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FILLING IN THE BLANKS ON REDUCING TOBACCO PRODUCT ADDICTIVENESS IN THE FCTC PARTIAL GUIDELINES FOR ARTICLES 9 & 10

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The existing Partial Guidelines for Implementation of Articles 9 & 10 of the WHO Framework Convention for Tobacco Control includes a strategy for regulating tobacco products to reduce their attractiveness, but does not yet provide any guidance for reducing either the toxicity or the addictiveness of tobacco products. Section 1.2.1.2, "Addictiveness (dependence liability)," states only that: "This section has been left blank intentionally to indicate that guidance will be proposed at a later stage." A related footnote says that the blanks will be filled "as new country experience, and scientific, medical and other evidence become available. . . [and] will also depend on the validation of the analytical chemical methods for testing and measuring cigarette contents and emissions."¹

As detailed below, sufficient evidence and accurate testing methods are now available to begin providing useful guidance to countries that have the capacity to implement new measures to reduce the addictiveness of tobacco products and enforce compliance. Using the format of the existing partial guidelines, this working paper suggests possible draft text for the blank "Addictiveness" section, followed by a concise summary of supporting research and analysis.

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¹ *Partial Guidelines for Implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control*, http://www.who.int/fctc/guidelines/Guidelines_Articles_9_10_rev_240613.pdf.



Proposed Text on Addictiveness for FCTC Guidelines

1.2.1.2 ADDICTIVENESS (DEPENDENCE LIABILITY)

Nicotine is the predominant ingredient in cigarettes and other smoked tobacco products that makes them physically addicting, playing the major role in moving many of the youth who experiment with smoking to initiate into regular addicted use, and in making it difficult for regular smokers to quit successfully. But available procedures and technologies now make it possible to reduce the total amount of nicotine in cigarettes and other tobacco for smoking by approximately 95% or more, to 0.4 milligrams per cigarette or 0.4 milligrams per gram of tobacco, or less. Consequently, from the perspective of public health, there is no justification for permitting cigarettes and similarly smoked tobacco products (which produce the vast majority of tobacco use harms and death) from containing more than the lowest technically achievable levels of nicotine, which would sharply reduce, if not eliminate, their ability to create or support physical addiction.

Minimizing the actual amount of nicotine in cigarettes and other smoked tobacco products would place a low ceiling on the maximum amount of nicotine they could possibly yield to smokers or youth who experiment. Requiring such minimal content levels (and not phasing them in) would also prevent smokers from being able to compensate by smoking more or more intensely. Indeed, existing research indicates that smokers provided with very low nicotine cigarettes are not likely to try to compensate but are likely to try to quit (even when full-nicotine cigarettes remain readily available).

Reducing the amount of nicotine permitted in cigarettes and other smoked tobacco products to the trivial, currently lowest achievable levels would also make it difficult, if not impossible, for manufacturers to compensate by reengineering the products so that they would still yield amounts of nicotine that could readily create or sustain nicotine addiction. To be prudent, however, restrictions in the laws or rules implementing the nicotine reduction should also specifically prohibit any such attempts to boost the yields from the remaining nicotine, as well as prohibit any other efforts by manufacturers to restore the addictiveness of the cigarettes or other tobacco products through using any other ingredients or new additives.

Once the nicotine reduction measures are in place, illegal operators will likely try to make illicit full-nicotine cigarettes available to those smokers who do not quit. But the potential size of this illicit market would be reduced considerably if smokers who do not quit all tobacco and nicotine use were able to turn, instead, to more readily available and legal non-combustible tobacco and nicotine products to get the nicotine they crave (which would, likely still reduce their health harms, at least to some extent).

Nevertheless, countries without the capacity to enforce against the possible emergence of an illicit trade in non-complying cigarettes may want to postpone implementing any nicotine-minimizing strategy until such a capacity is developed – especially in those countries that already have established networks for illegally importing, distributing and selling illicit cigarettes. It is also important that countries implementing the new nicotine limits have the capacity to inspect the cigarettes and other subject tobacco products that are offered for legal sale, use available testing methods to ensure that they comply with the new nicotine limits, and, when necessary, take related enforcement action, including seizure and destruction.

As the WHO FCTC, in its preamble, recognizes, cigarettes and other tobacco products are harmful and create and maintain dependence. But any reduction to their addictiveness from reducing the nicotine they contain in no way suggests that those tobacco products are less dangerous for human health – and all other efforts to reduce their use should be continued or increased.



Support for the Proposed New Guidelines Text on Reducing Addictiveness

Tobacco product addiction is complex, with chemical and environmental factors and physiological and behavioral components, and significant gaps remain in the available research and in our understanding of tobacco use addiction and its role in initiation and cessation. Nevertheless, it is beyond dispute that nicotine is the predominant ingredient in cigarettes and other tobacco products that makes them physically addicting, playing the major role both in increasing initiation from experimentation into regular, addicted use and in making it difficult for regular smokers and other users to quit successfully.

For example, in 1988 *The Health Consequences of Smoking: Nicotine Addiction*, a report of the U.S. Surgeon General, reviewed the research available at that time and concluded that: “Cigarettes and other forms of tobacco are addicting. Nicotine is the drug in tobacco that causes addiction.” More recently, the 2014 U.S. Surgeon General’s report, *The Health Consequences of Smoking—50 Years of Progress*, based on a quarter century of additional research and experience, reaffirmed that nicotine is addictive and concluded that “nicotine addiction figures centrally in initiation and in the difficulty of cessation.” As the 2014 report also noted, “Tobacco industry advertising and promotional activities cause youth and young adults to start smoking, and nicotine addiction keeps people smoking past those ages.”

Accordingly, available research and experience already tells us that reducing nicotine levels in cigarettes and other tobacco products offers enormous potential for preventing and reducing smoking and other forms of tobacco use and securing substantial new public health gains. Even modest gains in interrupting the progression from experimentation to addicted regular use and in helping the many current users who want to quit to do so would produce enormous public health benefits. At the same time, millions of people are already addicted to smoking and other forms of tobacco use, and any effort to reduce nicotine levels in tobacco products must, as discussed below, also accommodate that reality, as well as a range of other challenges.

Setting Effective & Achievable Reduced Nicotine Levels

It is well established that the major tobacco companies have carefully engineered their products to deliver the amounts of nicotine that are optimal for creating and sustaining addiction and maximizing consumption. For example, the U.S. federal court finding the major U.S. cigarette companies guilty of racketeering in 2006 concluded that they “have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction.”² That suggests that any significant reduction to existing nicotine levels would be at least somewhat helpful for reducing initiation and facilitating cessation. To secure maximum public health benefits, however, would require reducing the nicotine in the cigarettes and other tobacco products to levels that no longer create or sustain addiction at all.

² *USA v. Philip Morris*, U.S. District Court of the District of Columbia, 449 F. Supp. 1 (August 17, 2006).



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Given that existing research and experience does not yet tell us precisely at which lower levels of nicotine cigarettes or other types of tobacco products would no longer establish or maintain any addiction among any users, the prudent path forward is to require the lowest nicotine levels that are currently achievable given available procedures and technologies. As the World Health Organization concluded in a related analysis, “a precautionary principle urges that the maximum nicotine content should be as low as is technically feasible.”³ This approach ensures that the addictiveness of the cigarettes and other tobacco products will be reduced to the greatest possible extent, and does not require the industry to do anything that it cannot already do.

Setting even lower limits that cannot currently be achieved would encourage new research and innovation that might ultimately permit compliance. But until the new technologies or procedures were developed, requiring lower reduced-nicotine requirements would constitute a de facto ban on the sale of the subject cigarettes and other tobacco products, which would likely increase industry, smoker, and political opposition.

While regular cigarettes can contain 8 to 23 milligrams or more of nicotine per cigarette,⁴ cigarettes have been distributed for commercial sale or for research purposes that have only 0.4 milligram or less of nicotine per cigarette or per gram of tobacco.⁵ Using the International Organization for Standardization testing method, cigarettes that contain 11 to 13 mg/gm of nicotine yield 0.6 mg of nicotine when smoked, and cigarettes with 0.4 mg/gm of nicotine yield less than 0.04 mg of nicotine.⁶ Other research has found nicotine yields from major cigarette brands ranging from 0.66 to 2.42 mg/cigarette.⁷

While the strategy of reducing nicotine levels to the lowest possible levels to reduce initiation

³ WHO, *Work in progress in relation to Articles 9 and 10 of the WHO FCTC*, Sixth Session, Conference of the Parties to the WHO Framework Convention on Tobacco Control (July 24, 2014).

⁴ See, e.g., Report of the working group, “Annex 3: Background Paper on Tobacco Addictiveness Reduction” (November 12-17, 2012).

⁵ For example, the Quest 3 brand of cigarettes, marketed in the United States, has been reported as containing either 1 mg or 0.6 mg of nicotine per cigarette. See, e.g., Hammond & O’Conner, *Cancer Epidemiology, Biomarkers & Prevention* (August 22, 2014) and MacQueen, DA et al., “Transient Compensatory Smoking in Response to Placebo Cigarettes,” *Psychopharmacology* 223(1): 47-54 (September 2012). The Dutch Magic cigarettes, scheduled to be marketed in the Netherlands, have similarly low nicotine levels. See, e.g., Business Wire “22nd Century Group’s Goodrich Tobacco Company Grants Exclusive Distribution Rights For Very Low Nicotine Cigarette Brand in Benelux” (April 16, 2013). Spectrum cigarettes manufactured for the U.S. National Institutes of Health for research purposes also have nicotine levels as low as 0.4 mg/gm. See, e.g., Hatsukami, DK et al., “Dose-Response Effects of Spectrum Research Cigarettes,” *Nicotine & Tobacco Research* 15(6): 1113-1121 (June 2013). According to the website of the 22nd Century Group, Inc., which manufactures Spectrum cigarettes (www.xxiiicentury.com), they can supply cigarettes with approximately 0.5 mg. of nicotine per cigarette. It also appears that lower nicotine levels have been obtained for batches of smoking tobacco that are less suitable, from a taste and texture perspective, for commercial or smoker research cigarettes; but it appears that ongoing developments in the field could bring nicotine levels in smoking tobacco down to even lower levels, without the taste and texture problems. Although a new reduced-nicotine measure could require low amounts of nicotine that could be reached only by making the taste and texture of the tobacco less palatable and acceptable to users, that could increase industry, public and political opposition. The *Report of the working group*, “Annex 3: Background Paper on Tobacco Addictiveness Reduction” (November 12-17, 2012) states that available procedures have also reduced the nicotine in tobacco to 0.05 mg/gm (genetic engineering) and to 0.03 mg/gm (supercritical fluid extraction). But these very low levels suggest that the report might actually be referring to yield levels not the actual amount of nicotine in the tobacco, itself.

⁶ See, e.g., Hatsukami, DK et al., “Dose-Response Effects of Spectrum Research Cigarettes,” *Nicotine & Tobacco Research* 15(6): 1113-1121 (June 2013).

⁷ Morton, MJ & Laffoon, SW, “Cigarette smoke chemistry market maps under Massachusetts Department of Public Health smoking conditions,” *Regulatory Toxicology & Pharmacology* 51(1): 1-30 (June 2008).



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and increase cessation is theoretically sound, it is also directly supported by existing research. In particular, published studies have found that lower-nicotine cigarettes with the currently lowest nicotine levels and yields (e.g., 0.4 mg nicotine per gram or 0.6 mg per cigarette, or with test-measured smoking yields of 0.05 mg of nicotine per cigarette) do not prompt smoker compensation, as do low-nicotine cigarettes with higher levels, and produce more promising results in regard to promoting smoking cessation.⁸

Given the addictive power of nicotine, the fact that the tobacco industry could readily produce cigarettes and cigarette tobacco with only 0.4 mg of nicotine per gram, or less, and the research indicating that cigarettes with such low levels of nicotine would work more effectively to encourage cessation than low-nicotine cigarettes with slightly higher levels, there does not appear to be any justification, from a purely public health perspective, for permitting cigarettes to continue to contain more than 0.4 mg of nicotine, or even lower levels if it were established they could readily be achieved through existing technologies or processes.⁹

Restricting the amount of nicotine in a single cigarette, instead of just restricting nicotine yields, would facilitate enforcement and reduce the risk of creating loopholes that allow for evasive compliance. When the amount of nicotine in any single cigarette is limited, whether a given cigarette or brand complies can be readily determined through available lab tests.¹⁰ More importantly, the less nicotine permitted in the product the harder it will be for the product to deliver addicting levels of nicotine to consumers, either through product chemistry or design changes or through consumer compensation. Applying the limit to the entire cigarette would also prevent manufacturers from gaming the system. Under a per-gram of tobacco or filler limit, manufacturers could simply increase the overall weight of the tobacco filler so that the cigarettes could also contain and deliver more nicotine.¹¹ To further prevent manufacturer product manipulation to evade the new nicotine limits, the new nicotine limit could also require that all parts of the cigarette, other than the tobacco filler, be totally free of nicotine.

⁸ It is worth noting that the very-low-nicotine cigarettes produced these beneficial results regarding cessation in existing environments where full-nicotine cigarettes remained readily available, and other smokers, possibly including friends or family members of the study participants, were still smoking those full-nicotine cigarettes, making relapse to smoking full-nicotine cigarettes much easier and more likely than it would be if a new nicotine-limit for all cigarettes were implemented. See, e.g., Hatsukami, DK et al., “Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation,” *Addiction* 105:343–55 (2010); Hammond & O’Conner, *Cancer Epidemiology, Biomarkers & Prevention* (August 22, 2014). See, also, McDermey, SS et al., “Greater reductions in nicotine exposure while smoking very low nicotine cigarettes predict smoking cessation,” *Tobacco Control* (September 5, 2014).

⁹ A World Health Organization analysis relating to Articles 9 and 10 of the FCTC states, without citing any sources, that it is currently technically feasible to produce cigarettes with only 0.1 mg of nicotine per approximately 1 gram of tobacco, stating that “WHO TobReg [the WHO Study Group on Tobacco Product Regulation] recommends that this be established as the standard” for any reduced-nicotine requirement for cigarettes. [WHO, *Work in progress in relation to Articles 9 and 10 of the WHO FCTC*, Sixth Session, Conference of the Parties (July 24, 2014).] Related inquiries indicate that the sources may be flawed, and the text regarding achievable levels may be revised. It also is not clear whether the stated low level (if it can currently be achieved) could be reached without significantly changing the character and taste of the tobacco when smoked in a cigarette.

¹⁰ For one example of a lab test that can be done to determine nicotine levels in cigarette tobacco and other tobacco, see To-bLabNet, *Standard Operating Procedure for Determination of Nicotine in Cigarette Filler* (2014), http://apps.who.int/iris/bitstream/10665/102318/1/9789241503907_eng.pdf?ua=1.

¹¹ A typical cigarette contains less than a gram of tobacco filler. Under U.S. tax law, for example, 0.0325 ounces of RYO tobacco (about 0.92 grams) was taken to equal one cigarette when the tax on RYO tobacco was increased to parallel the new tax on cigarettes in 2009. See, also, the definition of “cigarette” in the *Master Settlement Agreement* between many of the U.S. States and the major U.S. cigarette companies at II(m) and Exhibit Q (November 23, 1998). Accordingly, it would be just as easy, if not easier, for manufacturers to comply with a 0.4 mg per cigarette requirement as to comply with a 0.4 mg/gm or tobacco requirement.



In contrast to the available tests for nicotine content, the currently available tests for measuring nicotine yields from cigarettes are less precise, and cigarettes could be designed so that they show low nicotine yields in the tests but offer much higher nicotine yields as actually smoked by consumers (e.g., if smokers block the vents in the filter or even remove the filter).¹² But a limit on nicotine yields could be included in a nicotine reduction strategy to supplement a core limit on the amount of nicotine permitted and perhaps facilitate enforcement. For example, a nicotine-reduction law could both limit the amount of nicotine permitted in any single cigarette to 0.4 mg/gm (or some lower technically achievable amount) and also require that no cigarette yield more than 0.04 mg of nicotine under the International Organization for Standardization testing method (or some lower technically achievable amount) – with a violation of either requirement making the cigarette non-compliant.

Preventing the Tobacco Industry from Circumventing the New Nicotine Limits

Enforcing compliance with the new nicotine limits among legally operating tobacco businesses would be less complicated and difficult than enforcing against illicit trade and illegal companies. Compliance among established tobacco product manufacturers and related business would likely be high if they were faced with having any non-complying cigarettes or other subject tobacco products seized and destroyed and those brands prohibited from reentering the market for some extended time period. Large monetary fines and other severe penalties would be a further disincentive, and any fines received from violators could be allocated to support expanded enforcement efforts. In addition, testing to ensure compliance with the nicotine content limits would be relatively straight forward because measuring the amount of nicotine per cigarette or cigarette-like cigar, or per unit of tobacco could readily done in a lab (without the imprecision and possibility of loopholes from lab tests of nicotine yields).

The nicotine limits could, for example, state that if cigarettes from five different packs of a specific brand were found, through lab tests, to have more than 0.4 mg of nicotine per cigarette, that brand would be subject to seizure and could no longer be legally manufactured, imported, distributed or sold (at least not until the manufacturer paid related penalties and convinced the relevant authorities that future versions of the brand would fully comply). Similar standards could be established for other combustible tobacco products, either on a per-stick or per-gram basis, using the same testing methods – and similar tests would likely be needed to make sure that the non-tobacco or non-filler elements of the subject tobacco products (e.g., filters, paper or flavor capsules) did not contain any nicotine. To provide adequate time for manufacturers to modify their tobacco products to meet the new nicotine limits, the laws establishing the new requirements could provide for a transition period of one year or some other time period.

The health benefits from the new restrictions on nicotine levels could, however, still be sharply reduced if the tobacco industry were able simply to re-engineer their cigarettes or other subject tobacco products so that they technically complied with the new nicotine limits but still delivered addicting levels of nicotine to users or delivered higher levels of nicotine alkaloids and

¹² For just one of the many studies on how design features can alter measured nicotine yields, see, e.g., Caruso, RV & R. O'Connor, "Cigarette Design Features in Low-, Middle-, and High-Income Countries," *Journal of Environmental & Public Health* vol. 2012, Article ID 269576, 6 pages (2012).



agonists or other addictive constituents or new additives.¹³ This risk would be minimized by:

- (a) Setting the maximum permitted amounts of nicotine in the subject tobacco products as low as is technically feasible, at which point the maximum amount of nicotine they could possibly deliver to consumers, even with new technologies or procedures, would be minimized, as well;
- (b) Prohibiting nicotine as an additive, and prohibiting any part of the subject tobacco products, other than the tobacco or tobacco mixture, from containing any nicotine or any other potentially addictive ingredients or components, such as nicotine analogues;
- (c) Prohibiting any existing tobacco products that are modified to comply with the new nicotine limit from adding any new ingredients or significantly increasing the levels of any of their other existing additives, ingredients or constituents (such as nicotine analogues), -- other than those changes in ingredients or in the chemistry of the cigarettes that occur naturally and unavoidably in the nicotine-reduction process and are not likely to be associated with making the reduced-nicotine cigarettes otherwise addictive;¹⁴
- (d) Prohibiting any of the subject tobacco products (whether modified existing brands or new brands) from having any ingredients not typically found in the subject tobacco products prior to the new nicotine limit or from having levels of any non-nicotine additives, ingredients or constituents (such as nicotine analogues) in excess of the levels typically found in each type of the subject tobacco products today -- other than those changes in ingredients or in the chemistry of the cigarettes that occur naturally and unavoidably in the nicotine-reduction process and are not likely to be associated with making the reduced-nicotine cigarettes otherwise addictive; and
- (e) Expressly prohibiting manufacturers from taking any action that is meant or expected to increase the addictiveness of any subject tobacco products.

These prohibitions, with substantial fines and other penalties for violations, would work to prevent any reactive changes to the cigarettes or other subject tobacco products that might increase other addictive ingredients or make any existing or new addictive ingredients in the tobacco products more accessible to users.

To make monitoring the industry and related enforcement easier, all prohibitions and requirements in the reduced-nicotine measure, including the above, could have fixed effective dates. Rather than allow businesses to deliver and sell their inventories of non-compliant

¹³ Potentially addictive nicotine analogues currently exist in cigarettes only at very low levels, and the technologies and procedures for reducing the nicotine in cigarettes and cigarette tobacco appear to reduce the already low nicotine analogue levels, as well. At much higher levels than currently found, it is possible that nicotine analogues could work independently, in a reduced-nicotine cigarette, to create or sustain addiction (e.g., if added into the cigarette by the manufacturer). See, e.g., Vagg, R. & S. Chapman, "Nicotine Analogues: A Review of Tobacco Industry Research Interests," *Addiction* 100(5): 701-12 (May 2005).

¹⁴ See, e.g., Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), European Commission, *Addictiveness and Attractiveness of Tobacco Additives* (November 12, 2010), <http://www.who.int/entity/fctc/guidelines/SCENIHR.pdf?ua=1>.



cigarettes and other tobacco products until they run out, the measure could prohibit any manufacture or import of non-compliant products after a certain, fixed date; prohibit any distribution or deliveries of non-compliant products between businesses after a fixed date (which could be the same as the prior fixed date or perhaps 90 days subsequent to allow for selling off inventories); prohibit all retail sales or deliveries of non-compliant products to consumers after that same or a subsequent fixed date; and require the related businesses to destroy all non-compliant products in their possession within some reasonable time period after each of these deadlines.

Possible Scope of the New Nicotine Limits

Maximizing public health gains would seem to suggest applying the nicotine reductions to all tobacco products, which would also prevent the tobacco industry from trying to switch users from those tobacco products that had their nicotine levels reduced to any that were excluded from the reductions. Such a pervasive ban, however, could prompt many smokers and other tobacco users to try to turn to illicit trade to obtain the nicotine they crave – and without any legal products to sell, some legally operating tobacco businesses might turn to illicit practices, as well. It is also likely that applying a new nicotine-reduction requirement to all tobacco products would increase the intensity and extent of industry, consumer and political opposition.

Where, exactly, to draw the dividing line between tobacco products required to minimize their nicotine content and those allowed to continue at current levels in order to maximize public health gains and minimize the other problems is not clear. But existing knowledge and experience does suggest how that line could be drawn constructively to move forward effectively and secure substantial public health benefits.

Throughout the world, the vast majority of tobacco use harms comes from smoking and, in particular, smoking cigarettes. All smoking is also especially pernicious because of the harms it causes to those exposed to secondhand smoke. In addition, much of the available research on nicotine levels in tobacco products and on how users react to reduced nicotine versions has focused on cigarettes and smoking. These facts support applying the nicotine limits at least to all cigarettes and cigarette-like tobacco products and possibly to all smoked tobacco products, which would make the most harmful tobacco products minimally addictive while allowing smokers who did not quit to switch to less harmful legal sources of nicotine.

Any such nicotine-reduction requirement should also prevent the tobacco industry from evading the new requirement simply by relabeling or otherwise re-structuring their full-nicotine cigarettes or full-nicotine roll-your-own tobacco so that they could be legally sold to continuing cigarette smokers as “cigars” or “pipe tobacco.” The simplest, most effective way to prevent that kind of evasion would be to apply the nicotine limit to all combustible tobacco products, including all combustible loose tobacco, however, labeled or described.



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For example, a maximum of 0.4 mg of nicotine per stick or per unit limit could be applied not only to all tobacco products labeled or sold as cigarettes but also to all tobacco products labeled or sold as cigars that (a) have a cigarette-like filter; (b) do not weigh significantly more than the largest conventional cigarettes; or (c) do not significantly exceed the length and diameter of conventional cigarettes. To supplement that, a 0.4 mg of nicotine per gram of tobacco limit could be applied not only to all cigarette tobacco but also to: (a) all roll-your-own tobacco (including RYO tobacco for cigars); (b) all cigars not subject to the per-stick limit; and (c) all tobacco labeled or sold as pipe tobacco – with that provision also prohibiting any nicotine in any other components sold for roll-your-own purposes (e.g., filters or papers).

Because of the higher moisture contents in bona fide pipe and cigar tobaccos, and the overall size of large cigars, a 0.4 mg per gram of tobacco limit would allow them to contain more nicotine per cigar or per pipe bowl full compared to cigarettes. Nevertheless, the limit would still substantially reduce the amount of nicotine currently available from bona fide pipe tobacco and bona fide cigars, thereby reducing the likelihood that they would deliver enough nicotine to support the nicotine addiction of currently addicted cigar or pipe smokers or of any cigarette smokers who try switching to large cigars or pipes after the nicotine levels of their cigarettes were reduced.

Such a comprehensive approach might, however, face some opposition because there is less evidence or experience about reducing nicotine levels in bona fide cigars or bona fide pipe tobacco. Although the same technologies and procedures currently used to reduce nicotine levels in cigarette tobacco should apply just as readily to bona fide cigar and pipe tobacco, there could be differences in the readily achievable reduced-nicotine limits, especially if there is a desire not to effect the basic taste and character of the modified tobacco. To address this concern, a new nicotine limits could initially focus just on all cigarettes, all cigarette-like cigars, and all tobacco that could be used for roll-your-own cigarettes. Such an approach would also directly follow the existing research, which focuses primarily on cigarettes. But excluding any cigars or other combustible tobacco products or tobacco would also likely leave some loopholes for manufacturers to develop and market excluded cigars or excluded tobacco that could be smoked much like cigarettes and enable smokers to still get substantial amounts of nicotine through smoking rather than quit or switch to less harmful forms of obtaining nicotine. To minimize such problems and maximize the public health benefits, while still excluding some bona fide cigars and all bona fide pipe tobacco, a new nicotine limit could apply to all combustible tobacco products and tobacco except for narrowly drawn exceptions only for certain bona fide “premium cigars” and bona fide pipe tobacco that cannot be smoked as or like a conventional cigarette (i.e., cannot be inhaled as deeply or actively as cigarettes and cannot be smoked in the same volume or with the same frequency). For example, bona-fide “premium cigars” could be removed from the reduced-nicotine requirement, without creating any significant loopholes, by excluding any cigars that are wrapped in whole tobacco leaf, do not include typical cigarette tobaccos (e.g., burley or flue-cured tobacco), do not have a filter, and are not mass produced or machine made (e.g., are made by hand with only simply, non-motorized tools).



Similarly, bona fide pipe tobacco could be excluded through not applying the nicotine limit to tobacco or tobacco mixtures that contain only those types of tobacco typically used for pipe tobacco (e.g., contain no burley or flue-cured tobacco) and that also have moisture levels that are typical for slow-burning pipe tobacco (e.g., moisture by weight of at least 8 to 10 percent), which makes the tobacco unsuitable for cigarette-type combustion.

While excluding such premium cigars could reduce the overall public health benefits from a nicotine reduction strategy, the higher prices of the excluded premium cigars, and the fact that their smoke is considerably more harsh and harder to inhale than cigarette smoke, would continue to provide significant barriers to prevent youth and adult initiation into addictive smoking and would likely work to promote cessation among any cigarette smokers who switch to the premium cigars to try to obtain the nicotine they could no longer get from cigarettes. Excluding bona fide premium cigars, and bona fide pipe tobacco, would also reduce opposition from the manufacturers and retailers of those products, and their political allies, and possibly even gain support from some of them.

Minimizing Illicit Trade Risks

The more tobacco and nicotine products that were excluded from the new nicotine limits, the smaller the possible size of any new illicit trade in non-complying cigarettes or other non-complying tobacco products. Even if the new nicotine limits applied to all combustible tobacco products, smokers who did not quit could still obtain the nicotine they craved from other readily and legally available alternative tobacco and nicotine products, such as smokeless tobacco products, nicotine replacement therapies (NRTs), or, in countries that have not banned them, e-cigarettes. Because they can be handled and inhaled much like cigarettes, and can deliver similar doses of nicotine, e-cigarettes could be an especially attractive alternative to for smokers who might otherwise try to obtain illicit trade cigarettes. At the same time, switching from smoking to e-cigarettes or to other non-combustible tobacco and nicotine products would still produce at least some health gains, both to users and to exposed nonusers, especially if concurrent measures are implemented to make e-cigarettes less harmful.¹⁵

Excluding “premium” cigars, as discussed above, would directly prevent any emergence of any new illicit trade in those expensive cigars, themselves. Such an exclusion would also reduce the risk or size of any new illicit trade in non-complying cigarettes by enabling some smokers of cigarettes that no longer deliver adequate amounts of nicotine to get the nicotine they crave from legal, readily available premium cigars, instead of trying to secure illicit full-nicotine cigarettes.

Regardless of what is done with premium cigars, the size of any new illicit trade in full-nicotine cigarettes would be significantly reduced by the numbers of existing smokers who would quit

¹⁵ Relatively simple measures to make e-cigarettes less harmful might include requiring child-proof packaging for the nicotine-containing liquids, prohibiting contaminants or any known toxins, other than nicotine, in the e-cigarette liquids, and prohibiting any combustion, whether intended or not, during their operation or use. Additional measures to restrict the marketing and sale of e-cigarettes could also be implemented to minimize the risk that making them available to smokers would go beyond helping to dampen any illicit trade in full-nicotine cigarettes and also increase initiation into nicotine addiction among youth and adult nonsmokers.



all tobacco use because of the new nicotine limits and by some smokers simply continuing to smoke the legally available cigarettes after the limits are in place (perhaps including some of the “social smokers” or “chippers”). There are also some natural limits to any new illicit trade in full-nicotine cigarettes, with some smokers not willing to engage knowingly in illegal activities, either for moral reasons or because they are unwilling to risk the penalties or embarrassment of being caught, and other smokers unwilling to tolerate the inconvenience of finding and securing illicit cigarettes, especially when legal alternative sources of tobacco and nicotine would still be readily available.

The risk of any new, significant illicit trade in non-complying cigarettes could be reduced further by prohibiting the manufacture in country of non-compliant cigarettes (e.g., for export) to reduce the risk of diversion into illicit trade. At the same time, restricting the distribution and sale of full-nicotine tobacco (and possibly other components or ingredients) for manufacturing and processing purposes would impede any in-country illegal manufacturing. Enhanced enforcement efforts against all aspects of illicit trade, including Internet and mail-order sales, would also reduce the extent to which smokers would be willing or able to try to sustain their smoking by seeking illicit full-nicotine cigarettes. More generally, the ongoing efforts by member countries to implement the FCTC protocol on illicit trade will both strengthen countries’ internal capacity to combat any illicit trade in full-nicotine cigarettes and also hinder efforts to divert full-nicotine cigarettes from other countries into that illicit trade.¹⁶

Fortunately, it would be more difficult to maintain an illicit trade in full-nicotine cigarettes compared to the existing illicit trade in cigarettes based on price. Most importantly, the full-nicotine illicit trade cigarettes could not look just like legally sold cigarettes (as many cigarettes in the current illicit trade market do) because smokers would not want to purchase cigarettes that looked just like the legal, reduced-nicotine brands. They would want clearly different, full-nicotine cigarettes. For the same reason, otherwise legally operating retailers could not profiteer by selling illicit full-nicotine cigarettes to unsuspecting smokers (like some do in the price-based illicit cigarette trade). Unlike the current illicit trade, an illicit trade in full-nicotine cigarettes would require the distribution and sale of clearly illicit cigarettes to knowing consumers, which would make it more visible and easier to enforce against. Eventually, as more and more countries implemented nicotine limits, there would also be fewer and fewer ready sources of full-nicotine cigarettes for illicit trade.

Nevertheless, countries that have not yet developed the capacity to enforce against the possible emergence of an illicit trade in non-complying cigarettes may want to postpone implementing any nicotine-minimizing strategy until they have done so – especially in those countries that already have established networks for importing, distributing and selling (through illegal vendors) illicit cigarettes. It is also important for countries to have the capacity to inspect and test the cigarettes and other subject tobacco products subject to the new nicotine limit that are offered for legal sale to ensure that they comply with the nicotine limits, and to take related enforcement action against non-compliant brands, including seizure and destruction.

¹⁶ WHO FCTC, *Protocol to Eliminate Illicit Trade in Tobacco Products* (2013), www.who.int/fctc/protocol/en.



The New Nicotine Limits Are Unlikely to Prompt Smoker Compensation (Unless Phased In)

The sharp reductions to nicotine levels proposed here could prompt some smokers to try to compensate for the products' reduced nicotine yields by changing how they consume the tobacco products (e.g., by inhaling more intensely) or by consuming larger amounts, which, if sustained, could increase their health harms from smoking. As recent studies suggest, however, such compensatory behaviors are unlikely to persist if the cigarettes and other subject tobacco products contained such small amounts of nicotine that they could not, even with new cigarette designs or compensatory behaviors, deliver sufficient nicotine to maintain addiction. For example, as noted previously, studies have found that low-nicotine cigarettes with the currently lowest nicotine levels and yields (e.g., 0.4 mg nicotine per gram or 0.6 mg per cigarette, or with test-measured smoking yields of 0.05 mg of nicotine per cigarette) produced more promising results than low-nicotine cigarettes with higher levels because they did not prompt any compensatory smoking behaviors and promoted smoking cessation more effectively.¹⁷

This research – and the absence of any research suggesting that gradually reducing nicotine levels provides any cessation or other benefits – also supports implementing the new minimum nicotine limits all at once, without phasing them in over time. Besides delaying cessation and postponing initiation reductions (because the minimal nicotine levels would not be reached as quickly), any gradual or step-by-step reduction in nicotine levels could also produce increased health harms by smokers compensating for the gradually reduced, but not yet minimal, nicotine levels, either by smoking more or by smoking more deeply. In contrast, once faced with minimum-nicotine cigarettes, as proposed here, smokers would soon abandon their inevitably unsuccessful compensatory efforts. Finding it impossible to obtain the nicotine they craved from the minimal-nicotine cigarettes, they would likely quit completely or switch to other products still on the market that could provide adequate amounts of nicotine to feed their addiction.¹⁸

Sustained Dual Use Is Unlikely to be A Significant Smoker Response

As discussed above, if the minimal-nicotine requirement applied to all of the most harmful tobacco products (e.g., all combustible tobacco products or all cigarettes and other tobacco products that can be smoked like cigarettes), the likelihood that cigarette smokers will simply switch to other equally harmful forms of still legally available tobacco use largely disappears. But a related concern has been raised that some smokers might continue smoking the reduced-nicotine cigarettes and turn to dual use with other legally available full-nicotine tobacco products to feed their addiction, such as smokeless tobacco or e-cigarettes, thereby increasing harms to those dual users. The extent to which such dual use would be more harmful than just smoking is not clear, however, and the risk of increased harm is likely diminished if the dual use reduces the amount smoked or if the dual use were only with nicotine replacement therapies

¹⁷ See, e.g., Hammond & O'Conner, *Cancer Epidemiology, Biomarkers & Prevention* (August 22, 2014) [and other studies cited therein]; Hatsukami, DK et al., "Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation," *Addiction* 105:343–55 (2010).

¹⁸ See, e.g., *supra*, previous note; and Benowitz & Henningfield *Tobacco Control* 22(Supplement 1): 14-17 (2013) [and the references cited therein].



(NRTs) or other clean-nicotine tobacco products.

More significantly, a major constraint (beyond inconvenience) to any such dual use is that it would roughly double the smokers' consumption costs; and existing research has established that higher tobacco use costs directly reduce consumption and prevalence (and initiation). Because of those costs, any dual use that did occur would likely be a temporary step toward switching completely to the less-harmful supplementary product (the only one providing nicotine) or quitting altogether. The fact that many of the user-perceived sources of satisfaction from the act of smoking (which come from addressing the smoker's nicotine addiction) would no longer exist, but all the negative aspects of smoking would remain, would further discourage any sustained dual use.

The risk of any such dual use would also be reduced to the extent that available alternatives to smoking provided smokers with a way to obtain nicotine in ways that were comparable to smoking full-nicotine cigarettes and made concurrent smoking unnecessary. E-cigarettes might offer just such an alternative, given that they enable smokers to inhale nicotine directly into their lungs, just as they do with cigarette smoking, can provide similar taste and mouth feel, and allow users to otherwise parrot smoking behaviors.

Existing Systems Can Handle the Increase in Smoker Quit Attempts

Concerns have also been raised that sharply reducing nicotine levels in tobacco products – even if it applied only to cigarettes and cigarette-like cigars – could prompt large, unprecedented numbers of current smokers to seek cessation assistance and other medical advice or treatment, possibly overwhelming existing cessation-assistance services. That could only happen, however, if the new nicotine limit was extremely effective at prompting smokers to try to quit tobacco and nicotine use completely, a highly desirable outcome from a public health perspective. Moreover, even if many smokers were unable to obtain the cessation assistance they desired, it is likely that many would quit, anyway.

Currently, the vast majority of smokers who have quit successfully to date have done so without any formal assistance or medical treatment. It is also possible that such assistance would not be needed by many of the smokers who were trying to quit in an environment where spontaneous or unplanned relapse into smoking would be much more difficult (because cigarettes or cigarette-like cigars delivering adequate amounts of nicotine to support relapse would no longer be legally or readily available). It is also likely that the pharmaceutical industry, to maximize profits, would respond to the nicotine-reduction measures by substantially increasing the availability of their nicotine replacement products and their related advertising and consumer education, which would both encourage more smokers to try to quit completely and provide them with instructions on how to do so using NRTs. Any smokers trying to quit who were unable to obtain all the cessation assistance they desired, and did not simply quit anyway, would likely find the nicotine they craved from the remaining, less-harmful tobacco and nicotine products, or NRTs, that were still legally on the market -- and their use of those products, instead of quitting altogether, would likely still secure significant public health



gains.

Nevertheless, to maximize the public health gains from implementing a nicotine-reduction strategy, and to help addicted smokers adapt most easily and constructively, countries with the resources to do so could also take concurrent steps to: (a) encourage smokers to respond to the nicotine reductions by quitting completely; (b) educate smokers about the most effective ways to quit completely and successfully; (c) make nicotine replacement therapies and cessation medications and treatments more readily available to those who might not otherwise be able to afford them; and (d) otherwise increase the availability and affordability of cessation assistance and related resources.

Minimizing Nicotine and Reduced Smoking Initiation (Even If Experimentation Increases)

What we know about nicotine's role in smoking initiation tells us that making cigarettes and other combustible tobacco products much less physically addicting, through reducing their nicotine levels to the minimal technical achievable levels, would significantly reduce the portion of youth who experiment with smoking that subsequently become physically addicted users – and there is no available research or data that suggests otherwise.

It is possible, however, that the nicotine reductions could make experimenting with smoking appear less risky, which might increase the total number of youth who give smoking a try. But other factors, besides concerns about nicotine, play more prominent roles in whether or not youth experiment with smoking (or continue on to regular smoking), and these factors would continue to prevent many youth from experimenting or initiating into smoking after any nicotine limits were put in place.¹⁹ For example, concerns about the non-nicotine harms from smoking and having family and friends that do not smoke or have anti-smoking attitudes would still prevent many youth from trying cigarettes.

More importantly, even if the number of youth experimenting with smoking increased from current levels, the new minimal nicotine levels would make it much less likely that the experimenters would become physically addicted and would still reduce the total number of youth who moved on to become regular smokers.²⁰

In addition, any increased youth experimentation that might be caused by the nicotine reductions could be minimized through efforts to ensure that the media, the general public and, especially, youth understood that the cigarettes and other tobacco products with lower nicotine levels remained just as deadly and harmful as before, both to smokers and to those exposed to secondhand smoke.

¹⁴ See, e.g., O'Loughlin, J. et al., "Determinants of First Puff and Daily Cigarette Smoking in Adolescents," *American Journal of Epidemiology* 170(5): 585-597 (July 27, 2009).

²⁰ On the standard trajectory from youth experimentation to regular, addicted, daily use, and the role of nicotine, see, e.g., Caraballo, RS., et al., "Linking quantity and frequency profiles of cigarette smoking to the presence of nicotine dependence symptoms among adolescent smokers: findings from the 2004 National Youth Tobacco Survey," *Nicotine & Tobacco Research* 11(1): 49-57 (January 2009).



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Any youth who still became regular adult smokers after the nicotine limits were in place would also find it easier to quit later on, because they would not be as physically addicted, and they would likely have equally strong motivations to try to quit as current smokers do (e.g., because smoking would still be just as harmful and at least as unpopular with nonsmokers). Quitting smoking would be easier not only because the smokers of the reduced-nicotine cigarettes would be much less physically addicted, but because high-nicotine cigarettes and other high-nicotine combustible tobacco products that could be smoked like cigarettes would not be readily, or legally, available, thereby reducing relapse opportunities and making relapse into smoking much less likely for those trying to quit.

Reducing Nicotine Levels is a Powerful Next Step for Global Tobacco Control Efforts

As described here, reducing tobacco use harms through reducing nicotine levels is not as simple as just reducing nicotine levels for cigarettes and possibly other tobacco products. But it is clear from existing knowledge and research that sharply reducing the amount of nicotine in cigarettes and most, if not all, other combustible tobacco products to the lowest currently achievable levels is now a viable strategy for many countries. It would secure the lion's share of the massive public health potential from a nicotine-reduction approach while minimizing related complications and unintended consequences.

Reducing the amount of nicotine in tobacco products to minimal levels would sharply reduce their ability to create and maintain dependence. But they would otherwise still be just as harmful and deadly as before, making it prudent to continue working to discourage and reduce their use through the other measures set forth in the WHO FCTC and related protocols and guidelines. Indeed, the implementation and enforcement of those other anti-smoking and tobacco control measures provide a strong foundation for implementing the reduced-nicotine approach described here and would help to increase its beneficial impacts.

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