The Fourth Pillar of the Framework Convention on Tobacco Control: Harm Reduction and the International Human Right to Health

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The Framework Convention on Tobacco Control (FCTC), while successful in its execution, fails to acknowledge the harm reduction strategies necessary to help those incapable of breaking their dependence on tobacco. Based on the human right to health embodied in Article 12 of the International Covenant on Economic, Social and Cultural Rights, this article contends that international law supports a harm reduction approach to tobacco control. Analyzing the right to health as an autonomy-enhancing right, countries must prioritize health interventions to promote those treatments most likely to increase autonomy among those least able to control their own health behaviors. Harm reduction can involve the use of novel, purportedly less hazardous tobacco products. By dissociating nicotine from the ancillary carbon monoxide and myriad carcinogens of smoking, these tobacco harm-reduction products may allow the individual smoker to retain addictive behaviors while limiting their concomitant harms. These less hazardous products, while not offering the preferred benefits of abstaining from tobacco entirely, might nevertheless become a viable strategy for buttressing individual autonomy in controlling health outcomes. Working through the FCTC framework, countries can create the international regulatory and research capacity necessary to assess harm-reduction products and programs.

The harms of smoking are truly global in scope. More than 1.1 billion people smoke worldwide, resulting in cardiovascular diseases, various cancers, and obstructive lung diseases.[1] Approximately one-quarter of all lifelong smokers will die in middle age (between 35 and 69) as a result of smoking, losing between 20 and 25 years of life. Another quarter of these smokers will die in their latter years as a result of smoking.[2,3] Globally, this "quiet pandemic" claims the lives of approximately 5 million persons per year, a figure that will rise to 10 million by 2030, with the burden of death increasingly being felt by developing countries.[4] With globalization's dismantling of trade barriers permitting the burgeoning initiation of smoking in unsated developing countries—particularly among the children and adolescents of these countries—tobacco is projected to become the world's leading cause of avoidable death.[5]

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In May 2003, the member states of the World Health Organization (WHO) challenged the global spread of tobacco by adopting an international tobacco control treaty, the Framework Convention on Tobacco Control (FCTC). The FCTC represents the first time in its 55-year history that WHO has used its authority to draft a binding international treaty.

While successful in its execution, this international legislation focuses primarily on non-health related approaches to tobacco control—including price and tax measures to reduce demand, strategies to reduce smuggling, indoor air laws, and limits on tobacco advertising—but fails to directly address smoking cessation and harm reduction strategies.[6] This article argues that the international human right to health supports a harm-reduction approach to tobacco control and that, working under the FCTC framework, countries should create international mechanisms to research and regulate harm-reduction products and programs.

Harm reduction can be defined as a strategy that lowers total tobacco-related mortality and morbidity despite continued exposure to tobacco-related toxicants.[7] Harm reduction strategies include using behavioral methods, nicotine replacement therapies, or so-called "safer" cigarettes manufactured by the tobacco industry to reduce daily cigarette consumption.[8] This article addresses these industry-sponsored substitute tobacco products—including, but not limited to, low-carcinogen cigarettes, devices that heat tobacco to release nicotine, smokeless tobacco, and novel nicotine products—all of which have yet unproven benefits.[9]

Many smokers who want to quit are unable to overcome their nicotine dependence. Despite advances in the treatment of nicotine dependence,[10] less than half of smokers achieve success with counseling and pharmacotherapy and only about one-fifth remain abstinent in the long term.[11] Moreover, traditional cessation treatments tend to aid the less dependent smokers, targeting only 5% to 20% of smokers interested in quitting immediately.[12] Harm reduction "recognizes a broader range of tobacco and nicotine goals, and accepts a longer or even indeterminate time frame to achieve the goals."[13] For those addicted to nicotine and unwilling or unable to quit smoking, harm-reduction strategies have the potential to minimize the net damage to their health and the economic ramifications of tobacco use.[14]

Addressing the needs of those addicted to nicotine, however, requires a new paradigm for international tobacco control: the human right to health. By applying the right to health to tobacco control, this article advocates for research in and evaluation of these purportedly less hazardous tobacco products through the FCTC framework. Only by acknowledging these tobacco harm-reduction products and appraising them as part of national comprehensive tobacco control strategies can governments realize their obligations under the right to health. Casting success as the reduction in exposure to toxins, these less hazardous nicotine-delivery products, while not offering the preferred health and economic benefits of abstaining from tobacco entirely, might nevertheless become a viable component of a nation's comprehensive tobacco policy.

NICOTINE ADDICTION AND THE ROLE OF HARM REDUCTION

Nicotine addiction does not result from a failure of will, but rather a neurological and psychiatric disorder brought on by psychosocial, cultural, environmental, and genetic factors. While generally understood as a disorder of altered brain function brought on by the use of a psychoactive stimulant, the neurobiology of nicotine use and the pharmacological mechanisms leading to nicotine addiction remain largely unknown.[15] At present, neuroimaging techniques have allowed researchers to theorize that nicotine activates acetylcholinergic receptors, specifically nicotinic cholinergic receptors, increasing the synthesis and release of dopamine to produce rewarding, pleasurable, stimulating, and anxiety-ameliorating effects on the brain.[16] These biological variables interact with psychological effects to create and maintain nicotine dependence.[17]

Although nicotine is not the direct agent of harm, it is nevertheless the behavioral and biological basis of tobacco smoking, causing deadly consequences for users and nonusers alike. It is now axiomatic that nicotine is a drug of addiction, inducing pharmacological and behavioral processes similar to those of heroin and cocaine.[18] Cigarettes and other tobacco products can therefore be viewed as highly engineered drug delivery vehicles, which, if used as directed, cause death.

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. Because tobacco use then results in a powerful addiction that impairs autonomous decision-making and impedes voluntary choice, an individual's decision to continue nicotine self-administration cannot be said to be the result of a free, informed choice.[3,19] As a result, tobacco control—once considered a private good, stemming from only lifestyle choices—must now be reevaluated as a public good, requiring a systemic health-based approach to treat involuntarily recalcitrant smokers.

Tobacco control efforts have frequently been articulated by three principal pillars: (*1*) prevention of initiation, (*2*) cessation for smokers, and (*3*) protection from environmental tobacco smoke. To this longstanding tobacco control triad, the introduction of harm reduction—a separate, fourth pillar—"seeks to minimize the net damage to health associated with the use of tobacco products."[20] Harm reduction acknowledges the pharmacologic and psychological effects of nicotine in preventing complete abstinence from tobacco and assumes that, even with effective cessation treatments, many smokers will be resistant to quitting altogether.[21] For these "hard-core" smokers—often vulnerable as a result of poverty, poor education, or a co-morbidity such as mental illness—harm reduction offers the promise of increasing individual autonomy while saving lives.[22] Similar to analogous harm-reduction approaches in other health-related fields—for example, providing clean needles or methadone to heroin addicts (which was also controversial upon inception but soon gained widespread acceptance)—tobacco harm reduction allows health practitioners to achieve modified health goals based upon individual needs.

FRAMEWORK CONVENTION ON TOBACCO CONTROL: ABSENCE OF HARM REDUCTION

The FCTC has created broad principles of normative consensus for international tobacco control, challenging the globalization of smoking through the globalization of tobacco control. WHO member states intend the broad obligations of the FCTC to be supplemented by several individualized protocols, which will develop specific governmental obligations for the respective aspects of tobacco control addressed by the FCTC. Despite this successful, albeit incremental, transnational approach to tobacco control, neither the FCTC nor any currently proposed protocols adequately addresses the subject of harm reduction with any specificity. Although the core text of the treaty recognizes the importance of cessation and product regulation, the FCTC fails to place affirmative obligations on countries vis-à-vis harm reduction, focusing instead on the globalized aspects of the tobacco pandemic—regulation of tobacco advertising, taxation, trade, and smuggling. In effect, the FCTC proposes to change the social environment for smoking through an emphasis on policy and legislative approaches but offers little direct help to smokers in overcoming their addiction through cessation or harm reduction. As a result, the FCTC—the first treaty drafted explicitly to protect public health—has been criticized for lacking a firm basis in public health.[6,23,24]

The harm reduction debate can transcend the nation under the aegis of the FCTC. Now that the community of nations has moved to regulate tobacco through international law, it is incumbent upon tobacco control advocates to question the absence of harm-reduction strategies in the FCTC. The FCTC goes far in addressing the global tobacco pandemic, but it neglects those already addicted to nicotine, with this failure treading heavily upon the right to health. In a previous article, one of the present authors enumerated mechanisms for drafting a protocol to the FCTC to address smoking cessation.[6] To address those unwilling or unable to overcome their nicotine dependence, it is vital that nations promulgate a similar protocol specific to harm reduction, affirming their commitment to health and human rights by analyzing the prospective benefits of harm-reduction products.

ANALYZING HARM REDUCTION

The effectiveness of harm reduction at the population level is questioned by some in the tobacco control community. Some warn that advising smokers to switch to harm-reduction products will undermine efforts to help larger populations of smokers through population-based cessation programs and result in a net increase in users.[25] There is a concern that the marketing of harm reduction, "choosing the lesser of two evils," will be viewed as a tacit acceptance of smoking, which retains inherent dangers eliminated only through permanent abstinence.[10] Critics fear that any legitimation of smoking by the medical establishment would "send the wrong message" about the best way to reduce harm—quit smoking. Further, critics caution that introducing new forms of tobacco will mollify health concerns among children experimenting with tobacco, with harm-reduction products acting as a gateway to conventional cigarettes and countenancing former smokers who reengage their addiction.[20,26] Thus, although the individual may reduce his or her individual harm, this approach may unintentionally lead to an aggregate increase in harm at the population level, through which acceptance of smoking for the individual, albeit limited, would sanction societal initiation or continuation of smoking.

Moreover, as borne out by the past disingenuous marketing of "light" cigarettes in the United States in the 1950s and low tar cigarettes in the early 1970s, critics fear that sophistic harm reduction claims will be made that contradict etiological and epidemiological evidence.[27,28] In the case of past cigarette regulation in the United States, although tobacco corporations marketed filtered cigarettes as a safer alternative for

smokers—an alternative to quitting altogether—these corporations knew at the time that the cigarettes posed the same risk for the smoker. Regulating cigarettes through the use of "smoking machines" to measure smoke and tar, the measurement machines employed by the United States Free Trade Commission failed to account for known smoking practices, through which smokers made use of "compensatory smoking behavior" (inhaling more deeply, smoking more cigarettes, covering the filter) to counterbalance any mitigating effects of the filter and thereby ingest an even greater amount of nicotine and its attendant carcinogens.[29] Thus, tobacco corporations were able to use the government-approved imprimatur of "light cigarettes" to undermine prevention and cessation efforts—providing a disincentive for motivated smokers to quit, encouraging nonsmokers to become dependent on tobacco, and making quitters more likely to relapse. Even after the myth of light cigarettes has been debunked, smokers continue to employ these lower-risk messages in justifying their continued smoking.[30] Once bitten, health officials, who once "attempted to collaborate with the tobacco industry to find a safer product only to learn that the industry had not cooperated in good faith,"[8] now find themselves reflexively distrustful of any harm-reduction product created by tobacco corporations.[20]

This inveterate hostility has resurfaced anew in the modern production of the so-called "safer cigarette," with scholars and organizations split on the appropriateness of harm reduction for smokers despite the prospect of reduction of harmful exposures to the individual smoker.[8] Among other tobacco products, Philip Morris, R.J. Reynolds, Star Scientific, and the Vector Group have all developed and marketed cigarettes or cigarette-like products that these corporations claim reduce or eliminate exposure to carbon monoxide, nicotine, and carcinogens.[31] Although the tobacco industry has attempted to collaborate with tobacco control researchers in producing such products, such efforts "have been met with scorn and have been boycotted by many in tobacco control . . . fear[ful] that collaboration, complicity, or acquiescence of the public health community in tobacco industry efforts could result in increased credibility of the tobacco industry, making it harder to oppose industry efforts that are genuinely detrimental to the public health."[22]

Tobacco control advocates' abjuration of the tobacco industry has served only to marginalize these professionals in the ongoing harm reduction development process. With the tobacco industry alone performing concerted research on these products, public health scholars and advocates have been left without an empirical voice in the harm reduction debate. Without the oversight of the scientific community and regulatory bodies, there is a risk of repeating the "lights" public health disaster.

To move this debate forward, research is needed on three fronts. First, research should determine exactly how different cultural and socioeconomic groups process and internalize messages of risk with regard to smoking and harm-reduction products. Even 14 years after nicotine replacement therapies were launched into the market, misconceptions about the safety of these products persist.[32] Second, there must be a better understanding of how harm-reduction products may alter the trajectory of tobacco use. Finally, and most importantly, an international regulatory framework is necessary within which independent research can be conducted to confirm tobacco industry claims that novel smoking products are less harmful than conventional cigarettes. The FCTC provides mechanisms to establish these regulatory norms, but countries must make the financial and political commitments necessary to build these international structures.[26]

APPLYING HUMAN RIGHTS TO HARM REDUCTION

The right to health may help guide the development of these regulatory structures. An individual's right to health is recognized as a fundamental international human right. Founded upon the non-derogable right to life, the Universal Declaration on Human Rights (UDHR) affirms 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. . . ."[33] 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 to include "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." To achieve the full realization of this right, Article 12.2 of the ICESCR requires countries 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."[34] Thus, under the plain language of the ICESCR, the right to health includes a right to health care. But 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 right to health encapsulates a "right to control one's health and body," guaranteeing the enjoyment of "a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."[35]

Harm reduction is in accordance with the right to health. Viewing the right to health as a right that enhances autonomy and human dignity, countries must prioritize health interventions "most likely to increase autonomy amongst those least able to exercise it without outside help."[36] Although harm reduction might increase the number of users at the population level, this is not the basis upon which a human rights-based approach should be judged. The right to health focuses on the autonomous individual; it is not a right to public health.[25,37] As an autonomy-enhancing individual right, the right to health necessitates the public heath tools required to protect the right of the informed individual to make healthy choices for him or herself. WHO has recognized that nicotine addiction is a disease and that "nicotine dependence is clearly a major barrier to successful cessation."[38] 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. Through a harm-reduction protocol to the FCTC, nations have a unique opportunity to reassert the legal dominion of the human right to health in tobacco control discourses.

QUESTIONS REMAIN

Although tobacco harm reduction may be necessary under the right to health to help those unable to quit smoking, the evidence necessary to determine the safety, efficacy, and risk reduction of new tobacco and tobacco-related products is not available. According to the Institute of Medicine report *Clearing the Smoke*, "regulation is a necessary prerequisite for assuring a scientific basis for judging the effects of using potentially risk reducing products and for assuring that the health of the public is protected."[7] However, no regulatory system currently exists at the national or international level to judge the effectiveness of harm-reduction products, with these potentially deleterious harm-reduction tobacco products are often subject to far less regulatory scrutiny than pharmaceutical cessation products.[21] While harm reduction may prove to be an integral part of national tobacco control policies, any legislative efforts to address harm-reduction strategies must necessarily address the regulation of harm-reduction products.[7] As noted by Fox and Cohen, such regulation involves tradeoffs:

> On the one hand, too cautious a stance may discourage the development of new products that are potentially effective in reducing at least some of the risks of smoking. On the other hand, proposed tobacco harm reduction strategies should result in more good than harm, and not simply substitute harm.[22]

Countries can improve health without falling prey to corporate malfeasance, so long as governments create evidence-based mechanisms to study these products and survey those who use them.[39] Yet these countries should not have to face such difficult scientific, psychological, and human rights issues alone, allowing transnational tobacco corporations to more easily "divide and conquer" in manipulating individual national policies.[5] Through a process termed "leap-frogging," scientific research and policy dissemination can allow "the adoption of measures in a forerunner state to serve as models elsewhere."[40]

The FCTC framework provides an ideal forum for culling research on harm reduction and monitoring the production and marketing of harm-reduction products. Under Article 9 of the FCTC:

> The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.[41]

WHO has already taken the initiative through the FCTC to monitor the production and marketing of tobacco products, establishing the Scientific Advisory Committee on Tobacco Products Regulation (recently renamed the WHO Study Group on Tobacco Product Regulation) to support countries in obtaining the best evidence for tobacco regulation.[42] This system should be expanded—with a new committee created under the auspices of the FCTC, either administratively or by way of a protocol to the convention—to research and evaluate potential harm-reducing tobacco products by assessing smokers' physiological and psychological responses to harm-reduction products and their exposure to carbon monoxide and carcinogens. Using global laboratory networks similar to those employed to study and combat Severe Acute Respiratory Syndrome (SARS), WHO has the capacity to coordinate product testing and research of novel tobacco products, allowing nations to work together to fulfill their obligations under the right to health.

CONCLUSION

Even though harm reduction is not perceived to be the most pressing issue facing many countries, it is—based upon its dignity-enhancing and life-saving potential—a fundamental component of the right to health. Bolstered by the authoritative force of the FCTC, countries have a unique opportunity to realize their obligations under the right to health to aid those addicted to nicotine. Researching and evaluating harm reduction through the FCTC would give countries direction in fulfilling their human rights obligations in tobacco control.

The adoption of the FCTC—enabling countries to overcome domestic and collective action problems to achieve a common good—should be seen as a great leap forward in tobacco control. While critical of the FCTC's approach, the authors 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.

Harm reduction is not a panacea for the ills of tobacco, but it could be, at best, a synergistic complement to the other tobacco-control approaches employed by the FCTC. Preventing initiation of smoking and promoting cessation remain the primary approaches of a comprehensive tobacco control program. However, nicotine addiction involves complex biological and psychological processes, and clearly no single approach to treatment of this addiction will be effective in addressing the individualized effects of nicotine products. In light of many countries' widespread failure to prevent initiation and promote cessation, both before and after the FCTC, these countries have a responsibility under the right to health not to deprive smokers of a possibly efficacious means of reducing harm through acceptable substitutes to conventional nicotine self-administration.

Unlike cessation efforts, nations need not do anything to introduce a harm-reduction strategy; private corporations already are developing and marketing these products without governmental encouragement. Through a robust regulatory process, national and international policymakers must be prepared to engage these harm-reduction strategies and to assess the placement of harm-reduction products within clinical best practices. This will be a challenge that need not be overcome on a country-by-country basis. Countries can work together within WHO to address issues of tobacco harm reduction, aiding each other in disseminating the results of basic science and translating these results into novel behavioral treatments, pharmacological regimens, and tobacco products.

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