

**Questions on Notice
Inquiry into Tobacco Harm Reduction**

**Response from Professor Chris Bullen and A/Prof Natalie Walker,
University of Auckland**

QoN 01

Are you aware of Australia's obligations under Article 5.3 of World Health Organisation's Framework Convention on Tobacco Control "*in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law*"?

CB: Yes NW:

Yes

QoN 02

Have you or your organisation received any support, whether financial or non-financial, direct or indirect, from any parties involved in the production, distribution or sale of tobacco, nicotine or vaping products?

YES

Please provide details of that support, including:

- a. the nature of that support;
- b. the amount or value provided;
- c. the name of the entity or person providing it; and
- d. any other related information.

Name of the entity/person receiving support	Nature of support and value	Name of the entity/person providing support	Other information
University of Auckland	Historical links for two University staff members in the late 1980s and mid- and late 1990s, as outlined in the paper by Thomson & Signal (2005). ¹ Unknown value	Tobacco Institute of New Zealand Philip Morris (Tobacco Company)	“At the University of Auckland, a statistician was employed by both the University and the Tobacco Institute of New Zealand during the late 1980s and early 1990s.” “A University of Auckland anatomist commented for Philip Morris on the 1997 California Environmental Protection Agency paper about tobacco smoke pollution, and for the Tobacco Institute of Australia on a similar Australian paper.”
Auckland UniServices Ltd* (University of Auckland)	Historical contracts for research and publications between 1988-1996, as outlined in the paper by Thomson & Signal (2005). ¹ At least US\$790,000	Philip Morris (Tobacco Company)	“In May 1988, the University of Auckland signed a contract with Philip Morris for a three-year research project. The project was for three experiments to further examine the theory that nicotine enhances “psychological comfort” and “mental and psychomotor performance”. The project was renewed (through the University of Auckland company UniServices Ltd) in 1990, 1992 and 1994, with a total funding of at least US\$790,000 during 1988–1996. From 1992, the University of Auckland project workers published a number of articles about this research in peer-reviewed journals.” These contracts were undertaken prior to Drs Bullen and Walker being employed at the University of Auckland

<p>Auckland UniServices Ltd*</p>	<p><u>Funding</u> for the WIRED cross-over trial² and <u>provision</u> of e-cigarettes</p> <p>NZ\$187,907</p>	<p>Health New Zealand Ltd</p>	<p>This project was <u>funded by</u> Ruyan Group (Holdings) Limited, Beijing and Hong Kong, via Health New Zealand Ltd. The study sponsors <u>supplied</u> the E-cigarettes used in the trial and funded the trial. The Clinical Trials Research Unit (an Auckland UniServices unit) contracted with Health New Zealand Ltd to conduct the trial, independently of Ruyan Group (Holdings) Ltd. The trial design, conduct, analysis and interpretation of results were conducted independently of the sponsors. The principal of Health New Zealand acted as contract manager with the sponsor, Ruyan Group (Holdings) Limited, via his company Health New Zealand Ltd. He, and Health New Zealand Ltd had no patent, stock or other financial interest in Ruyan Group (Holdings) Limited or any nicotine or tobacco company.</p>
<p>Auckland UniServices Ltd*</p>	<p>Novel oral nicotine replacement therapy for the NEWS cross-over trial.³⁻⁴</p> <p>66,000 GBP</p>	<p>Contract was with Queen Mary University of London, who contracted with Niconovum AB, the manufacturer.</p>	<p>This was an investigator-led project <u>funded by</u> both NicoNovum, the manufacturer of the study products, and the National Heart Foundation of New Zealand. Note: RJ Reynolds purchased Niconovum AB sometime after this study was completed and published.</p> <p>The company had no role in the design, conduct analysis or interpretation of the study findings, or writing of any resulting publications.</p>
<p>Auckland UniServices Ltd*</p>	<p><u>Free supply</u> of study product (e-cigarette and e-liquid) for ASCEND trial⁵</p> <p>Unknown value but assuming each product was NZ\$50, then estimate around NZ\$25,000</p>	<p>PGM International NZ. (Owner of Elusion brand e-cigarettes)</p>	<p>The e-cigarettes and cartridges were Elusion brand products <u>provided by</u> PGM International, New Zealand. PGM International had no role in the study design, data collection, data analysis, data interpretation, or writing of scientific reports and publications, and had no affiliation with the tobacco industry.</p>
<p>Auckland UniServices Ltd*</p>	<p>Nicotine replacement therapy (NRT) for the SONIQ clinical trial.⁶</p> <p><u>Purchase</u> of nicotine patch and gum: NZ\$19,205</p> <p><u>Free supply</u> of nicotine inhalers, tablets, and pouches. Unknown value but assuming each product was NZ\$40 per participant (N=706), then</p>	<p>Novartis Consumer Health Australasia Pty</p> <p>Johnson and Johnson Pacific</p> <p>Niconovum</p>	<p>NRT was <u>purchased</u> for the intervention arm of the study from Novartis Consumer Health Australasia Pty Ltd (patch and gum) and <u>provided free</u> by Johnson and Johnson Pacific (inhaler and sublingual tablet) and Niconovum (oral pouch). Note that the inclusion of Niconovum product in this study was prior to the purchase of the company by R.J. Reynolds.</p> <p>The companies had no role in the design, conduct analysis or interpretation of the study findings, or writing of any resulting publications.</p>

	estimate around NZ\$28,240		
Auckland UniServices Ltd*	<u>Funding</u> to undertake research regarding uptake of NRT. NZ\$41,050 from a pharmaceutical company	Confidential public/private partnership between a pharmaceutical company that manufactures NRT, and the NZ Ministry of Health	The company had no role in the analysis or interpretation of the study findings or writing of the final report.
Auckland UniServices Ltd*	<u>Purchase</u> of very low nicotine content (VLNC) cigarettes for use in the RELIQ clinical trial ⁷ exploring the impact of nicotine reduction on smoking cessation. NZ\$16,500	Vector Group Ltd, Miami, FL, USA (Tobacco Company).	The VLNC cigarettes used in the trial were <u>purchased</u> from Vector Group Ltd, Miami, FL, USA. The tobacco company had no role in development of the study design, data collection, data analysis, data interpretation or writing of the publication.
Auckland UniServices Ltd*	<u>Purchase</u> of very low nicotine content (VLNC) cigarettes for use in the ENRIQ clinical trial ⁸ exploring the impact of nicotine reduction and price on smoking cessation.	22nd Century, New York, USA. (Tobacco Company).	The study cigarettes were <u>purchased</u> from 22nd Century, New York, USA, a company that manufactures research cigarettes, but does not market them for sale. The company had no role in the design, conduct, analysis, or interpretation of the trial findings, or writing of the resulting publication.
Auckland UniServices Ltd*	<u>Purchase</u> of e-cigarettes and e-liquid for the ASCEND2 trial investigating the effectiveness of combining e-cigarettes with NRT on smoking cessation. ⁹ E-cigarettes: NZ\$72,633.36 E-liquid: NZ\$43,609 NRT: <u>supplied at no cost</u> . Unknown value	NZVAPOR (e-cigarette retailer) Nicopharm Australia (e-liquid) Novartis (NRT)	E-cigarettes were <u>purchased</u> from a New Zealand e-cigarette online retailer (NZVAPOR, https://www.nzvapor.com/), e-liquid was <u>purchased</u> from Nicopharm, Australia (https://www.nicopharm.com.au/), and nicotine patches were <u>supplied by</u> the New Zealand Government via their contract with Novartis (Sydney, Australia). NZVAPOR also provided, at no cost to participants, on-line and phone support regarding use of the e-cigarettes. Neither NZVAPOR nor Nicopharm have links with the tobacco industry. None of the above parties had any role in the design, conduct, analysis, or interpretation of the trial findings, or writing of any resulting publications.

Auckland UniServices Ltd*	<u>Purchase</u> of e-cigarettes and e-liquid for the STATUS trial investigating the effectiveness of combining e-cigarettes with varenicline on smoking cessation in people with mental illnesses and addictions. ¹⁰ E-cigarettes and e-liquid: NZ\$14,350	NZVAPOR (e-cigarettes and e-liquid)	The e-cigarettes and e-juice for this trial were <u>purchased</u> directly from NZVAPOR. NZVAPOR was not involved in the design, conduct or analysis of the trial, but did provide on-line and phone support to participants regarding use of their allocated e-cigarettes. The e-cigarettes used in the trial and NZVAPOR (including the Managing Director) have no links with the tobacco industry.
Chris Bullen	Consultancy fee NZ \$800	Johnson & Johnson KK (Japan)	Consultant on new NRT product and its performance.
Natalie Walker	Travel and accommodation to attend meeting in Australia. Dr Walker does not have record of the precise value.	GlaxoSmithKline (GSK)	2010: Member of the GSK Advisory Board on Nicotine Replacement Therapy.

*Business Unit of the University of Auckland

1. Thomson G, Signal L. Associations Between Universities and the Tobacco Industry: What Institutional Polices Limit these Associations? *Social Policy Journal of New Zealand*, 2005; 26: 186-204.
2. Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e-cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. *Tobacco Control*, 2010; 19: 98-103.
3. Thornley SJ, McRobbie H, Lin R-B, Bullen C, Hajek P, Laugesen M, Whittaker R. A single blind, randomised, cross-over trial of the effects of a nicotine pouch on the relief of tobacco withdrawal symptoms and user satisfaction. *Nicotine & Tobacco Research*, 2009;11(6): 715-21.
4. McRobbie H, Thornley S, Bullen C, Lin R-B, Senior H, Laugesen M, Whittaker R, Hajek P. A randomised trial of the effects of two novel nicotine replacement therapies on tobacco withdrawal symptoms and user satisfaction. *Addiction*, 2010; doi: 10.1111/j.1360-0443.2010.02950.x
5. Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, Walker N. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*, 2013; 382 (9905): 629–1637
6. Walker N, Howe C, Grigg M, Bullen C, Glover M, Vander Hoorn S, McRobbie H, Laugesen M, Whittaker R, Rodgers A. Does improved access and greater choice of nicotine replacement therapy affect smoking cessation success? Findings from a randomised controlled trial. *Addiction*, 2011; 106 (6): 1176-1185.
7. Walker N, Howe C, Bullen C, Grigg M, Glover M, McRobbie H, Laugesen M, Parag V, Whittaker R. The effect of very low nicotine content cigarettes, used as an adjunct to nicotine replacement therapy, on smoking cessation: a randomised controlled trial. *Addiction*, 2012; 107(10): 1857-67.

8. Walker N, Fraser T, Howe C, Laugesen M, Truman P, Parag V, Glover M, Bullen C. Abrupt nicotine reduction as an endgame policy: a randomised trial. *Tobacco Control*. 2014; Online First, published on November 14, 2014 as 10.1136/tobaccocontrol-2014-051801
9. Walker N, Parag V, Verbiest M, Laking G, Laugesen M, Bullen C. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic randomised trial. *Lancet Respiratory Medicine*, 2020; 8 (1): 54-64. Online September 9, 2019 [http://dx.doi.org/10.1016/S2213-2600\(19\)30269-3](http://dx.doi.org/10.1016/S2213-2600(19)30269-3).
10. Bullen C, Verbiest M, Galea-Singer S, Kurdziel T, Laking G, Newcombe D, Parag V, Walker N. The effectiveness and safety of combining varenicline with nicotine e-cigarettes for smoking cessation in people with mental illnesses and addictions: Study protocol for a randomised-controlled trial. *BMC Public Health*, 2018; 18: 596. doi: 10.1186/s12889-018-5351-7.

QoN 03

Have you or your organisation, received any support, whether financial or non-financial, direct or indirect, from associated entities of tobacco companies?

CB: No NW:

No

If yes, please provide details of that support, including:

- a. the nature of that support;
- b. the amount or value provided;
- c. the name of the entity or person providing it; and
- d. any other related information.

QoN 04

Have you received any assistance, or liaised or consulted with, any other person or organisation in the preparation of your evidence to this inquiry?

If yes, please provide the details of any persons and/or organisation that assisted, or with whom you liaised or consulted, in the preparation of your evidence to this inquiry, including:

- a. the name of the persons or organisation;
- b. the ABN or CAN, if applicable; and
- c. any other related information.

CB: No NW:

No

QoN 05

Did you make inquiries as to whether the persons/organisations you consulted or liaised with receive any support, whether financial or non-financial, direct or indirect, from parties involved in the production, distribution or sale of tobacco, nicotine or vaping products?

If yes, please provide the details of those inquiries, including:

- a. what assurances were sought;
- b. dates of those inquiries; and
- c. whether they were made in written form or orally.

CB: N/A NW:

N/A

QoN 06

Have you, or any organisation with which you are associated, received any support, whether financial or non-financial, direct or indirect, from the following organisations, or persons associated with, the following organisations:

- a. The Institute for Public Affairs;
- b. Centre for Independent Studies;
- c. The Sydney Institute;
- d. Australian Taxpayers Alliance;
- e. Australian Institute For Progress;
- f. Mannkal Economic Education Foundation;
- g. Legalise Vaping Australia; and
- h. any ATLAS network member organisation.

CB: No NW:

No

QoN 07

Please provide the details of support given by the organisations listed in question 4, including:

- a. name of the organisation;
- b. nature of the support;
- c. amount or value provided; and
- d. any other related information.

CB: N/A NW:

N/A

QoN 08

Have you consulted, or had any contact with the groups or persons associated with groups listed in question 4, regarding your submission to this inquiry, or regarding your policy on vaping, tobacco, nicotine or any related products?

If yes, please provide the details of the organisations listed in question 4 with which you had contact, including:

- a. name of the organisation; and
- b. what the nature of the contact was.

CB: N/A NW:

N/A