Rational tobacco and nicotine policy in Brazil

Response to ANVISA Public Consultation No. 314

Revision to RDC 90
Registration of tobacco-based smoking products

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Disclosure: **Clive Bates** is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, the UK's leading tobacco control organisation, campaigning to reduce the harms caused by tobacco. From 2003 to 2012 he served as a senior civil servant in the United Kingdom and United Nations. This report was written to assist health policy decision-makers in Brazil as part of Counterfactual's advocacy program without additional funding. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.

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Rational tobacco and nicotine policy in Brazil

Executive summary

We respectfully submit this response to the consultation on amendments the Collegiate Board Resolution – RDC 90 (2007), on the registration of tobacco-based smoking products.

- We believe that the Government of Brazil should use the opportunity of these amendments to think strategically about tobacco policy and to embrace the concept of 'tobacco harm reduction'. This will reduce the burden of disease and related costs, and set Brazil on a path towards eliminating smoking-related disease – the true public health 'endgame'.

- Tobacco harm reduction is a concept embedded in the WHO Framework on Tobacco Control definition of tobacco control (see Article 1 FCTC). It means the use of technology innovation and skilfully-crafted regulation to promote substitution of high-risk tobacco products (typically cigarettes) for low-risk tobacco and nicotine products (smokeless tobacco, e-cigarettes and vapour products, heated tobacco products and novel forms of consumer nicotine). Collectively, we refer to these low-risk products as Alternative Nicotine Delivery Systems (ANDS).

- ANDS have two important qualities: (1) they do not involve combustion and so do not create products of combustion, and (2) to an increasing extent they are capable of replacing smoking for many smokers. Because almost all of the harm associated with tobacco/nicotine use arises from exposure to smoke, not nicotine, then these products are likely, beyond any reasonable doubt, to be much less harmful than smoking (90-100% less harmful depending on product and regulatory standards). The fact that they appeal to smokers as satisfactory alternatives to smoking offers the potential for major changes in the way people use nicotine with great health benefits as a result.

- The science base has improved significantly in recent years and we can be confident that ANDS are much less harmful than smoking because of the physical processes involved, the toxicity of the emissions from these devices and the exposures to hazardous chemicals as measured by biomarkers in the body and other experimental means.

- There has also been good experience at population level in which the rise of ANDS has been associated with declines in smoking. In the United States and United Kingdom this has also applied to young people – suggesting that ANDS are protective of both adults and youth.

- ANDS would help Brazil to meet significant WHA and United Nations commitments to reduce non-communicable disease (NCD) mortality by 25% by 2025, and to meet targets to reduce tobacco prevalence if these were defined to refer to smoking – the dominant tobacco-related cause of NCDs.

- Cigarettes, the most harmful products, are widely available and available throughout Brazil. However, for two categories of much safer ANDS alternatives (heated tobacco products and e-cigarettes) are largely blocked from the market by an uncertain and opaque pre-market approval regime. Heated tobacco products, which are fundamentally different from cigarettes and other

traditional tobacco products, are currently not defined under the existing RDC 90, nor is there a clear pathway for their registration and authorization by ANVISA.

- E-cigarettes are *de facto* banned under RDC 46/2009, which "prohibits the sale, import and advertising of any electronic smoking device, known as electronic cigarettes". This left open the possibility for manufacturers to seek pre-market authorization, but in practice banned the category by establishing an uncertain and opaque pre-market approval regime.

- There is a danger that regulation is failing to keep pace with significant and potentially highly beneficial developments in the tobacco and consumer nicotine marketplace.

- This consultation is an opportunity to clearly define these new ANDS categories and establish reasonable criteria for their registration under a combined Resolution that would reflect the benefits of both heated tobacco products and e-cigarettes. This would bring clarity and allow for a much simpler registration process, while providing ANVISA with the necessary oversight and adopting a tobacco harm reduction strategy.

- A new regulatory regime could specify age restrictions, product standards, labelling, marketing and use restrictions as appropriate. There is an opportunity for Brazil to gain from early experience in the European Union and elsewhere, where there are many valuable lessons to learn.

- The effect of the current regulatory regime denies Brazilian smokers access to much lower risk products and has the unintended effect of protecting the cigarette trade and incumbent business interests of the major tobacco companies – even though these companies are trying to switch into marketing lower risk products. There is no justification for this.

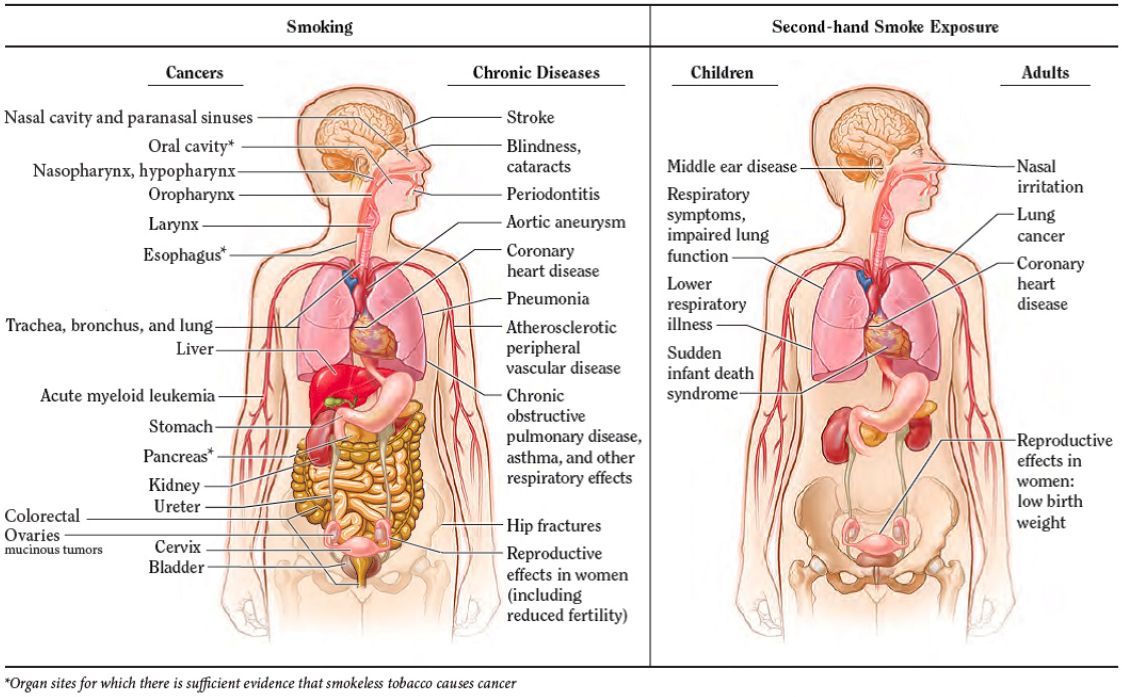
- We urge ANVISA and the Government of Brazil to embrace the use of tobacco harm reduction in Brazil's approach to tobacco control, and to create the appropriate regulatory and fiscal framework to allow low-risk products to displace smoking in the consumer market for nicotine. This would meet the demands of people who cannot or do not wish to quit completely, but with much less cancer, cardiovascular and respiratory disease as a result. The current consultation and intention to amend critical regulations provide an opportunity to start that process.

1 There are 20 million regular smokers in Brazil

Brazil is the largest country in South America, with a population of approximately 206 million and so Brazil's policy will have impacts on a large population. About 16% of adults smoke regularly - one in five (20.3%) men and one in eight (12.1%) women are smokers, according to WHO's standardized estimate of smoking prevalence for 2013[1]. This equates to about 21 million smokers in Brazil.

The harms of smoking are significant and well documented[2] – smoking is a major cause of cancer, cardiovascular disease and respiratory illness, as well as degraded welfare and wellbeing. The United States Surgeon General provided the following graphics to summarise the causes of harm:

Figure 1: Diseases arising from smoking



Source: US Surgeon General Department of Health & Human Services, 2014

These diseases reduce both the quality and length of life. According to the Tobacco Atlas[3], around 135,000 Brazilians die each year as a result of tobacco-related diseases.

The greatest and fastest reduction in health risk, economic damage and healthcare costs will arise from as many current smokers as possible stopping smoking as soon as possible. Over the longer term, ensuring as few as possible never start will lead ultimately towards the 'endgame' for smoking and smoking-related disease. Our main argument in this submission is that much of the death and disease caused by smoking can be addressed by offering consumers who cannot or do not want to quit completely the alternative to use low-risk forms of nicotine. These are collectively known as Alternative Nicotine Delivery Systems (ANDS), and are discussed in the following section.

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1 WHO. Report on the Global Tobacco Epidemic, 2015 [link]. Brazil Country Profile [link]

2 Surgeon General of the United States. The Health Consequences of Smoking—50 Years of Progress. Centers for Disease Control and Prevention (US) 2014. [link]

3 World Lung Foundation, American Cancer Society. Tobacco Atlas, 2015. [link] Brazil factsheet [link]

2 The low-risk alternatives to smoking

2.1 Alternative Nicotine Delivery Systems (ANDS)

The overwhelming majority of the risk associated with tobacco use comes from tobacco smoke and combustion, not from nicotine. Nicotine is a mildly psychoactive drug that can be addictive, but its addictiveness depends on how fast, in what form, and how much is delivered. However, nicotine itself is not particularly harmful. It is the tobacco smoke that holds and transports the nicotine to the lungs where it is absorbed that is the cause of cancer, cardiovascular and respiratory illnesses. Combusted tobacco smoke is the most effective delivery system for nicotine, but there are products that deliver a nicotine experience that is nearly as satisfying *but without the smoke* – and therefore with greatly reduced health risks. These products have four main generic forms:

Figure 2: Four sub-categories of alternative nicotine delivery systems

1. E-cigarettes and vaping products. These create much lower exposures to toxic agents[4 5 6 7 8 9] and are likely to be at least 95% lower risk than smoking[10 11].

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4 Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. [Link]

5 Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety* 2014;**5**:67–86. [Link]

6 Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* [Internet]. 2014 Aug 31 [link]

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

8 Margham J, McAdam K, Forster M, Liu C, Wright C, Mariner D, et al. Chemical Composition of Aerosol from an E-Cigarette: A Quantitative Comparison with Cigarette Smoke. Chem Res Toxicol. American Chemical Society; 2016 Oct 17;29(10):1662–78. [link]

9 Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users. Ann Intern Med. 2017 Feb 7;24:442–8. [link]

10 Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [link] E-cigarettes: an evidence update 19 August 2015. [link]

2. Heated tobacco products, in which a vapor is created by heating but not burning tobacco. Most of the research on these products has been conducted by the tobacco companies that make them. However, it is published in peer-reviewed journals. These products are likely to be at least 90-95% lower risk than smoking[12] [13] [14] [15] [16] [17]. Though these products may have higher emissions than e-cigarettes, it is likely that they will be a closer substitute for smoking for many smokers. Their health benefit will arise from reaching more smokers even if the products have marginally higher risks to health than e-cigarettes.

3. Unheated nicotine products, such as lozenges, films, inhalers and some forms of pharmaceutical nicotine replacement therapy (NRT). These are likely to approximate to NRT in their risk profile.

4. Smokeless tobacco such as well-established products like snus, which is likely to be at least 98% lower risk than smoking [18] and has been responsible for the lowest levels of smoking in the developed world in Sweden[19] and significant health gains[20].

2.2 The key insight: people smoke for the nicotine but die from the tar

The main motivation for smoking is to use the mildly psychoactive drug nicotine. But it is not the nicotine that causes most of the harm. The harms are overwhelmingly caused by toxic particles and gases that contain products of combustion of tobacco leaf, not the nicotine itself. While nicotine is not entirely safe, it accounts for a very small fraction of the direct harm caused by smoking. Studies of the health effects of prolonged NRT use and smokeless tobacco have allowed the nicotine health effect to be isolated from the overall smoking health effect.

The Royal College of Physicians (2016) describes the effects of nicotine alone as follows[21]:

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[11] Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

[12] Lüdicke, F., G. Baker, J. Magnette, P. et al (2016). Reduced exposure to harmful and potentially harmful smoke constituents with the Tobacco Heating System 2.1. *Nicotine and Tobacco Research* (2016) [link].

[13] Gonzalez Suarez, I., F. Martin, D. Marescotti, et al. In vitro systems toxicology assessment of a candidate modified risk tobacco product shows reduced toxicity compared to a conventional cigarette. *Chemical Research in Toxicology* 29(1): 3-18. [link]

[14] Zanetti F, Titz B, Sewer A, Lo Sasso G, Scotti E, Schlage WK, et al. Comparative systems toxicology analysis of cigarette smoke and aerosol from a candidate modified risk tobacco product in organotypic human gingival epithelial cultures: A 3-day repeated exposure study. Food Chem Toxicol. 2017 Mar;101:15–35. [link]

[15] Iskandar AR, Mathis C, Schlage WK, Frentzel S, Leroy P, Xiang Y, et al. A systems toxicology approach for comparative assessment: Biological impact of an aerosol from a candidate modified-risk tobacco product and cigarette smoke on human organotypic bronchial epithelial cultures. Toxicol Vitr. 2017 Mar;39:29–51. [link]

[16] Haziza C, de La Bourdonnaye G, Skiada D, Ancerewicz J, Baker G, Picavet P, et al. Biomarker of exposure level data set in smokers switching from conventional cigarettes to Tobacco Heating System 2.2, continuing smoking or abstaining from smoking for 5 days. Data Br. 2017 Feb;10:283–93. [link]

[17] British American Tobacco, Controlled aerosol release to heat tobacco: product operation and aerosol chemistry assessment. Poster presentation SRNT March 2016, Chicago. [link]

[18] Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. *Harm Reduct J*. England; 2013;10(1):36. [link]

[19] European Commission. Eurobarometer Special Survey 429: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2015. [link] Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health; 2016 Nov 9;13(11):1110. [link]

[20] Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Jan;12(1):14. [link]

> *As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user.* [Section 8.4.1 p125]

Nicotine is the main reason why people smoke, but not the direct cause of harm. To summarise[22]:

> *People smoke for the nicotine but die from the tar*

There is extensive evidence characterising the physics and chemistry of e-cigarette aerosol and cigarette smoke. E-cigarettes create *much* lower exposures to toxic agents. Taking account of the toxicology evidence, Public Health England[23] and the Royal College of Physicians (London) [24] provided a guideline assessment that e-cigarettes are likely to be at least 95 percent lower risk than smoking.

The Royal College of Physicians summarised its guidance as follows:

> *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".*
> (Section 5.5 page 87)

2.3 It is unethical to restrict ANDS unless there is a benefit to health

The key point is that the risk of ANDS use is very much lower than smoking – so what rationale could be used to restrict access to the much safer product while leaving the far more dangerous product widely available? There is no ethical, scientific or legal justification for denying smokers access to products that are a much safer way of using nicotine than smoking[25]. The questions that policymakers should address is: how can a government justify depriving smokers access to these products while keep the much more harmful cigarettes widely available on the market?

2.4 Restricting ANDS will inevitably create a black market

A *de facto* prohibition of ANDS does not mean these products will not be used in Brazil. In fact, there is already a thriving, though unquantified, consumer base of people who are using these products to reduce their smoking-related risks and to take control of their health outcomes.

The economics of the international trade incentivises users to purchase nicotine at higher concentrations (as high as 99 percent), and higher than they would generally use (typically up to 3.6 percent) and then handle, mix and dilute the high strength liquids down to their preferred mix with obvious handling risks. Purchases can be made from many high quality web sites, with prices in

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[21] Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [link]

[22] Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. BMJ 1976;1:1430–3. [link]

[23] Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [link] E-cigarettes: an evidence update 19 August 2015. [link]

[24] Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

[25] Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**:1061–7 [link]

multiple currencies, secure payments systems, reputable couriers and paperwork and certification, yet with uncertain quality, ingredients and safety[26].

We believe that a skilfully-regulated domestic market for these products would be a preferable way to meet the rational and legitimate expectations of Brazilian citizens to be able to use products that can dramatically reduce their risks. These products are widely available in Europe and the United States with no material harms arising.

3 Experience of ANDS use in other countries is very positive

Most of the experience of ANDS use arises from e-cigarettes and smokeless tobacco, though we are now starting to see growth in heated tobacco products, especially over the last twelve months. We do not have recent detailed data for e-cigarette use in Brazil. Experience from other countries suggests that the products in their current state of advancement can reach many smokers – but given continuing innovation they will reach many more in future if the regulation and risk communications are fair and proportionate.

3.1 United Kingdom – adult smoking falling rapidly

In the United Kingdom where e-cigarettes are widely available, the use of these alternatives is now at a significant scale relative to smoking. The Office of National Statistics reported data for 2015[27]

Figure 3: Smoking e-cigarette use in the United Kingdom 2015

Smoking and e-cigarette users 2015	British adults
Current smokers	8,843,000
Current e-cigarette users	2,201,000
Of the current e-cigarette users:	
Current smokers	1,297,000
Ex-smokers	849,000
Never smokers	56,000
Ex-smokers and ex-e-cigarette users	717,000

Figures rounded to nearest 1,000

The use of e-cigarettes by never-smokers in the UK is very low (0.2 percent of never smokers use e-cigarettes). This means the appropriate comparator is with the risks to nicotine users who are smoking. Many of those who are both smoking and using e-cigarettes may be on a path to eventual exclusive use and some evidence suggests that these 'dual users' are more likely to go on to quit[28]. The 849,000 current users and 717,000 former users who have stopped smoking represent a substantial inroad into the smoking population, though it is not possible to attribute their smoking cessation directly to e-cigarette use. However, the trend in smoking prevalence is also encouraging.

[26] See test purchase experience: Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, The Counterfactual [link]

[27] Office of National Statistics (UK), E-cigarette use in Great Britain, 2015 Dataset. 18 February 2016 [link] Table 2a.

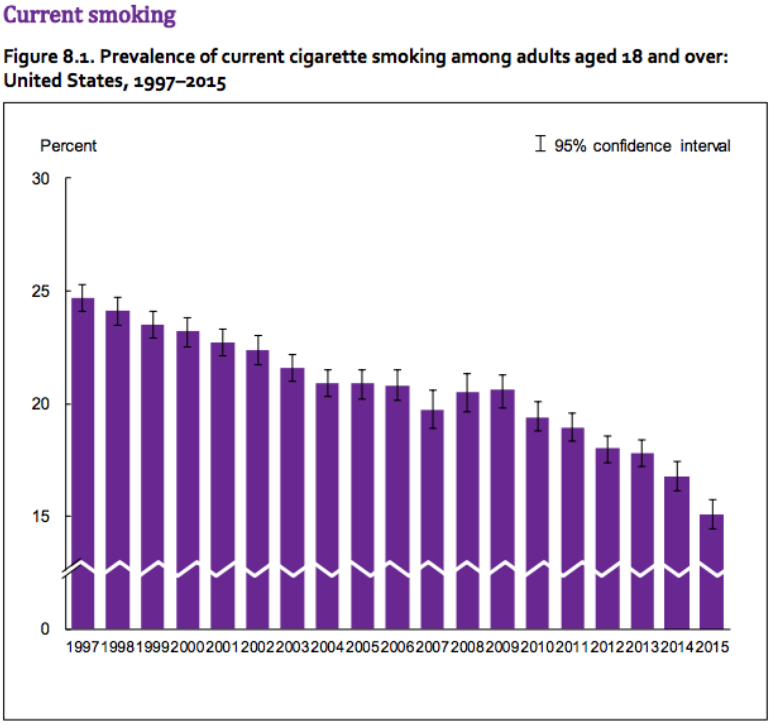
[28] Manzoli L, Flacco ME, Ferrante M, Vecchia CL, Siliquini R, Ricciardi W, et al. *Cohort study of electronic cigarette use: effectiveness and safety at 24 months.* Tobacco Control. 2016 [link]

The 8.8m current smokers represents current *record low* adult smoking prevalence of 17.5 percent[29]. After stalling in the late-2000s smoking prevalence has been falling rapidly as e-cigarette use has increased from negligible levels in 2011. Throughout this period of widespread ENDS use there have been no major health problems or any other problems – though many ENDS users are now no longer smoking and will be gaining significant benefit from smoking cessation.

3.2 United States – adult smoking falling rapidly

Similar patterns are seen in the United States. The National Health Interview Survey[30] shows that U.S. adult smoking prevalence (18 years and over) has fallen from 18.9 percent in 2011 to a record low of 15.1 percent in 2015 – with an especially sharp decline between 2014 and 2015. As with Britain, the impact of ENDS on the cigarette trade is substantial: in 2015, there were approximately 37.5m smokers, but there were 8.3m e-cigarette users of whom 2.5m were ex-smokers[31].

Figure 4: Decline in U.S. adult smoking prevalence 1997-2015



Source: National Center for Health Statistics, *National Health Interview Survey, 1997–2015*

3.3 Adolescent e-cigarette use is displacing smoking

There have been concerns expressed that adolescent uptake of e-cigarettes may be 'addicting future generations'. However, the data suggest a different pattern. Most use is by teenage smokers and data is consistent with e-cigarette use displacing smoking.

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29 Office of National Statistics (UK), Adult Smoking Habits in Great Britain1974-2014. 18 February 2016 [link] Table 1.

30 National Center for Health Statistics, *National Health Interview Survey, 1997–2015*, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [link]

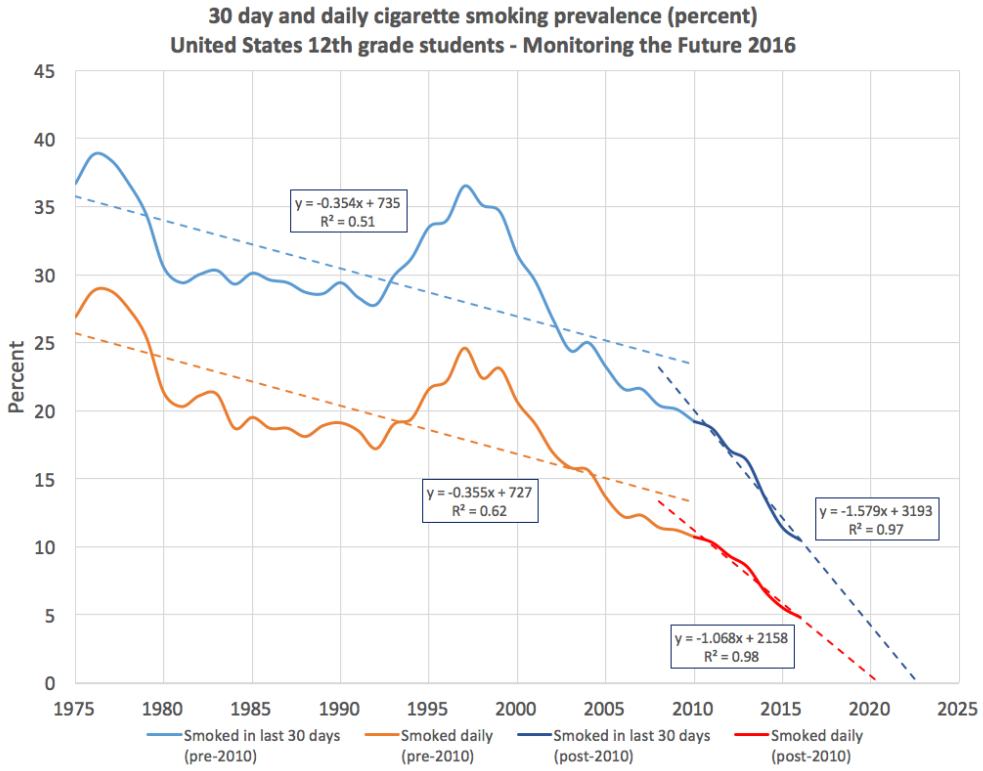
31 CDC, *National Health Interview Survey, 2015 Data Release* [link]; Cited in Rodu B. *How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015*, Tobacco Truth 17 July 2016 [link]

In the UK, use of ENDS among adolescents is low and confined mainly to young smokers. A March 2015 survey found 2.4 percent of 11-18 year olds had used e-cigarettes in the last month, and these were mainly smokers[32].

In the United States, almost all adolescent users of ENDS are former or current smokers, and therefore ENDS represents a *change* in the way nicotine is used for most. Analysis of CDC 2014 data shows that 90 percent of the 1.96m current e-cigarette high school users are current or former users of other tobacco products[33]. Some of the remaining 10 percent may have become smokers in the absence of e-cigarettes. There is no evidence supporting a gateway from ENDS to smoking[34].

In the United States, the rate of teenage and adult smoking has been declining rapidly since the introduction of e-cigarettes. For example, the Monitoring the Future dataset tracks the long-term trend in cigarette smoking in American 12th grade (age 17-18) students[35]. The chart below plots this data, and shows a post-2010 rate of decline *three times* the long run average prior to 2010 for daily smoking and four times for current smoking (in the last 30 days).

Figure 5: Accelerating decline in U.S. 12th grade smoking 1975-2010 and 2010-2016



[32] YouGov for Action on Smoking and Health (UK) Smokefree GB Youth Survey. Published in ASH Fact sheet [link]

[33] Rodu, B. Analysis of CDC National Youth Tobacco Survey 2014, The CDC Buries the Lead: Teen E-cigarette Use Rises as More Dangerous Cigarette Use Plummets, 13 October 2015 [link]

[34] McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [link] Section 4 *Gateway* page 37

[35] Miech RA, Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. Monitoring the Future national survey results on drug use, 1975-2016: Data tables. Table 2 - Trends in Prevalence of Use of Cigarettes in Grades 8, 10, and 12. University of Michigan; Ann Arbor: 2016. [Tables][Dataset]. Chart created Clive Bate [on-line]

Other surveys confirm that smoking among American adolescents has been falling rapidly. The National Youth Tobacco Survey (CDC)[36] shows that between 2011 and 2015, current use of cigarettes by high school students fell from 15.8 percent to 9.3 percent, and use of cigars and pipes also fell. There is no evidence that e-cigarettes are causing adolescents to become smokers as they enter adulthood[37].

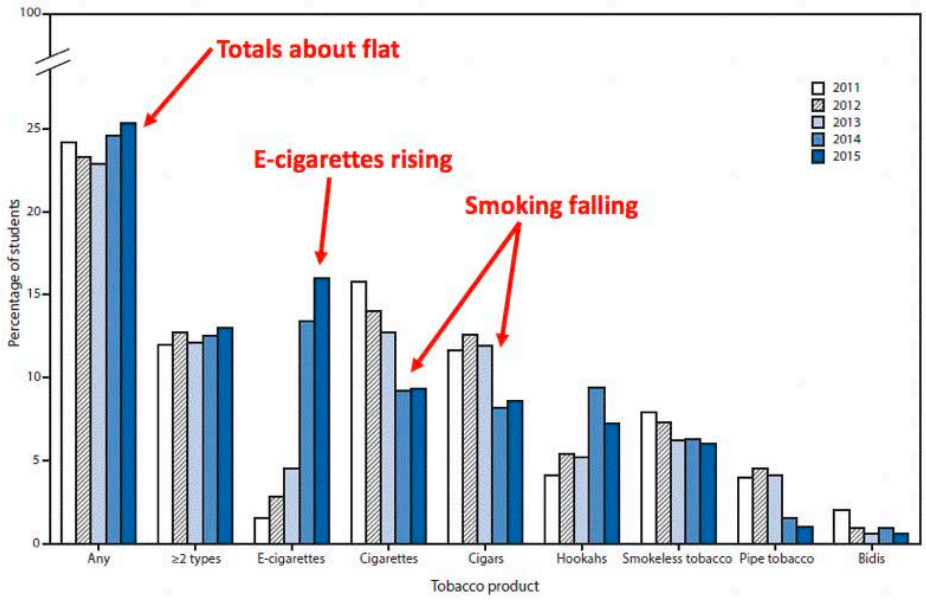
The data are consistent with a decline in smoking partly due to displacement by much lower risk ENDS (an 'exit gateway'). While the nature of the available data cannot show that the accelerated decline is *caused by* the rise of e-cigarettes after 2010, they do provide some reassurance that e-cigarettes are not creating a surge of new adolescent smokers emerging from the other side of a gateway. Far more likely is that they are providing an alternative to smoking and so opening an 'exit' gateway or diversion from smoking.

3.4 The rise in e-cigarette use is concentrated in smokers

In the United States, there has been a significant increase in the numbers of young people using e-cigarettes, and this has coincided with a decline in smoking over the period to 2015[38]. The chart below illustrates the shift in U.S. teenage nicotine use from highly harmful to much less harmful delivery systems. This represents a significant benefit.

Figure 6: Changing patterns of U.S. high school student nicotine and tobacco use 2011-15

FIGURE 1. Estimated percentage of high school students who currently use any tobacco products,* ≥2 tobacco products,† and select tobacco products§
National Youth Tobacco Survey 2011–2015



[36] Singh T, Arrazola RA, Corey CG, et al. *Tobacco Use Among Middle and High School Students — United States, 2011–2015*. MMWR Morb Mortal Wkly Rep 2016;65:361–367. [link] 15 April 2016

[37] O'Leary R, MacDonald M, Stockwell T, Reist D. Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, BC: Centre for Addictions Research of BC.; 2017 [link]

[38] Singh T, Arrazola RA, Corey CG, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2015. MMWR *Morb Mortal Wkly Rep* 2016;65:361–367. [link] 15 April 2016

However, it is important to understand what is happening below the headline figures. The measure used for e-cigarette use is "used at least once in the last 30 days". However, four characteristics about the rising e-cigarette use among young people stand out:

1. **Mostly infrequent use.** Most high school e-cigarette use is infrequent – in 2014, 45.4 percent of those using e-cigarette in the last 30 days had used on only 1-2 days and 61.6 percent on five days or fewer[39].
2. **Mostly non-nicotine**. The University of Michigan Monitoring the Future survey found that most e-cigarette use among teenagers is without nicotine and flavours only[40].

   Among students who had ever used a vaporiser, 65–66% last used 'just flavoring' in 12th, in 10th and in 8th grade, more than all other responses combined."

3. **Mostly concentrated in smokers**. Warner (2016)[41] examined prevalence and frequency of use among smokers and non-smokers:

   Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1–2 of the past 30 days. By contrast, current smokers are likely to use e-cigarettes and on many more days.

4. **With negligible use in never-smokers.** Villanti et al (2016)[42] found negligible frequent e-cigarette use among never smokers.

   Few never tobacco users had used e-cigarettes on 10 or more days in the past month (absolute percent < 0.1%).

The data reviewed here are consistent with a highly positive explanation: that frequent e-cigarette use with nicotine is concentrated in smokers, or people who would otherwise smoke, for whom it is an alternative to smoking or a means of quitting. Much of the rest of the use is infrequent and does not involve nicotine – i.e. it is experimental or frivolous use, rather than a consolidated habit that poses risk of addiction or risks to health.

3.5 Snus in Sweden

Sweden now has a smoking prevalence of approximately 10% (by far the lowest in the developed world[43] and compared to Brazil at 16%). This has happened because cigarette smoking has been displaced by a much lower-risk product, in Sweden's case 'snus'[44]. There have been significant

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39 Neff LJ, Arrazola RA, Caraballo RS, Corey CG, Cox S, King BA, et al. Frequency of Tobacco Use Among Middle and High School Students--United States, 2014. MMWR Morb Mortal Wkly Rep. 2015 Oct 2;64(38):1061–5. [link]

40 Miech R, Patrick ME, O'Malley PM, Johnston LD. What are kids vaping? Results from a national survey of US adolescents. Tob Control. 2016 Aug 25-2016-053014. [link]

41 Warner KE. Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014. Am J Prev Med. Elsevier; 2016 Aug;51(2):179–84. [link]

42 Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. Nicotine Tob Res. 2016 Dec 24;ntw388. [link]

43 European Commission. Eurobarometer Special Survey 429: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2015. [link]

44 Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Jan;12(1):14. [link]

reductions in the burden of disease as a result[45], notably among men, who are the main users of snus.

3.6 Heated tobacco products in Japan

Japan has proved to be an extraordinary testing ground for heated tobacco products. In one city, Sendai, the total share of heated tobacco products reached about 20% (Phillip Morris International 15% and BAT 5%)[46], this is with capacity constraints limiting production and the availability of the devices because of capacity constraints. Nationally, the volume share reached almost 10%[47]. The growth has happened in one year and reflects a dramatic change in the pattern of tobacco consumption.

4 ANDS are part of the solution not part of the problem

4.1 ANDS protect both adults and teenagers from smoking risks

There are also more proportionate means to protect young people than to deprive millions of adult nicotine users of the means to access much lower risk products. Young people also have an interest in the health of adults: their older relatives, and themselves, family and friends as they grow up. Overreaction to unproven and unlikely theoretical risks is not in their interests. The data on youth uptake of e-cigarettes and effects on youth smoking are misrepresented in the reasoning as presented, and provide no support for the interim decision.

4.2 No significant risks identified for long term nicotine use

The long term safety of nicotine has been extensively studied through the use of NRT[48] and snus (oral tobacco)[49] and not been found to be a cause of significant disease. The influence of nicotine on adolescent brain development remains speculative and based largely on animal studies[50], with little supporting evidence in humans – for example observations of adverse effects in the large population of nicotine users who have smoked over many decades. There is extensive knowledge available in systematic reviews – for example, Glasser and colleagues recently reviewed 687 published articles[51] to conclude:

> *Studies indicate that ENDS are increasing in use, particularly among current smokers, pose substantially less harm to smokers than cigarettes, are being used to reduce/quit smoking, and are widely available.*

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45 Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *Int J Environ Res Public Health*. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [link]

46 Jonathan Fell, tobacco sector analyst and investor, personal communication following PMI investor conference April 2017.

47 Philip Morris International, Investor Presentation,

48 Lee PN, Fariss MW. A systematic review of possible serious adverse health effects of nicotine replacement therapy. Arch Toxicol. Springer Berlin Heidelberg; 2016 Oct 3;1–30. [link]

49 Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. Harm Reduct J. England; 2013;10(1):36. [link]

50 Naiura R. Re-thinking nicotine and its effects, Schroeder Institute, Truth Initiative, United States. 2 December 2016 [link][PDF]

51 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. 2016 Nov;0(0):1469–71. [link]

4.3 Comprehensive tobacco control strategy embraces "harm reduction"

Policymakers have been working for five decades to control the burden of tobacco related diseases. The tobacco control strategy should be focussed on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as rapidly as possible. To that end, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking;
2. To motivate and help people to quit smoking;
3. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke;
4. To reduce harm to those who continue to use nicotine.

The fourth strand of tobacco control strategy is known as tobacco harm reduction. The WHO Framework Convention on Tobacco Control (article 1) explicitly endorses tobacco harm reduction strategies in tobacco control[52]:

> *(d) "tobacco control" means 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;* (emphasis added)

E-cigarettes can meet this need by providing a much safer way of using nicotine for people who cannot or do not wish to quit using nicotine.

Tobacco harm reduction remains controversial[53], but there is mounting evidence that it could be transformative in reducing the burden of disease. Many of the top scientists in the field of tobacco and nicotine research now recognise the opportunity to achieve rapid reductions in disease risk[54] and WHO has been severely criticised for presenting a distorted view of the risks and opportunities of e-cigarettes and harm reduction. It produced a poor quality assessment of science for delegates to the 7th Conference of the Parties of the WHO Framework Convention on Tobacco Control[55].

4.4 World Health Assembly targets to reduce tobacco use demand a new approach

The UN and WHA have agreed targets to reduce the premature death caused by non-communicable diseases (NCDs) mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. More than 36 million people die annually from NCDs (63% of global deaths), including 14 million people who die prematurely before the age of 70[56].

In a series of political declarations, the members of the UN General Assembly in 2011[57] and World Health Assembly in 2013[58] [59] committed to taking concerted action to reduce the burden of NCDs by

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52 WHO Framework Convention on Tobacco Control, Article 1(d), 2003 [link]

53 Abrams DB. Promise and Peril of e-Cigarettes Can Disruptive Technology Make Cigarettes Obsolete? JAMA 2014;311:135–6. [link] and Reply by Wasim Maziak [link]

54 Letter to Dr Margaret Chan, Director General WHO, Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control 26 May 2014 [context][letter]

55 UKCTAS, Commentary on WHO report on ENDS and ENNDS, October 2016 [link][PDF]

56 World Health Organisation, Non-communicable diseases and their risk factors [link]

57 UN General Assembly Resolution A/RES/66/2, Heads of State and Government in the United Nations Political Declaration on the Prevention and Control of Non-communicable Diseases [link]

58 World Health Assembly Resolution 66/8 Draft comprehensive global monitoring framework and targets for the prevention and control of non-communicable diseases, March 2013 [link]

attaining nine voluntary global targets[60], including an over-arching target to reduce non-communicable disease mortality and tobacco use.

Figure 7: Relevant World Health Assembly non-communicable disease targets

Framework element	Target	Indicators
Target 1: Non-communicable diseases	A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases by 2025 compared to 2010.	• Unconditional probability of dying between the ages of 30 and 70 from cardiovascular diseases, cancer, diabetes or chronic respiratory diseases • Cancer incidence, by type of cancer, per 100 000 population
Target 5: Tobacco use	A 30% relative reduction in the prevalence of current tobacco use in persons aged 15+ years by 2025 compared to 2010.	• Prevalence of current tobacco use among adolescents • Age-standardized prevalence of current tobacco use among persons aged 18+ years

It will be difficult for Brazil to meet these targets without a new element to its tobacco control strategy. We argue that this a strategy should be tobacco harm reduction, and that the primary means of realising tobacco harm reduction would be through e-cigarettes and other vapour products.

5 Brazil could establish a world-leading regulatory regime for ANDS

Brazil has an opportunity to define a world-leading proportionate public-health orientated regulatory framework for ANDS. The regime defined in the United States is built on legislation designed for tobacco products before most modern ANDS existed. The European Union Tobacco Products Directive is based on pre-2012 understanding of the risks and potential benefits. Neither provides a model for Brazil, or anywhere else. Regulation should be based on the following:

- **Age restrictions.** The products are for sale to adult smokers and sales to under-18s should be prohibited. These are likely to be a political pre-requisite for accessibility of e-cigarettes in the open market.
- **Products standards.** Such an approach would be based on industry-wide standards for ANDS. Standards would be proportionate to risk and address mechanical, thermal, electrical and chemical risks, together with testing regimes. Such standards could be variations on those developed for e-cigarettes by British Standards Institute (BSI)[61] and in France under the equivalent body, AFNOR[62], or a forthcoming European CEN standard. Standards for smokeless or novel tobacco products could follow the findings of WHO's "TobReg" advisory group[63] [64].

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59 World Health Assembly Resolution 66/9 Draft action plan for the prevention and control of non-communicable diseases 2013–2020 [link]

60 World Health Organisation, Global Monitoring Framework for NCDs About 9 voluntary global targets [link]

61 BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [link] July 2015

62 AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [link] and Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [link] March 2015

63 WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation: WHO Technical Report Series, no. 951, 2008 [link]

- **Child resistant packaging.** Standards that would make containers for e-liquids or other potentially harmful substances more difficult to open by children. ISO 8317:2015 *Child resistant packaging* provides such a standard.
- **Taxation.** Brazil could apply differential taxation to products to reflect the risk to users. This would be proportionate and non-discriminatory (i.e. products with different levels of harm would be treated differently) and provide financial incentives to switch from high-risk to low-risk products[65].
- **Labelling**. Provisions of useful information to consumers regarding risks and risk comparison to smoking, the hazards or nicotine liquids or other hazardous substances and what to do if exposed. Information on the producer and where to report any adverse effects or problems.
- **Marketing controls.** It is possible to place constraints on marketing – a practice used for many adult products including alcohol or gambling in many jurisdictions. The U.K. Committee on Advertising Practice has set out guidelines for U.K. advertising of e-cigarettes that were widely welcomed[66] and could be adapted for use in Brazil. These are similar to the restrictions placed on alcohol advertising in the UK. These guidelines could be adapted for any of the ANDS sub-categories.
- **Indoor use restrictions**. We do not consider legally mandated use restrictions on ANDS to be justified unless there is a material risk to bystanders – the so-called "harm principle" governing restrictions of adult choice and property rights. This has been the main justification for banning cigarette smoking in public and private indoor places. No such justification exists for e-cigarettes[67] or to our knowledge for heated tobacco products. For ANDS, the issue is one of nuisance and etiquette, and therefore it should be a matter for owners or managers to determine the best policy.

6 The danger that obstructing ANDS will lead to increased smoking

The danger of excessive regulation or prohibition is that it will do the exact opposite of what health authorities are trying to achieve: increase smoking and protect the cigarette trade. In its 2016 report, the Royal College of Physicians drew attention to this risk of unintended consequences:

> *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*

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[64] WHO TobReg: report on the scientific basis of tobacco product regulation: 5th report of a WHO study group. WHO Technical report series, no. 989. 2015. [link]

[65] Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. *New England Journal of Medicine* 2015;373:594–7. [link]

[66] Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [link]

[67] Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 2014 [link]

inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (Section 12.10 page 187 – emphasis added)

In fact, there is now tentative evidence suggesting that this is happening. Research from the United States suggests that age restrictions placed on vaping have the effect of *increasing* teenage smoking[68] [69] [70]. Note that if this effect is true for age restrictions, it is likely also to be true for any broader prohibitions (such as that proposed for Brazil) that blocks access to safer alternatives to smoking. This evidence should be taken as indicative of potential harmful unintended consequences arising excessive restriction of ANDS.

There is again scope for unintended consequences arising from excessive restriction of the advertising of low risk alternatives to smoking – namely that there will be more smoking and less use of low-risk alternatives. Basic economic analysis would support that expectation and some care is needed to avoid unintended consequences[71]. There are other restrictive policies that may risk increases in smoking:

- Warnings that scare users rather than informing them that ANDS are much less risky than smoking.
- Pervasive bans on ANDS use indoors may encourage relapse to smoking and discourage switching from smoking to e-cigarette use.
- Excessive taxation on ANDS would adversely change price differentials between e-cigarettes and cigarette, reducing or eliminating the financial incentive to switch.
- Bans on ANDS flavours or other product restrictions could make the products less appealing and discourage switching from smoking to e-cigarette use.

7 Summary: the benefits of the regulated availability of ANDS in Brazil

Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that alternative nicotine delivery systems (ANDS) could be a benefit to millions of smokers.

- Smokers who switch to well-regulated ANDS are likely to avoid at least 95% of the major smoking-related risks for cancer, heart disease and respiratory illness. They will also experience significant short-term gains in health and wellbeing and they are likely to be financially better off.
- Harm reduction strategies can contribute to meeting national health policy goals and international commitments to tackle non-communicable diseases and reduce tobacco use.

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[68] Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [link]

[69] Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med (Baltim),* February 2016 [link]

[70] Pesko M, Currie J. The Effect of E-Cigarette Minimum Legal Sale Age Laws on Traditional Cigarette Use and Birth Outcomes among Pregnant Teenagers. Cambridge, MA; 2016 Nov. [link]

[71] Tuchman A. Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising, Stanford University, (working paper) September 2015 [link]

- It is unethical to deny a smoker access to products that are much safer than the dominant product on the market, cigarettes. Outside the field of tobacco and illicit drugs, there are no precedents for obstructing access to safer alternatives to widely used products. No government should deliberately try to deny smokers this option – now adopted by millions of smokers world-wide.
- The availability of ANDS is not an alternative to conventional anti-smoking policy but complementary. By providing smokers with an easier way of responding to the pressures of high taxes and other "MPOWER" measures of conventional tobacco control, the overall tobacco control policy will become both more responsive and more humane.
- There is no credible evidence to suggest that ANDS undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence, when examined dispassionately, shows what a neutral observer would expect: people use much safer products to reduce their health risks or to quit smoking.
- ANDS are an effective tool for switching from smoking without the need for public spending or programmes. Individual smokers bear the costs and the 'health promotion' expenditures are made by manufacturers advertising ANDS as alternatives to smoking.
- A widespread switch to ANDS would also reduce exposure to second-hand tobacco smoke. E-cigarettes pose no material risk to bystanders and it is likely that exposures from heated tobacco products would be far lower than for cigarettes. It should be a matter for owners of public places, not the law, to decide if e-cigarette use should be permitted or not permitted.
- The quality of ANDS products available from reputable manufacturers is now very high and they are on widespread sale in Europe, North America and throughout Asia without any major problems. Brazil should aspire to develop this industry for exports and as a rival to the cigarette trade.
- There is a growing international experience with the regulation of e-cigarettes as popular consumer products, and, by changing its approach, Brazil has the opportunity to take a leadership role in these developments and in the regulation of heated tobacco products.
- It would be better for Brazil to have its own legitimate and properly regulated supply chain for ANDS and to have responsible producers contributing corporate and sales taxes as appropriate, and less international internet trade in illicit, unregulated, or counterfeit products.
- We urge the government of Brazil not to protect the cigarette trade in Brazil from competition from superior low-risk products by obstructing their access to market them. The danger of obstructing access to ANDS is that it will amount to unintentional protection of cigarette sales, inadvertent promotion of smoking and unnecessary harm to health.