Breathing Life into the Framework Convention on Tobacco Control: Smoking Cessation and the Right to Health

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The harms of smoking are global in scope, and states must act multilaterally to repel this global threat to public health. Embodying this cooperative spirit, the member states of the World Health Organization (WHO) have banded together to challenge tobacco through international law. While successful in its execution, this international effort to control smoking neglects cessation interventions, thereby offering little salvation to those whose health is at greatest risk—those already addicted to tobacco. Addressing these forgotten victims requires a new paradigm for tobacco control: the human right to health.

The WHO's Framework Convention on Tobacco Control (FCTC)[1] has created general principles of cognitive and normative consensus for international public health, challenging the globalization of smoking through the globalization of tobacco control.[2] Based upon a

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1. WHO Framework Convention on Tobacco Control, WHA Res. 56.1, World Health Assembly, 56th Ass., 4th plen. mtg, Agenda Item 13, Annex, WHO Doc. A56.VR/4 (May 21, 2003), http://www.who.int/tobacco/fctc/text/en/fctc_en.pdf [hereinafter FCTC].

2. *See* David P. Fidler, *International Law and Global Public Health*, 48 U. KAN. L. REV. 1, 2 (1999) (noting a "globalization of public health" to oppose harms to health resulting from economic globalization); Derek Yach & Douglas Bettcher, *Globalisation of Tobacco Industry Influence and New Global Responses*, 9 TOBACCO CONTROL 206, 206 (2000) (describing the "globalisation of public health," through which "a risk culture is emerging with the realisation that many problems are global, and that states cannot deal with these problems on their own").

"convention/protocol approach" to treatymaking, the member states of the WHO intend the broad obligations of the FCTC to be supplemented by several individualized protocols, which, once ratified, will develop specific obligations for the respective aspects of tobacco control addressed by the FCTC.[3] By first gaining the support of states for the minimal commitments of the framework convention, the drafters of the FCTC have assured that the Conference of the Parties for the FCTC will engage in a continuing dialogue on the specifics of international tobacco control as protocols are introduced, negotiated, and ratified.[4] Despite this successful, albeit incremental, multilateral approach to tobacco control, neither the FCTC nor any currently proposed protocol adequately addresses the subject of smoking cessation.[5]

While emphasizing measures that indirectly reduce the demand for

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3. Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control, *Future Protocols: Note by the Secretariat*, WHO Doc. A/FCTC/INB6/INF.DOC./2 (Jan. 18, 2003) [hereinafter Intergovernmental Negotiating Body] (noting that "the negotiation of a framework convention is not a complete process, but the beginning of one that will include the formulation of one or more protocols"); DANIEL BODANSKY, FRAMEWORK CONVENTION ON TOBACCO CONTROL: THE FRAMEWORK CONVENTION/PROTOCOL APPROACH 11 (1999) ("The framework convention/protocol approach allows law-making to proceed incrementall[y], beginning with a framework convention that establishes a general system of governance for an issue area, and then developing more specific commitments and institutional arrangements in protocols."); *International Law and Health, Two Approaches: The World Health Organization's Tobacco Initiative and International Drug Controls, Summary of Remarks by Laurence Boisson de Chazournes*, 94 AM. SOC'Y INT'L L. PROC. 193, 194 (2000) ("In deciding that it would take the form of a framework convention, member states have indicated that the legislative process to be used will be of a continuing nature."); Luk Joossens, *From Public Health to International Law: Possible Protocols for Inclusion in the Framework Convention on Tobacco Control*, 78 BULL. WORLD HEALTH ORG. 930, 930-31 (2000).

4. At the time of publication, an Open-Ended Intergovernmental Working Group for FCTC is currently negotiating the rules of procedure under which the Conference of the Parties will convene. Once established, the Conference of the Parties, in fulfilling its oversight role for the Convention, "shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention . . . ." FCTC, *supra* note 1, art. 23; *see also infra* note 52 and accompanying text (discussing the role of the Conference of the Parties in the adoption of "A Protocol on the Treatment of Tobacco Dependence").

5. Although this Article refers repeatedly to "smoking" and "smoking cessation," this phraseology is used primarily for rhetorical convenience and is not intended to exclude the use of cessation interventions for other forms of tobacco.

tobacco, the FCTC fails to place firm mandates on states to address clinical smoking cessation, thus abandoning the millions already addicted to nicotine and vulnerable to the morbidity and mortality of smoking. In Part I, this Article begins by examining the scope and harms of the tobacco pandemic, explaining the processes that led states to recognize the magnitude of this global threat and to draft the FCTC. In doing so, this Article highlights the unfulfilled promise of smoking cessation for stemming the tobacco pandemic, critically assessing the FCTC's failure to mandate clinical cessation interventions. Article 14, the only section of the FCTC to address cessation, obviates state responsibility to provide any clinical interventions for those addicted to nicotine. Although the WHO initially proposed a "Protocol on the Treatment of Tobacco Dependence," member states quickly abandoned this regulatory mechanism in favor of the less-obligatory policy recommendations of the FCTC.

Part II argues that such neglect—turning a blind eye to a dangerous and often deadly addiction—violates the international human right to health. After defining the scope of the right to health, Part II analyzes affirmative obligations on states to address smoking cessation pursuant to this right, laying out a hierarchy of resource-dependent options that states might employ in fulfilling their obligations to palliate the effects of the tobacco pandemic. Applying this analysis to the FCTC, Part III proposes that states party to the FCTC reengage a protocol to address nicotine addiction and clinical tobacco cessation interventions. This Article concludes that a FCTC cessation protocol would revitalize the right to health and give states the formalistic tools necessary to curb smoking, prevent disease, and promote public health.

I. SMOKING AND THE FCTC

A. Tobacco and Its Discontents

Countless others have elucidated the enormous public health ramifications of the tobacco pandemic.[6] Today, over 1.1 billion people worldwide smoke.[7] Approximately one-quarter of all lifelong smokers will die in their middle age (between the ages of thirty-five and sixty-nine) as a

6. *E.g.*, JUDITH MACKAY & MICHAEL ERIKSEN, THE TOBACCO ATLAS (2002); TOBACCO CONTROL IN DEVELOPING COUNTRIES (Prabhat Jha & Frank Chaloupka eds., 2000).

7. WORLD BANK, CURBING THE EPIDEMIC, GOVERNMENTS AND THE ECONOMICS OF TOBACCO CONTROL 13 (1999).

result of smoking, losing between twenty and twenty-five years of life.[8] Another quarter of these smokers will die in their latter years as a result of smoking.[9] Compounding this massive death toll and morbidity is the debilitating effect of passive inhalation of environmental tobacco smoke, so-called "second-hand smoke," which affects not only the individual smoker but also those family members, coworkers, and others whose lives place them in close proximity to a smoker.[10] Globally, this "quiet pandemic" claims the lives of approximately five million persons per year,[11] a figure that will rise to ten million by 2030, with the burden of death increasingly being felt by developing states.[12] With globalization's dismantling of trade barriers permitting the burgeoning initiation of smoking in unsated developing states—particularly among the children and adolescents of these states—the global death rate from tobacco is expected to increase exponentially, causing approximately 150 million

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8. Richard Peto & Alan D. Lopez, *Future Worldwide Health Effects of Current Smoking Patterns*, *in* CRITICAL ISSUES IN GLOBAL HEALTH 154, 155 exhibit 18.1 (C. Everett Koop et al. eds., 2001).

9. *Id.*

10. MACKAY & ERIKSEN, *supra* note 6, at 34-35 (depicting the myriad harms caused to adults and children by passive smoking of environmental tobacco smoke). In addition to heightened mortality and morbidity of those passively exposed to smokers through environmental tobacco smoke, fetuses may be exposed to smokers through mother to child transmission of nicotine and other chemicals.

11. WORLD HEALTH ORG., THE WORLD HEALTH REPORT: REDUCING RISKS, PROMOTING HEALTHY LIFE (2002). The deathe toll attributed to tobacco represented 8.8% of global deaths in 2000. Kenji Shibuya et al., *WHO Framework Convention on Tobacco Control: Development of an Evidence Based Global Public Health Treaty*, 327 BRIT. MED. J. 154, 155 (2003).

12. Peto & Lopez, *supra* note 8, at 157 (citing WORLD HEALTH ORG., TOBACCO OR HEALTH: A GLOBAL STATUS REPORT (1997)) (separating the causes of tobacco-related death by region); *International Law and Health, Two Approaches: The World Health Organization's Tobacco Initiative and International Drug Controls, Summary of Remarks by Allyn L. Taylor*, 94 AM. SOC'Y INT'L L. PROC. 193, 193-94 (2000) ("At current levels of consumption, the tobacco epidemic is expected to kill up to ten million people per year by 2030, *with 70 percent of these deaths occurring in developing nations.*") (emphasis added). For reasons underlying the tobacco industry's influence in the developing world and the birth of the "global smoker," see Jeff Collin, *Think Global, Smoke Local: Transnational Tobacco Companies and Cognitive Globalization*, *in* HEALTH IMPACTS OF GLOBALIZATION: TOWARDS GLOBAL GOVERNANCE 61, 71-75 (Kelley Lee ed., 2003) (noting that "TTCs [transnational tobacco companies] have sought to present the rise of cigarette sales as an indicator of modernity and symbol of economic progress within low-income countries"); and Melissa E. Crow, *Smokescreens and State Responsibility: Using Human Rights Strategies To Promote Global Tobacco Control*, 29 YALE J. INT'L L. 209, 210-11 (2004).

deaths in the next twenty-five years and one billion total deaths throughout the twenty-first century.[13] Combined with the detrimental micro- and macroeconomic consequences of tobacco cultivation and cigarette consumption[14]—exploiting entire populations in vicious cycles of poverty, malnutrition, and death—tobacco use has become a threat to the prosperity of the state itself.[15] This threat to global public health and human security, projected soon to become the world's leading cause of avoidable death, cannot conscionably be ignored.

B. Importance of Cessation

There is clear evidence that smoking cessation interventions can decrease the risk of premature morbidity and mortality.[16] In fact, the earlier a smoker quits, the more dramatic this decrease in risk of premature sickness and death.[17] Considering the pervasiveness of the tobacco pandemic, quitting smoking is the most efficient means of saving lives—"offer[ing] the only realistic way in which widespread changes in smoking status can prevent large numbers of tobacco deaths over the next

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13. Jeff Collin et al., *The Framework Convention on Tobacco Control: The Politics of Global Health Governance*, 23 THIRD WORLD Q. 265, 273 (2002) ("Trade liberalisation has led to increased consumption of tobacco, but while it has no substantive effect on higher income countries, it has a large and significant impact on smoking in low-income countries and a significant, if smaller, impact on middle-income countries."); Peto & Lopez, *supra* note 8, at 158, 160; *see also* WORLD HEALTH ORG., MAYO REPORT: ADDRESSING THE WORLDWIDE TOBACCO EPIDEMIC THROUGH EFFECTIVE, EVIDENCE-BASED TREATMENT (1999), http://www.who.int/tobacco/health_impact/mayo/en/ [hereinafter MAYO REPORT] ("By 2020, smoking will cause about one in three of all adult deaths, up from one in six adult deaths in 1990." (quoting Dr. Gro Harlem Brundtland)).

14. Martin Bobak et al., *Poverty and Smoking*, *in* TOBACCO CONTROL IN DEVELOPING COUNTRIES, *supra* note 6, at 41, 56-58 (analyzing the socio-economic gradient in smoking to determine causal processes underlying the correlation between poverty and smoking).

15. *See generally Tobacco and Poverty: A Vicious Circle*, WHO Doc. WHO/NMH/TFI/04.01 (2004) (noting the impoverishing effects of tobacco on individuals and states).

16. *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH BENEFITS OF SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL (1990).

17. WORLD BANK, *supra* note 7, at 27 (noting that the earlier a smoker quits, the better his or her probability of survival); WORLD HEALTH ORG., MONOGRAPH: ADVANCING KNOWLEDGE ON REGULATING TOBACCO PRODUCTS 10 (2001) (noting the dose-response relationship between tobacco use and most tobacco-related causes of death); Jack E. Henningfield & John Slade, *Tobacco-Dependence Medications: Public Health and Regulatory Issues*, 53 FOOD & DRUG L.J. 75, 79 (1998).

half century."[18] Indeed, the WHO has recognized the importance of cessation, noting that if "the goal for smoking control is a reduction of smoking-related mortality, special emphasis must be given to maximizing the number of individuals who quit smoking."[19] As compared with prevention, which averts death only in the distant future, cessation offers the promise of lowering morbidity and mortality in the short-term, validating tobacco control programs with tangible, life-saving results.[20]

Overall, some seventy-five to eighty percent of smokers want to stop smoking.[21] Yet quitting is not easily accomplished. Although approximately one-third of smokers worldwide attempt to quit each year (often without knowledge or use of cessation interventions[22]), a mere one to three percent of all those attempting to quit remain tobacco-free even six months later.[23]

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18. Peto & Lopez, *supra* note 8, at 158; *id.* at 159 exhibit 18.2 (noting that "halving global cigarette consumption per adult by the year 2020 . . . would prevent about one-third of the tobacco deaths in 2020 and would almost halve tobacco deaths in the second quarter of the century").

19. *See* WORLD HEALTH ORG., GUIDELINES FOR CONTROLLING AND MONITORING THE TOBACCO EPIDEMIC 18 (1998). Following commencement of the FCTC, WHO "urged governments to include anti-addiction treatments as part of comprehensive tobacco control programs." *WHO Calls for War on Tobacco To Include Anti-Addiction Treatment*, DRUG WEEK, Aug. 29, 2003, at 263.

20. Vera Luiza da Costa e Silva, *Foreword*, WORLD HEALTH ORG., POLICY RECOMMENDATIONS FOR SMOKING CESSATION AND TREATMENT OF TOBACCO DEPENDENCE, at x (2003) ("Evidence has shown that cessation is the only intervention with the potential to reduce tobacco-related mortality in the short- and medium-term."); Peto & Lopez, *supra* note 8, at 156 (noting that "the number of young adults who are taking up smoking around the year 2000 will strongly influence the number of deaths from tobacco around the year 2050 (and beyond)"); Martin Raw, *Fighting Tobacco Dependence in Europe*, 7 NATURE MED. 13, 14 (2001) (explaining that "adolescents suffer smoking related disease 40-60 years in the future, whereas for middle-aged adults it is 10-30 year [sic] away or less"); Kenneth E. Warner, *Reducing Harm to Smokers: Methods, Their Effectiveness, and the Role of Policy*, *in* REGULATING TOBACCO 111, 111-12 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) ("Any reduction in tobacco-produced mortality over the next three decades necessarily must come from reductions in the risks current smokers face.").

21. Michael Russell, *Help and Treatment for Addicted Smokers*, 16 WORLD HEALTH F. 19, 20 (1995).

22. Costa e Silva, *supra* note 20, at xvi. Knowledge of the risks of smoking and benefits of cessation significantly increases smokers' efforts to quit. *Id.*

23. ROYAL COLLEGE OF PHYSICIANS, NICOTINE ADDICTION IN BRITAIN: A REPORT OF THE TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS (2000); PAN AM. HEALTH ORG., NICOTINE ADDICTION AND SMOKING CESSATION (1999), http://165.158.1.110/english/hpp/wntd_policy.htm. For a country-by-country assessment of the demographics of

Among those who quit temporarily, "the majority persist in tobacco use for many years and typically cycle through multiple periods of relapse and remission."[24] Considering tobacco's pharmacologically addictive qualities and the tobacco industry's psychologically manipulative advertising (totaling well over $10 billion per year[25]), it comes as no surprise that the rate of unaided smoking cessation, burdened by a chronically high rate of relapse, remains low.[26] Because of the addictive effects of nicotine, regulatory reliance on education of the risks alone cannot be successful for many smokers. Clinical cessation interventions, when combined with other forms of institutional support, can significantly increase the number of attempts to quit and the likelihood of success at each attempt, dramatically improving the chances of breaking entrenched tobacco dependence.[27]

Despite the proven efficacy and cost-effectiveness of cessation

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quitting, see MACKAY & ERIKSEN, *supra* note 6, at 94-101 (noting, where available, the percentages of people who had quit smoking in a given country by 2002).

24. The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives, *A Clinical Practice Guideline for Treating Tobacco Use and Dependence: A US Public Health Service Report*, 283 JAMA 3244, 3246 (2000).

25. MACKAY & ERIKSEN, *supra* note 6, at 58 ("While there is no reliable estimate of global cigarette marketing expenditures, it is clearly in the tens of billions of US dollars a year. In the USA alone over $10 billion is spent a year on marketing cigarettes, and this at a time when advertising is prohibited on television and radio, when there are limitations on certain types of outdoor advertising and sponsorship, and when cigarette sales are falling.").

26. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, WHO EVIDENCE BASED RECOMMENDATIONS ON THE TREATMENT OF TOBACCO DEPENDENCE 3 (2001).

27. David P. Hopkins et al., *Reviews of Evidence Regarding Interventions To Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke*, 20 AM. J. PREVENTATIVE MED. 16, 33-40 (2001) (surveying success rates for various combinations of clinical cessation interventions); Thomas E. Novotny et al., *Smoking Cessation and Nicotine-Replacement Therapies*, *in* TOBACCO CONTROL IN DEVELOPING COUNTRIES, *supra* note 6, at 287, 288 (noting that "[t]he availability of effective cessation therapy might also help move smokers from pre-contemplation and contemplation stages to action and maintenance" increasing the number of quit attempts); The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives, *supra* note 24, at 3246 ("Although only about 7% of smokers achieve long-term success when trying to quit on their own, updated guideline analyses revealed that success rates can be increased to 15% to 30% by using guideline-recommended treatments."). For example, clinical smoking cessation efforts, combined with changing social norms, have helped to lower the prevalence of smoking in the United States from forty-seven percent in 1965 to twenty-two percent in 1999. WORLD HEALTH ORG., *supra* note 20, at 1 (citing NAT'L CANCER INST., POPULATION-BASED SMOKING CESSATION: PROCEEDINGS OF A CONFERENCE ON WHAT WORKS TO INFLUENCE CESSATION IN THE GENERAL POPULATION (2000)).

interventions,[28] a paucity of cessation programs exist at the state level,[29] as "smoking cessation is not seen as a public health priority" by national politicians.[30] Vera da Costa e Silva, the WHO's Director for Tobacco Control, has lamented that "the public health sector in many countries is not investing in smoking-cessation services, and in most countries only limited steps have been taken to provide treatment, train health care providers, and release financial resources."[31] Although tobacco cessation programs are cost-effective and health benefits are apparent in the short-term, states nevertheless resist these interventions because they still bear some initial cost, the benefits of which are not *immediately* demonstrable.[32] Without states engaging smoking cessation as a legislative priority, those

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28. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 6 ("Because tobacco dependence treatment is so cost effective, it should be provided by public and private health care systems."); WORLD BANK, *supra* note 7, at 77-78; Raymond Niaura & David B. Abrams, *Smoking Cessation: Progress, Priorities, and Prospectus*, 70 J. CONSULTING & CLINICAL PSYCHOL. 494, 502 (2002). For a discussion of the efficacy and cost-effectiveness of specific cessation interventions, see *infra* notes 123-167 and accompanying text.

29. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 4 (noting the lack of tobacco support and treatment programs in European health care systems); *see also* Raw, *supra* note 20, at 13 (noting the difficulty of finding funds to work internationally in smoking cessation); Costa e Silva, *supra* note 20, at xi ("[D]espite the availability of cost-effective treatment for tobacco dependence, the public health sector in many countries[] is not investing in smoking-cessation services, nor in the development of an infrastructure that will motivate smokers to quit and support them in doing so.").

30. Costa e Silva, *supra* note 20, at xi. Even in the United States, tobacco control efforts had been faulted for their emphasis on political expedience rather than public health. Clive Bates et al., *The Future of Tobacco Product Regulation and Labeling in Europe: Implications for the Forthcoming European Union Directive*, 8 TOBACCO CONTROL 225, 230 (1999) (noting that the U.S. Federal Trade Commission's regulation of tobacco content is flawed, legitimizing the myth of low-tar cigarettes).

31. *WHO Calls for War on Tobacco To Include Anti-Addiction Treatment*, *supra* note 19, at 16.

32. Gro Harlem Brundtland, *Achieving Worldwide Tobacco Control*, 284 JAMA 750, 750 (2000) (lamenting the limited impact of tobacco control by noting "that action is occurring too late, partially because policy makers have not been motivated to intervene in time"); Niaura & Abrams, *supra* note 28, at 502; *cf.* Collin et al., *supra* note 13, at 267 ("The paucity of regulation may reflect the importance of domestic interests, particularly in the small number of national economies that are heavily dependent on tobacco production." (citing TOBACCO CONTROL IN DEVELOPING COUNTRIES, *supra* note 6)). In addition to the lack of immediate political reward for actions to reduce the prevalence of smoking, national politicians are also besieged by relentless attempts by transnational tobacco corporations to manipulate individual national policies. *See infra* notes 196-198 and accompanying text (analyzing the influence of transnational tobacco corporations at the national level).

who need programs to help them quit cannot obtain the institutional support they need.

C. Exposing the Silent Pandemic—The Framework Convention on Tobacco Control

Recognizing the catastrophic impact of smoking on global public health, the World Health Assembly, representing all WHO member states, adopted Resolution 49.17 on May 26, 1996.[33] The resolution called upon the WHO "to initiate the development of a framework convention [on tobacco control] in accordance with article 19 of the WHO Constitution."[34] Although Resolution 49.17 met with substantial resistance both inside and outside the WHO,[35] international tobacco control took on renewed importance after the World Health Assembly elected Dr. Gro Harlem Brundtland, a staunch tobacco control advocate, as Director-General of the WHO.[36] Dr. Brundtland's commitment to tobacco control was embodied in

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33. *International Framework Convention for Tobacco Control*, WHA Res. 49.17, World Health Assembly, 49th Ass., 6th plen. mtg., WHO Doc. A49/VR/6 (May 25, 1996). The seeds for the FCTC were planted through conversations between Ruth Roemer, a professor of health law and advocate of legislative approaches to tobacco control, and Allyn Taylor, then a doctoral student at Columbia Law School. At that time, "[t]he idea of a convention that utilized international law to further public health was new." Judith Mackay, *The Making of a Convention on Tobacco Control*, 81 BULL. WORLD HEALTH ORG. 551, 551 (2003). At no point in the advocacy for the FCTC did either Roemer or Taylor address the issue of cessation interventions for current smokers. *See generally* Allyn L. Taylor, *An International Regulatory Strategy for Global Tobacco Control*, 21 YALE J. INT'L L. 257 (1996) (advocating an international regulatory strategy for tobacco control, including fiscal measures, regulation of advertising, regulation of smoking in public places, disincentives for youth tobacco consumption, and mandatory health education).

34. *International Framework Convention for Tobacco Control*, *supra* note 33. Prior to the adoption of Resolution 49.17, the WHO had commissioned an independent feasibility study for addressing tobacco control at the international level. *An International Strategy for Tobacco Control*, WHA Res. 48.11, World Health Assembly, 48th Ass., 12th plen. mtg., Annex 1, WHO Doc. WHA48/VR/12 (May 12, 1995). As part of this feasibility study, the WHO contracted with Roemer and Taylor, out of which WHO published its International Strategy for Tobacco Control. *See* ALLYN L. TAYLOR & RUTH ROEMER, INTERNATIONAL STRATEGY FOR TOBACCO CONTROL 17 (1996).

35. Mackay, *supra* note 33, at 551.

36. Gro Harlem Brundtland, Director-General Elect, The World Health Organization, Speech to the Fifty-First World Health Assembly, at 7, WHO Doc. A51/DIV/6 (May 13, 1998) (noting, in her opening speech to the World Health Assembly, that the WHO would take a leading role in "a broad alliance against tobacco, calling on a wide range of partners to halt the relentless increase in global tobacco consumption"). Prior to her ascension to

the creation of the WHO's international campaign against tobacco, the Tobacco Free Initiative.[37] By May 24, 1999, the World Health Assembly's 191 members had unanimously agreed to establish a Framework Convention on Tobacco Control, despite the fact that the WHO had never before drafted a binding international treaty in its fifty-five year history.[38] Following the establishment of, and two extensive drafting sessions by, the WHO's Working Group and Intergovernmental Negotiating Body,[39] the World Health Assembly unanimously adopted the FCTC on May 21, 2003,[40]

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the Director-General position at WHO, Dr. Brundtland had served three terms as Prime Minister of Norway. Gavin Yamey, *WHO in 2002: Have the Latest Reforms Reversed WHO's Decline*, 325 BRIT. MED. J. 1107, 1107 (2002) (assessing the effectiveness of Dr. Brundtland's tenure at WHO).

37. *See* MAYO REPORT, *supra* note 13 (highlighting that the WHO launched its "Tobacco Free Initiative," the organizational precursor of the FCTC, on the day Dr. Brundtland took office).

38. Although Article 19 of the WHO Constitution authorizes WHO to adopt conventions or agreements, the WHO had never before used this power. *Tobacco Free Initiative, Report by the Director General*, WHA Res. 52.18, World Health Assembly, 52nd Ass., 9th plen. mtg., Agenda Item 13, WHO Doc. A52/7 (Mar. 18, 1999). Because of the ineffectiveness of the WHO, based upon its past reluctance to legislate its health strategies, and the "modest level of global commitment to tobacco control," various commentators recommended that any WHO attempts to address the international tobacco pandemic involve only incremental standard setting. *E.g.*, Allyn Lise Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, 18 AM. J.L. & MED. 301, 303 (1992) (noting that the "WHO's traditional reluctance to utilize law and legal institutions to facilitate its health strategies is largely attributable to the internal dynamics and politics of the organization itself"). Now, in the wake of the FCTC, these same scholars look to the WHO's agenda-setting capacity, pushing it to leverage its role as a representative of the community of states to shape state behavior in resolving other issues of public health impervious to solution at the national level. *See* Allyn Taylor, *Global Health Governance and International Law*, 25 WHITTIER L. REV. 253, 261-62 (2003) ("I believe that the FCTC may signal a turning point—a new era in international health cooperation. The WHO's unconventional consideration of the role of international law and institutions in promoting public health policies suggests an expansion of the organization's traditional scientific, technical approaches to public health, and perhaps, an evolution of its traditional culture.").

39. The World Health Assembly established the Working Group to establish the FCTC's technical foundation and the Intergovernmental Negotiating Body to undertake the drafting components of the FCTC. *See Towards a WHO Framework Convention on Tobacco Control*, WHA Res. 52.18, World Health Assembly, 52nd Ass., 9th plen. mtg., Agenda Item 13, WHO Doc. A52/7 (Mar. 18, 1999) (establishing the Working Group and Intergovernmental Negotiating Body).

40. The World Health Assembly, encompassing delegates of all member states and

shifting implementation of convention provisions to the states.[41] By June 29, 2004, the day the FCTC closed for signature, 155 states had signed the FCTC, with ten states having already ratified it.

The sheer adoption of the FCTC—enabling states to overcome domestic and collective action problems to achieve a common good—should be seen as a great leap forward for tobacco control. Prior to the advent of the FCTC, only select Western states had enacted comprehensive tobacco control efforts.[42] While critical of the FCTC's approach, the author cannot and will not minimize the monumental importance of this effort, which overcame significant tobacco industry resistance to become a valuable precedent for national and global solutions to safeguard public health and eradicate disease.

Despite its many successes, the FCTC fails to place affirmative obligations on states vis-à-vis clinical smoking cessation. The Convention focuses instead on the globalized aspects of tobacco supply and indirect limitations on global demand. Through broad regulations on tobacco advertising, warning labels, taxation, and smuggling, the Convention seeks to change the social environment for smoking without actively changing individual behavior.[43] That is, the FCTC discourages consumption without encouraging cessation. As a result, the FCTC—the first treaty drafted explicitly to protect public health—has been criticized for lacking a firm

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meeting at annual or special sessions, acts to adopt WHO conventions or agreements by a two-third majority vote, with each member state having one vote in the Assembly. World Health Organization Constitution, July 22, 1946, arts. 59, 60, 62 Stat. 2679, 14 U.N.T.S. 185, *reprinted in* WORLD HEALTH ORG., BASIC DOCUMENTS (40th ed. 1994) [hereinafter WHO Constitution].

41. Shibuya et al., *supra* note 11, at 154 (noting that, following ratification of the FCTC, "further efforts are needed to establish national capacities to set the foundation for the later implementation of the treaty, to negotiate the protocols on specific subjects within the framework, and to implement effective interventions to reduce tobacco consumption globally"). In addition to states, over one hundred eighty civil society organizations from over seventy states, linked together through the Framework Convention Alliance, served a crucial role in developing the FCTC and will continue to serve as a resource in implementing and monitoring the FCTC. Collin et al., *supra* note 13, at 274, 278; Clive Bates, *Developing Countries Take the Lead on WHO Convention*, 10 BRIT. MED. J. 209, 209 (2001); R. Hammond & M. Assunta, Editorial, *The Framework Convention on Tobacco Control: Promising Start, Uncertain Future*, 12 TOBACCO CONTROL 241, 241 (2003); Crow, *supra* note 12, at 217.

42. Taylor, *supra* note 33, at 268 (suggesting national tobacco control strategies).

43. *See* FCTC, *supra* note 1, art. 13 (advertising); *id.* art. 10, 11 (warning labels); *id.* art. 6 (taxation); *id.* art. 15 (smuggling).

basis in public health.[44]

Although the FCTC's Preamble recognizes "that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence . . . and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,"[45] the Preamble uses neither the word "nicotine" nor the word "addiction," two words that form the public health basis of tobacco control.[46] Overall, the FCTC focuses on initiation of smoking but not cessation. Article 14, the only portion of the FCTC devoted to cessation, reads:

> Demand reduction measures concerning tobacco dependence and cessation
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> 1. 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.
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> 2. Towards this end, each Party shall endeavour to:
>
> (a) design and implement effective programmes aimed at promoting the cessation of tobacco use, in such locations as educational institutions, health care facilities, workplaces and sporting environments;
>
> (b) include diagnosis and treatment of tobacco dependence and counselling services on cessation of tobacco use in national health and education programmes, plans and strategies, with the participation of health workers, community workers and social workers as appropriate;
>
> (c) establish in health care facilities and rehabilitation centres programmes for diagnosing, counselling, preventing and treating

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44. *See, e.g.*, Crystal H. Williamson, *Clearing the Smoke: Addressing the Tobacco Issue as an International Body*, 20 PENN ST. INT'L L. REV. 587, 611 (2002) (noting that "participants [in FCTC drafting] themselves pointed out (and attempted to regulate) some matters that had decidedly more to do with trade than with health concerns").

45. FCTC, *supra* note 1, pmbl.

46. In 1964, the WHO Expert Committee on Drug Dependence defined "dependence" as "a state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioural and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence." WORLD HEALTH ORG., TECHNICAL REPORT SERIES NO. 407, WHO EXPERT COMMITTEE ON DRUG DEPENDENCE, SIXTEENTH REPORT 6 (1969); *see also* WORLD HEALTH ORG., MANUAL OF THE INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES, INJURIES, AND CAUSES OF DEATH 198-99 (1977). For a description of the rhetorical evolution of "dependence," see Harold Kalant, *Nicotine as an Addictive Substance, in* NICOTINE AND PUBLIC HEALTH 117, 119-22 (Roberta Ferrence et al. eds., 2000).

tobacco dependence; and

> (d) collaborate with other Parties to facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products pursuant to Article 22. Such products and their constituents may include medicines, products used to administer medicines and diagnostics when appropriate.[47]

Even here, the use of nonobligatory language—e.g., "endeavour to" following "shall" in the second paragraph—trivializes the role of cessation in a comprehensive tobacco control program. The use of hortatory rather than legal statements, soft rather than hard law, denies Article 14 of any self-executing requirements, leaving treaty implementation solely at the discretion of individual states.[48] This lack of mandatory provisions, compounded by weak implementation mechanisms and state reporting requirements,[49] provides no incentive for change in state cessation policy. Thus, while the FCTC's program initiatives may buttress smokers' psychological motivations to quit through, inter alia, health education programs, cigarette taxation, and smoke-free air laws, it commits states to do relatively little to reduce the psychological and addiction-related barriers to smoking cessation.[50]

Although the WHO had previously offered paeans to the importance of clinical cessation programs in tobacco control policy, member states did little to act on this belief in drafting the FCTC. The First Meeting of the

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47. FCTC, *supra* note 1, art. 14.

48. *See* Thomas Michael McDonnell, *Defensively Invoking Treaties in American Courts-Jurisdictional Challenges Under the U.N. Drug Trafficking Convention by Foreign Defendants Kidnapped Abroad by U.S. Agents*, 37 WM. & MARY L. REV. 1401, 1475 n.352 (noting that the presence of "shall endeavour to" language in extradition treaties denies relevant provisions of self-executing status); Annie Petsonk, *Challenges to International Governance: International Land-Use Law*, 87 AM. SOC'Y INT'L L. PROC. 488, 498 (1993) (remarks by Ralph Osterwoldt) (recognizing a distinction between "hard law, by which I mean binding obligations set out in international treaties and agreements, which typically provide that 'states shall do X,' and in 'soft law,' meaning guidelines, principles and hortatory statements contained in conventions, including requirements that states shall 'endeavor to cooperate, report, exchange information'").

49. Crow, *supra* note 12, at 218-20. The author notes that these weaknesses are not confined to Article 14 but serve to stymie the enforcement of many provisions within the FCTC.

50. *See* WORLD HEALTH ORG., *supra* note 19, at 19 (noting that "smoking control policies should contain both activities to strengthen smokers' motivation to quit (health education, public information, price policies, smoke-free policies, behavioural treatments, etc.) *and* activities to reduce dependence-related difficulties for smokers to quit (behavioural and pharmacological treatment)") (emphasis added).

Working Group on the WHO Framework Convention on Tobacco Control, which convened in October 1999, agreed that the FCTC should focus on tobacco demand reduction strategies, including the treatment of tobacco dependence.[51] In 2000, the Second Meeting of the Working Group on the WHO Framework Convention on Tobacco Control expanded this cessation mandate, with the WHO's Tobacco Free Initiative submitting "Possible Subjects of Initial Protocols" that included "A Protocol on the Treatment of Tobacco Dependence" (Proposed Dependence Protocol), reprinted herein as an annex to the present Article.[52] However, by 2003, suggestions for future protocols by the Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control addressed only the subjects of "advertising, promotion and sponsorship; tobacco-product regulation; illicit trade; and liability,"[53] leaving out the issues of tobacco dependence and cessation.

It is unclear exactly why member states abandoned the Working Group's Proposed Dependence Protocol without serious consideration, although many disparate factors likely influenced their decision. First, during preliminary negotiations, when the success of the FCTC remained in doubt, many nongovernmental organizations and states, seeking international consensus over legislative comprehensiveness,[54] criticized the

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51. *See* Allyn L. Taylor & Douglas W. Bettcher, *WHO Framework Convention on Tobacco Control: A Global "Good" for Public Health*, 78 BULL. WORLD HEALTH ORG. 920, 925 (2000) (citing World Health Org., WHO Framework Convention on Tobacco Control: Report of the First Meeting of the Working Group (1999) (unpublished manuscript)); Williamson, *supra* note 44, at 610 (noting, during the early drafting stages of the FCTC, that "[t]reatment is to become part of a broad strategy of the WHO, making cessation a key component of primary health care").

52. *Possible Subjects of Initial Protocols: Elaboration of Technical Components of Three Possible Protocols*, Working Group on the WHO Framework Convention on Tobacco Control, 2d mtg., Agenda Item 6, WHO Doc. A/FCTC/WG2/4 (Feb. 15, 2000) [hereinafter Second Meeting of the Working Group] (noting that "the treatment of tobacco dependence was generally supported as an important demand-reduction strategy to be addressed in a protocol"). Although WHO's Tobacco Free Initiative, as Interim Secretariat, developed the Proposed Dependence Protocol, the FCTC requires that any protocols for adoption be proposed by state parties at least six months prior to a session of the Conference of the Parties, which can only occur once the FCTC has entered into force (on the ninetieth day following the date of ratification by the fortieth state). FCTC, *supra* note 1, art. 33.

53. Intergovernmental Negotiating Body, *supra* note 3.

54. *See* Crow, *supra* note 12, at 213 ("Due to the uncertain political viability of obtaining consensus on a conventional treaty structure, WHO's governing body, the World Health Assembly (WHA), opted for a framework convention, which can be supplemented by specialized protocols." (footnotes omitted)).

protocol as legislative overreaching. Throughout the convention process, those involved in drafting the FCTC focused their legislative will on the international components of the tobacco epidemic,[55] often at the expense of costly domestic programs like cessation interventions. Further, many viewed a cessation provision as too great a boon for transnational pharmaceutical corporations, long derided for their close ties to the WHO, which would stand to gain enormous financial profit from the widespread distribution of smoking cessation products.[56] To alleviate such conflicts of interest, pharmaceutical corporations were not invited to the plenary drafting sessions of the FCTC, and lobbying for cessation was viewed with skepticism. Finally, many of the compromises reached by the WHO's Working Group and Intergovernmental Negotiating Body allow states to postpone economically painful decisions until a later date. For example, states financially dependent on tobacco exports face the short-term prospect of agricultural losses if cessation interventions are successful. Foregoing cessation programs minimizes the immediate impact on agricultural exports, alleviating the prospect of state public health

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55. *See* PHYSICIANS FOR A SMOKE-FREE CANADA, COMMENTARY ON WORLD HEALTH ORGANIZATION PROVISIONAL TEXTS OF PROPOSED DRAFT ELEMENTS FOR A WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL 15 (2000), http://www.smoke-free.ca/pdf_1/commentsondraftfctc.PDF ("This protocol contains not a single measure that is international in character. In fact, it contains some measures that are potentially end-runs around existing national drug regulatory mechanisms .... It is recommended that this draft protocol be dropped entirely from further consideration."); Action on Smoking and Health, ASH Briefing for the First Negotiations (Oct. 2000), http://www.ash.org.uk/html/international/html/ashfctcposition.html#_Toc496178643 ("In our view, this [Proposed Dependence Protocol] can only be a general 'plan and report' obligation, with a number of (strictly optional) measures that could be taken. Detail might be developed in the technical bodies. *There is therefore no need for a protocol.*") (emphasis in original); Framework Convention Alliance, Comments on the Chair's Text of a FCTC Joint New Zealand NGO Submission (Mar. 2001), http://fctc.org/archives/INB2nzngo.shtml ("We consider that personal treatment issues, ie treatment of tobacco dependence, need not have their own set of provisions but be included as a part of tobacco control programmes.").

56. *See* Collin et al., *supra* note 13, at 276-77 (noting pharmaceutical consortia interested in advising WHO on tobacco control); *see also* Raw, *supra* note 20, at 13 (noting sponsorship of the WHO European Partnership Project to Reduce Tobacco Dependence by cessation product distributors GlaxoWellcome, Novartis, Pharmacia, and SmithKline Beecham). In addition, multinational pharmaceutical corporations have invested heavily in supporting the academic underpinnings of pharmacological treatment for nicotine addiction. *E.g.*, INTERVENTIONS FOR SMOKERS: AN INTERNATIONAL PERSPECTIVE, at ix (Robyn Richmond ed., 1994) (thanking "Marion Merrell Dow Pharmaceuticals in the United States for generous support of this book").

ministries being overruled by finance ministries. For these and other reasons, states never seriously considered cessation interventions through the FCTC, viewing such efforts as a quixotic undertaking foisted upon state delegates by the WHO Secretariat.

Regardless of the precise reasons, the FCTC has effectively abandoned those addicted to tobacco. Even when the WHO has attempted to develop evidence-based policy recommendations to help states implement practical cessation interventions in accordance with adoption of the FCTC,[57] states have shown little interest in establishing such smoking cessation policy in the absence of strong normative consensus on the importance of cessation.[58] By failing to emphasize cessation interventions, member states have denied life-saving treatments to millions of smokers, acting in contravention of smokers' human right to health.

II. THE RIGHT TO HEALTH: A HUMAN RIGHTS APPROACH TO ARTICLE 14

A. An Introduction to the Right to Health

An individual's right to health is recognized as a fundamental international human right. Founded upon the non-derogable right to life,[59] the Universal Declaration of Human Rights (UDHR)[60] affirms in

57. Costa e Silva, *supra* note 20, at ix-x ("Treatment of tobacco dependence needs . . . to be part of a comprehensive tobacco-control policy along with measures such as taxation and price policies, advertising restrictions, dissemination of information and protection of non-smokers through the creation of smoke-free public places.").

58. Although the WHO Tobacco Free Initiative held a comparative strategy development meeting in 2002 "to explore and recommend potential avenues for progress in the areas of smoking cessation and treatment of tobacco dependence," this meeting garnered only thirty-one participants, with country representatives from only Brazil, Canada, Germany, Hong Kong, the Russian Federation, Seychelles, Thailand, the Philippines, Venezuela, and Qatar. Costa e Silva, *supra* note 20, at xii.

59. Universal Declaration of Human Rights, G.A. Res. 217A(III), art. 3, at 71-72, U.N. Doc. A/810 (1948) ("Everyone has the right to life, liberty and security of person.") [hereinafter UDHR]; Virginia A. Leary, *Implications of a Right to Health, in* HUMAN RIGHTS IN THE TWENTY-FIRST CENTURY 481, 487 (Kathleen E. Mahoney & Paul Mohoney eds., 1993) ("It does not strain imagination to consider the 'right to health' as implicit in the right to life.").

60. UDHR, *supra* note 59, art. 3. "Although the UDHR is not a legally binding document, nations (states) have endowed it with great legitimacy through their actions, including its legal and political invocation at the national and international levels." Jonathan M. Mann et al., *Health and Human Rights, in* HEALTH AND HUMAN RIGHTS 7, 9 (Jonathan M. Mann et al. eds., 1999).

Article 25(1) that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including . . . medical care and necessary social services . . . ."[61] The United Nations legislatively embodied the economic and social parameters of this right in the International Covenant on Economic Social and Cultural Rights (ICESCR), which elaborates the right to health in Article 12.1 to include "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[62] To achieve the full realization of this right, Article 12.2 of the ICESCR requires states to take affirmative steps necessary for "(b) [t]he improvement of all aspects of environmental and industrial hygiene; (c) [t]he prevention, *treatment*, and control of epidemic, endemic, occupational and other diseases; [and] (d) [t]he creation of conditions which would *assure to all medical service and medical attention* in the event of sickness."[63] Thus, under the plain language of the

61. UDHR, *supra* note 59, art. 25.

62. International Covenant on Economic Social and Cultural Rights, G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, art. 12(1), U.N. Doc. A/6316 (1966) [hereinafter ICESCR]. In addition, the right to life embodied in Article 6 of the International Covenant on Civil and Political Rights (ICCPR) obligates states "to take positive measures to ensure the right to life including steps to reduce infant mortality rates, prevent industrial accidents, and protect the environment." Cancado Trindade, *Environmental Protection and the Absence of Restrictions on Human Rights, in* HUMAN RIGHTS IN THE TWENTY-FIRST CENTURY, *supra* note 59, at 561, 573. Nonetheless, just a few scholars have attempted to place health care obligations on states through the ICCPR. *See, e.g.*, Crow, *supra* note 12, at 230 (arguing that the U.N. Human Rights Committee, the legal body established to monitor States Parties' compliance with the ICCPR, should consider the human rights dimensions of tobacco control under, inter alia, the right to life); Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT'L L.J. 325, 330-31 (2003) ("Given that medications can be indispensable for life, it is foreseeable that state policies likely to lead directly to diminished physical accessibility and affordability of certain medications will, in effect, deprive people of life."); Jonathan Wike, Note, *The Marlboro Man in Asia: U.S. Tobacco and Human Rights*, 29 VAND. J. TRANSNAT'L L. 329, 353 (1996).

63. ICESCR, *supra* note 62, art. 12.2 (emphasis added). The Committee on Economic, Social, and Cultural Rights (CESCR), the monitoring and interpreting body for the ICESCR, has specified that Article 12.2's requirements are included only by way of illustration and are not intended to be an exhaustive list of state obligations. *The Right to the Highest Attainable Standard of Health, CESCR General Comment 14*, U.N. CESCR, 22d Sess., Agenda Item 3, ¶ 13, U.N. Doc. E/C.12/2000/4 (2000) [hereinafter *General Comment 14*] (noting that Article 12.2 "gives specific generic examples of measures arising from the broad definition of the right to health contained in article 12.1"). In addition, scholars have noted that "a State party in which any significant number of individuals is deprived . . . of essential primary health care . . . is, prima facie, failing to discharge its obligations under

ICESCR, the right to health includes a right to health care. Beyond this, the Committee on Economic, Social and Cultural Rights (CESCR), the legal body charged in the ICESCR with drafting official interpretations of and monitoring state compliance with the ICESCR, has found that the reference in Article 12.1 of the Covenant to "the highest attainable standard of physical and mental health" is not confined to a right to health care. On the contrary, the drafting history and the express wording of Article 12.2 acknowledge that "*the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health,* such as food and nutrition, housing, access to safe and potable water and adequate sanitation, *safe and healthy working conditions, and a healthy environment.*"[64]

Further, in the context of elaborating the actions to be taken by states under Article 12.2 (b) through (d), the CESCR has delineated specific state obligations under (1) the right to a healthy natural and workplace environment to "discourage[] the abuse of alcohol, and the use of tobacco, drugs and other harmful substances;"[65] (2) the right to treatment and control of diseases to "make available relevant technologies;"[66] and (3) the right to health care facilities, goods, and services to provide "equal and timely access to base preventive, curative, rehabilitative health services and health education . . . appropriate treatment of prevalent diseases . . . [and] the provision of essential drugs."[67] The CESCR has found that states bear the responsibility to protect persons from corporate infringements of Article 12, specifically assigning state responsibility for "failure to discourage . . . consumption of tobacco."[68]

Since the ICESCR entered into force, various other multilateral

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the [ICESCR]." DAVID P. FIDLER, INTERNATIONAL LAW AND INFECTIOUS DISEASES 189 (1999) (quoting M.C.R. CRAVEN, INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A PERSPECTIVE ON ITS DEVELOPMENT 141 (1995)).

64. *General Comment 14, supra* note 63, ¶ 4 (emphasis added). Despite its devastating impact on health, tobacco is conspicuously absent from General Comment 14's list of examples of underlying determinants of health. *But cf.* Katherine Gorove, *Shifting Norms in International Health Law,* 98 AM. SOC'Y INT'L L. PROC. 18, 21 (2004) (criticizing the CESCR for "pulling out of nowhere an interpretation of what it believes to be the 'legal obligations' of states parties to the Covenant with respect to the right to the highest attainable standard of health").

65. *General Comment 14, supra* note 63, ¶ 15.

66. *Id.* ¶ 16.

67. *Id.* ¶ 17.

68. *Id.* ¶ 51.

treaties have given credence to a right to health.[69] Moreover, individual "[s]tates have long recognized an obligation to protect their population from obvious risks and hazards to their health,"[70] often embodying this right within their national constitutions.[71] To the degree that consistent

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69. Convention on the Rights of the Child, Nov. 20, 1989, art. 24(2)(b), 28 I.L.M. 1457 (requiring states to ensure the provision of necessary medical assistance, with an emphasis on primary health care, to all children); African Charter on Human and Peoples' Rights, June 27, 1981, art. 16(2), 1520 U.N.T.S. 217, 249 (requiring states to "take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick"); Convention on the Elimination of All Forms of Discrimination Against Women, Dec. 18, 1979, arts. 11.1(f), 12, 1249 U.N.T.S. 13, 18-19; International Convention on the Elimination of All Forms of Racial Discrimination, Mar. 7, 1966, art. 5(e)(iv), 660 U.N.T.S. 195, 222; European Social Charter, Oct. 18, 1961, art. 11(3), 529 U.N.T.S. 89, 104 (obligating states parties "to take appropriate measures designed *inter alia* . . . to prevent as far as possible epidemic, endemic and other diseases"); American Declaration of the Rights and Duties of Man, art. 11, OEA/Ser.L.V/II.82 doc. 6 rev.1, at 17 (1948) ("Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care . . . ."). Additionally, the obligation of states to protect the public health may be found through treaties protecting environmental health. David P. Fidler, *A Globalized Theory of Public Health Law*, 30 J.L. MED. & ETHICS 150, 156 (2002) (citing David P. Fidler, *Challenges to Humanity's Health: The Contributions of International Environmental Law to National and Global Public Health*, 31 ENVIRON. L. REP. 10048 (2001)).

In defining the contours of the right to health, the Preamble to the WHO Constitution declares that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being." It further notes that "governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures." WHO Constitution, *supra* note 40, pmbl. (defining health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"). Nevertheless, the WHO Constitution is not viewed as anything more than aspirational in defining the right to health. FIDLER, *supra* note 63, at 187 (citing Leary, *supra* note 59, at 489); Lawrence O. Gostin & Lance Gable, *The Human Rights of Persons with Mental Disabilities: A Global Perspective on the Application of Human Rights Principles to Mental Health*, 63 MD. L. REV. 20, 103 (2004) ("[I]f health is, in the World Health Organization's words, truly "a state of complete physical, mental and social well-being," then no one can ever achieve it.").

70. Leary, *supra* note 59, at 486; *see also* Fidler, *supra* note 69, at 156 ("The frequency with which states have used international law for the purpose of protecting and promoting human health speaks not only to states' legal powers to assure healthy conditions, but also to their respective duties to do so.").

71. *The Right of Everyone to the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission Resolution 2002/31*, U.N. ESCOR, 59th Sess., Agenda Item 10, ¶ 20, U.N. Doc. E/CN.4/2003/58

state practice under the aforementioned treaties and constitutions comports with a right to health, it has been advanced that these practices, followed out of a sense of legal obligation, have created norms of customary international law,[72] binding states to uphold the right to health.[73] However, since the right to health is consistently set forth in general, aspirational language that describes the ultimate goal but not the "actions that member nations must take,"[74] the treaty language, and possible customary law deriving therefrom, provides little guidance as to the specific scope of states' obligations under the right to health.[75]

The right to health remains a principle seeking a consensus. Outside of these sweeping platitudes, what specific rights does the right to health include? While criticized for its ambiguity,[76] the right to health has been

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(2003) (noting that either a right to health or a right to health care is codified in over sixty national constitutions).

72. Rights created through the general multilateral treaties transmute into universally applicable norms of customary international law when supported by widespread state practice upholding those norms. A. D'Amato, *Treaty-Based Rules of Custom*, *in* INTERNATIONAL LAW ANTHOLOGY 94 (A. D'Amato ed., 1994); *see* FIDLER, *supra* note 63, at 99 ("Typically, a rule of customary international law emanating from treaty-based practice originates in a multilateral treaty of general scope." (citing A. D'Amato, *supra*, at 100)). Likewise, multilateral treaties may codify existing custom.

73. *See* Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 IND. L. REV. 1457, 1464 (2001); Patrick L. Wojahn, Comment, *A Conflict of Rights: Intellectual Property Under TRIPS, the Right to Health, and AIDS Drugs*, 6 UCLA J. INT'L L. & FOREIGN AFF. 463, 493-96 (2002). *But see* Gostin & Gable, *supra* note 69, at 109 ("While the standard advanced by General Comment 14 may eventually become customary international law, the universal acceptance of a broad right to health may nonetheless not occur for an extended period of time."); Stephen J. Powell, *The Place of Human Rights Law in World Trade Organization Rules*, 16 FLA. J. INT'L L. 219, 229 (2004) (noting the silence of customary international law on the right to health).

74. Taylor, *supra* note 38, at 327. *But cf.* Gostin & Gable, *supra* note 69, at 101 (noting that "[r]egional instruments provide more detailed right to health provisions that more specifically outline State obligations").

75. FIDLER, *supra* note 63, at 188 (noting that "the text of [ICESCR] Article 12(2) is too general to provide insight into concrete actions States parties need to take"); David P. Fidler, *"Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries*, 42 HARV. INT'L L.J. 299, 348 (2001) ("No moral or legal standard exists that gives the right to health universal meaning.").

76. FIDLER, *supra* note 63, at 197 ("[T]he right to health is an international human right because it appears in treaties, but the right is so broad that it lacks coherent meaning and is qualified by the principle of progressive realization."); Lawrence Gostin & Jonathan Mann,

interpreted to include, at a minimum, basic provisions of health care necessary to save lives.[77] In 1978, the WHO International Conference on Primary Health Care issued "Health for All by the Year 2000," which has come to be called the Alma Ata Declaration, creating a model of state responsibility for universal access to primary health care.[78] Under the Alma Ata Declaration, the WHO laid out the essential aspects of primary health care, including:

> education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; *appropriate treatment of common diseases and injuries; and provision of essential drugs.*[79]

Twenty years later, the WHO followed up this conference with a new health policy, Health for All in the Twenty-First Century,[80] which focused primarily on health care. After reaffirming the essentials of primary health care from the Alma Ata Declaration, Health for All in the Twenty-First

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Toward the Development of a Human Rights Impact Assessment for the Formulation and Evaluation of Public Health Policies, *in* HEALTH AND HUMAN RIGHTS, *supra* note 60, at 54 (noting that "a human rights concept as the right to health has not been operationally defined"); Virginia Leary, *Concretizing the Right to Health: Tobacco Use as a Human Rights Issue*, *in* RENDERING JUSTICE TO THE VULNERABLE 161, 162 (Fons Coomans et al. eds., 2000) ("The efforts to clarify the right to health have often been either too theoretical or, alternatively, too detailed and unfocused, resulting in the widespread view that the right to health is an elusive concept and difficult to make operational."). *But see* Yamin, *supra* note 62, at 336 (arguing that "it can no longer be argued that the content of the right to health is unduly vague for implementing legislation or enforcement, or that it sets out merely political aspirations").

77. *See General Comment 14*, *supra* note 63, ¶ 36 (elaborating the specific state obligations necessary to fulfill the right to health under Article 12 of the ICESCR).

78. WORLD HEALTH ORG., GLOBAL STRATEGY FOR HEALTH FOR ALL BY THE YEAR 2000 (1981). For an explanation of WHO's organizational evolution through the "Health for All campaign," see Taylor, *supra* note 38, at 329, 314-23, 328-32 (noting that, despite its legal capacity to draft legislation, "WHO has been unable to ensure that nations give adequate and appropriate consideration to their obligations pursuant to the right to health").

79. ROSALIND POLLACK PETCHESKY, GLOBAL PRESCRIPTIONS: GENDERING HEALTH AND HUMAN RIGHTS 124 (2003) (quoting WORLD HEALTH ORG., *supra* note 78) (emphasis added).

80. *Health-for-All Policy for the Twenty-First Century*, WHA Res. 51.7, World Health Assembly, 51st Ass., Agenda Item 19, WHO Doc A51/VR/10 (May 16, 1998).

Century drew upon the right to health to recommit states "to strengthening, adapting and reforming, as appropriate, our health systems, including essential public health functions and services, in order to ensure universal access to health services that are based on scientific evidence, of good quality and within affordable limits, and that are sustainable for the future."[81]

Based upon these foregoing sources of international law, it can be concluded that while health care is a necessary component of the right to health, the right to health includes far more specific mandates on states.[82] In addition to disease prevention, the right to health requires states to address the treatments necessary for health promotion.[83] Individuals are entitled to certain "core elements" of the right to health, including the treatment of prevalent diseases, the provision of essential drugs, and safeguards against serious environmental health threats.[84] In assuring this individual right, states have affirmative obligations to provide universal access to health services and medications and to protect individuals from serious health infringements by third parties.[85]

But most obligations are not absolute. Outside of the core minimum content of the right to health,[86] states need only take steps toward the "progressive realization" of the right. In accordance with the principle of

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81. *Id.* art. III.

82. Mann et al., *supra* note 60, at 8; *see also* BRIGIT C.A. TOEBES, THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW 17-18 (1999) (comparing a "right to health" with a "right to health care" and finding the former to be more expansive and encompassing the latter).

83. WHO defines health promotion to include "the process of enabling people to increase control over, and to improve, their health." Ottawa Charter for Health Promotion, Nov. 21, 1986, http://www.who.dk/policy/ottawa.htm; *see also* LAWRENCE GOSTIN & ZITA LAZZARINI, HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC 29 (1997). At a minimum, a state has a duty "within the limits of its available resources, to *ensure the conditions necessary for the health* of individuals and populations." *Id.* (emphasis added).

84. TOEBES, *supra* note 82, at 284.

85. *Id.* at 337-38. Like all human rights, one aspect of state obligation under the right to health involves the obligation to protect, which "requires States to take measures that prevent third parties from interfering with article 12 guarantees." *General Comment 14*, *supra* note 63, ¶ 33.

86. "In order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations." *The Nature of States Parties Obligations (Art. 2, Par. 1), CESCR General Comment 3*, U.N. CESCR, 5th Sess., ¶ 10, U.N. Doc. E/1991/23 (1990).

progressive realization, legislatively enacted through the ICESCR, a state must take steps to uphold the right to health only "to the maximum of its available resources, with a view to achieving progressively the full realization of the rights."[87] Thus, in complying with the ICESCR's obligations under the right to health, states may justifiably differ in their actions based upon their respective political will, disease prevalence, and economic resources, so long as their compliance efforts "move as expeditiously and effectively as possible towards the full realization of article 12."[88] As a result, emphasis must be placed—particularly in developing states seeking to uphold the right to health—on the most cost-efficient delivery of life-saving services to the greatest number of people.[89]

B. Nicotine Addiction Implicates the Right to Health

The right to health does not include the right to be healthy, and, as such, it does not address an individual's lifestyle choices, regardless of their effects on health.[90] Yet, "[d]efining tobacco as a justice issue can be

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87. ICESCR, *supra* note 62, art. 2.

88. *General Comment 14, supra* note 63, ¶ 31; FIDLER, *supra* note 63, at 184 ("The principle of progressive realization stands, therefore, for two propositions: (1) the ability of States to fulfill the right to health differs because their economic resources differ; and (2) the different levels of economic development . . . mean that not all countries will enjoy an equivalent standard of health."); Steven D. Jamar, *The International Human Right to Health*, 22 S.U. L. REV. 1, 52 (1994) ("Implementation involves policy driven allocative judgments which are not based solely on principles or policies, but which are based also on political and economic considerations.").

89. Osita C. Eze, *Right to Health as a Human Right in Africa*, *in* THE RIGHT TO HEALTH AS A HUMAN RIGHT 76, 87 (1979) ("It is little use looking at the statistics to find out how many doctors and other auxiliary medical staff there are for a given number of the population; how many hospitals, clinics and beds are built or acquired every year, nor what percentage of the national budget is spent on providing health facilities to the population. It is necessary to ascertain how many benefit from these facilities."). As noted by Dr. Thomas Adeoye Lambo,

> The technologies to be used in achieving this transition [to the delivery of health care] should be capable of operations within the meagre financial and material resources of the poor communities of the Third World; be adapted to the available resources of human skills within the community; they should be socially and culturally acceptable and, lastly, be functionally efficient.

Id. at 78-79 (quoting A. Lambo, The Health of Man in a Sick World, paper presented at the 10th Anniversary Meeting of the Club of Rome).

90. *General Comment 14, supra* note 63, ¶ 8 ("The right to health is not to be understood as a right to be *healthy*."); *id.* ¶ 9 (excluding "unhealthy or risky lifestyles" from protection

contentious because many people still believe that tobacco use is solely an individual behavior choice and tobacco illness a lifestyle disease."[91] For smoking cessation to fall under the right to health, it is vital that smoking not be viewed as a personal decision or a distasteful habit but rather as a chronic illness largely outside the control of the individual.

For years, transnational tobacco corporations have successfully "blamed the victim," advancing the pseudo-scientific view that smoking is a lifestyle decision rather than a physiological addiction.[92] In doing so, the tobacco industry has tried to co-opt human rights rhetoric, cynically employing the language of "choice" to advance its corporate objectives.[93] However, smoking is not simply the result of conscious choice but rather the culmination of pharmacological, sociocultural, and demographic factors exploited by rapacious transnational tobacco corporations. Because tobacco use has been proven to result in a powerful addiction that impairs

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under the right to health in Article 12 of the ICESCR); Leonard S. Rubenstein, *Human Rights and Fair Access to Medication*, 17 EMORY INT'L L. REV. 525, 530 (2003) (noting that the right to health is "not a right to be healthy, since genetic make-up, *individual behavior* and other factors also affect health" (emphasis added)); Taylor, *supra* note 38, at 310 ("The right to health does not, however, constitute an entitlement to individual good health.").

91. Cheryl Healton & Kathleen Nelson, *Reversal of Misfortune: Viewing Tobacco as a Social Justice Issue*, 94 AM. J. PUB. HEALTH 186, 187 (2004).

92. *Id.* ("Tobacco marketers' public relations strategies have long sought, falsely, to frame the issue of tobacco use as one of 'freedom of choice' and 'smokers' rights' to downplay the nicotine-dependency argument.").

93. Crow, *supra* note 12, at 225 (suggesting the use of international legal bodies as a means of "enabl[ing] the tobacco control community to reclaim the language of rights from the tobacco industry, which regularly uses this tactic to promote its own objectives"); Peter D. Jacobson & Soheil Soliman, *Co-opting the Health and Human Rights Movement*, 30 J.L. MED. & ETHICS 705, 708 (2002) ("Internal tobacco industry documents show that the industry was aware early on that [human rights rhetoric] would be a powerful strategy for combating regulation.").

Despite this rhetoric of choice, the tobacco industry has been keenly aware of and exploited the commercial benefits of nicotine's addictive properties since at least 1962. STANTON A. GLANTZ ET AL., THE CIGARETTE PAPERS 58-60 (1996). Compounding this deceitful rhetoric, the CEOs of every major tobacco corporation swore before the U.S. Congress as late as 1994 that they believed nicotine not to be addictive. *See generally* PHILIP J. HILTS, SMOKE SCREEN: THE TRUTH BEHIND THE TOBACCO INDUSTRY COVER-UP (1996); Allan M. Brandt & Julius B. Richmond, *Tobacco Pandemic*, WASH. POST, Jan. 15, 2004, at A21. Even today, as tobacco executives attempt "to extricate the companies from the cul-de-sacs into which they had placed themselves by their earlier denial," they continue to deny the addictive power of nicotine, spuriously likening nicotine dependence to that of coffee and chocolate. Collin, *supra* note 12, at 77.

autonomous decision-making and impedes voluntary choice, an individual's decision to continue smoking cannot be said to be the result of a truly free and informed choice.[94] Through the addiction, "the freedom to commit obviously imprudent actions may have the consequence of creating conditions in which continuing autonomy can no longer be maintained."[95] As a result, tobacco control—once considered a private good, affecting only lifestyle choices—must now be reevaluated as a public good, requiring a public health based approach to treat involuntarily recalcitrant smokers.[96]

Although nicotine is not the direct agent of harm, it is nevertheless the pharmacological basis of tobacco smoking, causing deadly consequences for smokers and those exposed to environmental tobacco smoke. It is now axiomatic that nicotine is a drug of addiction, inducing pharmacological and behavioral processes similar to those of heroin and cocaine.[97] Cigarettes and other tobacco products can therefore be viewed as highly engineered drug delivery vehicles for sating this nicotine addiction, which, even if used as directed, can cause death. As such, it becomes clear that "[t]he cigarette did for nicotine what crack did for cocaine: it made the drug relatively convenient and uniquely addictive by making nicotine easily and conveniently inhalable."[98] Transnational tobacco corporations have marketed to this addition, with well over a billion people self-administering

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94. ROBERT E. GOODIN, NO SMOKING: THE ETHICAL ISSUES 7 (1989) (arguing that "what we are being protected from is something that would deprive us of the capacity for autonomous choice"). Furthermore, an individual's initial decision to begin smoking is made frequently when he or she is too young to be truly informed about the risks of smoking and give meaningful consent to those risks.

95. Albert Weale, *Invisible Hand or Fatherly Hand? Problems of Paternalism in the New Perspective on Health*, 7 J. HEALTH POL. POL'Y & L. 784, 800 (1983) (detailing the conditions under which "free decisions are unlikely to be the best guide to a person's interests"). Ironically, transnational tobacco corporations have consistently marketed cigarettes as a means of expressing freedom and individuality. Collin, *supra* note 12, at 72.

96. *See* Taylor & Bettcher, *supra* note 51, at 925 ("Traditionally, prevention or treatment of noncommunicable diseases was considered to be mostly a private good, since the risk factors associated with such diseases, including use of tobacco, are related to individual choices in lifestyle.").

97. U.S. DEP'T OF HEALTH & HUMAN SERVS., NICOTINE ADDICTION: THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL (1988); WORLD HEALTH ORG., *supra* note 1950, at 18; E.W. Lee & G.E. D'Alonzo, *Cigarette Smoking, Nicotine Addiction, and Its Pharmacologic Treatment*, 153 ARCHIVES INTERNAL MED. 34 (1993).

98. Henningfield & Slade, *supra* note 17, at 81 (citing John Slade, *Nicotine Delivery Devices*, *in* NICOTINE ADDICTION: PRINCIPLES AND MANAGEMENT 3 (C. Tracy Orleans & John Slade eds., 1993)).

a highly addictive psychoactive drug to maintain their deadly "habit." It is the nicotine addiction and withdrawal symptoms—not free choice—that prevent countless smokers from achieving and sustaining smoking cessation.[99] Thus, from a rights perspective, cessation interventions should be analyzed as nothing more than the clinical treatment of nicotine addiction and its concomitant manifestations of disease and death.

Nicotine addiction is a chronic illness, necessitating the state provision of medical resources to enhance individual autonomy in deciding whether or not to continue smoking. The WHO has recognized that nicotine addiction is a disease[100] and that "nicotine dependence is clearly a major barrier to successful cessation."[101] Viewing the right to health as a right that enhances autonomy and human dignity, states must prioritize health interventions to promote those treatments "most likely to increase autonomy amongst those least able to exercise it without outside help."[102] Treating those addicted to nicotine should be a priority. Yet the FCTC does not treat the addiction as a disease, denying tobacco the clinical diagnosis that would trigger obligations under the right to health.

C. A Right to Health Approach to Smoking Cessation

Although international treaties recognize a right to health, the right is frequently criticized for being "so broad that it lacks coherent meaning and is qualified by the principle of progressive realization."[103] Because of this, the WHO has rarely approached health issues from a human rights

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99. As noted by Drs. Henningfield and Slade in recognizing nicotine addiction as a disease unto itself:

> The American Psychiatric Association has identified two medical disorders that pertain to nicotine addiction: 1) nicotine dependence, which is a "pattern of repeated self-administration that usually results in tolerance, withdrawal, and compulsive drug-taking behavior," and 2) nicotine withdrawal, which causes "clinically significant distress or impairment in social, occupational, or other important areas of functioning."

Henningfield & Slade, *supra* note 17, at 79.

100. Second Meeting of the Working Group, *supra* note 52 (recalling, in the preamble of the Proposed Dependence Protocol, that "tobacco dependence is classified as a disease under the International Classification of Diseases (ICD-10), and that nicotine addiction is classified as a disease under the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)").

101. WORLD HEALTH ORG., *supra* note 19, at 19.

102. ALASTAIR V. CAMPBELL, MEDICINE, HEALTH AND JUSTICE: THE PROBLEM OF PRIORITIES 282 (1978).

103. FIDLER, *supra* note 63, at 197.

perspective.[104] In the present case, the FCTC never articulates the right to health as the normative justification for any of its obligations on states, robbing the FCTC of the moral authority necessary to enact comprehensive tobacco control programs.[105]

Under the right to health, states have affirmative obligations to provide tobacco cessation interventions that are available, accessible, culturally acceptable, and medically appropriate.[106] The AIDS pandemic refocused the right to health, reengaging primary health care as a bedrock of public health. Global control of the AIDS pandemic initially ignored the right of the afflicted to humane treatment. As noted by George Annas, this global AIDS strategy was based on a "war-containment or escalation discourse (the 'war on AIDS' strategy), in which control is viewed as an end in itself and the infected body becomes a battlefield."[107] Annas contrasted this with a "human rights discourse, in which our collective futures and the values of human flourishing and the right to humane treatment are paramount."[108] After years of scholarship and advocacy, this rights-based

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104. Leary, *supra* note 76, at 167 (noting that the WHO has "shown little interest in approaching health issues through the lens of human rights"). *But see also* Allyn L. Taylor, *Governing the Globalization of Public Health*, 32 J.L. MED. & ETHICS 500, 505 (2004) (recognizing that "notable strides were made to address the [WHO's] historical neglect of the linkage between health and human rights" during Dr. Brundtland's tenure as Director-General).

105. Although "[t]he possibility of including more direct references to the human rights implications of tobacco control in the FCTC was discussed at various points in the treaty's evolution," member states eventually relegated any mention of the right to health to the Preamble. Crow, *supra* note 12, at 222 n.78; *cf. International Law and Health, Two Approaches: The World Health Organization's Tobacco Initiative and International Drug Controls, Summary of Remarks by Virginia Leary*, 94 AM. SOC'Y INT'L L. PROC. 193, 195 (2000) (suggesting that "focusing on the problem of tobacco consumption is a useful means of concretizing the 'right to health' and thus joining the human right community in an alliance with the public health community in implementing that right"). While most studies attempt to expand the right to health to include aspects of preventive medicine, *e.g.*, FIDLER, *supra* note 63, at 305-07 (proposing a "Framework Convention on Infectious Diseases"), this Article attempts to define obligations pursuant to the core "health care" component of the right to health.

106. *See infra* note 114 and accompanying text.

107. George J. Annas, *The Impact of Health Policies on Human Rights: AIDS and TB Control*, *in* HEALTH AND HUMAN RIGHTS, *supra* note 60, at 37 (exploring the effect of discourse on public health strategies).

108. *Id.*; Yamin, *supra* note 62, at 330 ("The fundamental premise underlying the notion of universal human rights is that people are not expendable; those people's avoidable deaths are not just a tragic shame."); *see also infra* notes 168-185 and accompanying text (discussing the application of the right to health in establishing an entitlement to life-saving

discourse for AIDS treatment has now become engrained in the clarion call for access to antiretroviral therapies, with scholars arguing that "access to medications has been recognized as implicating both the right to life and the right to health under international law."[109] This paradigm shift has reinforced the normative content of the right to health, explicitly including a right to treatment for life-threatening disease. If humane medical treatment is to be found for smokers, it too may be found in the right to health.

Much like the inequity of focusing only on prevention while ignoring those suffering from AIDS, governmental focus solely on preventing the initiation of smoking violates the human rights of those already addicted to tobacco. In fulfilling obligations under the right to health with respect to tobacco control, states must develop intervention programs to treat addicted smokers.[110] As interpreted by the CESCR, a state's obligation to fulfill the right to health has three interrelated components:

> The obligation to *fulfil (facilitate)* [the right to health] requires States inter alia to take positive measures that enable and assist individuals and communities to enjoy the right to health. States parties are also obliged to *fulfil (provide)* a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal. The obligation to *fulfil (promote)* the right to health requires States to undertake actions that create, maintain and restore the health of the population.[111]

This tripartite framework requires states to establish a national policy to move progressively toward universal access to life-saving interventions.[112] Thus, states must intervene to provide access to tobacco cessation treatments—including, but not limited to, essential medications. In recognizing cessation under the right to health, it is imperative that states acknowledge cessation interventions as an essential treatment for the disease of addiction.

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medications).

109. Yamin, *supra* note 62, at 370.

110. Wike, *supra* note 62, at 360 (noting that "one could easily find a *state duty to render health care for those affected by tobacco,* both smokers and nonsmokers, as well as to redistribute the social costs of tobacco's ill effects") (emphasis added).

111. *General Comment 14, supra* note 63, ¶ 37.

112. Yamin, *supra* note 62, at 357-59.

D. Developing Hierarchy from the Cessation Continuum

The FCTC has promulgated low-cost policy approaches to smoking cessation that serve only to foster a social climate and supportive environment for quitting. These public health measures have allowed for the creation of smoke-free workplaces, increased taxation of tobacco, packaging regulations, enhanced education, and smuggling prohibitions. Although these measures do promote smoking cessation indirectly—denormalizing the act of smoking itself—such measures alone are clearly insufficient to aid those smokers addicted to tobacco and unable to quit.[113]

To fulfill its obligations under the right to health, a state must provide facilities, services, and essential medications that are: (1) available in sufficient quantity, (2) accessible without discrimination, (3) culturally acceptable, and (4) medically appropriate and of good quality.[114] While these aspects of the right to health are interrelated, each is essential to an equitable state cessation intervention. As science and technology have evolved, so too has the scope of each aspect of a state's obligations under the right to health.[115] Using these principles as a guide, states should undertake an evidence-based comprehensive health systems approach to tobacco control in addition to the public health programs within the FCTC.[116] This would allow states to take a more active role in smoking cessation by incorporating contemporary clinical best practices into their national health policy.[117]

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113. *E.g.*, Healton & Nelson, *supra* note 91, at 189 (noting that "[e]ven though cost may be an incentive to quit, tobacco addiction can be stronger than a rational financial decision").

114. *General Comment 14*, *supra* note 63, ¶ 12.

115. Taylor, *supra* note 38, at 311.

116. The distinctions between a public health approach and health systems approach to smoking cessation are noted in matrices developed at the June 2002 WHO meeting on Global Policy for Smoking Cessation in Moscow, Russia. WORLD HEALTH ORG., *supra* note 20, at 7-10.

117. *See General Comment 14*, *supra* note 63, ¶ 36 ("The obligation to *fulfil* [the right to health] requires States parties, *inter alia*, to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health."). Clinical best practices refer to evidence-based guidelines of smoking cessation compiled through meta-analyses of published research. The two major clinical best practices reports on tobacco cessation are the U.S. Agency for Health Care Policy and Research's *Clinical Practice Guideline for Smoking Cessation*, M. FIORE ET AL., U.S. AGENCY HEALTH CARE POL'Y & RESEARCH, SMOKING CESSATION: CLINICAL PRACTICE GUIDELINE NO. 18 (1996), *updated in* M. FIORE ET AL., U.S. DEP'T OF HEALTH & HUM. SERVS., TREATING TOBACCO

A health systems approach to smoking cessation includes both behavioral and pharmacological interventions to overcome an individual smoker's nicotine addiction.[118] This combination of interventions buttresses the individual smoker's ability to progress through the psychological stages of quitting (pre-contemplation, contemplation, readiness, action, and maintenance) while deterring relapse to addictive smoking behaviors.[119] Whereas providing a primary health care system is a core obligation of the right to health that cannot be deferred for lack of resources,[120] other resource-based obligations are to be assured through progressive realization over time.[121] Thus, although the health system's combination of behavioral and pharmacological interventions offers the

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118. Niaura & Abrams, *supra* note 28, at 499 (citing FIORE ET AL. (2000), *supra* note 117) (noting that "multicomponent programs enjoy greater efficacy compared with single component programs" and that "more is better"). The Proposed Dependence Protocol provides a preliminary definition of "tobacco dependence treatment," which "includes (singly or in combination) behavioural and pharmacological interventions such as education, brief counseling and advice, intensive support, administration of pharmaceuticals or other interventions that contribute to reducing and overcoming tobacco dependence in individuals and in the population as a whole." Second Meeting of the Working Group, *supra* note 52, at 6.

119. Multicomponent intervention outperformed either behavioral intervention or pharmacological intervention, when employed alone. MACKAY & ERIKSEN, *supra* note 6, at 82; John R. Hughes et al., *Recent Advances in the Pharmacotherapy of Smoking*, 281 JAMA 72, 75 (1999) (finding that pharmacological and behavioral interventions augment each other); Marcel E. Pieterse, *Effectiveness of a Minimal Contact Smoking Cessation Program for Dutch General Practitioners: A Randomized Controlled Trial*, 32 PREVENTIVE MED. 182, 188 (2001); Russell, *supra* note 21, at 20 ("When used as an adjunct to intensive support in specialized clinics NRT [nicotine replacement therapy] products are equally effective, with success rates averaging around 25-30% sustained, lapse-free, biochemically validated cessation throughout one year."). For theoretical hypotheses explaining the mechanisms through which behavioral and pharmacologic interventions augment each other, see John R. Hughes, *Combining Behavioral Therapy and Pharmacotherapy for Smoking Cessation: An Update*, *in* INTEGRATING BEHAVIOR THERAPIES WITH MEDICATION IN THE TREATMENT OF DRUG DEPENDENCE 92 (L.S. Onken et al. eds., 1995).

120. *General Comment 14*, *supra* note 63, ¶ 43; Rubenstein, *supra* note 90, at 531 (noting the importance of the obligation to provide essential drugs in assuring HIV antiretroviral therapies).

121. *See supra* notes 87-89 and accompanying text.

best hope for breaking tobacco dependence while remaining the least intrusive on other rights,[122] such comprehensive interventions are not currently within the capacity of many states. Still, for states seeking to allocate health resources to maximize the health of all of their citizens,[123] smoking cessation, relative to other public health measures, can offer the greatest return (in lives saved) on a state's investment.[124] Further, states can maximize efficiency by coordinating mechanisms of behavioral and pharmacological interventions through public or private insurance schemes. In allocating these resources to achieve the progressive realization of the right to health, the following cessation intervention hierarchy would allow states to prioritize smoking cessation methods in accordance with the right to health while acknowledging national circumstances and resource availability.[125]

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122. WORLD HEALTH ORG., *supra* note 19, at 19 ("In preparing national tobacco control plans and strategies, planners may wish to encourage the provision of a broad range of smoking cessation strategies that would include combinations of the most effective group programmes of smoking cessation, physician advice and, where appropriate, nicotine replacement therapy."); WORLD HEALTH ORG., *supra* note 20, at 51 (noting that "a combination of behavioural and pharmacological treatment produces the best outcomes"); Henningfield & Slade, *supra* note 17, at 79; Warner, *supra* note 20, at 115 ("The combination of serious physician counseling with patient follow-up and use of pharmacotherapy can produce cessation rates in the vicinity of 30%.").

123. *See* Theo C. Van Boven, *The Right to Health: Paper Submitted by the United Nations Division of Human Rights*, *in* THE RIGHT TO HEALTH AS A HUMAN RIGHT, *supra* note 89, at 54, 63-64 (noting that the United Nations Division of Human Rights has investigated "[w]hether advanced medical techniques for the prolongation of life should be applied to a few patients as long as the cost involved curtails the provision of less sophisticated medical care . . . for the many . . . where the economy cannot accord to every sick person the entire range of available medical treatment from which he could benefit").

124. *See* Lawrence O. Gostin, *Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann*, 29 J.L. MED. & ETHICS 121, 125 (2001) ("When public health authorities work in the areas of tobacco control, the environment, or occupational safety, for example, their belief is that everyone will benefit from smoking cessation, clean air, and safe workplaces."); Niaura & Abrams, *supra* note 28, at 502 ("[S]moking cessation interventions are arguably the most cost-effective of any preventive or other medical interventions. Moreover, interventions are cost-effective across a range of intensity, for example, from clinician advice to pharmacotherapy to specialized clinics . . . ." (citing Tammie O. Tengs et al., *Five Hundred Life Saving Interventions and Their Cost Effectiveness*, 15 RISK ANALYSIS 369 (1995)).

125. Whereas the Second Meeting of the Working Group articulates several of the cessation interventions analyzed herein, *see* Second Meeting of the Working Group, *supra* note 52, the Proposed Dependence Protocol fails to address how these mechanisms should

1. Behavioral Interventions

Behavioral interventions offer the best opportunity for states to control tobacco addiction at limited cost. Given that "[s]ocial support for quitting should be possible in all countries, even those with extremely limited resources,"[126] the right to health mandates that states undertake the lifesaving behavioral interventions discussed below without regard to state resources. More burdensome than the requirements of the FCTC, the following cessation programs require state action to establish a scientifically based institutional framework for behavioral interventions.

a. Physician Advice[127]

A state health system can only succeed in meaningfully reducing smoking prevalence where individual physicians reach out directly to their patients who smoke.[128] Studies have shown that even brief advice from a physician can dramatically increase cessation rates, improving abstinence rates by up to thirty percent.[129] Because of the frequency with which smokers are forced into the health care system and the efficacy of physician advice, physician interventions—including information, services, and referrals—promise to be the most efficient cessation treatment in successfully influencing the greatest number of smokers motivated to quit.[130]

Despite this, many physicians eschew treatment of tobacco addiction

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be attained in the context of the principle of progressive realization, *see supra* note 88 and accompanying text.

126. WORLD HEALTH ORG., *supra* note 20, at 51 (citation omitted).

127. In this context, "physician advice" refers to any one-on-one cessation intervention delivered in the context of other medical services by any health care provider, including doctors, nurses, nurse practitioners, pharmacists, and dentists.

128. Russell, *supra* note 21, at 20 ("It is only through the primary care system that large enough numbers of smokers can be reached to produce a significant reduction in national prevalence.").

129. ROYAL COLLEGE OF PHYSICIANS, NICOTINE ADDICTION IN BRITAIN: A REPORT OF THE TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS (2000); Niaura & Abrams, *supra* note 28, at 497 (noting that "there is a dose-dependent relationship between the intensity of person-to-person contact and successful cessation outcome") (citations omitted); Pieterse, *supra* note 119, at 187.

130. David B. Abrams et al., *Integrating Individual and Public Health Perspectives for Treatment of Tobacco Dependence Under Managed Health Care: A Combined Stepped-Care and Matching Model*, 18 ANNALS BEHAV. MED. 290, 294 (1996) (defining efficiency as the product of population, reach, and efficacy).

because they lack the resources, motivation, and understanding necessary for effective intervention.[131] Consequently, the WHO has advised that "[a]ll health professionals, including doctors, nurses and pharmacists, should be given both basic and in-service training so that they are capable of providing advice and treatment for tobacco dependence."[132] As noted in the FCTC, states should "include diagnosis and treatment of tobacco dependence and counselling services on cessation of tobacco use in national health and education programmes, plans and strategies, with the participation of health workers, community workers and social workers."[133] Realizing this aspiration involves education in smoking and smoking cessation as part of the core curriculum of schooling and post-graduate training, with detailed education in smoking for physicians specializing in oncology, cardiovascular disease, obstetrics, and adolescent health.[134]

By relating one-on-one with the patient, physicians can provide efficacious, culturally sensitive advice that is appropriately tailored to the patient's individual smoking habits and quitting methods.[135] This "patient-

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131. WORLD HEALTH ORG., *supra* note 20, at 52; *see also* L.H. Ferry et al., *Tobacco Dependence Curricula in US Undergraduate Medical Education*, 282 JAMA 825, 825 (1999); Niaura & Abrams, *supra* note 28, at 497 (listing the barriers that influence physician readiness to adopt smoking cessation interventions and recognizing that "effective strategies are needed to enhance the adoption of efficacious smoking cessation interventions within a population of primary care physicians and practices"); J.G. Spangler et al., *Tobacco Intervention Training: Current Efforts and Gaps in US Medical Schools*, 288 JAMA 1102, 1108 (2002). Although physicians generally are not trained for cessation services, or reimbursed for their counseling efforts, the availability of NRTs, *see infra* Subsection II.D.2.a, has given physicians a clinical reason to engage their patients about smoking. Warner, *supra* note 20, at 116. *But see* Hughes et al., *supra* note 119, at 75 (theorizing that "approval of OTC [over the counter] medications for smoking cessation may have prompted some physicians to become less interested in providing smoking cessation prescriptions").

132. WORLD HEALTH ORG., *supra* note 19, at 19; *see also* WORLD HEALTH ORG., *supra* note 20, at 17 ("Efficacious and highly cost-effective treatments have been reviewed in many countries and institutions and they advocate that all health-care personnel and clinicians should consistently deliver smoking cessation interventions to their patients.").

133. FCTC, *supra* note 1, art. 14(2)(b).

134. As noted by the WHO, this training could be accomplished "by working with international associations such as World Medical Associations, the World Organization of Family Practitioners, and the International Council of Nurses to develop model tobacco control curriculum and course outlines for basic training in delivering smoking-cessation therapies." WORLD HEALTH ORG., *supra* note 20, at 54. In addition, states should initiate their efforts by lowering the prevalence of smoking among those in the health professions. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 6.

135. *See* Warner, *supra* note 20, at 116 ("[B]ehavioral scientists have developed financially

treatment matching" would allow assessment prior to treatment, improving both cost-effectiveness and overall efficacy.[136] While personalized to the individual smoker, this opportunistic system of treatment nevertheless should be based on firm guidelines, for example the United States's Public Health Service's Guidelines' "five As" of individual smoking cessation: Ask about smoking at every opportunity and record smoking status; Advise the smoker to stop; Assess the smoker's willingness to stop; Assist the smoker to stop through recommendation of treatments and referral to specialists; Arrange follow-up with the smoker.[137] This intervention strategy is adaptable to several cultures and has been proven efficacious in controlled trials. Specific physician assistance can include helping the smoker to set a quit date, suggesting behavioral strategies to prevent relapse, and prescribing pharmacotherapies to aid those for whom breaking the nicotine addiction requires more than educational and motivational help.[138]

b. Counseling/Support Groups

In contrast to the brief advice of a physician, intensive counseling involves repeated behavioral interventions. As recognized in the FCTC, albeit with its nonobligatory language,[139] states "shall endeavour to" provide cessation counseling by "establish[ing] in health care facilities and rehabilitation centres programmes for diagnosing, counselling, preventing and treating tobacco dependence . . . ."[140] In practice, this will involve a

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feasible means of tailoring cessation messages and strategies to the needs and desires of specific individuals."); *cf.* Judith Mackay, *Combating Addiction in Developing Countries*, 16 WORLD HEALTH F. 25, 27 (1995) (noting that physicians often fail in promoting smoking cessation when they give the same advice to all smokers) (citing Professor Robyn Richmond).

136. Niaura & Abrams, *supra* note 28, at 499 ("The major theoretical advantage of matching is that smokers can be assessed according to some relevant, predictive dimension prior to treatment, be assigned to receive the treatment that is appropriate and adequate for them, and can avoid thereby the cumulative burdens of trial and failure." (citations omitted)).

137. FIORE ET AL. (2000), *supra* note 117; *see also* EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 5 (recommending guidelines for physician interventions) (citing TJ GLYNN & MW MANLEY, HOW TO HELP YOUR PATIENTS STOP SMOKING: A NATIONAL CANCER INSTITUTE MANUAL FOR PHYSICIANS (1989); FIORE ET AL. (2000), *supra* note 117).

138. *See infra* Subsection II.D.2.

139. *See supra* note 48 and accompanying text (noting the nonobligatory use of "shall endeavour to" in Article 14 of the FCTC).

140. FCTC, *supra* note 1, art. 14(2)(c).

"smoking cessation specialist," who works with either individuals or groups to offer coping skills and social support throughout smoking cessation.[141] These specialists need not be physicians, thus allowing every state to provide this intervention in meeting its obligations under the right to health.[142] However, because this intervention requires repeated, specialized interaction, it will be more expensive than physician counseling and less likely to appeal to the greatest number of smokers.[143] Consequently, this form of intervention is not the most advantageous primary means of tobacco cessation intervention, but may nevertheless prove cost-effective as a secondary means of cessation intervention for smokers unable to quit through other means.[144]

To ease patient cost outside of traditional counseling formats, telephone help lines,[145] in addition to nascent Internet-based counseling,[146] offer promise for efficacious future treatments as these burgeoning techniques become more widely available and progress from low-cost self-help materials to easily accessible interactive tools. By offering alternative forms of cessation interventions, state programs may more easily reach the smokers least motivated to quit while continuing to allow the interpersonal delivery of services tailored to each individual's needs.[147]

2. Pharmacotherapies

Pharmacotherapies, including nicotine replacement therapy (NRT) and non-nicotine medications, are medically appropriate means of breaking addiction and saving lives. While not guaranteeing the success of

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141. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 5-6.

142. *See* WORLD HEALTH ORG., *supra* note 20, at 51 ("All countries have lay persons who can provide informal social support for quitting and who can be trained to conduct more formal interventions.").

143. Niaura & Abrams, *supra* note 28, at 495 (noting that "expensive and more efficacious treatments (e.g., combined pharmacologic and behavioral interventions delivered by smoking cessation specialists) are by definition less able to be disseminated widely and are less likely to appeal to most smokers").

144. *Id.* (citing E. Lichtenstein & R.E. Glasgow, *Smoking Cessation: What Have We Learned over the Past Decade?*, 60 J. CONSULTING & CLINICAL PSYCHOL. 518 (1992)).

145. EUR. P'SHIP TO REDUCE TOBACCO DEPENDENCE, *supra* note 26, at 6 (noting that "[t]elephone help lines can be effective and are very popular with smokers").

146. WORLD HEALTH ORG., *supra* note 20, at 21-22 (discussing QuitNet, *at* http://www.quitnet.org; and stop-tabac.ch, *at* http://www.stop-tabac.ch).

147. For advantages of patient-treatment matching through tailored cessation interventions, see *supra* note 136 and accompanying text.

every quit attempt,[148] pharmacotherapies nevertheless represent a clinically effective means of cessation. Pursuant to the right to health, states should take steps to ease the regulation of NRT and non-nicotine medication and make such options available without prescription through either public or private insurance coverage. To assure this, states must use their public health apparati to assure that these medications are selected solely on the basis of clinical best practices and are accessible through reliable means of distribution to the greatest number of persons. Of course, any discussion of access to pharmacotherapies necessarily implicates the antagonism between international trade regimes and the right to health. As discussed in Section II.E, states should employ the public health exception to international trade agreements, making the production and importation of these treatments affordable, and thus economically accessible, to all. Eliminating institutional barriers to NRTs and non-nicotine medication use would spur pharmaceutical company investment in research and development of new pharmacotherapies.[149] To aid this effort, states may, in accordance with the right to health, collaborate in research regarding new NRT and non-nicotine therapies, incorporating these innovative pharmacotherapies into culturally appropriate cessation interventions.

a. Nicotine Replacement Therapy

In the form of patches, gums, sprays, lozenges, or inhalers,[150] NRT

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148. *See* Niaura & Abrams, *supra* note 28, at 500 tbl.1 (comparing the efficacies of various smoking treatments (i.e., gum, patch, spray, inhaler, bupropion, and clonidine) relative to placebo). Because these pharmacotherapies, as distinguished from "essential" HIV antiretroviral therapies, are neither absolutely necessary nor clearly sufficient to save lives, it is unclear whether access to these treatments can be considered core obligations under the right to health. *Cf. infra* text accompanying notes 191-192 (discussing the implications of pharmacotherapies being labeled "essential drugs").

149. *See* Henningfield & Slade, *supra* note 17, at 90 (noting that "decisions of corporate entities are based on all available sources of information—both the real and projected regulatory obstacles (including anticipated size of clinical trials), as well as past and projected marketing obstacles (including restrictions on claims)").

150. While there are some comparative advantages to each form of NRT—mostly dealing with "preference, affordability and side effects"—there are only marginal differences in cessation efficacy among the various forms. Hughes et al., *supra* note 119, at 75 (advocating patient preference as the "primary basis" for choosing among NRTs); Niaura & Abrams, *supra* note 28, at 500. For a description of the comparative clinical advantages of the various forms of NRT, see Karl Olov Fagerström, *Nicotine-Replacement Therapies*, *in* NICOTINE AND PUBLIC HEALTH, *supra* note 46, at 199, 200-03; and Henningfield & Slade, *supra* note 17, at 82, 86-88.

allows nicotine maintenance or reduction while diminishing or eliminating the deleterious consequences associated with the use of tobacco products, allowing smokers to modify their behaviors without additionally having to combat the addictive hold of nicotine and its associated withdrawal symptoms.[151] As such, NRTs disaggregate nicotine addiction from tobacco dependence, giving individuals the opportunity to abstain from tobacco without being forced to abstain additionally from nicotine.[152] The clinical community regards NRT to be safe (in both the short and long term) and effective, "doubl[ing] the success rates of other cessation efforts, whether or not other interventions are used in parallel."[153]

NRTs are cost-efficient,[154] self-administrable,[155] and do not require continuous physician intervention.[156] The widespread use of NRTs could avert the deaths of millions of smokers and those exposed to

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151. The use of NRTs is based on the theory that "tobacco users could use a safer form of nicotine delivery to break the nicotine-addiction cycle by enabling them to achieve and sustain abstinence from tobacco products while they established new behaviors to resist relapse." Henningfield & Slade, *supra* note 17, at 85 (citing Jack E. Henningfield, *Nicotine Medications for Smoking Cessation*, 333 NEW ENG. J. MED. 1196 (1995)).

152. It is important to note again that the FCTC refers only to "tobacco dependence," rather than "nicotine addiction." *See supra* notes 45-46 and accompanying text. Although the medical community often uses these two terms interchangeably, the advent of NRT clearly implicates the distinction between the uses of these terms in devising tobacco cessation programs.

153. WORLD BANK, *supra* note 7, at 54, 55 tbl. 4.3 (citing Raw et al., *Smoking Cessation: Evidence-Based Recommendations for the Healthcare System*, 318 BRIT. MED. J.182 (1999)).

154. WORLD HEALTH ORG., *supra* note 19, at 19 ("Although there can be an initially higher cost for NRT, it can be more cost-efficient in the long run for both individuals and governments."); Novotny et al., *supra* note 27, at 302 (noting that "NRTs could cost about $276 per disability-adjusted life-year (DALY) in low-income and middle-income countries," below the cost-effectiveness limit set by the World Bank for these settings); *cf.* WORLD BANK, *supra* note 7, at 56 ("The cost-effectiveness of nicotine replacement therapy has not been studied widely, especially in the low-income and middle-income countries where most smokers live."); Shibuya et al., *supra* note 11, at 156 tbl. (calculating the cost effectiveness of NRT by WHO geographic subregion).

155. At present, smokers may obtain many NRTs in varied doses of nicotine delivery, allowing them to self-adjust their nicotine intake. *See* Fagerström, *supra* note 150, at 200-02 (discussing the pharmacokinetics of nicotine gum, transdermal patch, nasal spray, oral inhaler, and sublingual tablet).

156. WORLD BANK, *supra* note 7, at 54 (noting the advantages of self-administration for smokers "in countries where there are limited resources for intensive support by health professionals").

environmental tobacco smoke.[157] Yet NRTs are significantly more difficult and expensive to obtain than tobacco products, particularly in the developing world.[158] In upholding the right to health, states must lower marketing regulations on NRTs and subsidize them to the greatest extent possible through either private or public insurance mechanisms, thereby making NRTs as readily available as the addictive products they serve to counteract.[159] As empirically shown, NRTs would be most effective in reaching the largest number of smokers if they became, in order of importance: (1) available over the counter, rather than solely by prescription;[160] (2) sold in lower supply, rather than as a whole course of

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157. *Id.* at 56.

158. As noted by the WHO,

> whereas the tobacco industry ensures that tobacco products are readily available, attractive, and highly affordable, pharmacotherapy is frequently out of reach, available often only by prescription or from limited points of sale, and is often more expensive on a daily basis and point of sale basis because it is generally distributed in packages that include behavioural treatment guidance and sufficient units to discourage simple occasional use as a temporary substitute for tobacco.

WORLD HEALTH ORG., *supra* note 20, at 16; *see also* Henningfield & Slade, *supra* note 17, at 76 (noting that "proven effective tobacco-dependence treatments remain far more restricted in marketing (and thus far less appealing), and far less accessible than tobacco products"); Novotny et al., *supra* note 154, at 293, 299 (noting the availability of NRT products in various countries and concluding that "the regulation of pharmaceutical nicotine products is considerably more extensive than the regulation of cigarettes . . . giv[ing] cigarettes market advantages"). In addition to financial accessibility, NRTs are less clinically appealing than cigarettes as a vehicle for nicotine administration. Henningfield & Slade, *supra* note 17, at 83 (noting that "individuals will choose a product (e.g., cigarettes) that provides an immediate, neurologically-based reward, albeit with a substantial risk of disease in the future, over a product (e.g., nicotine medications) that provides little immediate reinforcement and the distant reduction of the risk of tobacco-related disease").

159. *See* Henningfield & Slade, *supra* note 17, at 81 (noting that cessation interventions "may be viewed as countermeasures to the forces [of tobacco] (such as low unit purchase price, wide availability, ubiquitous advertising, images of glamorization, and comparatively high social acceptability relative to illicit drugs)").

160. Fagerström, *supra* note 150, at 205 ("[A doctor's prescription] can be a big obstacle for those who are not close to a physician or who do not have the resources to take time off to see a doctor and pay for the prescription. The need for a prescription may also reinforce an unfortunate notion that there are adverse effects with nicotine-replacement products, while cigarettes must be relatively safe because they are sold freely."). *But see* Niaura & Abrams, *supra* note 28, at 500 (noting that "the efficacy of the gum and patch in [the OTC] environment is less than that observed in controlled clinical trials and probably depends to a significant degree on factors such as underdosing, ceasing use prematurely, using

treatment with a large initial payment;[161] and (3) subsidized as part of a health care plan.[162] Through such steps, NRTs have the potential to reach those who need them, dramatically decreasing tobacco-induced disease and death.

b. Non-Nicotine Medication

Bupropion hydrochloride, an antidepressant, has been approved in the United States for use as a first-line therapy for smoking cessation.[163] Marketed by GlaxoSmithKline as Zyban®, this sustained-release formulation of bupropion is the first non-nicotine-based medication to receive approval by the United States Food and Drug Administration. In clinical trials, bupropion doubled rates of cessation as compared to placebo.[164]

In addition, the United States Food and Drug Administration has considered—but not yet approved—clonidine (an antihypertensive agent that alleviates withdrawal symptoms) and nortriptyline (an antidepressant) as effective pharmacotherapies for smoking cessation. While clonidine has proven efficacy, it is considered a second-line pharmacologic agent, "partly because of increased likelihood of side effects and rebound blood pressure problems on discontinuation of the drug," and, thus, it is recommended for use only contingent upon bupropion failure.[165]

Despite the early successes of non-nicotine-based medications, "[s]urprisingly little is know[n] about mechanisms of efficacy for

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inappropriately, and having an (un)availability of supplemental behavioral treatment"). For a state-by-state analysis of NRT availability over-the-counter, see MACKAY & ERIKSEN, *supra* note 6, at 82-83.

161. Fagerström, *supra* note 150, at 205 (noting that although NRTs are comparable in price to cigarettes, "[m]uch of the perception of high price is related to the larger package sizes compared with cigarettes, which require a greater outlay of money at one time").

162. If subsidized as part of a private or public health care plan, large-scale procurement would allow insurers to drive down the costs of therapy, using their bargaining leverage in ways similar to those used in obtaining vaccines. Christiane Poulin, *The Public Health Implications of Adopting a Harm-Reduction Approach to Nicotine*, *in* NICOTINE AND PUBLIC HEALTH, *supra* note 46, at 429, 432-33.

163. WORLD HEALTH ORG., *supra* note 20, at 34 (citing FIORE ET AL. (2000), *supra* note 117).

164. Richard D. Hurt et al., *A Comparison of Sustained-Release Bupropion and Placebo for Smoking Cessation*, 337 NEW ENG. J. MED. 1195, 1199 (1997).

165. Niaura & Abrams, *supra* note 28, at 500.

bupropion and other antidepressants such as nortriptyline."[166] There is concern that the product development pipeline may dry up unless research partners collaborate to share the burdens of pharmacotherapy research.[167] Through the FCTC framework, states—including state research partnerships with the private sector—have an opportunity to develop these collaborations in researching the biochemical mechanisms of action employed by non-nicotine medications, improving their use and efficacy and engendering the development of new therapeutic compounds.

E. Access to Medications

By invoking the right to health in the context of the FCTC, states would have obligations to provide these vital autonomy-enhancing medications in fulfilling the human rights of those addicted to nicotine.[168] Given the importance of pharmacotherapies in treating tobacco addiction, it is of paramount importance that states make these products accessible. Yet for a state to make these medications accessible in compliance with the right to health will require that they be both physically and economically accessible to all who need them.[169] This cannot be done solely through cooperation with pharmaceutical corporations, whose profit motive often conflicts with public health. Fulfilling these human rights, i.e., making

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166. *Id.*

167. *Id.* at 501-02. *But see* Brion J. Fox & Joanna E. Cohen, *Tobacco Harm Reduction: A Call To Address the Ethical Dilemmas*, 4 NICOTINE & TOBACCO RES. S81, S83 (2002) (noting that the majority of U.S. clinical drug trials are performed by pharmaceutical corporations, which forces researchers investigating NRT and non-nicotine therapies to work with, and possibly be controlled by, private corporations driven solely by profit).

168. In addition to the right to health, an argument may be made for universal access to NRTs pursuant to the ICESCR's guarantee of the right of everyone to enjoy the benefits of scientific progress and its applications. *See* GOSTIN & LAZZARINI, *supra* note 83, at 135 (noting that Article 15 of the ICESCR "aims to bring essential scientific advances to not only those who can pay for them"); Rubenstein, *supra* note 90, at 532 (arguing that the ICESCR implies a balance between human rights and intellectual property rights); Yamin, *supra* note 62, at 343-44 (advancing a right to antiretroviral therapies under, inter alia, ICESCR's right to the benefits of scientific progress). *Compare* ICESCR, *supra* note 62, art. 15(1)(b) (recognizing "the right of everyone . . . [t]o enjoy the benefits of scientific progress and its applications"), *with* ICESCR, *supra* note 62, art. 15(c) (recognizing "the right . . . [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author"). *But see also* FIDLER, *supra* note 63, at 212 ("Within the context of the ICESCR, the right to enjoy the benefits of scientific progress seems to have received less attention than the right to health.").

169. *General Comment 14*, *supra* note 63, ¶ 12(b).

medications affordable, will require states to combat the injurious mechanics of international trade, a confrontation intentionally avoided by the FCTC.[170] As with the medicalization of HIV treatment, expanded NRT access for states with limited resources will need to circumvent intellectual property protections provided for by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[171]

In complying with their obligations under the right to health, it is possible for states to circumvent pharmaceutical patents without acting in willful contravention of international trade laws. Maneuvering within the TRIPS regime, Article 8 of the TRIPS Agreement permits a limitation on the TRIPS requirement that states establish standards for protecting intellectual property rights where noncompliance is "necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."[172] The World Trade Organization drafted this admittedly ambiguous exception to balance "the goal of providing incentives for future inventions of new drugs and the goal of affordable

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170. Hammond & Assunta, *supra* note 41, at 242 ("The relationship between the FCTC provisions and international trade agreements—one of the most contentious issues in the negotiations—was left ambiguous in the final document, again a result of developed country pressure.").

171. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS]. Some scholars have argued, in the case of HIV antiretroviral therapies, that the rights to life and health should take precedence over intellectual property agreements, negating any discussion of TRIPS in providing access to life-saving medications. Rubenstein, *supra* note 90, at 532; Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 120-25 (2003). In so doing, these scholars advance the CESCR's interpretation of the right to health as "clearly alluding to the core obligation to provide essential medications . . . 'emphasiz[ing] that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or with any other right set out in the Covenant is inconsistent with the legally binding obligations of the state party.'" Yamin, *supra* note 62, at 344 (quoting *Human Rights and Intellectual Property*, U.N. CESCR, 27th Sess., ¶ 12, U.N. Doc. E/C.12/2001/15 (2001)).

172. TRIPS, *supra* note 171, art. 8. Nevertheless, it remains unclear how this exception will apply in practice. *See* Rubenstein, *supra* note 90, at 533 (arguing that the WTO should "take the next step beyond a vague commitment to public health to assure that its interpretations of trade agreements are consistent with international human rights law, including the right to health and its requirement of making essential medicines available").

access to existing drugs."[173] In fact, Brazil, India, Thailand, and South Africa employed this very argument to allow for the manufacture, compulsory licensing, and parallel importation of generic HIV antiretroviral therapies.[174] In the wake of this multinational rebellion against TRIPS's barriers to addressing the AIDS pandemic, the World Trade Organization has reaffirmed its commitment to the public health safeguard provisions, adopting at the 2001 Doha, Qatar conference the developing states' position that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[175] In so doing, the Doha Declaration recognizes access to life-saving medications as part of the human right to health.[176]

From this human rights perspective, both within and apart from the TRIPS framework, developed states may have an obligation under the right to health to provide assistance to developing states in realizing their obligations for smoking cessation.[177] These developed states currently fail to respect or protect the right to health by restricting developing states' access to medications, abusing TRIPS mechanisms in enforcing the rights of pharmaceutical corporations abroad.[178] In fact, these obligations on developed states, while not explicitly stated in rights discourse, underlie

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173. WORLD HEALTH ORG. & WORLD TRADE ORG., WTO AGREEMENTS & PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT 41 (2002).

174. PETCHESKY, *supra* note 79, at 81 (noting that the threats of lawsuits and economic sanctions by the United States and multinational drug companies may itself violate the TRIPS regime).

175. *Ministerial Declaration*, WTO Ministerial Conf., 4th Sess., WT/MIN(01)/DEC/1 (Nov. 14, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm. Rosalind Petchesky attributes the success of this position at the Doha conference to, inter alia, weakened U.S. opposition on the subject as a result of the United States's own consideration of compulsory licensing of the drug Cipro in the face of the U.S. anthrax deaths of 2001. PETCHESKY, *supra* note 79, at 106. However, Petchesky notes that the United States has systematically attempted to weaken consensus on the Declaration since the Doha conference. *Id.* at 107.

176. PETCHESKY, *supra* note 79, at 106.

177. *See* Rubenstein, *supra* note 90, at 53 (noting an "obligation of international assistance and cooperation" on developed states). Some have argued that developed states are currently failing to respect the right to health just by promoting tobacco and transnational tobacco corporations overseas, affirmatively causing harm to foreign citizens. Wike, *supra* note 62, at 359-60.

178. Yamin, *supra* note 62, at 353 (noting that "laws and regulations that would restrict access to medications by increasing prices—thereby decreasing access—would presumptively constitute a violation of the state party's obligations under the ICESCR").

the FCTC cessation provision, which encourages states to "collaborate with other Parties to facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products."[179] In complying with Article 14 of the FCTC, such collaborative efforts might include, for example, direct aid to developing states, the establishment of a "global fund" for tobacco cessation, or preferential humanitarian pricing for low-income markets. Similar arguments were successfully made in gaining access to HIV anti-retroviral medications under the right to health.[180] Member states clearly were aware of the AIDS treatment analogy when they drafted the text of Article 14.[181] Following the June 2002 WHO meeting on Global Policy for Smoking Cessation, the meeting's policy recommendations advocated that:

> It is critical to make cessation products more affordable to those who, so far, have been unable to afford them. It might be worthwhile to organize a campaign similar to that undertaken for AIDS treatment in Africa, which placed significant international pressure on pharmaceutical companies to reconsider their pricing policies for AIDS drugs in poor African countries where the pandemic was escalating. Similarly, there is an argument to be made for making available cheap generic variants of NRT and Zyban-like products and for the relaxation of patent laws for cessation products on the basis of the extremely high death toll exacted by smoking and other tobacco use.[182]

Yet despite this convenient AIDS analogy, smokers—with a less compassion-inducing cause and a lack of stigma-induced cohesion—clearly

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179. FCTC, *supra* note 1, art. 14(2)(d). This principle is advanced more specifically in the Proposed Dependence Protocol, which requires that "Parties shall take into account the particular needs of developing countries and assist in improving their national capacities and capabilities to participate in the measures [to treat tobacco dependence]." Second Meeting of the Working Group, *supra* note 52.

180. *E.g.*, WORLD HEALTH ORG., MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 86-90 (2001); Lazzarini, *supra* note 171, at 115-20. *But cf.* PETCHESKY, *supra* note 79, at 110 (criticizing the World Health Organization's differential pricing and public-private partnership arrangements because they "work to preserve the system of patents, pre-empt compulsory licensing, construct price reductions as a voluntary or 'charitable' response, and thus protect the entire system of markets and capitalist profits").

181. *See supra* note 179.

182. WORLD HEALTH ORG., *supra* note 20, at 57; *see also id.* at 58 (arguing that "consideration should . . . be given to the liberalization of trade rules where cessation products are involved").

lack the mobilization apparati that have been a hallmark of the myriad organizations fruitfully demanding treatment for HIV.[183] As noted in Professor Rosalind Petchesky's assessment of HIV advocacy, "[t]here is no doubting the effective role that demonstrations and other forms of direct action have played in pressuring the US government and transnational drug companies to make significant concessions and in creating a broad public awareness of access to treatment as a human rights issue."[184] Although tobacco will cause more preventable deaths than AIDS over the next century, anti-tobacco advocates have not approached the mobilization or litigation efforts of the global campaign for access to essential medicines for HIV treatment.[185] This is due in part to nongovernmental tobacco control organizations' inability and unwillingness to engage in the human rights debate necessary to lobby for access to pharmaceutical treatments.[186] Consequently, cessation advocacy groups have not gained the public relations leverage necessary to galvanize public opinion for access to treatment. Thus, although the FCTC emphasizes the importance of financial assistance, steadfast resistance from developed states postponed discussion of funding mechanisms until the (currently ongoing) Intergovernmental Working Groups for the establishment of the Conference of the Parties.[187] Once the Conference of the Parties meets, it will have the opportunity to discuss both protocol development and financial assistance to developing states. It is imperative that states act now,

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183. *Cf.* PETCHESKY, *supra* note 79, at 81-84 (chronicling the lobbying and legal strategies of the "global campaign for access to essential medicines" for HIV).

184. *Id.* at 85-104 (providing examples of direct action for HIV care and human rights in South Africa and Brazil).

185. For reasons underlying the intense mobilization of human rights activists around AIDS, see Yamin, *supra* note 62, at 326-27 (noting that "these diseases [AIDS, tuberculosis and malaria]—especially the HIV/AIDS pandemic—have garnered attention due to their economic and social consequences, as well as because of the human tragedies they represent"); and Salih Booker & William Minter, *Global Apartheid*, NATION, July 9, 2001, at 20 ("AIDS thus points to more fundamental global inequalities than those involving a single disease, illuminating centuries-old patterns of injustice.").

186. *See* Crow, *supra* note 12, at 222 n.78 (attributing the lack of rights language in the FCTC to, inter alia, "the lack of involvement of organizations with experience in rights-based approaches in the negotiations" and "the public health community's relative unfamiliarity with international human rights law" (citing Telephone Interview with Allyn Taylor, Former Senior Legal Adviser to WHO Tobacco Free Initiative (Aug. 19, 2003))); *cf.* Hammond & Assunta, *supra* note 41, at 241 (noting that the FCTC brought human rights organizations into the tobacco control movement).

187. Crow, *supra* note 12, at 217.

through human rights discourse, to assure that cessation is a part of any discussion on financing of tobacco control.

III. CESSATION PROTOCOL

The FCTC goes far in addressing the global tobacco pandemic, but it neglects the plight of those already addicted to nicotine, with this failure treading heavily upon the right to health. The FCTC is not enough. The convention-protocol approach of the FCTC possesses the inherent advantages and disadvantages of any incremental legislation: While states can assent to broad principles in the convention, this "enables nations to relieve some public pressure for action without resolving or committing to taking concrete steps to control tobacco production and consumption."[188] A protocol, separately negotiated and ratified, would possess the same legal weight as the FCTC and could thereby create the subsequent obligations lacking in the convention itself. The FCTC is ineffective in addressing smoking cessation, failing to uphold the right to health, where it does not cause states to alter their behavior in line with evidence-based clinical best practices for cessation interventions.[189] A global tobacco control program can be effective only through strong protocol language that upholds a right to clinical cessation interventions and clarifies its substantive obligations.

The initial Proposed Dependence Protocol, though never fully considered by the WHO's Intergovernmental Negotiating Body, offers valuable language for the development of a protocol to address the want of smoking cessation in the FCTC. Specifically, the Proposed Dependence Protocol obligates states to (1) take all practical, effective, and cost-effective measures to treat tobacco dependence within national health care and social welfare systems; (2) exchange information with and provide technical and financial support to other states; (3) survey and report on tobacco dependence treatments; and (4) support research and development into tobacco dependence treatments.[190] The Proposed Dependence Protocol provides a framework upon which a human rights based protocol might be drafted.

To address the deficiencies in the Proposed Dependence Protocol,

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188. TAYLOR & ROEMER, *supra* note 34, at 17; *see also supra* note 3 and accompanying text (discussing the FCTC's "convention/protocol approach" to treatymaking).

189. Taylor & Bettcher, *supra* note 51, at 923 (noting that "a measure of the agreement's effectiveness is determined by the extent to which it causes the states to alter their behaviour in line with the national obligations contained in the treaty").

190. *See infra* Annex; *see also supra* note 52 and accompanying text.

introducing many of the cessation strategies analyzed throughout this Article, it is vital that any protocol affirm member states' commitment to the right to health. A human rights basis for cessation would give credence to international regulation over that which is purely domestic in character. For example, simply by declaring NRTs to be "essential drugs" within the WHO Action Programme on Essential Drugs,[191] the Proposed Dependence Protocol would trigger state obligations to make these products available in sufficient quantity to address the needs of smokers.[192] Although tobacco cessation must be undertaken at the national level, it nevertheless requires that states band together in developing international solutions for these domestic problems. Reinstating the Proposed Dependence Protocol with explicit reference to human rights would create norms for tobacco cessation consistent with state obligations to protect and fulfill the right to health.

Tobacco cessation is not simply an issue confined to high-income developed states, but a globalized issue of universal importance. Transnational tobacco corporations have resisted international regulation, framing the FCTC as the "New Colonialism," a Western solution to a Western problem that has been forcibly imposed by Westerners on reluctant developing states.[193] However, belying the industry's argument, developing states have shown intense advocacy for transnational collaboration to address global tobacco, recognizing that they cannot each combat transnational tobacco corporations alone.[194] In light of this global

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191. *See WHO Model List of Essential Drugs*, *in* 13 WHO DRUG INFO. 249 (1999).

192. *General Comment 14*, *supra* note 63, ¶ 12(a) (establishing that access to "essential drugs, as defined by the WHO Action Programme on Essential Drugs" is part of the minimum core obligations of Article 12 of the ICESCR).

193. *See* Collin, *supra* note 12, at 79 ("An increasingly significant area in which the tobacco industry seeks to structure debate, and of particular interest in the context of globalization, is the attempt to present tobacco control as an issue for high-income countries.").

194. Bates, *supra* note 41, at 209 (noting that "the most powerful response [at the second meeting of the Intergovernmental Negotiating Body] came from the developing countries . . . dispel[ing] the myth inspired by the tobacco industry that poor countries somehow have other, more important, matters to consider than the tobacco epidemic").

> Although described by the tobacco industry as a "developed world obsession being foisted on the developing world," it was in fact developing countries which saved the FCTC from being gutted by a handful of developed countries which have no intention of ever implementing most of its provisions. Unlike other treaties, where developed countries dominate the debate, developing countries were vocal, spirited, and led the charge for most of the progressive provisions.

desire for international cooperation, the industry's argument that the FCTC is unresponsive to the needs of the poor appears to be nothing more than pretext for the true tobacco corporate strategy: By leaving individual states "free to develop the most appropriate policies for the specific circumstances of their country,"[195] transnational tobacco corporations can more easily "divide and conquer" in manipulating individual national policies.[196] Despite this, many nongovernmental tobacco control advocates have played into the tobacco industry's national tobacco control paradigm, eschewing cessation through the FCTC, in part because they lack the discursive skills to engage in the human rights debate.[197] The Proposed Dependence Protocol offers an opportunity, like the FCTC itself, to overcome this industry influence,[198] but, if the goal of member states is to

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Hammond & Assunta, *supra* note 41, at 241 (citation omitted).

195. News Release, British American Tobacco, British American Tobacco Proposes "Quantum Leap" for Sensible Tobacco Regulation (Aug. 29, 2000), http://www.bat.com, *quoted in* Collin, *supra* note 12, at 79.

196. *See* Brundtland, *supra* note 32, at 750 ("[A]ttempts to control tobacco face concerted opposition. Some tobacco companies act to manipulate public opinion, deceive the public about their efforts to develop nicotine delivery devices, target children, and fund research merely to sow doubt about the scientific evidence of the risks of tobacco use." (citations omitted)); Collin et al., *supra* note 13, at 266 (recognizing "the ability of transnational corporations (TNCs) to undermine the regulatory authority of national governments"); Deborah Arnott, *The Killer's Lobbyists*, GUARDIAN (London), May 15, 2003, at 30 (noting the monumental influence of the tobacco lobby in the developing world).

197. *See supra* note 186 and accompanying text.

198. While drafting the FCTC, there was concern that "the transnational tobacco conglomerates, which have tenaciously opposed the development of national tobacco control regulations, w[ould] wield their considerable economic and political power to obstruct any international legislation on tobacco control." Taylor, *supra* note 33, at 285; *see also* Henry A. Waxman, *The Future of the Global Tobacco Treaty Negotiations*, 346 NEW ENG. J. MED. 936, 938 (2002) (arguing against the United States's opposition, on behalf of tobacco corporations, to various FCTC provisions). Nevertheless, in crafting the FCTC, the WHO noted that the "ability of international organizations through the treaty-making process to encourage and assist nations in overcoming powerful and organized industry resistance to regulation is evidence of the important role that international law-making could play in efforts to regulate the activities of transnational tobacco conglomerates." TAYLOR & ROEMER, *supra* note 34, at 15. In adopting the FCTC through the World Health Assembly, the member states of the WHO were able to overcome intense industry resistance, succeed together where individual states had failed, and create global norms of tobacco control. For an analysis of the role of transnational tobacco corporations in attempting to influence the FCTC, see WORLD HEALTH ORG., TOBACCO COMPANY STRATEGIES TO UNDERMINE TOBACCO CONTROL ACTIVITIES AT THE WORLD HEALTH ORGANIZATION (2000); Collin et al., *supra* note

generate international norms for smoking cessation, it is imperative that they employ the human right to health. Grounding the Proposed Dependence Protocol upon human rights, as a benefit to states rich and poor, would enhance its global effectiveness.

Within this rights-based approach to smoking cessation, the Proposed Dependence Protocol should address the cultural acceptability of cessation interventions in developing states. As recognized in the overview of the Proposed Dependence Protocol, "widely varying circumstances in Parties will not allow an identical approach or a perfectly harmonized regulatory framework for treatment products."[199] Further, both the composition of the cigarette and the individual smoker's habits and pharmacological reactions to that cigarette vary by state and culture.[200] Thus, in addressing these cross-cultural concerns, the WHO should create technical assistance programs to fund research to (1) engage in a comparative analysis of state approaches to treatment of tobacco dependence between developed and developing states; (2) investigate culturally relative aspects of tobacco control, seeking to develop culturally appropriate standards for cessation interventions; and (3) define a range of state cessation interventions that are consistent with implementation of the Proposed Dependence Protocol and developing states' economic, social, and cultural norms. The WHO's Tobacco Free Initiative has already begun such efforts, contracting national experts throughout the world to create "specific report[s] about the successful use of effective access to tobacco dependence treatment in tobacco control."[201] However, these disparate, sporadically published efforts, while serving as models of best practices in cessation interventions, lack the coordination and resource centralization that an international technical assistance program would provide. Continuing the WHO's efforts through a

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13, at 271 ("Tobacco companies sought to influence policy by building relationships with WHO staff, including gaining contacts through hiring or offering future employment to officials, and placing industry consultants in positions within WHO.").

199. Second Meeting of the Working Group, *supra* note 52, at 5.

200. Collin, *supra* note 12, at 64 ("Cigarettes of the same brand, but produced for differing markets, may vary significantly, for example, with respect to tar, nicotine and nitrosamine content.") (citing N. Gray et al., *Variation Within Global Cigarette Brands in Tar, Nicotine, and Certain Nitrosamines: Analytic Study*, 9 TOBACCO CONTROL 351 (2000)); Caryn Lerman et al., *Individualizing Nicotine Replacement Therapy for the Treatment of Tobacco Dependence: A Randomized Trial*, 140 ANNALS INTERNAL MED. 426 (2004) (noting the effect of ethnicity and race on cessation intervention efficacy).

201. Tobacco Free Initiative, Terms of Reference of Agreement for Performance of Work (APW): For the Country Reports on Effective Access to Tobacco Dependence Treatment (July 2004) (on file with author).

coordinated international program, states, in implementing treatment interventions based on culturally relative clinical best practices, could use a proven global model while tailoring their national programs to meet the needs of different groups, with heightened attention paid to relevant indigenous communities, ethnic groups, racial minorities, and women.

In addition, member states should not disregard the need for equitable pricing of and access to pharmaceutical cessation interventions within the Proposed Dependence Protocol. Such a protocol should reaffirm member states' commitment to prioritizing the right to health above the rigid trade parameters of global capitalist structures while still permitting the lawful manufacture and parallel importation of generic treatments without subversion of the international market structures within TRIPS.[202] Shifting the locus of cessation interventions from the private interests of pharmaceutical corporations to the public interests of states reinforces state responsibility for alleviating the burden of tobacco-related disease under the right to health. Further, this generic pharmaceutical strategy would obviate the need for states to engage in lopsided differential pricing negotiations with pharmaceutical corporations on an "ad hoc, drug-by-drug basis."[203] By empowering states to uphold the right to health through their own national public health strategies, rather than relying solely on the ever-vacillating humanitarianism of developed states and pharmaceutical corporations, the Proposed Dependence Protocol would permit states to take an accountable, democratic role in addressing the needs of those affected most by tobacco.

To assist these developing states in financing generic cessation interventions, the Proposed Dependence Protocol should develop a global fund through the World Health Organization. Although generic pricing may lessen the burden on low-income markets, any large-scale access to cessation treatments will require large-scale funding that is not available solely through national financing. By unifying the donations of

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202. *See* Press Release, Infact, NGOs Denounce New Draft of Tobacco Control Treaty as Too Weak To Reverse Global Tobacco Epidemic (Jan. 15, 2003), http://www.infact.org/011503drft.html (arguing that the FCTC fails to prioritize public health over trade); *see also supra* note 170 and accompanying text.

203. *See* PETCHESKY, *supra* note 79, at 112. Petchesky notes:

> At the national level, the result of "differential pricing" is that "each price cut for each drug in each country is negotiated separately," or that countries must defend their right to seek cheaper alternatives in lengthy litigations in the national courts. Meanwhile, months and years go by and millions more die needlessly. *Id.*

nongovernmental organizations and developed states through mandatory assessments, the World Health Organization can overcome member states' collective action difficulties to achieve coordinated global cessation goals.[204] Developing states have long advocated the establishment of a trust fund to assist their tobacco control efforts, and, at their insistence, the WHO's Tobacco Free Initiative is researching this idea, along with other matters of tobacco control financing, in preparation for discussions by the Conference of the Parties.[205] States should incorporate this discussion into their consideration of the Proposed Dependence Protocol.

States can work together to solve issues of tobacco cessation, aiding each other in disseminating the results of basic science and translating these results into new behavioral treatments and pharmacological regimens. Through a process termed "leap-frogging," this method of scientific dissemination allows "the adoption of measures in a forerunner state to serve as models elsewhere."[206] The WHO's Tobacco Free Initiative, as the interim (and likely permanent) Secretariat for the FCTC, has an opportunity to coordinate a global laboratory network to research and evaluate tobacco cessation programs.[207] Applying this research to country-

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204. While such public-private partnerships would still rely on the humanitarian will of donors, a global trust fund could institutionalize these voluntary donations, providing a long-term, sustainable outlook on global tobacco cessation.

205. *Potential Sources and Mechanisms of Support, Report by the Secretariat,* Open-Ended Intergovernmental Working Group on the WHO Framework Convention on Tobacco Control, Agenda Item 9, WHO Doc. A/FCTC/IGWG/1/INF.DOC./1 (May 27, 2004), http://www.who.int/gb/fctc/PDF/igwg1/FCTC_IGWG1_ID1-en.pdf (exploring potential sources and mechanisms for financing the implementation of the FCTC).

206. Collin, *supra* note 12, at 83 (citing Framework Convention Alliance, Briefing Paper for the 2nd Meeting of the Intergovernmental Negotiating Body of the Framework Convention on Tobacco Control: Comments on the Chair's Text (Mar. 2001), http://www.fctc.org/FCTCfca.shtml); Taylor, *supra* note 104, at 501 (noting that "rapid worldwide dissemination of recent advances in scientific knowledge and technology has advanced international agreement and action by providing the evidence base and the technological tools needed for effective national action and international cooperation").

207. The WHO has already experimented with global research consortia, bringing together scientists from around the world for its Scientific Advisory Committee on Tobacco Product Regulation, a group that has published six detailed recommendations on the technical aspects of regulating tobacco products. In addition, the WHO has recently published an ambitious agenda for global tobacco research under the auspices of the FCTC. WORLD HEALTH ORG., BUILDING BLOCKS FOR TOBACCO CONTROL: A HANDBOOK 274-79 (2004); *see also* FCTC, *supra* note 1, art. 22 ("The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and

specific policy interventions, the WHO, using rapid assessment procedures,[208] may quickly assess regional tobacco cultures and help design culturally appropriate interventions. Through such collaborative cessation efforts, those global efforts originally envisioned by the framers of the FCTC, states can fight together in battling back against the scourge of tobacco.

CONCLUSION

Even though smoking cessation is not perceived to be the most pressing issue facing many states, it is—based upon its life-saving potential alone—a fundamental component of the right to health. Bolstered by the authoritative force of the FCTC, states have a unique opportunity to realize their obligations under the right to health to aid those addicted to nicotine. Cessation is the goal; the right to health is the key to achieving that goal. Adding a clear tobacco dependence protocol to the FCTC would give states direction in fulfilling their human rights obligations toward tobacco cessation. Yet the achievement of a protocol is not an end in itself; it is the beginning of a progressive evolution of the right to health to include obligations for tobacco cessation and life-saving interventions for other public health crises.

Even in its success, cessation is not a panacea for the ills of tobacco, but rather a synergistic complement to the other tobacco-control approaches employed by the FCTC. Smoking cessation can save millions of

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Parties with economies in transition. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen national tobacco control strategies, plans and programmes . . . .").

208. With a mixture of objective observations and brief interviews concerning a specific cultural issue, rapid assessment procedures (RAPS) allow health anthropologists to provide "timely qualitative descriptions of the research setting which can be used to assess the progress of the intervention programme." Roberta L. Hall et al., *Rapid Assessment Procedures To Describe Tobacco Practices at Sites Managed by Indian Tribes*, 4 TOBACCO CONTROL 156, 156 (1995). For an example of a tobacco cessation RAP conducted in a developing state, see Deborah Ossip-Klein, Understanding the Culture of Tobacco Use in the Dominican Republic Using Rapid Assessment Procedures (RAPS), Lecture as part of the Tobacco Seminar Series, Mailman School of Public Health, Columbia University (Mar. 11, 2004) (on file with author); *see also* David Seddon et al., *Developing Guidelines for Policy Research: Recommendations for Future Approaches and Methods*, *in* CASE STUDY REPORT: GLOBAL ANALYSIS PROJECT ON THE POLITICAL ECONOMY OF TOBACCO CONTROL IN LOW AND MIDDLE-INCOME COUNTRIES 105 (J. Patrick Vaughan et al. eds., 2000) (developing a programme for political economic analysis in implementing tobacco policies pursuant to the FCTC).

lives and bring every human being closer to the enjoyment of the highest attainable standard of health. Without smoking cessation programs, the positive health effects of the FCTC will not be felt for at least a generation, with FCTC programs offering little salvation from the steady and sustained death of current smokers. But it is the near-term benefit of cessation, the denormalization of smoking, that makes such interventions so politically perilous, with effective cessation programs resulting in an immediate decrease in tobacco consumption and sales. Consequently, governments and nongovernmental advocates should expect no greater intransigence from transnational tobacco corporations than when they explore state and international cessation efforts. With transnational tobacco corporations using their corporate leverage to block such life-saving measures, effective international mobilization will be needed to thwart the impertinence of the tobacco industry.

The success of the FCTC has heralded new mechanisms for collective action to challenge global threats to public health. For this globalization of public health to take hold, the FCTC precedent cannot fail to protect those most vulnerable. The FCTC exposes the silent pandemic of tobacco by chronicling efforts states may take to discourage the underlying determinants of smoking. Yet the FCTC forsakes those addicted to nicotine, offering no positive message to those trapped by their dependence on tobacco. Through a cessation protocol to the FCTC, states can act pursuant to the right to health, develop interventions to encourage cessation, and create the conditions necessary to foster dignity and hope.

ANNEX: PROTOCOL ON THE TREATMENT OF TOBACCO DEPENDENCE[209]

PROPOSED TECHNICAL COMPONENTS OF A PROTOCOL ON THE TREATMENT OF TOBACCO DEPENDENCE: AN OUTLINE OF BASIC OBLIGATIONS AND CONTROL MEASURES

Overview

This Protocol should create a basic duty to establish treatment measures that are practical, effective, cost-effective and available to all who require them. However, widely varying circumstances in Parties will not allow an identical approach or a perfectly harmonized regulatory framework for treatment products. In order that the measures taken constitute a coherent and systematic approach, the Parties should formulate a national programme. The national programme would be reported to an appropriate body of the Convention or Protocol. Technical assistance would be provided under the auspices of the Convention or Protocol to facilitate the creation and implementation of national programmes based on sound scientific evidence and best practice.

Preamble

The Parties to this Protocol,

Recalling that the objective of the framework convention on tobacco control includes the reduction of tobacco use,

Recalling that tobacco dependence is classified as a disease under the International Classification of Diseases (ICD-10), and that nicotine addiction is classified as a disease under the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV),

Recognizing that treatment of tobacco dependence reduces mortality and morbidity,

Recognizing also that treatment of tobacco dependence is effective across a wide range of settings,

Acknowledging that treatment of tobacco dependence is a cost-effective intervention,

Recognizing that in order to reduce mortality in the short term current smokers need to be encouraged to quit,

Aware that a high percentage of tobacco users wish to quit,

Confirming that cessation programmes must be gender sensitive,

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209. Second Meeting of the Working Group, *supra* note 52. This prospective protocol, first developed by WHO's Tobacco Free Initiative, forms the basis of the author's call for a FCTC protocol to address smoking cessation, to be drafted by the Permanent Secretariat of the FCTC and adopted by the Conference of the Parties.

Concerned that tobacco dependence is a form of addiction and that current success rates of attempts to quit without any form of support are low,

Recognizing the important roles of medical doctors, nurses, pharmacists, social workers, community workers, and other professional groups in the treatment of tobacco dependence,

Have agreed as follows:

Definitions

(Explanatory note: Definitions are usually added late in the negotiation process, when it is apparent, in light of the rest of the text, what terms need to be defined. Moreover, some definitions may be included in the framework convention and be applicable to protocols. Therefore, no proposed draft text is suggested, except for a possible technical definition of "tobacco dependence treatment.")

Tobacco dependence treatment – includes (singly or in combination) behavioural and pharmacological interventions such as education, brief counselling and advice, intensive support, administration of pharmaceuticals or other interventions that contribute to reducing and overcoming tobacco dependence in individuals and in the population as a whole.

Objective

1. The objective of the Protocol is to reduce and overcome individual dependence on tobacco by ensuring that tobacco users have access to appropriate [and affordable][costeffective] treatment for tobacco dependence, and thereby mitigating the health, welfare, economic and development burdens on individuals, families, communities and governments created by tobacco use.

Section I – Basic obligations

2. Each Party shall take all practical, effective and cost-effective measures to treat tobacco dependence and to promote cessation of tobacco use, taking into account local circumstances and priorities.

3. Each Party shall develop a national programme for the delivery and assessment of measures taken under [paragraph 2].

4. Taking into account local circumstances, each Party shall undertake the following measures:

(1) treatment of tobacco dependence within the national health care and social welfare systems;

(2) routine advice on and support for tobacco cessation by health professionals, including medical doctors, health practitioners, nurses, pharmacists, community workers and social workers based in primary care;

(3) development, implementation and promotion of the use of specialized services such as clinics, pharmacies, community-based support, telephone help lines, or Internet support;

(4) provision of pre- and postqualification education, training and information for health practitioners, community workers and social workers;

(5) promotional and education campaigns aimed at encouraging tobacco cessation;

(6) improved access to proven treatment interventions and products through both the private and public sector;

(7) removal [where appropriate or justified][when feasible] of economic barriers to treatment;

(8) removal of regulatory barriers in order to improve access to products for tobacco dependence treatment consistent with the protection of public health and sound science;

(9) fast-track approval of new proven products for tobacco dependence treatment consistent with protection of public health and sound science;

(10) public funding of proven behavioural and pharmacological treatments of tobacco dependence;

(11) integration of tobacco cessation treatments into reproductive health programmes such as the "safe motherhood" programme.

5. The Conference of the Parties shall take into account the particular needs of developing countries and assist in improving their national capacities and capabilities to participate in the measures referred to in [paragraphs 2 and 3] above.

Section II – Exchange of information and provision of technical support

6. Each Party shall cooperate in exchange of information and skills relevant to meeting the objectives of the Protocol. Each Party in a position to do so shall include in its national programme measures to be taken, if any, to assist other Parties in meeting the objectives of this Protocol either bilaterally or under the auspices of the Convention or Protocol.

7. The Conference of the Parties, at its first meeting, shall consider the establishment of a technical body, *inter alia*, to assist the Parties in undertaking effective cooperation and exchange of information and skills, and to determine guidelines for common statistical approaches to facilitate comparability of data gathered, taking existing surveillance systems into account.

Section III – National reports

8. Each Party shall communicate its national programme and report of

measures taken to implement the present Protocol to the [Conference of the Parties][Secretariat] of the [Convention][Protocol] within [. . .] months of the entry into force of this Protocol and [. . .] months before each meeting of the Conference of the Parties to the [Convention][Protocol].

9. Each Party shall undertake progressively, as a part of an integrated national surveillance system, to gather basic statistical data on tobacco cessation treatment services and products; to collect data on the availability of, access to and usage of tobacco dependence treatments; to gather data on their costs and effectiveness; and to include all these data in the planning for its national programme [paragraph 3].

Section IV – Research and development

10. Each Party shall support and further develop, as appropriate, national and international programmes and networks or organizations aimed at defining, conducting, assessing and financing research and data collection, taking into account the need to minimize duplication of effort.

11. Each Party shall, in accordance with its capabilities and the means at its disposal, initiate and cooperate in, directly or through competent international bodies, the further development of effective and necessary means for the treatment of tobacco dependence and ensure that such means for treating tobacco dependence are widely available and affordable, particularly in developing countries. Such research should be linked to improving access to pharmaceutical treatments for tobacco dependence as an important component of elaborating a sustainable national health sector strategy.

12. Each Party shall encourage and support research, development and demonstration activities related to:

- improving the effectiveness of tobacco dependence treatments;
- improving the cost-effectiveness of tobacco dependence treatment;
- improving the access to tobacco dependence treatment; appropriate frameworks and settings for delivery of tobacco dependence treatments;
- effective partnerships between public, private and nongovernmental bodies involved in tobacco dependence treatment;
- appropriate regulatory approaches for tobacco dependence treatments.