PUBLIC HEALTH

# Smoke and fire over e-cigarettes

## As nations adopt regulatory measures for e-cigarettes, it is imperative to understand how approaches to risk, cost-benefit, and trade-offs have shaped interpretations of evidence

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In advance of a critical Framework Convention on Tobacco Control (FCTC) held in October 2014, two groups of scientists and public health experts launched a global battle royal over electronic cigarettes—devices that heat liquid nicotine but involve no tobacco.

Leaked documents appearing in the late spring indicated that the World Health Organization (WHO) was preparing to take an uncompromising stance against e-cigarettes at the FCTC meeting, treating them as a threat equal to tobacco cigarettes. This set the stage for 53 researchers from 18 nations, dominated by the United Kingdom, United States, and Australia, to send an urgent appeal to Dr. Margaret Chan, Director-General of WHO, on 26 May 2014. It was critical, they argued, to remain open to evidence regarding "low-risk noncombustible nicotine or tobacco products that may become viable alternatives to smoking in the future" as a potential harm-reduction strategy (*1*). There was "no evidence at present of material risk to health from vapour emitted from e-cigarettes" nor "credible evidence" that e-cigarettes would serve as a gateway to tobacco smoking. "We hope," concluded the letter that "WHO will be in the vanguard of science-based, effective and ethical tobacco policy, embracing harm reduction."

Three weeks later, on 16 June 2014, a response was sent to Dr. Chan, organized by American researcher Dr. Stanton Glantz (*1*) and cosigned by 129 experts from more than 24 countries. E-cigarettes, the letter stated, were little more than a Trojan horse promoted by an industry bent only on "increasing profits" through "predatory" practices. The first letter to Chan, it charged, had made assertions about marketing, emissions, and harms that were "either contradicted by available evidence or for which no evidence is currently available." Indeed, the letter warned, the harm-reduction advocates had not cited "a single scientific study" (*1*). Charges and countercharges continued.

How can two groups, both of which seek to reduce the terrible burden of morbidity and mortality attributable to smoking, both of whom embrace the centrality of evidence-based policy, come to such different conclusions? To be sure, the strength of the current evidence and the basic soundness and logic of extrapolation based on that evidence are central. It may be years before these disagreements over the evidence—which involve profound contention over whether e-cigarettes will serve as "gateway" drugs, particularly for youth; whether "dual" use with tobacco cigarettes will undercut any morbidity and mortality benefits; and whether this potentially disruptive technology will prove to be an effective cessation tool—will be resolved.

Risk versus benefit.

But it is not evidence alone that accounts for this pitched battle. The opposing letters reflect very different understandings of what the protection of public health requires. Those who called upon WHO to remain open to the possibility that e-cigarettes could reduce the toll of smoking explicitly embraced harm reduction as an organizing principle. In contrast, the judgments of the second letter, while focused primarily on the science, were shaped implicitly by a precautionary impulse.

**HARM REDUCTION AND PRECAUTION.** arm reduction—an approach that embraces a posture of pragmatism and accepts that people will use drugs—has explicitly informed the position of those open to the use of e-cigarettes as a means to limit the toll of smoking-related morbidity and mortality (1). Some advocates argue that elimination of a habit like smoking should always be the goal; others maintain that risk minimization is sufficient (*2*). But regardless of how advocates position themselves on the question of cessation, the bar that must be met is not whether an alternative carries any risk, but whether there is enough evidence to suggest that the risks are less consequential than those of the behaviors in question. From this perspective, even uncertain evidence justifies action when the status quo—in the case of smoking, a projected one-billion deaths this century if left unchecked—is sufficiently threatening. Harm reduction requires that every piece of evidence be viewed against this deadly backdrop, including the harms of limiting or denying access to alternatives to tobacco cigarettes.

A very different approach informs those who want to ban or impose severe restrictions on e-cigarettes. For tobacco-control advocates taking a precautionary stance, those who would accept lesser harms are being duped by the industry, serving as little more than "naïve" pawns in a grand scheme to take back lost ground in the long battle over smoking (*3*). Given the long history of tobacco industry deception, such advocates assert that there can be no room for compromise when it comes to a product in which Big Tobacco has any interest.

This position echoes the Wingspread Statement of 1998, one of the foundational documents in the history of precautionary thinking: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" (*4*). The Wingspread authors were particularly concerned that assessment of risks be conducted in advance of allowing the introduction of new products or practices. This, of course, is the logic that supports the system of drug regulation in Europe and the United States, which requires that products be

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proven "safe and effective"—not in absolute terms, but, as in the case of harm reduction, in a kind of risk-risk calculus—before being allowed onto the market. Nicotine replacement therapies—such as the patch and nicotine gum, for which the field has accepted the potential risks of long-term use—are tolerable given the consequences of smoking and comfortably fit within this model.

There are multiple understandings of the Precautionary Principle, some of which acknowledge the necessity of trade-offs and risk-benefit analysis. Other versions find the very notion of trade-offs morally offensive (*5*, *6*). The question is, then, which version of the Precautionary Principle is at issue here?

In its strictest interpretation—sometimes called "deep green" precaution, reflecting the concept's roots in environmental protection—the principle holds that any suspicion of harm should be sufficient to trigger prohibition, even "in the absence of any scientific evidence" and "without regard to cost" (*6*, *7*). Deep green precaution has the virtue of consistency, demanding and prohibiting certain courses of action when evidence is contested or unavailable. In the recent clash, the fiercest opposition to e-cigarettes has reflected a logic resembling a "deep green" version of the Precautionary Principle. Opponents of this perspective, most notably Cass Sunstein, have referred to the Precautionary Principle as the "paralysis principle" (*8*), arguing that it substitutes intuitive fear for scientific proof and that its hostility to cost-benefit analysis would impose regulatory standards that, in the end, would be both socially costly and harmful. Indeed, in 2000, the European Commission offered guidelines that clearly sought to address the "mixed, and sometimes contradictory views" on precaution. What was essential in confronting risk, the guidelines stated, was "finding the correct balance" as a way to "avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism" (*9*).

Not all the supporters of a precautionary approach embrace an uncompromising conception of precaution. For example, the economist Frank Chalupka [who signed a letter from the opponents of harm reduction] maintains that his views are best reflected in the "middle ground" American Heart Association guidelines on e-cigarettes that he coauthored. This policy statement offers a nuanced view of the evidence (*10*) and suggests a balanced regulatory approach, much like that being vetted by the U.S. Food and Drug Administration (FDA), which acknowledges scientific uncertainty and tries to draft a flexible framework with the capacity to add regulation over time, in response to emerging evidence.

***The opposing letters reflect very different understandings of what the protection of public health requires.***

Like their harm reduction counterparts, those committed to precaution have been open about the role that values play in their judgments. Stanton Glantz, one of the chief antagonists of e-cigarettes, brings to the debate an intimate, unparalleled knowledge of tobacco industry documents that leaves no room for illusions about deception on the part of the tobacco companies. For Glantz and other signatories of the second letter to Dr. Chan, the "fundamental and irreconcilable conflict of interest" between tobacco and public health demands an unyielding stance (*1*). What such a strong position does not acknowledge is that this perspective also entails a cost: It only recognizes the potential benefits of erecting barriers to e-cigarettes without considering the potential toll measured by lives lost to combustible products. In a world of multiple risks, argues Jonathan Weiner, "precaution against one risk may induce other countervailing risks" and their associated burdens (*5*). Dr. Kenneth Warner, a signatory of the harm-reduction letter, argued in the 1990s, that it is critical to "recognize that what divides us are those judgments about trade-offs" (*11*).

**CONCLUSION.** Harm-reduction advocates, although not surprised, were bitterly disappointed, after the October 2014 FCTC meeting in Moscow, when WHO called on nation states to adopt very restrictive precautionary measures, urging that countries consider prohibiting e-cigarettes and banning advertising (*12*). Very different has been the response to the first Cochrane Review on e-cigarettes published on 17 December 2014. Although noting the need for more research, the review concluded that current evidence underscores the potential of e-cigarettes as cessation tools. Said one of the study's authors, "None of the studies in this review found that smokers who used electronic cigarettes short-term (2 years or less) had an increased health risk compared to smokers who did not use electronic cigarettes. We did not find any evidence from observational studies that people who used electronic cigarettes at the same time as using regular cigarettes were less likely to quit smoking" (*13*).

The clash between harm reduction and precaution is not limited to e-cigarettes. The comment period on Swedish Match's application to the FDA for Snus to be regarded as a Modified-Risk Tobacco Product (MRTP) remains open until 23 February 2015 (*14*). The current battle lines for this smokeless tobacco product are very much marked by the two letters to Dr. Chan over the summer. Warning labels on Snus and other smokeless tobacco products currently hew to precautionary syntax, stressing, "This product is not a safe alternative to cigarettes." Variants warn of gum disease, tooth loss, and oral cancer. If this first MRTP application is successful, the language of harm reduction with its emphasis on making clear both risks and benefits would prevail, with revised labels reading "No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes" (*15*).

Ultimately, decisions about how to proceed will be made in the face of evolving evidence and the undeniable burden imposed by tobacco cigarettes. Decision-making may draw on elements of both precautionary thinking and harm reduction, but weighing the risks and benefits is unavoidable. It is imperative to recognize that deep precaution precludes that possibility. It has served as a kind of trump argument, hostile to the notion of trade-offs, seeing in them perilous compromise. Such a posture does not serve either science or policy well.

## REFERENCES AND NOTES


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