What if... your research is suddenly affiliated with a tobacco manufacturing company?

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ABSTRACT
The tobacco industry is accountable for an annual global death toll of approximately 8 million people and cigarette smoking is the foremost risk factor for several types of cancer. In addition, the tobacco industry has a long and controversial history of trying to influence scientific research and of engaging in other morally problematic practices. In September 2021, the respiratory community was alarmed by the takeover of Vectura Group (Vectura) by Philip Morris International. As a reaction to this acquisition, strict measures were imposed by the International Respiratory Societies to prohibit the involvement of Vectura in respiratory research and its participation in societies’ activities. International Respiratory Societies argued that Vectura had become part of the tobacco industry due to this takeover and is, therefore, subject to the same rules and restrictions. From a healthcare and historical perspective, the reaction and imposed measures are very understandable. However, for researchers that were already affiliated with Vectura through long-standing agreements and for research that was funded by Vectura, the imposed measures have serious consequences. With this article, we provide an example of these consequences. By reflecting on this issue, we would like to start a conversation regarding the current measures and to encourage the respiratory community to begin thinking of a way to avoid these consequences in the future. In addition, we hope that with this conversation the Respiratory Societies can set an example for other medical societies on how to cope with possible morally tainted affiliations (eg, fast food companies, alcohol manufacturing companies) in the future.

TAKEOVER OF VECTURA
In the summer of 2021, the respiratory community was alarmed by the intention of Philip Morris International (PMI) to acquire a contract and development company that focuses on the development of inhaler therapies, Vectura group (Chippenham, UK) (Vectura), as part of their ‘beyond nicotine ambitions’.1,2 Health organisations and Respiratory Societies rightly reacted with deep concern to the proposed acquisition and urged Vectura’s shareholders and board members, as well as UK’s policy-makers to reject this takeover.3,4 However, despite the efforts of these organisations, the board of Vectura unanimously recommended the offer to their shareholders in August 2021. The Vectura board reasoned in their statement that the ‘stakeholders could benefit from PMI’s significant financial resources and its intentions to increase research and development investment and to operate Vectura as an autonomous business unit that will form the backbone of its inhaled therapeutics business’.5 In September 2021, PMI acquired more than 74.77% of the shares, which finalised the acquisition.

Tobacco manufacturing companies are accountable for an annual global death toll of approximately 8 million people and cigarette smoking is the foremost risk factor for several types of cancer. In addition, second-hand smoking greatly affects the well-being of patients with lung disease.6 It is, therefore, very understandable and morally justified that the acquisition of Vectura by PMI caused deep commotion in the respiratory community (ie, everyone working the field of respiratory medicine). As a reaction to this, acquisition measures were imposed by the Respiratory Societies to prohibit the involvement of Vectura in respiratory research and its participation in societies’ activities.

POSITION OF AUTHORS
The takeover of Vectura by PMI also meant that, on 15 September 2021, part of our research group was suddenly indirectly affiliated with a tobacco manufacturing company. In 2018, we had signed a 4-year agreement with Vectura, which consisted of an unconditional research grant for a PhD trajectory on the structure and function of small airways with severe asthma. This PhD project would entail multiple clinical studies. Hence, with this agreement still ongoing in 2021, we were now affiliated with a tobacco manufacturing company.
manufacturing company, which brought us deep moral concern.

In this paper, we explain from a personal point of view what these measures have meant for our Vectura-related research. We discuss whether the imposed measures elicited the desired effect or whether they also led to less desirable unintended consequences. In doing so, we want to emphasise strongly that we do not want to undermine the overall goal of these measures. As researchers from a non-profit organisation whose main goal it is to find better treatments against the type of devastating disease wrought by the tobacco industry, we are in full agreement with the stance that Respiratory Societies as a whole have taken against tobacco manufacturing companies. Still, by explaining the implications of the imposed measures, we want to open the conversation regarding a specific undesirable by-product of the current measures and call on the respiratory community to develop a more customised approach when it comes to the handling of Vectura-related research. As there is no legislation prohibiting ethnically questionable industries to acquire health-related businesses, a collective conversation about the do’s and don’ts of such an approach for the future will be useful.

**HISTORICAL PERSPECTIVE AND ONGOING NATURE OF THE TOBACCO INDUSTRY**

The tobacco industry has a long and controversial history of trying to influence scientific research. Over the years, tobacco manufacturing companies, as part of their public relations strategy, have tried to influence the societal beliefs regarding smoking-related disease. They did so by amplifying and endorsing the views of researchers that were sceptical about the relationship between cancer and smoking. In the 1950s, the tobacco manufacturing companies created an industry-sponsored research entity, called ‘the Tobacco Industry Research Committee’, with the main goal of causing doubt and uncertainty regarding the relationship between smoking and disease (more information on tobacco industry can be found in the book *The Cigarette Century* by Brandt). Despite the abolition of these industry-sponsored research entities, attributable to the master settle agreement and civil litigation, the Foundation for a Smoke-Free World was established in 2017. This newly established foundation, entirely financed by PMI, has been shown to be involved in highly questionable research practices over the last few years. The disinformation campaign and history of science manipulation, built on the conflict of interest of researchers, is the reason why respiratory journals and societies are very rightly reluctant to publish results from researchers that have an (in)direct link with the tobacco industry.

In general, the aim of physicians, healthcare professionals, scientists and other experts working in the field of respiratory medicine is health promotion, disease prevention and treatment of lung disease. The goal of the tobacco manufacturing companies, such as PMI, is to sell as much of their highly addictive and lethal product as possible by encouraging tobacco consumption. It seems cynical that PMI acquires a company that develops products for the treatment of lung diseases that can be caused and/or worsened by their own tobacco products. It is a major concern that through the acquisition of healthcare-related companies tobacco manufacturing companies are able to use the interest and influence of healthcare policymakers and governments for their own benefit, and this was rightly flagged by Respiratory Societies. In the past, tobacco companies have undeniably used the industry-science connection to influence the media, public opinion, regulation, and the law.

Hence, from both a healthcare and historical perspective, the strict rules that apply for the tobacco industry are justified, as there is an inherent conflict between the interest of public health policy and the interest of the tobacco industry. The resulting inability to publish results in respiratory journals for anyone with ‘any real or perceived, direct or indirect links, to the tobacco industry’ is a logical consequence.

**VECTURA BOYCOTT**

Directly after it became clear that PMI had acquired Vectura Respiratory Societies (British Thoracic Society (BTS), the European Respiratory Society, the American Thoracic Society and the Thoracic Society of Australia and New Zealand) issued statements condemning the takeover. In these statements, they announced that Vectura had become part of the tobacco industry and that the societies’ policy regarding the tobacco industry remained clear: ‘publication of papers funded by the tobacco industry in the society’s journals is specifically prohibited’ and that ‘medical institutions have strict rules against the involvement of individuals/companies that are linked to the tobacco industry in society activities, including membership, event participation and engagement with research activities’. Individual members of the Respiratory Societies also spoke up and called for a boycott of Vectura’s participation in respiratory conferences. As a result, Oxfords Global’s ‘formulation and delivery’ conference forced Vectura to withdraw from participation and the ‘drug delivery to the lungs’ conference removed Vectura from their sponsorlist. Another call for a boycott involved a call to all physicians working in the field of respiratory medicine to stop prescribing inhaled medication that was associated with Vectura. In this call, several suitable alternatives were given in order to ‘avoid funding the tobacco industry’.

Other pharmaceutical companies such as GlaxoSmithKline (GSK) and Novartis hurried to clarify how their inhaler products relate to Vectura. GSK stated that for the Ellipta inhaler ‘GSK does pay royalties for patent licences to a company acquired by Vectura (SkyePharma)’ but that this licence is merely to ‘allow access to the SkyePharma’s formulation technology relating to the use of...
magnesium stearate’. GSK emphasised that they are not in partnership with Vectura. Novartis declared that they pay ‘licensing fees to Vectura for the use of certain technology for the manufacture and formulation of glycopyrronium bromide’. In addition, they stated that ‘without the intellectual property licensed from Vectura, patients would not have access to Novartis’ respiratory products. The fact that pharmaceutical companies felt the need to clarify their relation with Vectura shows how controversial this acquisition was. Nevertheless, both Novartis and GSK continued their sales of Vectura linked inhalers after the acquisition. As the call by the respiratory community for changing inhaled medication with links to Vectura remains up until today, pharmaceutical companies may be reluctant to buy inhaler technology from Vectura in the future.

The acquisition of Vectura by PMI also came as an unwanted surprise for researchers that were now suddenly linked to the tobacco industry. Respiratory Societies such as the BTS and the Thoracic Society of Australia and New Zealand included in their statements that organisations and researchers that were linked to a tobacco company through a prior third-party agreement will be judged on an individual basis ‘in order to be assured that the said organisation’s link had not been made with intent and that all legal means to extricate itself from the relationship had been exhausted’. However, in a joint statement by the Forum of International Respiratory Societies issued in January 2022, no word was mentioned about researchers with prior, ongoing or long-standing agreements with Vectura. In this statement, it was specified that organisations and members of the Respiratory Society cannot approve ‘new interactions and links with any company wholly owned by a tobacco company such as PMI’ as this is in accordance with their rules and ethical codes. In addition, they reiterated their refusal to ‘engage in partnerships or accept financial support from tobacco companies’.

The strict measures that were imposed by the Respiratory Societies on research(ers) that were linked to Vectura sent a clear message that these takeover tactics will not be tolerated and to prevent this takeover tactic from happening again.

UNINTENDED CONSEQUENCES
We cannot emphasise strongly enough that we support the boycott of the tobacco industry and that we categorically disapprove of the use, production or promotion of commercial tobacco-related products. We also endorse the overall reasoning behind these measures. Nevertheless, this highly controversial takeover and the imposed measures of the Respiratory Societies have had serious consequences for researchers like us who were now unwantedly affiliated with PMI due to this takeover. All of us were now associated with a company that uses unscrupulous methods to sell as much of their lethal products as possible. This gave rise to strong moral unease.

First, because we do not want to be associated with an industry that has values diametrically opposed to ours. Second, because the sudden affiliation with the tobacco industry might convey the unwarranted impression that our research is contaminated and not independent. Our first reaction to this takeover and indirect affiliation was therefore to immediately terminate the ongoing agreement and to cut all existing ties with Vectura. In this way we, as healthcare professionals, would do what is ethically right according to various Respiratory Societies and make a strong statement towards the tobacco industry.

However, after this initial reaction, we contemplated what cutting all ties with Vectura would imply for our research projects. At the time of the takeover, we had two studies running and due to COVID-19-related delays one study with Research Ethics Committee approval which would be initiated in 2022. We had a dedicated research nurse working on these studies and the PhD candidate involved was finishing his third year and starting the final year of his PhD trajectory. Termination of the agreement would mean we would have to prematurely terminate our current running research projects and terminate the contract with both the research nurse and the PhD candidate. From a legal standpoint cutting all ties would result in a formal ‘breach of contract’. To invoke force majeure or unforeseen circumstances as escape option to end the agreement with Vectura was not desirable, as this would have resulted in legal wrangling. For our research participants, premature termination of our ongoing projects would squander the time, risk and burden invested by them. Moreover, premature termination of the projects would thwart the goal of acquiring better understanding of the role of small airways disease in asthma. Increased knowledge on small airways dysfunction in asthma is important as it might unravel new potential targets for treatment. Therefore, termination would have significant implications for our projects and long-term goals. We faced a moral dilemma: either terminate the agreement and take these losses, or continue and finish our research projects whilst being affiliated with a company that is owned by a tobacco manufacturing company. We decided to investigate whether the principles of good scientific research could guide us in making the right choice.

PRINCIPLES
What is ‘good’ scientific research? The research community has defined several principles of research integrity which have to be met in the conduct of scientific research. The kind and number of principles that are used vary between different research organisations. Although there are minor differences between research organisations, the majority of the principles are similar. To guide us in our decision in doing what is ‘ethically right’ in this moral dilemma, we used the ‘European code of...
conduct for research integrity’ of ‘All European Academies’ (ALLEA). This is a well-recognised framework for European Research, which has recently been revised. As our research is conducted in the Netherlands, this seemed the most appropriate and applicable. The framework provided by ALLEA identifies four fundamental principles on which good research integrity is based: reliability, respect, accountability, and honesty. WBvdB and HT evaluated whether termination or continuation of the agreement would conflict with these four principles. NJ and SvdV joined as the coordinators of research integrity education at the Erasmus MC. They had and have no stake whatsoever in the research discussed in this paper.

For the first principle ‘reliability in ensuring the quality of research’, we conclude that termination of the agreement with Vectura greatly affects this principle. Premature termination of the agreement would result in unfinished research projects and missing data. This would significantly decrease the scientific merit of the projects and waste the used research funds. ALLEA guides us towards ‘proper and conscientious use of research funds’. Therefore, continuation of the research according to this principle seems desirable, as that would ensure high quality of research and the proper use of resources.

For the second principle ‘respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment’ we assess after due consideration that both the continuation and termination of the agreement actually harms this principle. Respect is a broad term subject to individual norms and standards. One of our core values is to conduct research that respects the feelings, wishes, and rights of research participants, colleagues, funders, and institutions. Continuation of our agreement with Vectura might feel uncomfortable for research participants for the same reasons patients would want to switch inhaled medication: patients, in particular, may find it disrespectful to participate in a study that is indirectly funded by a tobacco manufacturing company, especially when their disease is caused or worsened by (secondhand) smoking. Yet, at the same time, termination of our agreement would mean that patients who have already participated in the study would see no research published as a result of their participation, which they may similarly consider disrespectful. The principle of respect is, therefore, not a decisive argument in this moral dilemma, as there are both arguments for and against termination and continuation.

For the third principle, the principle of ‘accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts’ we evaluated our responsibility and obligations that relate to the research process. The tobacco industry, through the promotion and sale of tobacco, can be held accountable for damaging human health and the environment. The acquisition of a health-related business, such as Vectura, may, therefore, well be a tactic of the tobacco industry to divert the attention of its accountability. In the past, the tobacco industry has funded well-respected scientists to rehabilitate its reputation and to split the public-health community views on the effects of smoking. The accountability of the tobacco industry is an argument for terminating the agreement.

At the same time, since our contract agreement in 2018, the primary aim of our research has been to unravel the structure–function relationship of the small airways in patients with (severe) asthma in order to improve the care for patients suffering from this heterogeneous disease. The takeover by Vectura has not changed our incentives, responsibilities, nor the relevance of our projects. On the contrary, a recent article emphasised once more the importance of research on the small airways in patients with asthma, as small airways disease is linked to exacerbations and loss of asthma control. We feel, therefore, more than ever responsible and determined to finish our research. Premature termination of the agreement would result in the inability to fulfil this responsibility. This is not only highly unfavourable for patients, staff and society but would also breach the principle of accountability in research integrity for us as research group.

The last principle, ‘honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent fair, full and unbiased way,’ is the most salient principle in this moral dilemma. The tobacco industry has been notorious for their tactics to influence scientific research in order to undermine legitimate research and to ensure that findings were not disadvantageous for the industry. By doing so, ‘the tobacco industry invented the modern problem of conflicts of interest’. Research with a link to the tobacco industry is, therefore, often considered unreliable and tainted. We share the concerns of the respiratory community that this acquisition is another way to infiltrate science and deceive the public. We would, therefore, never extend the current agreement or engage in a new agreement if it were affiliated with the tobacco industry. In our case, all studies that were agreed on in the contract of 2018 were investigator initiated. Moreover, during the conduct of our research neither Vectura nor PMI tried to influence our research in any way. After the acquisition we discussed the implications for our research with our contact at Vectura, they reassured us that nothing in the agreement had changed and that we remained fully independent. An important part of the principle of honesty and good research practice is the disclosure of a conflict of interests statement during the conduct or publication of the study. From 2018 up until now, we have clearly stated that ‘Vectura Group supported the research by an unconditional grant for a PhD research programme’. However, as from September 2021 reporting our conflict of interest in this way will lead to a problem. The author guidelines of BMJ Open Respiratory Research clearly state that they ‘will not consider for publication papers reporting work funded, in whole or in part, by a tobacco company or tobacco industry organisation. Nor will the journal consider...’
papers by authors who accept tobacco industry funding, including funding for research costs, for all or part of any author’s salary, or other forms of personal remuneration’. The reasoning behind this policy is clearly explained in the corresponding editorial dating from 2013.25

In the initial statements on the implications of research(ers) with links to the tobacco industry, exceptions were made for individuals who were suddenly linked to the tobacco industry through ongoing third-party agreements.11 12 However, in current author guidelines, no such exception is mentioned. The result of this ‘one-size-fits-all policy’ by respiratory journals means that complying with the principle of honesty would result in the inability for research with prior links to Vectura to be disseminated in academic journals, which is highly unfavourable.

Considering the four principles of research integrity, we want to make a well-considered decision in this intricate situation. The principles of respect and accountability are not decisive because the arguments for continuation and for termination are inconclusive. For the principle of reliability, however, termination of the agreement rather than continuation would breach these principles. For the first three principles, we carefully conclude that continuation of the agreement may be more favourable than termination. However, for the principle of honesty, respiratory journals leave us no other option than to terminate the agreement. Because honesty and transparency in reporting Vectura-related research in the conflict of interest statement would result in an immediate rejection.

Hence, for researchers who are undesirably affiliated with a tobacco manufacturing company through this acquisition, this ethical stance has serious consequences. For submission to a journal or attending a conference researchers are obligated to state their conflict of interest. In our case, stating that we received an unconditional grant from Vectura would mean that, based on our indirect affiliation with PMI, we are formally not able to submit a manuscript/abstract or participate in an academic conference. With such strict and general measures in place, not mentioning the affiliation during the submission becomes tempting, as the research is funded by a grant which was agreed on in 2018. However, as payment occurs on an annual basis, we were receiving funding from Vectura until 2022 and were, therefore, affiliated with them. In addition, deliberately holding back information regarding conflict of interest is a form of misconduct, as it would completely contradict the principle of honesty. Withholding information about our affiliation with Vectura is, therefore, not an option. The most honest and transparent way of handling this problem would be to declare our conflict of interest as usual and hope for the best. Choosing the last option, however, could possibly lead to our inability to publish the results of our study in renowned respiratory journals. This may lead to an unethical situation in which results of studies containing human subjects cannot be disseminated. This goes directly against the Declaration of Helsinki as ‘researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research’.26 In short, the justified ethical stance of Respiratory Societies may have direct unintended and undesirable implications.

POSSIBLE SOLUTION

In the end, the key question is whether we as a respiratory community agree that research or researchers can be denied on the basis of funding or affiliation alone, especially in a situation like this, or that a more differentiated policy in these specific cases is needed. Although our situation is probably rare, we do believe that similar scenarios could arise in the future. This could include instances where a (tobacco) company is taking over another company in order to improve its reputation, in an ‘attempt’ to shift product lines or purely for profit.

One of the first statements of the BTS after the takeover said that ‘senior members of BTS board and head office will assess each case on an individual basis in order to be assured that the said organisation’s link had not been made with intent and that all legal means to extricate itself from the relationship had been exhausted’.

This statement is an example of a more customised approach that also takes the intention of the researchers into account, rather than the affiliation alone. Besides the ‘researcher’s intention’, we would suggest using additional criteria to evaluate affiliations in these specific cases. These additional criteria should take into account the most important reasons why the Respiratory Societies will currently not consider work for presentation at international congresses or for publication in peer-reviewed journals. For instance, one of the most important reasons for not publishing tobacco industry-related research is that they have ‘repeatedly and systematically interfered with legitimate scientific research, and repeatedly used industry-funded scientists and their industry-facilitated findings to deceive consumers and undermine public health’.29 We, therefore, suggest adding ‘independency of the research(er)’ as a criterion on which affiliations should be evaluated in these specific cases.

Researchers can maintain their independence when the industry funding their research does not exert control over the research project’s objectives or outcomes, ensuring that it does not conflict with the project’s integrity and objectives. Given the tobacco industry’s historical involvement in manipulating and funding research(ers) to deceive consumers regarding the harmful effects of smoking, it is difficult to ensure the independence of tobacco-funded research regarding the health-related aspects of smoking. Research funded by the tobacco industry can, therefore, never include claims, recommendations, links or conclusions regarding electronic nicotine delivery devices, nicotine use or other tobacco-related products. Transparency of the research(ers) is crucial in order to be able to assess the ‘independency of
the research(ers)’ effectively. Evaluating the researcher’s independence and intentions may involve scrutinising initial contracts, study protocols, raw data and statistical analysis in conjunction with the research itself. This evaluation is a tedious task which should ideally be undertaken by a committee experienced in assessing research affiliations. We believe that the Respiratory Societies’ ‘ethics committee’ should take a leading role in the assessment of these criteria. Following their assessment, the ethics committee can have two options: either grant approval for the publication of the research in respiratory journals or declare that the research fails to meet the criteria, thereby precluding its publication in respiratory journals or presentation at conferences.

Development of a policy or a set of criteria for researcher(s) that find themselves in a similar situation may be helpful for the future. The goal of this article was not to provide such a clear-cut set of criteria that can be used to assess these affiliations. These should be developed by the respiratory community in careful consideration of the possible effects of these criteria. We do, however, suggest a list of criteria in Table 1, as an implementation of the fundamental principles of research integrity, in the hope that this will encourage members from within the respiratory community to start thinking of ways to improve the evaluation of affiliations in these specific cases. It is also worthwhile to see how we can built on the work of Jones who has attempted to develop criteria that ‘focus on issues such as transparency, conflict of interests, academic and scientific integrity and coercion’ when it comes to funding from morally tainted sources.31 By developing a differentiated policy the respiratory community may set an example for other medical disciplines on how to cope with other questionable affiliations as a result of takeovers (eg, fastfood companies, weapon industry, alcohol manufacturing companies) in the future.

The downside of using these criteria is that industries can still exploit these takeovers by using scientists as key ambassadors in their corporate legitimacy-rebuilding work.29 There is no failsafe set of criteria that can prevent this from happening. Alternatively, researchers could be offered the opportunity to apply for specific funding by Respiratory Societies to ensure the continuation of their research without interference of the (tobacco) industry.

To conclude our manuscript, we would like to emphasise that besides a differentiated policy, legislative safeguards are needed to make it harder for the tobacco industry to acquire health-related businesses in the future. We must not wait but urge policymakers at an international level to start working on legislation that can prevent this kind of acquisitions in the future.

Table 1 Criteria for evaluating conflicts of interest in special cases

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<th>The funded research has been taken out under a written agreement that is signed by a legal representative of the research organisation to which the researchers are affiliated. Within this contract, it should be made explicit that</th>
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<tr>
<td>1</td>
<td>The total amount of funding is predetermined and unconditional: its provision is not dependent on the consequences of the research project.</td>
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<td>2</td>
<td>The funding party cannot influence the research design and methodology of the research project.</td>
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<td>2</td>
<td>The funding party cannot influence which outcomes of the research project (ie, data, code, publications, hardware) can be disseminated, and how they are disseminated.</td>
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<td>3</td>
<td>The research project must comply with national and institutional guidelines for research integrity.</td>
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<td>4</td>
<td>The outcomes of the research project can be shared publicly under an open licence or become the property of the research organisation.</td>
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<td>5</td>
<td>The funding party can be mentioned in communication about the research project without permission.</td>
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<tr>
<td>6</td>
<td>The funding party can only mention the affiliation with the research organisation or researcher in external communication on approval of the researcher.</td>
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<tr>
<td>7</td>
<td>Non-disclosure clauses cannot have consequences for the possibility to disseminate the conclusions drawn from the research project.</td>
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Editor’s note BMJ recently introduced an enhanced policy relating to tobacco industry funding of content. Under this policy, journals will not publish content that
is funded wholly or partly by the tobacco industry; this includes research papers whose authors have personal financial ties with the tobacco industry, and which discuss smoking-related behaviours and diseases. Editors may at their discretion make an exception if they consider there is a compelling reason to do so. The editors of BMJ Open Respiratory Research carefully considered whether to exclude this paper under the policy. After consultation with the BMJ Content Integrity team they decided that as a non-research piece offering a useful perspective on the takeover of Vectura, and following external peer review, the paper could be published as an exception to the policy.

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