June 16, 2014 (updated)

Dr. Margaret Chan
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Dear Dr. Chan,

We, the 129 signatories to this letter, are writing to express our support for WHO's evidence-based approach to determine the best way forward for public health to respond to Electronic Nicotine Delivery Systems (ENDS), as expressed in WHO's June 3, 2014 statement.[1]

Recently, media attention was focused on a statement by a group of "specialists in nicotine science and public health policy."[2] Unfortunately, the statement makes several assertions about ENDS' marketing, emissions, harms, and use that are either contradicted by available evidence or for which no evidence is currently available. (Indeed, the statement does not cite a single scientific study.)

The statement also included several policy recommendations, including effectively exempting ENDS from FCTC Articles 8 and 13 and ignoring Article 5.3.

It is fundamental that WHO and other public health authorities not buy into the tobacco industry's well-documented strategy of presenting itself as a "partner."[3] If the tobacco industry was committed to reducing the harm caused by tobacco use, it would announce target dates to stop manufacturing, marketing and selling its "more harmful" products rather than simply adding e-cigarettes to its product mix and rapidly taking over the e-cigarette market.[4-5] It would also immediately desist from its aggressive opposition to tobacco control policies such as tax increases, graphic health warnings and plain packaging.

By moving into the e-cigarette market, the tobacco industry is only maintaining its predatory practices and increasing profits. As stated in the guidelines for Article 5.3 of the WHO FCTC, there is a "fundamental and irreconcilable conflict of interest" between the tobacco industry's interests and public health's interests."[6]

Public health embraced cigarette filters and "low tar" cigarettes as harm reduction strategies before manufacturers provided evidence and at a time when the manufacturers were well aware that these technologies did not actually reduce harm but were designed to promote cigarette sales by reassuring a concerned public that the new products were safer.[7-8] The negative consequences of these acts remain in cancer and heart disease hospital wards throughout the world. Ignoring the link between ENDS and the tobacco industry is overlooking

the WHO FCTC Parties' legal obligation to protect government policies against tobacco industry interference.

The aggressive marketing and promotion of e-cigarettes to youth is well-documented[9-10-11-12] and evidence from the US[13-14] and Korea[15] shows rapid growth in youth e-cigarette use, including disturbing rates among youth who have never smoked a cigarette. One e-cigarette manufacturer warns parents that "kids may be particularly vulnerable" to the flavoring in its products.[16]

Manufacturers of ENDS are making a range of false and unproven claims,[17-18-19] misleading the public into thinking these products are harmless (they are not) and effective cessation aids (unknown). Most ENDS users are "dual users" who continue to smoke cigarettes.[20] Reviews of evidence about reducing smoking (instead of quitting) show that dual users are unlikely to see any health benefit in terms of cardiovascular disease.[21]-[22] Population studies of all smokers consistently show that smokers who use ENDS are *less* likely to stop smoking.[23-24-25-26-27-28]

The evidence is insufficient to accept the assertions that ENDS are effective as a smoking cessation device. There is a single randomized controlled trial of early generation e-cigarettes that found no difference between ENDS delivered directly to experimental subjects compared with mailing subjects a voucher that they could take to a pharmacy to obtain nicotine replacement therapy.[29] One population-based cross-sectional study found that highly motivated smokers using ENDS to quit were less likely to be still smoking than smokers making unassisted quit attempts with over-the-counter NRT.[30] However, this cross-sectional study[31] showed a point prevalence of 80% of smokers using ENDS in a cessation attempt having failed, compared to 84.6% of those who tried to quit unassisted. Significantly, the former study is biased against conventional therapy (because of the additional barrier to getting the NRT) and the latter did not report a comparison with well-supervised approved cessation therapies.

There is already good evidence that ENDS emissions release several toxic substances into the environment that cause harm to health. These substances include ultrafine particles, propylene glycol, tobacco-specific nitrosamines; nicotine; volatile organic compounds (VOCs), and carcinogens and reproductive toxins, including benzene, lead, nickel, and others.[32-33-34-35-36-37-38-39-40] Proposals to allow ENDS use in indoor spaces like workplaces, bars and transportation could see significant exposure to these substances.

It is important to note that nicotine itself is not harmless, which is why strict regulatory measures are in place to control the marketing of Nicotine Replacement Therapy for smoking cessation. The 2014 U.S. Surgeon General Report includes an extensive review of acute and long-term effects of nicotine exposure. It concludes, among other things, that nicotine exposure has adverse effects on fetal growth and development, including fetal brain development.[41] The manufacturer of one electronic cigarette in the U.S. acknowledges in its product labeling that nicotine is not harmless.[42] Acute poisoning from nicotine is well established, and there has been an increase in documented cases of children being accidentally poisoned by ingesting the liquid content of ENDS cartridges.[43]

Remaining unregulated, risk profiles and potential harms these products may pose to the public are unknown. The absence of detailed evidence on adverse health effects is not evidence that no effect exists. Rather, insufficient time has elapsed to determine what effects exist and their magnitude on a population level.

Manufacturers have not secured regulatory approval for claims that ENDS are effective products for smoking cessation or harm reduction from regulatory authorities in any country. From a population perspective, it is important to know what new risks a consumer product may introduce in the market.

We applaud WHO's commitment to listen to the experience from Member States that have successfully implemented tobacco control and regulated sales, marketing and use of ENDS. Implementation of the WHO FCTC by its 178 parties demonstrates great progress in decreasing the harm caused by tobacco use and decreasing the burden from NCDs.

There is evidence of success from many countries, including Australia, Brazil and Turkey. The former prohibits import and sales of cartridges containing nicotine, the latter two banned import, sales and marketing of e-cigarettes until, and unless, manufacturers present safety information.

Both scientific evidence and best practices are available to support a regulatory framework that will best prevent initiation of use among youth and other non-tobacco users, protect bystanders in public areas from involuntary exposure, regulate marketing, and prohibit unsubstantiated claims.

Such a regulatory framework would require manufacturers to present safety and efficacy data. In this case, the use of these products as cessation aids (if the evidence supports such use) would operate under the supervision of a health authority that could control manufacturers' claims, impose health warnings about risks, require disclosure of ingredients and safety data and regulate product engineering as well as mandate surveillance.

This is the path that the WHO has been pursuing and encouraging. We urge you to continue doing so.

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