Regulations Are a Drag: The WHO Framework Convention on Tobacco Control and Its Potential Application to Electronic Cigarettes

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Kevin Oliver

Abstract

The Framework Convention on Tobacco Control (FCTC) aims to protect present and future generations from the consequences of tobacco consumption and exposure to tobacco smoke. While the treaty has enjoyed widespread adherence, the rise in popularity of electronic cigarettes presents new questions about its scope. These relatively new products do not contain any tobacco and are thus not a major focus of the FCTC. This Comment examines provisions of the FCTC that may authorize its possible application to e-cigarettes and concludes that the treaty has the power to regulate them if scientific consensus suggests that such regulation would be “effective.”

The scientific community is divided on the issue of e-cigarette regulation. Scholars and policymakers have sometimes invoked the precautionary principle (essentially, a “better safe than sorry” philosophy) to justify international regulation in the face of scientific uncertainty. This Comment addresses the precautionary principle’s lack of utility in the e-cigarette context and ultimately recommends against additional regulation under the FCTC. The current scholarship has not addressed the applicability of the FCTC to e-cigarettes, so this Comment sheds light on a potentially powerful international instrument for the regulation of a relatively new, popular, and possibly dangerous product.
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I. INTRODUCTION

In the past decade, Electronic Nicotine Delivery Systems (ENDS), or e-cigarettes, have rapidly gained popularity worldwide, presenting unique challenges to both domestic and international regulatory bodies. Although these battery-powered products do not contain tobacco, they deliver vaporized nicotine to a user's lungs, creating familiar concerns about addiction. E-cigarettes are frequently marketed as a healthier alternative to traditional tobacco products, but the scientific community has yet to reach many firm conclusions on the actual long-term health effects of these relatively new devices. Different countries and local governmental bodies currently employ varying legislative approaches to e-cigarettes, ranging from no regulation at all to outright bans on advertising and flavored e-cigarettes.

Traditional tobacco products are the most useful analogue for analyzing the legal status of e-cigarettes, as the latter were specifically designed to replace the former. Unlike e-cigarettes, traditional tobacco products fall under an extensive body of international guidelines and directives for controlling consumption. The most significant source of these is the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC). The FCTC, which came into force in 2005, is the first international health treaty. It aims “to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.” As defined in the treaty, “tobacco products”

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2 See id. at 447.
7 Id. art. 3.
include “products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.”

This definition leaves unanswered the question whether e-cigarettes may be classified as a tobacco product, as they contain only nicotine derived from tobacco, not tobacco itself. The answer to this question may have a significant effect on the overall effectiveness of the FCTC, insofar as e-cigarettes are used as a substitute for traditional tobacco products. Laws regulating the use, marketing, and sale of e-cigarettes could influence future trends in smoking, and if the FCTC is a legitimate source of e-cigarette regulation, it may shape the behavioral patterns of users and would-be users of both traditional tobacco products and e-cigarettes.

Separate from the inquiry of whether the principles and obligations of the FCTC can apply to e-cigarettes are the questions of whether and how they should apply. The complexity of these problems is illustrated by the myriad approaches different governments have taken, and the lack of a scientific consensus on the health effects of e-cigarette consumption. If the FCTC is in fact a legitimate source of authority for creating e-cigarette policy, it could become a useful unifying international mechanism for achieving its largely uncontroversial public health goals. But whether the treaty’s text justifies such authority depends on whether the FCTC can realistically compel the implementation of “effective legislative, executive, administrative and/or other measures” to protect smokers and indirect victims of tobacco-related harms. The controversy that arises in determining what constitutes an “effective” measure may render fruitless the attempts to rely on the FCTC for e-cigarette regulation (or any other type of regulation, for that matter).

In spite of the enforceability questions that are ubiquitous in international law and which appear to be particularly prevalent in the realm of e-cigarette regulation, the governing body of the FCTC has undertaken efforts to shape e-cigarette policies. The most recent Conference of the Parties (COP) ENDS Report recommends “a two-pronged regulatory strategy—regulating ENDS as both a tobacco product, in accordance with the provisions of the WHO FCTC,

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8 Id. art. 1.

9 See Daniela Saitta et al., Achieving appropriate regulations for electronic cigarettes, 5 THER. ADV. CHRONIC DIS. 50, 52 (2014), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3926346/ (“Rulings of national and international bodies around the world range from no regulation at all to complete bans.”) (citation omitted); Michael Freiberg, Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products, 21 ANNALS HEALTH L. 407, 436 (2012) (“[T]he health effects of nicotine-infused water vapor being expelled into the air are poorly understood at best . . . .”).

10 FCTC, supra note 6, art. 8 (emphasis added).
and as a medical product."\footnote{11} Whether the international community will embrace such an approach remains to be seen, but if the COP takes a firmer stance and announces that the FCTC requires this type of regulation, the treaty’s signatories may be bound.

This Comment will assess the current international state of e-cigarette regulation and the potential of the FCTC to further shape such regulation. While it appears that the FCTC’s obligations are binding on signatory states,\footnote{12} the correct use of this power is not to equate e-cigarettes with traditional tobacco products. This Comment argues that it would be more consistent with the WHO’s aims to prohibit many proposed legislative measures to restrict e-cigarette usage, and that the best alternative, given likely political resistance, is to take no action at all.

Section II of the Comment will introduce key components of the FCTC and how they may be relevant to the debate over the treaty’s application to e-cigarettes. This section also examines the high rate of compliance with the Convention, demonstrating its binding nature and potential to meaningfully affect e-cigarette regulation worldwide. Section III provides an overview of current e-cigarette regulation internationally, examining sources of confusion as to the most effective regulation and the continuing need for guidance. Section IV more specifically describes the WHO’s attempts to regulate e-cigarettes up to this point, as well as the textual basis for holding that such regulation is legally viable. Section V examines the scientific and scholarly debate surrounding e-cigarette regulation to determine whether such regulation can be considered “effective” under the terms of the FCTC. This section will also discuss the precautionary principle, a “[b]etter safe than sorry” adage often employed to support regulation of potentially harmful practices in the absence of clear


\footnote{12} See, for example, Sam F. Halabi, The World Health Organization’s Framework Convention on Tobacco Control: An Analysis of Guidelines Adopted by the Conference of the Parties, 39 GA. J. INT’L & COMP. L. 121, 127 (2010) (concluding that parties to the FCTC “are under an obligation to implement treaty provisions in light of the guidelines”); Jiyong Jin, FCTC and China’s Politics of Tobacco Control, The 4th GLF Annual Colloquium, Princeton University, at 6 (May 15, 2012), available at http://www.princeton.edu/~pglobal/conferences/GLF/jin.pdf (“On 27 February, 2005, the treaty came into force and became a binding international law after Peru became the 40th country that had ratified the FCTC.”); Workshop on Trade and Investment Issues Relevant to the WHO Framework Convention on Tobacco Control, Background Paper, at 3 (Mar. 27, 2014), available at http://www.who.int/fctc/2014_PM_WHO_FCTC_wshop_backgroundpaper.pdf?ua=1 (“Parties to the WHO FCTC undertake, under international law, to implement a number of complementary, mutually reinforcing measures for both reduction of demand for, and supply of, tobacco products. As a treaty with 178 Parties, the WHO FCTC is a powerful instrument, both legally and politically.”).
evidence of harm.\textsuperscript{13} Counterintuitively, in the case of e-cigarettes, the low-risk option appears to be a strong stance \textit{against} regulation.

\section*{II. The Framework Convention on Tobacco Control}

The FCTC has been ratified by 168 countries, which have effectively agreed “to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.”\textsuperscript{14} The treaty identifies itself as “evidence-based,”\textsuperscript{15} suggesting that the obligations ratification entails will change as research related to tobacco control reveals new findings. This idea is reaffirmed in the Convention’s preamble, which states that the FCTC’s parties are “[d]etermined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations.”\textsuperscript{16} Therefore, the practical elements of the treaty will necessarily evolve alongside scientific progress in the field of tobacco control.

\subsection*{A. Key Provisions}

Including its Introduction, the treaty consists of twelve parts, several of which contain articles that may be relevant to the Convention’s competence to regulate e-cigarettes.

Article 5 of the FCTC lays out the general obligations that the treaty imposes on members: “Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.”\textsuperscript{17} While no reading of this clause hints at the treaty’s applicability to e-cigarettes, the clause is significant in illustrating the binding nature of the Convention’s terms on its members. The use of the word “shall,” as opposed to a more permissive term, indicates that the instructions of this article are mandates, not mere suggestions.\textsuperscript{18} The labeling of this article’s contents as “obligations” as opposed to a more permissive term such as “Guiding Principles”\textsuperscript{19} further demonstrates that members of the treaty are not

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\textsuperscript{14} FCTC, supra note 6, art. 3.

\textsuperscript{15} Id. fwd.

\textsuperscript{16} Id. pmbl.

\textsuperscript{17} Id. art. 5.

\textsuperscript{18} See, for example, Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 35 (1998) (“[T]he mandatory ‘shall’ . . . normally creates an obligation impervious to judicial discretion.”).

\textsuperscript{19} FCTC, supra note 6, art. 4.
\end{tiny}
afforded discretion to ignore these directions.\textsuperscript{20} The language of Article 5 in particular should make the expectations of membership clear to signatories, hopefully alleviating concerns about the weakness of the FCTC as a binding legal mechanism.

Article 8 directly addresses the impetus for the creation of the FCTC: the harms of exposure to tobacco smoke. This article requires parties to “adopt and implement... effective legislative, executive, administrative and/or other measures ... providing for protection from exposure to tobacco smoke.”\textsuperscript{21} This Comment discusses the extent to which the specific reference to “tobacco smoke” limits the scope of the article, and the meaning of the word “effective,” in Section IV.

Article 11 is a third significant portion of the FCTC because it calls for perhaps the most controversial category of measures contemplated by the Convention: restrictions on the packaging and labeling of tobacco products.\textsuperscript{22} This article is illustrative of the controversy surrounding the legitimacy of the FCTC as a binding authority, as packaging and labeling laws have given rise to legal challenges by the tobacco industry worldwide.\textsuperscript{23} Article 11 also calls for

\begin{flushleft}
\textsuperscript{20} See ANTHONY AUST, MODERN TREATY LAW AND PRACTICE 30 (3d ed. 2013) (“[M]ost states now follow a practice of manifesting their intention to conclude a treaty by consciously employing a fairly standard form, and mandatory terminology such as . . . ‘shall’, ‘agree’, ‘undertake’, ‘rights’, ‘obligations’ and ‘enter into force.’”).
\textsuperscript{21} FCTC, supra note 6, art. 8.2.
\textsuperscript{22} See id. art. 11.
\textsuperscript{23} There appears to be particularly strong resistance in Latin America. See InterAmerican Heart Foundation, Framework Convention on Tobacco Control: Challenges for Latin America and the Caribbean, Civil Society Report 2010, available at http://www.ficargentina.org/images/stories/Documentos/reportecmct_ingles_1.pdf. Philip Morris has challenged the constitutionality of Uruguay’s warning requirements, arguing that the requirements devalue the cigarette company’s trademarks and investments in Uruguay. Philip Morris Products S.A. v. Oriental Government of Uruguay, ARB/10/7, I.C.S.I.D. (2010). A similar suit has been filed in Paraguay, and several other ratifying members of the FCTC have delayed implementation of the package warning requirements. See InterAmerican Heart Foundation, supra.

There is no lack of private opposition to packaging laws outside of Latin America either. Philip Morris launched a lawsuit against Australia after the Government passed its 2011 Tobacco Plain Packaging Bill in accordance with FCTC guidelines. Philip Morris Asia Limited v. Commonwealth of Australia, UNCITRAL, PCA Case No. 2012–12 (2012). Likewise, though the EU has decided to implement plain packaging laws pursuant to the FCTC, there remains a “legal war of the tobacco manufacturers, who will be using all available instruments such as lobbying, investment claims and aggressive advertisement campaigns to undermine plain packaging.” Peter K. Henning & Leonid Shmatenko, Plain Packaging on Its Way to Europe: Competence Issues and Compatibility with European Fundamental Rights, 9 TRANSNAT’L DISPUTE MGMT. 1, 12 (2012). In favor of the FCTC, however, is the fact that most of the challenges to Article 11’s demands come from the tobacco industry, whereas governmental action has largely been consistent with the treaty.
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“effective” measures regarding packaging and labeling.\textsuperscript{24} If packaging and labeling requirements have no effect on tobacco consumption, then the fact that the FCTC enjoys general support from governments is meaningless. If the requirements have an undesirable impact on tobacco consumption, then Article 11 may actually call for packaging policies that specifically elevate the perception of e-cigarettes above that of traditional tobacco products, a possibility that is discussed in Section V.

Article 12 addresses the education, communication, training, and public awareness of tobacco control issues.\textsuperscript{25} While this article does not appear to be directly related to any issues of the treaty’s legitimacy or to e-cigarette regulation, it may actually be relevant to discussion of the latter topic. One of the major concerns surrounding the increasing use of e-cigarettes, particularly by teenagers, is that their consumption will renormalize smoking.\textsuperscript{26} If there is evidence that e-cigarettes actually do have this normalization effect, then the FCTC’s text may justify policies aimed at educating the public about the dangers of e-cigarettes as a gateway to tobacco use.

Article 13 states that “[e]ach Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion, and sponsorship.”\textsuperscript{27} The text of this article does not render Article 11 superfluous. The packaging and labeling obligations refer to warning requirements and what tobacco sellers must do, whereas Article 13 expresses what they cannot do. The FCTC defines “tobacco advertising and promotion” as “any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly.”\textsuperscript{28} A “comprehensive ban” may therefore seem extensive, but the “in accordance with its constitution or constitutional principles” clause of Article 13 hedges this requirement. This clause shows that national law can override at least some provisions of the

\textsuperscript{24} FCTC, supra note 6, art. 11.1.\textsuperscript{25} See id. art. 12.\textsuperscript{26} See, for example, E-cigarettes – An update, CPHA HEALTH DIGEST, Spring 2014, available at http://www.cpha.ca/en/about/digest/38-1/8.aspx (“[A]dvocates against the sale of e-cigarettes remain adamant that the product threatens to re-normalize smoking, especially in youth, and use of e-cigarettes risks undoing years of smoking cessation gains.”); World Lung Foundation, \textit{WHO Right to Call for E-Cigarette Regulation} (Aug. 26, 2014), available at http://www.worldlungfoundation.org/ht/display/ReleaseDetails/i/32757/pid/6858 (“Public health experts also are concerned that e-cigarettes will undo decades of progress in public health by re-normalizing smoking in public and act as a gateway to cigarette use among youth.”).\textsuperscript{27} FCTC, supra note 6, art. 13.2.\textsuperscript{28} Id. art. 1(c).
FCTC. However, the concept of expressio unius est exclusio alterius works to maintain a higher level of power in the FCTC. The explicit carve-out for constitutional laws and principles implies that the demands of Article 13 preempt statutes, agency regulations, executive orders, local laws and the like. Additionally, Article 13 includes specific requirements for countries that are "not in a position to undertake a comprehensive ban due to [their] constitution or constitutional principles." Thus, the constitutional "exceptions" to FCTC obligations are narrow and do little to undermine the Convention's authority.

Article 14 demands measures concerning the reduction of tobacco dependence and cessation: "Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence." This article could provide the clearest textual support for using the FCTC as the basis for e-cigarette policy, depending on scientific assessment of the effect of e-cigarettes on tobacco consumption.

Article 15, which addresses illicit trade in tobacco products, does not directly relate to the topics at issue in this Comment. However, this article is highly relevant to the discussion of the FCTC's binding power over its members because it became the focus of the FCTC's first protocol, which was adopted on November 12, 2012. While the mandatory or suggestive nature of some of the FCTC's directions is questionable, the protocols later added to the Convention are unquestionably binding on their parties. Therefore, even if the FCTC currently carries limited weight as a regulatory instrument, a future protocol on e-cigarettes could conceivably strengthen its ability to shape policy.

Article 21 requires each party to "submit to the Conference of the Parties... periodic reports on its implementation of this Convention."

29 A canon of construction holding that to express or include one thing implies the exclusion of the other, or of the alternative. BLACK'S LAW DICTIONARY (10th ed. 2014).
30 FCTC, supra note 6, art. 13.3.
31 Id. art. 14.1.
32 See id. art. 15.
34 See FCTC, supra note 6, art. 33.5 ("Any protocol to the Convention shall be binding only on the parties to the protocol in question."); see also Lukasz Gruszczynski, The WHO Protocol to Eliminate Illicit Trade in Tobacco Products: A Next Step in International Control of Tobacco Products, 4 EUR. J. RISK REG. 91, 91 (2013) ("Contrary to guidelines, a protocol is binding on the Parties which accept it and has an equal legal status to the Convention.").
35 FCTC, supra note 6, art. 21.
this is unrelated to e-cigarettes, Article 21 reaffirms the authority and enforceability of the FCTC by providing a vehicle to monitor compliance with the treaty. The effectiveness of this vehicle, and the rate of compliance more generally, are discussed later in this section.

Finally, Article 22 mandates cooperation in the scientific, technical, and legal fields and provision of related expertise.\(^6\) If the scientific community comes out strongly in support of a certain policy on e-cigarettes, Article 22 may be read to demand a policy response. This article’s influence depends on ongoing collaboration between member states, as it “is fundamentally about knowledge transfer and capacity building within the network of FCTC parties.”\(^3\) Such collaboration, along with a growing body of evidence on the effects of e-cigarettes, may make Article 22 a powerful tool for encouraging expansive FCTC regulation.

B. The Force of the FCTC

Questions of legitimacy and enforceability are pervasive throughout international law, and the FCTC is not immune to these concerns. The treaty includes a set of guidelines and obligations, which are essentially binding, but in light of the inability to override constitutional law and the general weaknesses of international authority, it is fair to challenge the idea that countries can be held accountable for complying with the Convention’s instructions. An examination of different countries’ behaviors in response to the FCTC shows inconsistency in compliance with certain explicit obligations, but suggests that the treaty exerts a fairly heavy influence on its members.

This subsection addresses three conceptions of the overall strength of the FCTC and whether it can practically bind its signatories. Some argue that the Convention has no binding force at all. Others contend that future protocols can overcome the weakness of the FCTC as originally drafted. A third category of scholars is convinced that the text of the treaty itself is enough to establish its binding authority. The most realistic assessment is that the success of the treaty as binding authority hangs in the balance and depends on its interaction with other existing international authorities. This Comment will address each of these appraisals in turn.

1. The FCTC as a hollow document.

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\(^{36}\) See id. art. 22.


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Some scholars have read the provisions of the FCTC as “fundamentally hortatory,”38 leaving signatories the option simply to disregard the Convention and sculpt tobacco control policy at their discretion. Though the language of the FCTC often takes on a mandatory form, critics argue that “[g]iven the degree to which individual state’s laws are given deference in the document . . . it is relatively easy for a state to ignore the FCTC’s most strongly worded provisions by simply invoking the trump card of national law.”39 This contention is at odds with the language of Article 13.40 The explicit text appears to defer only to constitutions and constitutional principles, though these are vague terms, and pushback against the idea of a strong international health treaty is reasonable given the widespread skepticism surrounding the utility of international law. This skepticism may be exacerbated by the FCTC’s mixture of specific and general instructions, rather than a hard set of binding directives.41

At the very least, this pessimistic view about the prospect of the FCTC as an authoritative instrument for regulatory purposes deserves some credence based on the historical reasoning behind the treaty. The Convention “was designed as a compromise solution between a purely recommendatory instrument and a binding convention, so as to engage countries in an ‘incremental and flexible normative exercise’ in a novel area.”42 The concept of instructions that are stronger than recommendations—but not truly binding—can be confusing and leaves doubt as to whether the FCTC should be the driving force behind legislative action.

2. Eventual protocols as effective supplements to the current Convention.

It is clear that “the FCTC include[s] both advisory and obligatory language.”43 Thus, even if the international community views the treaty as a binding agreement, there is leeway for shirking some of its less straightforward demands. Article 33 allows for additional protocols to the treaty, which are inarguably binding on the parties that join them.44 The structure of the FCTC

39 Id. at 782 n.155.
40 See text accompanying supra notes 27–30.
41 See Valentina S. Vadi, Global Health Governance at a Crossroads: Trademark Protection v. Tobacco Control in International Investment Law, 48 STAN. J. INT’L L. 93, 102 (2012) (“[A]s the provisions of the FCTC present both general and specific elements, arbitrators may question the weight of its nonetheless binding provisions.”).
42 Halabi, supra note 12, at 124.
43 Id. at 183.
44 See FCTC, supra note 6, art. 33.
may in fact necessitate the supplementary force of protocols to effectively operate at all. Protocols can add useful specificity to an instrument that otherwise contains a substantial amount of general language. Indeed, it appears that the text of the framework alone was always intended to be merely the first step in a more robust regulatory system.

This heavy reliance on protocols is troubling, given the lack of a timetable for their addition to the framework. The creation of protocols is a permissive power granted by the FCTC, not a required development—Article 33 states that “[a]ny Party may propose protocols.” There is no guarantee that protocols will be proposed, and the treaty contains no mechanism to ensure that their strategic development will actually occur. In fact, the provisions of Article 33 make it somewhat difficult to adopt a protocol. The COP must first undertake “every effort . . . to reach consensus,” and “as a last resort” may adopt a protocol by a three-quarters majority vote. Even then, it appears that becoming a party to a protocol is optional, and protocols bind only “parties to the protocol in question.” The difficulty of effecting protocols helps to explain the fact that only one such protocol, the Protocol to Eliminate Illicit Trade in Tobacco Products, has been adopted since the ratification of the FCTC. Even this protocol has not yet entered into force. Thus, if the argument that protocols will be the driving force behind the FCTC’s effectiveness is correct, the COP’s limited progress in adopting such protocols in the nine years since the Convention took effect is highly discouraging.

3. The FCTC as legally binding.

Fortunately for those who view the FCTC as a potential source of meaningful regulatory authority, there is an abundance of evidence and scholarship suggesting that the Convention effectively binds its members.
Widespread reliance on the Convention supports reading it as a legitimate binding instrument. Countries “have massively adhered to the [FCTC], which has established a ‘cognitive and normative consensus’ for promoting global public health through tobacco control.” Scholars have recommended that the FCTC “must play a role in the future directions of U.S. policy.” Some have even argued that the Convention’s guidelines, not merely its clearly mandatory obligations, constitute “hard” rather than “soft” international law.

These observations, of course, have to be balanced against the legitimate concerns raised by the two less optimistic readings of the FCTC. Realistically, the FCTC cannot be effectively examined in a vacuum. Like all international law, the treaty constantly interacts with domestic law and policy, as well as other international sources of regulation addressing overlapping material. Before the treaty was finalized, at least one commentator aptly noted that “the FCTC’s success depends on its ability to stand on its own as binding international law among other binding international laws.” The treaty’s perceived success over the near-decade since its entry into force may demonstrate its binding potential. Such an inference would be even stronger if it were based on widespread examples of adherence to the Convention. The next subsection explores this evidence.

C. Levels of Compliance with FCTC Obligations

Several organizations have undertaken efforts to monitor compliance with the FCTC. The Convention supplies a useful instrument for such supervision: Article 21 mandates the reporting of certain information, primarily on measures taken to implement the treaty. Before the treaty entered into force, critics dismissed the potential for this article to have a significant effect. Beyond the reporting requirement, “the treaty lacks follow-up mechanisms to monitor States

72, 74 (2014) (noting the binding nature of the FCTC and its status as “one of the most widely subscribed to treaties in the United Nations system”); Ilona Kickbusch et al., Addressing Global Health Governance Challenges Through a New Mechanism: The Proposal for a Committee C of the World Health Assembly, 38 J.L. MED. & ETHICS 550, 553 (2010) (referring to the FCTC as a “successful” example of “binding international law in health”).

52 Vadi, supra note 41, at 95 (quoting Benjamin M. Meier, Breathing Life into the Framework Convention on Tobacco Control: Smoking Cessation and the Right to Health, 5 YALE J. HEALTH POL’Y L. & ETHICS 137 (2005)).


54 See Halabi, supra note 12, at 126 (suggesting that “the binding nature of the guidelines is stronger” than “principles and recommendations”).

55 Woo, supra note 51, at 1750.

56 See FCTC, supra note 6, art. 21.
Parties’ compliance with any recommendations that may be included in such reports.\textsuperscript{57} Post hoc evaluations of compliance, however, indicate that this may not be as problematic as early skeptics of the FCTC predicted.

The Framework Convention Alliance (FCA) works with the Institute for Global Tobacco Control at John Hopkins Bloomberg School of Public Health to compile an annual report of the information gathered under Article 21 obligations.\textsuperscript{58} These annual reports are limited in that the reporting schedule for parties is staggered based on when they ratified the Convention. Despite this, the international community has produced a substantial amount of useful data, as Phase I of reporting for the first forty-nine ratifying members of the FCTC took place in 2007, and member countries submitted Phase II reports in 2011.\textsuperscript{59} The reporting requirement itself was largely adhered to initially, as forty-three of the forty-nine parties submitted reports to the Convention Secretariat in 2007.\textsuperscript{60} Enthusiasm apparently waned during the next four years; only twenty-nine of these parties submitted their required reports by the next deadline.\textsuperscript{61} However, noncompliance does not appear to have been a conscious decision on the part of the failing parties’ governments, however. Rather, the salient issue appears to be carelessness, as multiple noncompliant parties cited forgetfulness or a need for reminders as the reason for failing to report.\textsuperscript{62} This lack of clear opposition to reporting may comfort FCTC proponents, but it may also be a sign that the treaty is not being taken particularly seriously.

In addition, the FCA attempts to monitor compliance with Article 8’s provisions for protection from exposure to tobacco smoke. This article is facially more demanding than Article 21 and is also more difficult to measure, as there is no deadline specified in the Convention for meeting Article 8’s associated obligations. While most FCTC members have taken steps to implement rules consistent with Article 8, almost a third had made “little to no progress” as of 2010.\textsuperscript{63} On the other hand, ten countries had comprehensive smoke-free air policies at the national level, sixteen had strong policies with limited exceptions, and five had comprehensive or strong policies at a sub-national level (including

\begin{thebibliography}{99}
\bibitem{58} See Halabi, supra note 12, at 132 n.50.
\bibitem{60} See id.
\bibitem{61} See id.
\bibitem{62} See id.
\bibitem{63} Id.
\end{thebibliography}
Australia, where 99% of the country is covered by strong local legislation).\textsuperscript{64} Additionally, Bhutan has banned the sale of tobacco products entirely.\textsuperscript{65}

Adherence to the Article 11’s instructions for packaging and labeling varies widely across countries. Compliance with this article is also difficult to measure because its provisions are fairly vague and contain both mandatory and voluntary language. The most salient requirement is that warnings about the harmful effects of tobacco must take up at least 30% of the display areas on tobacco product packaging.\textsuperscript{66} Of forty-eight countries for which the FCA collected data, thirty-seven had enacted laws to this effect.\textsuperscript{67}

Article 13, which regulates tobacco advertising, promotion, and sponsorship, presents compliance measurement difficulties for countries whose constitutions prevent them from placing a “comprehensive ban on advertising.”\textsuperscript{68} Furthermore, the FCTC does not specify precisely what advertising “restrictions” entail. Despite this source of confusion, the FCA gathered observational data on Article 13 compliance, but conclusions were limited by a lack of data, a consequence that stems partially from non-compliance with the reporting requirements of Article 21.\textsuperscript{69} Several reporting countries displayed either unwarranted self-evaluation or confusion regarding the Article 13 requirements; fourteen of twenty-three governments claimed to have a comprehensive ban on tobacco advertising, but only nine were fully compliant with outdoor bans and ten with print media marketing bans.\textsuperscript{70} Similarly, seven countries claimed to have a point-of-sale (POS) ban, and only one of these countries (Jordan) had a POS ban with no violations.\textsuperscript{71} The lack of compliance with Article 13 lends credence to the common criticisms of the FCTC, though this evidence is far from conclusive in light of the measurement difficulties presented by the language of the article and the fact that it is likely to implicate the treaty’s constitutional exception.

Outside of the FCA, other NGOs have performed their own evaluations of the FCTC’s efficacy. The International Tobacco Control Policy Evaluation Project (ITC Project) is one such organization. Geoffrey T. Fong of the Ontario Institute for Cancer Research presented the ITC project findings in September

\textsuperscript{64} See id.
\textsuperscript{65} See id.
\textsuperscript{66} See FCTC, supra note 6, art. 11.
\textsuperscript{67} See Bostic et al., supra note 59.
\textsuperscript{68} FCTC, supra note 6, art. 13.
\textsuperscript{69} See Bostic et al., supra note 59.
\textsuperscript{70} Id.
\textsuperscript{71} See id. POS bans are especially difficult to enforce due to the prevalence of street vendors and kiosks selling cigarettes.
Fong concluded that current domestic policies are inadequate and that the potential for “unintended consequences” of the FCTC is overstated.

Basic treaty interpretation, the weight of scholarship, compliance with the FCTC, and empirical evidence all support the contention that the Convention is a binding legal document. Even considering the general weaknesses of international laws, the largely adherent international response to the passage of the FCTC demonstrates its significant influence, providing a seemingly legitimate foundation upon which to regulate the e-cigarette industry.

III. CURRENT REGULATION OF E-CIGARETTES

Pressure to regulate e-cigarettes mounts worldwide as the popularity of these relatively new devices continues to grow. Some analysts predict that the sales of e-cigarettes will surpass traditional cigarette sales within a decade. Among young Americans, this phenomenon already appears to have taken place, as e-cigarette use among teenagers had surpassed the use of traditional cigarettes as of December 2014. What should be done about this trend is the subject of much debate. It is unclear whether e-cigarettes are best classified as an alternative to traditional tobacco cigarettes, a form of treatment, a gateway product, or something entirely different, and there is competing evidence within the scientific community. Before reaching that issue, however, it is instructive to examine some of the possible approaches to e-cigarette regulation that major governments have applied. These include not regulating e-cigarettes at all, regulating them in the same fashion as traditional tobacco products, or classifying them as medicine or nicotine replacement therapy.

A. No Regulation


73 Id. ("Proportion of homes allowing smoking has decreased in Ireland since . . . its ban on smoking in public places").


76 See, for example, Study of Smoking Cancer Patients Fuels E-Cigarette Debate, 30 WESTLAW J. TOBACCO INDUST. 4 (2014).
Many advocate treating e-cigarettes the same as any general good that can be legally sold. Apart from the purely libertarian view promoting the free trade of goods, scientists and academics who see e-cigarettes as a substitute for traditional tobacco products believe that regulating these devices would inhibit a chief reducer of tobacco use. Whether for this reason or simply because of a slow legislative process, the U.S. currently does not federally regulate e-cigarettes. Similarly, the e-cigarette industry in China operates in a "regulatory void." U.S. tobacco control laws do not address e-cigarettes because the relevant federal statute covers only products that are "made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." This language may leave open the argument that nicotine qualifies as a component or part of tobacco products, and the statute could therefore be read to cover e-cigarettes. This argument is addressed in the following subsection.

B. E-Cigarettes as Tobacco Products

If e-cigarettes are to be regulated under the FCTC, then classifying them as tobacco products or their equivalent would be the most straightforward method of demonstrating the Convention's applicability. The European Union has taken the lead in adopting policies that at least highly resemble this approach. In February 2014, the European Commission approved revisions of the EU Tobacco Products Directive, the scope of which has now been broadened to cover e-cigarettes. The new directive regulates nicotine-containing e-cigarettes in essentially the same way as traditional tobacco products, but does not impose the same restrictions on medicinal e-cigarettes. Whether this regulatory strategy is viable remains to be determined, as the U.K.'s largest e-cigarette manufacturer

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77 See, for example, Zachary Cahn & Michael Siegel, Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?, 32 J. PUB. HEALTH POL'Y 16, 24 (2011).
is challenging the validity of the EU Tobacco Products Directive (TPD) at the Court of Justice of the EU (CJ). If the CJ finds that the new directive is valid, it would be a boon for international supporters of e-cigarette regulation under the FCTC as precedent for the position that there is no disconnect between the content of the Convention and e-cigarettes.

As noted above, federal regulation in the U.S. has not taken this form, but case law and FDA proposals suggest that e-cigarettes could be regulated as tobacco products under most circumstances. In Sottera, Inc. v. Food & Drug Administration, an e-cigarette distributor sought a preliminary injunction preventing the FDA from regulating e-cigarettes under the Food, Drug, and Cosmetic Act (FDCA). The Court of Appeals for the D.C. Circuit granted the preliminary injunction, holding that the "FDA lacks FDCA drug/device authority to regulate all tobacco products marketed without claims of therapeutic effect." But if e-cigarettes are marketed with claims of therapeutic effect, then the FDA’s drug/device provisions give the agency the authority to regulate. And the Court found that if nicotine-containing e-cigarettes are marketed without claims of therapeutic effect, the FDA may regulate them under the Tobacco Control Act instead. Though the FDA was arguing for the ability to regulate e-cigarettes under the FDCA at the time, it appears to have changed its strategy since Sottera was decided. In 2014, the FDA proposed a “deeming rule” to regulate e-cigarettes as tobacco products. If the rule is adopted, then the U.S. and EU will each have laws regulating e-cigarettes as tobacco products.

The potential success of the U.S. and EU regulatory approaches to e-cigarettes may have competing implications for the FCTC. Some might argue that the treaty is useless when it comes to e-cigarettes, as governments will eventually adopt whatever policies they deem effective. Others might see the new U.S. and EU laws as a victory for the treaty, as the courts of these two major international powers have now found language similar to that in the FCTC applicable to e-cigarettes. Given the general trend of adherence to the Convention, it may only be a matter of time until stronger e-cigarette policies are adopted pursuant to FCTC obligations.

84 627 F.3d 891 (D.C. Cir. 2010).
85 Id. at 895.
87 Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891, 902 (D.C. Cir. 2010).
C. E-Cigarettes as Medicine

Designating e-cigarettes as medical devices is another possible strategy for subjecting them to regulation. In the U.S., the FDA can regulate e-cigarettes when they are marketed as therapeutic. Prior to Sottera, the FDA tried to regulate all e-cigarettes under the FDCA as “drug-device combination[s].” While U.S. courts have found this type of authority to be too broad for the FDA, the concept appears to be well within governments’ capacities to explore further.

Other countries have taken more assertive approaches to reaching similar policy ends. For example, in New Zealand, e-cigarettes that contain nicotine are regulated under the Medicines Act. The drawback to this classification is that, because medicines and medical devices are typically some of the most strictly regulated products, it could lead “to the paradoxical situation in which e-cigarettes are treated more harshly than tobacco products that are known to be very harmful.” Regulating e-cigarettes as medicine thus has the perverse effect of shifting consumption from a likely healthier alternative to traditional tobacco products back to regular cigarettes. This type of policy seems to run directly counter to the goals of the FCTC. Restricting the ability of e-cigarettes to compete with cigarettes in the marketplace exacerbates a universally established public health risk and may renormalize smoking to an even further extent than the widespread popularity of e-cigarettes allegedly already threatens to do.

Despite these seemingly powerful criticisms, countries other than New Zealand regulate e-cigarettes as medical devices. The U.K. decided in 2013 to regulate all nicotine-containing products as medicines under the Medicines and Healthcare Products Regulatory Agency. The government does not appear to be dismissing the idea that e-cigarettes may effectively promote the cessation of smoking tobacco (in fact, calling e-cigarettes “medicine” seems to embrace the

89 See Brown & Williamson, 120 S. Ct. at 1308.
92 Id.
93 See Peter Hajek. et al., Should e-cigarettes be regulated as a medicinal device?, 1 LANCET RESPIR. MED. 429–31 (2013).
idea), but wants to ensure that “people using these products have the confidence that they are safe, are of the right quality and work.”

D. Outright Bans

Nothing prevents a country or local governing body from enacting outright bans on e-cigarettes. This would be an extreme step, though, even beyond the WHO’s call for an indoor ban. The possibility of a complete ban in the future seems unlikely. More common approaches are bans of specific types of e-cigarettes (such as flavored e-cigarettes), bans in specific places (such as public areas or indoors), or bans on sales to minors. This Comment will not address bans in detail, as they are uncommon. And because the FCA has encouraged treaty members to regulate tobacco products more strictly than the FCTC requires, the countries applying bans are likely already complying with the FCTC and would be unaffected by a determination of whether the treaty may apply to e-cigarettes.

The specifics of each FCTC member’s current policies obviously vary widely and will likely continue to do so. There are arguments in both directions about whether any policy is consistent with the demands of the FCTC. While it is clearly possible to enact e-cigarette regulation without guidance from the FCTC, these examples may also serve as frameworks for more specific binding international regulations that can promote consistency across countries, as mounting scientific evidence continues to reveal the healthiest methods for addressing e-cigarettes. The next section describes some of the WHO’s efforts...

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95 Id.
97 See Esterl, supra note 4.
to use the FCTC as a vehicle for this purpose and the justifications for such efforts.

IV. ATTEMPTS TO REGULATE E-CIGARETTES UNDER THE FCTC

A. Historical Approach to E-Cigarettes

Though there is little scholarship assessing the applicability of the FCTC to e-cigarettes, the WHO has certainly contemplated international regulation of the devices under the treaty. Although there is no indication that the original treaty contemplated e-cigarettes, this is unsurprising, as e-cigarettes did not enter the market until 2004—after the WHO had already begun drafting the Convention. Since then, the explosion of the e-cigarette market has forced the WHO and FCTC members to consider the products and their effect on the tobacco market and public health. In 2010, the COP acknowledged the "regulatory gap" that e-cigarettes present for the FCTC. Member countries also acknowledged the increasing role that e-cigarettes may play in the public health debate, and "policymakers and regulators in many countries have sought guidance from WHO on the scientific evidence-base and optimal regulatory approaches to be taken with regard to these products."

Despite the demonstrable awareness of the issues presented by e-cigarettes, the 2010 FCA policy briefing did not answer whether the scope of the FCTC encompasses e-cigarettes. The report noted that e-cigarettes "could . . . be considered tobacco products" but concluded that "[i]t is not necessary at this time for the Conference of the Parties to make a decision as to whether electronic cigarettes fall within the scope of the FCTC." For certain parts of the treaty, the FCA explicitly abdicated responsibility for e-cigarette regulation: "FCA recommends against referring the matter of electronic cigarettes to the working group on Articles 9 and 10, as the issue of e-cigarettes is largely unrelated to the matters which the working group was mandated to deal with." Following the policy briefing, the COP largely delegated the burden of dealing

\[\text{\textsuperscript{102}} \text{See Hardin, supra note 1, at 437.}\]
\[\text{\textsuperscript{104}} \text{Id.}\]
\[\text{\textsuperscript{106}} \text{Id.}\]
with e-cigarettes to national policymakers, instructing regulators to "collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) Electronic Nicotine Delivery Systems to protect public health."\(^{107}\) Thus, as of 2010, it looked as though members of the FCTC were more confident in the ability of national governments to regulate e-cigarettes and comfortable with the original domain of the FCTC.

A changing of the guard occurred between 2010 and 2014, however, as e-cigarettes rose in popularity. FCTC parties learned more about possible links between e-cigarettes and traditional tobacco products, and many saw fit to address the related challenges on the international stage.\(^{108}\) Continuing research and trends in policymaking over those four years apparently influenced member nations to address e-cigarettes, as the Sixth Conference of the Parties (COP-6) included a specific report on ENDS, recommending that parties regulate them both as tobacco products and as medical products.\(^{109}\) COP-6 used permissive language regarding e-cigarettes, but invited parties "to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health."\(^{110}\) This report seems to support incorporation of e-cigarettes into the FCTC's regulatory domain, identifying them as a target of the Convention's objectives. The chosen language is not binding, but the report still reveals the Parties' expanding perception of the appropriate scope of international regulation. The presence of binding language elsewhere in the treaty coupled with the explicit consideration of e-cigarettes as part of the Convention's intended regulatory system indicates that party members believe it could serve as a legitimate source of authority for e-cigarette regulation. This idea is further supported by the fact that legal challenges come almost exclusively from the tobacco industry and have not significantly hindered the growing influence of the FCTC.

B. Textual Basis for E-Cigarette Regulation

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107 COP-4, supra note 103.

108 Compare COP-4, supra note 103 (establishing "two informal working groups to develop information documents on Electronic Nicotine Delivery Systems") with WHO Report, supra note 11 (concluding that e-cigarettes "should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking").

109 See WHO Report, supra note 11.

The significance of the COP's contemplation of e-cigarettes is debatable. There was never a question about whether countries were allowed to regulate e-cigarettes, and the FCTC's recommendations, while potentially influential, do not present an interesting legal question. Controversy would arise, however, if the FCTC required certain regulations for e-cigarettes, as it does for traditional tobacco products. Section II identified several possible textual hooks on which WHO officials or parties to the convention could potentially rely as a legitimate source for such requirements. Classifying e-cigarettes as a tobacco product is not as faithful to the text of the FCTC as it is to that of the U.S. Tobacco Act. In contrast to that Act, there is no "derived from" clause in the FCTC definition; tobacco products must be "made of the leaf tobacco." Thus, the best arguments for mandatory regulation of e-cigarettes are based on expansive readings of Articles 8, 14, and 22, which together may be interpreted as requiring e-cigarette regulation if scientific evidence suggests that e-cigarette regulation is necessary to accomplish the goals of the treaty.

E-cigarettes do not produce tobacco smoke, and therefore do not appear to be covered by Article 8, the portion of the FCTC that most directly addresses the treaty's primary goal: "protection from exposure to tobacco smoke." The concept of expressio unius suggests the negative inference that the inclusion of tobacco smoke in the article implies the exclusion of other potential targets of regulation. It remains possible, however, to read Article 8 in a manner that would allow for e-cigarettes to fall within its purview. The phrase "[p]rotection from exposure to tobacco smoke" does not necessarily imply that Article 8 only requires regulation of products that produce tobacco smoke. If research suggests that controlling the marketing, sale, or use of e-cigarettes has a negative effect on tobacco smoke exposure, then e-cigarette-related measures could provide indirect protection from exposure, as promoted by Article 8. Although the treaty stipulates that tobacco smoke is the only source of harm that the FCTC seeks to address, nothing in the Convention precludes measures that indirectly tackle this issue.

The second important element of Article 8 is the use of the word "effective." In the context of that article, effective measures "require the total elimination of smoking and tobacco smoke in a particular space or environment in order to create a 100% smoke free environment." While this may seem to require no less than a ban on tobacco products, the WHO guidelines also

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111 Compare 21 U.S.C. § 321(rr), with FCTC, supra note 6, art. 1(f).
112 FCTC, supra note 6, art. 8 (emphasis added).
113 Id. art 8.2.
encourage adoption of the “best practice” in implementing smoke-free measures, leaving policymakers some discretion to act in accordance with developing scientific consensus.\textsuperscript{115} The Framework Convention Alliance, a multinational confederation of organizations that supports the FCTC, has argued that “effective” means “evidence-based.”\textsuperscript{116} This heightens the significance of the treaty’s self-described reliance on scientific, technical, and economic considerations. Future research on e-cigarettes and policies addressing them will play a key role in determining whether the FCTC is a legitimate source of justification for such policies. That determination will, in turn, depend on whether e-cigarette regulation can be shown empirically to reduce (or increase) the use of traditional tobacco products or their associated consequences.

It should be noted that the word “effective,” as used in the sense described above, appears in the FCTC twenty-six times. Its presence in Article 8 is the most straightforward indicator of its relevance as a factor in assessing the FCTC’s ability to regulate e-cigarettes, but the overall prevalence of the idea of effectiveness serves as further evidence that the FCTC can only be a meaningful regulatory tool if the policies it spurs actually achieve their goals. The weight of evidence may eventually suggest that e-cigarette regulation is necessary to effectively protect the public from the harms of exposure to tobacco smoke and achieve the goals of Article 8. This could be the case if e-cigarette critics are correct about the normalizing impact that these products may have on smoking. But if e-cigarettes are shown to be merely a healthier substitute for cigarettes and to reduce the overall production of tobacco smoke, then a hands-off policy almost seems required by the FCTC, due to its emphasis on developing “effective” policies.

Article 14 is the best hook for FCTC guidance on e-cigarettes if the use of the products is in fact an effective cessation tactic. It states: “Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence.”\textsuperscript{117} The primary argument in favor of allowing the unrestricted marketing and sale of e-cigarettes is that they represent an effective tool to fight tobacco

\textsuperscript{115} See id. para. 3.


\textsuperscript{117} FCTC, supra note 6, art. 14.1.
dependence.\(^{118}\) If this is the case, then the most intuitive approach would be a hands-off policy towards e-cigarettes, as regulation would interfere with the positive impact the devices could have on cessation. At most, many have argued, e-cigarette regulation should be minimal.\(^{119}\) The prospect of e-cigarettes as a healthier alternative to traditional tobacco products may appear to cut against the concept of the FCTC as a regulatory instrument for e-cigarettes, but it may not implicate the treaty's applicability to the products. Instead, this notion could dictate the form of the FCTC's demands on its members. The guidelines that Article 14 requires parties to issue could include mandatory distribution of information regarding the positive effects of e-cigarettes and, at the extreme, could encourage subsidization. On the other hand, if the weight of scientific evidence suggests that e-cigarettes are not an effective method to promote cessation, and that normalization and gateway effects outweigh their substitution effects, then Article 14 seems like an effective textual hook for e-cigarette regulation that closely resembles that of traditional tobacco products.

Finally, the broad language of Article 22 ("[c]ooperation in the scientific, technical, and legal fields and provision of related expertise")\(^{120}\) may be useful in finding applicability of the FCTC to e-cigarettes. If the contents of the Foreword and Preamble were not enough to ensure parties understand that the demands of the Convention are intertwined with scientific progress, this article clarifies that point. The growing body of tobacco-related research and the development of new technologies (such as e-cigarettes) that may influence the effects of tobacco regulation will change the nature of the FCTC over time. Article 22 is yet another strong anchor in the text of the treaty justifying an international policy concerning e-cigarettes.

Article 17, titled "Provision of support for economically viable alternatives," deserves attention as well.\(^{121}\) The article refers to suppliers of tobacco, not to consumers. This article could become relevant if e-cigarettes are in fact a safer and economically viable alternative (which they appear to be). Supporting the e-cigarette industry, then, may become a function of the FCTC. This may be more difficult to implement in practice. The FCTC requires adoption of effective measures, but has no authority to prohibit adoption of

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\(^{118}\) See, for example, Saitta et al., supra note 9.

\(^{119}\) See, for example, Cahn & Siegel, supra note 77 at 27–28; Pasquale Caponnetto et al., Electronic cigarette: A Possible Substitute for Cigarette Dependence, 79 MONALDI ARCHIVES FOR CHEST DISEASE 12, 15 (2013) (noting data suggesting that e-cigarettes appear “to be much safer than traditional cigarettes and comparable in toxicity to conventional nicotine replacement products”); Nick Dantonio, Comment, Vape Away: Why a Minimalist Regulatory Structure is the Best Option for FDA E-Cigarette Regulation, 48 U. RICH. L. REV. 1319, 1321–22 (2014).

\(^{120}\) FCTC, supra note 6, art. 22.

\(^{121}\) Id. art. 17.
ineffective measures, so preventing e-cigarette regulation likely presents a larger challenge than validating such regulation. Additionally, it may be politically impossible for a young, controversial international treaty to require subsidization of an industry such as e-cigarettes, so it is unclear how Article 17 can be implemented in practice if it is in fact relied upon to address e-cigarettes.

Textual interpretation of the relevant articles of the FCTC strongly suggests that mounting scientific evidence could trigger applicability of the treaty to devices such as e-cigarettes. International courts have not weighed in significantly on this idea, as most cases have focused on the constitutionality of tobacco-related taxes or packaging requirements. The Supreme Court of Canada, however, has noted that domestic policies have responded to the growing body of evidence about secondhand smoke, and that the FCTC “is one of the most widely embraced of multilateral treaties.” Given widespread support for the Convention and the WHO’s continual efforts to respond to scientific developments, mounting evidence about the effects of e-cigarette usage on smoking habits would likely trigger at least functional authority for the FCTC to regulate the devices.

V. SCIENTIFIC UNCERTAINTY AND THE INADEQUACY OF THE PRECAUTIONARY PRINCIPLE

Setting aside these considerations, there appear to be plenty of ways for the FCTC to implement binding e-cigarette-related obligations. The remaining question is if it should. This is more than a simple policy matter; it implicates the role international conventions should play in shaping policy as well as international law principles regarding regulation.

A. The Academic and Medical Community’s Lack of Consensus

The goal of the FCTC, in a nutshell, is to reduce tobacco use. Does regulating e-cigarettes help or hinder that goal? Opinions are divided, and the evidence is conflicting. Many theorize that a minimalist approach to e-cigarette regulation is optimal. The main motivating factor is the potential for smokers to switch to a less hazardous alternative, potentially saving hundreds of

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124 See, for example, WHO Report, supra note 11.
125 See, for example, Dantonio, supra note 119, at 1323.
thousands of lives in the U.S. alone. \(^{126}\) Recent studies showing that e-cigarettes do decrease tobacco dependence bolster the minimalist argument. \(^{127}\) Results consistently demonstrate that using e-cigarettes is more effective in eliminating tobacco cravings than quitting cold turkey, leading to high rates of complete abstinence from tobacco and even higher rates of reduced use. \(^{128}\) The research suggests that, perhaps counterintuitively, e-cigarettes may serve as a gateway out of smoking cigarettes. \(^{129}\)

In spite of this research, it is still possible to argue that e-cigarettes can cause harm. Many medical experts worry, for example, that e-cigarette use may encourage higher consumption of nicotine, may perpetuate smokers’ addiction to nicotine making them less susceptible to quitting altogether, may expose users to the risk of accidental ingestion of e-liquid or as yet unknown health risks from long-term e-cigarette use, may make smoking socially acceptable again thus undermining current no-smoking policies, and may act as a gateway to tobacco, especially for youngsters. \(^{130}\)

There is less data supporting these more pessimistic viewpoints, but the novelty of e-cigarettes means that there is a lack of long-term data, and skepticism is probably healthy. Blind faith in the efficacy of e-cigarettes as a cessation tool may also be dangerous because “some consumers may forego proven cessation methods due to [reliance on e-cigarettes].” \(^{131}\) Aside from the uncertainty surrounding e-cigarettes’ medical usefulness, there are further concerns about the potentially harmful effects of their vaporized ingredients, which, even if less harmful than tobacco, may cause long-term damage. \(^{132}\)

\(^{126}\) See Press Release, E Cigarettes May Cover 2 of the Top 10 New Year’s Resolution According to Some Experts and Reports, BUS. JOURNAFS (Jan. 4, 2010), http://www.bizjournals.com/prnewswire/press_releases/2010/01/04/SF31533 (“If we get all tobacco smokers to switch from regular cigarettes (to electronic cigarettes), we would eventually reduce the US death toll from more than 400,000 a year to less than 4,000, maybe as low as 400,’ states Joel Nitzkin, MD, MPH, DPA, FACPM, Chair, Tobacco Control Task Force, American Association of Public Health Physicians.”).


\(^{128}\) See, for example, Karolien Adriaens et al., Effectiveness of the Electronic Cigarette: An Eight-Week Flemish Study with Six-Month Follow-up on Smoking Reduction, Craving and Experienced Benefits and Complaints, 11 INT. J. ENVIRON. RES. PUBLIC HEALTH 11220, 11248 (2014).

\(^{129}\) See Riccardo Polosa & Pasquale Caponnetto, Correspondence, Time for Evidence-Based E-Cigarette Regulation, 14 LANCET ONCOLOGY 582 (2013).

\(^{130}\) Saitta et al., supra note 9, at 54.

\(^{131}\) See E-Cigarette Regulations, 2014 WL 2077923, supra note 100.

\(^{132}\) See Rachel Grana et al., Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems), Center for Tobacco Control Research and Education, University of California, San Francisco, WHO
The status of e-cigarettes in the scientific community is unresolved. How international law tends to approach unresolved scientific questions that relate to potential regulation may dictate the future role of the FCTC.

B. The Precautionary Principle and its Practical Impotence

One source of guidance commonly considered in international law is the precautionary principle, which "reflects the classic adage: Better safe than sorry." More specifically, "the principle imposes a burden of proof on those who create potential risks, and it requires regulation of activities even if it cannot be shown that those activities are likely to produce significant harms." The principle is highly influential, particularly in the area of international environmental law. International bodies have heavily relied on the principle in drafting environmental treaties, declarations, and resolutions. Thus, it would be unsurprising to refer to the precautionary principle to justify the regulation of e-cigarettes under the FCTC. Already, "[m]any public health researchers have adopted a better-safe-than-sorry approach to regulating electronic cigarettes in general, advocating regulation, or even removal from the market, until research shows the devices are safe." Although most of the precautionary principle’s influence has come in the field of environmental law, several scholars have previously suggested its potential application to e-cigarette regulation. Daniela Saitta argues that the principle is particularly well-suited for this area because "risk assessment studies ... [would necessitate] many years to complete." There is reason to believe, however, that the principle is far less useful in this field and would likely be detrimental to the development of effective policy.

While any type of regulation has associated costs, regulating e-cigarettes differs from environmental regulation in one critical respect. Environmental cost...
Regulations Are a Drag

regulations, while potentially expensive and ineffective, typically pose no risk of making the environment worse off if they turn out to be failures. E-cigarette regulations, on the other hand, could actually have harmful public health benefits. It is unclear who is actually creating more risk to consumers in this case: e-cigarette manufacturers and distributors or regulators. Who should bear the burden of proof for justifying e-cigarette policy?

Cass Sunstein characterized this problem by arguing that, in its strong form, the precautionary principle offers no real guidance because, “in the relevant cases, every step, including inaction, creates a risk to health, the environment, or both.” These risks are particularly high in the case of e-cigarettes, suggesting that another mechanism would be more helpful than the precautionary principle. What the FCTC, as an evidence-based treaty, truly demands is a robust risk-balancing system. Though this will take time, the treaty is designed to evolve alongside scientific progress. It does not and should not demand an immediate solution, especially considering the fact that each individual member of the Convention faces different risks and legal barriers to implementing a regulatory scheme.

Interestingly, resisting regulation of e-cigarettes appears to be consistent with the principle’s core tenets. While there are many unanswered questions about e-cigarettes, most available evidence suggests that they are safer than traditional tobacco products. Thus, the precautionary approach would seem to suggest that any action that would shift consumption from e-cigarettes to tobacco should be avoided. In the status quo, the FCTC does not regulate e-cigarettes. The would-be regulators are the parties who would be introducing a new risk; the sale and use of e-cigarettes already exists. Requiring government regulators to carry the burden of proof is at odds with the traditional “Strong Precautionary Principle,” which, by definition, “shifts the burden of proof . . . from government regulators to private firms.” However, the international legal community has sometimes followed a “weak” version of the precautionary principle, which merely allows for regulation in the face of scientific uncertainty without shifting the burden of proof away from governments. This application

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140 Sunstein, supra note 134, at 1003.
141 See Cahn & Siegel, supra note 77, at 18.
143 See id. at 1292.
of the principle is embraced in the Rio Declaration, which specifically adopts a "precautionary approach" to environmental protection.\textsuperscript{144}

The weak version of the precautionary principle may do nothing more than "state a truism, one that is uncontroversial and necessary only to combat public confusion or the self-interested claims of private groups demanding unambiguous evidence of harm, which no rational society requires."\textsuperscript{145} However, considering the lack of knowledge on the substitution effects of regulating e-cigarettes, an intuitive conception of the "better safe than sorry" truism is appropriate. At present, there is no satisfying answer to the question of e-cigarette regulation in domestic law, much less in international law. Although the FCTC could exercise legitimate power to require regulation of e-cigarettes, there is not strong scientific support to do so, and one of the most prevalent guiding principles of international law does not alleviate this dilemma. The prudent decision, until the scientific community provides more reliable answers, is to step back from the issue.

\section*{VI. Conclusion}

Because of the FCTC's self-described nature as an "evidence-based treaty," the obligation it imposes to interact with the scientific community, and its mandates to implement "effective" measures, the ability (and even legality) of the FCTC to regulate e-cigarettes depends on further conclusions about the effect of e-cigarettes on consumer behavior. A comparison to certain national regulations of e-cigarettes suggests that the FCTC could regulate them as tobacco products, though this does not appear to be faithful to the text of the Convention. It would be consistent, however, to regulate e-cigarettes under the FCTC based on its enumerated goals and the vehicles it provides to accomplish them. This is only true, however, if regulation actually would be effective in doing so. The precautionary principle is less helpful to the case for regulation than some scholars would argue because it is regulation that presents the unknown risk, whereas the status quo is not nearly as murky. If anything, the principle may support a prohibition on regulating e-cigarettes, which would be an unprecedented role for international health law. The FCTC may be a broader and more powerful tool than even its framers originally conceived. But when it comes to e-cigarettes, the exercise of this power that is most faithful to the treaty's intentions is, unsatisfyingly, to do nothing at all.


\textsuperscript{145} Sunstein, supra note 134, at 1016.