Heated tobacco product claims by tobacco industry scrutinized by researchers

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Claims by the tobacco industry that heated tobacco products (HTPs) are safer than conventional cigarettes are not supported by the industry's own data and are likely to be misunderstood by consumers, according to

research published in a special issue of *Tobacco Control*.

The issue was assembled by Stanton A. Glantz, Ph.D., director of the UCSF Center for Tobacco Control Research and Education.

HTPs are aggressively promoted by the tobacco industry as less harmful than cigarettes because they heat tobacco rather than burn it to generate the aerosol that delivers nicotine to users' lungs. The industry argument is that because HTPs do not set the tobacco on fire, they release lower levels of harmful chemicals and so cause less disease than conventional cigarettes.

The papers, published October 23, 2018, represent the first comprehensive collection of industry-independent peer-reviewed analyses of HTPs.

Many of the papers focus on IQOS, an HTP sold by Philip Morris International (PMI) in 30 countries including Canada, Israel, Italy and Japan. The U.S. Food and Drug Administration (FDA) has not yet approved IQOS for sale in the United States. In the issue's introductory overview, Glantz noted that eight papers use data provided by PMI in its pending application to the FDA, while 12 provide independent assessments of IQOS and other HTPs, including their political and policy implications.

"Until now, most of the published research on HTPs had been done by tobacco companies," said Glantz. "We've seen this charade from Big Tobacco before, going back to the 1960s, and the goal is always the same: to convince governments and the public that a new tobacco product is 'safer,' 'cleaner' or 'less harmful' than existing tobacco products. But in paper after paper, the scientists writing in this issue demonstrate that the health and other claims made for IQOS and other HTPs are false and misleading."

Overall, said Glantz, the issue's contributors demonstrate that PMI's safety claims for HTPs are not supported by the company's own data, which further show that consumers are likely to misunderstand those claims. "While some impacts of IQOS may be lower than that of cigarettes, others may be as bad or worse," he said. "The evidence does not support PMI's broad claims of reduced harm." He noted that researchers also found that HTPs are not as new as the industry would have consumers believe, with precursor devices going back decades. In addition, HTPs may appeal to young people. A final set of papers describes how HTPs fit into the tobacco industry's global strategy to deal with increasing regulation worldwide; after a legal analysis, the authors conclude that the FDA should not allow IQOS to be sold in the U.S.

UCSF scientists contributed to 14 of the 22 papers. Among them are:

Stella Bialous, RN, DrPH, FAAN, UCSF associate professor of social behavioral sciences, and Glantz identified the introduction of HTPs as the latest in a line of similar past efforts by the tobacco industry to undermine government regulation of tobacco by marketing a new product as "safer" or representing "harm reduction." They called on governments to regulate HTPs as tobacco products or drugs, noting that tobacco companies are the "vector" for the tobacco epidemic and cannot be part of the global tobacco control solution.

Glantz analyzed PMI's publicly available data on biomarkers of potential harm and determined that there was no statistically detectable difference between IQOS and conventional cigarettes for 23 of 24 biomarkers of potential harm among American adult smokers, and no significant difference in 10 of 13 such biomarkers among Japanese adult smokers.

A team led by Jeffrey Gotts, MD, UCSF assistant professor of medicine, found that that HTPs could possibly cause some diseases not caused by conventional cigarettes. They identified animal and human studies in

PMI's FDA application suggesting that IQOS may cause liver toxicity not observed in cigarette users.

Lauren Kass Lempert, JD, MPH, law and policy specialist, UCSF Center for Tobacco Control Research and Education, and Glantz wrote that the non-tobacco components of HTPs have escaped effective regulation in many countries because they are packaged and sold separately from the tobacco-containing components. Lempert and Glantz argued that in countries where IQOS is currently marketed, all components of HTPs should be regulated at least as stringently as other tobacco products. They also argued that because PMI has not submitted sufficient evidence that marketing IQOS in the United States would be "appropriate for the protection of the public health," the standard companies must meet to market new tobacco products in the U.S., the FDA should not authorize sale of IQOS in the United States.

A team led by UCSF professor of medicine Pamela Ling, MD, analyzed the marketing campaign for Accord, a failed HTP that was introduced by Philip Morris in the late 1990s and early 2000s. The researchers observed that unlike the Accord campaign, PMI seeks to market IQOS as having reduced health risk compared with cigarettes, even though it contains more nicotine and tar than Accord. The researchers attributed this shift in marketing claims to a looser social and regulatory environment rather than a significant improvement in the product's aerosol chemistry.

Another investigation led by Dr. Ling used previously secret tobacco industry documents to describe how R.J. Reynolds Tobacco Company quietly secured a 1991 editorial in The Lancet endorsing Premier, an earlier HTP, two years after Premier had been removed from the market. According to the authors, this historical case illustrates the importance of endorsements by respected health leaders and the need to insist on full disclosures of potential conflicts of interest. They noted

that such endorsements are likely to play a critical role in determining the commercial fate of new HTPs, and may help the newest crop of modified tobacco products succeed where previous attempts have failed.

Wendy Max, Ph.D., UCSF professor of health economics and director of the Institute for Health & Aging in the UCSF School of Nursing, led a group that reviewed a computational model developed by PMI that compared the public health impact of cigarettes and HTPs on mortality from four diseases caused by smoking: lung cancer, ischemic heart disease, stroke and chronic obstructive pulmonary disease. PMI used results from the model as evidence for its claim that HTPs pose less health risk than cigarettes. The researchers found that the PMI model excludes morbidity, underestimates mortality, does not compare HTPs with any tobacco products other than cigarettes, does not include the potential of HTPs to initiate smoking among non-smokers and underestimates the health impacts of HTPs on nonsmokers.

Farzad Moazed, MD, UCSF assistant professor of medicine, led a research group that studied publicly available data submitted by PMI to the FDA and determined that, among human smokers, both IQOS and conventional cigarettes were associated with significant toxicity in the lungs and immune system, with no detectable difference in toxicity between the two. Additionally, rats exposed to IQOS showed evidence of pulmonary inflammation.

A group led by Gideon St. Helen, Ph.D., UCSF assistant professor of medicine, reviewed PMI's publicly available data comparing levels of 113 chemical constituents found in smoke from IQOS and conventional cigarettes. They found that 56 constituents were higher in smoke from IQOS, 22 were at least 200 percent higher and seven were at least a thousand percent higher. The potential harm that could be caused by these substances is unknown.

Matthew Springer, Ph.D., UCSF professor of medicine, led a team which showed that in rats, a single IQOS tobacco stick impaired the ability of arteries to become larger in response to increased blood flow to the same extent as smoke from a conventional cigarette. In addition, the team found that nicotine levels were about 4.5 times higher in rats after exposure to IQOS compared with cigarettes.

The papers from other institutions provided insights into how IQOS is being marketed in other countries, how users would misunderstand marketing claims, and adverse health effects of HTPs.

While the issue was assembled by Glantz, all the papers were independently peer-reviewed by outside editors selected by *Tobacco Control*.

"When it comes to regulating tobacco, governments, regulatory bodies and nonprofit agencies need to always keep in mind that the tobacco industry is the source of the problem and can never be part of the solution," said Glantz. "Tobacco companies exist to sell tobacco to as many consumers as possible, period. Partnering with them to control tobacco use or promote harm reduction is always going to be a losing strategy."

More information: tobaccocontrol.bmj.com/content/27/Suppl_1

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