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JUUL Labs’ sponsorship and the scientific integrity of vaping research

As of 2018, 98 countries regulate e-cigarettes, including their sale, marketing, packaging, manufacturing, taxation, reporting, and clean air laws.¹ Some countries have banned e-cigarettes completely, such as Argentina, Saudi Arabia, and Singapore,¹ whereas other countries, such as the UK, consider e-cigarettes as part of a public health harm reduction strategy.² The USA has regulated e-cigarettes as a tobacco product since 2016. Launched in 2015, JUUL Labs Inc (hereafter JUUL Labs) is the current market leader in the USA for e-cigarettes and accounts for almost 80% of retail sales of e-cigarettes in the USA.³ Between 2017 and 2018, the prevalence of current e-cigarette use among US high-school students increased from 12% to 21%.⁴ Vaping is associated with an increased risk of ever smoking cigarettes in young people who are non-smokers.⁵ In comparison, the prevalence of cigarette smoking in the USA increased from 7.6% in 2017 to 8.1% in 2018, reversing the trend in declining youth smoking rates since 2011.^{6,7} This rise led to the US Surgeon General declaring an epidemic of vaping among young people.⁸ JUUL Labs has been the focus of concern for this troubling trend. Initially branded as a Silicon Valley start-up, JUUL Labs received a US\$12.8 billion investment in late 2018 from Altria, manufacturer of cigarette brands such as Marlboro, for a 35% share in the company.⁹

Tobacco companies including Philip Morris USA, an Altria company, have had a long history of using findings from industry-sponsored scientific research

to positively portray the tobacco industry and lobby against regulatory actions.¹⁰ For instance, the industry founded the Tobacco Institute (1958–98) and the Center for Indoor Air Research (1988–98) to fund internal and external research by scientific consultants and research organisations to support their positions.¹⁰ Shortly after the investment from Altria, JUUL Labs appeared to employ similar strategies used by Philip Morris and other tobacco companies to influence research on vaping. JUUL Labs established JLI Science, in early 2019, with the stated goal to “better understand the effects and impact vaping products have in the long term, while also discouraging new users, and to share those results with the scientific community”.¹¹ JUUL Labs solicits research proposals from the scientific community, does its own internal research, and supports research contracts with organisations based in the USA, the UK, Canada, and New Zealand, including Enthalpy Analytical, Inc, Centre for Substance Use Research Ltd, Celerion, Inc, Rose Research Center, LLC, Inflamm Research, Inc, Christchurch Clinical Studies Trust, Ltd, and Cliantha Research.¹² A search on ClinicalTrials.gov in May, 2019, revealed six registered trials funded by JUUL Labs (five completed, one ongoing).¹³ Findings from JUUL Labs-funded studies were presented at several scientific meetings including the Society for Research on Nicotine and Tobacco (SRNT), SRNT-Europe, Global Forum on Nicotine Conference, and the Altria-sponsored Tobacco

Critique of investigator-sponsored research application guidelines	
Transparency and independence	Lack of transparency of scientific criteria for evaluation and selection of proposals, review committee members' qualifications, and independence
Competitive funding process	The review process, selection criteria for determining funding, and expertise of reviewers are not fully described
Ownership of data and freedom to publish	The extent to which the investigator owns the data and has the freedom to publish without interference from JUUL Labs irrespective of the findings is unclear
Independent research agenda	Research agenda is not determined independently of the company; meetings with investigators before submitting a proposal might pose a conflict with achieving an independent research agenda
Governance	Composition of the governance team, qualifications and independence of members, and by-laws are not described; there is no description of an independent research committee of experts
Protection against conflicts of interest	There is no stated policy, protections against conflicts of interest, or mechanisms in place to enforce policies related to conflicts of interest
Industry public relations gains that counteract public health	JUUL Labs promoted research findings favourable to the company's interests at scientific meetings and in press releases and the news media
Feasibility	The growing number of sponsored research studies suggest this is being implemented and thus is a feasible funding model

These eight evaluation criteria were adapted from Cohen and colleagues.¹⁷

Table: Summary of JUUL Labs funding of research studies using criteria for evaluating tobacco industry funding of research

Science Research Conference. These findings and conference presentation are available on JLI Science's website research library, press releases, and news reports.¹² For instance, in a March, 2019, press release about an article published in a "questionable" journal¹⁴ that reported a decline in cigarette consumption in adult smokers who purchased JUUL devices, Kevin Burns, CEO of JUUL Labs, was quoted as saying: "We are encouraged by the growing body of peer-reviewed research demonstrating the significant impact JUUL products may have on helping adult smokers eliminate or substantially decrease their cigarette consumption".¹⁵ JUUL Labs also increased its spending on lobbying operations and political contributions in 2018 to federal and state lawmakers and political committees, undermining JUUL Labs' public pledge to discourage youth use of their products.¹⁶

Drawing from historical precedents of the tobacco industry's influence on research, the underlying motivations of JUUL Labs' research activities on vaping should be viewed with caution and evaluated for potential impacts on public health. We used Cohen and colleagues' eight criteria for evaluating tobacco industry-supported scientific research: transparency and independence, competitive funding process, ownership of data and freedom to publish, independent research agenda, governance, protection against conflict of interest, industry public relations gains that counteract public health, and feasibility.¹⁷ Next, we reviewed the eight criteria individually,

discussed each criterion, and reached a consensus as a group on the critiques of the JUUL Labs-sponsored research programme based on information available on the JLI Science website.

We found potential weaknesses in JUUL Labs-sponsored research programme in seven of the eight criteria (table). First, there is a lack of transparency in the scientific criteria used for evaluation and selection of proposals, the review committee members' qualifications, and independence of reviewers from the company. Second, the review process, selection criteria for determining funding, and expertise of reviewers are not fully described. Third, the extent to which the investigator owns the data and has the freedom to publish without interference from JUUL Labs, irrespective of the findings, is unclear. Fourth, the research agenda is not determined independently of the company. Fifth, the composition of the governance team, qualifications of members, and by-laws of the governance team are not described. Sixth, there are no stated conflicts of interest policies such as disclosure of relevant financial relationships of investigators or prohibitions against certain relationships (eg, investigators holding equity in JUUL Labs). A review of research on e-cigarettes and health reported that studies with financial conflicts of interest were more likely to report no harm than those with no conflicts of interest.¹⁸ Seventh, JUUL Labs sought public relations gains by promoting research findings of sponsored studies that are favourable to the company's

See Online for appendix

interests at scientific meetings and in press releases and the news media.^{12,15,19–22} A detailed critique of each criterion is available in the supplementary appendix.

The above weaknesses undermine the scientific credibility of JUUL Labs-sponsored research, increase the risk of JUUL Labs influencing the research agenda of the tobacco control research field as a whole, and undermine public health. In light of these weaknesses and potential adverse impacts, we recommend continued scrutiny of JUUL Labs research funding activities, evidence arising from funded studies, and how these findings are disseminated and used for public relations gains and lobbying actions.

Rigorous and independent research is needed to establish acute and long-term risks and benefits of vaping for different populations and provide the evidence base for prevention and control interventions and regulation of vaping devices. The ultimate goal for research, interventions, and policies is to maximise potential public health benefits of vaping, if any, while minimising risks. Safeguarding against the industry's undue influence on the tobacco control research agenda will be necessary to maintain the scientific integrity of research and to protect the public's health.

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