HEALTH PROTECTION, PUBLIC POLICIES FOR SMOKING CESSATION AND REGULATION OF ELECTRONIC CIGARETTES IN BRAZIL AND THE UK: A STUDY OF COMPARATIVE PUBLIC LAW*

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Abstract: Il contributo esamina, in chiave giuridico-comparata, la regolamentazione delle sigarette elettroniche negli ordinamenti del Regno Unito e del Brasile. La scelta dei modelli da comparare è dovuta non solo alle soluzioni diametralmente opposte accolte nella disciplina della materia, ma anche al differente modo di declinare il diritto costituzionale alla salute nei due ordinamenti presi in considerazione. Lo studio di tale profilo consente all'A. di pervenire a talune osservazioni sulle peculiari applicazioni in UK e in Brasile, dei principi di precauzione e di riduzione del danno.

ABSTRACT: *The present essay features a legal and comparative assessment of e-cigarettes' regulation, including the analysis of the constitutional right to health, as well as the practical peculiarities of the legal principles at the basis of e-cigarettes' regulation: namely the precautionary principle and the principle of harm reduction. The paper focuses in particular on two legal systems: Brazil's and the UK's. These two countries are indeed interesting because they feature two diametrically opposed models of e-cigarettes' regulation.*

1. Introduction.

Having only been invented in 2003, e-cigarettes are relatively new to the market and countries are still in the process of determining the most effective policies. As a consequence, the global legislative landscape is highly varied, with some countries having no specific controls, while others banning them altogether[1].

This paper builds on the assumption that the regulatory environment adopted by a country affects the perceived harmfulness of e-cigarettes among citizens; and *vice versa*, the perceived harmfulness of e-cigarettes among policymakers and citizens may affect the choice of regulatory framework adopted in a given jurisdiction. Indeed, the use of e-cigarettes during a smoking quit attempt has been shown to facilitate short-term sustained abstinence in less restrictive regulatory environments, whereas restrictive regulatory environments may inhibit abstinence[2]. Moreover, the perception that e-cigarettes are less harmful than conventional cigarettes is significantly higher in less restrictive regulatory environments (e.g., United Kingdom) than in more restrictive regulatory environments[3].

Starting from this foundation, the paper aims at assessing e-cigarettes' regulation (and its impact) in two country studies, the United Kingdom ("UK") and Brazil, that -as will be discussed below- are placed at the antipodes of the regulatory spectrum. After having outlined the Constitutional right to health in general (Section 2), as well as it is enshrined in the UK and Brazilian Constitutions (Sections 2.1 and 2.2, respectively), the paper reconstructs the two main (alternative) principles for the declination of health protection, in general, as well as regulation of e-cigarettes, in particular, namely: the principles of harm reduction and the precautionary principle (Section 3).

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Governments' efforts to regulate e-cigarettes are complicated by the variety of forms these devices come in, as well as the variety of names associated with this product (including e-cigarettes, electronic nicotine delivery systems, vape pens, personal vaporizers) and even brands under which they are sold. Added complexities include whether e-cigarettes contain nicotine, whether manufacturers make therapeutic claims and whether they are designed to mimic a tobacco product. These aspects are outside the scope of this paper, for further discussion *see*, L.K. LEMPERT, R. GRANA, S.A. GLANTZ, *The importance of product definitions in US e-cigarette laws and regulations*, Tobac. Control 25 (2016); H.-H. YONG, R. BORLAND, J. BALMFORD, *Trends in e-cigarette awareness, trial, and use under the different regulatory environments of Australia and the United Kingdom*, 17 Nicotine Tob. Res. 17, 1203–1211 (2015).

[2] H.-H. YONG, S.C. HITCHMAN, K.M. CUMMINGS, *Does the regulatory environment for e-cigarettes influence the effectiveness of e-cigarettes for smoking cessation?: longitudinal findings from the ITC four country survey*, Nicotine Tob. Res. 19 (11), 1268–1276. (2017).

[3] *E.g.*, Australia. *See*, D.A. ERKU, S. KISELY, K. MORPHETT, K.J. STEADMAN., C.E. GARTNER, *Framing and scientific uncertainty in nicotine vaping product regulation: An examination of competing narratives among health and medical organisations in the UK, Australia and New Zealand*, Int. J. Drug Policy 78, 102699 (2020); H.-H. YONG, R. BORLAND, J. BALMFORD, *Prevalence and correlates of the belief that electronic cigarettes are a lot less harmful than conventional cigarettes under the different regulatory environments of Australia and the United Kingdom*, Nicotine Tob. Res. 19 (2), 258–263 (2017).

Afterwards the paper proceeds to deal with the alternative (administrative) models for e-cigarettes' regulation (Section 4), before considering specifically the UK and Brazilian systems (Sections 5 and 6, respectively). In conclusions, the paper puts forward some critical thoughts on the two principles (harm reduction and the precautionary principle) underlying the regulation of e-cigarettes (Section 7).

2. **Constitutional rights to health.**

The Constitutional right to health and health care, as declined by most fundamental charts around the world, finds its ancestors in international law. Indeed, in 1948 the United Nations formally recognized the international human right to health in the Universal Declaration of Human Rights ("the Declaration")[4]. in particular, art. 25 of the Declaration states the following:

> *Everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including ... medical care ... and the right to security in the event of ... sickness [and] disability ....*[5]

Subsequently, many nations adopted the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), one of the implementing treaties of the Universal Declaration. [6]Art. 12 of ICESCR provides that state parties *recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*[7]. ICESCR also provides enforcement provisions for states parties[8]. Since ICESCR, the UN has adopted other treaties that recognize the international human right to health and related health questions[9].

In addition, the World Health Organization ("WHO") recognizes the international human right to health in its constitution by stating that

[4] U.N. Doc. A/810, at 76 (1948).
[5] *Id*., at 51.
[6] U.N. Doc. A/6316 (1966).
[7] *Id.*, at 51.
[8] *See generally*, M.C. CRAVEN, *The international covenant of economic, social, and cultural rights*, 106-51, (1995) *(discussing states' obligations in implementing ICESCR*); M.C. CRAVEN, *The Domestic Application of the International Covenant on Economic, Social and Cultural Rights*, 40 Neth. Int'l L. Rev. 367 (1993) (*discussing problems and possible solutions for enforcing ICESCR, including direct applicability*).
[9] *See e.g.*, International Convention on the Elimination of All Forms of Racial Discrimination, U.N. Doc. A/6014 (1966) (entered into force Jan. 4, 1969) (*providing in article 5(e)(iv) for the right to "public health, medical care, social security and social services*); Convention on the Elimination of All Forms of Discrimination Against Women, U.N. Doc. A/RES/34/180 (1980) (entered into force Sept. 3, 1981); Convention on the Rights of the Child, U.N. Doc. A/44/49 (1989) (entered into force Sept. 2, 1990). *See also generally*, S. KILBOURNE, *U.S. Failure To Ratify the U.N. Convention on the Rights of the Child: Playing Politics with Children's Rights*, 6 Transnat'l L. & Contemp. Probs. 437 (1996) (*supporting adoption of the Convention and highlighting arguments of its opponents in the U.S.*); A. DUNDES RENTELN, *Who's Afraid of the CRC: Objections to the Convention on the Rights of the Child*, 3 ILSA J. Int'l & Comp. L. 629 (1997) (*providing historical overview on the Convention's adoption process in the U.S. and political controversy surrounding it*); E. SCHWELB, *The International Convention on the Elimination of All Forms of Racial Discrimination*, 15 Int'l & Comp. L.Q. 996 (1966) (*discussing origins of the Convention and providing detailed comparative analysis of its provisions*).

[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition[10].

These foundational instruments have clearly influenced provisions regarding health and health care in national Constitutions, especially those drafted after World War II. Unsurprisingly, the definition of *health* and *health care* have proved controversial[11].

For example, the WHO's constitution defines *health* broadly as *a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*[12].

Although the definition captures the full dimensions of the state of health, it is probably too broad a definition for government policy makers charged with the responsibility to define and establish a nation's health care. Similarly, the definition of *health care* is fraught with other difficulties. For instance, there is no consensus on what type and amount of health care services constitute adequate care. Nor is there an understanding of the true cost or quality of those services. Scholars, however, have endeavored to delineate the crucial issue of what governments should assure or provide in terms of health care services and, specifically, what may be the content of a morally acceptable package of health care services[13].

[10] CONST. OF THE WORLD HEALTH ORG, pmbl. (opened for signatures July 22, 1946) 10. For a list of member-states and their admission dates, see United Nations, List of Member States.

[11] *See e.g.*, F.H. MILLER (ed. by) *Rights and Resources*, (2003) (*featuring articles that discuss health care resources*) (2003); T. L. BEAUCHAMP, R. R. FADEN, *The Right to Health and the Right to Health Care*, 4 J. Med. & Phil. 118 (1979) (*arguing that the right to health is a positive right and that if there is a right to health care goods and assistance it is only because of the pre-existing obligation to allocate resources for the goods and assistance*); N. DANIELS, *Rights to Health Care and Distributive Justice: Programmatic Worries*, 4 J. Med. & Phil. 174 (1979) (*discussing distributive justice and other theoretical problems with defining health care*); C. FRIED, *Rights and Health Care- Beyond Equity and Efficiency*, 293 New Eng. J. Med. 241, 243-44 (1975) (*describing rights to health care as including distributional rights and patient's rights to not be deliberately misled, denied information, or abandoned by a physician*).

[12] CONST. OF THE WORLD HEALTH ORG. pmbl. (op.cit.)

[13] *See e.g.*, A. E. BUCHANAN, *The Right to a Decent Minimum of Health Care*, 13 Phil. & Pub. Aff. 55 (1984) (*attempting to define a decent minimum standard of care*); D. CALLAHAN, *What Is a Reasonable Demand on Health Care Resources? Designing a Basic Package of Benefits*, 8 J. Contemp. Health L. & Pol'y 1, 2-3 (1992) (*pointing out that Americans may have had more difficulty than Europeans with defining standard of health care, because Americans started to search for the definition at the time of technological advances and public's higher expectations*); COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (AMA), *Ethical Issues in Health System Reform: The Provision of Adequate Health Care*, 272 JAMA 1056, 1058 (1994) (*stating that the government should create a standard ensuring that every individual has adequate health care and emphasizing that adequate health care is case specific*); D. M. EDDY, *What Care Is 'Essential'? What Services Are 'Basic'?*, 265 JAMA 782, 782, 786 (1991) (*stating that defining essential care is thwart with difficulties because it must include considerations of cost, benefits and harms*); *see also* N. DANIEL ET AL., *Benchmarks of fairness for health care reform*, (1996) (*developing a tool for examining the fairness of health care reform proposals*).

From a comparative-constitutional-law point of view, one can identify five types of Constitutional provisions addressing health and health care in national Constitutions: (i) a statement of aspiration, stating a goal in relation to the health of its citizens[14]; (ii) a statement of entitlement, stating a right to health or health care or public health services[15]; (iii) a statement of duty, imposing a duty to provide health care or public health services[16]; (iv) a programmatic statement, specifying approaches for the financing, delivery or regulation of health care and public health services[17], and (v) a referential statement, incorporating by specific reference any international or regional human rights treaties recognizing a human right to health or health care[18].

The fact that countries adopted their Constitutions during different historical periods is a critical factor in determining whether the constitution addresses health or health care. Constitutions reflect the period of their formation as well as the level of the Constitutional law development in other countries and international law at the time[19]. For purposes of the present discussion, the basic periods of Constitution -making have been categorized as follows[20]: (i) 1660s-present, epitomized by England and its common law progeny, including the United States[21]; (ii) 1887-1960, epitomized by the European democratic states and constitutional

[14] *E.g.*, the Constitution of the Netherlands, ch. I, art. 22 (*The authorities shall take steps to promote the health of the population*).

[15] *E.g.*, the Constitution of Mozambique, pt. II, ch. III, art. 94 (*All citizens shall have the right to medical and health care, within the terms of the law, and shall have the duty to promote and preserve health*).

[16] *E.g.*, the Constitution of Uruguay, § II, ch. II, art. 44 (*The State shall legislate on all questions connected with public health and hygiene, endeavoring to attain the physical, moral, and social improvement of all inhabitants of the country. It is the duty of all inhabitants to take care of their health as well as to receive treatment in case of illness. The State will provide gratis the means of prevention and treatment to both indigents and those lacking sufficient means*).

[17] *E.g.*, the Constitution of Bulgaria, ch. II, art. 52 (*(1) Citizens have the right to health insurance that guarantees them accessible medical care and to free medical care under conditions and according to the procedure determined by law.(2) The citizens' healthcare is financed from the state budget, by employers, by personal and collective insurance payments, and from other sources under conditions and according to a procedure determined by law.(3) The state protects the health of the citizens and encourages the development of sports and tourism.(4) No one may be subjected to forced medical treatment or sanitary measures except in cases provided by law.(5) The state exercises control over all health institutions as well as over the production of pharmaceuticals, biologic[al] substances and medical equipment and over their trade*).

[18] *E.g.*, the Constitution of Czech Republic, ch. I, art. 10 (*International treaties, to whose ratification Parliament has consented and by which the Czech Republic is obligated, are part of the legal order; if the international treaty provides for something other than the law, the international treaty shall be used*).

[19] *See generally*, J.-E. LANE, *Constitutions and Political Theory*, ch. 2 (1996) (*discussing origins of modern constitutions*); J. T. MCHUGH, *Comparative Constitutional Traditions*, 4 (2002) ("*A constitution is an extrapolation of political, philosophical, sociological, economic, and other ideas and [I a manifestation of a higher purpose"*); E. MCWHINNEY, *Constitution-Making: Principles, Process, Practice,* 6-9 (1981) (*pointing out that constitutions reflect not only legal principles but political and social developments as well*); W.F. MURPHY, *Constitutions, Constitutionalism, and Democracy,* in ; D GREENBERG et al (edited by), *Constitutionalism and Democracy*, (1993), 7-14 (*providing overview of constitutions' functions and how they can reflect national changes*); D. P. FRANKLIN, M.J. BAUN (edited by), *Political Culture and Constitutionalism: A Comparative Approach*, (1995) (*containing articles comparing political cultures and constitutional traditions in different countries*).

[20] *See* J. ELSTER, *Forces and Mechanisms in the Constitution-Making Process*, 45 Duke L.J. 364, 368-70 (1995) (*analyzing constitution making process and factors that advance and hinder it*).

monarchies, including liberated nations after World War II in both the democratic West and the Communist Eastern Bloc[22]; (iii) 1945-1960; emergence of new nations from former colonies in Africa, Asia, and the Middle East[23]; (iv) 1983-1994, the Latin American Constitutional revolution, replacing Constitutions adopted in the 19th and 20th centuries following liberation from colonial rule[24]; and (v) 1989-present, the emergence of new democracies from the former Communist Bloc[25].

Despite being nowadays generally acknowledged and enshrined in the fundamental laws of many countries, great differences exist not as much as in the formal wording of the Constitutional provisions, as in the actual enforcement and availability of rights, which vary according to many factors, including: economic resources and degree of democratic maturity[26].

2.1 The UK Constitutional right to health

[21] *See e.g.*, W.P. ADAMS, *The first American Constitutions: Republican ideology and the making of the state Constitutions in the revolutionary era*, (1973); G.B. ADAMS, *The origin of the English Constitution* (1912); S.E. FINER et al., *Comparing Constitutions* (1995); G. CASPER, *Changing Concepts of Constitutionalism: 18th to 20th Century*, 1989 Sup. CT. Rev. 311 (*giving theoretical and philosophical background on American and Western European constitutionalism*); N. MACCORMICK, *Does the United Kingdom Have a Constitution? Reflections on MacCormick v. Lord Advocate*, 29 N. IR. Legal Q. 1 (1978).

[22] *See e.g.*, S.E. FINER (edited by), *Five Constitutions* (1979); H. J. SPIRO, *Government by Constitution* 3-42 (1959).

[23] *See e.g.*, J.M. BROWN, *Modern India: the origins of an Asian democracy* (1985); J. CRAWFORD, *The creations of states in international law*, (1979); J. HAYNES, *Democracy in the Developing World* (2001); H.W.O. OKOTH-OGENDO, *Constitutions Without Constitutionalism: Reflections on an African Political Paradox*, in D. GREENBERG ET AL. (edited by) (op.cit).

[24] *See* D. LEHMANN, *Democracy and development in Latin America: economics, politics and religion in the post-war period* (1990); C.S. NINO, *Transition to Democracy, Corporatism, and Presidentialism with Special Reference to Latin America*, in Constitutionalism and Democracy 46 in D. GREENBERG ET AL. (edited by) (op.cit); K.W. THOMPSON (edited by 1991), *The U.S. Constitution and the Constitutions of Latin America* 56-58; J. MILLER, *Judicial Review and Constitutional Stability: A Sociology of the U.S. Model and Its Collapse in Argentina*, 21 Hastings Int'l & Comp. L. Rev. 77 (1997) (*discussing the Argentinean Supreme Court's role in the 19th and 20th centuries and proposing a sociological model of judicial review*).

[25] *See e.g.*, A.E. DICK HOWARD (edited by), *Constitution making in Eastern Europe* (1993); R.R. LUDWIKOWSKI, *Constitution making in the region of former Soviet dominance* (1996); J. ELSTER, *Constitution making in Eastern Europe*: *Rebuilding the Boat in the Open Sea*, 71 Pub. Admin. 169 (1993); S. HOLMES, C.R. SUNSTEIN, *The Politics of Constitutional Revision in Eastern Europe*, in S. LEVINSON (edited by), *Responding to imperfection: the theory and practice of constitutional amendment*, 275 (1995).

[26] Clearly, not all countries that have provisions regarding health and health care in their Constitutions have in practice lived up to these mandates. Indeed, some of the most resounding Constitutional commitments to health and health care are found in poorer countries, characterized by tenuous democracies. Haiti's constitution is exemplary of this phenomenon. Its Constitution indeed mandates to: *Strengthen national unity by eliminating all discrimination between the urban and rural populations and by recognizing the right to progress information, education, health, employment and leisure for all citizens.* Constitution of Haiti, pmbl., § 5; *The State has the absolute obligation to guarantee the right to life, health, and respect of the human person for all citizens without distinction, in conformity with the Universal Declaration of the Rights of Man*. Id. at t tit. III, ch. 11, § A, art. 19. *The State has the obligation to ensure for all citizens in all territorial divisions appropriate means to ensure protection, maintenance and restoration of their health by establishing hospitals, health centers and dispensaries*. Id. at art. 23. Similarly, many countries that devote extensive resources to assuring the health of and providing health care to their populations have no relevant provisions in their Constitutions regarding health or health care. Therefore, the number and/or formal strength of Constitutional provisions does not appear to have a determinative role in the actual enforcement and availability of the right, as well as -economically speaking- the amount of resources that countries spend for the health care of their populations.

As it is well known, the UK lacks a formal written Constitution and thus derives its Constitutional principles from other laws. The UK is a signatory to the ICES and Cultural Rights and therefore there may be said to exist a commitment to the health-related rights expressed in those instruments. Furthermore, as to the supreme or Constitutional nature of the right, leading British scholars have emphasized the significance of rights (albeit not the right to health alone); the *fathers* of medical law as an academic discipline in the UK argued that the field was a *subset of human rights law*[27], while a more recent analysis notes a *strong argument that the conceptual unity of medical law is human rights*[28].

Yet, when we turn to the actuality of the right to health (and healthcare) in the UK, its fundamental rank becomes much less obvious.

This is perhaps unsurprising when one considers a broader historical and socio-political context, in which the relationship between the individual and the British state was traditionally regulated not through positive rights; but rather through negative *civil liberties*, meaning freedom and autonomy.

In the case of healthcare, this manifested itself through an organizational approach post-World War II; whereby (somewhat originally) the state-individual *nexus* was understood *not* in terms of rights of access to treatments and services, but rather as a duty placed upon government: *to promote the establishment in England and Wales of a comprehensive health service designed to secure improvement in the physical and mental health of the people ... and the prevention, diagnosis and treatment of illness.*[1]

This was to be done by establishing institutions and processes within a National Health Service ("NHS") underpinned by principles of comprehensiveness, universal access and free provision at the point of delivery. Hence, the creation of a sizable health infrastructure. Also paramount in the definition of a right to health of Constitutional rank is the UK's *domestication* of the European Convention on Human Rights via the Human Rights Act of 1998. Beyond the official formulations, one might say that the right to health in the UK is more and more coming to include two peculiar nuances, which prove relevant in the context of the regulation of e-cigarettes and the UK's embrace of the principle of harm reduction. First, over some two decades, there has been a consistent governmental emphasis upon expansion of a patient's *right to choose* within a health system which otherwise appears somewhat centralized and 'top-down' in orientation[29].

The goal is 'shared decision-making', ranging from relatively straightforward exercises of individual autonomy – such as the right to choose the time and location of specialist secondary care – to more complex decisional processes, such as agreed plans of care for particular

[27] I. KENNEDY, A. GRUBB, *Medical Law*, 3 ed, London (2000).

[28] *R v North West Lancashire Health Authority*, ex parte A, D and G (1999).

[29] The most recent (and radical) reform of the NHS, undertaken by the Conservative-Liberal Democrat administration, which was in office between 2010 and 2015, was in part underpinned by the slogan '*No decision about me, without me*', capturing the idea of the patient as active participant (albeit, perhaps not an equal partner) in treatment decisions.

conditions informed by the use of patient decision aid tools[30].

A further development has been the emergence of rights connected to decision-making on funding of healthcare treatments and services. Prompted in part by judicial decisions in the field[31], government has imposed legal obligations upon healthcare institutions to provide explanations for decisions to refuse particular forms of treatment to which a patient and their physician seek access. It has also mandated establishment of internal processes which enable patients to demonstrate that their individual circumstances warrant exceptional departure from an institution's policy not to fund a treatment or service for its local population. More generally, there is an expectation that decisions on treatments available –whether undertaken by national agencies such as the National Institute for Health and Care Excellence (NICE), or by local commissioners of health provision– will be rationally rooted in the best available evidence.

These requirements are expressed not only in the traditional form of duties placed upon NHS institutions, but also as rights vested in patients, set out in an NHS Constitution for England[32], even though it should be noted that this document is almost entirely declaratory in character –that is, it merely sets out existing rights and responsibilities derived from statute or common law rather than creating new ones– and the Government has conceded that *it is not yet having the effect originally intended*, in large part because awareness of its existence remains low[33].

2.2 The Brazilian Constitutional right to health

Brazilian current Constitution, approved in 1988 culminated Brazil's transition to democracy. Indeed, following the 1964 coup, Brazil endured two decades of repressive military rule. This dictatorship had a legalistic bent: it issued several Institutional Acts and even its own constitution in 1967 to legalize political purges and curtail most civil rights. Brazil's new Constitution would then need to dismantle those authoritarian institutions, and reverse the ways in which the military's economic policies had exacerbated socioeconomic and regional inequalities. In this context, it is important not dissociate the history of health as a human right in Brazil from the overall process of re-democratization that started in the late 1970s, and the strong social justice component that infused that process.

As the *economic miracle* (a period of exceptional economic growth during the military dictatorship)[34] started to wane and then turned into economic crisis, it became clear that poverty

[30] E. WICKS, *Human Rights and Healthcare*, Oxford (2007).

[31] K. SYRETT, *Law, Legitimacy and the Rationing of Health Care*, Cambridge (2007), ch. 6.

[32] Something of a departure for a jurisdiction with no codified Constitutional document delineating the structure and functions of its political institutions, the NHS Constitution was created as a means of articulating the purpose, principles and values of the NHS with a view to preserving them for the future, to strengthen accountability by specifying expectations and lines of accountability, and to 'empower' patients (and NHS staff) by clarifying rights and responsibilities through codification. *See*, DEPARTMENT OF HEALTH, *High Quality Care for All*, (2008), ch. 7.

[33] DEPARTMENT OF HEALTH, *Report on the Effect of the NHS Constitution*, (2012), para. 140.

[34] The *economic miracle* was a period of high growth, averaging around 10%, that lasted from the late 1960s to the mid-1970s; *see* A. FISHLOW, *Brazil's Economic Miracle*, The World Today, 474–481 (1973).

had not been solved by the *trickledown* strategy of that period[35]. As explained by Sonia Fleury, a leading Brazilian social policy expert *the construction of a democratic institutional order supposed a rearrangement of social policies in response to society's demands for greater social inclusion and equality*[36]. The Sanitary Movement, the strongest proponent of a Constitutional right to health, was part and parcel of that broader context. Its slogan *health and democracy* encapsulate its strong political message. As Sérgio Arouca, a leading member of the movement, forcefully put it during his opening address to the 8th National Health Conference of 1986 (a seminal step in the constitutionalization of the right to health): *Wealth grew in Brazil but the number of hungry people also grew. Wealth grew but the misery of a large majority of the population also grew. Wealth grew but marginalization also grew .... This is not bearable .... 'Health and democracy'!* Behind this phrase lays the understanding that it would be impossible to improve the well-being of the population unless the economic model would be reshaped too[37].

These social, economic and political dimensions of the historical context are crucial to the understanding of the project of the Sanitary Movement[38] that culminated with the legal recognition of health as a human right in the 1988 Constitution. The way the right to health came from the very beginning to be framed was not so much in term of resources[39], as of *universal access*, in other words to transform the very idea of health from the mere treatment of diseases into a broader concept of physical and mental well-being inextricably dependent on other social, economic and political factors[40].

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[35] R. P. BARROS, R. HENRIQUES, R. MENDONÇA, *Desigualdade e Pobreza no Brasil: Retrato de uma realidade inaceitável*, Revista Brasileira de Ciências Sociais, 123–142 (2000).

[36] S. FLEURY, *Brazilian Sanitary Reform: Dilemmas between the Instituting and the Institutionalized*, Ciência & Saúde Coletiva, at 745 (2009).

[37] S. AROUCA, Speech at the 8th National Health Conference, Brasilia (1986), video available at https://pensesus.fiocruz.br/sa%C3%BAde-%C3%A9-democracia. Translation of the author, from the original in Portuguese.

[38] Though the movement became perhaps more prominent during the constituent assembly, which took place between February 1987 and September 1988, it was not a specific-purpose campaign formed simply to include health as a right in the new constitution. It was actually much older and had a much broader and perennial goal – that is, to improve health in Brazil through reforms of not only the public health system but also the economic and political ones.11 1 *See* ESCOREL, *Reviravolta na saúde*. As a self-proclaimed movement with a distinct political identity, it dated back to the 1970s, when an interesting development started to occur, namely, the gradual prominence of a group of public-health experts with progressive, left-leaning ideas, in key technical posts in the bureaucracy of the military dictatorship.This group formed one of the early seeds of the Sanitary Movement, starting to introduce small incremental changes in the public system, such as the Piass, Programa de Interiorização de Ações de Saúde e Saneamento in 1976, aimed at expanding basic services and actions to the poor hinterlands of the country and the companion Ppreps, Programa de Preparação Estratégica de Pessoal de Saúde aimed at developing the human resources required to implement those actions and services. *See generally*, PAIVA, TEIXEIRA, *Health Reform and the Creation of the Sistema Único de Saúde*, at 7

[39] *See* N. R. COSTA, *Inovação Política, Distributivismo e Crise: A Política de Saúde nos Anos 80 e 90*, (1996) for the crisis of the health system, and also for the interesting debate about whether the military period, at least in the health-care sector, actually helped towards universalism and equity, *discussing* the argument of J. MALLOY, *A Política de Previdência Social no Brasil* (1985)

[40] Such an idea was of course influenced by international discussions promoted by the WHO and other international bodies, most prominently in the Alma Ata Conference and its Declaration of 1978, sponsored in collaboration by the WHO and UNICEF. *See* Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6–12 September 1978.

Indeed, in the First Symposium of National Health Policy in October 1979, taking place in the Brazilian National Congress, we find, perhaps for the first time in an formal document, the idea of health as a universal right, alongside several other principles and ideas that came to be adopted in the Constitution, such as the intersectoral character of the social determinants of health; the role of the state as regulator of the health market; decentralization, regionalization and hierarchization of the health system; popular participation and democratic control[41].

It wasn't just the timing that was favorable. The broader political context was also helpful for at least two reasons. First, the idea that the health system needed reform was maturing rapidly in Brazil with the increasing financial crisis of the social insurance system in the late 1970s (to which health belonged) and its incapacity to provide access to health services to large sections of the Brazilian population[42].

A plausible argument defended by the movement was that one important reason for this crisis was the high cost of services provided by private companies, whose participation in the system had grown during the military regime.

A credible solution accepted already during the final years of military period was, thus, to diminish private participation and enhance public delivery of services through what came to be known as 'integrated health actions' (Ações Integradas de Saúde – AIS), which aimed at greater integration of the municipal, state and federal levels of the public network.

Secondly, the movement's focus on health as a collective good of public relevance was in line with broader international trends. It was part of the international effort started in the 1960s and consolidated in the 1980s to transform the then-prevalent model of health from a curative, illness focused, hospitalcentric and high technology–based one into a preventive model, focused on primary care and the social determinants of health[43]. The Conference of Alma-Ata in 1978 and its goal of health for all by 2000 is perhaps the most prominent expression of this international consensus in that period[44]. The time seemed ripe, thus, for the ideas of the Sanitary Movement to percolate through the constituent assembly and find its way into the constitutional text. Often called the Citizen Constitution, Brazil's 1988 Constitution stands as one of the world's longest constitutions, with 250 articles that enumerate an impressive list of civil, political, social, economic, and even environmental rights.

One reason for its length is that this Constitution had to respond to the demands of different sectors of society. Formally, the responsibility for drafting the document fell to the National Constituent Assembly (Assembléia Nacional Constituinte - ANC), which deliberated for nearly two years. Heath care rights became a cornerstone of Brazil's new democracy.

[41] CORDEIRO, *O Instituto de Medicina Social*, at 346.

[42] T. M. LIMA, *O direito à saúde revisitado: Entre os ideais da Constituição de 1988 e o drama jurídico atual*, Revista de Informação Legislativa, at 183–184 (2014).

[43] PAIVA, TEIXEIRA, op. cit., at 19.

[44] It is noteworthy that no reference to international human-rights law is made in the Sanitary Movement's documents, despite the fact that the UN International Covenant on Economic, Social and Cultural Rights was adopted in 1966 and came into force in 1976.

The meaning and content of health care rights, moreover, would not be decided exclusively by jurists, experts, or politicians. The push to make health care an obligation of the state came from civil society, and from the health care sector in particular.

These efforts first took shape at the 8ª Conferência Nacional de Saúde in 1986, with doctors and public health professionals at the forefront of this political project to make health care a fundamental right. This group worked to give legal shape to health rights, as those gathered approved the first blueprint for the SUS as a universal and free system and drafted several resolutions that ultimately made their way into the Constitution. At the same time, as mentioned above, one of the central aims of this meeting was to propose a more ambitious definition for health, one that abandoned the disease-centric approach of prior public health regimes to instead treat health care as a social, economic, and environmental issue.

"Health" in legal and policy contexts now encompassed issues like food access and nutrition, housing, education, income, employment and labor conditions, transportation, rest and recreation, the environment, land rights, and access to health care services.

The working papers and resolutions approved at this meeting also asserted the importance of community participation in public-health initiatives, recognizing that health care could not be solely articulated as individualized care but needed to account for family welfare and the wellbeing of the community[45].

When the Constitution was finally promulgated on 5 October 1988, the text of the Health chapter was much closer to the Sanitary Movement's ideal proposal than anyone else's[46]. However, the movement's more radical aims of eliminating or significantly reducing the participation of private providers in the public system was not achieved. In a strategic concession, private providers were in the end admitted on a 'complementary' basis (Article 199), yet without access to public subsidies, and to this date have a significant presence in the health system. But the universal, egalitarian, state-funded right to health gained a place in the final text of the Constitution, reflecting almost entirely the ideas of the Sanitary Movement[47]. As the final text reads (in the main provisions): *Article 196. Health is a right of all and a duty of the state and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and egalitarian access to actions and services for its promotion, protection and recovery. Article 197. Health actions and services are of public importance, and it is incumbent upon the Government to provide, in accordance with the law, for their regulation, supervision and control, and they shall be carried out directly or by third parties and also by individuals or private legal entities.*

[45] What is remarkable about the health care debates in 1980s Brazil is how these ideas were not only conceived within national congresses and formal political processes, but also in the public sphere and through popular contestation. Women organized their own conference, the Conferência Nacional de Saúde e Direitos da Mulher, advocating for women's health issues while also pushing for a universal and nationalized system. Newspapers reported on the welfare of Brazilian society, publishing statistics on infant mortality, malaria infection, and malnourishment. These reports documented the impact of income inequality and regional disparities on health outcomes.

[46] The headline of Visão Magazine, a mainstream weakly of the time, gives a good if rather exaggerated indication. *Constituent: the end of private medicine*. *See* R. NETO, *Saúde*, at 84.

Article 198. Health actions and public services integrate a regionalized and hierarchical network and constitute a single system ... Paragraph 1. The unified health system shall be financed, as set forth in article 195, with funds from the social welfare budget of the union, the states, the federal district and the municipalities, as well as from other sources. Article 199. Health assistance is open to private enterprise. Paragraph 1. Private institutions may participate in a complementary manner in the unified health system, in accordance with the directives established by the latter, by means of public law contracts or agreements, preference being given to philanthropic and non-profit entities.

It is worth noting that the 1988 Constitution was not the first to enumerate social and economic rights in Brazil, nor the only one to mention public health as the responsibility of government. Indeed, some version of these rights already appeared in Brazil's 1934 constitution (and in the three constitutions that followed, including the two written for dictatorships). But those prior constitutions did not guarantee universal suffrage, and they placed conditions or restrictions on the exercise of individual and social rights. Similarly, Brazil's health care system prior to the SUS was a public system, but not a universal one[48]. This system was expanded and reformed over the next fifty-plus years, but it remained tied to profession, to the exclusion of rural workers, domestic workers, informal labor, and others. Those not covered by this system were designated INDIGENTES, and had to rely on charity health services.

The 1988 Constitution thus did away with the ways in which citizenship had previously been stratified in Brazil, with its insistence that socioeconomic rights would be equally enjoyed, independent of race, class, gender, or profession. This Constitution also became the first to acknowledge long-standing racial, socioeconomic, and regional inequalities in Brazil, and the first to commit to reducing these inequalities and eradicating poverty. Therefore, the importance of the right to health in the new Constitutional architecture cannot be overstated, as with the 1988 Constitution free and universal health care became *not only* an individual right, but *also* a socio-political strategy for dealing with structural inequalities.

[47] See PAIM, *A Reforma Sanitária Brasileira e o Sistema Único de Saúde*, at 632: The movement succeeded in inscribing a substantive part of its bill in the Constitution of the Republic and in the infra-constitutional legislation, even though it faced difficulties in the process of implementing what it had promised. It is interesting to note that, as progressive as they may seem, the Sanitary Movement's proposals were not progressive enough for the trade union movement, whose members wanted the complete elimination of private initiative from health. At the other end of the spectrum, health businesses thought those proposals were way too radical. *See* I. *FALLEIROS*, J. C. F. LIMA, G. MATTA ET AL., *A Constituinte e o Sistema Único de Saúde*, in C.F. PONTE, I. FALLEIROS, (edited by), *Na corda bamba de sombrinha: A saúde no fio da história*, Rio de Janeiro (2010), at 242. The speech of representative Arnaldo Faria de Sá (PTB-SP), of 18 June 1987, illustrates well the businesses' position: *If the state is unable to perform even basic health actions, or even eliminate mosquitoes that transmit disease, much less will it be able to perform medical and hospital services as the sanitarists want. In any case, if the project is approved as originally proposed, its price, once again, will be paid by the taxpayer. The nationalization will require that the tax burden on Brazilians will be doubled.* Senado Federal, Anais da Assembléia Nacional Constituinte, vol. 5, p. 2755. *See also* the speech of representative Inocêncio Oliveira: *to characterise health actions as being of public nature is to make the private sector unfeasible and, therefore, to make the entire health sector unfeasible in Brazil*. Senado Federal, Anais da Assembléia Nacional Constituinte, 23 July 1987, vol. 6, p. 3531.

[48] Starting in the 1930s, Brazil's government had created a network of social security funds (Institutos de Aposentadoria e Pensões, IAPS), which were differentiated according to profession, in a syndicalist-corporatist framework.

The SUS today guarantees coverage for all residents in Brazil, with about 70% of the population relying exclusively on its services. Brazil has a two-tiered system in which those who can afford it purchase private insurance plans. The SUS is unified but highly decentralized, with its various responsibilities divided between federal, state, and municipal levels of service. One of its accomplishments is the Programa de Saúde de Família (Program for Family Health, PSF), created in 1994 to provide primary care, dentistry, vaccinations, and medications for some of Brazil's poorest and most isolated communities. This unit leads Brazil's vaccination efforts, as the SUS oversees one of the world's largest vaccination programs in the world, combating more than 19 infectious diseases. The Programa de Saúde de Família innovates with its emphasis on families, instead of its individuals, as well as in its employment not only of doctors and nurses, but also of community health agents in order to strengthen links between the community and health services.

3. Regulating e-cigarettes between the precautionary principle and harm reduction

From a legislative/administrative point of view, approaches to e-cigarette regulation fall within a spectrum of options, based on different (even contrasting) principles at either pole. The spectrum ranges from e-cigarettes bans based on a (over)focus on health protection at one end; to using e-cigarettes for harm reduction at the other end. The first model -the one super-focusing on health-protection- rests upon the conviction that policies ought to prevent (all?) potential dangers to health, including those deriving from e-cigarettes' use. The other end of the spectrum, aims at incentivizing policies that reduce the more harmful toxicological effects of smoking tobacco cigarettes.

To simplify, health protection's proponents claim that e-cigarettes: (i) are harmful, (ii) normalize smoking behavior, and (iii) serve as a gateway to nicotine addiction for non-smokers and youth. Rather than aiding smoking cessation, may believe the sale of e-cigarettes will encourage continued use of conventional cigarettes resulting in the dual use of both products, consequently inhibiting complete cessation[49]. Countries that are committed to minimize the number of new users becoming addicted to nicotine (*i.e.*, health protection) enact prohibitive regulations, including restricting supply and/or imposing higher taxes.

At the other end of the spectrum, proponents of harm reduction argue that people will always use harmful products (and/or engage in risky behavior) and acknowledge that smokers eventually become addicted and cannot easily stop assuming nicotine. Therefore, the desirable goal is to divert people to use less harmful alternatives.

[49] W. HALL, C. GARTNER, C., FORLINI, *Ethical issues raised by a ban on the sale of electronic nicotine devices*, 110 Addiction, 1061–1067 (2015); N. KAUFMAN, M. MAHONEY, *E-cigarettes: Policy options and legal issues amidst uncertainty*, 43 JLME 1, 23–26 (2015); D.S. KENKEL, *Healthy innovation: Vaping, smoking, and public policy*, 35 J. Pol. Anal. Manag., 473–479 (2016).

And e-cigarettes represent one of such safer alternatives (the preponderance of the scientific evidence does show they are far less harmful than traditional cigarettes), as they can help reduce (at least some of) the negative health impacts of smoking[50]. Countries that are engaged in reducing harms (*i.e.*, harm reduction) enact less restrictive regulations, incorporate less-harmful products in their social agenda to reduce smoking, and might even allow positive financial incentive to encourage smokers to switch to a less harmful product.

It is evident that the two approaches reflect more than just a choice between adopting one legal principle rather than the other. They also mirror different social preferences (*i.e.*, the intensity of the dislike for people engaging in behaviors not illegal *per se*, but generally frowned upon), different views of the tradeoff between state control and individual freedoms (*i.e.*, a paternalistic state *vs* individuals' self-determination), as well as general attitudes towards addiction (*i.e.*, is addiction a "fault" to blame, or a medical condition to treat?).

One main difference between the two approaches is the population on which they are focused. Health protection generally focuses on the (relatively smaller) health hazards that e-cigarettes pose to the (relatively larger) population of non-smokers, especially non-smoking youth. *Vice versa*, harm reduction focuses instead on the (relatively larger) health hazards that tobacco poses to the (relatively smaller) population of conventional cigarette smokers[51].

Indeed, not only is smoking a *health hazard*, it is also a *social hindrance*, as smoking is more prevalent in lower socioeconomic groups, rather than in higher ones[52].

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[50] A.L FAIRCHILD, R. BAYER, *Smoke and fire over e-cigarettes*, 347 Science, 375–376 (2015). However, advocates of harm reduction do not always share the same views regarding the ultimate goals of e-cigarette use; some advocates argue that the goal should be to quit these harmful products entirely, whereas others believe risk minimization is sufficient. *See* id., A. Fairchild, J. Colgrove, *Out of the ashes: The life, death, and rebirth of the "safer" cigarette in the United States*, 94 Am. J. Public Health, 192–204 (2004).

[51] The notion of non-smokers' right to health – especially bystanders and children – underpinned much of tobacco control developments through the 1980s and 1990s. Those involved in the campaigns, especially in the US, saw themselves as warriors battling the economic and political interests of tobacco companies. Backed by the evidence of the damage caused by smoking and the increasing efforts to ban public smoking, campaigners seized the moral high ground as smokers became the new social pariahs. Harm reduction tends to focus more on another slice of the population: those who want to switch away from smoking and towards the use of safer products.

[52] As Dr M. Glover and colleagues commented: *The WHO target [of reducing global tobacco use] is unintentionally, but effectively, misdirecting the sector from focusing on how to reduce the incidence of smoking-related diseases, which is the real goal. The dictum to focus on reducing global tobacco use encourages a utilitarian focus on achieving behaviour change among as many people as possible for the least cost, regardless of unexpected negative consequences for the few. The least costly interventions are laws, regulations, taxes and mass media campaigns – blunt instruments applied state-wide or nationally. In this strategy, effectiveness is measured at a population level, using averages that erase outliers, such as disproportionately high smoking prevalence among subgroups. The policies are assessed for their potential to benefit the many, that is the most populous group, and this is usually the politically dominant group. ...Policies and laws designed to benefit the politically dominant group, inevitably leave aside the effects on minorities*.
M. Glover, et al., *Tobacco smoking in three "left behind" subgroups: indigenous, the rainbow community and people with mental health conditions*, Drugs and Alcohol Today (2020). Similarly, in an editorial in The American Journal of Public Health, D. Giovenco commented that: *harm reduction approaches…have the potential to accelerate the smoking 'endgame' and reduce inequalities more rapidly and effectively than traditional control initiatives…Without radical changes in our approach to tobacco control, unacceptable disparities in smoking-related disease and death may persist for decades* (emphasis added)

Moreover, lower socioeconomic groups commonly start smoking at a younger age, smoke more cigarettes per day and stop smoking less often than people in higher socioeconomic groups. Therefore, low-income smokers are more intensely addicted to nicotine and are likely to require more support to stop smoking[53]. Furthermore, families in poorer countries are likely be more severely affected by the economic impact of smoking deaths and disease[54].

In particular, harm reduction strongly focuses on socially-disadvantaged groups who would be most in need of easy(er) access to low-risk products, including: indigenous populations[55], lower-income groups (featuring a higher smoking prevalence than the general population and disproportionate tobacco-related health issues); and populations generally more likely to have enduring drug[56], alcohol, and/or mental health problems.

These special populations of smokers (especially those living in the poorer countries) are often more disadvantaged in trying to access e-cigarettes because, for instance: they live in environments (such as public housing, prisons[57], mental health hospitals[58], etc.) more prone to outright domestic bans; they might be able to access e-cigarettes only thorough the Internet (as well as ready access to electricity), which in turn requires a credit card for purchases (and an address for delivery[59]); onerous taxation severely affects their disposable income[60].

Therefore, failure to embrace harm-reduction principles (and products) afflicts *poor people specifically*, but also *societies as a whole*, as it exacerbates social disparities, marginalization, and

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D.P Giovenco, *Different Smokes for Different Folks? E-Cigarettes and Tobacco Disparities*, 109 American Journal of Public Health, 109, 1162–1163 (2019). This author was also the lead author of a study which looked at sales of combustible tobacco products and SNP in socio-demographically diverse part of New York City, concluding that the marketing of inexpensive, combusted tobacco products disproportionately saturates low-income, minority communities, while potentially lower risk, non-combusted products are more accessible in largely White and higher income neighborhoods. This pattern may exacerbate tobacco-related inequities. Public health policies should prioritize reducing the appeal and affordability of the most harmful tobacco products to help reduce health disparities. D.P. Giovenco et al., *Neighborhood Differences in Alternative Tobacco Product Availability and Advertising in New York City: Implications for Health Disparities*, 21 Nicotine & Tobacco Research, 21, 896–902 (2019).

[53] *See generally*, WHO, *Tobacco and inequities; guidance for inequities in tobacco-related harm*, (2014). The conclusions drawn for Europe are easily relevant for other parts of the world as well. Indeed, smoking prevalence among vulnerable groups in the UK is considerably higher than in the general population. *See*, L. SZATKOWSKI, A. MCNEILL, *Diverging trends in smoking behaviours according to mental health status. Nicotine and tobacco research*, 356–60 (2015). In 2018, the Australian Parliament conducted a review of e-cigarettes and heard evidence from academics and clinicians about the smoking toll among vulnerable groups. One witness focused on the risks of smoking posed to Aboriginal and Torres Straits islanders, while another stated that 70% of those with a diagnosis of schizophrenia and 61% of bipolar patients smoked. PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA, *Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia.* In Bangladesh, tobacco use is higher in the most vulnerable groups. Greater percentages of slum and illiterate Bangladeshis use smokeless tobacco (26% and 24%, respectively) compared to urban and highly-educated Bangladeshis (8% and 6%, respectively). A greater percentage of urban (46%) and highly-educated (52%) Bangladeshis did not use any tobacco at all compared to slum residents (36%), and illiterate Bangladeshis (32%). Moreover, poorest people are the least aware of the risks of tobacco. P. DRIEZEN ET AL., *Awareness of tobacco-related health harms among vulnerable populations in Bangladesh: findings from the international tobacco control (itc) Bangladesh survey*, 13 International Journal of Environmental Research and Public Health, 848 (2016).

[54] Indeed, these countries house the world's largest populations of smokers, who are invariably men. It is men who are typically the main breadwinners while women remain at home looking after the family and household. Should the breadwinner be lost to smoking-related disease, the situation for women, already in a precarious economic situation can only worsen.

discrimination. Thus, prohibitionist regulatory environments that deny and/or restrict access to low risk products (including e-cigarettes) have the (perhaps unintended, but surely practical) effect of showing little compassion and assistance precisely to those most in need.

Legally speaking, the two approaches are based on two different legal principles. Health-protection systems are based on (a strict) application of the *precautionary principle*; whereas harm-reduction systems are based on *harm reduction*, which finds it desirable to encourage the reduction of harm associated with the use of combustible cigarettes, which includes encouraging users to switch to a less harmful product (e.g., e-cigarettes). Before zooming in on the different models of regulation (Section 4) and, specifically the UK and Brazilian ones (Sections 5 and 6, respectively), we find it useful to spend some words on both legal principles.

[55] Information on indigenous populations relies on the work of Dr Glover (op.cit). Indigenous or first-nation people live in over 90 countries, numbering around 370 million, making up 5% of the global population and for about 15% of the global poor (largely due to the multiple negative social, racial, political and economic impacts of colonization over centuries). Data indicate the high prevalence of smoking among indigenous peoples (e.g., 83% of Yolŋu men in Australia; 74% of Nenets men in Russia). Moreover, many indigenous populations have long-standing tobacco-using traditions with social and cultural landscapes very different from those observed in non-indigenous communities (e.g., in New Zealand, smoking rates among Māori women are much higher than non-Māori women). In 2019, Dr Glover made a submission to the Danish government concerning the Kalaalit Nunatt people of Danish-administered Greenland pointing to all the diverse ways in which colonisation has impacted on the health and wellbeing of the people (compared to other Nordic countries) and how one-size-fits-all Nordic tobacco control policies are potentially damaging to this population. According to Dr Glover, tobacco-prevention measures failing to take account of the varieties of traditions which exist among indigenous populations infringe on the very FCTC's art. 4.2c stating: *the need to take measures to promote the participation of indigenous individuals and communities in the development, implementation and evaluation of tobacco control programmes that are socially and culturally appropriate to their needs and perspectives*. It is also worth mentioning that some indigenous communities have positively responded to the introduction of low-risk products, for instance: the Sami people from northern Scandinavia and Finland have been making the transition from smoking to snus; in New Zealand, Māoris have opened vape shops and implemented a switching program called Vape2Save.

[56] The high level of smoking among those with substance-use problems can exacerbate drug-related health issues. Services around the world report in excess of 85-90% of those attending for treatment also smoking tobacco. In recent years, drug-related deaths in the UK have been rising, particularly among older, long-term users also suffering from smoking-related diseases, which generally rank high in the list of co-morbidities for those addicted to opiates. Similarly, in a cohort study of 845 users in residential substance use treatment in the USA, around a quarter died during the course of the study, with smoking-related causes outstripping those related to drugs and alcohol. R.D. HURT ET AL., *Mortality following inpatient addictions treatment. Role of tobacco use in a community-based cohort*, 275 JAMA, 1097–1103 (1996).

[57] Smoking is an entrenched part of prison culture, not least because tobacco itself is a currency in many prisons. Coming largely from economically and socially disadvantaged communities, most of those subject to jail time are already smokers. Studies from different countries put smoking levels at up to 80%. in prisons, smoking helps inmates deal with the manifest stresses of incarceration: boredom, isolation from family as well as the constant risk of violence and intimidation. *See*, M. BAYBUTTET AL., *Tobacco use in prison settings: A need for policy implementation*, in WHO, *Prison Health Guide* (2012). R. RICHMOND, ET AL., *Tobacco in prisons: a focus group study*, 18 Tobacco Control, 176–182 (2009).

[58] In one meta-analysis across 20 countries, those with a diagnosis of schizophrenia had an average smoking prevalence of 62%, while a study of US veterans with PTSD had a smoking prevalence nearly double that of veterans without PTSD. ASH, *Smoking and Mental Health* (No. 12; Fact Sheet) (2019). Also in the UK, 40-80% of people with a mental health condition smoke and they consume 42% of all tobacco, smoking more heavily and frequently. While smoking prevalence among UK adults has dropped to around 15 per cent, smoking rates among those with mental health problems have remained stubbornly unchanged for around 20-30 years. F RYAN, *The psychology behind smoking cessation – Mindsets, culture and preventing relapse*, Smoking Cessation and Mental Health Summit, Royal Society of Medicine, London (30 September,2019).

3.1 The right to health, as declined by the principle of harm reduction.

Harm reduction refers to policies, regulations, and actions focused on *reducing* (rather than *eradicating*) health risks, usually by providing safer forms of hazardous products, or encouraging/incentivizing less risky behaviors. Harm reduction can be traced as far back as the 1920s (even though at the time, it was not called as such, neither was it a coherent principle, legal or otherwise); interestingly, its origins are rooted in the response of the scientific/medical communities to inhibiting state regulation.

Indeed, following the first legal bans on unauthorized possession of opiates, doctors in both the USA and the UK prescribed morphine or heroin to addicted patients to help them manage their condition. In 1926, a committee of UK doctors agreed it was legitimate medical practice to prescribe addicted patients (as a treatment of last resort) morphine, heroin, and/or cocaine[61].

In the 1960s, the rise of recreational drug use across North America and Europe favored the dissemination of harm-reduction sensibility among consumers, epitomized by the development of lay advice about how to use drugs in a safer way[62]. Harm reduction for safer consumption of alcoholic beverages and spirits goes back to early provisions regulating the content of alcoholic drinks in order to reduce contamination and risk of poisoning.

Later complemented by attempts to modify drinking practices in drinking venues and finally, by the 1970s, the trend was to make drinking safer for drinkers and those affected by drinking. Harm reduction as a health strategy came to prominence during the HIV/AIDS epidemic of the 1980s[63]. Among other things it was encapsulated in the slogan *safer sex*, one of the very epitomes of the harm-reduction approach, as it acknowledges that sexual abstinence was neither a practical or actually feasible method to prevent HIV transmission, whereas condoms and safer-sex behaviors were key[64].

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[59] For homeless people, cigarettes provide the whole panoply of benefits including emotional calming, relief from boredom, and socializing aspects. L. DAWKINS ET AL., *A cross sectional survey of smoking characteristics and quitting behaviour from a sample of homeless adults in Great Britain*, 95 Addictive Behaviors, 35–40 (2019). C. MATTHEWS, *Smoking and the Homeless: There is Hope*, Vaping Daily. https://vapingdaily.com/support/ homeless-community/ (2019, March 5). However, their homeless status makes it even more difficult for cessation services to intervene.

[60] Homeless people on the streets, smoking and sharing cigarettes can be an aspect of social glue or a way of coping with both stress and boredom for a group of otherwise isolated and marginalized people. This is also the case for those living alongside generations of smokers.

[61] Ministry of Health, UK, *Departmental committee on morphine and heroin addiction*, Rolleston report (1926).

[62] G.V. STIMSON, *Minimising harm from drug use*, in J. Strang, J., M. Gossop (edited by), *Heroin Addiction and Drug Policy: The British System*, Oxford (1994).

[63] The phrase came to be associated with those in gay communities on the American west coast and in New York, who bonded together in grassroot-action groups to protect their health in the face of fear and vilification from society at large.

[64] At the time the Ottawa Charter was published, the USA was in the grip of an HIV/AIDS epidemic.in the early '80s, there were all kinds of myths and misinformation about AIDS, ranging from a public perception that you can *catch* AIDS from toilet seats, or touching sufferers, through to pulpit rantings about God's revenge on homosexuals. But once it was established that the AIDS virus was transmitted through bodily fluids, gay activists in the most affected cities of San Francisco and New York began a grassroot, community-based, self-help initiative to educate and support their peers about safer sexual practices.

Once it became clear that people injecting drugs were similarly at risk, new campaigns arose demanding safer initiatives for those that (for whatever reason) would continue to inject drugs (e.g.: needle and syringe exchanges, opiate substitute therapy, overdose prevention, and drug consumption rooms). By the mid-1980s, there was already a Dutch drug-using group who were offering help and peer support to users in the Netherlands. This was very much in the context of what might be termed *guerrilla public health*, initially undertaken with no support from health professionals. The UK took this further in the form of a partnership of user activists and public health officials and clinicians that offered both practical support and secured critical political backing. This created a safe environment for injecting-drug users, who had access to opiate substitute prescribing and needle exchange facilities.

Similarly, the opioid crisis which has hit the USA at the end of the '90 and early 2000s has changed official thinking on drug-harm reduction. Funding is now available for opiate substitute treatment and the provision of the drug naloxone which immediately reverses the effect of opioid overdose, while the Surgeon General has publicly supported the provision of needle exchange[65].

Today, Harm Reduction International defines *drug harm reduction* as: p*olicies, programs and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop*[66]. The defining features being the focus on: (i) the prevention of harm, rather than of the drug use itself; and (ii) the people continuing to use drugs". Nowadays, harm reduction is pervasive in every legal system. Indeed, more or less everywhere in the world everyday lives are replete with potentially dangerous products or behaviors being modified (by manufacturers, regulators or consumers) to *enable use while reducing risk of harm* (e.g.; designing motor vehicles and roads to make travel safer; mandating use of seat belts and crash helmets while driving, separating drinking and driving by law; driver licensing; etc.); or the introduction of products offering *safer options* (e.g.,: zero-calories soda drinks and low-fat foods; even refrigerators as means to improve food storage and reduced food contamination).

However pervasive the current (even subconscious) application of harm reduction, smoking lagged behind[67], mainly due to the "late" discovery of cigarettes' actual danger to health, as well as the lack of reduced-risk options[68]. Indeed, from the 1980s, the main tobacco harm-reduction product was nicotine replacement therapy ("NRT"), *i.e.* the provision of controlled doses of pure nicotine *via* gums, patches, lozenges, inhalers and sprays[69].

[65] M. Meehan, *Surgeon General Supports Needle Exchanges To Limit Disease From Opioid Crisis* (2018), available at: http://wfpl.org/surgeon-general-supports-needle-exchanges-to-limit-disease-from-opioid-crisis/.

[66] HARM REDUCTION INTERNATIONAL, *What is harm reduction? A position statement*, available at https://www.hri.global/what-is-harm-reduction.

[67] The idea of tobacco harm reduction can be traced to Professor Michael Russell, a UK psychiatrist. He observed that people smoke for the effects of nicotine, but that illness and premature mortality result from the tar that they inhale. Russell pointed to the health gains that might be achieved if the tar in cigarettes could be reduced, while maintaining nicotine levels.[7]

[68] Notable (yet not widespread) exceptions being snus in Scandinavia and smokeless tobaccos in the USA.

E-cigarettes (a relatively new product) are arguably the newest frontier of tobacco harm-reduction, as they prove to be *far less harmful* (up to 95% less harmful[70]) than traditional cigarettes, and provide an *enjoyable* way to consume nicotine. In turn, this has raised challenges for governments in terms of appropriate regulatory models, and the legal principle on which to base it.

Tobacco harm reduction has travelled a separate road to drugs, sex and alcohol harm reduction. Indeed, in the context of reducing harm from smoking, smokers ought to be allowed to be informed about services and/or products that can reduce harm.

Governments should then create policies, and regulations that enable smokers to have information about and access to such harms-reducing services and/or products[71]. Similarly, manufacturers who can provide products that are less harmful than smoking (including tobacco companies) ought to be allowed (even encouraged?) to produce them. At this point in the global debate on e-cigarettes, these two elements are not (always) aligned. Products are available, but governments are not providing access to them or information about them. Scientific evidence is available, from some of the world's leading scientific and medical institutions, and yet there is a resistance to accept it from some of the world's most significant tobacco control activists[72].

The UK (which deservedly is one of the study countries of this paper) undoubtedly stands out for embracing tobacco harm-reduction policies. In 2007, the UK Royal College of Physicians ("RCP") explicitly advocated for tobacco harm-reduction in its report *Harm reduction in nicotine addiction*, which argued that *Harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes*, and suggested the potential for rebalancing the market in favor of safer nicotine products[73].

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[69] NRT was first used in the USA in 1984. It is now the medically approved way to consume nicotine without tobacco and is included in the WHO's List of Essential Medicines.

[70] In 2018, Public Health England experts reviewed the available studies of biomarkers of exposure. Based on its assessment of the evidence, Public Health England concluded in 2018: *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. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping* Public Health England, Evidence review of e-cigarettes and heated tobacco products (2018).

[71] Among others, Prof. Kozlowski has been writing about the rights of smokers to be properly informed about harm reduction options. One of his earliest papers framed this premise as follows: *The right to information derives from the principle of respect for autonomy […]. If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health. In a tradition deriving from the Nuremberg Code (1949)10 and the United Nations Declaration of Human Rights (1948), the American Public Health Association concluded, 'Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances in accordance with internationally recognized standards'*. L.T. KOZLOWSKI, *Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options*, Nicotine and Tobacco Research, 67–72 (2002).

[72] This is especially the case for Swedish snus, where there is approximately 50 years of epidemiological evidence to prove the issue. From a human rights perspective, smokers should be allowed to have information about and access to snus, and yet it is banned in many countries in the world. This makes no sense when the most harmful of nicotine delivery devices, a cigarette, is freely available almost everywhere in the world.

[73] ROYAL COLLEGE OF PHYSICIANS, TOBACCO ADVISORY GROUP, *Harm reduction in nicotine addiction: helping people who can't quit*, p. 241 (2007).

3.2 The right to health, as declined by the precautionary principle

Defining the precautionary principle is not an easy task. Indeed, it has been said that there exist at least 20 different definitions of the principle; many incompatible with one another[74].Originally rooted in sociology and philosophy[75], the precautionary principle stood as an ethical rule regulating human behavior in the so-called *society of risk*, and only relatively recently has it come to assume a central role as a legal principle.

The distinguishing feature underlying the precautionary principle is the impossibility to meaningfully assess the risks deriving from (un)identified sources.

Hence, it does not concern so much the *actual risks*, but rather the *potential risks* that scientific uncertainty does not (yet) allow to fully establish. From this perspective, it is necessary to distinguish the precautionary principle from the prevention principle, which allows interventions aimed at preventing the occurrence of certainly-existing and already-proven risks. In other words, we can say that the precautionary principle is aimed not at *actual risks* (which are covered by the prevention principle), but at *potential ones i.e.*, risks about which there are scientific uncertainties.

Indeed, if prevention takes place to avoid the occurrence of a certain risk, precaution aims at regulating a still-uncertain risk whose occurrence can neither be excluded, nor proven with certainty. Prevention needs sufficient data to identify a certain or probable risk, whereas precaution kicks in when such information is missing, and therefore it is impossible to determine the probability of risk occurrence. This also means that the precautionary principle requires early intervention, so as to prevent the transformation of a potential risk into a real one. Generally (depending on the definition of the principle), such an intervention is justified only in order to avoid potentially-grave and irreversible damage. Precautionary measures also need to be based on at least plausible scientific hypotheses. The precautionary principle therefore stands for the approach that scientific uncertainty should not prevent the application of preventive and cost-effective measures in cases of potentially serious or irreversible harmful effects, which can be identified mainly by scientific progress and technological developments[76].

The legal nature of the precautionary principle appeared for the first time in German environmental law, where it aimed at providing a rationale for regulation in cases of an unclear causal relationship between the source of the harm and the potential damage[77].

There is no agreement as to when the principle made its first appearance in international law, even though its origins can probably be traced back to the 1980s, when several charters and

[74] See generally C.R. SUNSTEIN, *The Laws of Fear: Beyond the Precautionary Principle*, Cambridge (2005).

[75] This meaning dates back to the classical works of H. JONAS, *Das Prinzip Verantwortung. Versuch einer Ethik für die technologische Zivilisation* (Suhrkamp Verlag 1979) and *Technik, Medizin und Ethik. Zur Praxis des Prinzips Verantwortung* (Suhrkamp Verlag 1985). *See also* U. BECK, *Risk Society: Towards a New Modernity* (1992). For further references to the precautionary principle in philosophy, *see particularly* L. MARINI, L. PALAZZANI (edited by), *Il principio di precauzione tra filosofia, biodiritto e biopolitica* (2008).

conventions made reference to some elements of precaution[78].

Finally, the 1992 Rio Declaration provided the first relatively precise articulation of the precautionary principle, stating that *where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*[79]. More recently, this formulation was reaffirmed by several eminent scholars and ecological non-governmental organizations in the so-called 'Wingspread Statement', which states that *when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically*[80]. This definition has quickly become the most accepted and referred-to formulation of the principle, nowadays widely (even if not uniformly[81]) applied in different countries[82] as well as at the international level, including in areas other than environmental law, as (relevant for purpose of our discussion) protection of health[83].

However, given the mutable formulations of the precautionary principle in different international instruments, it comes as no surprise that no uniform application of the principle has been achieved in international law.

At a certain general level, one may say that *the essence of the precautionary principle is that positive action … may be required before the existence of a risk has been scientifically established*[84].

However, when it comes to details, any overall consensus disappears[85], both across countries and at the international-law level (including in areas other than environmental law

[76] More precisely, the precautionary principle applies in any case where activities might cause risks for human health and – in more general terms – for the enjoyment of rights, but such risks are only potential, as there is not yet definitive evidence as to their existence and scope. In such cases, public authorities can allow the activities only after collecting data which might reasonably exclude the potential for grave dangers, therefore complying with the principles of proportionality, non-discrimination, and coherency. There is also a disclosure obligation imposed on the public authorities towards those who are exposed to such risks. Such understanding of the precautionary principle has been shaped by the case law of the European Court of Human Rights (ECtHR). *See in particular*, *Guerra et al v Italy* (1998) App. No. 14967/89; *Tatar v Romania* (2009) App. No. 67021/01; *McGinley v United Kingdom* (1998) App. No. 21825/93; *Roche v United Kingdom* (2005) App. No. 32555/96. Compare also D. Xenos, 'Asserting the Right to Life (Article 2, ECHR) in the Context of Industry' (2007) 3 Ger Law J 231.

[77] *See* L. GRUSZCZYNSKI, *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement* Oxford (2010) 158 (*quoting* S. Boehmer-Christiansen, 'The Precautionary Principle in Germany – Enabling Government' in T. O'Riordan, J. Cameron (edited by), *Interpreting the Precautionary Principle* (1994)).

[78] *See for example* the 1982 World Charter for Nature (requiring special precautions to be taken in order to prevent discharge of radioactive or toxic wastes) and the 1989 Montreal Protocol on Substances that Deplete the Ozone Layer (*determined to protect the ozone layer by taking precautionary measures to equitably control total global emissions*).

[79] Rio Declaration on Environments and Development, 14 June 1992, UN A/Conf 151/5/Rev 1 (1992), reprinted in 31 ILM 876 (1992) principle 15.

[80] Wingspread Statement on the Precautionary Principle, 25 January 1998, reprinted in C. Raffensperger, J. Ticker (edited by), *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (1999); *cfr.* Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 031.

[81] For instance, differences exist with respect the thresholds of scientific uncertainty for the principle's application, the requirement (or lack thereof) to carry out a cost-benefit analysis, the proportionality test, and allocation of the burden of proof. *See generally*, Gruszczynski (op. cit.) 160-161.

(for instance the protection of human life and health[86]). Indeed, differences exist in the precautionary principle's actual application and its procedural workings. For instance with respect to: (i) the thresholds of scientific uncertainty for the principle's application; (ii) the requirement (or lack thereof) to carry out a cost-benefit analysis; (iii) the proportionality test; and (iv) allocation of the burden of proof[87].

4. Regulation of tobacco products (e-cigarettes?) in international law

As mentioned above, international law does acknowledge a general right to health. In 1981 the WHO published the Global Strategy of Health for All by the Year 2000[88]. Its guiding principle was that *all people in all countries should have at least such a level of health that they are capable of working productively and of participating actively in the social life of the community in which they live*.

[82] The precautionary principle has gradually taken on a central role in EU law, even if somewhat it seems to be applied more strictly than does international law. First, it seems there are different thresholds for the application of the principle. Indeed, the Rio Declaration seems to imply that only *serious or irreversible threats* can trigger the application of the principle. On the other hand, EU law provides for a much lower threshold, having recourse to the precautionary principle simply in cases of *potential* risks. *See*, Communication from the Commission on the Precautionary Principle, 2 February 2000, COM/2000/0001 final, 17. Note, however, that other instruments of international law also provide for lower thresholds. See for instance, the Biosafety Protocol, which only speaks about a 'potential adverse effect' without qualifying its seriousness and probably presuming the irreversible character of threats connected with genetically modified organisms, or the Convention on Biological Diversity, which refer to 'threats of significant reduction or loss'. Second, prior to invoking the precautionary principle, EU law requires a scientific (and as-complete-as-possible) risk analysis in order to identify and assess uncertainties. *See*, Communication from the Commission on the Precautionary Principle (n 17) 13–14. International law adopts a more permissible approach in this regard, referring only to 'the lack of full scientific certainty' (Rio Declaration) or to a situation in which 'some cause-and-effect relationships are not fully established scientifically' (Wingspread Statement). The most important difference between the precautionary principle in international and EU law is probably that in the latter the principle is formulated as a mere signpost for risk managers, meaning that it simply gives a justification for regulatory action, without compelling risk managers to act in the first place. Ibid 15–16 (stating that 'the Commission or any other Community institution has broad discretionary powers, notably as regards the nature and scope of the measures it adopts' and 'responding does not necessarily mean that measures always have to be adopted. In this case, the decision to do nothing may be a response in its own right'). On the other hand, in international law, the principle is usually formulated as an imperative, requiring action in cases of uncertainty (if there is a threat of serious or irreversible damage).

[83] See for example the Cartagena Protocol on Biosafety (touching upon the protection of human health as a part of its objective of safeguarding biodiversity); the Stockholm Convention on Persistent Organic Pollutants (*asking for a precautionary approach with regard to the protection of human life and health*).

[84] J. BOHANES, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle* 40 Columbia J Trans Law 331 (2002).

[85] GRUSZCZYNSKI (op. cit.) 160.

[86] *See for example* the Cartagena Protocol on Biosafety (*touching upon the protection of human health as a part of its objective of safeguarding biodiversity*); the Stockholm Convention on Persistent Organic Pollutants (*asking for a precautionary approach with regard to the protection of human life and health*).

[87] As a consequence of the alteration of the traditional allocation of the burden, the burden of proving the *potential* risks associated with a specific product (or its safety) may fall not on regulators, but rather on producers, manufacturers or importers. However, establishing the product's safety with absolute certainty is often exceedingly difficult (or even impossible) and may, in many cases, take many years (or even decades) to determine. *See generally*, L. GRUSZCZYNSKI, *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement,* Oxford (2010) at 160-161.

[88] WHO, *Global Strategy of Health for All by the Year 2000,* (1981) available at http:// apps.who.int/iris/handle/10665/38893.

The following commitment to health promotion was enshrined in the 1986 Ottawa Charter for Health Promotion[89]. The Charter stressed, at the top of the list, the imperative to build public policies supporting health (*any obstacles to health promotion should be removed with the aim of making healthy choices the easiest choices*). The Charter also makes clear that: *health promotion policy requires the identification of obstacles to the adoption of healthy public policies in non-health sectors, and ways of removing them. The aim must be to make the healthier choice the easier choice for policy-makers as well*. Furthermore, it puts people at the center of this (*people cannot achieve their fullest health potential unless they are able to take control of those things which determine their health*).

However, the acknowledging the right to *health for all* did not mean embracing the principle of harm reduction, especially for those engaging in risky behaviors, such as drug users. Indeed, there was no attempt to encourage member states to empower and strengthen these individuals and their communities to make healthier choices.

Instead, the WHO and the UN Office of Drugs and Crime (UNODC) were staunchly opposed to the whole concept of harm reduction for these categories, as public health was viewed through a prism of abstinence, prevention, treatment, and regulation[90]. As far as the WHO, UNODC were concerned, harm reduction for risky behaviors was simply a mechanism for condoning drug use. It took quite some time to for these international bodies to come to endorse drug harm-reduction interventions such as needle exchange. Specifically for tobacco-control policies, during the Ninth World Conference on Tobacco and Health in Paris in 1994, the WHO passed a resolution on the need to take international legal action to combat the global smoking epidemic. The international convention on tobacco control, to be known as the WHO Framework Convention on Tobacco Control ("FCTC"), was unanimously adopted in May 2003, during the 56th World Health Assembly.

Even though the FCTC does not itself contain any explicit vaping regulations, but its generic provision requiring signatories to '*take measures to prevent the initiation … of tobacco products in any form*'[91] has unleashed the regulatory trend to extend the restrictions already applied to tobacco products to e-cigarettes as well (often by calling upon the precautionary principle); or even to prohibit e-cigarettes altogether. In its own words, the FCTC declares itself deriving from the universal right to health for all, as cemented in a patchwork of international treaties: … *Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, … Recalling also the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the*

[89] WHO, *Ottawa Charter for Health Promotion*, (1986), available at http://www.who.int/healthpromotion/conferences/previous/ottawa/en/.

[90] G.V. STIMSON, AID*S and injecting drug use in the United Kingdom 1988-93: the policy response and the prevention of the epidemic*, 41 Social Science and Medicine; 699-716 (1995).

[91] FCTC, art. 4.2(b).

highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, … Recalling that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care. … Recalling further that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health.

In February 2005, the FCTC entered into force in international law as the world's first multi-lateral health treaty. The FCTC sets a framework for countries to construct *their own* tobacco control policies[92], particularly the low/middle income countries who do not have the necessary resources to formulate their own policies from scratch. Its opening Convention statements (a.k.a., the Preamble) make specific reference to the right to health, namely, *the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*[93]. Every two years, the Parties to the FCTC participate in the so-called FCTC Conference of the Parties (COP).

The very first article of the FCTC (art. 1d) defines *tobacco control* as *a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke*. However, the FCTC does not define harm reduction *per se* in its widest sense, therefore it could come to be interpreted as referring to any control intervention[94]. Moreover, if on the one hand it is true that at the time of drafting the FCTC, the WHO had finally acknowledged the public-health imperative in relation to HIV and drugs, and therefore knew what harm reduction meant in those circumstances; on the other hand, it must be acknowledged that biases towards risky behaviors, including smoking, are strong[95]. Furthermore, at the time there was an exceedingly limited variety of harm-reduction tools available at the time[96]. Moreover, the legal history of the FCTC itself does suggest a certain (even strong) wariness towards the tobacco industry and its intentions. Indeed, art. 5.3 of the Convention expresses such wariness of the industry, even though in quite measured terms.

[92] While the FCTC is *legally binding*, all this means in practice is that Parties have signed up to enacting controls in the spirit of custom and practice as applied to all international treaties. But aside from smuggling, tobacco control is an issue for domestic law and ultimately what passes into law remains in the gift of individual governments.

[93] This is the same definition of contained in art. 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966.

[94] The lack of a properly-defined and implemented harm reduction *pillar* in the FCTC to sit alongside the three established pillars to prevent initiation, promote cessation and protect from environmental impact was criticized by Meier and Shelley as far back as 2006. In the light of the fact that many nations were failing to deliver on what the authors call *the first three pillars of the FCTC*. In their words: *unlike cessation efforts, nations need not do anything to introduce a harm reduction strategy; private corporations already are developing and marketing… products without government encouragement…Countries can work together within WHO to address issues of tobacco harm reduction, aiding each other in disseminating these results of basic science and translating these results into novel behavioural treatments, pharmacological regimes and tobacco products*". B.M. MEIER, D. SHELLEY, *The Fourth Pillar of the Framework Convention on Tobacco Control: Harm Reduction and the International Human Right to Health*, 121 Public Health Reports, 494–500. (2006).

It states that: *in setting and implementing their public health policies with respect to tobacco control, Parties shall act to* ***protect these policies from commercial and other vested interests of the tobacco industry*** *in accordance with national law*. (**emphasis** added)

These words were agreed by consensus of the 193 governments drafting the treaty. Subsequently, however, during the less formal and legal negotiation of the FCTC Guidelines (occurred in COP working groups of only a small number of governments, together with NGOs), art. 5.3 was extrapolated to a set of Principles. NGOs and the WHO itself have pushed the 5.3 principles for interpretation to be the norm and they have become almost customary in terms of national interpretation and subsequent implementation. Such principles are:

Principle 1: *There is a* ***fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests****. The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore,* ***Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible***. (**emphasis** added)

Principle 2: Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent. Parties should ensure that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent[97].

Principle 3: Parties should require the tobacco industry and those working to further its interests to

[95] At the E-Cigarette Summit held in London in November 2017, S. Jakes from the NNA made some key points that from a consumer point of view, smoking is not a disease, but a pleasurable activity that nonetheless presents serious health risks which smokers should be able to mitigate through personal choice access to low-risk products: *The word 'pleasure' seems to be something of an anathema to some in public health. One of the biggest challenges for consumers is in getting regulators, and those who advise them, to understand that for a great many people vaping is not a medicine, or simply a smoking cessation intervention, it works precisely because it isn't those things. It works because they enjoy it. They love the personalization that's made possible by the diversity of the market in devices, and the thousands of flavors available. They enjoy the identity of being a vaper and the sense of community that that entails. They love that vaping is similar to smoking, but at the same time a million miles away from it. "But vaping is more than just a pro-choice campaign. Whilst many vapers do regard it simply as a more pleasurable alternative to smoking, many others place more importance on the reduction in harm to their health, or the ability to use e-cigarettes to stop smoking. "We want to be able to make our own choices based on accurate information [but] we see the choices that are taken away from people by the arbitrary and counterproductive restrictions on reduced risk products*.

[96] At that time (1999–2003), e-cigarettes and vaping were unheard of and the only reduced harm product known was Swedish snus. The only alternatives to smoking spoken about were pharmaceutical nicotine replacement products, as referenced in the cessation section of the FCTC contained in art. 14.

[97] The Principles' requirement that member states' dealings with the tobacco industry be open, accountable and transparent has, on practice, been overinterpreted to mean that *any and all* kinds of interaction with industry personnel (e.g., simply holding meetings or being present at events where tobacco industry staff are present) is deemed to be in contravention of the FCTC. Moreover, this extends beyond member state officials, to anybody with any connection to the industry that can be banned from attending the COP or international tobacco control meetings. Health 24, *Ex-WHO expert banned from tobacco conference after links to Marlboro* (2018) https://m.health24.com/News/Public-Health/ex-who-expert-banned-from-tobacco-conference-after-links-tomarlboro-maker-20180307. Moreover, NGOs and medical organizations frequently lodge complaints if industry representatives are invited to speak to parliamentarians and other public bodies investigating the new products. *See* for example, *The Australian Parliament Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia* (2018).

operate and act in a manner that is accountable and transparent. The tobacco industry should be required to provide

Parties with information for effective implementation of these guidelines.

Principle 4: Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses. Any preferential treatment of the tobacco industry would be in conflict with tobacco control policy.

Arguably then, actual harm-reductions (rather than *precautionary*) considerations were not the primary concerns leading the FCTC negotiations. Given this context, it is somewhat understandable that the thrust of the FCTC has been to reduce *all* tobacco use (*i.e.*, a *precautionary* approach), rather than to focus on the relative risks of different tobacco products (*i.e.*, a *harm-reduction* approach).

Consequently, most tobacco-control measures, promoted under the FCTC, have traditionally focused on reducing the supply of and demand for tobacco, thereby tending to treat e-cigarettes as just another declination of traditional cigarettes, rather than a different low-risk product, thereby neglecting the (significant) positive potential they carry for public health in general, and current smokers in particular.

The FCTC does not itself contain any explicit vaping regulations, its generic provision requiring signatories to '*take measures to prevent the initiation … of tobacco products in any form*'[98] has unleashed the regulatory trend to call upon the PP in order to extend the restrictions already applied to tobacco products to e-cigarettes as well; or even to prohibit ENDS altogether.

However, things may be changing. Indeed, in 2014, the WHO published a report *Electronic nicotine delivery systems*, which states that public health authorities should prioritize research into e-cigarettes, and to invest adequately to develop the evidence as soon as possible, however stating (somewhat perplexing, given that the mistrust towards the industry is so string to have found its way in legal treaties) that *the greater responsibility to prove claims about e-cigarettes scientifically should remain with the industry*[99].

Furthermore, the WHO and the FCTC COP Secretariat have started including e-cigarettes (as well as heat-not-burn products) in initial discussion papers and on the agenda at recent COPs. In particular, the COP held in 2014 ("COP 6") asked the WHO to prepare a briefing paper for the following COP in relation to e-cigarettes (and low-risk products in general).

The work was delegated to the WHO Study Group on Tobacco Product Regulation who

[98] FCTC, art. 4.2(b).

[99] WHO, *Electronic nicotine delivery systems*, para. 35 p.10 (21 July 2014). Very interesting to notice that the "antipathy" towards the tobacco industry is reiterated in the WHO's Time to Deliver report on tackling noncommunicable diseases. Indeed, in the section dealing with private sector relationships, the WHO encourages member states to engage *constructively* with the private sector, but specifically excludes the tobacco industry citing art. 5.3. It is also interesting to notice that such profound mistrust is not similarly directed towards other high-risk products industries. For instance, governments are encouraged to work with the alcohol industry by encouraging *economic operators in the area of alcohol production and trade to consider ways in which they could contribute to reducing the harmful use of alcohol in their core areas*. WHO, *Time to Deliver*, p.23 (2018), available at http://www.who.int/ncds/management/ time-to-deliver/en/.

came up with what, from a harm-reduction point of view, does seem a very promising report. In particular, para. 5 of the report on the potential role of low-risk products in tobacco control states that: *if the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement*[100].

Given this context, one may even argue that it would be time to amend the guidelines principles mentioned above, as the tobacco companies have diversified their production to include products (*i.e.*, e-cigarettes specifically) that are neither *lethal*, nor give rise to *a variety of social ills*. However, demands for precaution are still very loud. TobRegNet produced another report in 2019[101], which specifically demands recourse to the precautionary principle in the regulation of e-cigarettes.

5. The several approaches to the regulation of e-cigarettes

As mentioned above, many different approaches have been generated for regulating e-cigarettes, whereby the (strict?) application of the precautionary principle or the (lax?) recourse to harm reduction are only two extremes along a regulatory line that has within it many different possibilities. Indeed, some jurisdictions ban e-cigarettes altogether, while others

regulate them as medicinal products, poisons, tobacco products, consumer products, and/or unique products. And of course, not regulating e-cigarettes at all is also an option. Moreover, regulatory classifications are not mutually exclusive, as some countries use hybrid approaches, whereby e-cigarettes fall under several regulatory schemes. For the purpose of easier comparison and classification, this section provides an overview of seven ways governments can regulate e-cigarettes.

5.1 Prohibition

As mentioned above, the strictest approach, prohibiting all legal access to e-cigarettes, is often motivated by the application of the precautionary principle and a desire to avoid all possible risks, whether or not such risks are scientifically substantiated[102]. Prohibition is usually implemented by banning the manufacture, export, import, sale and/or possession of e-cigarettes[103]. The decision to ban e-cigarettes prioritizes the goal of avoiding use by non-smokers, such as most youth and never smokers[104].

[100] WHO, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems* (2016), available at https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.

[101] WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. (No. 1015; WHO Technical Report Series). (2019), available at https://apps.who.int/iris/bitstream/handle/10665/329445/9789241210249-eng.pdf.

[102] K. FARSALINOS, J. LE HOUEZEC, *Regulation in the face of uncertainty: The evidence on electronic nicotine delivery systems (e-cigarettes)*, Risk Manag. Healthcare Pol. 157–167 (2015).

Prohibition also addresses other important concerns, such as the health risks associated with dual use and the renormalization of smoking in public spaces[105]. However, e-cigarette prohibition raises several ethical issues, as it infringes on smokers' autonomy and may perpetuate harm by preventing tobacco smokers from accessing a less harmful product[106]. Indeed, by prioritizing the wellbeing of non-smokers and youth, banning e-cigarettes may pose harm to those who are looking for a less harmful smoking alternative[107].

5.2 Regulation as medicinal products

Regulating e-cigarettes solely as medicinal products is the second strictest regulatory approach and is motivated by a desire to strictly limit e-cigarettes to those who will use them to quit smoking[108], rather than for recreational purposes.

On its own, this approach involves blocking all legal access to e-cigarettes except for use as smoking-cessation therapy. Regulatory mechanisms under this classification aim to promote safety among those who use e-cigarettes for therapeutic purposes and to ensure accurate product labelling[109]to enforce product standards and prevent companies from making false health claims[110].

This model of regulation addresses some concerns at both ends of the health protection-harm reduction spectrum. This approach prevents non-smokers from legally accessing e-cigarettes, while allowing access to current smokers in order to reduce the harms associated with conventional tobacco smoking. Additional implementation options include: (i) restricting e-cigarettes' purchases to accredited pharmacies, (ii) applying strict regulation of internet sales in order to ensure compliance with pharmaceutical standards[111], and (iii) requiring a medical prescription for purchase. While regulating e-cigarettes solely as a medicinal product constitutes a very stringent approach, most jurisdictions that regulate e-cigarettes in this way have done so in conjunction with other regulatory schemes[112].

[103] About 30 countries around the world have prohibited the sale of e-cigarettes, regardless of nicotine concentration (Institute for Global Toba, 2020). For example, in Lebanon, a decision of the Lebanese Republic Ministry of Public Health (Decision No. 1/207) prohibits the importing and trading of e-cigarettes, and the Lebanese government ordered that e-cigarettes be entirely removed from the country's market (Institute for Global Toba, 2020). Similarly, Singapore's Tobacco Control Act prohibits the sale, distribution, and importation of e-cigarettes in the country (Institute for Global Toba, 2020).

[104] K. FARSALINOS, J. LE HOUEZEC (op. cit).

[105] N. KAUFMAN; M. MAHONEY (op. cit).

[106] W. HALL et al. (op. cit), FARSALINOS, J. LE HOUEZEC (op. cit).

[107] FARSALINOS, J., LE HOUEZEC (op. cit).

[108] P. HAJEK, A. PHILLIPS-WALLER, D. PRZULJ, ET AL., *A randomized trial of e-cigarettes versus nicotine-replacement therapy*, NEJM 380 (7), 629–637 (2019).

[109] FARSALINOS, J., LE HOUEZEC (op. cit).

[110] Conference of the Parties to the WHO Framework Convention on Tobacco Control, *Electronic Nicotine Delivery Systems and Electronic Non-nicotine Delivery Systems (ENDS/ENNDS)*, (2016).

[111] P. CAPONNETTO, D. SAITTA, D., SWEANOR, R. POLOSA, *What to consider when regulating electronic cigarettes: Pros, cons and unintended consequences*, Int. J. Drug Policy 26 (6), 554–559 (2015).

Despite the numerous advantages of this approach, there are also a few drawbacks. Indeed, regulatory burdens and a lengthy pharmaceutical approval process could create an *interim* black market for unregulated e-cigarettes purchases[113], such black market may consequently become permanent if companies never go through the pharmaceutical approval process. Furthermore, the pharmaceutical approval process is likely to result in cost increases for e-cigarette manufacturers, raising prices and making these products less affordable to current smokers. Many e-cigarette and e-liquid manufacturers may also lack the necessary expertise or resources to register their products or comply with stringent medicinal regulatory standards[114].

Moreover, applying medicinal regulations to e-cigarettes also creates unique challenges regarding access to these products. Indeed, requiring a prescription to use e-cigarettes will limit their accessibility and may encourage potential users to continue smoking tobacco.

Finally, while regulating e-cigarettes solely as medicinal products restricts accessibility, regulating e-cigarettes as a medicinal product *on top of other regulatory approaches* actually increases their accessibility by creating an additional pathway for accessing these products.

5.3 Component ban

Regulatory mechanisms that constitute a component ban include: (i) setting product standards (e.g., banning e-cigarette liquids that contain nicotine concentrations above a designated level), (ii) entirely banning e-liquids that contain nicotine, or (iii) selectively banning certain e-liquid flavors[115]. Imposing an e-cigarette component ban by prohibiting the sale of flavored e-liquids may discourage youth and young adults (who are presumed to prefer flavored e-cigarettes[116]) from initiating e-cigarette use. The most notable disadvantage of an e-cigarette component ban is that regulating the nicotine content of e-liquids, either by placing restrictions or banning nicotine-containing e-liquids entirely, may encourage current tobacco smokers to continue using conventional cigarettes.

[112] For instance, Norway regulates e-cigarettes as medicinal products, tobacco products, and as unique products (Institute for Global Toba, 2020). There are 20 countries that regulate e-cigarettes as medicinal products (Institute for Global Toba, 2020). For example, the Philippines classifies e-cigarettes as medicinal products and medical devices (Institute for Global Toba, 2020), which means they must pass all quality, efficacy and safety evaluations conducted by the Food and Drug Authority of the Philippines before they can be sold (Republic of the Philippines Department of Health, 2014).

[113] W. HALL et al. (op. cit).

[114] P. CAPONNETTO, D. SAITTA, D., SWEANOR, R. POLOSA P. CAPONNETTO, D. SAITTA, D., SWEANOR, R. POLOSA (op.cit).

[115] Conference of the Parties, (2016). E-liquids can be manufactured in a variety of flavors including menthol, fruit, candy, dessert, and tobacco. M.F. PESKO, D.S. KENKEL, H., WANG, J.M., HUGHES, *The effect of potential electronic nicotine delivery system regulations on nicotine product selection*, Addiction 111 (4), 734–744 (2016). Four countries have banned the sale of nicotine-containing e-liquids, and 32 countries regulate the nicotine concentration of e-liquids (Institute for Global Toba, 2020). Finland is currently the only country to place a ban on flavored e-liquids. E. OLLILA, *See you in court: Obstacles to enforcing the ban on electronic cigarette flavours and marketing in Finland*, Tob. Control (2019). In addition to a flavor ban, Finland has banned e-liquids that contain nicotine concentrations greater than 20 mg/ml (Institute for Global Toba, 2020). Israel has also implemented a component ban on e-cigarettes. The country has banned the manufacture, importation, and sale of e-cigarettes that have a nicotine concentration greater than 20 mg/ml (Institute for Global Toba, 2020).

[116] M.B. HARRELL, S.R. WEAVER, A. LOUKAS, ET AL., *Flavored e-cigarette use: Characterizing youth, young adult, and adult users*, Prev. Med. Rep. 5, 33–40. (2017); M.F. PESKO, D.S. KENKEL, H., WANG, J.M., HUGHES (op. cit).

5.4 Regulation as poisons or hazardous substances

Regulating e-cigarettes as a poison or hazardous finds its rationale in the poisonous and potentially fatal nature of high nicotine concentrations[117]. Possible regulatory mechanisms of this sort include banning nicotine-containing e-cigarettes or placing restrictions on nicotine concentrations in e-liquids[118]. Banning nicotine-containing e-liquids would help address the goal of preventing current non-smokers from developing an addiction to nicotine. However, this selective ban does not address the risk of non-nicotine e-liquids and may complicate the achievement of smoking cessation goals[119].

5.5 Regulation as tobacco products

Tobacco products can be defined as *any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product*[120].

By this definition, the classification of e-cigarettes as tobacco products is legally justified by the fact that nicotine is derived from tobacco[121]. Many policymakers find it convenient to classify e-cigarettes as tobacco products in order to include them in already well-established tobacco legislation. Under this approach, e-cigarettes would be available for purchase in the same manner and in the same places as conventional tobacco cigarettes[122].

Adopting a health-protection perspective, the same legal arguments motivating the strict regulation of tobacco products can be applied to e-cigarettes, in that the latter are also highly addictive products that cause harm and may serve as a gateway to even more harmful behaviors[123].

Moreover, a notable benefit of regulating e-cigarettes as tobacco products is that the relevant legislation is already well-defined in most jurisdictions.

However, there also are several notable disadvantages, mostly deriving from harm-reduction considerations.

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[117] D.S. KENKEL, *Healthy innovation: Vaping, smoking, and public policy*, J. Pol. Anal. Manag. 35 (2), 473–479 (2016).

[118] Australia, Belgium, Malaysia and Brunei Darussalam have adopted this regulatory approach (Institute for Global Toba, 2020). In Australia, it is illegal to possess or use nicotine as a non-therapeutic good, since nicotine is considered to be a dangerous poison. H. DOUGLAS, W. HALL, C. GARTNER, *E-cigarettes and the law in Australia*, Aust. Fam. Physician 44 (6), 415–418 (2015). This does not constitute a complete ban on nicotine-containing e-cigarettes, as these products can be purchased for therapeutic purposes with either a permit or prescription from a doctor. W. HALL et al. (op. cit), YONG ET AL., 2017 (op. cit). Non-nicotine e-cigarettes do not face this regulatory hurdle in Australia, therefore they can be sold and used legally. YONG ET AL., 2015 (op. cit). The regulation of e-cigarettes in Brunei Darussalam, on the other hand, focuses specifically on nicotine concentration. E-liquids with a nicotine concentration above 7.5% are classified as poison, whereas those with a nicotine concentration under this amount are classified as a tobacco product (Institute for Global Toba, 2020).

[119] FARSALINOS, J., LE HOUEZEC (op. cit).

[120] U.S. Food & Drug Administration, 2019, December 9, *Vaporizers, e-cigarettes, and other electronic nicotine delivery systems (ENDS)*, available at http://www.fda.gov/tobacco-products /products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends.

[121] FARSALINOS, J., LE HOUEZEC (op. cit).

Indeed, regulating e-cigarettes as restrictively as tobacco products (including conventional tobacco cigarettes, cigars, and smokeless tobacco) despite different health risks may discourage people from switching completely to a less harmful alternative. Moreover, this regulatory approach is not be suitable whenever e-cigarettes do not contain nicotine[124].

5.6 Regulation as consumer products

Countries can regulate e-cigarettes as consumer products in order to include them within existing legislation promoting consumer protection[125]. Regulating e-cigarettes as consumer products would generally address the risks relating to devices' possible unsafety or faultiness[126]. As such, possible regulatory mechanisms include: (i) the creation of quality control standards for e-cigarette products[127], (ii) tamper-proof containers, (iii) labeling rules regarding nicotine concentrations[128], (iv) post-market surveillance, (v) and product recall systems[129].

[122] W. HALL et al. (op. cit). They would be subject to the same policies as other tobacco products, including product labelling requirements, restrictions on advertising, minimum age requirements for purchase, and use restrictions in public places. 54 countries regulate e-cigarettes as tobacco products (Institute for Global Toba, 2020). In the United States, the Food & Drug Administration (FDA) has regulatory authority over all tobacco products, including e-cigarettes (U.S. Food and Drug Administration, 2016). The FDA classifies e-cigarettes as tobacco products, with an exception made for when they are marketed as drugs or combination products (*i.e.*, to use as a smoking cessation tool) (Institute for Global Toba, 2020). Manufacturers, importers and retailers of e-cigarettes are subject to the applicable provisions in the Family Smoking Prevention & Tobacco Control Act and the Food, Drug & Cosmetic Act. The Tobacco Control Act permits the FDA to regulate e-cigarette manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution. J.K. MERRILL, A.J. ALBERG, J.R. GOFFIN, S.S. RAMALINGAM, V.N. SIMMONS, G.W. WARREN, *American society of clinical oncology policy brief: FDA's regulation of electronic nicotine delivery systems and tobacco products*, J. Oncol. Pract. 13 (1), 58–60 (2016). The FDA has established three restrictions on e-cigarettes under this authority related to minimum age of purchase, health warning labels, and where tobacco products may be sold, and has announced that more restrictions are forthcoming (Food and Drug Administ, 2019).

[123] W. HALL et al. (op. cit).

[124] FARSALINOS, J., LE HOUEZEC (op. cit).

[125] Unless additionally regulated or otherwise specified, e-cigarettes would then be available like other consumer products – in convenience stores, specialty shops, and on the internet. Id.

[126] P. CAPONNETTO, D. SAITTA, D., SWEANOR, R. POLOSA P. CAPONNETTO, D. SAITTA, D., SWEANOR, R. POLOSA (op.cit).

[127] Id.

[128] FARSALINOS, J., LE HOUEZEC (op. cit).

[129] Consumer protections vary substantially between different jurisdictions, so regulation as a consumer-product will inevitably have different meanings in different places. Fifteen countries currently regulate e-cigarettes as consumer products (Institute for Global Toba, 2020). In Hungary, e-cigarettes are regulated primarily as consumer products (Institute for Global Toba, 2020), and are subject to art. 20 of the Tobacco Products Directive (2014/40/EU) (European Commission, 2017). This directive establishes safety and quality requirements for e-cigarettes, packaging and labelling rules, as well as monitoring and reporting requirements for manufacturers and importers (European Commission. Elec, 2017). By regulating the sale of e-cigarettes as consumer products, Hungary aims to achieve multiple competing objectives. The mandated use of warning labels, advising non-smokers to refrain from using e-cigarettes, and the prohibition of all e-cigarette promotion attempts to prevent non-smokers from adopting smoking behaviors, while still allowing current smokers to have relatively easy access to these products. It has been argued that this regulatory approach fails to specifically address the issues surrounding nicotine concentrations and may potentially give the impression that e-cigarettes are safe for anyone to use. FARSALINOS, J., LE HOUEZEC (op. cit). Some countries have opted to regulate non-nicotine e-cigarettes as consumer products, while implementing stricter approaches for e-cigarettes that contain nicotine including prohibition, component bans, or regulating them as poisons or hazardous substances (Institute for Global Toba, 2020). Countries that have taken this bifurcated approach include Australia, France, Moldova, and Switzerland (Institute for Global Toba, 2020).

5.7 Regulation as unique products

Rather than situating them within existing regulatory frameworks, some jurisdictions classify e-cigarettes as a unique product, enabling government policymakers to create new *ad hoc* legislation that pertains specifically to e-cigarettes[130]. This approach enables policymakers to tailor ecigarette regulation to the unique needs, situations and goals of their citizens. As such, regulating e-cigarettes as a unique product can take on features that place it anywhere on the health protection/harm reduction spectrum, and even pursue both health protection and harm reduction, potentially making e-cigarettes accessible to current smokers while restricting access to non-smokers and youth[131].

Regulating vaping and tobacco products in this way opens up the possibility of risk-proportionate regulation that would reflect the relative risks of each[132]. In contrast, if countries view e-cigarettes as entirely harmful, regulating them as a unique product allows a precautionary approach, such as restricting access for the entire population. The drawback of this approach is the amount of time it takes to develop and adopt new legislation, and the resources that must be dedicated to the process.

6. Regulation of e-cigarettes in the UK

[130] About 68 countries have regulated e-cigarettes as a unique product (Institute for Global Toba, 2020). In Denmark, e-cigarettes that are not considered medicines are regulated under the Electronic Cigarettes Act (Act No.426) (Institute for Global Toba, 2020). This Act regulates the sale, manufacture, import, packaging, labelling, advertising, and use of e-cigarettes (Danish Ministry of Health, 2016). It allows the sale of e-liquids with a nicotine concentration of up to 20 mg/L (Institute for Global Toba, 2020), and bans the sale of e-cigarettes to those under 18 years old (Danish Ministry of Health, 2016). The Act requires manufacturers and importers to notify the Danish Safety Technology Authority before introducing a product containing nicotine to the market, and it has provisions for packaging, labelling, and health warnings (Danish Ministry of Health, 2016). Advertising e-cigarettes is prohibited in Denmark and their use is forbidden in many public spaces (Danish Ministry of Health, 2016). Canada provides a similar example of how e-cigarettes can be regulated as a unique product. In Canada, e-cigarettes are regulated under the Tobacco & Vaping Products Act (TVPA) (Institute for Global Toba, 2020), in addition to the Canada Consumer Product Safety Act, the Food & Drugs Act, and the Non-Smokers' Health Act (Government of Canada, 2019). The TVPA regulates the manufacture, sale, labelling, and promotion of e-cigarettes sold in Canada (Government of Canada, 2018). The stated goal of the TVPA is to prevent youth from using tobacco and e-cigarettes (i.e., health protection), while allowing adult smokers to access e-cigarettes as a less harmful smoking alternative (i.e., harm reduction) (Government of Canada, 1997). The TVPA prohibits the sale of e-cigarettes to anyone under 18 years of age, as well as the sale of e-cigarettes that may be appealing to youth in the way that they look or function (Government of Canada, 2019). Canada has banned lifestyle advertising, advertising that is appealing to youth, and the use of testimonials and endorsements (Institute for Global Toba, 2020). Under the TVPA, certain additives have been banned, and restrictions have been placed on marketing flavored e-liquids (Institute for Global Toba, 2020). While Canada and Denmark have both taken a relatively moderate approach to regulating e-cigarettes, other countries have opted for far more restrictive approaches, while still operating under a unique product framework. For example, Cambodia, which has also classified e-cigarettes as a unique product, has taken a more restrictive approach. In *its Circular on Measures to Prevent & Terminate Consumption, Sales & Imports of Shisha and E-Cigarettes in the Kingdom of Cambodia*, Cambodia's National Authority for Combatting Drugs banned the sale, importation, and use of e-cigarettes in the country (Royal Government of Cambodia, 2014). This example constitutes a precautionary approach, reflecting the health protection perspective.

[131] As demonstrated by Canada.

[132] K.M. CUMMINGS, S. BALLIN, D. SWEANOR, *The past is not the future in tobacco control*, Prev. Med. 140 (2020).

Before Brexit, the UK used to regulate the e-cigarettes market, like the rest of the European Union, as mandated by the European Union Tobacco Products Directive ("TPD") (2014/40/EU), entered into force on 19 May 2014, and implemented in the UK through the Tobacco and Related Products Regulations of 2016 ("UK Regulation")[133]. After Brexit, the UK passed two sets of regulations (in 2019 and 2020) to amend the UK Regulation. However, even after these modifications, the UK e-cigarettes regulatory scape remains for the most unchanged. Indeed, the Government itself indicated that it was not seeking to go above and beyond what was already in the TPD[134].

Following Brexit, the first amendment, the *Tobacco Products and Nicotine Inhaling Products* (Amendment Etc.) (EU Exit) Regulation was passed in 2019. It sought to enable tobacco regulation to continue to function following the UK's withdrawal from the EU, including measures to allow for the establishment of new notification systems for producers placing tobacco products and e-cigarettes on the UK market. The Government subsequently introduced the *Tobacco Products and Nicotine Inhaling Products* (Amendment) (EU Exit) Regulation in 2020 to ensure that the UK met its obligations in relation to tobacco control and vaping products under the European Union (Withdrawal Agreement) Act 2020[135]. The Department of Health and Social Care also has a statutory duty to regularly review the regulatory impact of the UK Regulations and publish a report (known as a post implementation review). setting out its conclusions[136].

The UK implements an *ad hoc* regulation for e-cigarettes setting out requirements that cover: (a) product standards and nicotine strength; (b) safety; (c) labelling, and packaging; (d) notification and vigilance; and (e) advertising; and (f) annual reporting. Concerning product standards and nicotine strength, the requirements are as follows: (i) e-cigarette tanks are limited to a capacity of no more than 2ml; (ii) the maximum volume of e-liquid for sale in one refill container is restricted to 10ml; (iii) e-liquids are limited to a nicotine strength of no more than

[133] The UK Tobacco and Related Products Regulations 2016 ("the Tobacco Regulations") implemented the TPD in the UK in full and came into force on 20 May 2016. The subject matter of the legislation is largely reserved and concerns harmonizing of trade. The Department of Health, therefore, has agreed to transpose the TPD on behalf of the Devolved Administrations in Scotland, Wales and Northern Ireland.

[134] DEPARTMENT OF HEALTH ET AL, *Government response to the consultation on implementation of the revised Tobacco Products Directive (2014/40/EU)*, January 2016. For example, in October 2016 the Government stated that it had "*no further plans to ban or restrict the sale of flavoured ecigarettes in England*". Question for Department of Health, 8 October 2016, available at Written questions and answers - Written questions, answers and statements - UK Parliament, and reiterated this point in November 2018. See Vaping - Hansard - UK Parliament. Similarly, the Government stated that it had "*no current plans to extend smoke-free legislation to e-cigarettes or smokeless tobacco products*". Question for Department of Health, 18 October 2016, available at Written questions and answers - Written questions, answers and statements - UK Parliament.

[135] Under the 2020 regulations, the new notification system for tobacco products and e-cigarettes (set out in the 2019 regulations) would be used for the Great-Britain (GB) market only; the MHRA notes that "*producers placing products on the Northern Ireland market will be required to notify using the EU Common Entry Gate (EU-CEG) system for the notification of tobacco and e-cigarette products*". *See*, E-cigarettes: regulations for consumer products - GOV.UK (www.gov.uk). The 2020 regulations also ensure that fees are only paid once when products are notified to both the EU and GB databases.

[136] Written evidence submitted by the Department of Health (England) to the House of Commons Science and Technology Committee inquiry into e-cigarettes, March 2018, para 18. At the time of writing the PIR report has not yet been published.

20mg/ml; (iv) certain ingredients/additives including colorings, caffeine and taurine are banned; and (v) nicotine doses should be delivered by e-cigarettes at consistent levels under normal conditions of use.

Regarding safety, the UK mandates that e-cigarettes and refill products must: (i) be child-resistant and tamper evident; (ii) protected against breakage and leakage; and (iii) have a mechanism that ensures refilling without leakage (unless it is a disposable e-cigarette), in compliance with the standards for ensuring refilling without leakage set out in section 36 (10) of the UK Regulations 2016. Regulations for packaging and labelling mandate labelling and warning requirements, including: (i) statements of all substances contained in the product, and information on the product's nicotine strength, on the label; (ii) displaying instructions for use, information on addictiveness, and toxicity on the packaging and accompanying information leaflet, this should include a reference that the product is not recommended for use by young people and non-smokers, as well as warnings for specific risk groups and possible adverse effects; and (iii) a health warning covering 30% of the surfaces of the unit packet and any outside packaging stating *this product contains nicotine which is a highly addictive substance*.

Regarding notification and vigilance, requirements are as follow: (i) all e-cigarettes and e-liquids are required to be notified to the Medicines and Healthcare products Regulatory Agency ("MHRA") before sale; (ii) producers of new, or substantially modified, e-cigarette and refill container products must submit a notification to the MHRA six months before they intend to put their product on the UK market; and (iii) producers of e-cigarettes or refill containers must establish and maintain a system for collecting information about all of the suspected adverse effects on human health of the product. Concerning advertising, the UK prohibits: (i) advertising or promotion (both, direct and indirect) of e-cigarettes and refill containers in print media, on the radio and television; (ii) promotional elements on e-cigarette packaging; and (iii) cross-border advertising and promotion of e-cigarettes.

Finally, the last set of restrictions concerns annual reporting. In particular, manufacturers and importers of e-cigarettes and refill containers will have to submit, annually, to the Secretary of State: (i) comprehensive data on sales volumes, by brand name and type of the product; (ii) information on the preferences of various consumer groups, including young people, non-smokers, and the main types of current users; (iii) the mode of sale of the products; and (iv) executive summaries of any market surveys carried out in respect of the above[137].

At the moment of writing, there is no national legislation restricting the use of e-cigarettes in public places[138]. Both Action on Smoking and Health ("ASH") and Public Health England ("PHE") produced guidance on developing policies on the use of e-cigarettes in public places and workplaces, but ultimately the choice to allow employees to use e-cigarettes at work rests

[137] Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulations for consumer products*, (29 February 2016); ASH, *Countdown to 20th May 2016: Changes to tobacco regulations* (May 2016); ASH, *The impact of the EU Tobacco Products Directive on e-cigarette regulation in the UK*, (April 2016); Council Directive 2014/40/EU, OJ L 127, 3 (April 2014).

on employers[139]. Some organizations (including: councils, hospitals and schools) and businesses (such as train companies and restaurants) have prohibited the use of e-cigarettes on their premises.

PHE aimed to make its guide *non-prescriptive* on the grounds that *no one-size-fits-all answer exists to the issue of e-cigarette use in public places and workplaces*. The document is a true embracement of harm-reduction considerations and in particular it sets out five key principles to consider, namely: (1) making clear the distinction between vaping and smoking; (2) ensuring that policies are informed by the evidence on health risks to bystanders; (3) identifying and managing risks of uptake by children and young people; (4) supporting smokers to stop smoking and stay smokefree, and (5) supporting compliance with smokefree law and policies[140].

Similarly, ASH also embraces harm reduction and provides the following *tips* when formulating a workplace policy on nicotine containing products: (i) be clear about what you are trying to achieve, especially on how you are intending to improve the situation; (ii) be clear about precisely what you are prohibiting, *i.e.*: electronic cigarettes, things that could be confused with cigarettes, or both; (iii) make sure your policy is good for health, by helping and not hindering smokers to reduce the harm caused by smoking to themselves and others; and (iv) consider the part that your policy can play in *renormalizing* or *de-normalizing* smokefree environments and promoting the right role models to children[141].

6.1 Further restrictions in the devolved nations

In addition to the provisions set out by the UK Regulations, devolved nations may choose to apply greater restrictions and, in some instances, have done so. In particular, further restrictions in the devolved nations have addressed the sale of e-cigarettes to minors, mimicking the restrictions already in place for tobacco products. Regarding **England and Wales**, age restrictions on the purchase of tobacco products have been in place since the early 1930s. Under the Children and Young Persons Act 1933, it was an offence to sell tobacco to a person who appeared to be under the age of 16. The Children and Young Persons (Sale of Tobacco etc.) Order 2007 amended the 1933 Act and increased the minimum age of sale of tobacco from 16 to 18 years. Seven years later, Section 91(1) of the Children and Families Act 2014 also made it an

[138] Unlike traditional cigarettes. Indeed, smoke-free legislation, introduced under the Health Act 2006, and enacted through a series of regulations across the devolved nations (including: Smoke Free Premises etc. in Wales; Regulations 2007, Prohibition of Smoking in Certain Premises in Scotland, Regulations 2006, and The Smoking in Northern Ireland, Order 2006) prohibits smoking in enclosed public places and workplaces, on public transport, and in vehicles used for work. Further details can be found in the House of Commons Library Briefing Paper on *Smoking in public places*. Under Section 1(2)(a) of the Health Act 2006 "*smoking*" refers to *smoking tobacco or anything which contains tobacco, or smoking any other substance*. E-cigarettes do not burn tobacco and do not produce smoke. The use of e-cigarettes therefore falls outside of the scope of current smoke-free legislation.

[139] ASH, *Will you permit or prohibit electronic cigarette use on your premises?*, (October 2015).

[140] PHE, *Use of e-cigarettes in public places and workplaces Advice to inform evidence-based policy making*, (July 2016).

[141] Ash (2015), (op. cit).

offence for an adult to buy tobacco on behalf of someone under the age of 18 (a.k.a. *proxy purchasing*).

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 extended these provisions to apply to nicotine products, like e-cigarettes. Regulation 2 makes the proxy purchasing of nicotine products an offence, while Regulation 3 prohibits the sale of nicotine inhaling products to persons under the age of 18. The Regulations include exemptions, however, for both prescription-only, and authorized, medicinal products and devices that are indicated for the treatment of a person under 18. Following a DHSC consultation between the 22 July 2019 and 15 September 2019 on the Post implementation review of tobacco legislation (which included the Nicotine Inhaling Products, Age of Sale and Proxy Purchasing) Regulations 2015), in January 2021 the Department of Health and Social Care ("DHSC") published the results of the review[142].

Regarding nicotine-inhaling products, the DHSC concluded that: (i) e-cigarette smoking prevalence amongst 11-15-year olds had increased only slightly since 2014, indicating that the legislation has served to check growth in e-cigarette use, whereas adult prevalence over the same period had continued to increase, (ii) there is no evidence of significant costs to business from this legislation, and (iii) consultation responses from health-related NGOs, public sector bodies and businesses were generally supportive of this legislation[143]. It added that while the DHSC had received limited evidence on NIPs, there was enough to conclude that the legislation had "achieved its original objective by limiting increases in use of NIPs amongst young people" and thus that the regulations would remain in force, without any changes[144].

Finally, the Welsh Government also attempted to introduce controls on the use of e-cigarettes in public places in 2015/16. Part 2 of the Public Health (Wales) Bill proposed restricting the use of nicotine inhaling devices in enclosed and substantially enclosed public and work places, thereby bringing the use of these devices in line with existing provisions on smoking. The Bill was ultimately rejected[145]. A new Public Health (Wales) Bill 2016 was introduced in November 2016, though earlier proposals to restrict the use of e-cigarettes in public places were not included.

Moving to **Scotland**, restrictions on e-cigarettes were introduced under the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, which came into force on April 1st, 2017. The Act brings Scotland in line with England and Wales by making it an offence to sell *a nicotine vapor product to a person under the age of 18* and to *knowingly [buy or attempt] to buy a nicotine vapor product on behalf of a person under the age of 18*.

[142] Department of Health and Social Care, *A Post Implementation Review Report of Tobacco Legislation Coming into Force Between 2010-2015*, (January 2021).

[143] Id.

[144] Id.

[145] A vote by the Assembly to pass the final text of the Bill in March 2016 was tied at 26-26. The Presiding Officer then exercised her casting vote and voted against the motion. Welsh Assembly, Stage 4 of the Public Health (Wales) Bill, "Decisions", 16 March 2016.

As mentioned above, the UK Regulation prohibits cross-border advertising of e-cigarettes through a number of media channels, including radio, television and print media. Scotland is currently considering whether to go further in this respect. The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 provides powers for Scottish ministers to prohibit and restrict the advertising of vapor products (regardless of whether or not they contain nicotine) through secondary legislation, although this is not yet in place. The Scottish Government has outlined plans to launch a consultation on *restricting the advertising and promotion of Nicotine Vapour Products*[146].

Finally, in **Northern Ireland**, the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 makes provision for the Department of Health in Northern Ireland to enact regulations that would prohibit the sale of nicotine products to those aged under 18 years. It also allows for

Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978 (purchase of tobacco on behalf of persons under 18) to be amended so that it applies (with or without modifications) in relation to nicotine products.

6.2 Tobacco Control Plan for England

On 17 July 2017, a new Tobacco Control Plan for England, updating the 2011-2015 Plan, was published. We believe it is important to mention in this paper as it is yet another manifestation of the UK's harm-reduction-driven approach to the regulation of e-cigarettes.

There is no move in the new Tobacco Control Plan for e-cigarettes to be covered by the smokefree legislation. Instead, the Plan states that PHE will *support local areas looking to implement local smokefree policies differentiating the levels of harm caused by existing tobacco products including e-cigarettes and other novel products*[147]. The overall vision set out in the Plan is *to create a smokefree generation*, which it states, will have been achieved when *smoking prevalence is at 5% or below*. Regarding e-cigarettes, the Plan reiterates that the Government is *committed to evidence-based policy making* and thus aims to: help people to quit smoking by permitting innovative technologies that minimize the risk of harm, as well as maximize the availability of safer alternatives to smoking.

The Plan states that the DHSC will: monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England, including evidence on safety, uptake, health impact and effectiveness of these products as smoking cessation aids to inform our actions on regulating their use[148].

PHE is tasked in the Plan with updating its *evidence report on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022*, as well as continuing to

[146] At the time of writing, the consultation documents had not been published. Scottish Parliament, Written Question: S6W-02154, answered by Maree Todd on 27 August 2021. For more information on the advertising of e-cigarettes, please see the June 2019 Commons library briefing paper, Advertising: vaping and e-cigarettes.
[147] Department of Health, *Towards a Smokefree Generation A Tobacco Control Plan for England*, (July 2017), at 22.
[148] Id., at 16.

provide smokers and the public with: clear, evidence based and accurate information on the relative harm of nicotine, e-cigarettes, other nicotine delivery systems and smoked tobacco, to enable informed decision-making[149].

Embracement to harm-reduction was also clear during a Westminster Hall debate in November 2021 on the forthcoming Plan, the Minister set out the Government's position on e-cigarettes: *The evidence is clear that e-cigarettes are less harmful to health than smoking. It remains the goal of the Government to maximize the opportunities presented by e-cigarettes to reduce smoking while managing any risks. Our regulatory framework enables smokers to use ecigarettes to help them to quit, but we do not want to encourage nonsmokers and young people to take up those products*[150].

7. Regulation of e-cigarettes in Brazil

In August 2009, the Brazilian National Sanitary Surveillance Agency ("ANVISA") passed a resolution stating that the authorization of sales and imports of any *electronic smoking device* intended either for smoking cessation, or as a substitute for conventional cigarettes was subject to confirmatory epidemiological and toxicological studies[151].

This restriction was extended to all accessories and all formats of *electronic smoking devices*, regardless of their nicotine contents. Moreover, the resolution also banned their advertising at national level (however, the resolution did not prohibit individuals to bring these devices from other countries when for personal use). As no manufacturer has complied with these requirements so far, the 2009 measure has been acting, in fact, as an actual ban, thereby placing Brazil at the very opposite end of the spectrum between regulatory approaches based on harm reduction on the one hand, and precaution on the other. This was a primary reason for choosing Brazil as one of the two study countries this paper focuses one.

ANVISA's prohibition of ENDS advertising and restriction of sales may have had some effect in delaying their dissemination in the national territory, as Brazil still has lower proportions of e-cigarettes use, compared to countries with less restrictive measures on them[152]. However, recent studies suggest that use of e-cigarettes does exist -and grow- in Brazil despite its exceedingly restrictive regulation[153], though such market is mostly illicit. Furthermore, the increasing availability of heat-not-burn products poses additional pressure on current e-cigarettes' restriction[154].

Another reason why Brazil was chosen as a country-study in this paper is that it is currently in the process of revising its e-cigarettes' regulation in a way that could make it finally lean more towards harm-reduction considerations.

[149] Id. A new Tobacco Control Plan was expected in July 2021, but has not yet been published at the time of writing.

[150] Tobacco Control Plan - Hansard - UK Parliament.

[151] Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, *Proíbe a comercialização, a importação e a propaganda de quaisquer dispositivos eletrônicos para fumar conhecidos como cigarro eletrônico*, RDC 46/2009, available at http://bvsms. saude.gov.br/bvs/saudelegis/anvisa/2009/res0046_28_08_ 2009.html.

A revision of Brazilian general resolution on tobacco product registration (in force since 2007)[155] has already been started in March 2017. The original definition of the tobacco products includes *manufactured products derived from tobacco using leaves or extracts of leaves or other parts of tobacco plants in their composition, intended to be smoked, chewed or inhaled*.

At that time, the proposition was made to consider e-cigarettes as a *new non-tobacco special product*[156]. Nonetheless, at the end of the public consultation process, the original resolution remained unaltered[157].

[152] S. GRAVELY, G.T. FONG, K.M. CUMMINGS, M. YAN, A.C. QUAH, R. BORLAND, ET AL., *Awareness, trial, and current use of electronic cigarettes in 10 countries: Findings from the ITC project*, Int J Environ Res Public Health (2014); S.L. YOONG, E. STOCKINGS, K.L. CHAI, F. TZELEPIS, J. WIGGERS, C. OLDMEADOW, ET AL., *Prevalence of electronic nicotine delivery systems (ENDS) use among youth globally: a systematic review and meta-analysis of country level data*, Aust N Z J Public Health (2018); S. GRAVELY, P. DRIEZEN, J. OUIMET, A.C.K. QUAH, K.M. CUMMINGS, M.E. THOMPSON, ET AL., *Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project*, Addiction (2019); N. BERTONI, A. SZKLO, R.D. BONI, C. COUTINHO, M. VASCONCELLOS, P. NASCIMENTO SILVA, ET AL., *Electronic cigarettes and narghile users in Brazil: Do they differ from cigarettes smokers?*, Addict. Behav. (2019); Instituto Brasileiro de Geografia e Estatística, *Pesquisa Nacional de Saúde 2019: Percepção do estado de saúde, estilos de vida e doenças crônicas – Brasil, Grandes Regiões e Unidades da Federação*, IBGE Rio de Janeiro (2020); A. SZKLO, C. PEREZ, T. CAVALCANTE, L. ALMEIDA, L. CRAIG, S. KAAI, ET AL., *Increase of electronic cigarette use and awareness in Brazil: findings from a country that has strict regulatory requirements for electronic cigarette sales, import, and advertising*, Tob. Induc. Dis. (2018); H. DAI, A.M. LEVENTHAL, *Prevalence of e-cigarette use among adults in the United States, 2014-2018*, JAMA (2019).

[153] However, the two most recent nationally representative studies to address this issue found that between 2015 and 2019 the prevalence of ENDS use among individuals aged 15-65 years increased from 0.45% (about 0.7 million people) to 0.72% (about 1.1 million people). N. BERTONI, A. SZKLO, R.D. BONI, C. COUTINHO, M. VASCONCELLOS, P. NASCIMENTO SILVA, ET AL. (op. cit.); Instituto Brasileiro de Geografia e Estatística (op. cit.). The International Tobacco Control Policy Evaluation Project (ITC) conducted in three of the most populous Brazilian cities showed that the proportions of EC awareness and EC ever use increased between 2013 and 2017 both among smokers and non-smokers who came to know and acquired the products through the internet, outside country, and/or in popular markets. A. SZKLO, C. PEREZ, T. CAVALCANTE, L. ALMEIDA, L. CRAIG, S. KAAI, ET AL. (op. cit.). According to A. Hazard, a specialist in the e-cigarette market in Brazil, regulation of tobacco-alternative products would be beneficial in increasing consumer safety. He told ECigIntelligence: *If ANVISA is really technical and pragmatic, analyzing it based on science, it will notice that the ban is no longer effective because the market is already out of control*. Hazard, who is president of Direta, a new non-governmental organization focused on reducing harm from smoking, believes that legalizing e-cigarettes would bring an increase in tax collection as well as leading to a safer market. "*Consumers are going to avoid irregular commerce and have more control over what they are buying,*" he said. Public opinion A recent survey by Datafolha, a leading Brazilian research institute, found that 72% of the population had heard of e-cigarettes and that 3% of Brazilian over-18s used them daily or occasionally. However, 67% of respondents thought e-cigarettes should not be allowed in the country, while 11.5% thought their sale should be regulated. The survey was carried out among 1,985 adults. The illegal trade in vaping products is believed to have grown uncontrollably during the course of the ban. "*There is not a reliable survey to estimate this market, but it has certainly passed the BRL1bn ($180m) mark, including an exponential growth of illegal import of products from Paraguay*," said Hazard. Between 2018 and 2019, ANVISA issued 76 notices of violations involving advertising and sales of e-cigarette and heated tobacco devices. Statements available at ecigintelligence.com-End of the ban Brazil nearing a decision at last on regulation of e-cigarettes.pdf.

[154] Relatório Reservado, Souza Cruz pressiona Anvisa por tabaco eletrônico, (4/06/2019), available at https://relatorioreservado.com. br/noticias/souza-cruz-pressiona-anvisa-por-tabaco-eletronico/; WHO, *Heated tobacco products: information sheet - 2nd edition*, available at https://www.who.int/publications/i/item/WHO-HEP-HPR-2020.2; The Motley Fool, *Will "heat-not-burn" e-cigs kill off vaping? With a more cigarette-like experience, the next generation of electronic cigarettes could make vaping obsolete*, available at https://www. fool.com/investing/2017/01/24/will-heat-not-burn-e-cigs-killoff-vaping.aspx.

More specifically for what concerns e-cigarettes, in June 2019 ANVISA kicked off the discussion about revising e-cigarettes' restrictions (in force since 2009)[158] in the light of updated scientific studies and growing international experiences about e-cigarettes' use and their impact on tobacco-control outcomes[159]. All scientific and technical evidence presented during the public hearings is to be evaluated and consolidated and finally included in a *final broader regulatory impact assessment*. Additionally, the *social participation plan* was conceived to establish a further independent expert working group to review the existing literature on e-cigarettes[160]. The deadline for completion of the regulatory impact assessment and, therefore, for also delivering a final decision on a new resolution on e-cigarettes, was October-December 2021. Therefore, it was expected that the results would be available for assessment in this paper. Unfortunately, the workings are running late and at the time of writing has not yet been delivered. We are thus obliged to leave to future works the assessment of any potential novelty in the Brazilian e-

[155] Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, RDC 90/2007, *Dispõe sobre o registro de dados cadastrais dos produtos fumígenos derivados do tabaco*, avaialable at https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2007/ rdc0090_27_12_2007.pdf; Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, Consulta Pública N. 314 de 17/03/2017, available at http:// antigo.anvisa.gov.br/legislacao#/visualizar-etapa/343830.

[156] And heat-not-burn products derived from tobacco. Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, *Planilha de contribuições – análise*, available at http://antigo. anvisa.gov.br/documents/10181/61.282192821970/CP +314-2 017+-+Planilha+de+Contribui%C3%A7%C3%B5es+-+An%C 3%A1lise/6d931f81-83e8-427d-9711-0a0183bef3f8; Relatório Reservado, (op. cit.).

[157] Consulta Pública N. 314 (op. cit.).

[158] Ministéro de Saúde du Brasil, RDC 46/2009 (op. cit); Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, TEMA 11.3 – *Novos tipos de produtos fumígenos*, available at https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/ agenda-regulatoria/2017-2020/temas/tabaco/arquivos/11-3.pdf; Ministéro de Saúde du Brasil, Agência Nacional de Vigilância Sanitária, *Cigarro eletrônico* (05/10/2020), available at https://www.gov. br/anvisa/pt-br/assuntos/tabaco/cigarro-eletronico. In order to allow a broad participation of the actors involved in this regulatory discussion, a "social participation plan" was outlined by ANVISA and included two public hearings held in 2019. Ministéro de Saúde du Brasil. Agência Nacional de Vigilância Sanitária. *Cigarro eletrônico*. (05/10/2020), available at https://www.gov. br/anvisa/pt-br/assuntos/tabaco/cigarro-eletronico.

[159] M. SLEIMAN, J.M. LOGUE, V.N. MONTESINOS, M.L. RUSSELL, M.I. LITTER, L.A. GUNDEL, ET AL., *Emissions from electronic cigarettes: key parameters affecting the release of harmful chemicals* Environ Sci Technol (2016); R.B. JAIN, *Concentrations of cadmium, lead, and mercury in blood among US cigarettes, cigars, electronic cigarettes, and dual cigarette-e-cigarette users*, Environ Pollut (2019); Q. LIU, C. HUANG, X. CHRIS LE, *Arsenic species in electronic cigarettes: determination and potential health risk*, J Environ Sci China (2020); N.D. FRIED, J.D. GARDNER, *Heat-not-burn tobacco products: an emerging threat to cardiovascular health*. Am J Physiol Heart Circ Physiol (2020); R.J. WANG, S. BHADRIRAJU, S.A. GLANTZ, *E-cigarette use and adult cigarette smoking cessation: a meta-analysis*, Am J Public Health (2021); M.E. PIPER, T.B. BAKER, N.L. BENOWITZ, D.E. JORENBY, *Changes in use patterns over 1 year among smokers and dual users of combustible and electronic cigarettes*. Nicotine Tob Res (2020); J.N. KHOUJA, S.F. SUDDELL, S.E. PETERS, A.E. TAYLOR, M.R. MUNAFÒ, *Is e-cigarette use in non-smoking young adults associated with later smoking? A systematic review and meta-analysi,* Tob Control (2021); S.M. GAIHA, B. HALPERN-FELSHER, *Public health considerations for adolescent initiation of electronic cigarettes*, Pediatrics (2020); U.S. Department of Health and Human Services, *E-cigarette use among youth and young adults: a report of the Surgeon General. US Department of Health and Human Services, Centers for Disease Control and Prevention and Health Promotion, Office on Smoking and Health Atlanta*, (2016), available at https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.p; S. Soneji, J.L. BARRINGTON-TRIMIS, T.A. WILLS, A. M. LEVENTHAL, J.B. UNGER, L.A. GIBSON, ET AL., *Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: a systematic review and meta-analysis*, JAMA Pediatr (2017) 171.

[160] Ministéro de Saúde du Brasil, TEMA 11.3 (op. cit.).

cigarettes' regulatory landscape.

8. Considerations on the potential dangers of precaution

Legal recourse to the precautionary principle is problematic for the simple reason that it generally does not take into account the possibility that regulation of one risk will actually increase the occurrence of other risks[161]. Moreover, application of the precautionary principle raises three more reasons for concern: it is too vague, incoherent, and its application may forestall technical innovation.

First, the precautionary principle is *too vague* to effectively be a compass of good regulation. Indeed, as the appropriate amount of precaution derives from balancing several different interests, identifying the level of protection for precautionary purposes cannot avoid being influenced by consideration of *ad hoc* circumstances and – possibly – a high degree of political discretion, given the exceedingly discretionary nature of choosing the degree of (scientifically unprovable) risk that society can or cannot tolerate. It is also important to note that the legal evaluation of pre-emptive measurers based on the precautionary principle shifts the general rules on the burden of proof, thereby further undermining product innovation.

Consequently, application of the precautionary principle will ultimately depend very little on legal arguments and more on both the intended level of protection (mainly a political choice) and on the evaluation of the available scientific data. It is therefore fair to conclude that the precautionary principle's intrinsic vagueness makes its application an issue more of a *political* rather than *legal* nature[162].

Moreover, not only is the precautionary principle hopelessly vague, it is also *incoherent*. Indeed, precautionary steps create dangers of their won that almost always fail to be appreciated[163]. In particular, what often escapes consideration is that there are risks on all sides of social situations, and a comprehensive account of all these risks, makes application of the precautionary principle literally incoherent[164]. In some cases, regulation might well deprive society of significant benefits, and hence produce serious harm that would otherwise not occur. In some cases, regulation eliminates the "*opportunity benefits*" of a process or activity, and thus causes preventable deaths.

[161] *See*, G.E. MARCHANT AND K.L. MOSSMAN, *Arbitrary and Capricious: The Precautionary Principle in the European Courts,* Washington DC (2004), 52-54.

[162] For a detailed argument of the political use of the precautionary principle in European law, *see* G.A. FERRO, C. NICOLOSI, *Vaping and the Precautionary Principle*, in L. GRUSZCZYNSKI (edited by), *The regulation of e-cigarettes* (2019).

[163] C.R. SUNSTEIN, (op. cit):

[164] Worse yet, taken at face value, application of the precautionary principle may result to be paralyzing, as accounting for uncertainty -and risks for all sides- would forbid to take any potential step the precautionary principle requires, because each precautionary steps creates new risks of its own. Indeed, because risks are on all sides, the precautionary principle forbids action, inaction, and everything in between. Id., p. 4. If the principle argues against any action that carries a small risk of imposing significant harm, then we should be reluctant to spend a lot of money to reduce risks, simply because those expenditures themselves carry risks. Here is the sense in which the precautionary principle, taken for all it is worth, is paralyzing: it stands as an obstacle to regulation and non-regulation, and to everything in between. Id., p. 33.

If this is so, regulations turn out to be hardly precautionary. Sometimes, precautionary responses are likely to cause fear that outweighs any health benefit from other responses[165]. Regulation sometimes violates the precautionary principle because it gives rise to *substitute risks*, in the form of hazards that materialize or are increased as a result of regulation[166].

Finally, the precautionary principle's application *can forestall and undermine technical innovation* because the potential risks of new technologies and process are, by their very nature, unknown and are bound to remain so in the short and medium terms. Application of the precautionary principle could therefore, prevent new processes and invention to be disposable to society because of more-or-less supported uncertainty about its potential risks, and without taking into due account its potential benefits. The case of regulation of electronic cigarettes and related products (e.g., flavoring) provides a good example of all the dangers underling the precautionary principle's application.

Indeed, despite years of research, we still lack scientific certainty as to the extent of human-health risks (or their actual existence) resulting from use of e-cigarettes.

Indeed, the position that seems to be dominant in the current regulatory practice (including, Brazil) is to impose strict regulations because of the many uncertainties surrounding e-cigarettes use and the need to ensure a high level of human-health protection in the face of *potential risks*[167]. Indeed, the underlying assumption in many jurisdictions is that vaping is potentially just as harmful as regular smoking and that it might represent a gateway or *rite of passage* towards consumption of traditional cigarettes[168] and produce a *normalization effect* (that is, increase social acceptance for smoking as a result of the growing popularity of e-cigarettes). Fear of a gateway effect into smoking is also found in the FCTC[169].

Application of the precautionary principle in practice may lead to undesirable results. Indeed, human beings, cultures, and nations often single out one or a few social risks as "salient", and ignore the others. Especially if people lack statistical knowledge, they consider risks to be significant if they can easily think of instances in which those instances come to fruition.

To support regulation, it may be unreasonable to think it is enough that someone somewhere urges that a risk is worth taking seriously. But under the precautionary principle, the threshold burden is usually minimal, and once it is met, there is something like a presumption in favor of

[165] M. TUBIANA, *Radiation Risks in Perspective: Radiation-induced Cancer among Cancer Risks*, Radiat. Environ. Biophy. 3, 8-10.

[166] *See* the discussion of risk-risk tradeoffs in J. GRAHAM, J. WIENER, *Risks vs. Risks*, Harvard University Press, Cambridge MA (1995); C.R. SUNSTEIN, *Health-Health Tradeoffs*, in C.R. SUNSTEIN, *Risk and Reason*, Cambridge University Press, Cambridge (2002), 133-52.

[167] *See* for example, Southeast Asia Tobacco Control Alliance, *Statement on Singapore's ban on emerging tobacco products like e-cigarettes*, (31 January 2018) <https://seatca.org/?p=12027>

[168] *See* also art. 20.7 of the TPD, which requires member states to monitor market developments concerning e-cigarettes, in particular with respect to evidence relating to potential gateway effects.

[169] WHO Framework Convention on Tobacco Control, opened for signature 16 June 2003 (entered into force 27 February 2005) 2302 UNTS 166.

regulatory control. In this sense, the precautionary principle cannot provide any actual useful guidance, but only the illusion of guidance based on identifiable features of human cognition.

This paragraph aims at taking a step further in this direction by applying some results taken from behavioral economics and cognitive psychology[170]. The aim of the paragraph is to show how using precautionary principle -in all its vagueness- for regulatory purposes inevitably leads to focus on some aspects of the regulatory situation, while downplaying or disregarding others. The reasons are to be found in an understanding of behavioral economics and cognitive psychology, particularly five points: (1) availability heuristic; (2) probability neglect; (3) loss aversion and familiarity; (4) a (mythical) belief in the benevolence of nature; and (5) system neglect.

The rest of the paragraph borrows such five concepts from social sciences and, as well as the legal works of Prof. Sunstein[171] to apply them to the case of (legal) regulation of e-cigarettes.

8.1 The availability heuristic

The availability heuristic refers to the cognitive phenomena that make some risks seem especially likely to come to fruition whether or not they actually are. When people use the availability heuristic, they assess the magnitude of risks by resorting to examples that can readily come to mind[172]. If people can easily think of instances in which the risk did occur, they are far more likely to be frightened than if they cannot. The availability heuristics illuminates the operation of the precautionary principle by showing why some hazards are widely acknowledged while some others go neglected.

Indeed, the happenstance that smoking products be purposefully aimed at young adults has already occurred in the past with the use of so-called Joe Camel (officially, Old Joe) in cigarettes advertising. Joe Camel was the advertising mascot for Camel cigarettes from late 1987 to 1997, appearing in magazine advertisements, billboards, and other print media and alleged to be purposefully directed at children and youth because of its manly appearance[173].

Through the availability heuristic, the fact that youth targeting has already happened in the

[170] C.R. SUNSTEIN, *The Law of Fear* (op. cit.).

[171] *See* in particular, C.R. SUNSTEIN, *The laws of fear* (op. cit.).

[172] See A. TVERSKY, D. KAHNEMAN, *Judgement under Uncertainty*, in D. KAHNEMAN, P. SLOVIC, A. TVERSKY, *Judgement under Uncertainty: Heuristics and Biases*, Cambridge University Press, Cambridge (1982).

[173] Joe Camel lacked many typical camel traits, essentially appearing as a muscular humanoid with a camel's head. Feet were always to be covered, in footwear consistent with the rest of the outfit. The character also lacked a tail or hump. Advertising presented Joe Camel in a variety of "fun and entertaining, contemporary and fresh" situations, wearing "bold and bright" colors, blue and yellow where appropriate. His face remained the same in different advertising pieces, and images of his hands only used when necessary. In 1991, the *Journal of the American Medical Association* published a study showing that by age six nearly as many children could correctly respond that "Joe Camel" was associated with cigarettes as could respond that the Disney Channel logo was associated with Mickey Mouse, and alleged that the "Joe Camel" campaign was targeting children, despite the contention that the campaign had been researched only among adults and was directed only at the smokers of other brands. At that time, it was also estimated that 32.8% of all cigarettes sold illegally to underage buyers were Camels, up from less than 1%.

past does influence (i.e., increases) the perceived likelihood that the same phenomenon might be occurring again, this time using e-cigarettes.

Familiarity also affects the perceived riskiness. A risk that is familiar, like that associated with smoking, will be seen as more serious than risks that are less familiar. Salience (i.e., availability of images seen and able to be recollected) is relevant as well. The problem with the availability heuristic playing in the regulatory application of the precautionary principle is that it can lead to serious errors, in terms of both excessive fear and neglect. Sometimes a certain risk, said to call for precautions, is cognitively available, whereas others, including the risks associated with regulation itself are not[174].

8.2 Probability neglect

Probability neglect leads people to focus on the worst-case scenario even if it is highly unlikely. Indeed, people tend to attempt little or no assessment of probability at all when strong emotions are involved. And smoking -and associated dangers- does raise strong emotions that are easily conveyed to products considered "analogous", such as e-cigarettes. The actual issue of probability (*i.e.*, the far less harmfulness of e-cigarettes compared to traditional smoking) tends to be neglected altogether, as people focus on one emotionally-gripping outcome among a large set of possibilities. When an image of a bad outcome is easily accessible, people will become greatly concerned about a risk, holding probability constant.

In the case of regulation of e-cigarettes and related products, probability neglect manifests itself also in the form of excessive public concern with certain low-probability hazards, an example of which is the 2019 "EVALI" outbreak of lung injuries in the United States. EVALI, which was initially thought to be caused by the intrinsic danger of vaping, was instead caused by the addition of a cutting agent, Vitamin E Acetate, to illicit cannabinoid vape pens[175]. Only a small percentage of patients with EVALI reported vaping only nicotine, but they were primarily in states where tetrahydrocannabinol (THC) was illegal, and most had no toxicology testing[176].

Once the potential harm of vitamin E acetate was publicized and adulterated THC removed

[174] For tests on the effects of ease of imagery on perceived judgements of risk, *see* S.J. SHERMAN ET AL., *Imagining Can Heighten or Lower the Perceived Likelihood of Contracting a Disease: The Mediating Effect of Ease of Imagery*, in T. GILOVICH, D. GRIFFIN, D. KAHNEMAN (edited by), *Heuristics and Biases: The Psychology of Intuitive Judgement* 82, Cambridge University Press, Cambridge (2002).

[175] C. BATES, *The outbreak of lung injuries often known as "EVALI" was nothing to do with nicotine vaping*, Qeios (2021); V.P. KRISHNASAMY, B.D. HALLOWELL, J.Y. KO, ET AL., *Update: characteristics of a nationwide outbreak of e-cigarette, or vaping, product use-associated lung injury—United States, August 2019*, (2020); B.C. BLOUNT, M.P. KARWOWSKI, P.G. SHIELDS, ET AL., *Vitamin E acetate in bronchoalveolar-lavage fluid associated with EVALI*, N Engl J Med. (2020); T. MUTHUMALAGE, J.H. LUCAS, Q. WANG, T. LAMB, M.D. MCGRAW, I. RAHMAN, *Pulmonary toxicity and inflammatory response of e-cigarette vape car-tridges containing medium-chain triglycerides oil and vitamin E acetate: implications in the path-ogenesis of EVALI*, Toxics (2020).

[176] I. GHINAI, L. NAVON, J.K.L. GUNN, ET AL., *Characteristics of persons who report using only nicotine-containing products among interviewed patients with e-cigarette, or vaping, product use-associated lung injury—Illinois, August–December 2019*, MMWR Morb Mortal Wkly Rep. (2020).

from the US market by Federal drug enforcement raids, the incidence of new cases fell precipitously[177].

However, interestingly for the consequences of the proposed ban and for our discussion, the failure to rightly assess the cause of EVALI has led to adverse changes in relative risk perceptions[178] and restrictions on Juul-flavored products. Therefore, if at all in the context of e-cigarettes regulation, the EVALI outbreak is relevant to show the risk of Do-It-Yourself (DIY) products, which -ironically enough- HC's proposed flavor ban would increase[179], thereby possibly exposing users to increased levels of toxicity and other dangers[180].

Indeed, data show that *banning flavors became part of the problem, not the solution*.

Indeed, the restrictions on Juul-flavored products have led to a rise in Puff Bar products, which a recent analysis showed to be potentially more harmful than the Juul equivalents[181].

8.3 Loss aversion and familiarity

Economic scholarship has long shown that people are far more willing to tolerate familiar risks than unfamiliar ones, even if they are statistically equivalent[182]. In particular, loss aversion and familiarity make people dislike losses from the *status quo*, by making perceive loss from the *status quo* more undesirable than a gain is seen desirable[183]. The workings of loss aversion make application of the precautionary principle problematic when regulatory decisions fixate on potential losses while downplaying potential gains form the status quo, thereby overall increasing risks and decreasing wellbeing.

In the case of regulation of e-cigarettes, the working of loss aversion seems extremely problematic as the well-being of adult smokers (who like teens also enjoy e-cigarettes flavoring) and wannabe quitters (who vape flavors as a quitting tool to stop smoking) is not given due consideration.

Indeed, not only do adults consume non-tobacco flavors (including "kid-appealing" fruit

[177] V.P. KRISHNASAMY, B.D. HALLOWELL, J.Y. KO, ET AL., *Update: characteristics of a nationwide outbreak of e-cigarette, or vaping, product use-associated lung injury—United States, August 2019–January 2020*, MMWR Morb Mortal Wkly Rep. (2020).

[178] D. DAVE, D. DENCH, D. KENKEL, A. MATHIOS, H. WANG, *News that takes your breath away: risk perceptions during an outbreak of vaping-related lung injuries*, J Risk Uncertain (2020).

[179] A study estimates that up to 38.2% vapers would mix their own flavors if non-tobacco flavors were banned, P. DU, R. BASCOM, T. FAN, A. SINHAROY, J. YINGST, P. MONDAL, J. FOULDS, *Changes in flavour preference in a cohort of long-term electronic cigarette users*, Annals of the American Thoracic Society, (2020).

[180] As PHE has identified, adding food flavorings to liquids does present an unknown risk.

[181] E.E. OMAIYE, W. LUO, K.J. MCWHIRTER, J.F. PANKOW, P. TALBOT, *Flavour chemicals, synthetic coolants and pulegone in popular mint-flavoured and menthol-flavoured e-cigarettes*, Tob Control (2021).

[182] *See* P. SLOVIC, *The Perception of Risk* 140-43, London (2000).

[183] To see how loss aversion and the so-called *endowment effect* work, see R.H. THALER, *The Psychology of Choice and the Assumptions of Economics, in Quasi Rational Economics* 137, 143, New York (*arguing that losses loom larger than gains*); D. KAHNEMAN, J.L. KNETSCH, R.H. THALER, *Experimental Tests of Endowment Effect and Coase Theorem*, J. Pol. Econ. 1325, 1328 (1990); C. CAMERER, *Individual Decision Making*, in J.H. KAGEL, A.E. ROTH (edited by), *The Handbook of Experimental Economics* 587, 665-70, Princeton University Press, Princeton NJ (1995).

and candy) and sweeteners[184]; they are by far the largest market for these products, and flavors are integral to their vaping experience[185] (surveys show that adults like dessert, fruit, and candy flavors more than tobacco flavors[186]. Similarly, a large survey shows extensive and increasing use by adults of non-tobacco flavors in the United States[187]). Critically important, adults use non-tobacco flavors and sweeteners as an effective technique to quit smoking cigarettes[188], so flavor bans could have the harmful effect to reduce quitting smoking.

Even more so considering that adult smoking is a significant driver of health disparities[189]. Indeed, adult smokers in middle age or older constitute the sub-population at most immediate risk of serious diseases and premature death. They are the population that benefits most immediately and substantially from smoking cessation. Indeed, the use of e-cigarette flavors also predicts for adult smoking cessation[190] and use of fruit and other sweet flavored e-liquids is positively related to smokers' transition away from cigarettes[191]. Compelling evidence shows that the rise of Juul in the United States was very effective in helping adults to switch completely away from cigarettes[192].

Surely, youth vaping trends must be carefully monitored, with the goal of learning more about potential harms and identifying effective prevention strategies. However, the overarching focus on youth vaping loses sight of the potential of e-cigarettes to help adults quit smoking. That may come at a significant public health cost. Anything that can reduce the toll of morbidity and mortality from smoking deserves serious attention. When smokers believe that vaping is as dangerous as or more dangerous than smoking[193], many struggling to quit will be unwilling

[184] C. MEERNIK, H.M. BAKER, S.D. KOWITT, et al., *Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review*, BMJ Open (2019).

[185] S. GRAVELY, K.M. CUMMINGS, D. HAMMOND, ET AL., *The association of e-cigarette flavors with satisfaction, enjoyment, and trying to quit or stay abstinent from smoking among regular adult vapers from Canada and the United States: Findings from the 2018 ITC four country smoking and vaping survey*. Nicotine Tob Res (2021).

[186] C. RUSSELL, N. MCKEGANEY, T. DICKSON, M. NIDES, *Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA*, Harm Reduct J (2018). Moreover, one study found 68% of American adult e-cigarette users had used non-tobacco flavors in the past 30 days; of these, 45% had used fruit, 44% menthol or mint, and 26% candy, chocolate or other sweet flavors. M.G. BONHOMME, E. HOLDER-HAYES, B.K. AMBROSE, C. TWOREK, S.P. FEIRMAN, B.A. KING, ET AL., *Flavoured non-cigarette tobacco product use among US adults: 2013-2014*, Tob Control (2016).

[187] C. RUSSELL, N. MCKEGANEY, T. DICKSON, M. NIDES (op. cit).

[188] Sustained use of e-cig based on flavors does not appear to be statistically significant, KASZA ET AL., *E-Cigarette Flavors and Frequency of E-Cigarette Use among Adult Dual Users Who Attempt to Quit Cigarette Smoking in the United States: Longitudinal Findings from the PATH Study*, International journal of environmental research and public health (2021).

[189] At least in the United States, CDC, *Current cigarette smoking among adults in the United States and Tobacco-related disparities*.

[190] D.M. JONES, D.L. ASHLEY, S.R. WEAVER, M.P. ERIKSEN, *Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016-2017*, Tob Regul Sci (2019); Friedman AS, Xu S., *Associations of Flavored e-Cigarette Uptake with Subsequent Smoking Initiation and Cessation*, JAMA Netw Open (2020).

[191] L. LI, R. BORLAND, K.M. CUMMINGS, ET AL., *How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys*, Nicotine Tob Res (2021).

[192] S. PRAKASH, Y. XU, N.I. GOLDENSON, R. WISSMANN, R. GOUGELET, S. SHIFFMAN, *Transitions in smoking among adults newly purchasing the JUUL system*, Am J Health Behav (2021).

[193] National Cancer Institute. Health Information National Trends Survey. HINTS 5 cycle 3 (2019).

to try vaping as an alternative.

This invariably translates into less smoking cessation than if smokers correctly understood the relative risks of vaping and smoking.

Potential lifesaving benefits of e-cigarettes for adult smokers should not be less deserving of attention than youths[194] who will not experience smoking-related or possibly unproven vaping-related chronic diseases for three decades. Concurrently social pressures and public health campaigns to quit smoking will remain strong.

Finally, loss aversion contributes to neglect a growing body of evidence indicating that vaping can support smoking cessation. Randomized trials[195], and population studies report a near doubling of quit attempt success, and furthermore e-cigarettes are the most frequently used aid in quit attempts[196]. The totality of the evidence indicates that regular vaping increases the success rate for adult smoking cessation.

Smokers are 82% more likely to quit with e-cigarettes compared to nicotine replacement therapy[197]. Smokers unable to quit smoking with currently approved cessation methods[198] should be well informed about the relative risks of vaping compared to continued smoking and the efficacy of vaping to help them quit smoking. They should understand that completely substituting vaping for smoking reduces health risks, possibly substantially[199].

For quitting smoking, flavor vaping (in particular, switching from tobacco/menthol flavors to other flavors) increases the likelihood of successful quitting because non-tobacco flavors are *more* effective for cessation success[200]. Studies show that smokers who use non-tobacco flavored vape are more than twice as likely to quit as those who stay with tobacco flavors. A ban on flavors would force adults to switch back to tobacco flavors[201], decreasing their success at quitting cigarettes, and possibly acting as a trigger for cigarette use.

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[194] T.J. MILLER, *The harm-reduction quandary of reducing adult smoking while dissuading youth initiation*, Am J Public Health (2020).

[195] J. HARTMANN-BOYCE, H. MCROBBIE, N. LINDSON, ET AL., *Electronic cigarettes for smoking cessation*, Cochrane Database Syst Rev. (2020); A. MCNEILL, L.S. BROSE, R. CALDER, E. SIMONAVICIUS, D. ROBSON, *Vaping in England: An Evidence Update Including Vaping for Smoking Cessation*, 2021; *A Report Commissioned by Public Health England*, Public Health England (2021).

[196] R.S. CARABALLO, P.R. SHAFER, D. PATEL, K.C. DAVIS, T.A. MCAFEE, *Quit methods used by US adult cigarette smokers, 2014–2016*, Prev Chronic Dis. (2017).

[197] Impartial bodies such as the Cochrane Collaboration endorse vaping as a way to quit smoking. Conventional smoking cessation therapy has barely changed in the last 20 years, and has left 4.6 million Canadians, 15% of the population, still smoking.

[198] US Department of Health and Human Services, *Smoking Cessation: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion*, Office on Smoking and Health (2020).

[199] National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes*, The National Academies Press (2018).

[200] O'LEARY E AL., *Critical appraisal of the European Union Scientifc Committee on Health, Environmental and Emerging Risks (SCHEER) Preliminary Opinion on electronic cigarettes*, Harm reduction journal (2021).

[201] *See e.g.*, *Please, Health Canada, do not make vapers return to tobacco!*, J. Oyston (2021).

For those using flavored e-cigarettes as a quitting tool, precautionary measures risk to substantially increase reversion to smoking cigarettes. Indeed, Health England states that following a flavor ban, adults and teens will stop vaping and revert to cigarette smoking. This is consistent with other studies, which find: (i) that restrictions on minors' access to e-cigarettes are associated with higher adolescent cigarette smoking[202]; (ii) a considerable switching effect towards smoking cigarettes following a flavor ban; as people -faced with lack of their preferred product- do choose to revert to a (more harmful) habit. Indeed, in one of the most recent surveys, 33.2% of adult vapers said they would go back to smoking if all vape flavors except tobacco were banned[203]; (iii) that making e-cigarettes less attractive to adolescents (e.g., by tax increases on adolescents) has the effect of increasing cigarette use[204]; (iv) that initial data on the impact of the flavor ban in San Francisco resulted in a statistically significant increase in cigarette smoking among young adults from 27.5% to 37.1%, and this increase *was not* replicated in districts without a flavor ban[205].

A potential health benefit (that however the precautionary principle let go unremarked) is achieved whenever flavored e-cigarettes contribute to smoking cessation, or offer a substitute for smoking, or reduce smoking to low levels, or prevent initiation of use of combustible products[206]. These benefits accrue to both adults and youth.

8.4 A (mythical) belief in the benevolence of nature

The belief in the benevolence of nature makes men-made decisions and processes seem especially suspect. Indeed, studies show that people overestimate the carcinogenic risks from pesticides while underestimating the risks of natural carcinogens[207].

Especially relevant for the case of regulation of e-cigarettes and related products, the belief in the benevolence of nature plays a major role in the operation of the precautionary principle especially for products and process that involve new technologies, such as e-cigarettes or appear too "artificial" (as in the case of sweet flavorings). Human intervention in the process of smoking is tainted by the biases towards all new technologies deriving from the belief in the benevolence of nature, as well as from the specific biases attaching to smoking itself, considered more as a despicable habit rather than a painful addiction.

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[202] A.S. FRIEDMAN, *How does electronic cigarette access affect adolescent smoking?*, J Health Econ. (2015); Pesko MF, Hughes JM, Faisal FS., *The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use*, Prev Med. (2016).

[203] POSNER ET AL., *Reactions to sales restrictions on flavored vape products or all vape products among young adults in the US*, Nicotine & Tabacco research (2021).

[204] M.F. PESKO, C. WARMAN, *The Effect of Prices on Youth Cigarette and E-Cigarette Use: Economic Substitutes or Complements?*, SSRN Electron J. (2017).

[205] A.S. FRIEDMAN, *A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California*, JAMA Pediatr. (2021).

[206] L.T. KOZLOWSKI, K.E. WARNER, *Adolescents and e-cigarettes: Objects of concern may appear larger than they are*, Drug Alcohol Depend. (2017); p. 174.

[207] *See* P. SLOVIC, *The Perception of Risk* 291, (op. cit.).

8.5 System/Tradeoff neglect

Finally, system/tradeoff neglect refers to the inability to see that risks are part of systems, and that interventions into those systems can create risks of their own[208]. Much of the time, people neglect the systemic effect of one-shot interventions. They tend to assume that a change in a social situation would alter the part at issue without affecting other parts. System neglect can derive in the inability to give due consideration to the above-mentioned risks of resorting to DIY product and driving e-cigarettes users (back) to smoking, as well as other "less visible" social and economic risks, such as the resort to the black market[209].

This possibility -however generally neglected- is consistent with the data. According to Public Health England a flavor ban would drive users to the black market and one study estimates that 30% of e-cigarette users would go to the illegal market due to a flavor ban[210]. Another study finds that 19.2% of users would "find a way to buy" following a flavor ban[211].

Precaution cannot be taken against *all* risks, not just because resources are limited, but also because efforts to redress any set of risks might produce other risks of their own. To the extent that the precautionary principle offers guidance, it is often because adverse systemic effects are simply being neglected[212]. The precautionary principle often seems helpful because analysts are focusing on the "target" risk, rather than on the systemic, risk-related effects of being precautionary, or even on the risk-related consequences of risk reduction.

9. Conclusions

[208] C.R. SUNSTEIN, *Laws of Fear*, p. 35 (op. cit.).

[209] Without non-tobacco flavors, widespread use of tobacco products will continue. Indeed, youth have been willing to use products with tobacco flavor over many decades. The underlying drivers of tobacco and nicotine use are stronger and deeper than the recent availability of non-tobacco flavors in e-liquids. Therefore, any restrictions on flavored products may cause unintended consequences, such as a surge in black-market products. The persistence of illicit drug use is a reminder that outlawing something does not make it go away; it mainly changes how it is supplied, meaning it could foster the further development of the black-market supply chain. The RIAS does not include any evaluation of the likely supply-side response to a vaping flavor ban. It has been estimated that a federal flavor ban in the United Stated would generate a black-market worth over $US 12 billion. It is likely that existing illicit suppliers and informal social supply networks may add flavor vaping to their range of drugs. The result would be an increase in illegal actors having contact with youth with the risk of introducing youth to a wider range of illicit and dangerous substances and behaviors. R. COOMBER, L. MOYLE, N. SOUTH, *The normalisation of drug supply: The social supply of drugs as the "other side" of the history of normalisation*, Drugs Educ Prev Policy (2016).

[210] FREITAS-LEMOS ET AL., *The Illegal Experimental Tobacco Marketplace I: Effects of Vaping Product Bans*, Nicotine & Tobacco Research (2021), pp. 1-10. According to the study, 30% of e-cigarette users would go resort to the illegal market in response to a flavor ban.

[211] P. DU, R. BASCOM, T. FAN, A. SINHAROY, J. YINGST, P. MONDAL, J. FOULDS, *Changes in flavour preference in a cohort of long-term electronic cigarette users*, Annals of the American Thoracic Society, (2020).

[212] *See* H. Margolis for his studies on risk judgements and cognitive foundations for the precautionary principle and to cast light some apparent anomalies in ordinary thinking about risks. Margolis suggests that people are sometimes subject to a kind of optical illusion, in which they focus on the harms associated with some activity or process, but fail to see the benefits. They will tend to think *better safe than sorry*, otherwise they will grasp both harms and benefits and engage in the kind of tradeoff analysis. See H. MARGOLIS, *Dealing with Risk*, Chicago University Press, Chicago (1996).

E-cigarettes are a relatively new product that might not only disrupt the tobacco market as we know it, through the redefinition of the smoking experience; it also may accrue enormous health benefits to those deciding to vape instead of smoking. However, regulations around the world are somewhat failing to acknowledge e-cigarettes' novelty and peculiarities and, for the most are treating (and taxing and restricting access to,…) them just like traditional cigarettes.

This paper aims at providing a comparative study of e-cigarettes' regulation, focusing on two study countries: the UK and Brazil. These countries indeed, lie at the opposite of possible regulatory choices, and thus are good for comparison, albeit so different. The paper also provides a legal analysis of the two legal principles at the foundation of e-cigarettes' regulation: the principle of harm reduction on the one hand, and the precautionary principle on the other.

Before concluding, the paper drawn a critical analysis of the precautionary principle. borrowing from social sciences, as well as renowned legal works, the paper argues that the precautionary principle might not turn out to be the best operative principle inspiring e-cigarettes' regulation. Beyond the legal reasoning, we find it important to understand how other forces (e.g., psychological) affect the actual application of the legal principles.

E-cigarettes provide huge (potential?) gains in terms of public health and governments perhaps ought to be less *precautious* of the potential harm and more *cautious* of the actual benefit they forgo.