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REGULATORY RESTRICTION OF E-VAPOR PRODUCTS UNDER INTERNATIONAL HUMAN RIGHTS LAW

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EXECUTIVE SUMMARY

uman rights law is increasingly important in international and domestic tobacco control debates.¹ More generally, human rights have proven essential in shaping health and socioeconomic policies and in ensuring accountability.² They are also directly relevant to the regulation of e-vapor products (EVPs), which are still surrounded by controversy. Accordingly, the present study explores the relevance of human rights—in particular the right to health, as enshrined in various international human rights treaties—to the regulatory freedom enjoyed by the states with respect to the regulation of EVPs.

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For the purposes of this study, the term "EVP" covers electronically heated tobacco products (EHTPs) and e-cigarettes. However, the arguments provided herein have broader implications and may be applicable to other categories of smoking alternatives (e.g. snus), which are not examined in this study specifically. These arguments provide potential grounds to regard human rights treaties as conducive to liberal EVP markets, as opposed to the increasingly restrictive approach being taken in a number of countries. The conclusions reached can therefore be particularly helpful as an alternative to policy-making that proposes complete bans or stringent fiscal measures on EVPs, such as equal taxation treatment for EVPs and cigarettes.

Taken together, the human rights treaties reflect a comprehensive body of law that includes relevant standards and obligations for governments in relation to tobacco control. This means that any international law norm (for example, the Framework Convention on Tobacco Control)³ emerges in a wider context of international law that is made up of pre-existing treaties (e.g., the International Covenant on Economic, Social, and Cultural Rights in the field of human rights). This, of course, is largely premised on the fact that there is no strict hierarchy in international law (as opposed to domestic law), as its development is generally guided by the desire to avoid inconsistencies and tensions with existent norms. Put simply, this means that the obligation of governments around the world to provide health for its citizens as

See, e.g., "Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery ery Systems (ENDS/ENNDS)," World Health Organization, August 2016, pp. 7-12. https://www.ho.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.

^{2.} For example, in relevant case law on access to medicines in which human rights play an important role. See, e.g., S. Katrina Perehudoff et al., "Essential Medicines in National Constitutions" *Health and Human Rights Journal* 141 (2016), p. 18. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5070687</u>.

^{3.} WHO Framework Convention on Tobacco Control, World Health Organization, updated 2005. https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013. pdf;jsessionid=9565B1F912E2FE2E4438D862FDB1CD47?sequence=1.

enshrined in human rights treaties may preclude States from introducing overly restrictive regulations on EVPs.

INTRODUCTION

Despite the existence of evidence that shows reduction in health risks for individual smokers who switch entirely from smoking conventional cigarettes to e-vapor products (EVPs),⁴ some nations have set up direct or indirect bans on sales and possession of these products. Today, roughly twenty-seven countries have entirely banned the introduction of e-cigarettes into their territories.⁵ In nine others, the sale of nicotine-containing e-cigarettes is prohibited.⁶ Along with e-cigarettes, a ban on electronically heated tobacco products (EHTPs) is applied by several countries like Brazil, Panama, New Zealand, Taiwan,⁷ Thailand and Norway. India is currently considering a ban on e-cigarettes, as well.⁸

Another important challenge States have to tackle is a taxation structure that incentivizes smokers to switch while minimizing uptake in non-smokers. Some governments fail to consider the potential reduced risk of these products compared to traditional cigarettes, and therefore apply or propose high taxation. For example, in the United States, California increased taxes on e-cigarettes and other nicotine delivery devices sold in combination with nicotine at a rate equivalent to those applied to combustible cigarettes.⁹ The implications of such a policy is that a conscious decision is being made not to financially incentivize smokers to switch to comparatively reduced-risk EVPs. Such a policy is likely to have a particular impact on those in disadvantaged socioeconomic groups, as they are more likely to be price sensitive and already suffer health inequalities. For these reasons, the optimum taxation of EVPs should be determined with consideration for the potential of these products to deliver positive results in efforts to control the health consequences of smoking. Such an approach would align with the due pursuit of ensuring the right to health to a nation's citizens.

Moreover, the international community has recognized that the enjoyment of a high standard of health is an integral part of the rights to which every human being is entitled. The protection of this right to health must be taken into consideration during the design and implementation of all public laws and policies, including those regarding trade and taxation. Therefore, tax and trade measures must not prevent the protection of the human right to health, but rather must reflect a committed pursuit of this objective. In fact, failing to incorporate public health considerations into the design of fiscal policies and market regulations may constitute a violation of the duty of every State to protect human health. In the context of EVPs, this may particularly require consideration of lower taxes and less-strict regulations in order to allow a wider group of current smokers to access such products.

There is evidence that EVPs are rightly perceived by a substantial number of smokers as a less risky alternative to conventional cigarettes. Data published in the British Medical Journal in 2014 shows that the use of EVPs was especially high among smokers, with 32 percent in 2012 and 50 percent in 2013 reporting having tried EVPs.¹⁰ As such, to replace smoking with these products has the potential to reduce smoking-related diseases for those who switch entirely or even partially to EVPs. Thus, it could be argued that restricting access-either directly with explicit bans or indirectly through excessive regulations or taxation-may deprive smokers of the opportunity to reduce the health risks to which they are exposed, thereby contravening the States' obligation to protect the right to health. Accordingly, States should instead responsibly facilitate consumer access to such products, which encourages people to take individual responsibility for the protection of their own wellbeinganother obligation of the international right to health.

National Academies of Sciences, Engineering, and Medicine, *Public Health* Consequences of E-Cigarettes (The National Academies Press, 2018). <u>https://doi.org/10.17226/24952</u>.

^{5.} Bans exist in Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Gambia, Greece, Jordan, Kuwait, Lebanon, Mauritius, Nepal, Nicaragua, Oman, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, Turkmenistan, Uganda, United Arab Emirates and Uruguay. Data retrieved from <u>http:// globaltobaccocontrol.org/e-cigarette/policy-domains</u> with further rectifications by the author.

^{6.} The full list includes Australia, Canada, Costa Rica, Jamaica, Japan, Malaysia, Mexico, New Zealand and Switzerland. Data retrieved from http://globaltobacco-control.org/e-cigarette/policy-domains. It should be noted that following intense domestic debates on optimal tobacco control strategies, Australia, New Zealand and Switzerland are considering lifting the ban on e-cigarettes. Indeed, it is difficult to keep track of the constantly changing legislation on EVPs, but for a recent summary, see Jim McDonald, "Vaping Laws: Where on Earth are Vapes Banned or Restricted," Vaping 360, Feb. 11, 2019. https://globaltobacco-control strategies, Australia, New Zealand and Switzerland are considering lifting the ban on e-cigarettes. Indeed, it is difficult to keep track of the constantly changing legislation on EVPs, but for a recent summary, see Jim McDonald, "Vaping Laws: Where on Earth are Vapes Banned or Restricted," Vaping 360, Feb. 11, 2019. https://yaping360.com/rules-laws/countries-where-vaping-is-banned-illegal/#why-do-countries-ban-vaping.

^{7.} On Taiwan, see: "Tough Times Ahead for Taiwan's E-Cig Market," Trade Pacts, March 21, 2017. <u>https://tradepacts.com/news/tough-times-ahead-for-taiwans-e-cig-market</u>.

^{8.} See, e.g., Sushmi Dey, "Govt likely to stub out 'toxic' e-cigarettes," *The Times of India*, Aug. 1, 2017. <u>https://timesofindia.indiatimes.com/india/govt-likely-to-stub-out-toxic-e-cigarettes/articleshow/59855386.cms; and Carrie L. Wade and Marina Foltea</u> "India has over 100 million adult smokers, yet it wants a safer alternative banned," *Quartz India*, May 22, 2019. <u>https://gz.com/india/1625143/india-must-realise-that-e-cigarettes-vaping-curb-smoking</u>.

Mark Glover, "Think cigarettes cost too much? Wait until Saturday," *The Sacramento Bee*, March 30, 2017. <u>https://www.sacbee.com/news/business/article141834509.</u> <u>html</u>.

^{10.} Jessica Pepper et al., "Effects of advertisements on smokers' interest in trying e-cigarettes: the roles of product comparison and visual cues" *Tobacco Control* 23 (2014), p. iii31. http://tobaccocontrol.bmj.com/content/23/ suppl_3/iii31.full#xrefref-16-1. See also Marina Foltea and Anna Markitanova, "The 'likeness' of E-Vapour products and cigarettes in the WTO," *European Journal of Risk Regulation* 8:2 (June 2017), pp. 350-51. https://www.cambridge.org/core/journals/european-journal-ofrisk-regulation/article/likeness-of-evapour-products-and-cigarettes-in-the-worldtrade-organization/913935C281AC02DE4DFFF7321C9B63C9.

A COMPARISON OF COMBUSTIBLE CIGARETTES TO ALTERNATIVES

Smoking tobacco is the most harmful way to consume nicotine. This is because combustion of the tobacco leaf is responsible for the production and release of over 7,000 chemicals, many of which are recognized as harmful or potentially harmful to health.¹¹ In most cases, the consumption of nicotine is the main driver behind smoking.¹² However, while smoking tobacco is generally the most popular way to consume nicotine, innovative technologies such as EVPs have emerged as a way to deliver nicotine without combustion. This involves the heating of tobacco or a liquid without the actual combustion of tobacco leaf.

Several studies indicate that the use of EVPs instead of smoking may significantly reduce the risk of developing a number of smoking-related diseases.¹³ For instance, a study from the American College of Physicians found that "long-term use of [Nicotine Replacement Therapy (NRT)] and e-cigarettes is associated with lower levels of carcinogens and toxins than cigarette smoking," and that "these lower levels [...] support the assertion that e-cigarettes may be less harmful than smoking."¹⁴ Further, a study from Cancer Research UK concluded:

Studies show that people who switch completely from tobacco to e-cigarettes are less exposed to key harmful chemicals in tobacco smoke. There are still some questions about long-term safety, as e-cigarettes [have not] been around that long, but the evidence is pointing towards them being much safer than tobacco. In fact, research suggests that in terms of safety, e-cigarettes are far closer to nicotine replacement therapy (NRT)—a long-established safer alternative to smoking—than they are to cigarettes.¹⁵ For these reasons, e-cigarettes can be useful as cessation aids and thus can help to improve health outcomes of current smokers. Indeed, the most recent report issued by the Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems (operating within the structure of the National Academies of Sciences) noted that there was:

sufficient literature to suggest that, while there are risks associated with e-cigarettes, compared with combustible tobacco cigarettes, e-cigarettes contain fewer toxicants; can deliver nicotine in a manner similar to combustible tobacco cigarettes [...] and might be useful as a cessation aid in smokers who use e-cigarettes exclusively.¹⁶

The same conclusion was reached in a 2018 report commissioned by Public Health England, which indicated that: "Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking."¹⁷

And finally, in its December 2017 report, the independent Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (UK) made similar findings with respects to EHTPs. In particular, the Committee noted that:

The exposure to compounds of concern in using heatnot-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products.¹⁸

In addition to these findings about the reduction of health risks associated with switching, it has also been demonstrated that the use of EVPs may increase the chances of successfully quitting smoking.¹⁹ For example, the authors of the Public Health England report observed that e-cigarette use may be associated with improved quit-success rates in the United Kingdom over the last year and thus responsible for an acceleration in the drop-in smoking rates across the country. In this context, they particularly note that e-cigarettes

^{11.} See, e.g., Gerry E. Stimson, "Report of Professor Emeritus Gerry Stimson for the High Court of Justice," Queen's Bench Division, Administrative Court, Jan. 30, 2017, p. 5 https://nnalliance.org/images/documents/NNA_Expert_Statement_of_Professor_ Emeritus_Gerry_Stimson_redacted.pdf; and Michael A. Russell, "Low-tar Medium-Nicotine Cigarettes: A New Approach to Safer Smoking," British Medical Journal 6023 (1976). https://www.ncbi.nlm.nih.gov/pubmed/953530.

See, e.g., Russell, pp. 1430-33; and "The Nature of Nicotine Addiction," in *Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*, B.S. Lynch and R.J. Bonnie, eds., (National Academies Press, 1994). <u>https://www.ncbi.nlm.nih.gov/books/NBK236759</u>.

^{13.} See, e.g., A. McNeill et al., "E-cigarettes: An Evidence Update A Report Commissioned by Public Health About Public Health England," Public Health England, August 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/Ecigarettes an evidence update A report_commissioned by Public Health England FINAL.pdf. According to this review, e-cigarettes are 95 percent less risky than smoking regular cigarettes. See also: Tobacco Advisory Group, "Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit," Royal College of Physicians, 2007. https://shop.rcplondon.ac.uk/products/harm-reduction-in-nicotine-addiction-helping-people-who-cant-quit?variant=6509405637.

Henri-Jean Aubin et al., "E-Cigarettes and Toxin Exposure," Annals of Internal Medicine 167:7 (2017), pp. 524-25. <u>https://annals.org/aim/article-abstract/2656194/ecigarettes-toxin-exposure</u>.

^{15. &}quot;Are e-cigarettes harmful?", Cancer Research UK, Nov. 28, 2017. <u>http://www.cancerresearchuk.org/about-cancer/causes-of-cancer/smoking-and-cancer/e-ciga-rettes?</u> ga=2.195728036.989904343.1513355662-238555395.1513355662.

^{16.} Public Health Consequences of E-cigarettes. http://nationalacademies.org/hmd/ reports/2018/public-health-consequences-of-e-cigarettes.aspx.

A. McNeill et al., "Evidence review of e-cigarettes and heated tobacco products 2018, A report commissioned by Public Health England" Public Health England, 2018, p. 20. <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/</u> <u>attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_</u> <u>tobacco_products_2018.pdf.</u>

^{18. &}quot;Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary," Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, Dec. 11, 2017. <u>https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf</u>.

^{19. &}quot;Tobacco consumption statistics," Eurostat, December 2017. <u>http://ec.europa.eu/</u> <u>eurostat/statistics-explained/index.php/Tobacco_consumption_statistics</u>.

could be contributing to at least 20,000 successful new quits per year.²⁰ Moreover, it has been argued that the use of these potentially lower-risk alternatives may produce better results than other nicotine replacement therapies (NRTs) in reducing smoking levels.²¹ Therefore, both EHTPs and e-cigarettes could (and likely do already) constitute very useful tools in the process of improving the health of current smokers.

THE HUMAN RIGHT TO HEALTH

International Law and the Right to Health

International law is the pillar upon which the laws of nations are built. It sets out rules that establish basic principles that can be improved and adapted to the on-the-ground reality of each of the States that has agreed to its rules and principles. It is a supra-national set of standards that guides national legislators toward the attainment of common objectives. While domestic law may take into consideration the particular circumstances of the enacting State, any national law enacted must not depart from the substance of the international rules to which they are related. And thus, the flexibility granted by international law to national legislators should not be equated to an exemption from compliance with the international obligations contained in the applicable treaties or customary rules. In this way, international law establishes the contours of the legislative space that countries enjoy when regulating certain areas of human activity.

The fact that health is recognized as a right under international law demonstrates that public health is of the utmost importance for most nations. It amounts to a universal recognition that the protection of human health is a *responsibility* that must be undertaken by *all States*. Accordingly, numerous international agreements on human rights have recognized that the right to health is a prerogative inherent to every human being.²² Fundamentally, these are elicited from the 1948 *Universal Declaration of Human Rights* (*UDHR*) and the 1969 *International Convention on the Elimi*-

nation of All Forms of Racial Discrimination.²³ The UDHR reflects the importance of protecting individuals against illegitimate government interference and of vesting them with certain rights-claims against governments, including access to facilities, goods and services essential to address at least basic needs.²⁴ Moreover, the 1969 International Covenant on Civil and Political Rights (ICCPR) and the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) were adopted in order to give legal teeth to the UDHR. The ICESCR establishes, for example, in Article 12 that everyone is entitled "to the enjoyment of the highest attainable standard of physical and mental health."25 The full realization of this right requires State parties to take actions toward the "prevention, treatment and control of epidemic, endemic, occupational and other diseases," and the "creation of conditions which would assure to all medical service and medical attention in the event of sickness."26

The Nature and Scope of the Right to Health

The recognition of the protection of health as a basic human right requires actions aimed at the improvement of public health. Thus, such a goal must take a central role in the construction of public policies and the ordering of social life. The right to health also requires that governments take decisive actions within their means to prevent health risks among their populations, and to empower individuals and communities to protect their own health. More precisely, under human rights law, States have obligations to respect, protect and fulfill human rights.²⁷ Thus, depending on the context and the applicable right, States are obliged to abstain from illegitimate interference with a right (respect), to (protect) individuals from illegitimate interference of their rights by others, and to take deliberate and active steps toward the full realization of human rights (fulfill). In sum, human rights law traditionally places duties upon States and vests individuals with the right to claims on the government.²⁸

^{20. &}quot;Evidence review of e-cigarettes and heated tobacco products 2018," p. 16. 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.

^{21.} Robert West et al., "Estimating the population impact of e-cigarettes on smoking cessation in England," *Addiction* 111:6 (2016), pp.1118-19. <u>https://onlinelibrary.wiley.com/doi/full/10.1111/add.13345</u>, See also, Jen Makki, "The incentives created by a harm reduction approach to smoking cessation: Snus and smoking in Sweden and Finland," *International Journal of Drug Policy* 26:6 (2015), pp. 569-74. <u>https://www.ncbi.nlm.nih.gov/pubmed/25214359</u>.

^{22.} See, e.g., Universal Declaration of Human Right (1948); International Convention on the Elimination of All Forms of Racial Discrimination (1969); International Covenant on Civil and Political Rights (1969); and International Covenant on Economic, Social and Cultural Rights (1966).

^{23.} See: Universal Declaration of Human Rights, Dec. 10, 1948, Art. 25(1). <u>http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf</u>. See also, International Convention on the Elimination of All Forms of Racial Discrimination, Dec. 21, 1969, Art. 5(e)(iv). <u>http://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx</u>.

^{24.} The UDHR includes both civil and political rights, as well as economic, social and cultural ones. For example, Article 3 includes the right to life, which is a classic civil right, whereas Article 25 includes the right to health, which is a typical social right.

^{25.} See: *The International Covenant on Economic, Social and Cultural Rights*, Dec. 16, 1966. <u>http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx</u>.

^{26.} Ibid., ¶ C.

^{27.} Maastricht Guidelines on Violations of Economic, Social, and Cultural Rights (1997, reissued Oct. 2, 2000), ¶ 6. https://undocs.org/en/e/c.12/2000/13. CESCR, "General Comment No. 14 on The Right to the Highest Attainable Standard of Health (Art. 12)," Aug. 11, 2000, ¶ 4. https://undocs.org/en/E/C.12/2000/4.

^{28.} Anders Henriksen, International Law (Oxford University Press, 2017), p. 177.

TOBACCO CONTROL POLICY IN THE RIGHT-TO-HEALTH CONTEXT

With respect to tobacco control policy specifically in this context, governments have the obligation to protect and fulfill the right to health and any related rights. Moreover, research into international and regional human rights law and tobacco control demonstrates that governments have obligations to regulate the entire supply chain of tobacco products in the fulfilment of the right to health of citizens.²⁹ That said and given the impact of EVPs on public health, these obligations should also inform the approach of governments toward the regulation of EVPs.

In terms of EVPS, the right to health could be elicited from a number of legal provisions. The obligations of the States arising thereof can be summarized as follows: 1) to provide access to information on EVPs; 2) to include EVPs in harm reduction strategies and; 3) to provide environmental health protection. Accordingly, these obligations are discussed in greater detail in the following sections.

Access to Information

Information accessibility is a central component to the adequate realization of the right to health, as complemented by the right to information enshrined in Article 19 of the *ICCPR*.³⁰ Moreover, in light of Article 12 of the *ICESCR*, information accessibility broadly includes "the right to seek, receive and impart information and ideas concerning health issues."³¹ With respect to EVPs, in the affirmative, this right includes consumer access to information regarding the alleged benefits and/or harms of EVPs. However, a State would also be in breach of its health-related information obligation if it were to promote misinformation or to fail to take steps to prevent interested third parties from doing so.

As the tobacco market moves quickly toward reduced-risk products, including both EHTPs and e-cigarettes, for the sake of accurate information, it is first important to distinguish between the degree of harm caused by these products.³² Indeed, individuals are equally misled when all nicotinecontaining products are lumped under the same umbrella as equally harmful.³³ Therefore, "greater efforts should be undertaken to promote more accurate perceptions of relative health risks between tobacco product[s]."³⁴ This can start with public health officials acknowledging that EVPs are less risky than cigarettes. Continued mixed messages from government officials and tobacco use prevention organizations confuse people regarding the actual risks from EVPs.³⁵

Such access to information is also important in another context. Aside from the elements illustrated below, the right to health also entails an obligation on the States to encourage people to take individual responsibility in the protection of their own health. Thus, States must not only adopt measures that prevent the development or spread of diseases amongst their populations, but also facilitate the conditions that would enable individuals to protect their health by abandoning unhealthy practices, for example. This has also been recognized in the preamble of WHO Constitution, which states that "[i]nformed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people."36 The WHO has also acknowledged that "[t]he responsibility for health promotion in health services is shared among individuals, community groups, health professionals, health service institutions and governments."37

Including EVPs in Harm Reduction Strategies

The *ICESCR* provides various grounds upon which governments have to ensure access to harm reduction programs. For example, Article 12.2(d) requires governments to ensure access to health facilities, goods and services with emphasis on health rehabilitative services and education.³⁸ In the case of tobacco control, products like Nicotine Replacement Therapies (NRTs), such as nicotine patches, gum or mouth spray, are generally regarded as valid for harm reduction purposes. And particularly since smoking abstinence is limited

^{29.} See, e.g., Carolyn Dresler et al., "The Emerging Human Right to Tobacco Control," Human Rights Quarterly 28 (2006), p. 599. https://pdfs.semanticscholar.org/82b6/94 <u>Taalc44b45a7lbed76d7a432d69c82f9lc.pdf</u>, Rangita de Silva de Alwis et al., "Reconceptualizing Human Rights to Challenge Tobacco" *Michigan State International Law Review* 17 (2009), p. 304. https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?artic le=2690&context=faculty_scholarship.

^{30.} Article 19 of the ICCPR states: "1. Everyone shall have the right to hold opinions without interference. 2. Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice." https://www.ohchr.org/en/professionalinter-est/pages/ccpr.aspx.

^{31.} See "General Comment No. 14 on The Right to the Highest Attainable Standard of Health (Art. 12)," ¶ 12.b. <u>https://undocs.org/en/E/C.12/2000/4</u>.

^{32.} Marie Elske Gispen et al., "A human rights approach to the regulation of electronic cigarettes," in *The Regulation of E-cigarettes: International, European and National Legal Challenges*, ed. Lukasz Gruszczynski (Edward Elgar Publishing, 2019), p. 8.

^{33.} See, e.g., Brad Rodu et al., "Tobacco Harm Reduction" Harm Reduction Journal 15:3 (2006). For an analysis of both sides of the misinformation issue, see: Lynn T. Kozlowski et al., "Obsolete Tobacco Control Themes Can be Hazardous to Public Health" BMC Public Health 16 (2016), p. 4. <u>https://bmcpublichealth.biomedcentral.</u> com/articles/10.1186/s12889-016-3079-9.

^{34.} W.E. Callery et al., "The appeal of smokeless tobacco products among young Canadian smokers: the impact of pictorial health warnings and relative risk messages," *Nicotine Tobacco Research* 13:5 (2011). <u>https://www.ncbi.nlm.nih.gov/pubmed/21357730</u>.

^{35.} Carrie Wade, "Applying harm reduction to smoking," *Truth on the Market*, Nov. 13, 2018. <u>https://truthonthemarket.com/2018/10/15/applying-harm-reduction-to-smoking</u>.

^{36.} Constitution of the World Health Organization (July 21, 1946). <u>http://www.who.int/</u>governance/eb/who_constitution_en.pdf.

^{37.} The Ottawa Charter on Health Promotion, World Health Organization, Nov. 21, 1986. https://www.who.int/healthpromotion/conferences/previous/ottawa/en.

^{38. &}quot;General Comment No. 14 on The Right to the Highest Attainable Standard of Health (Art. 12)," ¶ 1. <u>https://undocs.org/en/E/C.12/2000/4</u>.

as a strategy to tackle the tobacco epidemic,³⁹ the harm reduction approach should be extended to include the use of EVPs alongside NRTs. Following this logic, States would be in violation of the obligation to respect the right to health if they were to impose a complete prohibition on the sale, possession or use of EVPs and did not make an exception from these restrictions for harm reduction purposes. This is also true with respect to stringent fiscal policy applicable to EVPs, which only disincentivizes the consumer from using these alternatives.

Providing Environmental Health Protection

The environmental health protection obligation arises from Article 12.2(b) of the *ICESCR*, which prescribes States to improve "all aspects of environmental and industrial hygiene."⁴⁰ This provision has been discussed in relation to tobacco smoking exposure where environmental health protection obligations specifically require governments to discourage the use of tobacco and other harmful substances.

Since no exposure at all to the harmful substances linked to tobacco smoking is clearly the preferred scenario, it is reasonable to propose that if all current smokers were to replace cigarette smoking with EVPs, which contain much lower levels of environmental toxic substances,⁴¹ the current negative impact from second-hand smoking would be reduced considerably. This is also true considering that indoor smoking bans are either not implemented universally or are simply circumscribed. In any event, given the difficulty of quitting entirely, any immediate reduction in airborne toxicity from traditional cigarettes cannot be reduced if alternative products with reduced toxic emissions are being prohibited or otherwise restrained.

The European Union's Example

Notably, under the law of the European Union (EU), the right of preserving human health is implicit in the right to life, which is contained in Article 2(1) of the *Charter of Fundamental Rights* of the EU (*CFR*). Article 35 of the *CFR*, which specifically refers to healthcare, further recognizes that the attainment of a high level of human health protection is a desirable goal.⁴² Thus, under European law, the right to health is not circumscribed to the enjoyment of only basic health conditions. Put simply, this means that the *CFR* provides that everyone is entitled to have access to adequate preventive and curative healthcare.

But, while such treaties do enjoin the actions of governments, responsibility for the protection of health does not solely fall to them. Rather, States and individuals must act together in pursuit of the same objective. For this reason, Article 11 of the *European Social Charter* provides that the protection of the human right to health is a shared responsibility between States and individuals.⁴³ Thus, EU Members must not only take actions to prevent health risks, but they must also encourage the individual responsibility to protect health.⁴⁴

On the part of the States, the protection of the right to health may be achieved through the combined action of various policies, laws and regulations, even those that are not directly linked to health (e.g. fiscal and trade measures).⁴⁵ For this reason, Article 168 of the *Treaty of Lisbon*, for example, requires that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."⁴⁶ It also bolsters such a requirement by acknowledging that this has also been recognized by the World Health Organization (WHO), which provides that: "In pursuing a rights-based approach, health policy, strategies and programs should be designed explicitly to improve the enjoyment of all people to the right to health, with a focus on the furthest behind first."⁴⁷

The wide historical policy experimentation on tobacco control, where some policies have been less successful than others, allows for informed and pragmatic decisions over the current regulation of EVPs. The policy ambition to attain

45. See, e.g., Amy Eyler et al., eds., *Prevention, Policy, and Public Health* (Oxford University Press, 2016), pp. 9-10; Marvin Waterstone, ed., *Risk and Society: The Interaction of Science, Technology and Public Policy* (Springer, 1992), p. 137.

46. Treaty on the European Union (Dec. 13, 2007). <u>http://eur-lex.europa.eu/legal-con-tent/EN/TXT/PDF/?uri=CELEX:12007L/TXT&from=EN</u>.

47. "Human rights and health," World Health Organization, December 2017. <u>https://www.who.int/en/news-room/fact-sheets/detail/human-rights-and-health.</u>

^{39.} Wade. https://truthonthemarket.com/2018/10/15/applying-harm-reduction-tosmoking.

^{40.} ICESCR, Art. 12.2(b). http://www.ohchr.org/EN/ProfessionalInterest/Pages/ CESCR.aspx.

^{41.} For EHTPs, see Kanae Bekki et al., "Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes," *Journal of The University Occupational Environmental Health* 39 (2017), pp. 201-07. <u>https://www.ncbi.nlm.</u> <u>nih.gov/pubmed/28904270. For ENDS</u>, see Esteve Fernández et al., "Particulate Matter from Electronic Cigarettes and Conventional Cigarettes: a Systematic Review and Observational Study," *Current Environmental Health Reports* 2:4 (2015), pp. 423-29. <u>https://www.ncbi.nlm.nih.gov/pubmed/26452675</u>.

^{42.} Article 35 of the CFR states: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities." <u>https://www.europarl.europa.eu/charter/pdf/text_en.pdf</u>.

^{43.} The European Social Charter is available at: https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168006b642.

^{44.} Article 11 of the CFR also states: "With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed inter alia: 1.to remove as far as possible the causes of ill-health; 2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; 3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents." https://www.europarl.europa.eu/charter/pdf/text en.pdf.

a high level of human health protection should therefore leave an open door for factoring in innovation in this field even where the investment in these (reduced-risk) products emerges from traditional tobacco companies. The ability of the consumer to access accurate information over the relative risk of EVPs in combination with their inclusion in harm-reduction policies will show real commitment to the goal of improving public health.

ACCOMODATING THE RIGHT TO HEALTH IN POLICY-MAKING

The importance of the right to health, and its recognition by governments, is reflected in the adoption of the following recent policy and judicial decisions in the areas of women's health products and marijuana for medical purposes. Such steps are important ones and can inform future regulatory work on EVPs.

Taxation of Women's Health Products

Many countries impose a tax on female hygiene and sanitary products. In the last few years, there have been widespread high-profile advocacy campaigns demanding the exemption of these products from tax, with advocates successfully citing the "right to health" as justification.⁴⁸ As a result, Canada removed its tax on female hygiene products in 2015.⁴⁹ After a widespread public campaign, the United Kingdom has reduced its Value Added Tax on female sanitary products,⁵⁰ and New York state eliminated its sales tax on feminine hygiene products in 2016.⁵¹

Legalization and Reclassification of Medical Marijuana

Marijuana use for medical purposes has been legalized in many countries. For example, in Brazil, a claim that a prohibition on the import of cannabidiolbased products for medical use was incompatible with the "right to health" was successfully argued in a class action legal dispute in 2015. The injunction obtained against the State of Brazil meant that the substance was removed from a list of banned substances and could be imported for use.⁵² Moreover, the UN Special Rapporteur on the Right to Health has called for the decriminalization and legal regulation of drugs "within which the right to health must remain central."⁵³

Designing Health-Oriented EVP Policies

In the context of EVPs, the right to health will be duly recognized only if these products are available as an alternative to combustible products. Beyond diverting people away from the risks of smoking, it could be argued that the protection of the right to health requires States to encourage people to protect their health, for instance, by switching from smoking to potentially lower-risk alternative products, such as EVPs.⁵⁴ On the other hand, to impose trade restrictive measures (e.g. complete bans on EVPs) and/or high taxes on these products overtly obstructs consumers' access to, and the affordability of, these products. Such a regulatory approach may represent a failure to comply with the States' obligation to protect human health as enshrined in the various international human rights treaties discussed in this study.

Allowing free trade in EVPs and using health-friendly fiscal measures would also be consistent with the principle of autonomy and choice embedded in Articles 1 and 7 of the *Charter of Fundamental Rights* of the EU. According to this principle, individuals' dignity and private life must be respected, including their ability to make personal choices in their own lives. Therefore, consumers should be empowered to choose the means of consuming nicotine, especially if such means entail much lower health risks compared to those presented by other products available in the market.

Since the use of EVPs has the potential to significantly decrease the health risks associated with smoking cigarettes and may enhance the chances of quitting smoking, allowing the presence of these reduced-risk alternatives on the market is also compatible with the tobacco harm reduction objectives recognized in the WHO's *Framework Convention on Tobacco Control (FCTC)*, which require States to aim at both reducing and eliminating the harms associated with smoking tobacco.⁵⁵

Anastasia Kyriacou, "Period Poverty: A Bloody Injustice," *Huffington Post*, September 2017. <u>http://www.huffingtonpost.co.uk/anastasia-kyriacou/period-poverty-abloody-i_b_18116758.html.</u>

^{49.} See, e.g., "The Bill introduced and statements of support from Canadian MPs, which focus on women's health," Oct. 16, 2013. <u>https://openparliament.ca/bills/41-2/C-282</u>; Haydn Watters, "Tampon Tax' will end July 1," CBC, May 28, 2015. <u>http://www.cbc.ca/news/politics/tampon-tax-will-end-july-1-1.3091533</u>.

^{50.} See, e.g., "Deal reached to scrap 'tampon tax', officials say," BBC News, March 17, 2016. <u>http://www.bbc.com/news/uk-politics-35834142.</u>

^{51.} See, e.g., New York State, "Governor Cuomo Signs Legislation to Exempt Sales and Use Taxes on Feminine Hygiene Products," Press Release, July 21, 2016. <u>https://www.governor.nv.gov/news/governor-cuomo-signs-legislation-exempt-sales-and-use-taxes-feminine-hygiene-products</u>.

^{52.} Iago Morais de Oliveira, "Using International Human Rights Law to Guarantee the Right to Health: a Brazilian Experience," London School of Economics and Politics, Dec. 13, 2016. https://blogs.lse.ac.uk/humanrights/2016/12/13/using-internationalhuman-rights-law-to-guarantee-the-right-to-health-a-brazilian-experience.

^{53. &}quot;Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," United Nations General Assembly, April 4, 2016. https://documents-dds-ny.un.org/doc/UNDOC/GEN/GI6/067/53/PDF/GI606753.pdf?OpenElement.

^{54.} See, e.g., "Human Rights and Health," last accessed Nov. 14, 2019. <u>https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health</u>; Alberto Alemanno, "Public health: How to encourage people to lead a healthier lifestyle" HEC Paris, 2012. <u>http://www.hec.edu/Knowledge/Business-Environment/Social-societal-trends-and-issues/Public-health-How-to-encourage-people-to-lead-a-healthier-lifestyle</u>.

^{55.} This is found in Article 1(d) of the WHO Framework Convention on Tobacco Control. http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf?ua=1.

Furthermore, the State's obligation to protect human health should not be limited to allowing free circulation and access to these products. They should go further and encourage the use of these healthier options as substitutes for conventional cigarettes. Thus, adopting tax measures that allow wide consumer affordability of EVPs may empower people to take individual responsibility to protect their own health. Imposing the same tax burdens on EVPs and conventional cigarettes fails to take into consideration the potential harm reduction derived from the use of these new products. Such an approach appears inconsistent not only with the duty to protect human health, but also with the FCTC, where it is recognized that: "price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons."56

In summary, implementing policies that allow for the free trade of EVPs and create economic incentives for (or at least do not obstruct) their use would enable people to potentially reduce the health risks from smoking. This is also consistent with the tobacco control strategies provided in the FCTC, which according to Article 1 include: "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." By allowing access to EVPs in their domestic markets, governments could expand the supply of nicotine delivery alternatives to products that do not involve the inhalation of smoke produced by tobacco leaf combustion. Subjecting EVPs to lower taxes may also divert the demand from conventional cigarettes to potentially lower-risk alternatives for nicotine delivery. Finally, enabling people to opt for EVPs may significantly reduce the harm associated with tobacco consumption for smokers. Hence, putting these policies in place would not only be compliant with the obligation to protect human health, but also with the tobacco control strategies set out in the FCTC.

Finally, while there is not much jurisprudence available as to how to interpret the right to health in relation to smoking alternatives, the New Nicotine Alliance (NNA) has intervened in support of a judicial case launched by the snus producer Swedish Match before the Court of Justice of the European Union (CJEU), which argues that the ban on snus contravenes the right to a high level of health protection. According to the NNA:

Snus protects against smoking by reducing the uptake of smoking, helping people reduce smoking, and helping people to stop. In Sweden and Norway, the increase in the use of snus has been accompanied by a major decrease in smoking. As a consequence, the prevalence of male adult smoking in Sweden and Norway is now the lowest in Europe. $^{\rm 57}$

Thus, health -oriented policies should be drafted with due oversight of the above principles that arise from international law. The legitimacy of this approach resides in the acceptance of these norms by a wide number of countries that have committed to their observance.

CONCLUSION

Smoking tobacco is not the only form of consuming nicotine; it can also be achieved by use of alternative products such as EVPs. Even though more research on the effects of EVPs on tobacco consumption is needed, there is already substantial evidence to indicate that their use may significantly reduce the health risks associated with smoking. They may also be very effective tools in improving quit rates.

The right to health is a prerogative inherent to every human being. The protection of the human right to health requires States to take into consideration this objective in the design and implementation of their laws and policies, including those regarding taxation and trade. Consequently, governments must examine the perceptions and behaviors of consumers, and in so doing, should not neglect the data that shows there is a growing number of consumers using EVPs as an alternative or substitute to smoking.

The full realization of the right to health requires States both to adopt measures that prevent the development or spread of diseases amongst their populations and to facilitate the conditions that would enable individuals to protect their own health, for instance, by abandoning unhealthy practices. The provision of information regarding the relative harm of these products to consumers is therefore essential.

While the scope of the right to health and the extent to which it requires governments to provide access to potentially reduced-risk products has not previously received judicial consideration in the context of tobacco control, banning EVPs may contravene governments' obligations under various international human rights treaties. On the other hand, facilitating access to these products may have a considerable effect on harm reduction for smokers, and would therefore comply with the State's international obligation to protect the human right to health. Allowing the presence of potentially less risky alternatives on the market is also compatible with the tobacco harm reduction objectives recognized in the WHO *FCTC*, which require both the reduction and elimination of harms associated with smoking tobacco.

^{57.} New Nicotine Alliance, "NNA challenges the ban on snus," Press Release, last accessed Nov. 14, 2019. (date not available). https://nnalliance.org/nna-challenges-the-ban-on-snus.

^{56.} Ibid

And finally, subjecting EVPs to the same taxation regimes as conventional cigarettes may contravene the international human rights commitments of States. Therefore, by creating economic incentives for the use of potentially lower-risk nicotine deliverers such as EVPs, governments may encourage people to switch away from smoking, thereby complying with their duty to respect the human right to health.

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