Means and ENDS – E-Cigarettes, the Framework Convention on Tobacco Control, and Global Health Diplomacy in Action

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Abstract

E-cigarettes are a new and disruptive element in global health diplomacy (GHD) and policymaking. This is an ethnographic account of how e-cigarettes and other Electronic Nicotine Delivery Systems (ENDS) were tackled at the 6th Conference of the Parties to the World Health Organization's Framework Convention on Tobacco Control. It demonstrates how uncertainty about ENDS and differences of opinion are currently so great that 'agreeing to disagree' as a consensus position and 'strategic use of time' were the principles that ensured effective GHD in this case. Observers representing accredited non-governmental organizations were active in briefing and lobbying country delegates not to spend too much time debating an issue for which insufficient evidence exists, and for which countries were unlikely to reach a consensus on a specific regulatory approach or universally applicable regulatory measures. Equally, the work of Costa Rica in preparing and re-negotiating the draft decision, and the work of the relevant Committee Chair in managing the discussion, contributed to effectively reining in lengthy statements from Parties and focusing on points of consensus. As well as summarizing the debate itself and analysing the issues surrounding it, this account offers an example of GHD working effectively in a situation of epistemic uncertainty.

Keywords: global health diplomacy; e-cigarettes; Framework Convention on Tobacco Control; collaborative event ethnography; international law; anthropology

Introduction

ENDS – a challenge for global health diplomacy and policy-making

From a Chinese patent issued in 2003, the marketing, sales and use of electronic cigarettes or e-cigarettes have expanded rapidly around the world. Between 2009 and 2013, for example, sales in the US rose from \$20m to \$1bn; the UK has followed a similar trajectory (Stimson, Thom, & Costall, 2014). Since the e-cigarette is but one of a category of products remarkable for their diversity of brands, types and nomenclature (Zhu et al, 2014), 'Electronic Nicotine Delivery Systems' (ENDS) has become the preferred term in policy circles. ENDS commonly contain a liquid mixture of propylene glycol and/or vegetable glycerin, flavourings, water and (usually) nicotine. A battery-powered element heats the liquid to produce a vapour that is inhaled and exhaled.

ENDS represent a 'disruptive innovation' (Stimson et al., 2014), by which is meant a new product causing rapid, dramatic changes in manufacture, marketing, and consumer behaviour but also, in this case, dilemmas for global health diplomacy (GHD) and policy-making. In this article we describe and analyse the way in which ENDS were handled in global health policy-making at the 6th Conference of the Parties (COP6) of the World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC). The FCTC, the first international public health treaty ever negotiated by the WHO (Nikogosian, 2010), came into force in February 2005 and is one of the most quickly and widely embraced treaties in the history of the United Nations. The COP is the governing body of the FCTC, and meets biennially to oversee its progress and make decisions about its further development. One hundred and seventy-eight countries had become Parties to the FCTC by the start of COP6, of which 137 sent representatives. Observers representing six non-Party states, four intergovernmental organizations (IGOs), and 10 nongovernmental organizations (NGOs) also participated. The largest of the NGOs, with 110 of the 171 NGO participants, is the Framework Convention Alliance (FCA), a global tobacco control alliance of some 500 NGOs formed in 2000 to work for the development, ratification, and implementation of the FCTC (Lencucha, Kothari, & Labonté, 2011; Lencucha, Kothari, & Labonté, 2012; Mamudu & Glantz, 2009). Seven hundred and five participants in total attended COP6, which took place at the World Trade Centre in Moscow from 13-18 October 2014.

Events prior to COP6 suggested that ENDS would be a contentious issue. On 26 May 2014, 53 scientists wrote to Margaret Chan, Director General of the WHO, arguing that e-cigarettes

were a much safer form of nicotine and that the burden of tobacco-caused diseases would be greatly reduced if smokers were encouraged, through appropriate policies, to switch from smoking cigarettes to using e-cigarettes (Abrams et al., 2014). Two weeks later Chan received a second letter, this time from 129 doctors and public health professionals (Atkan et al., 2014). Its signatories argued that e-cigarettes were a means for the global tobacco industry to continue doing what it has always done, but by the back door, i.e., reap huge profits by selling the addictive drug nicotine in an ostensibly healthier drug delivery device, using the same predatory and deceptive marketing practices (cf. Ashton, 2014). The writers also countered the claims made in the first letter regarding the cessation benefits and minimal health risks of e-cigarettes.

COP6 was not the first time the issue of e-cigarettes had been examined by Parties to the FCTC. At COP4, held in Uruguay in 2010, Parties requested the Convention Secretariat, the administrative organ of the FCTC, to prepare a report together with the WHO's Tobacco Free Initiative (TFI) on ENDS for COP5 to consider. Discussion of this report at COP5 led to a further invitation from the Parties for the Convention Secretariat to 'identify options for the prevention and control of ENDS and examine emerging evidence on the health impacts of the use of such electronic systems' (FCTC, 2014a, p. 1) in time for COP6. This report was prepared by a TFI Programme Manager and was made public on 21 July 2014 (FCTC, 2014b).

In this article we consider the debate, discussions, and final decision concerning ENDS at COP6 as an example of effective GHD in action. For some, GHD is a field of research and training (Adams, Novotny, & Leslie, 2008; Fairman, Chigas, McClintock, & Drager, 2012; Fidler, 2011; Ozdemir, Husereau, Hyland, Samper, & Salleh, 2009; Wipfli & Kotlewski, 2014), but more recently it has been looked at as a political process (Kevany, 2014; Kickbusch & Rosskam, 2012; Labonté & Gagnon, 2010) involving a set of activities or methods (Kickbusch & Rosskam, 2012; Michaud & Kates, 2013). Diplomacy has been defined as 'the art or practice of conducting international relations through negotiating alliances, treaties and other agreements' (Lee & Smith, 2011, p. 2). GHD is an example of 'new diplomacy' (ibid.), reflecting the novelty of health being considered a foreign policy issue like security and economics. Kevany (2014) goes further, arguing that global health has a unique role to play in furthering broader diplomatic and foreign policy goals in the 'New World Order'. 'New' also refers to the changing actors in the forums of international policy-

making and diplomatic process. State actors (such as country diplomats and civil servants with issue expertise) find themselves negotiating not only with other state actors but also with non-state actors such as NGOs, IGOs and private-public partnership organizations, in a variety of policy platforms. All of these actors find themselves having to develop new skills and knowledge (for example, diplomats in global health, and tobacco control experts in international law and diplomacy). GHD's breadth as a concept has been critiqued for merging the three distinct but overlapping activities — politics, diplomacy, and governance — that constitute it (Fidler, 2011). Since our data pertains specifically to the negotiations that occurred at COP6, our focus is on the diplomacy aspect of GHD.

There is a growing body of research on the processes involved in GHD. Thaiprayoon and Smith (2014), for example, combine observation of meetings and semi-structured interviews to piece together Thailand's experience of capacity building in GHD for health-related trade issues. Their in-depth analysis of the negotiation process and insider perspectives concludes that while Thailand's successes offer useful lessons to other nations, complete coherence between trade and health has yet to be achieved. Lencucha et al (2010; 2011; 2012) investigate the involvement of Canadian NGOs in GHD at the time of the FCTC negotiations, demonstrating their vital role in making GHD for tobacco control less state-centric and more cosmopolitan in its approach (Lencucha, 2013).

There have also been first-person reflections on the processes of GHD. Rosskam and Kickbusch's edited volume includes several such accounts intended for 'new health diplomats' (from state and non-state sectors) 'to increase their understanding of the dynamics as well as the art of global health diplomacy and to improve their negotiation skills' (2012, p. 6). Bernard (2012) describes the process of negotiating the FCTC treaty as head of the US delegation. He highlights the important role of chairmanship and the impact of a chair's particular diplomatic skills in shaping negotiations. He also criticizes the 'hostile rhetoric' of the NGOs during the negotiations, feeling that the US in particular was singled out for unfair criticism. Taylor and Dhillon (2011) offer similar insider perspectives on the negotiation of the WHO Global Code of Practice on the International Recruitment of Health Personnel. They demonstrate the importance of effective leadership in containing the drafting process, the strategic contributions of developing nations, and the actions of developed nations to weaken the language of the Code.

Most commentators (e.g., Bernard, 2012; Mamudu & Glantz, 2009; Mamudu, Gonzalez, & Glantz, 2011; Roemer, Taylor, & Lariviere, 2005) and the transcripts of a seminar organized in Geneva at the time of the FCTC's fifth anniversary (Reynolds & Tansey, 2012), reflect primarily on the negotiations to establish the FCTC rather than on how GHD has worked since it came into force. As well as 'mapping GHD' (Fidler, 2011), however, the specific topic we address — ENDS at COP6 — shows how global tobacco control's 'epistemic community' (Mamudu et al, 2011) responds to circumstances of uncertainty regarding the potential harms of ENDS and disagreements over appropriate regulatory strategies.

Our ethnographic approach facilitates looking at GHD processually rather than through the analysis of documentary outputs or post-hoc interviews. It offers more nuanced understandings of the strategies adopted to contain debate on ENDS at COP6 by various key actors in the process: Costa Rica, the FCA, and the Chair of the Committee in which the issue was formally discussed. Two principles of GHD in conditions of epistemic uncertainty emerge from our analysis. The first is 'agreeing to disagree', whereby an issue over which uncertainty exists, causing intractable differences of opinion, can be effectively 'parked' so as not to destroy the consensus politics on which GHD depends. The second is the 'strategic use of time', concerning where disruptive issues are placed on the agenda and how they are handled so as not to consume a disproportionate amount of time. Both, we argue, are valuable principles of effective GHD in contexts of ontological and epistemological uncertainty.

Methods

The value of ethnographic methods for political research has been cogently argued, but ethnography is still under-represented as a methodology in this field (de Volo & Schatz, 2004; Schatz, 2009; Wedeen, 2010). Our research followed a modified form of Collaborative Event Ethnography (CEE). CEE uses a team approach to fieldwork, covering as many microevents as possible in the transnational 'mega-event' (Little, 1995, p. 265) represented by the COP. Originally developed for research on the Framework Convention on Biodiversity and its associated COPs (e.g., Brosius & Campbell, 2010), we are the first to use CEE to research the COPs of the FCTC. The careful description and micro-analysis of real-time negotiations that ethnography provides offers insights which may be applicable to other contexts.

AR and MW attended COP6 as anthropologists affiliated to Action on Smoking and Health (ASH UK), a member of the FCA. MT was a member of the FCA Board and attended COP6

as a representative of the Non-Smokers' Rights Association in Canada, also a member of the FCA. She was responsible for giving talks on the FCA's position on ENDS at the FCA briefing day and at a lunchtime seminar during COP6, and she wrote an article on ENDS for the FCA daily *Bulletin*. As accredited NGO observers and members of the FCA, the authors followed the ENDS debate at the FCA pre-COP briefing session, daily FCA morning and evening meetings, regional meetings, plenary sessions, committee meetings, and lunchtime seminars, as well as engaging with COP participants during coffee and lunch breaks and at the social events hosted by the Russian Federation.

Much of the work at the COP takes place in two committees, which normally meet simultaneously. Committee A deals with substantive policy issues, while Committee B addresses institutional and procedural issues including budgetary matters. CEE enabled us to cover the work of both committees as well as attend the regional meetings appropriate to the regions from which we came (Europe and the Americas). Detailed, frequently verbatim, notes were made by hand or on laptops. ENDS was but one of eight major topics debated at COP6. We took particular interest in the arguments made about how to deal with ENDS, who was making them, and what tone they used. We also noted the extent to which the issue was discussed in different venues. We collected, documented, and analysed the types of supporting information participants drew upon in their discussions. As well as the formal meetings, we spoke with many participants 'off the record' — during lunch and refreshment breaks, on the buses back to the conference hotels, around the WTC cloakrooms and even (on one occasion) the bathroom! The COP is a frenetic environment in which the majority of participants are fully engaged in negotiations, meetings, phone calls, lobbying and seminars from early morning until late into the night. For this reason, we felt it inappropriate to conduct formal interviews.

We discussed our findings at daily CEE evening meetings and compared them post-COP with published verbatim recordings of the plenary sessions and summary records of the meetings of the two COP6 committees. The authors speak three of the six official UN languages (English, French, and Spanish). Headphone receivers transmitting simultaneous translation of all six official UN languages were available for all plenary, committee and regional meetings.

Our protocol was approved by the Ethics Committee of the Anthropology Department at Durham University prior to commencing our research. In what follows we are mindful of the fact that many of the sessions at COP6 on which we report were closed to members of the public, in order to stop the tobacco industry from influencing proceedings in real time. This is in keeping with Article 5.3, a cornerstone of the treaty, which concerns the general obligation that 'in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law' (WHO, 2003, p. 7). We therefore anonymise individual Party speakers in order to respect the decision of the COP and to protect individuals from any potential harassment by industry representatives or those unduly influenced by the industry in their home countries.

Findings

The FCA briefing: from 'recommendations' to 'principles'

One important task the FCA undertakes is the development of policy briefings on key issues for forthcoming COP sessions. These documents, available on the FCA's open-access website, are widely circulated to NGOs, state Party and non-Party civil servants, and IGOs both in advance of and during the session. Given the discord within the tobacco control community regarding the regulation of e-cigarettes, the FCA's five-page briefing on ENDS was particularly important. The product of five months' deliberation by members of FCA's E-cigarette Task Force and subsequently its Policy Committee, it identified five distinct (but sometimes overlapping) policy approaches to dealing with ENDS – in the same way as tobacco products; as therapeutic products; as general consumer items; as a unique category; and as products that are prohibited altogether. The briefing advised that 'because of differences in regulatory systems and national circumstances, it will be difficult to reach consensus at COP6 on specific regulatory approaches to ENDS' (FCA, 2014b, p. 1), although agreement on some 'broad principles or concerns' might be possible (ibid., p. 3) (Table 1).

[Table 1 near here]

For some, the potential health risks of ENDS and the risk of ENDS enabling tobacco companies 'to return to lifestyle advertising and rehabilitate their reputation — and, by implication, that of their tobacco products — via clever cross-marketing with e-cigarettes' (ibid., p. 4) more than outweigh any possible benefits to smokers unable or unwilling to forsake nicotine who might be less harmed by switching to e-cigarettes. For others, allowing — and indeed, encouraging — smokers in this position to switch to e-cigarettes could have

massive health benefits that more than compensate for the danger of letting the tobacco industry in 'by the backdoor'. The FCA also acknowledged that differences in resources and technical expertise among the Parties were important factors in determining how best to regulate ENDS, since 'a regulatory approach that might be appropriate in a high-resource setting — involving, say, extensive testing of products and surveillance of marketing practices — might be entirely impractical in a low-resource setting' (ibid., p. 4). The FCA also underlined the deficits in the knowledge base for ENDS upon which guidelines might be produced. 'We are not convinced the evidence base of national experiences exists to definitively recommend, at the global level, a detailed list of specific approaches to many of the complicated regulatory issues these products raise' (ibid.).

In discussing the FCA briefing, one FCA member commented that 'the briefing may be difficult for delegates who look to the FCA for a position'. He was corrected by another affiliate who argued there was a position, one of 'agreeing to disagree'. Reaching consensus was clearly something which was 'likely to take some time' (ibid., p. 5) and, in the words of another FCA representative, Parties 'could waste a lot of time discussing this issue'. Time was limited at COP6, and NGO delegates were warned that while the first day and a half was usually slow, the pace of the meeting would quickly pick up; diplomatic and advocacy strategies therefore needed to take the time issue into account. Where items are placed in the agenda puts them at more or less risk of receiving insufficient time for discussion, and items likely to generate lengthy debates of opposing views with little chance of developing policy consensus require careful handling so that they do not monopolize the time available. One FCA representative talked of the e-cigarette issue needing to be kicked 'into the long grass'. Another said it should be 'parked', so that Parties could focus instead on issues that were more likely to achieve a position of consensus or compromise from which real change could take place. Thus, the FCA proposed the establishment of an expert body to meet after COP6 to examine the emerging scientific evidence on e-cigarettes and lessons learnt from the experiences of Parties adopting different regulatory approaches.

The FCA also played a valuable information-brokering role during COP6. It hosted a lunchtime briefing on the first day, at which it presented its positions on the key issues on the COP6 agenda, including ENDS, and responded to delegates' questions. FCA members lobbied delegates during the week, reiterating why agreement on a specific regulatory approach to ENDS at this time was neither possible nor desirable. In addition, the FCA

published a pertinent article in its daily *Bulletin* the morning ENDS was on the agenda of Committee A. It concluded 'given significant differences in Parties' legal systems, smoking prevalence, the state of tobacco control, the market penetration of e-cigarettes within their borders, and the resources and technical expertise they can devote to regulating the product, *a one-size-fits-all regulatory framework for e-cigarettes will not work*' (FCA, 2014c, p. 1; our italics).

Costa Rica's draft decision

Costa Rica assumed a leadership role on the ENDS issue from the outset, distributing a 'draft decision' on day two, 'Prevention and control of electronic nicotine delivery systems, including electronic cigarettes' (FCTC, 2014a), prior to official discussion of ENDS. Costa Rica's proposal reflected key points of the WHO report to COP6 and the FCA's position. It highlighted the different regulatory approaches adopted by different Parties and that 'ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased' (FCTC, 2014b, p. 1). Thus the draft decision merely proposed that Parties should 'consider taking measures' to achieve 'at least' the four regulatory objectives listed in the WHO report (Table 2).

[Table 2 near here]

The Costa Rica draft decision amended the third and fourth objectives slightly, adding the clause 'or likely to create an erroneous impression about their characteristics, health effects, hazards or emissions' to a rephrased need to 'prohibit the promotion of ENDS by any means that are false, misleading, deceptive'. Invoking Article 5.3 bolstered the fourth objective of protecting existing tobacco control efforts from 'commercial and other vested interests of the tobacco industry'. The draft decision proposed that Parties and the WHO monitor ENDS use among smokers and non-smokers and that the Convention Secretariat establish an expert group to report to COP7 with updated evidence on their health impacts, efficacy for smoking cessation, and regulatory options. Costa Rica's draft thus accorded with the FCA's position of proposing a few broad objectives, monitoring, and an expert group, without getting distracted by the different viewpoints that had emerged about ENDS.

Discussing the WHO report and negotiating the draft decision

The Chair of Committee A opened the ENDS agenda item on the afternoon of 15 October by inviting a staff member to summarize the WHO report. E-cigarettes were described as a disputed terrain, 'filled with promise as well as threat'. Product heterogeneity, the involvement of tobacco companies, the possible health effects of ENDS on users and bystanders, their potential to re-normalize smoking and for uptake by young people, were the key issues raised. While ENDS were almost certainly less toxic for smokers than conventional cigarettes, the level of risk reduction was uncertain. In these circumstances, regulation of ENDS was 'a necessary precondition for establishing a scientific basis on which to judge the effects of their use' (FCTC, 2014b, p. 10).

Following a summary of its draft decision by Costa Rica, the Chair opened the floor to comments from Parties. The ensuing discussions and proposed changes to the draft decision reflected some (but not all) of the different policy approaches identified in the FCA briefing. China, for example, suggested amending Costa Rica's draft from 'consider taking measures' towards four specific regulatory objectives to 'consider the regulation of ENDS products as other tobacco products'. Kenya supported this approach and suggested the wording of the draft decision should simply propose banning all forms of advertising and promotion, as is the case with tobacco products. The Russian Federation called into question the second objective of Costa Rica's draft decision, arguing that the objective should be to eliminate entirely any health risks to non-users from ENDS rather than minimizing them, and explaining that this was the reason for introducing measures to prohibit the production and sale of ENDS within its borders. Sri Lanka (speaking on behalf of the South East Asia region) expressed the view that ENDS are a safety threat as well as a potential gateway to tobacco use and to dual use with tobacco. Thailand and Iran had already banned ENDS, and Sri Lanka encouraged all Parties to do the same. 'We would like to stress how dangerous and toxic these ENDS are', said a Party representing the Eastern Mediterranean region, before recommending their complete global prohibition.

The European Union (EU)'s position was more moderate, welcoming the commitment of Parties to conducting further research and to developing appropriate regulatory options. The EU saw the central research issues as the health risks for users and non-users, the efficacy of ENDS in helping smokers quit, the risks associated with dual use, and the impact of ENDS on existing tobacco control efforts. It felt it was too early to determine or even recommend a position at international level (a point endorsed by Senegal), since experience had been

insufficient to ascertain which of the different approaches adopted by Parties would ultimately deliver the best health outcomes, and whether a single approach could ever be universally applied. Panama raised the question of what ENDS actually are and whether there was a need to review the definition of tobacco products in the FCTC, since there was a danger of confusion arising between ENDS and other products being marketed as stop smoking aids.

An NGO member of the World Heart Federation (WHF) took the floor to point out the impact of nicotine on the cardiovascular system and to stress that the full consequences of ENDS for human health would not be known for several decades. The WHF agreed it was too early to adopt global regulations, but advocated a ban on misleading advertising and sales to minors, amongst other things. The Chair then called for an informal drafting group, as proposed by the EU, to meet separately after the session. A further, much larger, drafting group meeting took place the following day, in order to have the draft revised and submitted for translation the day after. Parties attending the first drafting group meeting decided not to permit accredited observers to attend.

Negotiating the revised draft decision

The revised draft decision (FCTC, 2014c) came to Committee A on 17 October. 'Prevention and Control' in Costa Rica's original title was the only text in square brackets, indicating that there was no other language over which consensus was lacking. There were numerous subtle and not-so-subtle changes between the original draft decision and the drafting group's revisions. These can be seen by comparing FCTC (2014a) with FCTC (2014c) and with the final decision (FCTC, 2014d) (Table 3).

[Table 3 near here]

There were rumours that the African region countries (AFRO), who strongly opposed ENDS, might attempt to undermine the revised draft decision by pushing for a recommendation to ban all ENDS. Discussions about the title showed how easily the non-strategic use of time could derail the whole debate, with numerous different titles proposed in a manner that one FCA representative afterwards called 'wordsmithing'. The Chair sought flexibility from delegates in order to reach a consensus on the title and move onto content. She asked Parties who felt strongly about the title to join a group at the back of the hall and return with a

suggestion, since time was limited. A sense of time pressure pervaded this second committee discussion of the ENDS issue, with the Chair frequently asking delegates to make their interventions brief.

Following discussion of another agenda item, a small group returned from the back of the hall with an agreed proposed title, 'Electronic nicotine delivery systems and electronic non-nicotine delivery systems' (ENDS and ENNDS). This triggered no further interventions. The Chair then asked, very tentatively, whether Parties could accept the rest of the text.

Kenya, reflecting the hardline AFRO position, queried whether a redrafted phrase 'prevent unproven health claims being made about ENDS' was in danger of 'opening an avenue for the promotion of these products', and suggested reverting to the 'prohibit the promotion of ENDS' wording in Costa Rica's original draft decision. The Chair pointed out that the decision had already been discussed in drafting groups for two days and asked Kenya for flexibility in not re-opening the document too much. She accepted that the 'unproven health claims' clause implied that health claims might be made, but India suggested a further deletion from the rest of paragraph 2(c) (Table 3) which was acceptable to all Parties.

South Africa moved to the issue of what the expert group should do, and questioned whether a proposal to look at the effectiveness of ENDS for smoking cessation might prejudge the issue. The Chair suggested changing 'effectiveness' to 'use', but India proposed deleting the investigation of their potential for smoking cessation altogether. For the EU, on the other hand, the word 'potential' simply indicated a question with no assumption about an answer: after all, the WHO report also mentioned the possibility of using e-cigarettes as a smoking cessation aid. Uganda, however, argued that whether smoking or using ENDS, one was taking in nicotine and hence 'smoking cessation' was a problematic term.

At this point the Chair intervened: 'I think we are running the risk of having a night-time session without translators, so I think we need some real flexibility among Parties, that if you can live with something, please, let it go ... If not, we are going to go after 6.00 p.m. without translation, because I thought we were doing very well and wouldn't need a night-time session'. Simultaneous interpretation during night-time sessions is dependent on the COP budget and must be arranged in advance. Without it, not all Parties can understand what is being decided, making consensus decision-making impossible. The Chair asked Uganda and

the EU to have bilateral discussions at the back of the room, as they seemed to be the only two Parties with divergent views on the matter of smoking cessation. Iran added its voice to the call to remove 'their potential role in smoking cessation', stressing the difficulties inherent in this phrase for countries that had adopted strong prohibition measures. The Chair encouraged Iran to join Uganda and the EU in their discussions.

The EU returned with the 'middle way' they said their discussions had found — to change the wording from investigating ENDS' 'effectiveness for smoking cessation' to 'their potential role in quitting tobacco usage.' The Chair was delighted: 'I see the power of bilateral negotiations,' she said, to some laughter. The only issue that proved intractable was the Russian Federation's wish to delete 'as consumer products' from the list of ways Parties might consider regulating ENDS/ENNDS. Since no compromise or consensus could be found, the Chair proposed making a note of the Russian statement that would go into the COP6 final report. The ENDS/ENNDS decision was then agreed by Committee A to general applause and adopted by the plenary session the next day without further comment. The final report on COP6 item 4.4.2 notes the Russian Federation's opposition to including the option of regulating ENDS as consumer products (FCTC, 2014e, p. 15).

Discussion

The different regulatory schemas proposed reflect different ontological assumptions about ENDS. If they are another form of tobacco product (Grana, Benowitz, & Glantz, 2013; Grana, Benowitz, & Glantz, 2014), then their advertising and dissemination in any form is as problematic as tobacco. If, on the other hand, one takes seriously the arguments by McNeill et al. (2014) that ENDS can be a tobacco substitute, prohibiting their use (or banning them altogether) means depriving smokers of a potential lifesaver. The policy implications of these different perspectives were starkly apparent to some Parties. For Iran, raising the possibility of ENDS having a role in smoking cessation was ethically and epistemically challenging to a country with a strongly prohibitionist line. The UK to date, however, has had little regulation of ENDS other than as a consumer product, and current estimates are that 1.1 million of the 2.6 million ENDS users are former smokers (ASH UK, 2015, p. 1). In this circumstance, banning them would be impossible and might prompt former smokers to return to cigarette smoking. Their 'potential role in quitting tobacco usage', a more tentative phrase than 'effectiveness in smoking cessation', appeared to achieve the necessary bridging of these opposing regulatory approaches.

Discussions also reflected the FCA's point that regulatory approaches might need to differ according to resource levels. The low- and middle-income countries tended to argue for treating ENDS like tobacco products or banning them altogether. The EU reflected the views and policies of some higher income countries that favoured other regulatory approaches. The divergent viewpoints went beyond any simplistic dualism of 'supporters' and 'opponents'. Geertz's (1984) argument that one can be 'anti-' opposition to something like e-cigarettes without being unequivocally 'for' them offers an anthropological reflection on the subtleties of how some participants viewed ENDS.

From an ethnographic perspective, the ENDS discussions demonstrate two overriding principles of effective GHD when knowledge is uncertain. One is the need to nurture consensus on particular issues by 'agreeing to disagree'. The FCA maintained a strong and consistent line in both its briefing documents and the lobbying work carried out by some of its representatives during COP6, that the controversy over ENDS was unresolvable, and hence 'principles' rather than 'recommendations' were the way forward. While achieving consensus was no easy task, within the FCA as well as among delegates, the FCA maintained its reputation for making recommendations that broker the policy divide in circumstances of limited scientific evidence (Lencucha et al., 2011). In this way the FCA helped pull the debate from narrow, state-centric concerns towards more cosmopolitan, 'person-centred' perspectives (Lencucha, 2013).

Costa Rica's important role was in formulating a draft decision which gave the initial debate 'the power of a good proposal' (Fairman et al., 2012, p. 157), one that was broadly acceptable to most delegations. 'Small country diplomacy' has been previously recognised as an important aspect of GHD, where countries such as Costa Rica (and Uruguay at COP4) (Russell, Wainwright, & Mamudu, 2015) can 'punch above their weight' and enhance their status as champions of tobacco control. We lacked direct access to many of the negotiations that took place 'behind the scenes', but were told Costa Rica worked effectively with other countries in drafting groups and bilateral negotiations, and that much of the lobbying by NGO representatives to back up the FCA's briefing document was fruitful. Betzold (2014) notes the difficulties in obtaining reliable empirical data about the many corridor contacts that occur between NGOs and government delegates at climate change summits. Much diplomacy

in tobacco control is similarly informal, depending on relationships that are developed and nurtured before, during, and after the COP itself.

The other, overlapping principle these discussions exemplify is the 'strategic use of time'. Time is widely acknowledged in international negotiations as 'a major source of power and influence' (Reychler, 2015, p. 142). Late night GHD is a common feature of such global policy meetings (Taylor & Dhillon, 2011), but only when there is a realistic prospect of developing workable regulatory agreements. One FCA representative warned colleagues 'we don't want to have a night session in Committee A just to bang our collective heads against the wall on this'. Some general regulatory objectives were agreed, but the vastly different viewpoints, the limited experience of governments in regulating these new devices and insufficient scientific research made it neither advisable nor possible to seek agreement on a specific regulatory approach or a universally applicable set of regulatory measures. The FCA recognised that, without containment, the ENDS issue risked derailing the rest of the COP6 agenda by taking up too much time or causing irreconcilable and, in GHD terms, disastrous lack of consensus.

The potential for 'derailment' caused by excessive use or misuse of time exemplifies the theory of anarchy some international relations experts attribute to international policymaking. Anarchy in international politics arises because there is no agreed-upon, superior authority beyond states. For Fidler 'the concept of "open-source anarchy" provides one way to make sense of the proliferation of players, problems, processes, and principles in global health diplomacy' (2011, p. 29). Formerly the monopoly of states, anarchy (in GHD as in international politics more generally) has become a condition 'that non-State actors can access, participate in, and influence as never before' (Fidler, 2008, p. 259). 'Weaker' states such as Costa Rica can assume more power, while non-state actors such as the FCA and the Chair (a form of non-state actor not included in Fidler's list) manage the potential for anarchy in how time is used. In researching GHD in action, we have never witnessed a COP Chair 'cutting-off' a long-winded or off-topic delegate. Indeed, once a delegate has been 'given the floor', it is very difficult to control how much time they take or how much they keep to the topic under discussion. In the case of ENDS, the Committee A chairperson was crucial in managing, containing and re-directing the temporal anarchy that could otherwise have prevailed. She gave virtually every Party that wished to speak the chance to do so (and an NGO on one occasion) and, despite the long-winded and at times frustrating progress, her

patient and respectful approach (using phrases such as 'I very much appreciate that' in response to a Party's demonstration of flexibility on an issue) made it easier to gently 'ramp up' the pressure on delegates as the deadline for concluding the discussions approached. Her practice of sending off delegates with differing viewpoints to engage in bilateral (and sometimes multilateral) negotiations to come to some kind of compromise position also paid dividends. As one delegate from an African nation said to us, 'The Chair makes you feel like she really is listening to you'. Time was also an important structural player in the decision-making process. We cannot know, for example, on what grounds the EU and Uganda reached a compromise about the wording of the declaration that changed 'effectiveness for smoking cessation' to 'potential role in quitting tobacco usage', but the sense of an impending deadline (Galbraith, 2015), as well as the 'diplomatic momentum' engendered by the clock as well as the Chair (Bjola, 2015), undoubtedly played an important part.

Conclusions

The COPs of the FCTC show GHD operating on a treaty that is in force. It is marked by a drive towards consensus politics and a focus on those areas of tobacco control in which clear, globally applicable policy measures can be agreed; indeed, there has never been an issue at an FCTC COP decided by a vote rather than the development of consensus. We have also seen how the 'strategic use of time' can prevent topics such as ENDS, where uncertainty makes agreement impossible, from derailing the whole negotiation process. Parties' drastically different approaches to and opinions about ENDS and their regulation were not allowed to become an insurmountable problem at COP6. Instead, the four 'regulatory principles' adopted drew Parties' attention to the importance of regulation as a precursor to gathering the evidence needed for further action.

Agreeing to disagree and being strategic about time are important GHD principles for new global health diplomats to incorporate into their work. These strategies came to fruition not through the actions of one category of actor, but through the combined efforts of Parties, the Chair, and members of civil society. CEE and 'mapping GHD' (Fidler, 2011) by thick description addresses the need for research that describes how specific actors participate in and influence GHD (Lee & Smith, 2011). Successful developments in global health policy and practice depend on functioning and respectful relationships between stakeholders, and global health diplomats need a sophisticated understanding of both the institutional structures and the ways in which these relationships work (Adams et al., 2008). For those engaged in

GHD, our ethnography of ENDS at the FCTC COP6 provides a seminal case study of how multiple stakeholders shape GHD in action.

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Table 1: 'Broad principles and concerns' regarding the regulation of e-cigarettes

- 1. The global burden of death and disease from tobacco is primarily caused by smoking.
- 2. While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.
- 3. For those unable to quit tobacco, switching to alternative sources of nicotine that are less harmful can reduce, often very substantially, the harm smoking causes to the individual.
- 4. The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.
- 5. The risks of such an approach would be minimised by taking measures to limit uptake by never-smokers, in particular amongst young people, to protect non-users, and to discourage long-term dual use.
- 6. There could be negative unintended consequences from over-regulation just as there could be from under-regulation.
- 7. The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

Source: FCA (2014b: 3-4)

Table 2: The 'Four Regulatory Objectives'

- (a) impede the uptake of ENDS by non-smokers, pregnant women and youth;
- (b) minimize potential health risks to ENDS users and non-users;
- (c) prohibit any kind of false, misleading or deceptive promotion of ENDS; and
- (d) protect tobacco control efforts from the tobacco industry that produces and sells ENDS.

Source: FCTC (2014b: 10)

Table 3: Differences between the draft decision proposed by Costa Rica (FCTC 2014a) the draft decision by the working group (FCFC 2014c) and the final decision (FCTC 2014d)

FCTC/COP6(9) [Prevention and control of] Electronic nicotine delivery systems, including electronic cigarettes and electronic non-nicotine delivery systems 2

Draft dDecision proposed by Costa Rica

The Conference of the Parties (COP),

Recalling its decision FCTC/COP4(14) to request the Convention Secretariat to prepare jointly with WHO's Tobacco Free Initiative a comprehensive report based on the experience of Parties on the matter of electronic nicotine delivery systems (ENDS) for consideration at the fifth session of the COP;

Recalling its decision FCTC/COP5(10) to request the Convention Secretariat to invite WHO to identify options for the prevention and control of ENDS and examine emerging evidence on the health impacts of the use of such electronic systems; and report on the outcome to the sixth session of the COP;

Recognizing that the Parties have adopted various regulatory strategies with respect to ENDS, such as an outright ban on their sale, the adoption of regulation similar to that applicable to the marketing of medicines, their control as tobacco products, or no control at all;

Noting that the report by WHO to the COP at its sixth session (document FCTC/COP/6/10 Rev.1) correctly points out that "ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased", summarizes the public health debate and limited nature of the evidence on ENDS and presents both general objectives and specific regulatory options for consideration by Parties,

- 1. WELCOMES the report contained in document FCTC/COP/6/10 Rev.1 and invites Parties to take careful note of it;
- 2. INVITES Parties, when addressing the challenge posed by ENDS/ENNDS, to consider taking measures such as those referred to in document FCTC/COP/6/10 Rev.1 in order to achieve at least the following objectives, in accordance with national law:
- (a) impede the uptake of prevent the initiation of ENDS/ENNDS by non-smokers, pregnant women and youth with special attention to vulnerable groups;
- (b) minimize <u>as far as possible</u> potential health risks to ENDS/ENNDS users and <u>protect</u> non-users <u>from exposure to their emissions</u>;
- (c) prevent unproven health claims from being made about ENDS/ENNDS prohibit the promotion of ENDS by any means that are false, misleading, deceptive or likely to create an erroneous impression about their characteristics, health effects, hazards or emissions; and
- (d) protect existing to bacco-control activities from <u>all</u> commercial and other vested interests <u>related</u> to <u>ENDS/ENNDS</u>, <u>including interests</u> of the tobacco industry that produces and sells <u>ENDS</u> with measures similar to those considered in Article 5.3,;

- 3. INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;
- 4. URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS;
- 3.5. INVITES Parties and WHO to <u>comprehensively</u> monitor the use of ENDS/<u>ENNDS</u>-among smokers and non-smokers, especially among youth, including the relevant questions in all <u>appropriate</u> surveys on risk factors for noncommunicable diseases promoted by the Parties or WHO; and
- 4.6. REQUESTS the Convention Secretariat jointly with to invite WHO to form prepare an expert group to report, with independent scientists and concerned regulators, to the COP at its for the seventh session of the Conference of the Parties with an update on the evidence of the health impacts of ENDS/ENNDS, their efficacy for potential role in quitting effectiveness for smoking eessation to bacco usage, impact on tobacco control efforts and to subsequently assess policy options to achieve the objectives outlined in paragraph 2 of this decision and to consider the methods to measure contents and emissions of these products.

Sources: FCTC 2014a, 2014d, 2014e

KEY

Strikethrough text: appeared in Draft decision by Costa Rica, but not in Draft decision by the Working Group or Final Decision.

<u>Underlined text</u>: appeared in Draft decision by Working Group and Final decision but not in Draft decision by Costa Rica

Italicized text: appeared in Draft decision by Working Group and/or temporarily in subsequent discussions but not in Final Decision

¹Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that vaporize a solution, which may include nicotine, or not, the user then inhales.

² Electronic non-nicotine delivery systems (ENNDS)