

## RESEARCH PAPER

## Tobacco harm reduction: what do the experts think?

E G Martin, K E Warner, P M Lantz

*Tobacco Control* 2004;13:123–128. doi: 10.1136/tc.2003.006346

See end of article for  
authors' affiliations

Correspondence to:  
Dr Kenneth E Warner,  
Department of Health  
Management & Policy,  
School of Public Health,  
University of Michigan,  
109 South Observatory,  
Road, Ann Arbor,  
Michigan, 48109-2029,  
USA; kwarner@umich.edu

Received 2 October 2003  
Accepted 23 January 2004

**Objective:** To assess experts' opinions about the future of, and potential to improve individual and public health through "tobacco harm reduction" (THR), the use of novel nicotine containing products purporting to reduce the health risks from cigarette smoking.

**Design:** Semi-structured telephone interviews on nine topic areas, with qualitative content analysis of coded transcripts.

**Participants:** 29 professionals with expertise related to tobacco and interest in THR, including prominent tobacco control advocates (7), pharmaceutical (3) and tobacco industry scientists/officials (5), non-industry scientists (12), and Congressional staff (2).

**Results:** Respondents agreed that harm reduction is at minimum theoretically plausible, that characteristics of "good" and "bad" THR products can be identified, that government regulation is essential but not likely in the foreseeable future, and that additional scientific data are very much needed. However, there was no consensus on specifics, such as preferred regulatory strategies or examples of ideal THR products. Disagreement was seen not only across but also within respondent categories. Mistrust of key stakeholders—for example, tobacco control advocates distrust of tobacco industry scientists and vice versa—was pervasive, and cited frequently as a barrier to regulation and collaboration.

**Conclusions:** Continued dialogue and debate are essential as we enter a new and uncertain era of products purporting to reduce tobacco produced harm. Experts have concluded that effective government regulation is crucial to minimising the risks associated with THR and maximising potential benefits.

Debate over whether it is possible, and if possible prudent, to manufacture and promote less hazardous tobacco and nicotine products has recently resurfaced, under the guise of "tobacco harm reduction" (THR).<sup>1–4</sup> THR promotes the substitution of reduced risk products for cigarette smokers who cannot or will not quit.<sup>5</sup> New generation products currently debated as potential harm reduction devices range from cigarettes with reduced levels of specific carcinogens to nicotine wafers.<sup>6–9</sup>

Because the introduction of novel products may well affect the future of tobacco's impact on health,<sup>5</sup> it is imperative that the tobacco control community contemplate the implications of this development and determine how to respond to it. In a recent paper, we found that a large proportion of the tobacco control community was completely unaware of the issue.<sup>3</sup> Many experts in the field have been considering THR for the past several years. This study represents an attempt to understand their thinking better and to share their ideas with the broader tobacco control community. Ultimately, the tobacco control community may well play a central role in determining whether THR works for the betterment or worsening of the health of the public, through tobacco control professionals' involvement in policy development and adoption, education of consumers and health professionals, and so on. Better understanding of the issues is essential.

## METHODS

### Subjects and setting

We identified 36 professionals with expertise related to tobacco from the USA and four from other countries, including tobacco control leaders, non-industry scientists, pharmaceutical and tobacco industry scientists and officials, Congressional staff, and a journalist. To do so, we reviewed the authorship of all major publications on tobacco harm reduction, the membership of an Institute of Medicine (IOM) committee that studied THR,<sup>2</sup> as well as participants in the committee's hearings, and our personal knowledge of key

figures. A few respondents were identified through snowball sampling. Within each respondent category (for example, tobacco control advocates), we invited individuals with a wide range of publicly stated opinions to achieve maximum variation in ideas and philosophies.

Individuals were invited to participate through an email or phone call from the principal investigator (KEW). Twenty nine respondents, including all four non-US invitees, agreed to be interviewed (72.5%). These consisted of 12 non-industry scientists (of 12 invited), 6 tobacco control leaders (of 6), 5 tobacco industry scientists/officials (of 7), 2 Congressional staff (of 3), 3 pharmaceutical industry scientists (of 6), 1 tobacco industry whistleblower (of 2), 0 Food and Drug Administration officials (of 3), and 0 journalists (of 1). The most commonly cited reason for declining to participate was concern about legal liability.

### Procedure

Semi-structured interviews were conducted over the telephone by EGM from mid June to mid September 2002. The purpose and format of the interview were explained and informed consent obtained. Interviews were tape recorded with the respondents' permission. Interviews lasted 20–75 minutes (mean 48 minutes). For two participants who declined taping, the interviewer's handwritten notes were transcribed for data analysis.

All interviews started with the following working definition of THR:

For the purposes of this interview, we are using the term "tobacco harm reduction" to mean reducing harm to the health of cigarette smokers who are unable or unwilling to

**Abbreviations:** FDA, Food and Drug Administration; IOM, Institute of Medicine; NRT, nicotine replacement therapy; THR, tobacco harm reduction

stop using nicotine through traditional methods (primarily cigarette smoking) by encouraging the substitution of other nicotine yielding products that may pose fewer health risks to individuals. Examples include (but are not limited to): cigarettes modified to remove one or more toxic substances, nicotine pharmaceuticals, cigarette-like devices that heat (rather than burn) tobacco, nicotine lozenges, and smokeless tobacco.

The interview instrument contained 10 open ended questions, refined through pilot testing (table 1).

### Data analysis

We jointly reviewed transcribed audiotapes and identified 21 main themes or key issues, used to develop a codebook. EGM applied the codebook to the transcribed data using Atlas.ti software.<sup>10</sup> EGM and KEW performed content analysis on the coded data. Data were analysed by respondent type.

## RESULTS

### “Good” and “bad” harm reduction products

Most interviewees shared a general conception of what constitutes a “good” or “bad” harm reduction product. However, there were vast differences in the specific products they placed in either group. There was no consensus on whether a “good” harm reduction product currently exists, and if not, whether one will in the future.

Respondents largely (but not universally) concurred on the following characteristics of “good” THR products:

- substantial disease risk reduction
- minimal unintended consequences, including harm to users, increased initiation, relapse among former smokers, and decreased cessation
- no combustion and large decreases in toxins suspected of contributing to disease risk (tobacco industry interviewees disagreed with “no combustion”)
- acceptability to consumers, including satisfying nicotine dose and economic feasibility
- documented scientific basis for harm reduction.

**Table 1** Interview guide

1. What are the major areas of agreement and disagreement with regard to tobacco harm reduction? What are your personal perspectives on these major issues?
2. How will the debate regarding tobacco harm reduction evolve over the next five years?
3. What is the potential of tobacco harm reduction to reduce health risks to smokers in the future, and why?
4. What kinds of unintended consequences, if any, do you think there might be from the use of harm reduction products?
5. What do you perceive to be the characteristics of “good” and “bad” or “dangerous” harm reduction products? Are there any current products on the market that meet these definitions?
6. What, if anything, should the US government do in terms of regulating harm reduction products, and why?
7. Where will the US be in regard to regulating harm reduction products 5–10 years from now?
8. With regard to tobacco harm reduction, what are the importance and prospects for eventual collaboration between: (a) the public health community and the tobacco industry, (b) the public health community and the pharmaceutical industry, and (c) the tobacco and pharmaceutical industries?
9. What do you think about the Institute of Medicine’s conclusion regarding the use of surrogate measures to indirectly measure harm? What are areas of greatest scientific uncertainty?
10. Is there anything else about the topic of tobacco harm reduction that we haven’t talked about that you would like to discuss?

Almost half of the respondents said that no products currently available meet their criteria for a good THR product, for reasons ranging from little consumer acceptability (for example, few smokers would find medicinal nicotine a satisfying substitute) to inadequate data on product toxins.

Respondents agreed that medicinal products (for example, nicotine patches, gum, and lozenges) represent the safest form of THR, although there was considerable debate over their efficacy and the adequacy of their nicotine content. Dissenting views about product desirability increased as one moved from the medicinal products to tobacco products, especially combusted products. Only the tobacco scientists (and one congressional aide) were optimistic about a sizable reduction in harm from combusted products.

Smokeless tobacco posed a unique situation. Grassroots tobacco control advocates have expressed strong negative views towards non-combusted tobacco products.<sup>3</sup> The non-industry scientists and tobacco control advocates in the present study were fairly evenly divided on the subject, clearly more receptive than grassroots advocates. In particular, the foreign interviewees in the present study were optimistic about snus (Swedish snuff),<sup>11,12</sup> and there was some criticism of the US reluctance to eagerly accept similar products. As one interviewee stated:

“Whatever anyone says, you do not need 40 years of randomized controlled trials to know that low [nitrosamine] smokeless tobacco products are...much less hazardous than cigarettes. [C]ommon sense should suffice, but there’s plenty of evidence around as well, from Swedish snus and ... the use of smokeless tobacco in the United States. When people here say that there’s not [sufficient] evidence, they are being completely disingenuous...or unscientific.”

Respondents mentioned the following as characteristics of “bad” products:

- more harm during actual use than anticipated
- use of new active ingredients that may pose harm to users—for example, palladium in Omni (a reduced carcinogen cigarette)
- likely to fail the risk–use equilibrium test,<sup>13</sup> increasing population dependence more than decreasing individual risk
- unjustified claims, illusion of safety without supporting evidence
- marketed to complement smoking rather than replace it
- high cost (said of products that respondents supported, such as nicotine replacement therapies (NRT))
- under priced and over marketed (said of products that respondents opposed)
- lack of consumer appeal
- unregulated.

All types of products were listed as “bad” products, although the example most often cited was light cigarettes, labelled “the prototype for a bad harm reduction product” by one interviewee.<sup>14</sup> Participants outside of the cigarette industry consistently mentioned modified cigarettes (for example, Omni) and pseudo-cigarettes (for example, Eclipse, a device that heats rather than burns tobacco papers) as “bad” products. A few participants were negative about all products. Several tobacco industry scientists did not provide any specific examples of “bad” products.

### The social context of THR products

Nearly all participants, including those affiliated with the tobacco industry, emphasised characteristics outside the tobacco technology itself. These included marketing practices, regulation, actual use, consumer deception, cost, and consumer appeal. One participant said we had our questions on what constituted a “good” or “bad” product phrased poorly, because:

“...the problem is never the product alone... [T]he tobacco industry and frankly some advocates have tricked us into...talking about the product as if you can talk about it in isolation. Harm reduction is a combination of the product, who uses it, and how it’s marketed. [I]n talking about good or bad characteristics ...you have to...take into account all of those factors.”

We suspect that some of the products described as “bad” were so categorised for these reasons. For example, some respondents expressed negative sentiment towards US Smokeless Tobacco’s new product, *Revel*, due to its marketing campaign (“For when you can’t smoke”), rather than because of its physical attributes.

### Unintended consequences

Predictions of unintended consequences from promoting THR products and estimates of their severity were central to how interviewees delineated “good” and “bad” products. The principal unintended consequences fell into two categories. The first related to possible harm to users, stemming from an illusion of safety:

- decreased quitting, including some smokers combining use of THR products and cigarettes
- increased initiation by non-smokers (primarily youth)
- relapse by former smokers
- unanticipated harm to users from some constituent in the product (for example, fibreglass particles in *Eclipse*<sup>15</sup>).

The second category consisted of a benefit to the tobacco industry at the expense of tobacco control. This included diversion of public policy attention and money from traditional effective prevention and cessation programmes. A few participants noted an inherent inconsistency of mixing THR with prevention and cessation messages.

A handful of participants mentioned the effects of *not* doing harm reduction, with the unintended consequence “that more people continue to take their nicotine in the most hazardous way possible [that is, cigarette smoking]”.

Opinions of the likelihood and importance of unintended consequences varied widely across and within respondent categories. Some respondents were very concerned about “the potential to do harm by approaches that are intended to reduce harm.” In contrast, another said “[T]oo much emphasis is placed on the hypothetical fears that, from a common sense point of view, don’t seem to be very likely”. Most tobacco industry respondents dismissed the possibility that these products would appeal to youth. One acknowledged, however, that “it’s never going to be a perfect world... [With] any other [public health] policies..., on any topic, there are always unintended consequences, [which] ...you strive to minimize.”

Respondents’ beliefs about the future importance of negative unintended consequences influenced their personal conceptions of “good” and “bad” products. The few who worried about an incapacitated future tobacco control movement were not likely to consider any product “good”.

### Individual versus population harms and benefits

Another recurring theme was the individual versus population debate,<sup>2,5</sup> integrally linked to the previously described unintended consequences. This debate focuses on the concern that, while reducing disease risks for individual smokers, THR products could inadvertently increase the aggregate damage to the health of the entire population. This could result if the appearance of low risk led people who otherwise would be using no tobacco or nicotine products to adopt the new product. Even a true reduced risk, compared to smoking, could generate net increases in total public health damage if the new product were sufficiently widely adopted by otherwise tobacco- and nicotine-free members of the population.<sup>13</sup>

Participants expressed different interpretations of how the individual-versus-population concern relates to specific THR products. Cigarette company interviewees foresaw a possibly significant reduction in disease outcomes by using reduced yield combusted products. As one put it, reflecting general agreement that a combusted product would be far more appealing to smokers than a pharmaceutical: “[E]ven though the risks of [a modified burning cigarette] have not changed as dramatically as [would be the case with a non-combusted product]...it is the only product that can be put in the hands of the majority of people who continue to smoke. [As such] it will have a greater impact on public health.”

Cigarette industry respondents did not believe that combusted reduced risk cigarettes would appeal to children or former smokers. In contrast, non-industry interviewees worried about the unintended consequences of decreased cessation and increased initiation and relapse. They saw a need to ensure a large reduction in individual risk to compensate for a possible increase in the prevalence THR product use. They concurred that worries about population effects preclude supporting any combusted product.

### Regulation

All respondents endorsed some kind of regulation of THR products, but without consensus on preferred regulatory strategies, motivations for wanting regulation, or the prospects for effective government oversight in the near future.

### Preferred regulatory strategies

Discussions about regulation focused on the USA. Most participants supported THR product regulation by the Food and Drug Administration (FDA) or a similar agency, recognising that effective regulation would require new legislation creating the regulatory authority and significant new resources. Opinions about the desirable nature of regulation and the products to be covered varied widely, however.

A central theme expressed outside the tobacco industry was a desire to “level the playing field” between heavily regulated nicotine pharmaceuticals and unregulated tobacco products.<sup>16</sup> One pharmaceutical industry scientist explained: “[B]ecause these [novel tobacco] products are apparently going to have some health claim associated with them, they need to have the same sort of rigor as any health claim product... [T]he debate is on whether the FDA would review the [modified] cigarettes in the same way they’re reviewing the drugs... [I]f they’re both being used for the same outcome, then they need to be [reviewed] for this particular use.”

A tobacco industry scientist wanted to see government mandated performance standards (for example, maximum nitrosamine yields) but not design standards (specific requirements as to how to achieve the desired performance). Several respondents, including one within the tobacco

industry, wanted to see higher taxes on the more toxic products. Concerned about misleading advertising, a non-industry scientist suggested requiring manufacturers to achieve technologically feasible reductions in toxin yields, but not permitting advertisement of reduced yields lacking definitive evidence of an actual reduction in disease risk.

Many participants outside the tobacco industry expressed displeasure at the idea of permitting existing conventional cigarettes to be subject to less stringent regulation than novel products, mentioned in the IOM report,<sup>2</sup> fearing this would lead to strong regulation, and eventual elimination, of all products “except for Marlboros”.

A few respondents cautioned against stringent regulation, one tobacco control advocate explaining: “[E]ven the small, innovative tobacco or pharmaceutical companies...say...that if you raise the bar too high, we go home.”

### Prospects for regulation

Respondents agreed that regulation is likely in the future, though probably not within five years. A Congressional staffer predicted that the next Congress would pass “some kind of FDA [THR] regulation legislation”, but concurred that the process will not be easy:

“[T]here’s no consensus yet among policymakers, or the public..., that we know how best to regulate, or that there is a need...for regulation. The companies themselves are split.”

Another interviewee dismissed the likelihood of congressional action: “[T]here’s no political stomach for [regulation] and...we’re not likely to see firm regulation in this area until there is a quite different climate in Congress.”

The FDA will move cautiously if at all, respondents agreed, without a congressional mandate to regulate THR products. One participant described the FDA as “sticking its head in the sand”. Another explained that the FDA will only act in the most “egregious instances of violating current law”, which precludes regulation of tobacco products. “In the current system, the FDA is probably only going to go after [non-mainstream companies] that sell the safer products.”

Respondents listed additional barriers to regulation:

- the Republican administration and Congress, which many respondents consider supportive of the tobacco industry’s interests
- lack of consensus among policymakers, the public, and the tobacco control community about the need for and nature of regulation
- competing congressional priorities
- belief that the Master Settlement Agreement resolved outstanding tobacco control issues
- discomfort created by the “moral” nature of harm reduction debates
- a climate of distrust among stakeholder groups.

Many participants considered divisions within the public health community regarding preferred regulatory strategies as itself a significant barrier to regulation. “[W]e have little enough influence when we have consensus, but when we violently [disagree], ...we at best fail to exercise any influence, and at worst, actually push for nothing to happen.”

### Tobacco industry motivations for supporting regulation

Many non-industry participants questioned the tobacco companies’ motives for wanting to engage in harm reduction.

Said one, “[I]n every case where they have been involved, their only purpose is to retard progress”. Of the industry’s espoused desire to discuss THR issues with the public health community, echoed repeatedly by our industry interviewees, another observed “[T]he companies are interested in the dialogue so that they can rebuild their tarnished images”. Said another, “[T]hey’re struggling against this pariah image, ...desperately...seeking some sort of acceptability as a legitimate business, and one way they can get that is by subjecting themselves to regulation”. Tobacco opponents argued, however, that industry inspired regulation would protect the industry from litigation, absolve them from future harm, and give them legitimacy. There was a strong perception that the tobacco industry wants weak regulation.

Tobacco industry interviewees explained that regulation would create a standard of what harm reduction is and what types of products are acceptable. The companies could then determine what constitute acceptable claims and how to communicate them to consumers. An industry scientist lamented: “[W]e don’t have any clear-cut ground rules. Virtually everything we do or choose not to do is...criticized as being irresponsible or inappropriate behavior. If we had ground rules, then we’d know what...to do.” Regulation, said another, “might improve the ability of the tobacco companies and the public health community to...work together”.

### Prospects for and importance of collaboration

The theme recurred often: is it possible, and if so desirable, for public health and tobacco industry scientists to collaborate to develop THR in a health enhancing manner? The industry possesses far greater knowledge about tobacco product construction and yields than do non-industry scientists. Public health scientists wishing to move THR in a constructive direction might therefore benefit from learning from tobacco industry scientists. Conversely, the industry needs public health ratification that new products reduce toxin yields, and concurrence they do so in a manner likely to reduce disease risks.

All tobacco industry interviewees felt that collaboration was essential. In contrast, tobacco control leaders and non-industry scientists expressed scepticism, citing decades of industry deception. While one deemed it irresponsible not to work with the industry, most concurred that regulation of the industry, not collaboration with it, was the sensible approach to establishing a framework for future THR product development. Several were open to dialogue with the industry, which they distinguished from collaboration.

### Developing the science base for harm reduction

All interviewees concurred that it is virtually impossible to assess the true harm reduction potential of reduced exposure products. To advance the science, the IOM recommended examining use of surrogates or biomarkers, measurable attributes of products or bodily function that could be employed to predict adverse health outcomes.<sup>3</sup> Examples include specific chemical constituents of tobacco or products of tobacco consumption; early biochemical, histologic, or physiologic effects in product users; or early health effects.

Most respondents considered the IOM’s recommendation necessary because long term randomised controlled trials to establish harm reduction would be expensive, time consuming, and impractical. Still, nearly all participants concurred that answers to basic scientific questions would not come quickly or easily. Some respondents from outside the tobacco industry expressed concern that the biomarker approach does not incorporate behavioural responses to new products, such as increased initiation. One worried that promotion of biomarkers might be a tobacco industry ploy. “Surrogate markers,” he said, “need to be our tool for reducing harm,

not the tobacco industry's tool for marketing new products." In contrast, some respondents, both inside and outside the industry, worried that public health community caution about THR translates into an opposition that could stymie development and marketing of scientifically defensible products.

### The future and potential of THR

Most respondents expect little significant change in the THR situation over the next five years, with the exception of more new products. There was consensus, nevertheless, that something will happen eventually, although little agreement as to what that "something" will be. In general, opinions about the future of THR were not strongly held. Predictions on the eventual potential of harm reduction varied from unsure and sceptical to anticipation of a large impact. The lack of consensus existed in all respondent groups. Still, almost all individuals were open to the *possibility* of a net positive impact of THR on public health.

Many respondents expressed considerable concern about the future, reflecting everything from the perceived cynical motivation of the tobacco industry to the industry's sense that tobacco control organisations are simply out to "score victories". Regarding the latter, one respondent concluded that, if successful, tobacco control petitions to ban potentially less harmful products like Ariva (a powdered tobacco lozenge) would leave the market open to only the most hazardous products, cigarettes, conventional or modified. Others observed that THR could have a negative impact on tobacco control. Said one, "splintering within the...public health community will create a division...the tobacco manufacturers will drive a truck through".

THR's risks led respondents to qualify their predictions on THR's potential with resolution of:

- the nature and extent of regulation
- how products are marketed
- product acceptability to cigarette smokers
- product type and its position on the risk–use equilibrium<sup>13</sup>
- the degree of scientific scrutiny
- tobacco control community reaction.

Many interviewees stressed that, despite uncertainty about its future, harm reduction is and will remain a pressing issue. There was a noticeable underlying sense of urgency among both supporters and opponents. Many of the former discussed the high death toll from existing patterns of smoking. As one said:

"[W]hat are we going to do in between [now and the acceptance of harm reduction], because...every year we have 440,000 [Americans] dying from cigarette smoking...[G]lobally, you're talking about a staggering number of people for [whom] there's no...real option, other than pharmaceutical products and...they don't seem to have widespread appeal."

Another summed it up as follows: "[E]verything really comes down to the awfulness of the situation we're currently in, where cigarettes are highly toxic and highly available." To address these problems, new products come to market. As one participant observed, there is a "massive business case" for harm reduction. The tobacco industry respondents generally appeared eager to get into this market.

Believing that harm reduction will "win the debate," one interviewee concluded:

"...it's a matter of how many bodies are left in the wake, both how many additional smokers are going to die who wouldn't necessarily have to die and how many people in public health are going to...throw themselves bodily in front of this, because of their concerns about... the morality of somebody using a drug, the possibility of a pharmaceutical company making some money, the potential role of tobacco companies..."

### DISCUSSION

We caution that our sample of experts is not necessarily representative of the broader group of tobacco control and tobacco and pharmaceutical industry experts interested in the subject. The very subjectivity entailed in defining who constitute a field's "experts" may make the task of identifying a scientifically "representative" group inherently impossible. Nevertheless, we are confident that our sample effectively represents the expertise available on the subject and the range of opinions about it.

Despite the diversity of their opinions, our interviewees concurred that, short of an unanticipated regulatory barrier, THR products will become a significant part of the tobacco-and-health landscape, with uncertain health consequences. Product innovation by the mainstream tobacco companies, other start up companies, and possibly the pharmaceutical companies ensures that outcome. As such, it behooves the field of tobacco control to ready itself for this new development.

Our interviewees have been very engaged in the THR debate, although without a well defined consensus as to how to respond. All agree on one point, however: tobacco products, new and old, and other nicotine delivery devices must be subject to government regulation. At a minimum, say our respondents, this should entail approval of claims on product labelling and advertising. At a maximum, it would grant the government authority to impose performance or design standards that would ratchet down the delivery of toxins, while prohibiting advertising exposure reductions unless demonstrably associated with significant harm reduction. Conclusive demonstration of harm reduction associated with most toxin reductions, our interviewees concurred, would be difficult to achieve. While interviews focused on the US situation, we believe that most of the observations concerning regulation also apply to other developed countries.

Interviewees' knowledge of and attitudes toward THR differ notably from those of the general US tobacco control community.<sup>3</sup> The interviewees are more open to the potential of THR to contribute to tobacco control and more active in their efforts to secure a regulatory framework within which THR can evolve constructively. If the tobacco control community as a whole is to have a say in THR's future, its members must become informed about the issue and involved in its resolution.

Our interviewees exhibited considerable sophistication in thinking about THR. Illustrative is the oft repeated observation that one cannot judge the desirability of a THR product in a vacuum. Rather, it is the package of the physical attributes of a product, how it is marketed, and how it is used by consumers in everyday practice that determines its potential for achieving true harm reduction. Each of those dimensions is shaped, if not defined, by the regulatory framework (if one exists) within which the product is manufactured, marketed, and sold. Respondents agreed that securing an effective regulatory framework in the foreseeable future will be a tall order, given support of the tobacco industry (or at least benign neglect of it) by the current Congress and Administration.

## What this paper adds

Despite the development and sale of novel, purportedly reduced risk tobacco and nicotine yielding products, the tobacco control community has not achieved consensus as to how it should respond to this rapidly emerging "tobacco harm reduction" (THR) market. To date, there has been no formal attempt to determine the opinions of experts in the field, whose views can guide development of future policy.

Professionals with THR expertise and interest, including tobacco control leaders, independent scientists, and tobacco and pharmaceutical industry scientists, concur that harm reduction is theoretically possible, that characteristics of desirable THR products can be identified, that government regulation is essential, and that THR is a pressing issue. These experts exhibit much disagreement on specifics, however, such as the nature of needed regulation or the potential contribution of specific product types to reducing harm. Continued dialogue and debate will be vital as we enter a new and uncertain era of products purporting to reduce tobacco produced harm. Effective government regulation is crucial.

Experts both within and outside the tobacco industry concur that research is vital to evaluating the exposure reduction and risk reduction potential of new products, as well as tackling the challenging issue of the population effects of marketing new products as exposure or risk reducing. The IOM committee discussed research needs in detail,<sup>2</sup> as have Hatsukami and colleagues.<sup>17</sup>

The public education task that lies ahead is daunting. After 40 years of public education, much of the public still believes that nicotine is the most dangerous substance in cigarette smoke, responsible for the cancer with which smoking is now indelibly associated in the public mind. How does one transmit a comprehensible and useful message about THR to the very same public? This task is greatly complicated by uncertainty as to what the message ought to be. Our interviewees debated whether the public is able to appropriately interpret information on toxin exposure reductions. Both representatives of the tobacco industry and the tobacco control community observed that consumers should have access to accurate, useful information.<sup>18</sup> Yet smokers, current and former, may misinterpret information on exposure reduction, eager to find risk reducing alternatives to quitting. An information campaign, public or private, could backfire, creating adverse population effects that outweigh any possible risk reduction for individuals. Besides, as one interviewee noted, if toxin reduction cannot be definitively associated with risk reduction, is there truly a compelling argument favouring dissemination of information to the public?

An era of tobacco harm reduction, real or as illusory as that associated with the introduction of light cigarettes,<sup>14</sup> appears to be rapidly approaching. The complexity of the issue—how

to think about it and what to do about it—ranks THR among the most perplexing developments in the history of tobacco and health. A lot of excellent minds are focused on addressing the pressing questions. To date, however, answers have eluded them.

## ACKNOWLEDGEMENTS

This work was supported by a grant from the Robert Wood Johnson Foundation of Princeton, New Jersey, through the Foundation's Substance Abuse Policy Research Program. We are grateful to the 29 professionals who consented to be interviewed, as well as to the three colleagues who pilot tested the interviews. We also thank two reviewers for helpful suggestions and About Words (Ann Arbor, Michigan) for prompt and excellent transcription of the interviews.

## Authors' affiliations

**E G Martin, K E Warner, P M Lantz**, Department of Health Management & Policy, School of Public Health, University of Michigan, Ann Arbor, Michigan, USA

## REFERENCES

- Hébert R, ed. Harm reduction. *Nicotine Tob Res* 2002;4(suppl 2):s47-193.
- Stratton K, Shetty P, Wallace R, et al. *Clearing the smoke: assessing the science base for tobacco harm reduction*. Washington DC: Institute of Medicine, National Academy Press, 2001.
- Warner KE, Martin EG. The U.S. tobacco control community's view of the future of tobacco harm reduction. *Tobacco Control* 2003;12:383-90.
- Joseph AM, Hennrikus D, Thoele MJ, et al. Community tobacco control leaders' perceptions of harm reduction. Working paper. University of Minnesota, 2003.
- Warner KE. Tobacco harm reduction: promise and perils. *Nicotine & Tobacco Research* 2002;4(suppl 2):S61-71.
- Shiffman S, Gitchell JG, Warner KE, et al. Tobacco harm reduction: conceptual structure and nomenclature for analysis and research. *Nicotine Tob Res* 2002;4(suppl 2):S113-29.
- Anon. Nicotine water. URL: <http://rcheck.host.sk/cool/nw.htm> [accessed September 25, 2003].
- Anon. Nicotine fruit juice. URL: <http://www.tobacco.org/news/134298.html> [accessed September 25, 2003].
- Anon. No smoking? No problem. URL: <http://www.nicotinevafer.com/faq.htm> [accessed September 25, 2003].
- Scientific Software. Atlas.ti software. Scientific Software, 1997.
- Foulds J, Ramstrom L, Burke M, et al. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco Control* 2003;12:349-59.
- Bates C, Fagerstrom K, Jarvis MJ, et al. European Union policy on smoking tobacco: a statement in favour of evidence based regulation for public health. *Tobacco Control* 2003;12:360-7.
- Kozłowski LT, Strasser AA, Giovino GA, et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tobacco Control* 2001;10:201-3.
- National Cancer Institute. Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. *Smoking and Tobacco Control Monograph No. 13*. Bethesda, Maryland: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, October 2001. (NIH Publication No. 02-5074).
- Pauly JL, Lee HJ, Hurley EL, et al. Glass fiber contamination of cigarette filters: an additional health risk to the smoker? *Cancer Epidemiology, Biomarkers & Prevention* 1998;7:967-79.
- Page JA. Federal regulation of tobacco products and products that treat tobacco dependence: Are the playing fields level? *Food and Drug Law Journal* 1998;53(suppl):11-42.
- Hatsukami DK, Slade J, Benowitz NL, et al. Reducing tobacco harm: research challenges and issues. *Nicotine Tob Res* 2002;4(suppl 2):S89-101.
- Kozłowski LT. Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine Tob Res* 2002;4(suppl 2):S55-60.