group had statistically significantly *lower* levels of some biomarkers for toxicants. This study therefore concludes that complete, long-term switching from smoking to EC use only may yield health benefits. Consistent with this, another study based on data from the US finds that EC-only users had significantly lower levels of biomarkers of toxicants than do smokers.[42]

There is less work on the health harms from ANDS other than ECs, but these studies universally find that ANDS other than ECs are significantly less harmful than smoking.

Compared with cigarettes, HTP products reduce levels of harmful and potentially harmful toxicants by at least 62% and particulate matter by at least 75% -- benefiting both users of HTP products and bystanders, relative to smoking.[43] These findings have been endorsed by both Public Health England (which found that "[t]he available evidence suggests that heating tobacco products may be considerably less harmful that tobacco cigarettes"[44]) and the US Food and Drug Administration (which approved the sale an HTP product in the US "for the protection of the

[41] Shahab L, Goniewicz ML, Blount BC, et al, Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users, Annals of Internal Medicine 2017;166:390-400.

[42] Goniewicz ML, Smith DM, Edwards KC, et al, Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes, JAMA Network Open 2018;1(8):e185937.

[43] Simonavicius E, McNeill A, Shahab L, et al, Heat-not-burn tobacco products: a systematic literature review, Tobacco Control 2019;28:582-94.

[44] McNeill A, Brose LS, Calder R, et al., Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018.

public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes."[45])

Snus may be even less harmful than HTP products, since it is manufactured to avoid several tobacco-related toxicants (§ III.A.1). In any event, use of snus is much less harmful than smoking (or use of other oral tobacco products, such as smokeless tobacco in the US): use of snus is not associated with oral cancers,[46] pancreatic cancers,[47] or circulatory disease,[48] although high consumption of snus has been identified as a risk factor for type 2 diabetes.[49]

Modern oral nicotine pouch products – which are both smokeless and tobacco-free – have the potential to be even more harmless than snus. Recent unpublished research suggests that this is the case: relative to snus, modern oral nicotine pouch products have lower levels than snus of Harmful and Potentially Harmful Constituents as defined by the US FDA, with levels of toxicants close to those of NRT.[50]

In summary, in my view, the difference in toxicity between ANDS and smoking is so large that ANDS availability creates net direct health benefits. In the US in 2018, for example,

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[45] https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

[46] Araghi M, Galanti MR, Lundberg M, et al, No association between moist oral snuff (snus) use and oral cancer: pooled analysis of nine prospective observational studies, Scandinavian Journal of Public Health 2020: 1-8.

[47] Araghi M, Galanti MR, Lundberg M, Use of moist oral snuff (snus) and pancreatic cancer: Pooled analysis of nine prospective observational studies, International Journal of Cancer 2017;141:687-93.

[48] Rostron BL, Change JT, Anic GM, et al, Smokeless tobacco use and circulatory disease risk: a systematic review and meta-analysis, BMJ: Open Heart 2018;5:e000846.

[49] Carlsson S, Andersoon T, Araghi M, Smokeless tobacco (snus) is associated with an increased risk of type 2 diabetes: results from five pooled cohorts, Journal of Internal Medicine 2017:1-9.

[50] Azzopardi D, Liu C, Murphy J, Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums, Draft 2020.

only 1.1 percent of never-smoking adults were EC users[51] – approximately 1.8 million people.[52] If ECs in 2018 enabled even 1 percent of the approximately 34 million US smokers[53] to quit, the direct health benefits to quitters would have exceeded any direct harms from their use by never-smokers.[54]

B. Potential Indirect Health Harms

Some researchers have hypothesized that ANDS use may provide a "gateway" to smoking initiation among youth or otherwise "renormalize" smoking in the minds of the public. Proponents of this hypothesis most frequently cite to studies that find a positive association between youth vaping and subsequent smoking.[55] If these studies' positive association between vaping and subsequent smoking represents a causal effect of vaping on smoking, then vaping may cause indirect health harm, even if it does not cause any direct health harm.

The substance abuse literature, however, offers an alternative explanation for these studies' positive association between vaping and subsequent smoking, sometimes described as the "joint susceptibility" or "common liability" hypothesis. This hypothesis suggests that these studies' positive association between vaping and smoking is due to individual characteristics that

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[51] Villarroel MA, Cha AE, Vahratian A, Electronic Cigarette Use Among US Adults, 2018, NCHS Data Brief 365, April 2020.

[52] Villarroel MA, Blackwell DL, Jen A. Tables of summary health statistics for U.S. adults: 2018 National Health Interview Survey. National Center for Health Statistics. 2019. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/NHIS/SHS/2018_SHS_Table_A-12.pdf. 1.8 million ≈ 159,659 million × 0.011.

[53] Id.

[54] If ECs enabled 340,000 smokers to quit (340,000 = 1 percent of 34 million), then the benefits of ECs to quitters would exceed the harms to the 1,800,000 never-smoking EC users, as long as smoking is at least 6.3 times as harmful as EC use [6.3 ≈ (1,800,000 + 340,000) / 340,000], which it clearly is.

[55] Soneji S, Barrington-Trimis JL, Willis TA, et al, Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis, JAMA Pediatrics 2017;171(8):788-97. Smoking initiation among adults is extremely rare, and there is no evidence that vaping is associated with smoking initiation among never-smoking adults.

cause both vaping and smoking rather than a causal link between vaping and smoking. To the extent that studies finding a positive association between vaping and smoking fail to account fully for such characteristics, they will incorrectly infer a causal link between vaping and smoking when none actually exists.

There is substantial evidence that these studies' positive association between youth vaping and smoking does not represent a causal effect. In particular:

1. Although some studies find a positive association between youth vaping and smoking at *the individual level*, there is a strong *negative* association between youth vaping and smoking *at the population level* in the UK,[56] New Zealand,[57] and the US.[58] This negative association is inconsistent with the gateway hypothesis, unless there were so many other contemporaneous forces that were correlated with vaping as to more than undo its gateway effects, which is unlikely[59];
2. Vaping has a weak or absent association with smoking after adjusting for a large set of factors known to affect both vaping and smoking;[60] and

[56] Hallingberg B, Maynard OM, Bauld L, et al, Have e-cigarettes renormalized or displaced youth smoking? Results of a segmented regression analysis of repeated cross-sectional survey data in England, Scotland, and Wales, Tobacco Control 2020;29:207-16.

[57] Walker N, Parag V, Wong SF, et al, Use of e-cigarettes and smoked tobacco in youth aged 14-15 years in New Zealand: findings from repeated cross-sectional studies (2014-19), Lancet Public Health 2020.

[58] Levy DT, Warner KE, Cummings KM, et al, Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check, Tobacco Control 2019;28:629-35.

[59] Id.

[60] Kim S, Selya AS, The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factors, Nicotine & Tobacco Research 2019: 1-8.

3. Evidence other than the positive association between youth vaping and smoking generally does not satisfy the Hill conditions[61] for causality.[62]

There is also evidence that use of other ANDS, such as snus, do not increase smoking.[63] For these reasons, I conclude that there is no convincing empirical evidence of indirect health harms from ANDS use acting as an alleged gateway to smoking.

C. Simulation Models Confirm That the Benefits From ANDS Outweigh the Harms

§ III - § IV.B show that the health benefits from ANDS outweigh the health harms. However, if there were a significant gateway effect of EC on smoking – despite the lack of convincing empirical evidence – this conclusion could be reversed. To investigate the robustness of this conclusion to the possibility of a significant gateway effect, researchers have used simulation models to weigh the known health benefits against the possibility of health harms. Results from these models allow researchers to calculate how large gateway effects would have to be in order to outweigh ANDS' health benefits.

Under any plausible assumption about the magnitude of gateway effects, these models conclude that the health benefits from ANDS outweigh the health harms.[64] This is because the health benefits from ANDS are so large that they overwhelm the health harms from even the most pessimistic hypotheses about vaping-induced smoking. For example, even assuming the gateway effect implied by the largest published positive association between youth vaping and

[61] Hill AB, The environment and disease: association or causation? Proceedings of the Royal Society of Medicine 1965;58:295-300.

[62] Etter JF, Gateway effects and electronic cigarettes, Addiction 2017;113:1776-83.

[63] Ramstrom L, Borland R, Wikmans T, Patterns of Smoking and Snus Use in Sweden: Implications for Public Health, International Journal of Environmental Research and Public Health 2016;13:1110-24, 1112.

[64] Warner KE, Mendez D, E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation, Nicotine & Tobacco Research 2019:41-7, 44.

smoking – despite the lack of evidence that this association is causal – 80 percent of youth who would otherwise not have smoked would have to seriously experiment with EC in order to wipe out ECs' net health benefits.[65] Experimentation with EC of this magnitude is many times greater than actual rates of vaping.[66] Even simulation models designed by researchers who are skeptical about the health benefits from ANDS show net health benefits over a range of plausible assumptions.[67] The only simulation model that shows net health harms relies on studies that are known to be flawed.[68]

V. International Public-Health Law and the Concept of Harm Reduction

According to the World Health Organization and the US Centers for Disease Control, the key principle of public-health law is "to provide the maximum possible benefit to the largest number of people."[69] According to Professor Lawrence Gostin, the Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, public-health law also should promote equity, individual rights, and prevention of disease.[70]

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[65] Levy DT, Borland R, Villanti AC, et al, The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States, Nicotine & Tobacco Research 2017:149-59, 153.

[66] Gentzke AS, Creamer M, Cullen KA, et al, Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011-2018, MMWR 2019;68(6):157-64.

[67] Warner KE, Mendez D, E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation, Nicotine & Tobacco Research 2019:41-7, 44 citing Kalkhoran S, Glantz SA, Modeling the Health Effects of Expanding e-Cigarette Sales in the United States and United Kingdom, JAMA Internal Medicine 2015;175(10);1671-80.

[68] Warner KE, Mendez D, E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation, Nicotine & Tobacco Research 2019:41-7, 45 citing Soneji SS, Sung HY, Primack BA, et al, Quantifying population-level health benefits and harms of e-cigarette use in the United States, PLoS One 2018;13(3):e0193328.

[69] https://www.who.int/violenceprevention/approach/public_health/en/; https://www.cdc.gov/publichealth101/documents/introduction-to-public-health.pdf, p.6.

[70] Gostin LO, A Theory and Definition of Public Health Law, Journal of Health Care Law & Policy 2007;10:1-12.

The additional principles proposed by Professor Gostin serve as important refinements to public-health law's utilitarian base. In addition to the prevention of disease, the promotion of equity, or social justice, requires that public-health law consider the distribution of health benefits and harms across individuals in addition to the simple sum of health benefits and harms. In particular, the promotion of equity suggests that public-health law give special weight to the health benefits and harms of disadvantaged groups in order to ameliorate impediments to their well-being from which they would otherwise suffer.[71] Promotion of individual rights limits the scope of public-health law's activities when those activities infringe on individuals' autonomy, privacy, or liberty.[72] Finally, the prevention orientation of public-health law emphasizes the prevention of disease as opposed to its cure.[73]

Typically, the principles of public-health law are in tension with one another. For example, the equity principle might lead to regulations that benefit the least-well-off in society, even if the regulations may impose costs on the most-well-off. The desire to protect individual rights might preclude regulations that benefit the population in aggregate, if those regulations unacceptably limit individuals' ability to make their own choices. In these cases, implementation of the principles of public-health law requires complex tradeoffs. Because individuals may not agree on the terms of these tradeoffs, public-health law typically does not provide a clear answer to real-world regulatory questions.

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[71] Gostin LO, A Theory and Definition of Public Health Law, Journal of Health Care Law & Policy 2007;10:1-12, 10-11.

[72] Gostin LO, A Theory and Definition of Public Health Law, Journal of Health Care Law & Policy 2007;10:1-12, 4.

[73] Gostin LO, A Theory and Definition of Public Health Law, Journal of Health Care Law & Policy 2007;10:1-12, 9-10.

In the case of regulation of ANDS, however, these principles all point in the same direction: ANDS should be regulated less stringently than CT. The benefits of ANDS outweigh the harms; ANDS contribute to health equity; and ANDS use is voluntary.

Many believe that international human rights law, starting with the Constitution of the WHO in 1946, establishes a "right to health."[74] According to the Preamble of the Constitution, "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[75]

If international law establishes a right to health, and the right to health is to embody the basic principles of public-health law above, then international law requires States to regulate ANDS less stringently than CT. Several specific interpretations of the right to health support my conclusion:

1. The UN International Covenant on Economic, Social and Cultural Rights ("ICESCR") calls on States to take steps to achieve the full realization of the right to health including those necessary for "[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases."[76] The UN Committee that oversees the implementation of the ICESCR has explained that the obligation to control diseases includes States' efforts to "make available relevant technologies"

[74] UN OHCHR and WHO, Right to Health Fact Sheet No. 31, p. 1.

[75] Constitution of the World Health Organization 1946, http://www.who.int/governance/eb/who_constitution_en.pdf.

[76] International Covenant on Economic, Social and Cultural Rights 1966, http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx, Article 12(c).

to achieve this objective.[77] Because ANDS are a "relevant technology" to reduce smoking-related disease, the ICESCR at the least obligates States to allow their use with less stringent regulation than CT.

2. The ICESCR states that the entitlements to a right to health "include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health."[78] Because ANDS availability contributes to health equity, the ICESCR at the least obligates states to allow their use with less stringent regulation than CT.

3. The World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) mandates a strategy of harm reduction. The WHO FCTC defines "tobacco control" as a "range of supply, demand, and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."[79] The US Institute of Medicine defines "tobacco harm reduction" as "decreasing total morbidity and mortality, without completely eliminating tobacco and nicotine use."[80] Because ANDS achieve tobacco harm reduction, the WHO FCTC mandates States to allow their use with less stringent regulation than CT.

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[77] ICESCR General Comment 14: The Right to the Highest Attainable Standard of Health (Art. 12), para. 16, http://www.refworld.org/pdfid/4538838d0.pdf. See also Article 15 of the ICESCR that everyone has a right "[t]o enjoy the benefits of scientific progress and its applications."

[78] Id., para. 8.

[79] https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf, Part I, Article 1.d.

[80] Stratton K, Shett P, Wallace R, et al, Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction, National Academies Press 2010, p. 25.

VI. Restrictions on ANDS Availability Generally Increase Smoking

A large empirical literature examines the impact of specific policies that restrict availability of ANDS on the smoking rate. According to these studies, increases in taxes on, expansions in regulations of, or decreases in exposure to advertising for ANDS generally increase smoking.

The first set of studies examines the effect of EC taxes on smoking, and finds that increases in EC taxes are associated with increases in smoking.[81] One study uses Nielsen Retail Scanner data from across the US for 2011-2017. These data contain the volume and price of EC and tobacco products purchased from a sample of approximately 30,000 retailers by UPC code.[82] The study matches the Nielsen data at the level of US localities (either states or counties) to EC and tobacco taxes, along with several other characteristics of US localities including smoking and EC-use restrictions; alcohol taxes; state Medicaid (government-subsidized insurance for low-income people) regulations; unemployment rates; and demographic characteristics. It finds that holding all other factors constant, increases in EC taxes (as measured by the portion that are

[81] One set of related studies examines the effect of *tobacco* taxes on EC use. These studies generally find that increases in tobacco taxes are associated with increases in EC use (e.g., Pesko MF, Courtemanche C, Maclean J, The Effects Of Traditional Cigarette and E-Cigarette Taxes On Adult Tobacco Product Use, NBER working paper 26017 (2019), available at http://www.nber.org/papers/w26017.). Although these studies support the hypothesis that EC use substitutes for smoking (and therefore facilitates smoking cessation), they do not directly assess the effect of EC use or policies toward ECs on smoking. A second set of related studies examines the effect of EC *prices* on smoking. These studies generally find that increases in EC prices increase smoking (e.g., Stoklosa M, Drope J, Chaloupka FJ, Prices and E-Cigarette Demand: Evidence from the European Union, Nicotine and Tobacco Research 2016;18(10):1973-80; Saffer H, Dench D, Dave D, et al, E-Cigarettes And Adult Smoking, NBER working paper 24212 (2018), available at http://www.nber.org/papers/w24212; Cantrell J, Huang J, Greenberg MS, et al. Impact of e-cigarette and cigarette prices on youth and young adult e-cigarette and cigarette behavior: evidence from a national longitudinal cohort, Tobacco Control 2019:1-7.). However, these studies are more likely to suffer from confounding, as EC prices are more likely than taxes to be determined by demand and supply changes that may be correlated with smoking.

[82] Cotti C, Courtemanche C, Maclean J, et al, The Effects Of E-Cigarette Taxes On E-Cigarette Prices And Tobacco Product Sales: Evidence From Retail Panel Data, NBER working paper 26724 (2020), available at http://www.nber.org/papers/w26724. This paper supercedes Cotti C, Nesson E, Tefft N, The relationship between cigarettes and electronic cigarettes: Evidence from household panel data, Journal of Health Economics 2018;61:205-219.

passed through to consumers) are associated with increases in tobacco sales. This study is consistent with earlier work that examined Minnesota's imposition of large EC taxes in 2010 and 2013, and found that State's EC tax to have reduced smoking cessation significantly (by 32,000 smokers out of Minnesota's approximately 600,000 smokers) from what it would have been.[83]

The second set of studies examines the effect of EC regulations on smoking – in particular, age restrictions on EC use – and generally (although not universally) finds that restrictions on EC use are associated with increases in smoking. The first study on this topic uses data from the US National Survey on Drug Use and Health from 2002-13, and finds that bans on EC use by minors are associated with a statistically significant increase in youth smoking.[84] Subsequent work, using more-recent data from the US Youth Risk Behavior Surveillance System from 2005-15, qualifies this result, concurring that EC-use age restrictions increase youth smoking, but finds that the higher youth smoking rates do not persist beyond the point at which youth age out of the laws.[85] One novel study uses data on maternal tobacco use from birth certificates from 32 US states and finds that EC-use age restrictions increase prenatal smoking.[86] Studies based on earlier and shorter time periods are mixed, with some finding that

[83] Saffer H, Dench D, Grossman M, et al, E-Cigarettes And Adult Smoking: Evidence From Minnesota, NBER working paper 26589 (2019), available at http://www.nber.org/papers/w26589.

[84] Friedman AS, How does electronic cigarette access affect adolescent smoking? Journal of Health Economics 2015;44:300-8.

[85] Dave D, Feng B, Pesko M, The effects of e-cigarette minimum legal sale age laws on youth substance use, Health Economics 2019;28:419–436.

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EC-use age restrictions increase youth smoking,[87] and others finding that EC-use age restrictions actually decrease smoking.[88]

The third set of studies examines the effect of EC advertising exposure on smoking, and finds that exposure to EC television advertising is associated with reductions in smoking. One study matches individual-level data on EC use and smoking, television viewing, and magazine reading patterns from the proprietary Simmons National (US) Consumer Survey with data on the volume of EC advertising by television program and magazine title; it finds that exposure to EC television advertising (but not magazine advertising) increases smoking cessation among adults.[89] Another study matches US local-area-market-level data on EC television advertising with data on EC and cigarette purchases, and finds that exposure to EC television advertising is associated with greater EC use and reduced smoking.[90]

The evidence on the impact of stringent regulation on the developing and evolving ANDS sector was summarized in a recent study:

> In contrast to many of the [countries with less restrictive policies], rates of use were quite low in the [most restrictive] countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of [nicotine vaping products] laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them.[91]

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[89] Dave D, Dench D, Grossman M, et al, Does e-cigarette advertising encourage adult smokers to quit?, Journal of Health Economics 2019;68:102227.

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VII. Conclusion

The availability of ANDS, which allow adult consumers of tobacco to have access to a range of products that are significantly less risky than smoking, leads to health benefits that outweigh potential health harms. Moreover, accepted international public-health law principles – and, by implication, international law that embodies these principles – require States to devise policies that weigh health benefits and harms. Therefore, in my view, States are to regulate ANDS less stringently than CT. My conclusion is strengthened by evidence that the health benefits from ANDS availability accrue disproportionately to disadvantaged groups: people from disadvantaged groups are not only more likely to use EC, but also more likely to successfully quit smoking using EC. Moreover, because restrictions on ANDS generally increase smoking – thereby resulting in net harm to the population – such restrictions should be adopted only after analysis to ensure that their net benefits, in terms of harm reduction, exceed their costs, in terms of restricting access to a proven tool for smoking reduction and cessation. This conclusion applies to all forms of ANDS, including EC, HTP and oral nicotine pouches.

Arguments that ANDS should be regulated stringently generally rely on claims that ANDS availability will somehow serve as a "gateway" to or otherwise "renormalize" smoking. There is no convincing empirical evidence to support these claims. First, although there is some limited evidence of a positive association between youth vaping and subsequent smoking, this association can be explained by the presence of common but unobservable individual characteristics that cause both vaping and smoking (rather than a causal link between vaping and smoking). This idea, which is well-accepted in the substance-abuse literature, means that the observed positive association between vaping and smoking overstates the extent to which ANDS availability will lead to smoking. However, even if the observed positive association between

vaping and smoking does represent a gateway effect in part, simulation models show the benefits of ANDS outweigh the potential harms under any plausible assumption about the magnitude of gateway effects.

Second, the claim that ANDS availability will renormalize smoking is inconsistent with the accelerated rates of smoking cessation in countries with widespread availability of ANDS such as the UK, the US, and the Nordic countries as compared to Australia and the rest of the EU.

Thus, regulation that bans or effectively bans ANDS is inconsistent with accepted international public-health principles and, if international law is to embody these principles, with international law as well. It is also inconsistent with the harm-reduction objective that is incorporated in the WHO FCTC. Rather, allowing the sale of ANDS with less-stringent regulations, standards, and taxes than CT is a proven way to achieve the goal of improving public health through evidence-based tobacco control.

Signed on the 20th of December, 2020, at Stanford, CA, US.

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Daniel P. Kessler

Appendix A: Curriculum Vitae

Daniel P. Kessler
Law School, Graduate School of Business, Hoover Institution,
and Stanford Institute for Economic Policy Research
Stanford University
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Education:

Ph.D.	Economics, Massachusetts Institute of Technology, 1994
J.D.	Stanford Law School, 1993
B.A.	Economics, Harvard University, 1988

Academic Positions:

Director of Research, Hoover Institution, 2019-
Senior Fellow, Stanford Institute for Economic Policy Research, 2016-
Professor, Stanford Law School, 2009-
Professor, by courtesy, Stanford School of Medicine, Department of Health Research and Policy, 2008-20
David S. and Ann M. Barlow Professor in Management, Graduate School of Business, Stanford University, 2007-10
Visiting Professor, Harvard Law School, 2007
Senior Fellow, Hoover Institution, Stanford University, 2006-
Professor, by courtesy, Stanford Law School, 2004-2009
Professor, Graduate School of Business, Stanford University, 2003-
Visiting Associate Professor, Wharton School, University of Pennsylvania, 2002-03
Associate Professor, Graduate School of Business, Stanford University, 1998-2003
Assistant Professor, Graduate School of Business, Stanford University, 1994-98

Awards, Fellowships, and Other University Affiliations:

Affiliate, Stanford Center on Longevity, 2008-
Health Care Research Award, National Institute for Health Care Management Foundation, 2003
Fellow, Center for Advanced Study in the Behavioral Sciences, 2003-04
Graduate School of Business Trust Faculty Fellow, 2000-01
Affiliate, Center for Social Innovation, Stanford Graduate School of Business, 2000-
Research Associate, National Bureau of Economic Research, 1999-
Public Policy Advising Award, Stanford University, 1998
Kenneth J. Arrow Award for Best Paper in Health Economics, International Health Economics Association, 1997
Affiliate, Center for Health Policy, Stanford University, 1997-
Class of 1969 Faculty Scholar, Stanford Graduate School of Business, 1997-98
National Fellow, Hoover Institution, 1997-98
John M. Olin Faculty Fellow, 1996-97
Faculty Research Fellow, National Bureau of Economic Research, 1994-99

Academic Publications:

"Does Multispecialty Practice Enhance Physician Market Power?" with Laurence C. Baker and M. Kate Bundorf, *American Journal of Health Economics* 6(3): 324-47 (2020).

"The Effects of Medicare Advantage on Opioid Use," with Laurence C. Baker and M. Kate Bundorf, *Journal of Health Economics* 70: 102278 (2020).

"Why Don't Commercial Health Plans Use Prospective Payment?" with Laurence C. Baker, M. Kate Bundorf, and Aileen M. Devlin, *American Journal of Health Economics* 5(4):465-80 (2019).

"Competition in Outpatient Procedure Markets," with Laurence C. Baker and M. Kate Bundorf, *Medical Care* 57(1): 36-41 (2019).

"Neurophysiological monitoring during cervical spine surgeries: Longitudinal costs and outcomes," with John P. Ney, *Clinical Neurophysiology* 129: 2245-51 (2018).

"ACA Marketplace Premiums and Competition Among Hospitals and Physician Practices," with Maria Polyakova, M. Kate Bundorf, and Laurence C. Baker, *American Journal of Managed Care* 24(2): 85-90 (2018).

"The Effect of Medicare Advantage on Hospital Admissions and Mortality" with Christopher Afendulis and Michael Chernew, *American Journal of Health Economics* 3(2): 254-79 (2017).

"Hospital Ownership of Physicians: Hospital Versus Physician Perspectives" with Laurence C. Baker, Aileen M. Devlin, and M. Kate Bundorf, *Medical Care Research and Review*: 1-12 (2016).

"The Effect of Hospital/Physician Integration on Hospital Choice" with Laurence C. Baker and M. Kate Bundorf, *Journal of Health Economics* 50: 1-8 (2016).

"Medicare Advantage Plans Pay Hospitals Less Than Traditional Medicare Pays" with Laurence C. Baker and M. Kate Bundorf, *Health Affairs* 35: 1444-51 (2016).

"Does Health Plan Generosity Enhance Hospital Market Power?" with Laurence C. Baker and M. Kate Bundorf, *Journal of Health Economics* 44: 54-62 (2015).

"Designing Antitrust Policy for Accountable Care Organizations," with Laurence C. Baker and M. Kate Bundorf, *Journal of Competition Law & Economics* 11: 317-29 (2015).

"Expanding Patients' Property Rights in Their Medical Records," with Laurence C. Baker and M. Kate Bundorf, *American Journal of Health Economics* 1: 82-100 (2015).

"Patient Preferences Explain a Small But Significant Share of Regional Variation in Medicare Spending," with Laurence C. Baker and M. Kate Bundorf, *Health Affairs* 33: 957-63 (2014).

"Vertical Integration: Hospital Ownership of Physician Practices Is Associated With Higher Prices and Spending," with Laurence C. Baker and M. Kate Bundorf, *Health Affairs* 33: 756-76 (2014).

"Medical Malpractice, Defensive Medicine, and Physician Supply," in the *Encyclopedia of Health Economics*, Volume 2, ed. Anthony J. Culyer, Elsevier (2014).

"Why Are Medicare and Commercial Insurance Spending Weakly Correlated?" with Laurence C. Baker and M. Kate Bundorf, *American Journal of Managed Care* 20: e8-e14 (2014).

"Regulatory Neutrality Is Essential To Establishing A Level Playing Field For Accountable Care Organizations" with Gary E. Bacher, Michael E. Chernew, and Stephen M. Weiner, *Health Affairs* 32: 1426-32 (2013).

"Reforming Medicare," *Tax Law Review* 65 (2012): 811-833.

"How Should Risk Adjustment Data Be Collected?" *Inquiry* 49 (Summer 2012): 127-140.

"Reforming the Tax Preference for Employer Health Insurance," with Joseph Bankman, John F. Cogan, and R. Glenn Hubbard, in *Tax Policy and the Economy, Volume 26*, ed. Jeffrey Brown, MIT Press (2011).

"Vertical Integration and Optimal Reimbursement Policy," with Christopher C. Afendulis, *International Journal of Health Care Finance and Economics* 11 (2011): 165-179.

"The Effect of Tax Preferences on Health Spending," with John F. Cogan and R. Glenn Hubbard, *National Tax Journal* 64 (September 2011): 795-816.

"The Effect of Bivalirudin on Costs and Outcomes of Treatment of ST-segment Elevation Myocardial Infarction," with Eugene Kroch and Mark A. Hlatky, *American Heart Journal* 162 (2011): 494-500.

"Evaluating the Medical Malpractice System and Options for Reform," *Journal of Economic Perspectives* 25 (2011): 93-110.

"Does Patient Satisfaction Affect Patient Loyalty?" with Deirdre Mylod, *International Journal of Health Care Quality Assurance* 24 (2011): 266-73.

Regulation versus Litigation: Perspectives from Economics and Law, ed., University of Chicago Press (2011).

"The Persuasive Effects of Direct Mail: A Regression Discontinuity Approach," with Alan Gerber and Marc Meredith, *Journal of Politics* 73 (January 2011): 140-55.

"HMO Coverage Reduces Variations in the Use of Health Care Among Patients Under Age Sixty-five" with Laurence Baker and M. Kate Bundorf, *Health Affairs* 29 (November 2010): 2068-74.

"The Effect of Massachusetts Health Reform on Employer-sponsored Insurance Premiums," with John F. Cogan and R. Glenn Hubbard, *Forum for Health Economics and Policy* 13 (2010): article 5.

"The Effect of Medicare Coverage for the Disabled on the Market for Private Insurance," with John F. Cogan and R. Glenn Hubbard, *Journal of Health Economics* 29 (May 2010): pp. 418-25.

"Why Is Health Reform So Difficult?" with David Brady, *Journal of Health Politics, Policy, and Law* 35 (April 2010): 161-75.

"Who Supports Health Reform?" with David Brady, *PS: Political Science and Politics* 43 (January 2010): 1-6.

"Putting the Public's Money Where Its Mouth Is," with David Brady, *Health Affairs* 28 (September/October 2009): w917-w925.

"Do Markets Respond to Quality Information? The Case of Fertility Clinics," with M. Kate Bundorf, Natalie Chun, and Gopi Shah Goda, *Journal of Health Economics* 28 (2009): 718-27.

"Empirical Study of the Civil Justice System," with Daniel L. Rubinfeld, in the *Handbook of Law and Economics*, eds. A. Mitchell Polinsky and Steven Shavell, North-Holland (2007).

"Tradeoffs from Integrating Diagnosis and Treatment in Markets for Health Care," with Christopher Afendulis, *American Economic Review* 97 (June 2007): 1013-20.

"Evaluating Effects of Tax Preferences on Health Care Spending and Federal Revenues," with John F. Cogan and R. Glenn Hubbard, in *Tax Policy and the Economy, Volume 21*, ed. James Poterba, MIT Press (2007).

"The Effects of the Medical Liability System in Australia, the UK, and the US," with Nicholas Summerton and John R. Graham, *Lancet* 368 (2006): 240-46.

"The Effect of Cardiac Specialty Hospitals on the Cost and Quality of Care," with Jason Barro and Robert Huckman, *Journal of Health Economics* 25 (2006): 702-21.

"The Effects of the US Malpractice System on the Cost and Quality of Care," with David Becker, in *Medical Malpractice and the US Health Care System: New Century, Different Issues*, eds. William Sage and Rogan Kirsch, Cambridge University Press (2006).

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Healthy, Wealthy, and Wise: Five Steps to a Better Health Care System, with John F. Cogan and R. Glenn Hubbard, Hoover Institution/AEI Press (1st. ed., 2005; 2nd. ed., 2011).

"The Effects of Competition on Variation in the Quality and Cost of Medical Care," with Jeffrey Geppert, *Journal of Economics and Management Strategy* 14 (2005): 575-89.

"Impact of Malpractice Reforms on the Supply of Physician Services," with David Becker and William Sage, *JAMA* 293 (6/1/05): 2618-25.

"Detecting Medicare Abuse," with David Becker and Mark McClellan, *Journal of Health Economics* 24 (2005): 189-210.

"The Medical Liability System: Current Debates," in *Power to the Patient: Selected Health Care Issues and Policy Solutions*, ed. Scott W. Atlas, Hoover Institution Press (2005).

"Toward Better Drugs for Less (book review)," *Science* 306 (12/24/04): 2192-3.

"Advance Directives and Medical Treatment at the End of Life," with Mark McClellan, *Journal of Health Economics* 23 (2004): 111-27.

"Is More Information Better? The Effects of 'Report Cards' on Health Care Providers," with David Dranove, Mark McClellan, and Mark Satterthwaite, *Journal of Political Economy* 111 (2003), pp. 555-88.

"Ownership Form and Trapped Capital in the Hospital Industry," with Henry Hansmann and Mark McClellan, in *The Governance of Not-for-Profit Firms*, Edward L. Glaeser ed., University of Chicago Press (2003).

"How Liability Law Affects Medical Productivity," with Mark McClellan, *Journal of Health Economics* 21 (2002), pp. 931-55.

"The Effects of Hospital Ownership on Medical Productivity," with Mark McClellan, *RAND Journal of Economics* 33 (Autumn 2002), pp. 488-506.

A Global Analysis of Technological Change in Health Care: Heart Attack, ed., with Mark McClellan, University of Michigan Press (2002).

"Technological Change in Heart Attack Care in the United States: Causes and Consequences," with Mark McClellan, Nathan Every, Alan Garber, Paul Heidenreich, Mark Hlatky, Joseph Newhouse, and Olga Saynina, in *A Global Analysis of Technological Change in Health Care: Heart Attack*, ed., with Mark McClellan, University of Michigan Press (2002).

"Malpractice Pressure, Managed Care, and Physician Behavior," with Mark McClellan, in *Regulation Through Litigation*, W. Kip Viscusi ed., Brookings Institution Press (2002).

"Does Party Matter in Senators' Voting Behavior? An Historical Test Using Tariff Votes," with David Brady and Judith Goldstein, *Journal of Law, Economics, and Organization* 18 (April 2002), pp. 140-54.

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"Designing Hospital Antitrust Policy to Promote Social Welfare," with Mark McClellan, in *Frontiers in Health Policy Research: Volume 2*, ed. Alan Garber, MIT Press (1999).

"A Global Analysis of Technological Change in Health Care: The Case of Heart Attacks," with Mark McClellan for the TECH Investigators, *Health Affairs* 18 (May/June 1999), pp. 250-55.

"Using Sentence Enhancements to Distinguish Between Deterrence and Incapacitation," with Steven Levitt, *Journal of Law and Economics* 42 (April 1999), pp. 343-365.

"The Link Between Liability Reforms and Productivity: Some Empirical Evidence," with Thomas Campbell and George Shepherd, *Brookings Papers on Economic Activity: Microeconomics* (1998).

"The Role of Discretion in the Criminal Justice System," with Anne Morrison Piehl, *Journal of Law, Economics, and Organization* 14 (Winter 1998), pp. 256-276.

"The Law and Economics of Tying Arrangements: Lessons for Competition Policy Treatment of Intellectual Property," with William Baxter, in *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy*, eds. Robert Anderson and Nancy

Gallini, Industry Canada Research Series, University of Calgary Press (1998).

"The Effects of Malpractice Pressure and Liability Reforms on Physicians' Perceptions of Medical Care," with Mark McClellan, *Law and Contemporary Problems* 60 (Winter 1997), pp. 81-106.

"Institutional Causes of Delay in the Settlement of Legal Disputes," *Journal of Law, Economics, and Organization* 12 (Winter 1996), pp. 432-460.

"Dynamics of Cosponsorship," with Keith Krehbiel, *American Political Science Review* 90 (September 1996), pp. 555-566.

"Do Doctors Practice Defensive Medicine?" with Mark McClellan, *Quarterly Journal of Economics* 111 (May 1996), pp. 353-390.

"Explaining Deviations from the Fifty Percent Rule: A Multimodal Approach to the Selection of Cases for Litigation," with Thomas Meites and Geoffrey Miller, *Journal of Legal Studies* 35 (January 1996), pp. 233-261.

"Liability Reforms and Economic Performance," with Thomas Campbell and George Shepherd, in *The Mosaic of Economic Growth*, eds. Ralph Landau, Timothy Taylor, and Gavin Wright, Stanford University Press (1996).

"Fault, Settlement, and Negligence Law," *RAND Journal of Economics* 26 (Summer 1995), pp. 296-313.

"Toward a Consistent Theory of the Welfare Analysis of Agreements," with William Baxter, *Stanford Law Review* 47 (April 1995), pp. 301-317.

"Birth Order, Family Size, and Achievement: Family Structure and Wage Determination," *Journal of Labor Economics* 9 (October 1991), pp. 413-426.

Academic Manuscripts in Progress:

"Can Ranking Hospitals on the Basis of Patients' Travel Distances Improve Quality of Care?" NBER Working Paper 11419.

Nonacademic publications:

"The Health of Obamacare," *Wall Street Journal*, December 11, 2015, p. C3.

"By Reducing Competition, ObamaCare Raises Costs," *Investor's Business Daily*, June 11, 2014, p. A13.

"ObamaCare is Raising Insurance Costs," *Wall Street Journal*, June 4, 2013, p. A13.

"The Coming ObamaCare Shock," *Wall Street Journal*, April 30, 2013, p. A17.

"ObamaCare's Broken Promises," *Wall Street Journal*, February 1, 2013, p. A13.

"Real Medicare Reform," *National Affairs*, Fall 2012.

"The Wrong Remedy for Health Care," *Wall Street Journal*, June 29, 2012, p. A13.

"ObamaCare's Bogus Cost Savings," *Wall Street Journal*, March 14, 2012, p. A12.

"Medicare Reform: Obama vs. Ryan," with John Taylor, *Wall Street Journal*, August 17, 2011, p. A15.

"How Health Reform Punishes Work," *Wall Street Journal*, April 25, 2011, p. A15.

"ObamaCare and the Truth About Cost Shifting," with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, March 11, 2011, p. A15.

"Voters on Obamacare: Informed and Opposed," with David W. Brady and Douglas Rivers, *Wall Street Journal*, October 15, 2010, p. A17.

"Health Care: The Prognosis," with John F. Cogan, *Hoover Digest* (2010).

"A Better Way to Reform Health Care," with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, February 25, 2010, p. A13.

"Health Care Is Hurting Democrats," with David W. Brady and Douglas Rivers, *Wall Street Journal*, January 19, 2010, p. A17.

"Public Opinion and Health Reform," with David W. Brady, *Wall Street Journal*, October 22, 2009, p. A15.

"Doubling Down on a Flawed Insurance Model," with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, September 25, 2009, p. A15.

"The Uninsured's Hidden Tax on Health Insurance Premiums in California: How Reliable is the Evidence?" with John F. Cogan, Matthew Gunn, and Evan J. Lodes, *Hoover Essays in Public Policy* (2007).

"Not a Panacea..." with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, February 9, 2006, p. A12.

"Keep Government Out," with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, January 13, 2006, p. A12.

"Reforming Health Care," *Hoover Digest* (2005).

"Reforming Malpractice Liability," *Hoover Digest* (2005).

"Brilliant Deduction" with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, December 8, 2004, p. A12.

"Healthy, Wealthy, and Wise," with John F. Cogan and R. Glenn Hubbard, *Wall Street Journal*, May 4, 2004, p. A20.

"Want to Sue HMOs? It'll Cost You," *Wall Street Journal*, July 25, 2001, p. A16.

"The Economic Effects of the Liability System," *Hoover Essays in Public Policy* (1998).

"Robbing Smokers to Pay Lawyers," with Jeremy Bulow, *Wall Street Journal*, April 7, 1998, p. A16.

"If You Smoke, Florida Wants to Tax You," with Jeremy Bulow, *Wall Street Journal*, November 26, 1997, p. A16.

Case Studies:

"Asian Neighborhood Design," with Lauren Dutton and Melinda Tuan, Stanford GSB (1998) (updated in 2003 by Rick Aubry and Susan Mackenzie).

"The Roberts Enterprise Development Fund," with Lauren Dutton, Jed Emerson, and Melinda Tuan, Stanford GSB (1998).

"Echelon and the Home Automation Standard," with David Baron, Keith Krehbiel, Erik Johnson, and Michael Ting, Stanford GSB (1997).

"The European Union Carbon Tax," with David Baron and Daniel Diermeier, Stanford GSB (1996).

Unpublished reports:

"Cost Shifting in California Hospitals: What is the Effect on Private Payers?" for the California Foundation for Commerce and Education (2007).

"The Determinants of the Cost of Medical Liability Insurance," for Physician Insurers Association of America (2006).

"The Effects of Behavioral Health Interventions on Health Care Costs," for the Foundation for Better Health (2005).

"The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of the Empirical Literature," for Pharmaceutical Research and Manufacturers of America (2004).

"The Impact of the Balanced Budget Act of 1997 on Skilled Nursing Care in California," with Chris Afendulis, Jeffrey Geppert, and Owen Kearney, for the California Health Care Foundation (2003).

Referee/reviewer:

American Cancer Society; *American Journal of Health Economics; American Economic Review; Health Affairs; Journal of Health Economics; Journal of Health Politics, Policy, and Law; Journal of Law, Economics, and Organization; Journal of Law and Economics; Journal of Legal Studies; Journal of Political Economy;* National Science Foundation; National Institutes of Health; *RAND Journal of Economics; Quarterly Journal of Economics*

Appendix 8

THE QUESTION OF THE APPLICATION OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL TO ALTERNATIVE NICOTINE DELIVERY SYSTEMS

Expert Opinion by Prof. Dr. Jan Wouters

Credentials

Professor Jan Wouters (°1964) is Full Professor of International Law and International Organizations, Jean Monnet Chair *ad personam* EU and Global Governance and founding Director of the Leuven Centre for Global Governance Studies and of the Institute for International Law at the University of Leuven (KU Leuven). As Visiting Professor at Sciences Po (Paris), Luiss University (Rome) and the College of Europe (Bruges) he teaches EU external relations law. As Adjunct Professor at Columbia University he teaches comparative EU-US perspectives on international human rights law. As Visiting Professor to the Universities of Ottawa and Trento in 2019, he teaches global and regional perspectives on international law. He has been working for more than 20 years as *Of Counsel* at Linklaters, Brussels.

Professor Wouters offers 30 years of academic scholarship and more than 25 years of practical experience in most areas of international law, from general international law to international criminal law, international economic law, international humanitarian law, international human rights law, international investment law, the law of international organizations (in particular the United Nations, UN specialized agencies and the World Trade Organization) and the law of outer space, as well as in the law of the European Union, corporate law and banking and financial law and global governance. He brings a strong insight in the multifaceted interactions between legal norms at international, European and national levels.

Professor Wouters is Member of the Royal Academy of Belgium for Sciences and Arts. He taught at the Universities of Antwerp and Maastricht, was Visiting Professor at Liège University, Kyushu University, the Pontificia Universidad Católica de Chile, the Hebrew University, the University of Ottawa and Trento University, and *Référendaire* at the European Court of Justice (1991-1994). He is Editor of the *International Encyclopedia of Intergovernmental Organizations*, Deputy Director of the *Revue belge de droit international*, Editor-in-Chief of the International Law book series with Intersentia Publishers and of the Leuven Global Governance book series with Edward Elgar Publishers, and editorial board member in eleven international journals. He has published widely on international and EU law, international organizations, global governance, and corporate and financial law, including more than 70 books, 130 journal articles and 200 chapters in international books. His most recent books include *Informal International Lawmaking* (2012), *Private Standards and Global Governance* (2012), *China, the European Union and Global Governance* (2012), *The EU's Role in Global Governance* (2013), *National Human Rights Institutions in Europe* (2013), *The Law of EU External Relations* (2nd ed. 2015), *China, the EU and the Developing World* (2015), *Global Governance of Labour Rights* (2015), *Global Governance Through Trade* (2015), *The Contribution of International and Supranational Courts to the Rule of Law* (2015), *Global Governance and Democracy* (2015), *Armed Conflicts and the Law* (2016), *Judicial Decisions on the Law of International Organizations* (2016), *Internationaal Recht in Kort Bestek* (2nd ed. 2017), *Research Handbook on EU Energy Law and Policy* (2017), *Commercial Uses of Space and Space Tourism* (2017), *The Commons and a New Global Governance* (2018), *EU Human Rights and Democratization Policies* (2018), *International Law: a European Perspective* (2018), and *The G7, Anti-Globalism and the Governance of Globalization* (2018). Apart from his participation in international scientific networks, he advises various international organizations and governments, trains international officials and is often asked to comment international events in the media.

Educational Qualifications

- PhD in Law, KU Leuven (1996)
- Visiting Researcher, Harvard Law School (1990-91)
- Master of Laws, Yale University (1990)
- Lic. Juris, Antwerp University (1987)
- Bachelor of Philosophy, Antwerp University (1984)

Positions Currently Held

- Jean Monnet Chair *ad personam* EU and Global Governance, KU Leuven
- Full Professor of International Law and the Law of International Organizations, KU Leuven; courses on European and International Law, Public International Law, Law of International Organizations, Law of the World Trade Organization, Humanitarian and Security Law from a European Perspective, Space Law and Policy, Seminar/Master Thesis/Practical Exercises International Law and International Organizations
- Director of the Leuven Centre for Global Governance Studies and Institute for International Law, KU Leuven
- Visiting Professor, Faculty of Law (Common Law), University of Ottawa; Sciences Po (Paris), Luiss University (Rome), College of Europe (Bruges), Faculty of Law, Pontificia Universidad Católica de Chile, University of Ottawa, Trento University; Adjunct Professor, Columbia University (SIPA): courses on EU External Relations, International Law, Comparative Human Rights Law
- *Of Counsel*, Linklaters, Brussels
- Expert, Indicative List for Panels of the World Trade Organization
- Member, Roster of Panelists, Free Trade Agreement between the EU, Colombia and Peru

Former Positions

1994-2006	Professor of Corporate Law (mergers and acquisitions), Catholic University of Brussels (postgraduate programme KU Leuven-KUB in corporate law)
1997-2003	Professor of European Banking and Securities Law, Maastricht University
1997-1998	Senior Lecturer on European, Economic and Financial Law, Antwerp University
1993-1998	Lecturer and Senior Lecturer in European and International Law, Maastricht University
1991-1994	Law Clerk (*référendaire*), European Court of Justice, Luxembourg
1989	Legal Adviser to the Belgian Minister of Finance, Brussels
1987-1989	Assistant in Financial, Economic and Commercial Law, Antwerp University

Academic Honours

- Member, Advisory Council, Queen Mary Global Policy Institute (since 2018)
- Visiting Professor, the Hebrew University of Jerusalem, 2016-2017
- Herbert Smith Freehills Visiting Professor, Lauterpacht Centre for International Law, Cambridge University, 2016-2017
- Member, Advisory Board, Centre for Multilevel Federalism, Delhi, India (since 2015)

- Senior Visiting Fellow, the Graduate Institute, Geneva, Spring 2014
- International Chair, Luiss University, Rome, Spring 2014
- Visiting Professor, Université Nice Sophia Antipolis, Spring 2014
- Senior Visiting Fellow, Institute of Advanced Studies, University of Bologna, 2013
- Course Holder of the course « *Le statut juridique des standards publics et privés dans les relations économiques internationales* », Hague Academy of International Law, 29 July - 2 August 2013, The Hague
- Visiting Scholar, Centre d'Etudes européennes, SciencesPo, Paris, 2012
- Senior Visiting Fellow, European Union Institute for Security Studies, Paris, 2012
- Fellow, Netherlands Institute for Advanced Study in the Humanities and Social Sciences (NIAS), 2010
- Honorary President, United Nations Association Flanders – Belgium (*Vereniging voor de Verenigde Naties)* (since 2009; President 2003-2009, 2013-2018)
- Jean Monnet Chair *ad personam* European Union and Global Governance granted by European Commission (2009)
- Member of the Royal Flemish Academy of Belgium for Sciences and Arts (since 2008)
- Fernand Braudel Fellow, European University Institute, 2008
- Honorary Member, Association of International Relations ("Kring Internationale Betrekkingen", Leuven), since 2002
- Stibbe Prize, 1997
- Walter Leën Prize for Social Law, 1996
- Rotary Foundation Fellow, 1990-91
- Francqui Fellow, Belgian American Educational Foundation, 1989-90

Other Professional Activities

- Visiting professorships: Master of Laws in International Economic Law and Policy (LL.M. IELPO), University of Barcelona (2010-2017); European Master's Degree in Human Rights and Democratisation (EMA), Venice (2009-2016); Executive Master of European and International Business Law M.B.L.-HSG, University of Sankt-Gallen (2001-2008); Leiden University (International Tax Programme, since 2003); University of Kyushu (Master of Laws Programme, 2007); Ghent University (Master of Laws Programme, 2003-2009); Liège University (D.E.A./D.E.S., 1996-1998); Université Libre de Bruxelles (European Programme in International Economic Law, EPIEL, 2005-2006)
- Membership of international and national expert bodies: Expert, Indicative List for Panels of the World Trade Organization; Member, roster of panelists, Free Trade Agreement between the EU, Colombia and Peru; Member, Group of Independent Experts on the European Charter of Local Self-Government, Council of Europe; Panel Member, European Research Council (ERC) 2013 and 2015 Consolidator Grants; Chair of the Panel 'Law and Criminology', Research Foundation Flanders (FWO), Belgium (2017; panel member 2012-2017); Member, Belgian Expert Group on National Minorities
- Coordination and membership of academic networks: Co-Chair, Community of Practice on Human Rights and Development (Global Forum on Law, Justice and Development) since October 2014; Convener and Coordinator of the international research network on 'Global Governance Through Informal Intergovernmental Institutions' (Scientific Research Community, funded by FWO, 2017-2021); Member of the Coordinating Team, international research network on 'Business and Human Rights Innovation Platform: Connecting Law and Management for Human Rights

(BHRIP)' (Scientific Research Community, funded by FWO, 2014-2018); Programme Director, research programme 'constitutional processes in the international legal order', Ius Commune Research School, Section Public Law (research alliance between KU Leuven, Maastricht University, Utrecht University and Amsterdam University); Coordinator, Belgian National Point of Contact, European Centre for Space Law; Member, Board of LASA (Leuven Centre for Aero and Space Science, Technology and Applications)

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- Membership academic journals: Deputy Director, *Revue Belge de Droit International*; member, Editorial Board: *International Journal of Public Law and Policy; International Organisations Research Journal; Journal of International Economic Law; Human Rights and International Legal Discourse; European Business Law Review; Zeitschrift für Öffentliches Recht – Austrian Journal of Public and International Law*; member, Editorial Advisory Board: *Asia Europe Journal; International Organizations Law Review*; *Maastricht Journal of European and Comparative Law*; *Legal Issues of Economic Integration*; *European Business Organization Law Review*; editorial member for European and international law, *Rechtskundig Weekblad*; member, Scientific Board, *European Papers – Carnets européens – Quaderni Europei*; external reviewer, *Annuaire canadien de droit international, European Journal of International Law, European Law Journal, European Law Review, Hague Journal of Diplomacy, Journal of Common Market Studies, World Tax Journal, World Trade Review*
- Membership of professional organizations : Academic Council on the United Nations System (ACUNS); American Society of International Law; Belgian Society of International Law; European Society of International Law; Harvard Club Belgium; International Law Association and Belgian Branch of International Law Association; International Society for Military Law and Law of War; Royal Dutch Society of International Law.
- Membership of jury of scientific prizes: Fernand Collin Prize (most prestigious scientific prize for Dutch-speaking legal scholarship in Belgium); Prize of the *Revue belge de droit international*; Prix de thèse René Cassin.

Research

- General interest for public international law, the law of international organizations, European Union law and global governance
- Present research priorities include: law of treaties and other sources of public international law, including informal lawmaking; the International Criminal Court and fight against impunity, including corporate accountability ; legitimacy and accountability of international organizations; the international and European security architecture ; the law of the World Trade Organization ; international humanitarian law ; the EU in international relations and global governance

I. Introduction

This expert opinion (opinion) examines questions of public international law relating to the scope of application of the World Health Organization's Framework Convention on Tobacco Control (FCTC or Convention). In particular, the opinion aims at responding to the question whether the FCTC applies to what health experts call Alternative Nicotine Delivery Systems (ANDS). The opinion focuses in particular on (i) electronic nicotine delivery systems (ENDS, also known as e-cigarettes or vapour products), that generally do not contain tobacco, (ii) heated tobacco products (also known as Heat Not Burn or tobacco heating products), which do contain tobacco but do not burn it, and (iii) nicotine pouches.

The opinion will address three main questions:

1. Based on the text of the FCTC, as interpreted in accordance with the general rules of treaty interpretation of the Vienna Convention on the Law of Treaties[1] (VCLT), do ANDS fall within the scope of application of the FCTC?
2. Based on the principles relating to the temporal application of treaties under public international law, should the FCTC be interpreted to apply to ANDS despite the FCTC's textual limitation to tobacco products?
3. What, if any, is the legal relevance of the discussions of the Conference of the Parties (COP) of the FCTC on ANDS for purposes of determining the scope of application of the FCTC?

To put it in a non-technical manner: the main question addressed in this opinion is whether under the FCTC the Parties have committed themselves to adopting measures restricting or prohibiting the marketing, promotion and sale of certain products that – as will be seen further in this opinion - did not exist at the time of adoption of the Convention, and that do not present the same risk profile as the products that are covered by the Convention.

The opinion starts with recapturing some of the basics about the rationale for, and nature of, the FCTC, as well as the features of ANDS and the chronology of events relating to the Convention and ANDS. It will then look at the text of the FCTC and examine in particular the definition of the term "tobacco products", which determines the scope of application of the FCTC. Applying the VCLT, the opinion will look at the ordinary meaning of the terms used in this definition, in their context and in the light of the object and purpose of the Convention. Finally, the opinion will examine if there is any subsequent agreement or subsequent practice of the Parties that needs to be taken into consideration together with the context.

II. The FCTC and ANDS: nature, rationale, chronology

This section recaptures some of the basics about the rationale for, and nature of, the FCTC as well as the features of ANDS, and the chronology of events relating to the Convention and ANDS. Given the novel nature of these "next generation" products, it is important to start the analysis at the time of the adoption of the FCTC to see in respect of which products and for what reasons States agreed to a joint approach to tobacco control.

[1] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.

a. The FCTC

The FCTC is an international treaty on *tobacco control*.[2] This is reflected throughout the FCTC, for example (i) in its title (the Framework Convention on *Tobacco Control*); (ii) in its preamble (e.g. "[r]ecognizing that the spread of the *tobacco* epidemic is a global problem…; [r]eflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of *tobacco* consumption and exposure to *tobacco* smoke"); (iii) in Article 1(d), which defines "tobacco control" as "a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of *tobacco* products and exposure to *tobacco* smoke"; and (iv) in Article 3, which states the "Objective" of the FCTC as follows: "The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of *tobacco* consumption and exposure to *tobacco* smoke…". More ample considerations on the Convention's scope of application will be developed *infra,* III.

It is important to recall that the FCTC constitutes a *framework treaty*. It is characteristic for a framework treaty that it formulates certain objectives and principles and sometimes also an institutional framework on the basis of which later more detailed treaties (possibly in the form of protocols) are meant to come out. Such a framework treaty is legally binding under international law, although its framework nature implies that it outlines objectives and principles rather than laying down specific obligations, even though typically it contains a number of minimum obligations.[3] In that sense, the FCTC constitutes a treaty that sets forth a number of minimum obligations, the general objectives of the Parties and the institutional mechanisms (including legal instruments, i.e. protocols) by which such aims will subsequently be negotiated, developed and implemented. The "framework" nature of the Convention implies that it is an agreement that sets forth certain broad objectives rather than specific legal obligations, with the exception of a limited set of obligations that are expressly included "as a minimum." Needless to say, to interpret the broadly worded principles of a framework convention as comprehensive and specific legal obligations would fail to give due account to the intent of the drafters and render redundant the need to develop specific obligations through the institutions and mechanisms created by the framework convention.

In addition, the FCTC's generally worded obligations and frequent instances of deference to national law and constitutional principles highlight the fact that the FCTC's objectives and obligations are subject to limitations imposed by each Party's national law. They signify an element of "subsidiarity", taking into account the great diversity of national legal systems, and thereby leaving flexibility to the Parties to determine the manner in which they intend to meet their obligations.

b. ANDS

ANDS are not conventional tobacco products (such as cigarettes), but represent alternative tobacco and nicotine products that do not burn tobacco to deliver nicotine to the user. ANDS may be used to support smoking cessation attempts and are generally considered as being

[2] Emphasis added here and in the further quotes in this paragraph.

[3] See J. Wouters, C. Ryngaert, T. Ruys and G. De Baere, *International Law: a European Perspective* (Hart Publishing, 2018), 71.

significantly less risky than cigarettes and are part of harm reduction strategies in several countries.[4]

Thus, it has been stated about e-cigarettes that there is a "growing consensus that they are significantly less harmful than tobacco use",[5] and that "[t]he most widely cited estimate of relative risk is from PHE's 2015 e-cigarette evidence review – which concluded that it would be reasonable to estimate that e-cigarette use is likely to be around 95% safer than smoking".[6] Similar considerations relating to the contribution of novel tobacco products to harm reduction strategies also apply to non-combustible, heated tobacco products.[7] The need to distinguish between combustible and non-combustible products was recently highlighted by a group of 72 well-known, independent health experts. In their letters to the WHO and the FCTC COP8, they considered both ENDS and heated tobacco products as ANDS.[8] Indeed, whereas conventional tobacco products are burnt through combustion – creating a complex mixture of gases and smoke particles, which leaves ash behind – heated tobacco products apply heat to the tobacco material, but there is no combustion, no smoke like a cigarette, and no ash.

The lack of combustion greatly reduces exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.[9] For example, the 2018 United States Annual Review of Public Health states: "Most reviews of toxicological, clinical, and epidemiological evidence indicate that the chemicals found in e-cigarettes, when used as intended, are far fewer and well below levels seen in cigarette smoke. According to the Royal College of Physicians in the United Kingdom, 'the available data suggest that they are unlikely to exceed 5% of those associated with combusted tobacco products'".[10] Therefore, there are important differences in the physical characteristics of combustible and non-combustible products, including the chemical properties of the resulting combustible smoke and the aerosol produced by ENDS and heated tobacco products.

The opinion evaluates whether the FCTC applies to the following ANDS categories:

1) *ENDS*. These are rechargeable, battery-powered devices, commonly known as e-cigarettes, that heat liquid formulations – e-liquids – to create a vapour that is inhaled. Most e-liquids contain water, propylene glycol and glycerol, flavourings and nicotine, although some e-liquids do not contain any nicotine. These products do not contain tobacco. In addition, the vapour contains far fewer of the toxicants found in the smoke produced when tobacco is burned and those it does contain are emitted at substantially lower levels.

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[4] See e.g. British Medical Association, E-cigarettes: Balancing risks and opportunities (2017); A. McNeill, L. S. Brose, R. Calder, L. Bauld and D. Robson, Evidence review of e-cigarettes and heated tobacco products (Public Health England, 2018).
[5] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 1.
[6] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 6.
[7] Simonavicius E, et al., Heat-not-burn tobacco products: a systematic literature review. Tobacco Control Published Online First: 04 September 2018. doi: 10.1136/tobaccocontrol-2018-054419 ("Peer-reviewed evidence on heated tobacco products indicates that HnB are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes.").
[8] Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf
[9] NASEM (2018), Public Health Consequences of E-Cigarettes ("There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes").
[10] Abrams et al (2018) Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives, Annu. Rev. Public Health 2018. 39:193–213.

2) *Heated tobacco products*. These are rechargeable, battery-powered devices that heat tobacco to generate a nicotine-containing aerosol with a tobacco taste that the user inhales. The heated tobacco vapour includes nicotine, water, humectants, and some natural and familiar tobacco flavours. Because the tobacco has not been burned or excessively heated, the aerosol produced by heated tobacco products contains far fewer and lower levels of odorous, irritant, or toxic chemicals than conventional cigarette smoke. As the U.S. FDA has recognized, "the products produce fewer or lower levels of some toxins than combustible cigarettes".[11]
3) *Nicotine pouches*: These are oral nicotine pouches which consumers place under their lip and the nicotine is then absorbed through their gum. They are available in a range of flavours and nicotine strengths. They are not for chewing or sucking and do not contain tobacco.

c. Chronology

The FCTC was signed in 2003 and entered into force on 27 February 2005. This is well before the globalization of ENDS and heated tobacco products. It seems indeed beyond doubt that the first e-cigarettes entered the European and US markets in 2006 and 2007, respectively,[12] and that their use doubled between 2008 and 2012 in North America and the EU.[13] While electronic heated tobacco products have come on the market even more recently,[14] especially nicotine pouches are among the most recent developments.[15]

As a matter of fact, it must therefore be clear from the outset that the drafters of the FCTC did not – and could not - discuss ANDS, i.e. products that differ from any of the existing tobacco products and that do not present the same risk profile as the tobacco products which gave rise to the Convention's provisions.

This point has been recognized in an important letter to the WHO about the role of ANDS in a harm reduction strategy for tobacco control. The October 2018 letter from a group of 72 independent health experts mentioned above called on the WHO to embrace technology innovation in the fight against diseases caused by smoking, stating:

> "In the field of tobacco control and public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through

[11] See FDA, "FDA News Release: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway" (30 April 2019), available at https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway ("[T]he agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes.").").
[12] See the timeline on http://www.casaa.org/historical-timeline-of-electronic-cigarettes/
[13] See R. Grana, N. Benowitz and S.A. Glantz, 'E-cigarettes: a scientific review', *Circulation* 219 (2014), e490-e492.
[14] See A. McNeill, L.S. Brose, R. Calder, L. Bauld and D. Robson, Evidence review of e-cigarettes and heated tobacco products, at 25.
[15] See S. Poynton, J. Sutton, S. Goodall, J. Margham, M. Forster, K. Scott, K. McAdam, J. Murphy and C. Proctor, 'Novel hybrid tobacco product that delivers a tobacco flavor note with vapour aerosol' (Part 1), *Food and Chemical Toxicology* 106 (2017), 522-532.

> 'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4)."[16]

Admittedly, the Parties to the FCTC began to analyse one type of ANDS, namely ENDS or vapour products, in 2010 when the COP requested the FCTC Convention Secretariat to prepare a report based on the experience of Parties on the matter of ENDS for consideration at the fifth session of the COP in 2012.[17] Thereafter, the FCTC has continued to evaluate scientific, regulatory and market developments in relation to ENDS as well as heated tobacco products – most recently in COP8 in 2018.[18] For further considerations on the COP's work in this matter, see *infra,* V. Importantly, the fact that the COP discusses these matters does not turn these products into tobacco products covered by the Convention. Whether a product is covered by the FCTC depends on the definition of covered tobacco products. That is what the following section looks into.

III. The definition of "tobacco products" in the FCTC in their context and in the light of the object and purpose of the FCTC

a. Introduction

The FCTC defines "tobacco products" in its Article 1(f) as follows: "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing".

The Convention deals with tobacco control writ large and in that context imposes specific minimum obligations with respect to covered "tobacco products" such as in Articles 11 and 13 of the FCTC. The objective of the Convention, formulated in its Article 3, uses terminology that focuses on the devastating consequences of tobacco use and exposure to tobacco smoke:

> "The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of *tobacco consumption* and exposure to *tobacco smoke* by providing a framework for *tobacco control measures* to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of *tobacco use* and exposure to *tobacco smoke*" (emphasis added)

One therefore has to consider the text and object and purpose of the FCTC more widely. For this purpose it is important to rely on the general rules on treaty interpretation in international law. These rules are laid down in Articles 31-33 of the VCLT, which are considered to reflect

[16] See https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf at p1.
[17] See Decision FCTC/COP7(9) at https://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf
[18] See e.g. FCTC/COP/8/1/, https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_1_Provisional_agenda-en.pdf

customary international law.[19] They do not need to be described in detail here. As is known, the basic rule for treaty interpretation is laid down in Article 31(1) VCLT, pursuant to which "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose."

Last but not least, it is important to emphasize that it is unnecessary to apply the principles of treaty interpretation when the text is clear. In this respect, the Permanent Court of International Justice has stated that '[h]aving before it a clause which leaves little to be desired in the nature of clearness, [the Court] is bound to apply this clause as it stands'.[20] In the words of Vattel, the first general maxim concerning interpretation is that it is not permitted to interpret what does not require interpretation.[21]

b. Ordinary meaning of the terms used in the definition of covered "tobacco products"

As indicated above, the FCTC is a treaty on tobacco control. A core notion is clearly the one of *"tobacco products"*, as defined in its Article 1(f), cited above: it is referred to in the fourth, fifth, 11th and 12th recitals of the preamble, as well as in Articles 1(d), (e) and (f), 4(2)(b) and (4), 6(2)(a) and (b) and (3), 13(1) and (4)(c), 19(2)(a). Moreover, it is the central concept used in Articles 9, 10, 11, 15 and 16, as the title of these articles (except Article 16) indicates, and it is used repeatedly therein.

The FCTC aims at regulating and controlling not just the demand and supply of tobacco products but at "the widest possible international cooperation" on "the spread of the tobacco epidemic" (second recital of the preamble), which also includes scientific and technical cooperation and communication of information (Part VII of the Convention).

The term "cigarettes" is used only sparingly in the FCTC (fourth, sixth, 12th recital of the preamble, Articles 15(4)(b) and (c), 16(3)), and it is clear that the Convention also aims to apply to "other tobacco products" (fourth and 12th recitals of the preamble). It is thus clear that "tobacco products" is a term that concerns not just cigarettes but also any other product covered by the definition of "tobacco products" in Article 1 (f) – i.e. a product that (1) is made of tobacco leaf and that (2) is manufactured to be used for smoking, sucking, chewing or snuffing.

Determining the scope of application of the Convention is therefore first and foremost dependent on the interpretation of the notion of "tobacco products".

As stated, Article 1(f) of the Convention defines this notion as "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing".

The text of this definition is rather clear. It is surely a very broad definition: not just because it applies to any product that is entirely *or partly* made of the leaf tobacco as raw material, but

[19] See *inter alia* International Court of Justice (ICJ), *Arbitral Award of 31 July 1989* ICJ Rep [1991] 69–70 para. 48; *Kasikili/Sedudu Island* (Botswana v Namibia) [1999] II p. 1074, para. 18; *Certain Questions of Mutual Assistance in Criminal Matters* (Djibouti v France) ICJ Rep [2008] p. 219, para. 112.
[20] *Question Concerning the Acquisition of Polish Nationality* [1923] PCIJ Series B, No 7, 20.
[21] Cited by C Rousseau, *Droit international public* (Paris, Sirey, 1970) 269, own translation from French: '[l]a première maxime générale sur l'interprétation est qu'il n'est pas permis d'interpréter ce qui n'a pas besoin d'interprétation'.

also because the product can be used for multiple purposes: smoking, sucking, chewing or snuffing.

On the other hand, the text of the definition makes clear that it only applies to products that use *"the leaf tobacco as raw material"*. It also makes clear that not every use of tobacco is covered but only the "smoking, sucking, chewing or snuffing" thereof. If the drafters had intended to include any and all products made at least in part of the leaf tobacco as raw material, there would have been no need to add the second element of the definition, which limits the group of tobacco products to those "manufactured to be used" for these four specific actions.

As *ENDS products* and *nicotine pouches* do not contain tobacco, a textual interpretation of the FCTC would immediately exclude them from the Convention's scope of application.

This is different for *heated tobacco products*: they involve tobacco as a raw material, even though the tobacco is not being burned or excessively heated. They would thus seem to meet the first part of the definition relating to the raw material, i.e. "entirely or partly made of the leaf of tobacco".

However, the relevant question for these products is whether the heating of tobacco amounts to "smoking, sucking, chewing or snuffing" so as to meet also the second part of the definition. Clearly, the consumer of a heated tobacco product is not sucking, chewing or snuffing the tobacco. The question remains whether heating tobacco without burning it is to be equated with "smoking" the tobacco.

The ordinary meaning of the term "smoking" – which as such is not defined in the FCTC - appears to refer to the "visible suspension of carbon and other particles in air, given off by a burning or smouldering substance."[22] The burning or smouldering substance in this case would be tobacco. In the context of ENDS, there is no tobacco to be burned and thus no combustion (i.e. "an act or instance of burning"[23]). In the context of heated tobacco products, the tobacco is heated but not burned. There is therefore no "burning or smouldering" of the substance. The verb "to smoke" is defined as to "inhale and exhale the smoke of tobacco or other substance from a pipe, cigar or cigarette."[24] The focus in these definitions is thus on the combustion or burning of the tobacco and the inhaling of the resulting smoke. That definition does not seem to fit with the way heated tobacco products are consumed. In a heated tobacco product, the consumable in the device is not combusted or burned but merely heated to the point that it creates an aerosol that is then inhaled. The product is a vaping product and not a smoking product because it is a "non-combustible" product, as has been recognized by numerous public health authorities.[25]

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[22] *Shorter Oxford Dictionary*, sixth edition, definition of the noun "smoke" p. 2886.

[23] *Merriam-Webster Dictionary*, "combustion" (2019), available from: https://www.merriam-webster.com/dictionary/combustion.

[24] *Shorter Oxford Dictionary*, sixth edition, definition of the verb "to smoke" p. 2887.

[25] FDA, "FDA News Release: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway" (30 April 2019), available at https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway (noting that these heated tobacco products are "non-combusted"); Public Health England, Evidence review of e-cigarettes and heated tobacco products (January 2018) (referring to heated tobacco products as "non-combustible" products and distinguishing ENDS from "combustible tobacco products").

In other words, because it is not combusted or burned, the heated tobacco product is a product that is partly made of the leaf of tobacco which is manufactured to be used for vaping, and not smoking.

Based on a textual analysis of the concept of "tobacco products" as defined in the FCTC it is therefore held that heated tobacco products are made of the leaf tobacco and thus potentially fall within this concept, but ENDS products, which are not made of the leaf tobacco, certainly do not. For heated tobacco products, the relevant question is whether the tobacco is used for "smoking". The preliminary conclusion based on the ordinary meaning of the term "smoking" is that this does not apply to these novel products.

The question may arise, however, whether, despite these clear textual conclusions, ENDS products could be held to fall within the scope of application of the FCTC on the basis of other principles of treaty interpretation, notably an interpretation "in the light of its object and purpose", or on the basis of principles of effectiveness and/or evolutive treaty interpretation (on the latter two, see *infra,* IV). These principles may also shed further light on the question whether heated tobacco products should be covered by the definition of "tobacco products" despite the clear textual limitations resulting from the use of the term "smoking".

The objective of the FCTC, as laid down in the aforementioned Article 3 of the Convention, is to "protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke". However, as seen above, scientifically there is a "growing consensus" that e-cigarettes "are significantly less harmful than tobacco use"[26] and that "it would be reasonable to estimate that e-cigarette use is likely to be around 95% safer than smoking".[27] In other words, with respect to ENDS products, one cannot really speak of "devastating health, social, environmental and economic consequences" and of a "spread of the tobacco epidemic" in the sense of "a global problem with serious consequences for public health", as stated in the second recital of the FCTC's preamble. It is important to note in this respect that there is also no scientific consensus that ANDS would be a "gateway" to ordinary smoking: a 2016 WHO report confirmed that the debate on this issue "is unresolved".[28]

In light of the foregoing, it has to be concluded that ENDS products do not only fall outside the scope of application of the FCTC based on the ordinary meaning of the terms of the Convention, but also, in the current state of scientific knowledge, in light of the Convention's object and purpose.

A similar conclusion seems to impose itself for heated tobacco products, which are grouped by health experts together with e-cigarettes as ANDS, and which may play an important role in a harm reduction strategy. It was concluded above that the ordinary meaning of the terms "used for smoking" does not apply to these products, in which the tobacco is used for vaping the aerosol that is produced by heating the tobacco.

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[26] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 1.
[27] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 6.
[28] Report by WHO, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), FCTC/COP/7/11, 6. Nevertheless, and despite the lack of legal force of these additional comments, the report adds that "preventing this eventuality requires making the initiation and persistence of smoking as difficult as possible" and recommends Parties that have not banned the importation, sale, and distribution of these products to consider a number of options.

The context and object and purpose of the FCTC confirms that there is no reason for reading the term "smoking" more broadly. Looking at the tobacco control-related context as well as the above described object and purpose of the FCTC of protecting consumers from the devastating health effects of tobacco consumption and exposure to tobacco "smoke" while stimulating harm reduction strategies, leads to the conclusion that the term "smoking" in this context must be equated with the "combustion" of the tobacco, since that is what causes the harm to health.

Indeed, as noted earlier, science establishes a need to distinguish between combustible and non-combustible products, as the lack of burning tobacco greatly reduces exposure to toxicants and carcinogens present in combustible tobacco cigarettes.[29] There are therefore important differences in the physical characteristics of combustible and non-combustible products, including the chemical properties of the resulting combustible smoke and the aerosol produced by ENDS and heated tobacco products.

The important role that ANDS (including heated tobacco products) can play in a strategy of tobacco harm reduction was recently emphasized in a letter by independent experts. The public health experts noted that: "[m]illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products."[30] Therefore, the context of the need to fight the tobacco epidemic and the references in for example the Convention's Preamble to the fact that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, do not necessarily apply to heated tobacco products, which are not used for "smoking".

The object and purpose of the FCTC, as reflected in Article 3 of "protect[ing] present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke", referred to above (*supra,* III.a), appears to confirm the interpretation advanced above of the term "smoking." ANDS such as heated tobacco products, would not only not be covered in light of the ordinary meaning to be given to the term "smoking" but also there is no generally agreed scientific evidence that their "consumption" has the aforementioned devastating effects. Such products rather seem to play an important positive role as part of a harm reduction policy, which is a key aspect of tobacco control. Applying the same obligations and restrictions to heated tobacco products as to tobacco products under the Convention would result in removing the less harmful alternative from the market and, in that sense, go against the need to pursue a harm reduction strategy.

[29] NASEM (2018), *Public Health Consequences of E-Cigarettes*; Abrams et al (2018), 'Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives', Annu. Rev. Public Health 2018. 39:193–213; and Letter to WHO, 'WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products', available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf.

[30] Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf

IV. Impact of principles of temporal application of treaties on the scope of application of the FCTC

This section evaluates whether the application of international law principles on the temporal interpretation of treaties calls for ANDS to be covered by the terms of the FCTC.

a. Principles of effective and evolutive treaty interpretation

The principle of *effectiveness*, *principe de l'effet utile* or *ut res magis valeat quam pereat* (it may rather have effect than be destroyed) entails that where there are two possible interpretations of a treaty, the interpretation that gives meaning and effect is to be preferred.[31]

Apart from this, the principle of *evolutive interpretation* implies that a treaty is to be interpreted in light of the contemporary legal order rather than in light of the law as it stood at the time of its adoption. This approach allows treaties to inform social life as it evolves.[32] In Europe, especially the European Court of Human Rights has developed an approach of evolutive interpretation as an interpretative method of its own.[33]

However, neither an *effective* nor *evolutive* treaty interpretation calls for an undue extensive interpretation of treaties in the sense of going beyond what is expressed in the terms of the treaty. The International Law Commission has specifically commented on this tension between an *effective* and *evolving* interpretation so as not too statically read a treaty, on the one hand, and the risk of extending the meaning of treaties illegitimately beyond their text, on the other. It has pronounced that there "are definite limits" to the use which may be made of such principles to illegitimately go beyond the text of treaties, and that "to adopt an interpretation which ran counter to the clear meaning of the terms would not be to interpret but to revise the treaty".[34]

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[31] See International Law Commission, 'Draft Articles on the Law of Treaties with commentaries' (1966) *Yearbook of the International Law Commission*, Vol. II, at 219. See further H. Gutièrrez Posse, 'La maxime ut res magis valeat quam pereat (interprétation en fonction de l'"effet utile"): les interprétations "extensives" et "restrictives"' (1972) 23 *Österreichische Zeitschrift für öffentliches Recht* 229.

[32] See R. Kolb, *The Law of Treaties: An Introduction* (Chelthenham, Edward Elgar, 2016),158; G. Distefano, 'L'interprétation évolutive de la norme internationale' (2011) 2 *Revue générale de droit international public* 373; C. Djeffal, *Static and Evolutive Treaty Interpretation: A Functional Reconstruction* (Cambridge, CUP, 2015); S.T. Helmersen, 'Evolutive Treaty Interpretation: Legality, Semantics and Distinctions' (2013) 6 *European Journal of Legal Studies* 127.

[33] The Court first mentioned this approach in the *Tyrer v United Kingdom* case, where it had to decide whether judicial corporal punishment of juveniles amounted to degrading punishment within the meaning of Article 3 of the European Convention on Human Rights. The Court held that it did. For this purpose, it held that 'the Convention is a living instrument which […] must be interpreted in the light of present day conditions', and that, '[i]n the case now before it the Court cannot but be influenced by the developments and commonly accepted standards in the penal policy of the Member States of the Council of Europe in this field': *Tyrer v The United Kingdom* App no 5856/72, 25 April 1978, para. 31. This passage inaugurated the Court's pervasive use of evolutive interpretation in later years, see e.g. *Marckx v Belgium* App no 6833/74, 13 June 1979. See further J.E. Helgesen, 'What are the Limits to the Evolutive Interpretation of the European Convention on Human Rights?' (2011) 31 *Human Rights Law Journal* 275; T. Thienel, 'The "Living Instrument" Approach in the ECHR and Elsewhere: Some Remarks on the Evolutive Interpretation of International Treaties', in J. Delbrück, U.E. Heinz, K. Odendahl, N. Matz-Lück and A. von Arnauld (eds.), *Aus Kiel in die Welt: Kiel's contribution to international law: Festschrift zum 100-jährigen Bestehen des Walther-Schücking-Instituts für Internationales Recht* (Berlin, Duncker & Humblot, 2014), 165–200.

[34] International Law Commission, 'Draft Articles on the Law of Treaties with commentaries' (1966) *Yearbook of the International Law Commission*, Vol II, at 219.

b. Application of these principles to ANDS and the FCTC

The question arises whether, despite not being named in the Convention or even conceived of at the time of its negotiation, the FCTC can be held to apply to ANDS based on an application of the international law principles of *effective* and *evolutive* treaty interpretation.

As noted above (*supra,* II.c), ANDS were not part of the negotiations for the FCTC. This is true for both e-cigarettes and other ENDS products, nicotine pouches as well as tobacco-containing ANDS such as heated tobacco products. Non-tobacco based ANDS such as ENDS products and non-combustible tobacco products were definitely not part of the FCTC at the time of its adoption. That is also what is reflected in the text of the FCTC, in particular in the definition of the two-pronged test for "tobacco products" (*supra,* III.b). As indicated by the International Law Commission, there are clear limits under international law for extending the meaning of the FCTC beyond its text as interpreted through the tools of *effective* and *evolutionary* interpretation. To utilize these tools in order to bring non-covered products within the scope of application of the FCTC, would be problematic. It would unduly extend the text of the FCTC beyond its ordinary meaning and beyond its general objectives, as stated above.

Moreover, as will be indicated below, there is no evidence that the FCTC Parties have entered into a subsequent practice that would call for these products to fall within the remit of the Convention. In fact, very few Parties to the FCTC regulate ENDS and heated tobacco products in the same way as covered "tobacco products". For example, the UK Government is actively supporting the use of non-combustible products as part of its tobacco harm reduction activities. It imposes different marketing and excise regulations, and generally allows public place vaping and retail display. Even regulators in jurisdictions that have historically prohibited alternatives to conventional tobacco products, such as Canada and New Zealand, are stepping away from such regulatory regimes. For example, with respect to ENDS , Canada in 2018 enacted a new legislative framework for ENDS products with the aim "to protect youth from nicotine addiction and inducements to tobacco use, while allowing adults to legally access vaping products as a less harmful alternative to tobacco".[35]

The International Law Commission has confirmed that "subsequent agreements and subsequent practice, like other means of interpretation, 'may assist in determining whether or not the presumed intention of the parties upon the conclusion of the treaty was to give a term used a meaning which is capable of evolving over time'".[36]

The work done to date in relation to ANDS has focused mainly on evaluating the situation in terms of their impact on tobacco control and their potential as smoking cessation tools. There therefore does not seem to be a subsequent practice to suggest that Parties consider that the same treatment should be given to covered tobacco products and ANDS.

With respect to ANDS, including tobacco containing ANDS such as heated tobacco products, an evolutive interpretation would not likely suffice to apply the FCTC to non-combustible tobacco products. Given their different characteristics and risk profile, to do so would not appear to be necessary to ensure an effective application of the FCTC either. As indicated

[35] Health Canada, https://www.legco.gov.hk/general/english/library/stay_informed_overseas_policy_updates/new-tobacco-and-vaping-products-legislation.pdf

[36] See Second Report on Subsequent Agreements and Subsequent Practice in Relation to Treaties, http://legal.un.org/docs/?symbol=A/CN.4/671, p. 50, para. 115. See also International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties. Text of the draft conclusions adopted by the Drafting Committee on second reading, 11 May 2018, A/CN.4/L.907, Conclusion 8.

above, the text and context of the term "tobacco products" and the object and purpose of the FCTC appear to militate against an expansive reading of the FCTC to a novel product that is less harmful to health and may play an important positive role in a harm reduction strategy.

Independent research by the UK Department of Health in 2017 found that consumers using heated tobacco devices are exposed to between 50-90% less "harmful and potentially harmful" compounds compared with conventional cigarettes.[37] Similarly, a report by Public Health England in 2018 found that "compared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds", and added that "[t]he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes".[38]

V. Legal relevance of COP discussions for the scope of application of the FCTC

The analysis in this section aims at verifying whether one can find in the discussions of the COP with regard to ANDS possible indications of "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" or "any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation", which would have to be taken into account for the interpretation of the FCTC, together with the context, as prescribed by Article 31(3) VCLT.

In the first place some terminological clarifications are due. A "subsequent agreement" is an agreement between the parties, reached after the conclusion of a treaty, regarding the interpretation of the treaty or the application of its provisions, while a "subsequent practice" consists of conduct in the application of a treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty.[39]

For example, in the case-law of the World Trade Organization ("WTO"), the term "subsequent agreement" has been interpreted to refer to "substance rather than to form". Thus, so as long as an agreement "clearly expresses a common understanding, and an acceptance of that understanding among Members with regard to the meaning of the term in question" it would be considered to meet the definition of a 'subsequent agreement'.[40] The Appellate Body has explained that the extent to which a subsequent agreement will inform the interpretation and application of a treaty term or provision depends on "the degree to which it 'bears specifically' on the interpretation and application of the respective term or provision".[41] This means that the subsequent agreement must represent an "authentic interpretation" of the treaty parties of the specific term or provision in question in order for it to be taken into account.[42]

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[37] Department of Health UK, Statement on the toxicological evaluation of novel heat-not-burn tobacco products (December 2017).
[38] Public Health England, Evidence review of e-cigarettes and heated tobacco products (January 2018).
[39] International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties (Text of the draft conclusions adopted by the Drafting Committee on second reading), 11 May 2018, A/CN.4/L.907, Conclusion 4.
[40] See, e.g. Appellate Body Report, *US – Clove Cigarettes*, para. 267.
[41] See, e.g. Appellate Body Report, *US – Tuna II (Mexico)*, para. 372 (referring to Appellate Body Report, *US – Clove Cigarettes*, para. 265).
[42] See, e.g. Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, paras. 389-390 (referring to "Report of the International Law Commission on the Work of its 18th Session, Geneva, 4 May-19 July 1966" (1966) II Yearbook of the International Law Commission 172, at 221, para. 14).

In the second place, in relation to "subsequent practice", the WTO has established that this requires a "concordant, common and consistent" sequence of acts or pronouncements, which are sufficient to establish a discernable pattern implying the agreement of the parties regarding a particular interpretation of a treaty term or provision.[43] In one instance, the International Court of Justice has even held that a subsequent practice of the parties to a treaty "can result in a departure from the original intent on the basis of a tacit agreement".[44] This is, however, not the case in the WTO where the Appellate Body has made it clear that it would not accept an interpretation that would result in a modification of a treaty obligation, as this would not anymore be an "application" of an existing treaty provision.[45] On the basis of this apparent divergence, Professor Georg Nolte, Special Rapporteur for the International Law Commission, recently noted that "a treaty may preclude the subsequent practice of the parties from having a modifying effect. Thus, the treaty itself governs the question in the first place"[46] and that "[t]he possibility of amending or modifying a treaty by subsequent practice of the parties has not been generally recognized" in international law.[47]

In the third place, the obligation under Article 31(3)(c) of the VCLT to take account of any relevant rules of international law applicable in the relations between the parties requires a systemic interpretation of all relevant international law rules. Specifically, an interpretation may have to take account of material sources external to a treaty, such as other treaties, customary rules, or general principles of law, which are relevant to the interpretation of the treaty term or provision in question to arrive at a consistent meaning.[48] The International Court of Justice endorses this position, stating for example that "an international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of the interpretation".[49] In the WTO, the Appellate Body has referred with approval to the above-quoted statement by the International Court of Justice.[50] It has also explained that in order for another rule of international law to be "relevant" it needs to "concern the same subject matter as the treaty terms being interpreted",[51] and that it is likely insufficient for the rule to apply only between *some* of the WTO Members for it to be relevant.[52]

In light of the foregoing considerations it needs to be considered whether the FCTC Parties have entered into a subsequent agreement or practice since the inception of the FCTC, or whether there exists an applicable rule of international law, that would call for the treaty to apply to ANDS.

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[43] See, e.g. Appellate Body Report, *Japan – Alcoholic Beverages II*, para. 26.
[44] *Dispute regarding Navigational and Related Rights (Costa Rica v. Nicaragua)*, Judgment, I.C.J. Reports 2009, para. 64; see also *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970)*, Advisory Opinion, I.C.J. Reports 1971, para. 22.
[45] See, e.g. Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 391.
[46] G. Nolte, Second report on subsequent agreements and subsequent practice in relation to the interpretation of treaties (26 March 2014), A/CN.4/671, para. 139.
[47] International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties (Text of the draft conclusions adopted by the Drafting Committee on second reading), 11 May 2018, A/CN.4/L.907, Conclusion 7, para. 3.
[48] Report of the Study Group of the International Law Commission, "Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law", 2006, p. 180.
[49] *Namibia (Legal Consequences)*, Advisory Opinion I.C.J. Reports 1971, p. 31.
[50] Appellate Body Report, *US – Shrimp*, fn. 109.
[51] Appellate Body Report, *US – Anti-Dumping and Countervailing Duties (China)*, para. 308.
[52] Appellate Body Report, *EC and certain member States – Large Civil Aircraft*, para. 845.

The FCTC was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. As indicated above, this is before the globalization of ENDS and heated tobacco products, which first entered the European and US markets in 2006 and 2007 respectively, whereas heated tobacco products have come on the market more recently (see *supra,* II.c).

It was only years after the inception of the FCTC that the Parties started to analyze ANDS:

- In 2008, the FCTC Working Group on Articles 9 and 10 made a recommendation in its report to the Third session of the COP (COP3) to request the WHO to identify best practices in reporting to regulators on the contents, emissions and the characteristics of products, including electronic systems (see Decision FCTC/COP3(6));
- In 2010, the FCTC Secretariat presented a report to the Fourth session of the COP (COP4) on the Control and Prevention of Smokeless Tobacco Products and Electronic Cigarettes (see Report FCTC/COP/4/12). The report noted that there was a growing global concern about the quality, safety and "regulatory gap" of these emerging products, broadly called ENDS;
- Also in 2010, the FCTC Working Group on Articles 9 and 10 requested the COP to indicate whether it agreed that ENDS are to be considered "tobacco products" and should be part of future work of the working group (FCTC/COP/4/6 Rev.1). There was, however, no decision made on whether ENDS should be considered tobacco products;
- In 2012, the COP5 requested the Convention Secretariat to identify options for the prevention and control of ENDS and to examine emerging evidence on the health impacts of ENDS use (see Decision FCTC/COP/5/13);
- In 2014, the COP6 requested the Convention Secretariat to invite the WHO to prepare a report on ENDS and electronic non-nicotine delivery systems (ENNDS) for the Seventh session of the COP (COP7) (See Decision FCTC/COP6(9)). The WHO also presented a report to COP6 on the evolution of novel tobacco products (see Report FCTC/COP/6/14);
- In 2016, the WHO presented the report to COP7 updating the evidence of the health impact of ENDS/ENNDS, their potential role in tobacco cessation and their impact on tobacco control efforts, as well as an assessment on regulatory options (see Report FCTC/COP/7/11);
- Also at COP7, a decision was taken inviting the Parties to consider applying some regulatory measures suggested in the report prepared by the WHO, such as prohibition or restriction of the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS (see Decision FCTC/COP7(9));
- In 2018, the FCTC Secretariat presented a report to the Eight session of the COP (COP8) on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (see Report FCTC/COP/8/10); and
- The COP8 stated in its decision on novel and emerging tobacco products that "heated tobacco products are tobacco products and are therefore subject to the provisions of the WHO FCTC" (see Decision FCTC/COP8/(22)).

Based on the foregoing synopsis of the work of the FCTC in the area of ANDS, there is support for concluding (i) that the FCTC has not adopted a subsequent agreement or practice on

applying the FCTC to non-tobacco ANDS such as ENDS products; and (ii) that it should be examined further whether there is a subsequent agreement or subsequent practice that the FCTC applies to other ANDS tobacco products developed after the inception of the Convention.

First, in relation to non-tobacco ANDS such as ENDS products, there is no evidence that the FCTC Parties have reached a subsequent agreement or entered into a subsequent practice that would call for these products to fall within the remit of the treaty. The work done to date has focused mainly on evaluating the situation in terms of the impact of these products on tobacco control and their potential as smoking cessation tools, as well as to identify best practices among the Parties. Importantly, in 2010, at the direct request from the FCTC Working Group on Articles 9 and 10, the Parties considered but did not take a decision recognizing that ENDS are to be considered "tobacco products". Accordingly, there appears to be no evidence that the FCTC Parties "clearly expresse[d] a common understanding" that non-tobacco ANDS shall be covered by the Convention.[53] In particular, there is no subsequent agreement that "bears specifically"[54] on the interpretation and application of a specific FCTC term or provision that would call for such ANDS to be covered by the Convention, as the work done to date has focused on evaluating the impact of these products on tobacco control and their potential as smoking cessation tools. Nor does it seem that there has been a "concordant, common and consistent" sequence of acts or pronouncements, sufficient to establish a discernable pattern, implying the agreement of the FCTC Parties that non-tobacco ANDS shall be covered by the Convention.[55] Moreover, to our knowledge there are no other relevant rules of international law that would seem to bear upon the interpretation of the FCTC so as to include non-tobacco ANDS within its remit.

Second, in relation to heated tobacco products, the above referenced COP8 Decision FCTC/COP8/(22) "recognizes" in its preamble that such products are "tobacco products and are therefore subject to the provisions of the WHO FCTC".[56] Moreover, in its para. 5, the Decision

> "REMINDS Parties about their commitments under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products such as heated tobacco products and devices designed for consuming such products, and consider prioritizing the following measures in accordance with the WHO FCTC and national law:
> (a) to prevent the initiation of novel and emerging tobacco products;
> (b) to protect people from exposure to their emissions and to explicitly extend the scope of smoke-free legislation to these products in accordance with Article 8 of the WHO FCTC;
> (c) to prevent health claims from being made about novel and emerging tobacco products;
> (d) to apply measures regarding advertising, promotion and sponsorship of novel and emerging tobacco products in accordance with Article 13 of the WHO FCTC;
> (e) to regulate the contents and the disclosure of the contents of novel and emerging tobacco products in accordance with Articles 9 and 10 of the WHO FCTC;
> (f) to protect tobacco-control policies and activities from all commercial and other vested interests related to novel and emerging tobacco products, including interests of the tobacco industry, in accordance with Article 5.3 of the WHO FCTC;

[53] See, e.g. Appellate Body Report, *US – Clove Cigarettes*, para. 267.
[54] See, e.g. Appellate Body Report, *US – Tuna II (Mexico)*, para. 372 (referring to Appellate Body Report, *US – Clove Cigarettes*, para. 265).
[55] See, e.g. Appellate Body Report, *Japan – Alcoholic Beverages II*, para. 26.
[56] Sixth recital to the preamble of Decision FCTC/COP8/(22).

(g) to regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products, as appropriate to their national laws, taking into account a high level of protection for human health;
(h) to apply, where appropriate, the above measures to the devices designed for consuming such products;"

At first glance, the explicit language in the preamble and in the operational part of Decision FCTC/COP8/(22) appears to express the view of the COP that heated tobacco products fall within the scope of application of the FCTC as "tobacco products". However, the question arises whether the "recognition" in the Preamble of this non-legally binding Decision of the COP and the "reminder" of existing commitments in the FCTC which apply to "tobacco products" suffice to constitute a subsequent agreement or a subsequent practice. In this respect, it should first of all be noted that the Decision does not "bear specifically" on the question whether novel tobacco products are covered by the definition of "tobacco products". In fact, it simply asserts as much in the Preamble. Importantly, in the Preamble, the Decision also "recognizes" that "some Parties have adopted various regulatory strategies with respect to heated tobacco products, in particular concerning their inclusion in smoke-free legislation,"[57] thereby indicating that the Parties do not share the common understanding that novel tobacco products should be treated the same way as covered tobacco products. This casts doubt on the extent to which there is a shared understanding of whether heated tobacco products actually are covered or should be covered by the definition of tobacco products under the CFTC such that all rules and restrictions apply.

Nor does it appear that this "recognition" in the preamble of this Decision or the general reminder of existing FCTC commitments amounts to a "concordant, common and consistent" sequence of acts or pronouncements, which are sufficient to establish a discernable pattern implying the agreement of the parties regarding a particular interpretation of a treaty term or provision. In fact, the reason why attention is given to ENDS and novel tobacco products seems to be because there is no common practice of treating these products in the same way as covered tobacco products. If it remains isolated to a single occurrence, the Decision's "recognition" can hardly be seen as a common and consistent sequence of acts and pronouncements. Had there been a common understanding among the Parties that heated tobacco products are covered tobacco products to which the same commitments apply, there would have been no need for the discussion that was had in the most recent COP meetings.

Therefore, with regard to heated tobacco products the COP8 Decision does not appear to be sufficient evidence for a subsequent practice, in the sense that it would amount to "conduct in the application of the treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty". As seen above, in practice a number of Parties to the FCTC do not treat ANDS the same way as covered tobacco products. If the Parties wanted to amend the FCTC, there is a mechanism for this which requires consensus. Given the very divergent approaches to ANDS, including heated tobacco products, there is not likely to be such a consensus.

[57] Eighth recital to the preamble of Decision FCTC/COP8/(22).

VI. A Final Word on the Relevance of the FCTC to ANDS

This legal opinion considers that the FCTC does not apply to ANDS, for the reasons set out above. There is one aspect of the FCTC that does seem worth highlighting as it further supports the above conclusion that it would not be approriate to apply the same strict tobacco-related regulation to ANDS.

In defining tobacco control, Article 1(d) of the FCTC refers to the adoption of "harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke" (emphasis added).

The WHO has also recognized the role of tobacco harm reduction, stating that "[i]f the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement."[58]

In sum, the FCTC recognizes harm reduction as a part of the strategy for improving public health by reducing tobacco consumption and exposure to tobacco smoke. Tobacco control and public health are furthered through reducing exposure to tobacco and smoke, which is equally recognized in Article 3 on the "Objective" of the treaty. The question therefore arises whether a proper application of the FCTC should not require a more favourable treatment of ANDS.

The harm reduction approach to tobacco control in the context of ANDS has much support from a range of stakeholders. The letter of 72 health experts to the WHO referred to earlier in this opinion emphasizes that authorities should "adopt a more positive approach to new technologies and innovations that have the potential to bring the epidemic of smoking-caused disease to a more rapid conclusion".[59] Noting that the "the major distinction between nicotine products is whether they are combustible or non-combustible",[60] these experts recommend that the "FCTC and its implementation should embrace 'risk-proportionate regulation'", which "means that the stringency of regulation or taxation applied to product categories should reflect risk to health".[61] They continue:

> "WHO and Parties to the FCTC should be aware of and careful to avoid the harmful unintended consequences of prohibitions or excessive regulation. If WHO-endorsed policies make noncombustible alternatives to smoking less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibit innovation and development of new and improved products, then these policies can cause harm by perpetuating smoking".[62]

Additionally, the impact of excessive regulation on the ANDS sector was underscored in a recent independent, peer-reviewed research publication which found that:

> "[w]ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and

[58] WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems ("ENDS") and Electronic Non-Nicotine Delivery Systems ("ENNDS") to the seventh session of the Conference of the Parties*, available at http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf at paragraph 5.
[59] See https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf, at p. 1.
[60] Ibid.
[61] Ibid, at p. 2
[62] Ibid. (underlining added)

by country income" and "[i]n contrast to many of the [less restrictive policies] and [restrictive policies] countries, rates of use were quite low in the [most restrictive policies] countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of [nicotine vaping products] laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them".[63]

In sum, by prohibiting or severely restricting the sales of these new categories of products and/or by extending to them combustible regulations as would be the consequence of applying the strict requirements of the FCTC to ANDS, countries could unwillingly contribute to perpetuating smoking. The question arises whether such policies would be fully consistent with the harm reduction considerations of the FCTC.

VII. Conclusion

The analysis in the opinion leads to the following conclusions:

1. The chronology of events confirms that ANDS were not part of the covered products of the FCTC at the time of its adoption, since they did not exist as such.

2. In accordance with the general rules of treaty interpretation of the Vienna Convention on the Law of Treaties, ENDS products and nicotine pouches do not only fall outside the scope of application of the Framework Convention on Tobacco Control based on the ordinary meaning of the terms of the Convention, but also, in the current state of scientific knowledge, in light of the Convention's object and purpose.

3. Heated tobacco products, by contrast, meet the first part of the definition of covered tobacco products for the purpose of the application of the FCTC since they contain tobacco. However, they do not appear to meet the second part of the definition, which requires that the tobacco products "are manufactured to be used for smoking, sucking, chewing or snuffing". Heated tobacco products do not involve burning the tobacco and inhaling the smoke of the burnt tobacco. They merely imply the vaping of the aerosol created by heating the tobacco. The context as well as the object and purpose of the FCTC seem to confirm that novel tobacco products do not fall within the scope of application of the Framework Convention on Tobacco Control.

4. There is no evidence that the Parties to the Framework Convention on Tobacco Control have entered into a subsequent agreement or subsequent practice that brings non-tobacco products such as ENDS products and nicotine pouches within the remit of the Convention.

5. The Preamble to Decision FCTC/COP8/(22) of the Conference of the Parties to the Framework Convention on Tobacco Control appears to reflect the view of the Conference of the Parties that heated tobacco products fall within the scope of application of the FCTC as "tobacco products". However, for various reasons, this single reference in the Preamble to this Decision is insufficient to amount to a

[63] Gravely, et al (2019) "Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project", *Addiction*. Available at https://doi.org/10.1111/add.14558.

subsequent agreement or subsequent practice within the meaning of Article 31(3)(b) of the Vienna Convention on the Law of Treaties, in the sense that it amounts to "conduct in the application of the treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty". In fact, the Parties' application of the FCTC with respect to novel tobacco products confirms a widely divergent practice, as some parties promote the use of novel tobacco products as part of a harm reduction strategy, while others treat them as ordinary tobacco products. A statement in the Preamble of this single Decision does not change that reality, and cannot amend the text of the definition of covered products by expanding it to apply to products made of tobacco that is not intended for smoking, sucking, chewing or snuffing.

Date: 9 July 2019

Signature:

Prof. Dr. Jan Wouters

Appendix 9

Alternative Nicotine Delivery Systems (ANDS) such as e-cigarettes and heated tobacco products

Legal Opinion on Consistency of their Ban with WTO Law

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Terms of Reference and Executive Summary

I am a professor of WTO Law at Columbia Law School, New York and at the University of Neuchâtel. I am associate editor of the Journal of World Trade, on the editorial board of The World Trade Review, and several Columbia Law journals. I recently served as chief co-rapporteur at the American Law Institute (ALI) for the project "Principles of International Trade Law: The WTO" (2013).

I am the author and editor of several books on international trade law. My most recent publication is The Regulation of International Trade, MIT Press, 2016, which won the 2017 Certificate of Merit in a Specialized Area of International Law from the Executive Council of the American Society of International Law (ASIL). I have also written around 80 articles referenced in peer-reviewed journals, and 80 chapters in books. A full CV is attached.

I was asked to opine on the consistency of a measure that would ban the importation and sale of novel tobacco products such as heated tobacco products as well as other new types of "electronic nicotine delivery systems" including e-cigarettes ("ENDS"). E-cigarettes are handheld devices that heat a liquid containing nicotine and flavours that are heated to form a vapour, which is inhaled to simulate the experience that smokers have but do not involve tobacco and often do not even look like a traditional cigarette. Heated tobacco products only heat tobacco and generate a nicotine-containing vapour. These products produce an aerosol that provides nicotine as well as a sensation similar to that of smoking traditional cigarettes (TC), but do not involve the burning of tobacco, and are thus non-combustible products.

Both novel products come under the generic term of "Alternative Nicotine Delivery Systems" (ANDS), a term that has been used by health experts for grouping these non-combustible products.[1] Recently, independent health experts have found that ANDS play an important role in a harm reduction strategy, precisely because they function as a less harmful alternative to smoking TCs.[2] Health experts, consequently, have called for a positive, less restrictive

[1] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, p. 2, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[2] There are various studies, which support the view that ANDS, while addressed primarily to smokers and aiming to act as substitute for TCs, are less of a health concern than TCs, see, for example, https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040617-013849. This observation is important for various parts of the legal analysis included in this Note. How can, to provide but an illustration, a measure be judged necessary to protect human health, if it addresses the lower risk for human health (that represented from

regulatory approach to ANDS. Indeed, it goes beyond the scope of this legal opinion, but it appears that the international legal regime on the right to health would indeed require a less rather than a more restrictive regime for these products. Depriving smokers of this less harmful alternative would go against the internationally protected right to health of those that smoke.[3] In sum, there is no doubt, as these letters as well as a recent scientific study also demonstrate,[4] that ANDS may provide an alternative to traditional cigarettes, since the risk to human health is likely to be reduced.

An import and sales ban is under consideration against ANDS in, for example, Singapore and Hong Kong (China).

For the purposes of this Note, I use the English translation of the Singaporean law as an accurate description of the measure, the consistency of which with the relevant WTO law I will analyse as an example.

The question is whether the ban on ANDS is consistent with the relevant WTO law. As the measure stands, it would be characterized as import embargo, since the letter of the law leaves us in no doubt that imports of ANDS will not be allowed in Singapore.

One cannot exclude, nevertheless, that a panel characterizes the measure as a domestic sales ban of ANDS. In this case, the domestic sales ban, would simply be enforced at the border (and would cover imported ANDS).

The legal test for consistency of an import ban, and a domestic sales ban, under the GATT, is not identical. We will be examining the consistency of the measure with WTO law under either scenario.

In addition, if the measure does not take the form of a simple ban, but, rather, the form of a technical regulation that lays down product characteristics of tobacco products and related

consumption of ANDS), while leaving un-addressed the higher risk emanating in the consumption of the substitute product, namely, TCs?

[3] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[4] https://journals.sagepub.com/doi/pdf/10.1177/2397847318773701.

products, such as arguably ANDS, the consistency of the measure could also be examined under the disciplines of the Agreement on Technical Barriers to Trade (TBT Agreement). Very similar considerations relating to discrimination and the requirement that the measure be "necessary" to fulfil the legitimate health objective as discussed in this note would apply under, in particular Articles 2.1 and 2.2 of the TBT Agreement respectively. In particular, Article 2.2 requires that a technical regulation not be more trade restrictive than necessary. Given the potential contribution to harm reduction offered by ANDS as highlighted by independent health experts, a measure that effectively bans ANDS or that imposes the same restrictions that are justified on TCs would have a very trade restrictive effect on these novel products in an emerging market. Therefore, even applying the same restrictions on ANDS as are applied to TCs necessarily appears to be violating this important provision given its highly trade restrictive character of a measure that would go against the health objective of harm reduction. Given that we are considering a straightforward ban on ANDS, we will not further address the TBT Agreement in this Note.

In summary form, our conclusion is that an import ban on ANDS violates Article XI of GATT, since it constitutes a prohibition on importation, and thus a prohibited zero import quota. In addition, assuming the measure is characterized as domestic sales ban, our conclusion remains that a sales ban on ANDS, while no ban has been imposed on TCs, violates Article III of GATT. Our conclusion is based on the fact that ANDS and TCs are like products and a ban on imported ANDS, while allowing the sale of domestic TCs, amounts to Less Favourable Treatment for imported like products. As we explain in this Note, there is no need to inquire into the regulatory intent of the discriminatory ban on ANDS since any modification of the conditions of competition to the detriment of imported like products is prohibited.

Finally, we consider that the regulating Member will fail in trying to justify its measures under the general exceptions of Article XX of GATT, irrespective of whether the established violation concerns Article III or XI of GATT. There are good reasons to believe that the regulating Member will not meet the necessity-requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary, it seems. In any case, even if the regulating Member were to be successful in demonstrating the

"necessity" of the ban on ANDS, its measure will fail the requirements of the chapeau of Article XX of GATT. This is so because, the ban is a disguised restriction on trade and applied in a manner that constitutes unjustifiable discrimination: in the name of protecting human health (and/or public morals), the regulator will be banning the sale of certain goods while not banning the sale of like goods that are at least as harmful to health and probably much more harmful to health. Thus, it will find it impossible to explain why its decision to ban some and not other (more harmful) products, is rationally connected with the health objective of the measure. In sum, the measure is in violation of the GATT/WTO commitments of the regulating Member. The precautionary principle is of no relevance to the applicable GATT/WTO obligations and cannot, therefore, be invoked to save the measure.

To the extent that there exists a more general regime under public international law in favour of a right to health, it seems clear that this measure is inconsistent with such a right as it deprives smokers of products that are likely to be less harmful to health and that fulfil a similar end use. This was highlighted in a letter of seventy-two independent health experts, as discussed below.

1. Import Ban on ANDS

Since we deal with an import ban, the relevant provision is Article XI of GATT. Consequently, the legal question before us is, whether an import ban on ANDS is consistent with this provision.

Article XI.1 of GATT reads:

> No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

Since the early GATT case France-Import Restrictions, it is clear that measures expressed in numbers (e.g., 1,000 tons of widgets; or, 1,000 litres of widgets) are considered quotas, that is, one of the three forms that a quantitative restriction can revert into.

In *India – Quantitative Restrictions*, the panel (§5.129), when interpreting the term "restriction" appearing in the body of Article XI of GATT, clarified that this term covers both import- as well as export restrictions. We quote the relevant passage:

> [T]he text of Article XI:1 is very broad in scope, providing for a general ban on import or export restrictions or prohibitions 'other than duties, taxes or other charges'. As was noted by the panel in Japan –Trade in Semi-conductors, the wording of ArticleXI:1 is comprehensive: it applies 'to all measures instituted or maintained by a [Member] prohibiting or restricting the importation, exportation, or sale for export of products other than measures that take the form of duties, taxes or other charges.' The scope of the term 'restriction' is also broad, as seen in its ordinary meaning, which is 'a limitation on action, a limiting condition or regulation'.

A ban on imports of ANDS is obviously a covered "prohibition" on importation, as it imposes a zero quota.

There is no need to demonstrate that the measure has had certain trade effects, even if it would be quite obvious that a measure that bans all imports has an effect on trade.

Nor does the regulatory intent matter. In other words, it is irrelevant that a Member such as Singapore did not seek to protect a domestic industry.

Standing case law already from the GATT-era (Japan – Trade in Semi-conductors; US – Superfund) has confirmed the above, and has consistently held that there is no room for reviewing the regulatory intent within the four corners of complaints under Article XI of GATT.

This analysis leads to the conclusion that an import ban of ANDS is not consistent with WTO Members' obligations under Article XI of GATT.

Conclusion under GATT Article XI

A ban on imports of ANDS is a violation of Article XI of GATT.

2. Sales Ban on ANDS

The challenged measure could be re-phrased, as we have suggested in the introduction to this Note, and presented as a sales (as opposed to an import-) ban. The Interpretative Note ad Article III of GATT reads:

> Any internal tax or other internal charge, or any law, regulation or requirement of the kind referred to in paragraph 1 which applies to an imported product and to the like domestic product and is collected or enforced in the case of the imported product at the time or point of importation, is nevertheless to be regarded as an internal tax or other internal charge, or a law, regulation or requirement of the kind referred to in paragraph 1, and is accordingly subject to the provisions of Article III.

If the measure, thus, were re-designed to read that "sales of ANDS are prohibited within the sovereignty of …", it could be enforced at the border with respect to imported ANDS, just like an import embargo. It will, in other words, operate as an import ban, even though the legal nature of the measure suggests that it qualifies as a behind the border non-tariff barrier.

Contrary to the scenario discussed under Section 1, the measure, as re-phrased here, applies to both imported, as well as domestic goods.

In this scenario, the relevant legal question is whether there is treatment less favourable for imported goods when compared to treatment afforded to domestic "like" goods.

A sales ban is a domestic (behind the border) measure, and as such, it must observe the discipline embedded in Article III.4 of GATT. A sales ban as envisaged here is covered by the disciplines of Article III.4 since it is undoubtedly a law, regulation or requirement affecting commerce (i.e. the products' internal sale, offering for sale, purchase, transportation, distribution or use).

The sequence established (in the sense of order of analysis), is to first examine what is the class of goods that are considered "like", and then, examine if imported goods have been afforded "less favourable treatment" (LFT).

2.1 Are ANDS and Traditional Cigarettes Like/Directly Competitive or Substitutable (DSC) Goods?

For the purposes of our discussion, we assume that the claim is that the sales ban concerns ANDS (domestic and imported), and does not concern domestic and imported traditional cigarettes (TCs). So, while TCs irrespective of origin can be sold in a given market, ANDS cannot.

The question we address here is whether an imported ANDS, and a domestic TC are like products. In this vein, we can draw strong parallels with *EC – Asbestos*, the leading case under Article III.4 of GATT, which dealt with a dyad of goods of this sort.

The term "like products" appears in both Article III.2 as well as III.4 of GATT. The former provision distinguishes between "like" and "directly competitive products". Both terms refer to the competitive relationship between domestic and imported goods, the first to an intense, and the second to a looser competitive relationship. In *Japan – Alcoholic Beverages II*, the Appellate Body held that two goods are like, if they are in a strong competitive relationship. The latter could be evidenced, for example, when two goods share the same elaborate classification. In this case, the Appellate Body held that, sharing the same six-digit classification, was enough of an indication supporting a finding of likeness (pp. 23-24). In a subsequent case, in *Philippines – Distilled Spirits*, the Appellate Body underscored that it was not necessary to share the same six-digit classification for two goods to be like. What mattered was that they were in a strong competitive relationship (§§182, and 226 *et seq.*).

In our case, TCs and ANDS do not share the same six-digit classification. The former come under HS 2402, whereas ANDS can come under various headings. In fact, there is still quite a bit of debate on where these new products should be classified. This debate is still ongoing before the World Customs Organization (WCO).

As per the ruling on *Philippines – Distilled Spirits* though, the fact that ANDS and TCs do not share the same six-digit classification, is not determinative of whether the goods are

"like" one another.[5] More important than classification, the adjudicator will have to look into other criteria before concluding whether this is or is not the case, such as, among others, physical characteristics, end uses, and consumer preferences.

We submit that in this case, the answer is clear. In *EC – Asbestos*, the Appellate Body held that the term "like" in Article III.4 of GATT should be understood as encompassing not only "like" as per Article III.2 of GATT, but also directly competitive or substitutable ("DCS") goods as per the same provision (§§98-100). Consequently, even goods in looser competitive relationship can still be considered "like" as per Article III.4 of GATT.

Competitive relationship is of course, a matter of appreciation by consumers. Case law has consistently underscored that, in the context of claims discussed under Article III of GATT, it is consumers that will decide whether two goods are competing with each other. Products' physical characteristics, end uses, and, of course preferences of consumers are key factors, as per standing case law, in deciding on the competitive relationship across two goods. ANDS, on the one hand, and TCs, on the other, share the same end use of delivering nicotine. "Satisfying an addiction to nicotine" and "creating a pleasurable experience associated with the taste of the cigarette and the aroma of the smoke" are end-uses of TCs that were recognized by the Appellate Body in *US – Clove Cigarettes*. Similarly, satisfying nicotine cravings and creating a pleasurable experience with the taste and aroma of the vapour are end-uses that apply to ANDS.[6] There is ample empirical evidence to this effect. The Appellate Body has ruled that the evidence on end-uses (and of consumer preferences) of the products is especially relevant in cases where the evidence relating to properties, nature and quality of the products indicates that the products at issue are physically different.[7]

What about price? Consumers, after all, are typically characterised by scarcity of monetary resources, and purchases by definition comport an opportunity cost. In *Korea – Alcoholic Beverages*, the Appellate Body relegated them to second order concern (§§114 et seq.). So,

[5] Nor is it so that because of a "like" product conclusion, the tariff classification of these products needs to be the same. Tariff classification is not what is driving the likeness determination and vice versa. The fact that products are "like" product does not in any way require that they be treated the same for tariff classification purposes. The latter is simply a matter of customs law and principles which focus on the physical characteristics of the product rather than their competitive relationship.

[6] Appellate Body Report, *US – Clove Cigarettes*, para. 132.

[7] Appellate Body Report, *EC – Asbestos*, para. 118.

while important, it is not the decisive concern in the eyes of the Appellate Body. At any rate, the fact that consumers use these products to serve a similar end-use and the fact that they are normally sold through similar distribution channels at similar retail places suggests that the two goods we discuss here (ANDS, TCs) are like goods.

And what about health concerns? How do they influence choice by consumers? In *EC – Asbestos*, the Appellate Body held that a reasonable consumer would always prefer a health-promoting over a health-impairing good (that could share the same intended function), and hence the two goods should be regarded unlike. In that case, the Appellate Body was dealing with construction material some made of asbestos (health-impairing), and some of fibres (health-promoting).

Would this reasoning apply here to support a conclusion that ANDS and TCs are not "like" products? The short answer is no. In *EC – Asbestos*, the Appellate Body was dealing with a different situation: consumers knew that some construction material is carcinogenic and some is not. This is not the case here. Both TCs and ANDS represent a risk to human health, even if the risk is of a different nature and degree.

Therefore, and since both products serve the same purpose, reasonable consumers will treat TCs and ANDS as like goods. Since imported ANDS and domestic TCs are like goods, the question we need to now address is whether the ban on ANDS constitutes LFT. We turn to this issue in what now follows.[8]

[8] Although like products require similar treatment in terms of taxation and laws and regulations affecting the sale of the product, it would not be correct to conclude that different excise tax treatment or a different regulatory regime could not be necessary, adequate and proportionate. In fact, in the situation under examination, it would seem permissible and rational to apply a different, more favourable tax and regulatory regime to potentially less harmful, "like products", such as ANDS, since such a different treatment would be justified as necessary for the protection of health and any distinctions would be related to this objective of health protection given the role played by ANDS in a harm reduction strategy. In fact, precisely because of that, most countries have been imposing significantly less burdensome taxes for these different, but competitively "like products" and have not imposed the same strict regulations on ANDS as have been applied to TCs, since this would mean the failure of the new categories. By way of example, most recently, the US FDA in its decision to allow the sales of Heated Tobacco Products in the United States as "appropriate" to protect public health and allowed for forms of advertising via social media different from what is the case for TCs. See, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders A more lenient regulatory treatment has also been proposed in Canada. See https://www.newswire.ca/news-releases/new-tobacco-and-vaping-products-legislation-receives-royal-assent-683483681.html Canada's Bill S-5 allows for more flavours for vapour than for cigarettes (which is none including no menthol) as well as some advertising freedoms that are not afforded to combustibles such as sponsorships and celebrity endorsements. This different, more favourable approach can be justified in light of the text of Article XX of the GATT that nothing prevents the adoption of measures necessary to protect health.

2.2 Does the Sales Ban Afford Less Favourable Treatment to Imported ANDS?

Case law has established that the LFT-requirement embedded in Article III.4 of GATT incorporates the categoric imperative of Article III.1 of GATT to avoid applying domestic measures so as to afford protection to domestic production, without requiring a demonstration of such protectionist intent or effect. In *EC – Bananas III*, the Appellate Body held to this effect that (§ 216):

> Article III:4 does not specifically refer to Article III:1. Therefore, a determination of whether there has been a violation of Article III:4 does not require a separate consideration of whether a measure afford[s] protection to domestic production.

In *EC – Seal Products*, the Appellate Body was evaluating the consistency of a measure conditioning access of seal products upon the satisfaction of certain process-related requirements. In §§5.109-110 of its report, the Appellate Body dismissed the relevance of regulatory intent, when discussing whether the challenged measure was affording LFT to imported (like) goods in the following manner:

> The proposition that distinctions may be drawn between imported and like domestic products without necessarily according less favourable treatment to the imported products implies only that the "treatment no less favourable" standard, under Article III:4, means something more than drawing regulatory distinctions between imported and like domestic products. There is, however, a point at which the differential treatment of imported and like domestic products amounts to "treatment no less favourable" within the meaning of Article III:4. The Appellate Body has demarcated where that point lies, in the following terms:
> [T]he mere fact that a Member draws regulatory distinctions between imported and like domestic products is, in itself, not determinative of whether imported products are treated less favorably within the meaning of Article III:4. Rather, what is relevant is whether such regulatory differences distort the conditions of competition to the detriment of imported products. If so, then the differential treatment will amount to treatment that is "less favourable" within the meaning of Article III:4. In the light of the above, we do not agree with the European Union's reading of the Appellate Body's statement in EC–Asbestos. Specifically, we do not consider that the Appellate Body's statement that a Member may draw distinctions between imported and like domestic products without necessarily violating

> Article III:4 stands for the proposition that the detrimental impact of a measure on competitive opportunities for like imported products is not dispositive for the purposes of establishing a violation of Article III:4.

It follows that detrimental impact suffices in and of itself to meet the LFT-requirement. The relevant detrimental impact is the impact on "competitive opportunities". The impact is thus to be determined in the sense of the potential (as opposed to occurrence) for adverse trade effects. This suffices in and of itself to meet the LFT-requirement. In this respect, we recall also that Article III of GATT aims to protect competitive conditions, and not quantified or quantifiable trade targets. It, therefore, protects latent or potential competition as well as actual competition. Consequently, a ban on sales of imported ANDS (a like product to domestic TCs) and the consequential absence of sales ban for domestic TCs qualifies as LFT.

Furthermore, the GATT panel report on US – Superfund has dismissed the relevance of trade effects when it comes to demonstrating a violation of Article III.4 of GATT. In *Korea – Various Measures on Beef*, the Appellate Body confirmed this finding (§267). The consequence is quite straightforward. The complainant has to show differential treatment, without having to show how it has actually affected imported goods. In this vein, the absence of domestic production is irrelevant as well. A domestic ban violates Article III.4 even if there is no domestic production of either ANDS or TCs. What matters is that consumers view TCs and ANDS in a given market as like products and LFT is accorded to ANDS. And, of course, similar measures would violate Article I.1 as well, since this provision explicitly extends the coverage of the MFN clause to matters coming under the aegis of Article III of GATT.

Conclusion under GATT Article III

When the ban on ANDS is viewed as a domestic sales ban that is covered by the disciplines of Article III.4 of GATT, the conclusion is once again that it violates the relevant GATT/WTO commitment of the regulating Members since it imposes less favourable treatment on imported ANDS that are like domestic TCs. Neither the regulatory intent nor the lack of domestic production of TCs is relevant in this respect.

2.3 Preliminary Conclusion

Our analysis so far supports the conclusion that, no matter whether expressed as an import ban, or as a sales ban, a prohibition of ANDS to access a market, while allowing for the sale of TCs is inconsistent with the GATT.

In the first case, the measure will be in violation of Article XI of GATT, and in the second case, the measure will violate Article III of GATT.

The regulator, assuming no recourse to a request for waiver is made, can only defend its policies by invoking Article XX of GATT. We turn to this discussion in what now follows.

3. Responding to Invocation of Article XX of GATT

The party invoking Article XX of GATT (the WTO member imposing the import/sales ban) carries the associated burden of proof. In *US – Gasoline*, the Appellate Body explained that the party invoking this provision, will have to satisfy a two-tiered test (p. 22):

> first, provisional justification by reason of characterization of the measure under XX(g); second, further appraisal of the same measure under the introductory clauses of Article XX.[9]

Thus, as explained further below, the party adopting the measure would have the burden of proof of the following:

- That the measure falls within one of the subparagraphs of Article XX (e.g. public health or public morals);
- That the measure is "necessary" to achieve that aim;
- That the measure does not constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevail; and
- That the measure is not a disguised restriction on international trade.

The party complaining about the import and sales ban will have, of course, the opportunity to rebut the arguments and evidence presented by the regulating party. Since the ball is on the

[9] In US-Shrimp (§§119-120) provided the rationale for this approach, which is now well embedded in case law.

other side, we will have to first explore the possible legal justifications that the original defendant might raise. As we will show in what now follows, the legal test for consistency stays the same, irrespective of the potential justification raised.[10]

3.1 Potential Justifications

A successful defense of measures under Article XX of GATT requires that the party invoking this provision meets cumulatively the requirements of the sub-paragraph invoked, as well as those embedded in the chapeau of the provision.

The sub-paragraphs of Article XX of GATT contain various possible justifications of an otherwise GATT-inconsistent measure. To justify the import/sales ban, the importing State could, in principle, raise one of the following two grounds:

- XX(b), the likeliest option, since it aims to protect human health, which is very much the rationale for a ban on ANDS;
- XX(a), a less likely, but possible option, if it raises the argument that ANDS violate public morals, since smoking and anything related to it such as the use of ANDS for example, is incompatible with the prevailing standards of right and wrong.

Both provisions include a necessity-test, hence it is irrelevant if the importing state invokes one or the other alternative. It will still have to meet the requirements of the same test. If it fails to do so, then complainant prevails. If it manages to meet the requirements of the necessity-test, then it will also have to meet the requirements of the chapeau-test.

3.2 Is an Import Embargo/Sales Ban Necessary?

To respond to the question whether an import/sales ban can be provisionally justified under Article XX(b), or XX(a) of GATT, we need to circumscribe briefly the case law understanding of the necessity-requirement. In doing that, we will be explaining whether the challenged measure meets the test, as developed in case law.

[10] In what follows, we present an exhaustive discussion of all potential justifications that the regulator might raise.

3.2.1 Means are Justiciable, not Ends

As long as the ends are among those set out in Article XX, the WTO will not question the legitimacy of the ends but will examine only whether the means are designed to address these ends and have the required relationship with the ends in question. This is the direct consequence of the negative integration character of the GATT contract. In *Korea – Various Measures on Beef*, the Appellate Body put it in eloquent terms (§176):

> It is not open to doubt that Members of the WTO have the right to determine for themselves the level of enforcement of their WTO-consistent laws and regulations.

This means that, in case of litigation, WTO courts cannot question, neither why the importer aims at promoting public health/morals, nor the level of protection/enforcement sought. They can only ask whether an import/sales ban serves the achievement of the intended regulatory objective.

By deciding on the level of enforcement, a WTO member ipso facto prejudges the means it can use to attain it: a very demanding level of enforcement would give little scope for measures other than an embargo. This is precisely the situation we are facing in this case. And yet, in *Brazil – Retreaded Tyres*, the Appellate Body put a dent in the right to use the most drastic measures, even if the requested level of enforcement is quite high. In light of the importance of this issue for the facts of this case, we will explain this point in sufficient detail.

In this report, the Appellate Body held that measures like an import/sales ban would be accepted, only if the party adopting them managed to prove that they have made a "material contribution" to the attainment of the objective (§150):

> As the Panel recognized, an import ban is "by design as trade-restrictive as can be." We agree with the Panel that there may be circumstances where such a measure can nevertheless be necessary, within the meaning of Article XX(b). We also recall that, in Korea–Various Measures on Beef, the Appellate Body indicated that "the word 'necessary' is not limited to that which is 'indispensable.'" Having said that, when a measure produces restrictive effects

> on international trade as severe as those resulting from an import ban, it appears to us that **it would be difficult for a panel to find that measure necessary unless** it is satisfied that the measure is apt to make a material contribution to the achievement of its objective. Thus, we disagree with Brazil's suggestion that, because it aims to reduce risk exposure to the maximum extent possible, an import ban that brings a marginal or insignificant contribution can nevertheless be considered necessary. (emphasis added)

It seems to us, that the Appellate Body wanted to convey that, for a very restrictive measure to be accepted as necessary, it must make a real (material, in its parlance) contribution to the attainment of the stated objective. In other words, unless that measure was used, the objective would either not have been attained, or its attainment would have been severely eviscerated. In this vein, the Appellate Body sees a trade-off between two competing propositions:

- On the one hand, it cannot prejudge the level of enforcement sought, but
- On the other, it does not allow the use of very restrictive measures, unless they are really really necessary to achieve the stated objective.

Consequently, the message that the Appellate Body wanted to convey here, is that it would not lightheartedly accept the most egregious cases of market segmentation. One would have intuitively thought that some sort of measurement of the contribution would be necessary. The Appellate Body took the view that this measurement can also take the form of a qualitative assessment that is supported by sufficient evidence.

In *EC – Seal Products* as well, the panel underscored that it would find it hard to reconcile total bans on sales with the necessity requirement, absent a finding to the effect that the challenged measure had made a material contribution to the attainment of the stated objective (§§7.633 *et seq.*). It then found that the challenged measure, for various reasons, "may have contributed to a certain extent" to the attainment of the objective, because it would reduce the overall demand for seal products (§§7.637–638).[11] The Appellate Body, in a lengthy passage (§§ 5.211 *et seq.*) found nothing wrong with the panel's conclusion that the measure may have contributed to the objective (§ 5.225).

[11] This panel ultimately concluded that the EU measure, although it was in its view necessary to protect public morals, it still violated the chapeau of Article XX of GATT.

This is the last contribution of case law to this discussion. There is of course, some distance between "material contribution", and "contribution to a certain extent". One possible explanation of the more relaxed attitude of the Appellate Body in *EC – Seal Products*, the more recent case, could be that the measure anyway was in manifest contradiction with the requirements of the chapeau of Article XX (which we discuss later). Furthermore, even though the Appellate Body did use different language to express the same concept, it did not signal deviation from the standard established in *Brazil – Retreaded Tyres*.[12]

As a result, the finding that recourse to drastic measures like embargoes, will be accepted only if the contribution to the attainment of the regulatory objective is substantial, is, in our view, still good law. Therefore, the regulating party must prove that the ban will make a "material" or close to indispensable contribution to the health objective. As discussed below, this is not likely to be proven given the reduced risk nature of ANDS compared to TCs.

3.2.2 The Importance of the Objective Pursued Matters

The Appellate Body asked this question about the relevance of the importance of the policy objective for the first time, in its report on *Korea – Various Measures on Beef*. We quote from §162:

> It seems to us that a treaty interpreter assessing a measure claimed to be necessary to secure compliance of a WTO-consistent law or regulation may, in appropriate cases, take into account the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect. The more vital or important those common interests or values are, the easier it would be to accept as "necessary" a measure designed as an enforcement instrument.

This was confirmed in *EC – Asbestos* (§172).

This being said, the importance of the objective in terms of its impact on the review process should not be over-estimated. What the Appellate Body wanted to convey here, is simply

[12] In *EC – Seal Products*, the Appellate Body confirmed this understanding in §5.215, footnote 1300.

that, when going through its "weighing and balancing" process, it will control also for the importance of the objective sought. Thus, the importance of the objective sought, does not emerge as the decisive factor in deciding whether the necessity-requirement has been met or not. It will affect the standard of review, that much is clear, but it will complement and not substitute for the remaining analysis under Article XX of GATT.

3.2.3 Necessary Means Close To Indispensable

In an often-cited passage, the Appellate Body, in its report on *Korea – Various Measures on Beef* (§§161 *et seq.*), explained that the term "necessary" should be understood as closer to the term "indispensable" rather than to the term "making a contribution". The more a measure contributes to realizing an objective the easier it will be for an adjudicator to pronounce on its necessity.

In the same passage, the Appellate Body held that the less a measure has an impact on international trade, the closer it comes to its understanding of "necessity".

What do we make of this analysis for the case we discuss here? The import/sales ban must ideally contribute significantly to the objective (protection of human health/public order) while, at the same time not restrict international trade that much.[13] The measure definitely does not meet the second leg of the test, since a ban by definition has the maximum restrictive impact on international trade. As far as the first leg of the test is concerned, the lack of contribution of the ban to the protection of health renders the ban unnecessary, it seems. An assessment of the contribution of the measure that focuses only on the potential harm caused by the consumption of ANDS is one-sided and ignores the substitution effect that ANDS have for consumers who would otherwise smoke the potentially riskier TCs because of the unavailability of ANDS.

As noted by the seventy-two independent health experts in their letter to the WHO/FCTC, "[a] lost opportunity for a public health gain represents a real harm to public health, and

[13] This passage is reminiscent of the theory of first-best instruments to address distortions, but the agreement does not require the adoption of first-best instruments.

should be recognised as such".[14] Indeed, in a related letter to the WHO, a number of independent health experts explained that "[m]illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products".[15]

Therefore, ANDS play an important positive role in a harm reduction policy that offers what these experts believe to be a safer alternative for smokers. To ban ANDS while allowing ordinary TCs would undo the positive effect on smoking caused by the availability of ANDS. A measure can never be necessary to fulfil the objective or be justifiable if it goes against that objective.[16] In presence of a ban (import- or sale) of ANDS, the only reasonable consequence is that TC users do not have the opportunity to switch to a potentially less harmful alternative to smoking TCs.

3.2.4 Absolute As Opposed To Relative Necessity

In *China – Publications and Audio-visual Products*, the Appellate Body provided a comprehensive analysis of the understanding of the necessity-requirement in relative terms, and not in absolute terms (§327). In other words, if an alternative measure is reasonably available that provides an equivalent contribution to the fulfilment of the legitimate objective, the measure will not be necessary. This is how it would work in our case.

The defendant would have to make a prima facie case to the effect that its measure (import/sales ban) is necessary to protect human health, taking into consideration, however, that that the sales of TCs (the riskier product) is already taking place. This fact alone appears to make the prima facie requirement very difficult, if not impossible, to meet. If the

[14] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, p. 2, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[15] See, Letter from Professor Abrams and Professor Niaura of the NYU College of Global Public Health, "WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products", 3 September 20187, p.2, Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf.

[16] WTO Appellate Body Report, *Brazil – Retreaded Tyres*, para. 228.

complainant can point to another measure that could achieve the same objective without also creating a similarly restrictive effect on international trade (say, labelling requirements on the health externalities from use of any such products or related information campaigns), then the defendant will have one additional hurdle to overcome. It will have to explain why such alternatives are not reasonably available to it. To do this, it would have to, for example, show that financing a campaign to raise awareness of the risks, as suggested by the complainant, would entail as consequence a financial burden it could not possibly sustain (this is the "hardship"-test, that the Appellate Body has been referring to in this and related case law).[17] This is an argument that would be nearly impossible to sustain in light of the fact that governments run such campaigns all the time. In any case, the costs of such labelling requirements would be borne by the producers and importers of the products, and not the government. Therefore, the argument must fall. The availability of less restrictive alternatives to a ban such as labelling requirements or information campaigns on the health externalities are additional reasons why the ban must be unnecessary.

3.2.5 Preferring a GATT-Consistent rather than a GATT-Inconsistent Option

The *Thailand – Cigarettes* dispute, a GATT panel case of 1990, stands for the proposition that a measure is not necessary, if a GATT-consistent or less GATT-inconsistent alternative exists. There are strong similarities between this and the case under consideration in this Note. Thailand had imposed an import ban on cigarettes, while allowing for the sale of domestic cigarettes in its market. When challenged, it argued that its embargo on the importation of cigarettes, while restricting the overall quantity of cigarettes sold in its market, was justified by the fact that it aimed to ensure the quality of cigarettes imported. The panel (§75) felt that Thailand could have ensured its objective (good quality of cigarettes sold and restrictions on demand), through the use of non-discriminatory, and hence GATT-consistent, measures (non-discriminatory labeling, etc.). In so doing, the GATT panel even went against the suggestions of the World Health Organization, which had effectively advocated in favour of banning imported manufactured cigarettes.

[17] In *Dominican Republic – Import and Sale of Cigarettes*, the Appellate Body almost verbatim exported the allocation of the burden of proof as per *US – Gambling*, in the trade in goods-context as well (§70).

In our case, if the objective of the importer was to protect human health/public morals, then the most appropriate way to do it, would be to warn (potential) consumers of the alleged danger that consumption of ANDS represents to health. It could have chosen a GATT-consistent option, that is. By imposing an import/sales ban on ANDS only, it does not serve the regulatory objective unilaterally set.

3.3 Preliminary Conclusion

It is difficult to conclude in definitive manner whether the defendant will manage to successfully demonstrative substantive compliance with the relevant sub-paragraphs of Article XX, even though the better arguments lie with a negative response. This is so for two important reasons, namely, because:

- drastic measures only exceptionally will be allowed;
- a GATT-consistent option could probably help it reach its objective.

In our view, there are thus good reasons to believe that the regulating member will not meet the necessity requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary.

But let us assume for the sake of argument that the defendant has managed to demonstrate that its measures pass the first leg and are necessary to achieve their objectives. This is not the end of the road, as we have already suggested. The defendant must also demonstrate that its measures meet the requirements of the chapeau. We turn to this discussion in what now immediately follows.

3.4 Does an Import Embargo/Sales Ban Meet the Requirements of the Chapeau?

For a WTO member to successfully discharge its burden of proof under the chapeau of Article XX, it must demonstrate that its measures do not constitute an arbitrary, or unjustifiable discrimination, or a disguised restriction of trade. The third requirement is of

course distinct from the first two, which concern degrees of discrimination. Case law though, is quite fuzzy as to whether these two requirements are distinct, or overlapping. In *US – Shrimp (Article 21.5–Malaysia)*, the Appellate Body held that these three requirements are distinct (§118). And yet, the same Appellate Body, in its report on *US – Shrimp*, held the opposite (§150).

We submit that this discussion is inconsequential. What matters is what the substantive content of the three terms amounts to.

3.4.1 Substantive Consistency and Application

We quote §625 of the Appellate Body report on *China – Rare Earths*, which is probably the best explanation of the standard of review adopted when examining claims of inconsistency with the chapeau:

> Although… the focus of the inquiry is on the manner in which the measure is applied, the Appellate Body has noted that whether a measure is applied in a particular manner "can most often be discerned from the design, the architecture, and the revealing structure of a measure." It is thus relevant to consider the design, architecture, and revealing structure of a measure in order to establish whether the measure, in its actual or expected application, constitutes a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.

An enquiry into the design, architecture, and revealing structure of the challenged measure is thus warranted in order to decide on its consistency with the chapeau. For the purposes of our discussion, this would mean that a panel would look into the ban on ANDS of course, as well as into the rationale for the measure (public health/public morals).

3.4.2 The "Plat de Resistance": the Even-Handedness Requirement

On its face, the chapeau of Article XX of GATT imposes a requirement of even-handedness. We quote the relevant passage:

> … the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, …[18]

The question that naturally arises, is whether the term "discrimination" should be co-extensive to the manner in which "so as to afford protection" has been understood in the case law regarding Article III of GATT.

In *US – Gasoline*, the Appellate Body addressed this issue directly, and found that the legal test for consistency is not identical across the two provisions (Articles III and XX).
On p. 26 in the same report, the Appellate Body explained itself as to where it saw the difference in the legal test:

> We have above located two omissions on the part of the United States: to explore adequately means, including in particular cooperation with the governments of Venezuela and Brazil, of mitigating the administrative problems relied on as justification by the United States for rejecting individual baselines for foreign refiners; and to count the costs for foreign refiners that would result from the imposition of statutory baselines. In our view, these two omissions go well beyond what was necessary for the Panel to determine that a violation of Article III:4 had occurred in the first place.

Of interest to our discussion, is the Appellate Body's view that the two omissions, which go beyond what was necessary to find violation of Article III, should be taken into account in order to find violation of the chapeau. The requirement thus, for even-handedness under the chapeau, is quite elaborate. This in turn, entails an even higher burden for the party invoking the chapeau when drawing regulatory distinctions in treatment.

We now turn to the interpretation of the term "disguised restriction of trade". There are some banal interpretations that have seen the light of day, of no or marginal interest to our

[18] It is of course, debatable whether "disguised restriction of trade" should be treated as part and parcel of the even-handedness requirements. Arguably, it is a distinct requirement. In this Note, I will treat it as part of it though, since this is how case law has discussed it so far. In my view though, it is distinct requirement. The way I personally understand the legal discipline in the chapeau of Article XX, it contains two distinct elements: an element of even-handedness, which invites comparison of treatment of a particular good in countries (including the regulating country) where the same conditions prevail; and a separate requirement to avoid disguised restrictions of trade, which is akin to abuse of law. This requirement amounts to a legal imperative to use means for stated ends, and not in order to advance other, hidden objectives.

discussion. In *US – Gasoline*, the Appellate Body rejected the interpretation that the term "disguised restriction of trade" is limited to concealed or unannounced restrictions only. It upheld, in other words, the idea that the obligation to avoid disguised restrictions of trade is not a mere exercise in transparency.

What is then "disguised restriction of trade" all about? Case law has provided a framework to use when addressing claims that a measure falls short of this requirement. We turn once again to the Appellate Body report on *US – Gasoline* (p. 25):

> … the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination," may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article.

This view is reminiscent of the French doctrine of "abus de droit".[19] In other words, in the name of protecting one of the values embedded in the body of Article XX, WTO members should not, in under-handed manner, promote the interests of local produce. "Abus de droit" falls squarely within the parameters of this statement: use an instrument not for the intended, and acceptable, function, but for a different one (un-intended, as well as un-acceptable).

How does all this relate to our discussion?

Article XX, unlike the provisions regarding obligations assumed under the GATT, does not prescribe instruments that must be disciplined in a specific way. It enlists grounds, which, if genuinely pursued, allow WTO members to deviate from the disciplining of instruments as per the obligations assumed (Articles I, II, III, XI of GATT).

We have established that ANDS and TCs are like goods. We have also established that banning the former, and allowing the sale of the latter amounts to LFT. Even if we assume that the defendant has met its burden under Article XX(a)/XX(b) of GATT, it cannot pass the hurdle of the chapeau. A measure, which allows the sale of TCs and ANDS is a disguised

[19] The Appellate Body, in its report on *Brazil – Retreaded Tyres*, endorsed this analysis in §§224 *et seq.*

restriction of trade, and/or an unjustifiable, and arbitrary discrimination that thus violates the GATT. This is why: if the purpose is to protect public health, it simply cannot be that between two like goods, only half of them are banned. If the purpose is protection of health, all like products (ANDS, and TCs alike) must be banned/disciplined, unless there are good reasons for a regulatory distinction that is necessitated by the health objective such as providing a less stringent regime for ANDS given their potential role in a harm reduction strategy.[20] If only ANDS are banned, consumption of TCs will increase because of the role in a harm reduction policy played by ANDS that substitute for TCs, as we have discussed earlier, and the regulatory purpose will be defeated, since overall consumption at best will remain unaffected. By failing to do as much, the defendant has ipso facto failed to meet the requirements of the chapeau.

There is an additional argument in favour of this conclusion under the chapeau. In *Brazil – Retreaded Tyres*, the Appellate Body held that if the adjudicator concludes that the basis for the measure bears no rational connection with the objective pursued, then it has to find that the chapeau has been violated (§227). Under the terms "arbitrary-", "unjustifiable discrimination", and "disguised restriction of trade", the Appellate Body saw a minimum requirement that must be satisfied as well: rational connection between end sought, and means in place.[21]

The "rational disconnect" standard appeared yet again in *EC – Seal Products*. There, Canada had argued that the European Union was not pursuing protection of animal welfare, when it allowed the killing of seals by the Inuit community of Greenland. The Appellate Body interpreted first the Canadian claim as a statement to the effect that, a rational disconnect between the means (imports of seal products from these brutally killed seals) and the objective (protection of animal welfare) existed, as a result of the only partial exclusion of seal products from the EU market, when the objective was to ban all goods produced following unacceptable methods of harvesting seals (§5.319).

[20] Recall, that it is not the complainant who has to demonstrate that the defendant is operating a disguised restriction of trade, or operating an arbitrary and/or unjustifiable discrimination. It is the defendant, i.e. the member imposing the ANDS ban that must prove that it does not. Consequently, the complainant does not have to demonstrate, for example, that the defendants' producers of TCs will profit from limited competition.

[21] Irrespective whether we base ourselves on the "rational disconnect" thesis, or the substitution effect discussed earlier, the analysis is the same: there is no need to inquire into trade effects.

This case thus, is quite relevant for our discussion here. As in *EC – Seals Products*, the regulating state here is facing two types of products, both of which allegedly represent a health risk. And yet, it bans only one of them, the less risky one. The question of rational disconnect is posed in almost identical terms across the two cases.

Under this case law, consequently, the regulating state by not addressing the reasons why it bans ANDS but not TCs, is violating the rational-disconnect obligation.

In other words, under the chapeau, the regulating state will have to explain why there is one sauce for the goose so to speak, and one for the gander. What explains in other words, the ban on sales of ANDS and the permission to trade TCs? The regulating state cannot avoid this question. And we have difficulty seeing how it could ever explain this given that, in the opinion of the above quoted seventy-two health experts, the banned ANDS are less risky than the permitted TCs.

Consequently, a ban on ANDS would violate the requirements included in the chapeau of Article XX of GATT, even if the ban applied to all imports and domestic ANDS alike, since it would be excluding TCs from its scope.

Furthermore, the MFN (most favoured nation) requirement is explicitly embedded in the chapeau, which requests absence of discrimination across countries, where the same conditions prevail. This term has been consistently understood as prohibiting discriminatory behaviour.

In the WTO-era, the Appellate Body in *US – Gasoline* discussed the issue whether this requirement should be understood as referring exclusively to exporting countries or, conversely, whether it should encompass the regulating country as well. Although the Appellate Body did not formally rule on this issue on this occasion, it saw no reason to deviate from the prevailing practice, which privileged the latter interpretation (pp. 23–24):

> It was asked whether the words incorporated into the first two standards "between countries where the same conditions prevail" refer to conditions in importing and exporting countries, or only to conditions in exporting countries. The reply of the United States was to the effect that it interpreted that phrase as referring to both the exporting countries and importing

> countries and as between exporting countries. At no point in the appeal was that assumption challenged by Venezuela or Brazil. we see no need to decide the matter of the field of application of the standards set forth in the chapeau nor to make a ruling at variance with the common understanding of the participants.

Finally, there is once again no need to demonstrate actual trade effects or to measure their significance. What matters is that the even-handedness requirement has been violated, irrespective of the trade volumes that will be eventually reduced.

One final comment is warranted at this stage. One might not exclude that the regulating state invokes the precautionary principle, arguing that, since the risk from ANDS has not been precisely assessed, its measures are necessary to address, on precautionary grounds, the potential risk. This argument it seems to me, is easy to thwart. The precautionary principle has not been recognized in the GATT legal order in any of the reports issued so far and the Appellate Body found that the "precautionary principle" had not yet attained authoritative formulation outside the field of international environmental law "did not release Members from their WTO obligations".[22]

[22] Appellate Body Report, *EC – Hormones*, paras. 123-125. See also Appellate Body Report, *Japan – Apples*, para. 233.

4. Brief Concluding Remarks

In this Note, we discussed the consistency of an import/sales ban on ANDS with the relevant WTO rules, when no similar prohibition on the same of TCs has been put into place.

Our conclusions are as follows:

- An import ban on ANDS, mandated by a formal law, violates Article XI of GATT, since
    - it constitutes a prohibition on importation, and thus a prohibited zero import quota;
    - it is attributable to the importing WTO member;
    - there is no need to show trade effects, and
    - the regulatory intent of the ban is irrelevant;
- A sales ban on ANDS, mandated by a formal law, violates Article III of GATT, since
    - ANDS and TCs are like products;
    - a ban on imported ANDS, while allowing the sale of TCs, amounts to LFT for imported like products;
    - there is no need to demonstrate trade effects and it is thus irrelevant if the banned products represent only a small volume of trade; and
    - the regulatory intent of the discriminatory ban on ANDS is not relevant under Article III of GATT, since any modification of the conditions of competition to the detriment of imported like products is prohibited even if there is no evidence of any protectionist intent;
- The regulating WTO member may seek to justify its measures by invoking Article XX(b) and/or Article XX(a). Both provisions include the same "necessity" test for consistency, and thus, it is simply irrelevant if the importing WTO member will invoke one or the other, or both of them. There are good reasons to believe that the defendant will not meet the necessity-requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health, and the availability of less restrictive alternatives to a ban such as information campaigns and labelling support a finding that the ban is unnecessary;

- In any case, even if the regulating member were to be successful in demonstrating the "necessity" of the ban on ANDS, this will not suffice to justify the ban. We examined in particular the consistency of the measure under the chapeau of Article XX of GATT, and found that the ban on ANDS will fail to meet the chapeau requirements, since
    - the ban is a disguised restriction on trade for two, distinct reasons relating to the substantive basis for the difference in treatment as well as the procedural explanation for the different treatment:
        - because the regulating state, in the name of protecting human health (and/or public morals) is banning the sale of certain goods while not banning the sale of like goods that are, according to many scientists, much more harmful to health; and
        - because it has not explained its decision to ban some and not other, more harmful products, and is unlikely to be able to provide the required reasoned and reasonable explanation that is rationally connected with the health objective of the measure.
    - the ban is also an unjustified and/or arbitrary discrimination, since the importing WTO member has banned the sales of some imported products, as opposed to other like products that are more harmful to health, without any reasoned and reasonable explanation that is rationally connected with the health objective of the measure.

Dated:

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63. Human Rights, Developing Countries and the WTO Constraint: the Very Thing that Makes you Rich Makes me Poor?, pp. 244-260 in Eyal Benvenisti and Moshe Hirsch (eds.), The Impact of International Law on International Cooperation, Cambridge University Press: Cambridge, UK, 2004.

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67. National Health Regulation and the SPS Agreement: the WTO Case-Law of the Early Years (co-authored with Henrik Horn), pp. 255–284 in Thomas Cottier and Petros C. Mavroidis (eds.),The Role of the Judge in International Trade Regulation, Experience and Lessons for the WTO, The World Trade Forum Series, vol. IV, The University Of Michigan Press: Ann Arbor, Michigan, 2003.

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74. The White Paper Network: Making the Network Operate (co-authored with Damien J. Neven), pp. 207-221 in Claus-Dieter Ehlermann (ed.), European Competition Law Annual, The Modernisation of EC Antitrust Policy, Hart Publishing: Oxford, UK, 2001.

75. The WTO Agreement on Telecommunications: It's Never Too Late (co-authored with Damien J. Neven), pp. 307-318 in Damien Geradin (ed.), The Liberalization of State Monopolies in the European Union and Beyond, Kluwer: London, 2000.

76. Trade and Investment (in Greek), pp. 221–235 in P.N. Stangos and A. Bredimas (eds.), The Legal Regime of International Investments: The Draft Multilateral Agreement on Investment, Sakkoulas Publications: Athens – Thessaloniki, 2000.

77. Le Pouvoir et les Méthodes d'Interprétation du Juge en Droit Domestique et en Droit International (co-authored with Pascal Mahon). pp. 397-410 in Mélanges Offerts en l'Honneur de Carlo Augusto Cannata, Collection Neuchâteloise, Helbing & Lichtenbahn: Basel, 1999.

78. Some Reflections on the Extraterritorial Application of Laws: a Law and Economics Analysis (co-authored with Damien Neven), pp. 1297-1325 in Mélanges Offerts à Michel Waelbroeck, PUB: Bruxelles, 1999.

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81. The Treatment of Dumping, Subsidies and Restrictive Business Practices in Regional Arrangements: A comment, pp. 389-396 in Paul Demaret, Jean-François Bellis, Gonzalo Garcia Jimenez (eds.), Regionalsim and Multilateralism after the Uruguay Round, Convergence, Divergence and Interaction, European Interuniversity Press, Series European Policy No 12, Brussels 1997.

82. International Antitrust Policies for High-tech Industries? (co-authored with Bernard Hoekman), pp. 113-128 in Horst Siebert (ed.), Towards a New Global Framework for High-Technology Competition, Institut für Weltwirtschaft an der Universität Kiel, J.C.B. Mohr (Paul Siebeck): Tübingen, 1997.

83. Trade, Environment and the WTO: The Dispute Settlement Practice Relating to Art. XX of the GATT, (co-authored with Aaditya Mattoo), pp. 325-344 in Enrst Ulrich Petersmann (ed.), International Trade Law and the GATT/WTO Dispute Settlement System, Kluwer: Amsterdam, 1997.

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85. The EC Trade, Competition and Industrial Policies; Complementarities and Conflicts: A comment, pp. 115–121 in A. Jacquemin, P. Buigues (eds), The EEC Policies on Competition, Trade and Industry, Complementarities and Conflicts, Elgar: Aldershot, UK, August 1995.

86. Linking Competition and Trade Policies in the Central and Eastern European Countries (co-authored with Bernard Hoekman), pp. 111–154 in Alan Winters (ed.), Foundations of an Open Economy, Trade Laws for Eastern Europe, CEPR Publications: London, UK, 1995.

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1. Global Warming and the Global Trading System" by Gary C. Hufbauer, Steve Charnovitz and Jisun Kim, (co-authored with Caroline Fisher), Journal of Economic Literature, XLVIII: 21-23, 2010.

2. Law and Competition in Twentieth Century Europe: Protecting Prometheus, by David Gerber, Columbia Journal of European Law, 6: 259-264, 2000.

3. Lexcalibur: The House that Joe Built, A review of "The Constitution of Europe: Do the New Clothes Have an Emperor?", by Joseph H.H Weiler, Columbia Journal of Transnational Law, 38: 669-677, 2000.

4. International Trade Regulation, by Michael J. Trebilcok and Robert Howse, Journal of World Trade, 34: 171-172, 2000.

5. International Trade Regulation, by Edmond McGovern, Journal of World Trade, 33: 205-206, 1999.

6. The World Trading System, 2nd edition, by John H. Jackson, Journal of World Trade, 32: 185-188, 1998.

7. Antidumping Industrial Policy; Legalized Protectionism in the WTO and What to do About it, by Brian Hindley and Patrick Messerlin, Journal of World Trade, 31: 167-168, 1997.

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9. The GATT/WTO Dispute Settlement System, by Ernst-Ulrich Petersmann, Leiden Journal of Interantional Law, 9: 513-515, 1996.

10. GATT Uruguay Round, edited by Thomas Cottier, Aussenwirtschaft, 50: 515–518, 1995.

11. Enforcing International Trade Law, by Robert E. Hudec, Aussenwirtschaft, 49: 625–628, 1994.

12. Der Agäis-Konflikt, by Heintschell von Heinegg, Révue Hellènique de Droit International, 42: 461–464, 1990.

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Sultans of Swing, The Emerging WTO Case Law on TBT (with Carlo M. Cantore), European Journal of Risk Regulation, 258-260, 2013.

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The European Union as an International Actor, Columbia Journal of European Law, 6: 271-274, 2000.

OTHER PUBLICATIONS

2019: China and the WTO: Towards a Better Fit, with André Sapir, Bruegel, Brussels

2018: All Quiet in the Western (European Football) Front: Regulation of Football in the European Continent, EUI Working Papers, RSCAS, EUI: Fiesole, Italy, 2018/26
Summary reprinted in Oxford University Business Law Blog
https://www.law.ox.ac.uk/business-law-blog/blog/2018/07/all-quiet-western-european-football-front-regulation-football

CUTS-international.org

2012: Briefing Paper, On Compliance in the WTO, Enforcement Among Unequal Disputants (2012/4)

EUI

Data set on WTO dispute settlement
http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

Dissenting Opinions in the WTO Appellate Body: Drivers of their Issuance and Implications for the Institutional Jurisprudence (with Evan Y. Kim), RSCAS 2018/51: EUI, Florence.

ICTSD (International Centre for Trade and Sustainable Development)

Opposites Attract: Bringing the Trade and Regulatory Communities Together
http://e15initiative.org/blogs/opposites-attract-bringing-the-trade-and-regulatory-communities-together/

VoxEU.org

2008: The WTO's Difficulties in Light of the GATT's History, VoxColumn, VoxEU.org, 29 July 2008

2013: Race for the WTO Director-General Job: Seven Candidates Speak, VoxEU.org, E-book (co-edited with Bernard M. Hoekman), April, http://www.voxeu.org/sites/default/files/file/WTO%20book(1).pdf

2013: Pay Attention to the WTO Leadership Contest: It Matters!, (co-authored with Bernard M. Hoekman), VoxEU, April 4, http://www.voxeu.org/article/pay-attention-wto-leadership-contest-it-matters

2013: Developing Countries and DSU Reform (co-authored with Marc L. Busch), pp. 99-104 in Simon Evenett and Alejandro Jara (eds.), Building on Bali, a Work Programme for the WTO, VoxEU.org E-book http://www.voxeu.org/article/building-bali-new-voxeu-ebook

2014: Members Only: Embracing Diversity in the WTO (co-authored with Bernard M. Hoekman), VoxEU.org http://www.voxeu.org/article/members-only-embracing-diversity-wto

2016: Clubs and the WTO post-Nairobi: What is Feasible? What is Desirable? (co-authored with Bernard M. Hoekman) http://www.voxeu.org/article/clubs-and-wto-post-nairobi

Social Science Research Network

My papers are available on SSRN at: http://ssrn.com/author=202909

RESEARCH GRANTS

1. American Law Institute (1991-2012): Principles of International Trade: the Law of the World Trade Organization (WTO). The study was conducted and co-authored with Henrik Horn (chief co-editor) and Kyle W. Bagwell, Gene M. Grossman, Robert W. Staiger, and Alan O. Sykes.

2. Bruegel (2009-2010): Preferential Trade Agreements. The study was co-authored with Henrik Horn, and André Sapir and published by Bruegel. A shorter version appeared in the World Economy, 2010 (cited supra).

3. MISTRA (2007-2013): I participated in a research consortium (www.entwined.se) working on various issues regarding the intersection of trade (WTO) law and environmental policies with special focus on policies relating to climate change. The outcome of this research has appeared in academic journals as cited supra.

4. ASEAN (2011-2013): I participate in a research consortium aiming at improving the current dispute settlement system of the ASEAN.

5. World Bank (2000-2010): Research grant for the WTO data set (www.worldbank.org/trade/wtodisputes)

6. EUI (2011-PRESENT):Research grant for the WTO data set http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

7. EUI (2010-PRESENT): Research grant for the WTO case law-project http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

HONOURS

Doctor Honoris Causa

Honorary Doctor of Laws: University of Antwerpen (Anvers), Belgium, 2013.

Honorary Doctor of Laws: Gothenburg University, Sweden, 2010.

Awards

American Society of International Law (ASIL) 'Certificate of Merit for a Work in a Specialized Area of Law' for the monograph 'The Regulation of International Trade', vols. 1 and 2, MIT Press: Cambridge, Massachusetts, 2017.

American Society of International Law (ASIL) 'Certificate of Merit for a Work in a Specialized Area of Law' for the monograph 'Trade in Goods', 2nd Edition, Oxford University Press: Oxford, UK, 2013.

International Franqui Medal (and Chair): University of Leuven, Belgium, 2009.

American Society of International Law (ASIL) 'Award of Highest Technical Craftsmanship' for The WTO Law, Practice and Policy (co-authored with Mitsuo Matsushita, and Thomas J. Schonbaum), Oxford University Press: Oxford, UK, 2005.

MEMBERSHIP IN BOARDS

1. **International Academic Advisory Council, University of Gothenburg, School of Business, Economics, and Law:** Member of the Council.

2. **Council of the World Trade Law Association**: Member of the Board.

3. **Columbia Journal of Trans-National Law**: Member of the Board of Advisors.

4. **Columbia Journal of European Law**: Member of the Board of Advisors.

5. **Global Trade and Finance Series, Kluwer Publishing**: Member of the Advisory Board.

6. **Journal of World Investment and Trade**: Associate Editor (2002-2013); Editorial Advisory Board (2013-).

7. **Journal of World Trade**: Associate Editor.

8. **The World Trade Review**: Editorial Board.

9. **The Geneva Post Quarterly**: Editorial Board.

10. **Yearbook on International Investment Law and Policy**: Advisory Board.

11. **Journal of International Trade,** Board of Advisors.

REPORTER FOR ACADEMIC ASSOCIATIONS

1. **American Law Institute (ALI):** Chief Co-Rapporteur in December 2001 to the project "Principles of Trade Law: The World Trade Organization" which was published in 2013.

2. **International Law Association (ILA), International Trade Law Committee (ITLC):** Rapporteur.

MEMBER OF ACADEMIC ASSOCIATIONS

1. **American Law Institute** (**ALI**): Member (as of 2007).

2. **Centre for Economic Policy Research** (**CEPR**) Fellow (2003-2011).

3. **The Swiss Institute of Comparative Law**, Lausanne: Member of the Scientific Board (as of 2012).

MISCELLANEOUS

1. **Court of Arbitration for Sport (CAS)**: Arbitrator (2007-).

2. **Commission on Financial Fair Play**, UEFA, Member (2008-).