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FEATURE

TOBACCO

Why e-cigarettes are dividing the public health community

The tobacco industry used to be seen as the enemy of public health, but the move into e-cigarettes and harm reduction has seen some experts shift their views. Are they right or does industry have more cynical motives? **Jonathan Gornall** reports

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Even the man from British American Tobacco (BAT) struggles to keep the sense of wonder out of his voice as he recounts the strange event that took place earlier this year in San Jose, California. The occasion was the 2015 annual meeting of the American Association for the Advancement of Science. Sharing the floor at the San Jose Convention Centre were two unlikely bedfellows: Deborah Arnott, chief executive of the UK charity Action on Smoking and Health, and Kevin Bridgman, chief medical officer of BAT's electronic cigarette (e-cigarette) company, Nicoventures.

"Imagine that happening 10 years ago," says Will Hill, public relations manager for BAT. "We're now starting to share podiums with people like ASH at e-cigarette conferences."

It's a proposition that fills some in the public health community with dismay.

The subject of the symposium was "E-cigarettes: killing me softly or our greatest public health opportunity?" and Arnott and Bridgman—a former GP who is now working for Nicoventures offshoot Nicovations—were singing from the same hymn sheet.

Arnott's talk highlighted her concern that "some groups" were calling for an outright ban on e-cigarettes, despite a lack of evidence of harm, "especially in comparison to smoking." She wanted to focus on "counteracting moralistic dogma and separating fact from fiction."[1]

Bridgman's message was that "regulators should resist the urge to apply highly restrictive measures that would have the perverse effect of prolonging cigarette smoking."[2]

For some, such an apparent convergence of views is a sign that the industry's enthusiastic—and, critics maintain, cynical—embrace of the controversial concept of "harm reduction" in tobacco control is paying dividends.

"If the tobacco industry is busy arguing for deregulation and a number of our colleagues in public health find themselves arguing in the same direction as the industry then, with respect, we think that's time to pause," said Simon Capewell, professor of public health and policy at Liverpool university's Institute of Psychology, Health and Society.

"It's really regrettable," says Capewell, who supports the Faculty of Public Health position that e-cigarettes should be "subject to the same controls as tobacco" and that the benefits of fewer people smoking must be weighed against "the risk of electronic cigarettes leading to more people starting to smoke, particularly children."[3]

If the big tobacco companies were genuinely concerned about the disease and the harm they caused, says Capewell, "they would cease production—end of discussion. They would go into e-cigarette production 100%."

Capewell and others argue that e-cigarettes help to glamorise and renormalise smoking. Worse, he says, they are being used by the industry "as a trojan horse to get inside ministries of health. They are saying 'This is all about harm minimisation, we're part of the solution, we're no longer the problem.'"

Over at ASH, however, Arnott summarily dismisses such fears. "There are people in the public health community who are obsessed by e-cigarettes," she says. "This idea that it renormalises smoking is absolute bullshit." Furthermore, she insists, "There is no evidence so far that it is a gateway into smoking for young people."

ASH's concern, she says, "is quite the reverse—that because there is so much bad publicity about them, people's understanding about the relative risk of smoking and e-cigarettes is being undermined. The risk is that smokers who could potentially use these as an alternative to smoking are being discouraged, and that's not a good thing."

For Arnott, the concept of harm reduction boils down to a simple proposition: "Do you want the tobacco industry to carry on making cigarettes which are highly addictive and kill when used as intended, or do you want them to move to a product which

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is much nearer licensed nicotine replacement therapy and is unlikely to kill anyone?"

Pragmatists versus idealists

Several experts on both sides of the harm reduction debate that I spoke to characterised the divide as being between pragmatists and idealists. The pragmatists are often practising clinicians with patients with progressive lung disease who still smoke, and they can see how they might be helped by switching even partly to e-cigarettes. The idealists are generally those working in public health who take a population view and suspect the industry's motives.

In 2014 the tension boiled over into a pitched battle of words, fought in public in the run-up to the sixth conference of the parties to the World Health Organization's Framework Convention on Tobacco Control.

The first salvo was fired in May 2014, when 56 "specialists in nicotine science and public health policy" wrote to Margaret Chan, director general of WHO, to complain that the "critical strategy" of harm reduction had been "overlooked or even purposefully marginalised" in preparations for the conference. Harm reduction, they insisted, was "part of the solution, not part of the problem."[4]

There was a swift retaliation from the other side of the debate, signed by 129 public opposing experts organised by Stanton Glantz, director of the WHO Collaborating Centre on Tobacco Control and American Legacy Foundation distinguished professor of tobacco control at the University of California.

It was "fundamental," they wrote, that WHO and other public health bodies did not "buy into the tobacco industry's well-documented strategy of presenting itself as a partner." If it were serious about reducing tobacco harm, it would stop manufacturing cigarettes, "rather than simply adding e-cigarettes to its product mix and rapidly taking over the e-cigarette market." By moving into the market, the tobacco industry was "only maintaining its predatory practices and increasing profits."

As the letter demonstrated, there were many in public health who had neither forgotten nor forgiven the industry's cynical adoption of "low tar" cigarettes while knowing that they "did not actually reduce harm but were designed to promote cigarette sales by reassuring a concerned public that the new products were safer."

The letter cited a US court ruling in 2006, which found that three tobacco companies— including Philip Morris, the world's largest—had "deliberately deceived" consumers about "the lack of any significant health benefit from smoking 'low tar,' 'light,' 'ultralight,' 'mild' and 'natural' cigarettes."[5]

The consequences of this, said the Glantz letter, could be seen today "in cancer and heart disease hospital wards throughout the world."[6]

The original authors rapidly returned fire, accusing their critics of "an attempt to influence policy through misrepresentation of evidence." The basic proposition of harm reduction, they stressed, was not that the alternative nicotine products are harmless but that they reduce the risk by at least 95% more compared with cigarettes and "provide a viable alternative to smokers who cannot or do not wish to quit."

The challenge was "to find an appropriate framework for realising the significant public health opportunities this offers while managing residual risks."[7]

Industry embrace

That BAT was following this spat with more than casual interest became apparent when it quickly incorporated a quote from the letter into its promotional material extolling the virtues of harm reduction.

In a public relations report, *Harm Reduction: the Opportunity*, BAT said an "increasing number of people in the scientific and public health community" were "now advocating harm reduction as the way forward for helping the 1.3 billion people worldwide who continue to smoke despite the known health risks."

The only stumbling blocks to such progress, according to BAT, were that few governments currently supported harm reduction and that there were "some public health experts and organisations with concerns that not enough is known yet about the health risks of e-cigarettes and that they could undermine efforts to denormalise tobacco use." Such doubters were "also suspicious of the tobacco industry's involvement in tobacco harm reduction."

While the company understood that this was "a contentious topic" it hoped that its actions would "demonstrate our continued commitment to harm reduction and that governments will carefully consider the potential benefits it can bring as part of a progressive approach to public health policy."[8]

To those suspicious of the concept of harm reduction, this was breathtaking. The industry that had been killing so many people for so long was now planning to profit by offering a solution to the very problem it had created—if only all those obstructive scientists and governments would just get on board.

One of those who had was Gerry Stimson, former director of the department of social science and medicine at Imperial College London and one of the organisers of the first letter to WHO and the subsequent response to its critics. The letter was published on the website Nicotine Science and Policy, a forum run by Stimson's company Knowledge-Action-Change. KAC is "committed to the development and promotion of evidence-based policies and interventions in the field of substance use and related areas of public health and public policy."

Stimson has made no secret of his relations with the tobacco industry. From 2011 to 2013, he was a member of the NICE programme development group producing guidance on tobacco harm reduction. Minutes of the group's first meeting, in October 2011, record he declared he had "received hospitality from British American staff and has reciprocated."

In May 2012 he had "attended a Christmas drinks reception at British American Tobacco" and in February 2013 it was noted that he was "the director of a company, Knowledge-Action-Change, which has requested and received development funding from [the BAT offshoot] Nicoventures for a project to support smoking cessation in a closed setting."[9]

The NICE guidelines on which Stimson worked were published in June 2013 and superseded an earlier document, published in 2008. The titles of the two documents tell their own story about the change of emphasis in the approach to smoking: document PH10, "Smoking cessation services," had been replaced by PH45, "Tobacco: harm-reduction approaches to smoking."

Stimson did not respond to requests for an interview. But in an earlier email he said he believed that "much of the work we need to do to reduce harm from legal psycho-active substances means that we will have to work with people who are producing and selling them."

E-cigarettes and other nicotine delivery systems had "huge potential . . . to help shift people away from smoking," he added. But "the quandary for many public health experts . . . is that the solution to smoking might well lie with the much reviled tobacco industry."

Others clearly think so too. One is Karl Fagerström, a Swedish clinical psychologist who specialised in smoking cessation and nicotine dependence, was a founder of the Society for Research on Nicotine and Tobacco, and now runs his own consultancy.

Fagerström wrote an article for Nicotine Science and Policy, the website run by Stimson's company KAC.[10] He has also accepted money from BAT in the form of its flagship harm-reduction proxy, Nicoventures.

In March 2014 Fagerström was the coauthor of a paper published in *Addictive Behaviours* arguing that "the significant positive impact on public health that could be gained from encouraging people to switch from cigarettes to licensed medicinal nicotine products cannot be ignored." The paper was funded by Nicoventures, and Fagerström's coauthor was Bridgman, then the medical director of the company, which is now poised to market Voke, the first licensed medicinal nicotine product from a tobacco company.[11]

It isn't the only time Fagerström has worked with the company. *The BMJ* has seen a copy of a lobbying letter sent by Nicoventures to members of the Australian parliament in July 2014, offering them a briefing from Fagerström, who is described as "a leading international smoking cessation/nicotine dependence expert."

He would "be able to brief you on tobacco harm reduction—including the growing body of evidence around the benefits of significantly safer products including e-cigarettes in helping smokers transition away from harmful traditional cigarettes, and the approach many respected medical groups are taking towards them."

Fagerström told *The BMJ* that he had now stopped doing consultancy work for Nicoventures. He had supported the development of Voke because it was regulated, but the company was now working on other products that would not be licensed as medicines.

Nevertheless, he considered that products such as e-cigarettes could have a role in reducing the harm caused by smoking and accused some in public health of losing sight of the true objective.

"When I started to become interested in [tobacco harm] in the mid-70s, we wanted to get rid of the diseases that followed tobacco," he said. "But nowadays, there is a target conflict. For some, it's more about getting rid of the tobacco industry rather than helping the poor smokers or to-be smokers."

Evidence of this, he said, could be found in the way the attitude towards e-cigarettes altered among the public health community after the tobacco industry took over most of the small, independent pioneers in the field.

"When they first came on the market, five or six years ago, there was a positive openness and curiosity," he said. But after the tobacco industry became involved the attitude changed, to one of suspicion and opposition.

Another of the signatories to the pro-harm reduction letter sent to Chan was John Britton, an epidemiologist who heads the UK Centre for Tobacco and Alcohol Studies, a network of 13 universities providing international research and policy development. He also sat as a member of the NICE programme development group, as had Stimson and Arnott of ASH, and is an ASH trustee.[12]

"I'm no apologist for or friend of the tobacco industry," Britton told *The BMJ*. "But the fact is people smoke tobacco because they are addicted to nicotine, and tobacco companies are in the business of selling them nicotine. So if an alternative means of delivering nicotine to them comes along it's inconceivable that tobacco companies will not get involved and seek to exploit it, and that's a risk that has to be managed."

He was, he said, concerned at the way the debate about harm reduction had evolved.

"Now it's 'The tobacco industry is getting into this, the tobacco industry is evil, therefore as a policy this is a bad idea, and anybody who argues otherwise is either an idiot or a tobacco industry poodle.'"

Public health experts who have grown up thinking of the industry as the evil opposition "find it very difficult when the tobacco industry, whether you trust it or believe it, starts to look as if it is coming up with a product that is actually a solution to some people's dependence on smoking tobacco."

For some, accepting this meant "softening a position that many have built careers on, and that's quite difficult."

But there's another take on the tobacco industry's rush into the e-cigarettes market, and it's one that concerns Britton.

The industry, he says, "has been taken by surprise by e-cigarettes. It would rather they weren't there, but now all the companies are buying them. The biggest threat is that they are buying them to have them fail."

Profit motive

In September 2013, Bristol based Imperial, the world's fourth largest tobacco company, bought Dragonite International, a Chinese company credited with inventing the e-cigarette. A year later, Imperial's subsidiary Fontem Ventures launched Puritane, the company's first e-cigarette market.[13]

But the true value to Imperial of the £48m (€67m; $76m) Dragonite purchase may lie in the multiple e-cigarette patents it now owns. It is too early to know conclusively how Imperial intends to wield this sword, but in March 2014 the company's e-cigarettes division launched legal attacks against nine US makers of e-cigarettes, claiming they were in breach of its newly acquired patents.[14]

For Martin McKee, professor of European public health at the London School of Hygiene and Tropical Medicine there is no doubt that tobacco companies are entering the e-cigarette market "solely so they can say they are part of the solution."

McKee freely admits he is "an e-cigarettes cynic." He has also been an active supporter of ASH and says he has been "greatly dismayed" by its support for e-cigarettes. But there was, said McKee, still no evidence that e-cigarettes were effective in helping people to quit smoking, with recent studies indicating that smokers who used them might even be less likely to quit than those who did not.

Indeed, a recent meta-analysis of 11 published studies that compared smoking cessation rates among smokers who used e-cigarettes with those who did not, concluded that smokers who used e-cigarettes were "about 30% less likely to quit smoking than smokers who do not use e-cigarettes."[15]

More recently, a draft report by the US Preventive Services Task Force concluded that current evidence was "insufficient to recommend electronic nicotine delivery systems for tobacco cessation" and that doctors should direct patients who smoked to "other cessation interventions with established effectiveness and safety."[16]

Furthermore, reducing smoking—an ambition of 48% of the respondents to an ASH survey of e-cigarette use[17]—as opposed to stopping altogether, did not confer significant health gains, said McKee. A prospective 30 year Norwegian cohort study published in *Tobacco Control* in 2006 had looked at outcomes for a mix of more than 50 000 smokers, non-smokers, and former smokers and concluded there was "no evidence that heavy smokers who cut down their daily cigarette consumption by >50% reduce their risk of premature death significantly."[18]

Personal attacks

McKee says the debate about harm reduction has been invaded and clouded by personal attacks on social media launched by "vapers" (as those who use e-cigarettes describe themselves) and others. After he wrote an article for *The BMJ* in 2013,[19] "sceptical and raising a number of questions, I got attacked beyond belief."

In a subsequent electronic response on thebmj.com he reported, "Within a few hours of it being posted on *The BMJ* website I was attracting hundreds of messages on Twitter, almost all personally abusive ('Vile cretin' was one of the kinder ones). I had no idea that the e-cigarette lobby was so well organised."

In a letter to the *Lancet* in December 2014, McKee, Glantz, and two others noted that "anyone with the temerity to suggest that e-cigarettes are anything other than the game changing solution to the problem of tobacco will be subject to grossly offensive attacks, with growing evidence that these are being orchestrated.

"One recent example, a tweet directed at two of us, contained a picture of a noose with the caption 'Your days are numbered.'"[20]

"It has been seriously unpleasant," says McKee. "But when you're getting that sort of treatment you realise you're on to something."

One of the problems, says Capewell, is that "the amount of time and effort that different public health folk are spending on fighting among themselves could be better used fighting the tobacco companies."

Image makeover

And, as the debate rages on, the tobacco industry is quietly exploiting the schism in public health to gain the moral high ground.

In November 2014, after a letter from a member of the Electronic Cigarette Consumers Association and the New Nicotine Alliance appeared in the *Lancet* complaining that vapers were not being listened to in the public health debate,[21] Imperial Tobacco was quick to pick up the ball.

In a press release issued by Fontem Ventures, its e-cigarette subsidiary, it said that while it understood that e-cigarettes represented a regulatory challenge for the government, it was important to "look at the big picture and assess the overall impact on society." The company would "welcome the opportunity to meet with regulators to ensure that consumers are given clear signals—in taxation, accessibility, and conditions of use."[22]

BAT is already in the business of meeting with health regulators. An important waypoint on the industry's journey to self rehabilitation was passed in September last year, when BAT became the first tobacco company to win marketing authority from the UK Medicines and Healthcare Products Regulatory Agency for a medical product, the nicotine inhaler Voke (box). Though it looks like an ordinary cigarette, it involves no heat, combustion, or smoke and, thanks to its medicinal licence, it will be sold in pharmacies.

But regardless of their true value in the battle against tobacco harm, and the ferocious row they have triggered in the public health community, are all such products anything other than a mere sideshow, designed to make the tobacco industry look good as cigarettes continue to kill up to half of the people who use them?[25]

While BAT says it is "committed to developing and promoting a range of next generation tobacco and nicotine products," in its 2014 annual report it states clearly that tobacco remains "at the core of our business and will continue to provide us with opportunities for growth."[26]

Indeed, despite economic downturns, tougher regulatory environments and higher taxes almost worldwide, the entire industry continues to enjoy vast profits and predicts future expansion of the global smoked tobacco market.[27]

BAT says "we want to reduce the public health impact of our products." But anyone who thinks it would ever do so by heeding public health's invitation to stop making them is fooling themselves, says Hill, its public relations manager.

"We have made meaningful steps in our journey to tobacco harm reduction," he insists. "This is something we are committed to and that's really happening."

On the other hand, "BAT is a legal business [and] the lion's share of our revenue and profits, certainly for the coming years, is going to come from the traditional cigarette side of our business.

"Simply to turn off that side of the business would not be acting in the best interests of our employees, our partners and suppliers or, of course, our shareholders."

No mention, in that sentence, of the best interests of the six million killed each year by cigarettes.[25]

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Voke approval less than transparent

The Voke development provides further evidence that ASH has been highly influential in the harm reduction debate. Arnott, the charity's chief executive, was also a member of the MHRA's nicotine products working group that considered the Voke marketing application in 2013.[23]

Three more of the working group's 18 members were signatories of the Chan letter urging WHO to support harm reduction: Britton, Martin Jarvis, professor of health psychology at University College London, and Marcus Munafò, professor of biological psychology at the University of Bristol. They also served with Arnott and Gerry Stimson on the NICE programme development group that produced guidance on tobacco harm reduction.

Under the Freedom of Information Act *The BMJ* asked the MHRA to provide all documents and communications relating to the granting of the marketing and manufacturing licences for Voke. Claiming that the exercise would cost more than the £600 ceiling set for dealing with these requests, the regulator provided only one document, an "excerpt" of the January 2013 meeting of the working group.

It was a less than transparent disclosure. Under sections 40 (personal information), 41 (information provided in confidence), and 43 (commercial interests) of the act, virtually the entire document was redacted. Consequently it is not clear which members of the working group attended this meeting. However, it did reveal that it had considered the Voke marketing authorisation application.

Asked for a copy of the minutes, Arnott referred *The BMJ* back to the MHRA and did not respond to a request to disclose the names of the other members of the working group. The names, however, were finally provided by the MHRA, which added that the minutes of the working group's meeting, which had taken place 18 months earlier, "are yet to be published because some of the issues are still under discussion."

After the MHRA granted the Voke medicines licence in September 2014, Arnott welcomed the decision in an ASH press release. Voke was a "new alternative to smoking, which . . . will allow smokers to choose a product which meets the high standards of medicines regulation and could be provided on prescription to help them stop smoking," she said. ASH dismissed concerns that the device will be marketed by a tobacco company. Medicines regulation "will minimise the risk that tobacco companies market their products inappropriately."[24]

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