Transparency and Truth

Thematic Dossier No. 2

FACTUAL CHRONOLOGY

The studies undertaken by the University of Zurich for Philip Morris on the effect of plain packaging on smoking prevalence in Australia

The detailed list of references, with links to the documents, is available at the following address: https://tnt.oxysuisse.ch/tntreferences.php?n=2

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INTRODUCTION

This document contains all the facts that we could collect about the contract between the University of Zurich (UZH) and Philip Morris International (PMI), which was concluded in July 2013. The purpose of this contract was "to analyze whether a causal link between the Plain Packaging Act 2011 and smoking behavior (smoking prevalence, initiation, and intensity) in Australia can be established", applying "statistical and econometric methods to real-world data"[1].

The facts are presented in chronological order. They are supported by source documents to which reference is made in the footnotes. In the quotations, the use of bold character is added for emphasis. When bold text comes from the original, this is noted. Comments and elements of interpretation are shown in serif font.

CHRONOLOGY

1. MAY 2013 - THE PROJECT PROPOSAL

On *22 May 2013*, Prof. Michael Wolf ("Wolf") and Prof. Dr. Ashok Kaul ("Kaul") jointly submit a project proposal (the "Project Proposal") to Philip Morris International (PMI[2]) in Lausanne. Its title: "Project Proposal: Intervention Analysis: the Effect of Plain Packaging for Tobacco Products on Smoking Behavior in Australia"[3].

Wolf is presented as "Chair of Economics & Applied Statistics, Department of Economics, University of Zurich, Switzerland" and Kaul as "Chair of Economic Policy, Director of IPE – Institute for Policy Evaluation, Saarland, Germany".

The Institute for Policy Evaluation (IPE) is a German consulting firm located in Saarland, whose "research director" is Kaul[4] and whose "senior researcher" is Wolf[5]. According to their website[6], "The IPE Institute for Policy Evaluation Saarland provides services for companies and organizations that strive for a better understanding of how political decisions impact the areas in which they are active."

[1] Reference 1
[2] In this document, the terms "Philip Morris" and "PMI" will be used interchangeably.
[3] Reference 1c
[4] Reference IPE-5
[5] Reference IPE-5a
[6] Reference IPE-5b

After describing the objectives of Australia's Plain Packaging Act 2011 and its implementation at the end of 2012, Kaul and Wolf make the following observation:

> *So far there is no empirical evidence that the measures prescribed by the Plain Packaging Act 2011 are effective in attaining the stated goals of the Australian government [bold in text]. In fact, there is hitherto not a single research paper that empirically links the introduction of plain packaging in Australia to changes in smoking prevalence, smoking initiation or smoking intensity in Australia.*

The two professors then explain their "understanding of the project":

> *The Australian plain packaging initiative is unprecedented in its approach and scope. Therefore, the scientific evidence on* ***whether such a drastic measure does prevent individuals from smoking or encourage them to quit is difficult to assess*** *[bold in text]. [...] Whether the introduction of standardized (or "plain") packaging has any effect on smoking rates is a priori unclear. However, the measure comes at a very high cost to the tobacco industry and consumers. It is a severe restriction of intellectual property rights related to brands and logos and drastically restricts consumers' freedom of choice.* ***Whether this policy measure is effective is therefore of major importance. Only the empirical analysis of real-world data can answer this question*** *[bold in text].*

They then describe the goal of the project:

> *The main goal of this project is to analyze whether a causal link between the Plain Packaging Act 2011 and smoking behavior (smoking prevalence, initiation, and intensity) in Australia can be established. To do so we apply statistical and econometric methods to real-world data.*

Their suggested approach is then outlined as follows:

> *A thorough statistical analysis of the empirical evidence on plain packaging in Australia involves the review of other research, a novel research design, data collection and analysis, and a comprehensive interpretation of the results. Hypotheses and optimal model selection typically develop in the course of the analysis and trigger adaptations in the design of the analysis. Therefore, a* ***high level of flexibility on our side regarding timing and phases is a prerequisite for a successful project completion*** *[bold in text].*

The suggested approach requires a close collaboration between UZH/IPE and Philip Morris:

The proposed project includes four "phases", with "main deliverables" at each phase:

- "Phase 1: Review of databases and check of consistency across the various data streams"
- "Phase 2: Internal Data Base Building; Final Assessment of Regulatory Background"
- "Phase 3: Statistical Intervention Analysis and Internal Assessment"
- "Phase 4: External Document"

> *Also regular meetings of PMI team members and our team members, regular conference calls, and frequent email communication is inevitable for reaching our project goals.*

For phase 1 ("Review of databases and check of consistency across the various data streams"), the proposal indicates that "The main insights from phase 1 will be summarized in a comprehensive report of about 20 pages. This report will be compiled for PMI internal use only." In this report, the two professors will suggest "directions for long-term strategic planning of research and data building/collection", and in particular:

Right after having spelled out these strategic criteria, Kaul and Wolf say that "At the end of phase 1, we would ideally identify a first data set, i.e., *one* very promising database, for a statistical analysis."

> - *Which directions for future research are worth pursuing from a PMI point of view?*
> - *Which developments in the tobacco control research on plain packaging (in Australia) pose a threat to the interest of PMI?*

Kaul and Wolf then make the following request:

> *During phase 1, we would expect the PMI team involved in the project to work on a detailed assessment of regulatory interventions in order to identify significant changes to the regulatory environment in prior years, including tax and price increases, and changes in tobacco control policies. To speed up the data analysis of phase 2, it would also be desirable that the PMI team identify available data from New Zealand and/or Canada as possible comparison countries [...].*

Phase 2 ("Internal Data Base Building; Final Assessment of Regulatory Background") is described as follows:

The main task in this phase is to prepare the analysis of various data sets using statistical soltware. Important data therefore have to be collected, adequately cleaned, and built into a database ready for statistical analysis. Also, the joint team should agree on key changes in the regulatory background over the last decade that might affect the assessment of the effects of plain packaging in Australia. [...]
It is crucial to thoroughly describe the regulation under consideration and other relevant policy measures in the past. [...] As part of phase 2 we would therefore - based on PMI material and information - document regulatory interventions in order to ***identify significant changes to the regulatory environment in prior years, including tax and price increases as well as changes in tobacco control policies****. These regulatory changes would then be coded in a way that the relevant information can be included in a statistical analysis [bold in text].*

Again, the main deliverables from phase 2 includes a "comprehensive report" which "will be compiled for PMI internal use only" summarizing the "main insights from phase 2". Among the key aspects of this internal report will be a "Summary of our assessment of how changes in the regulatory background should be taken into account in the statistical analysis."

In phase 3 ("Statistical Intervention Analysis and Internal Assessment"), Kaul and Wolf make the following proposal:

First, we will carry out a statistical intervention analysis on the impact of plain packaging based on time series data. This step involves model selection, diagnosis and estimation. Key insights for internal use are derived. Based on these insights, a decision on the tasks to be carried out in phase 4 is possible.

Again, the main deliverables of this phase include "a comprehensive report of about 30 pages" summarizing "the main insights from phase 3**",** which "will be compiled for PMI internal use only". "Key aspects" of this internal report are the "Results and insights from the time series-analysis" and "A proposal how to continue in phase 4".

Phase 4 relates to the production of "external document". This phase is conditional and is presented as follows:

The work to be performed in phase 4 will depend on the results of phases 2 and 3, i.e., the availability and quality of data. Depending on the internal assessment of PMI, it will have to be determined whether and in which format the results of the analysis should be presented to a broader audience.

The main deliverables of this phase also include “a comprehensive report of about 30 pages” summarizing “the main insights from phase 3”, which “will be compiled for PMI internal use only”. However, it also foresees another deliverable, described as follows:

> *A second possible deliverable is a first research paper (20-30 pages including appendices). Whether the paper can or should be written depends on the results of the data analysis in phases 3 and 4. A possible decision at the beginning of phase 4 is not to write a research paper but to allocate the free resources to further statistical analyses for internal use. In case it is decided that a research paper is to be written, the paper will present the statistical analysis and the results of one of the data streams (most likely it will be based on aggregate time series data) in a way that it can serve as an external document. Whether the document will eventually be published and in which form shall be decided by PMI.*

In the section about the project organization and the project team, we see that the “lead researchers” are Wolf and Kaul. Wolf is presented as “full professor of Econometrics and Applied Statistics at the University of Zurich” and Kaul as “full professor of Economic Policy at Saarland University, Germany”. The project team also includes two IPE consultants.

The last section of the proposal deals with cost, billing, and non-disclosure agreement. We learn that “The fee budget for the project is CHF 340,800 for one year (CHF 28,400 per month) excluding incidentals and VAT.” The arrangement to split the budget between UZH and IPE between is described as follows:

> *The budget of CHF 28,400 per month would be split as follows between the two involved contractors, IPE - Institute for Policy Evaluation, Saarland, Germany, and the University of Zurich, Switzerland:*
> *IPE - Institute for Policy Evaluation, Saarland: CHF 18,500 per month.*
> *University of Zurich: CHF 9,000 per month plus 10 percent university overhead (CHF 900 per month) = CHF 9,900 per month.*

The Project Proposal presents IPE as taking the main role in the project, while UZH is treated as an auxiliary partner:

> *If PMI accepts **our proposal**, we would start the project on July 1, 2013. We would have to set up a separate contract (University Services Contract on Statistical Consulting Services) with the University of Zurich (UZH). From our experience we know that this may take around four weeks; however, this would leave our staffing and project work unaffected. […] No minimum initial term is part of the contract based on **this proposal between IPE and PMI**.*

For non-disclosure agreements, the following is specified: “UZH undertakes upon execution of this agreement to sign a non-disclosure agreement **on substantially the same terms as are contained in the nondisclosure agreement Ashok Kaul and Michael Wolf have already signed**.”

The Project Proposal ends with the following remark:

> *In the **unlikely** event that UZH is not willing to contract with PMI, IPE will take over all services described in this proposal. The staffing and project work as well as the total fee budget would be unaffected in this case.*

NOTES

Preliminary remark: It should be noted that this document, which occurs at the first place in our chronology is the one that was maintained secret for about 10 years, since it was released by UZH in May 2023. Had this document been released when it was requested, in early 2015, the whole affair would have taken an entirely different turn.

The heading "Our understanding of the project" suggests that the Project Proposal is the result of prior discussions between Philip Morris and the two professors and that it encapsulates what has been agreed between them. The language used by the two professors to describe the purpose of the project has some similarity with the tobacco industry’s narrative: they describe plain packaging as “a drastic measure” which “comes at a very high cost to the tobacco industry and consumers” and is “a severe restriction of consumers’ freedom of choice.”

This proposal places the project under the full control of PMI, from the beginning and until publication of the results at the end (which is left to PMI to decide).

At the start of the project, in phase 1, the “PMI team involved in the project” is planned to work “on a detailed assessment of regulatory interventions”, while “it would be desirable that the PMI team identify available data from New Zealand and/or Canada”.

At the end of each of the four “phases” of the project, the two professors and the IPE team produce a “deliverable”, a 20-page or 30-page report that is “compiled for PMI internal use only”.

The reports produced at the end of phase 2 and phase 3 include “a proposal how to continue in [the next] phase”, which is presumably submitted to PMI for its approval (as the word “proposal” suggests).

The research work is done by “the joint team” with “regular meetings of PMI team members and our team members, regular conference calls, and frequent email communication,” which is “inevitable for reaching our project goals”.

The "directions for long-term strategic planning of research and data building/collection" indicate two key criteria the professors will apply to orient their research work:

1. **which research is desirable for PMI** ("which directions for future research are worth pursuing from a PMI point of view?") and,
2. **which research may threaten the interests of PMI** ("Which developments in the tobacco control research on plain packaging (in Australia) pose a threat to the interest of PMI?").

The sentence "Whether the document will eventually be published and in which form shall be decided by PMI" shows that the tobacco multinational has the final say not only on the publication of the results, but also on the form of the publication, if it decides to publish.

In their proposal, Kaul and Wolf insist on the need to consider regulation and other relevant policy measures in the past. This requirement is mentioned several times in their proposal:

In phase 1:

> *During phase 1, we would expect the PMI team involved in the project to work on a detailed assessment of **regulatory interventions** in order to identify significant changes to **the regulatory environment** in prior years, including tax and price increases, and changes in tobacco control policies.*

and in phase 2:

> *Phase 2: Internal Data Base Building; Final Assessment of **Regulatory Background***
>
> *[…]*
>
> *Also, the joint team should agree on key changes in the **regulatory background** over the last decade that might affect the assessment of the effects of plain packaging in Australia.*
>
> *[…]*
>
> *Australian Data Regulation*
>
> *It is crucial to thoroughly describe the **regulation under consideration** and other relevant policy measures in the past. If policy interventions are combined, it is desirable to disentangle the effects of each measure. As part of phase 2 we would therefore - based on PMI material and information - document **regulatory interventions** in order to identify significant changes to the **regulatory environment** in prior years, including tax and price increases as well as changes in. tobacco control policies. These **regulatory changes** would then be coded in a way that the relevant information can be included in a statistical analysis.*

The deliverable of phase 2 is a "comprehensive report of about 30 pages" to "be compiled for PMI internal use only" which includes the following:

> *Summary of our assessment of how changes in **the regulatory background** should be taken into account in the statistical analysis.*

However, as it will be seen later, their two working papers ignore regulatory changes as potential explanatory variables and use instead a rudimentary univariate linear regression, with time as the only explanatory variable, which is not able to detect a plain packaging effect.

In a peer-reviewed study, Diethelm and Farley re-analysed the data used by the two professors, taking into account regulatory changes. Using a statistical model which accommodated for key tobacco control interventions, they obtained results that refuted Kaul and Wolf's published findings: [7]

> *"Using the same data set as Kaul and Wolf, we have shown in this paper that with the more realistic assumption that tobacco control measures can be potentially effective – as was shown by Wakefield et al. - we arrive at the conclusion that three key tobacco control measures that were introduced during the 13-year period under study, namely comprehensive smoke-free policies, the large tax increase of April 2010 and plain packaging, were all associated with a clear and statistically significant reduction in smoking prevalence. This suggests consequently that all these measures were effective. In particular, the reduction in smoking prevalence that followed the introduction of plain packaging appears to have been even greater than expected."*

It is difficult to understand why the two professors did not follow their research protocol, which was perfectly logical and obvious, except that, had they done so, they would have obtained a result that was not in the interests of their sponsor.

The budget for the project is CHF 340'800 for one year, the greatest part of which (about two thirds) goes to IPE.

The contribution of the University of Zurich to the project seems only to attach its name to it, since "in the unlikely event that UZH is not willing to contract with PMI", IPE is ready to take over the entire project, with the same budget and the same personnel. This statement further implies that the two professors think it unlikely that UZH could be reluctant to contract with Philip Morris. It also shows that Professor Wolf has two affiliations, one as professor at UZH and the other as member of IPE's personnel.

[7] Reference 85

Finally, we note that, at the time of the submission of the Project Proposal, Kaul and Wolf have already signed non-disclosure agreements with PMI.

It is ironical that the submission of the Project Proposal to PMI by the University of Zürich, jointly with German consulting firm IPE, happens less than three months after a group of eminent scholars and writers published the **Zürcher Appell**, subtitled "International Appeal for the protection of academic independence."[8] The 27 signatories of the appeal start by recalling the importance of protecting the *academic* ethos:

> *"Universities grew out of the idea of establishing a place where freedom of research, education and scholarship is protected and beyond venal influence. They serve the common good and in turn are supported by the community. Directly linked to this founding idea is the academic ethos that preserves the institution of the university as a special place, free from political, ideological and commercial interests.*
> *[...]*
> *Against this background, it is self-evident that a public university should neither cooperate with nor accept sponsorship from institutions associated with public scandal or unethical conduct. That is damaging to the academic reputation of any university. And it impinges upon the independence of the scholars concerned, particularly those directly funded by such institutions, undermining their status as guarantors of independence and ethically-minded scholarship."*

The appeal was prompted by a CHF 100M sponsorship agreement secretly concluded in 2012 between the University of Zürich and the Swiss bank UBS for the establishment of a "UBS International Centre of Economics in Society" within the scope of the university. For the appeal signatories, "This procedure brings the issue of sponsorship into sharp focus. The Executive Board of the University concedes that the bank is **using the university as a platform to further its interests**. However, UBS is a particular case of a business that has been shown in the past to have engaged in **unethical practices**. [...] This shows that sponsorship involving specific vested interests and secret deals – in contrast to altruistic patronage and donation by benefactors – represents a threat to the impartiality of university research and teaching. The very academic ethos is at risk."

The signatories concluded their manifesto with the following appeal:

> *"As citizens, researchers, academics and students, we appeal to the leaders of the universities and all who bear responsibility for our educational institutions, at home and abroad, to safeguard the precious heritage of free and independent scholarship, and to* ***avoid endangering the academic ethos in controversial collaborations****."*

[8] Reference 0e

2. JULY 2013 - THE CONTRACT BETWEEN UZH AND PHILIP MORRIS

A Services Agreement (the “Contract”) is signed between UZH and PMI on 16 July 2013[9].

The purpose of the contract is not directly stated in the text, which describes the "Services" in general terms and refers to “Schedule 1” for more detailed information:

> *SERVICES*
>
> *University shall provide the **Services**, and deliver to PMIM all required **Work Product**, as specified in Schedule 1.*

Schedule 1 in turn refers to Annex 1, which, on page 4, provides the following information:

> ***The main goal of this project is to analyze whether a causal link between the Plain Packaging Act 2011 and smoking behavior (smoking prevalence, initiation, and intensity) in Australia can be established. To do so we apply statistical and econometric methods to real-world data***. [bold in text]

The Contract has a strict confidentiality clause and gives PMI full control over the work product. UZH is not allowed to reveal “the existence or terms of this Agreement or any other aspect of the relationship between the Parties” without the prior express written approval of PMI. (point 9.1)

If contacted by news organization, UZH is not allowed to answer questions related to the project and must notify PMI of the contact:

> *If at any time either Party or either Party's Personnel is contacted by a third party, including any news organization, conceming the Services provided under this Agreement, such Party and/or such Party's Personnel shall make no comment, notify the other Party of the third party contact, and refer the third party to such other. (9.2)*

With regard to publication rights, the Contract specifies that “Neither party will use the other party's name in connection with any publication or promotion without the other party's prior, written consent.” (10.1)

The University is not allowed to make presentations or other scientific communication on the research work product without PMI’s formal approval:

[9] Reference 1

> *University agrees [...] to refrain from disclosing any aspect of the Work Product to any third party including any Work Product embodied in products developed by the University for PMIM and/or its Affiliates, or from using any Work Product for any third party's benefit or in any other manner not authorized in writing by PMIM.*

Publication may contain Philip Morris confidential information and is thus subject to requirements of "Schedule 1":

> *Given that Work Product prepared or developed under this Agreement will typically contain or be derived in whole or in part through the use of Confidential Information of PMIM, any publication of Work Product is subject to the requirements set out in Schedule l. (10.2)*

"Schedule 1" is on page 12 of the contract. It contains a single paragraph:

> *The services shall be performed as described in the "Project Proposal: Intervention Analysis: the Effects of Plain Packaging for Tobacco Products on Smoking Behavior in Australia," (the "Project Proposal") attached as Annex l to this schedule.* ***For the avoidance of doubt the terms of the Project Proposal are hereby incorporated as material terms of this Agreement****.*

UZH agrees that their results be reviewed by Philip Morris:

> *If and to the extent Work Product does not contain and is not derived in whole or in part through the use of Confidential In formation of PMIM, University shall have the right, consistent with academic standards, to publish the results of the Services performed under this Agreement, provided such publication does not disclose Confidential Information of PMIM (as defined within this Agreement). University agrees that, prior to submission to publisher of a manuscript describing the results for publication, University shall forward to PMIM 30 days prior to planned publication a copy of the manuscript to be submitted to PMIM for review and comments and University will take into account in good faith the said comments. (10.3)*

The Contract makes no mention of Kaul or IPE. It is exclusively between UZH and PMI.

Concerning the personnel involved in the project, the Contract refers to the Project Proposal (see 1. above) under 3.1: "The agreement University shall provide Services through fully trained and competent University Personnel (as described in Annex 1 to Schedule 1 of this Agreement) having a skill level appropriate for the tasks assigned to them."

The compensation indicated in the Contract corresponds to the amount specified in the Project Proposal (referred to as “Annex 1”):

> *As full compensation for the Services provided in accordance with this Agreement, PMIM shall pay University the monthly fee of CHF 9,000 excl. VAT, if applicable and University overhead of CHF 900 per month, to be paid each month following the Effective Date and concluding as of the termination date of this Agreement, as explained in Annex 1 to Schedule l (the* ***"Fee").*** *VAT, if applicable shall be paid additionally by PMIM.*

The contract expires on 30 June 2014: “This Agreement [...] shall continue in effect until 30 June 2014, by which date University must have completed the Services to the reasonable satisfaction of PMIM as agreed upon in this Agreement.”

It is signed by Professor Wolf and the Vice President of UZH, Professor Daniel Wyler on behalf of the University of Zurich and by Till Olbrich, Vice President and Associate General, PMIM, and Ryan Wick, Senior Counsel, on behalf of Philip Morris.

NOTES

The 11-page “services agreement” between PMI and the University of Zurich conceals the reality of the researchers' subservience to the tobacco multinational. Annex 1, which was supposed to remain confidential (for reasons of protection of trade secrecy), reveals that Philip Morris had a high degree of control over the research carried out by the two professors, over all four phases of the project. The clause specifying that the University agrees to submit to PMI 30 days prior to planned publication a copy of the manuscript for review and comments is a smokescreen. It creates the illusion of the researchers' relative independence, with proofreading by PMI only taking place in the closing stage of the research process, whereas, in reality, PMI controlled everything from the first stage.

The absence of any mention of IPE in the main contract document is a major breach of transparency (IPE is only mentioned in Annex 1, which was kept confidential). The “full compensation for the Services provided in accordance with this agreement” of CHF 9,900 corresponds to the part attributed to UZH in Annex 1, out of a monthly project budget of CHF 28,400, the remaining part going to IPE. The German consulting firm appears to be the main contributor to the project. All members of the project team are linked to IPE: Kaul is IPE’s “Director”, Wolf is IPE’s “Senior Researcher”[10], the two other members being “consultants to IPE”. Annex 1 adds that “all team members have worked on joint research/consulting projects”.

This means that Wolf was associated with IPE before May 2013, when the Project Proposal was submitted to PMI. A copy of the “Research Network” page of IPE website made on 25 January

[10] Reference IPE-5

2015[11] shows Wolf as "Senior Advisor"; he has an IPE email address (*m.wolf@ipe-saarland.de*). In the current Register of Vested Interests of the professors at the University of Zurich[12] (which is based on the self-declaration of the professors), Wolf declares his link with IPE since July 2013. When he signs the contract with PMI on behalf of the University of Zurich, Wolf is in a situation of conflict of interest between his position as faculty member of the University of Zurich and academic researcher committed to the principles of scientific integrity and his position as employee of a consulting firm working for Philip Morris, a corporation whose commitment is to guarantee revenue growth to its shareholders. This conflict of interest is left undeclared. In his CV published in April 2015[13] on the website of the University of Zurich, Wolf makes no mention of IPE, although PMI appears among the private companies and public institutions listed under "Consulting Experience". In a more recent CV (January 2024)[14], the "Consulting Experience" section has been deleted and neither IPE nor Philip Morris is mentioned.

The research conducted by the two professors deals with an issue that is at the centre of major national, bilateral, and multinational legal and political battles.

- In February 2010, PMI, via its Swiss and Uruguayan subsidiaries, initiated an investor-state dispute settlement case against Urugay invoking a bilateral investment treaty between Switzerland and Urugay. PMI challenged two tobacco control packaging and labelling requirements implemented by Uruguay in 2009 and 2008: large graphic health warnings covering 80% of the front and back of cigarette packs and the ban of cigarette brand variants. Without going as far as the Australian model of plain packaging with large graphic health warnings, the Uruguayan requirement comes close, limiting to one-fifth the surface area available on the cigarette pack for branding elements. As of July 2013, the case was still pending (judgment will be handed down in July 2016).

- In July 2011, Philip Morris Asia Limited, based in Hong Kong, launched legal action against the Australian government over the country's decision to introduce plain packaging for cigarette, arguing that it violates a bilateral investment treaty (BIT) between Australia and Hong Kong. One of Philip Morris arguments is that plain packaging together with enlarged graphic health warnings contravene the substantive protections of their investments, invoking in particular "the lack of credible evidence that plain packaging will achieve its stated goals"[15]. The tobacco company claims that "Enactment of plain packaging legislation and the GHW regulation will cause PM Asia **significant financial loss, potentially amounting to billions of dollars**."

- As of July 2013, three countries have initiated a dispute process against Australia before the WTO, by requesting for the establishment of a panel – Ukraine, on 17 August 2012[16],

[11] Ibid.
[12] Reference 2a
[13] Reference 2b
[14] Reference 2c
[15] Reference 0o
[16] Reference WTO-12

Honduras, on 17 October 2012[17] and The Dominican Republic, on 14 November 2012[18]. Despite being supported financially by British American Tobacco, Ukraine will drop out of the WTO dispute[19]. The two remaining countries will be joined by Indonesia on 6 March 2014 and Cuba on 14 April 2014[20]. In their submissions to WTO, the complaining countries argued that Australia's plain packaging decision breached the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) because it is an "unjustifiable" encumbrance on the use of tobacco trademarks, thus violating article 20 of the TRIPS Agreement. According to some sources, Philip Morris is covering legal costs for the Dominican Republic and Cuba[21] and British American Tobacco is doing the same for both Ukraine and Honduras[22].

- In 2010, the UK Government announced its intention to introduce plain packaging for cigarettes and other tobacco products. In 2012, it launched a consultation to "look at whether the plain packaging of tobacco products could be an effective way to reduce the number of young people who take up smoking and to support adult smokers who want to quit, and consult on options by the end of the year."[23] However, no decision was made following the consultation, and on 12 July 2013, 4 days before the UZH signed its contract with Philip Morris, the British Government announced that it would await the outcomes of plain packaging in Australia before going ahead with legislation in the UK.[24]

The circumstances just described put considerable pressure on the tobacco industry, and particularly on PMI, to "prove" that plain packaging did not work in Australia. The general principle of WTO dispute settlement is that the burden of proof lies with the complainant[25]. To convince the WTO panel which will examine their complaints and thus win their case, the four countries must provide convincing evidence that the introduction of plain packaging is not *justifiable* from a public health point of view. In other words, they must show that plain packaging did not reduce smoking in Australia. Furthermore, the evidence needs to come from a reputable and trusted research institution, independent from the industry. Indeed, research produced directly or indirectly by the tobacco industry in areas implicating its commercial interests is known to be manipulated, when it is not blatantly fraudulent.[26]

[17] Reference WTO-13
[18] Reference WTO-14
[19] Reference WTO-14
[20] Reference WTO-20
[21] A. Martin, Philip Morris leads plain packs battle in Global Trade arena, Bloomberg Business News, 22 August 2013, accessed December 2015
[22] Reference WTO-21
[23] Reference 0q (3.6, page 22)
[24] https://tobaccotactics.org/article/plain-packaging-in-the-uk/
[25] Reference WTO-19
[26] The most comprehensive documentation of such scientific misconduct of the tobacco industry is provided by Judge Kessler's decision in the United States of America v. Philip Morris USA, Inc. et al. Civil Action No. 99-2496 (GK), August 2006 https://www.justice.gov/civil/cases/tobacco2/amended%20opinion.pdf ; see also Robert N. Proctor. 2012. *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition*. Berkeley and Los Angeles: University of California Press

It is against this highly sensitive backdrop that the University of Zürich signs the research contract with PMI. Annex 1 of the contract shows that in such a politically- charged context, the University of Zurich decides to side with Philip Morris (and the tobacco industry), committing itself to providing the company with the "scientific" research it crucially needs to win its cases against plain packaging and defeat Uruguay, Australia, the United Kingdom, and the World Health Organization which supports these countries in their decisions to implement plain packaging.

3. MARCH 2014 - KAUL AND WOLF MEETING WITH THE UK CHANTLER REVIEW TEAM

On 20 March 2014, as part of the UK Chantler Review (in preparation of UK plain - "standardized" - packaging law), Kaul and Wolf are heard by two members of the review secretariat (Christopher Cox and James Collins). Notes are taken Lucy Edwards. The purpose of the meeting is "to discuss 'The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis' working paper"[27].

The meeting is arranged at the request of Philip Morris and takes place before the publication of Kaul and Wolf's first working paper (which is dated 23 March 2014 in the PDF[28]) on the UZH website. In the first exchanges between the participants, Christopher Cox explains that "Philip Morris approached us to arrange this meeting".

Kaul and Wolf present themselves as professors of their respective academic institutions and make no mention of the role of the consulting firm they work for, IPE, in the project:

> *PROFESSOR MICHAEL WOLF: I am Michael Wolf, I'm Professor of Statistics and Applied Econometrics in the University of Zurich and I am part of the team working on the statistical analysis of the data to see whether there was any plain packaging effect; and we are going to talk about all of these things in detail.*

> *PROFESSOR DR ASHOK KAUL: I am Ashok Kaul, I am a Professor of Economics at Saarland University, and I work with Michael together on this topic. My research area is mainly Applied Economics, I work as a government consultant for the several German federal and state ministries and also do some consulting for the industry.*

[27] Reference 3
[28] Reference 4

Asked "about the work you are doing, how it came about, how you come to be doing that work and what, if any, is the particular aim of that piece of work", Kaul and Wolf reply as follows:

> *PROFESSOR DR ASHOK KAUL: So as you may know, this work was funded by Philip Morris International, and we started working on this in July 2013, not on this particular piece of work but on this funded research on the statistical effects of plain packaging. The way Phillip Morris approached us was: I was working for a big German consultancy as a technical adviser on a paper on the effects -- on the labour market effects essentially -- of the new TPD, new Tobacco Products Directive, in the EU so they got to know me, that's why they approached me, they asked me and I guess several other people whether we could do this kind of work and --*
>
> *PROFESSOR MICHAEL WOLF: And he (meaning Ashok Kaul) asked me.*
>
> *PROFESSOR DR ASHOK KAUL: And we have been working together for many years.*

Kaul and Wolf describe their statistical analysis method and say that they found no plain packaging effect on minors. About their results, Wolf explains:

> *But I can say from upfront* ***the methodology that we have employed is the one that gives the most leeway to finding an effect, if there had been any*** *[...] we are not claiming there was no effect, we are saying there is no evidence for any effect; I just want to make it very clear.*

They admit that their study is "**a very simple, purely time-series analysis, not controlling for anything else**" (p. 23). They explain that "this is the first output we produced and obviously it is easier to produce a time series paper based on a univariate time series than doing a full-fledged micro-data analysis." (p. 23) When asked by one member of the review secretariat "how do you differentiate any effect, if there was one, that you attribute to standardised packaging as opposed to, say, increases in taxation?", Wolf answers: "**That's a very good point because we don't take these other variables into account in this simple time-series analysis**," adding "we can analyse the micro-level data and we have that information, the **other variables [...] such as [...] the information of the taxes[;] there were perhaps other policy interventions, banning smoking outdoors -- or indoors**. **All these things can be also thrown into the model and then we can control for the other variables and compare to the plain packaging effect, if any.**"

When asked whether they are planning to publish their paper in a journal, Wolf replies "Yes, we are thinking about it, we finished that a couple of weeks ago so the usual process is extended and we wait for feedback. **We have published all our papers in peer-reviewed journals so there's no reason to stop here**."

NOTES

Kaul and Wolf introduce themselves as professors of their respective universities (University of Saarland for Kaul and UZH for Wolf) without disclosing their links with IPE and, thus, remaining silent on the central role played in their research by the German consulting firm (in which they have a vested interest) and its contract with Philip Morris. On the website of the University of Saarland, Kaul's involvement in the Philip Morris project appears under "Consulting".[29]

The notes from the meeting show that Kaul and Wolf are aware of the limitations of their simple "univariate time series" analysis. Their "very simple, purely time-series analysis, not controlling for anything else" is not what they presented in the Project Proposal (see 1. above): "As part of phase 2 we would therefore - based on PMI material and information - document regulatory interventions in order to identify significant changes to the regulatory environment in prior years, including tax and price increases as well as changes in tobacco control policies. These regulatory changes would then be coded in a way that the relevant information can be included in a statistical analysis."

Although Kaul and Wolf acknowledge that their study is "**a very simple, purely time-series analysis, not controlling for anything else**", at the same time, they claim "upfront" that "**the methodology that we have employed is the one that gives the most leeway to finding an effect, if there had been any**." This seems contradictory.

Furthermore, they recognize that a better model would have been one in which they could "control for the other variables [representing regulatory changes] and compare to the plain packaging." The reason they offer for limiting their analysis to the simplistic (and inadequate) "univariate time series": **it is "easier"**. This is a puzzling decision, as in the Project Proposal, the two professors deemed it "crucial" to have a statistical model that accommodates for regulatory changes. It is also an unconvincing explanation, considering the staff resources (four people) and budget (CHF 340'000) allocated to their project. It is even more surprising when the work of agreeing "on key changes in the regulatory background over the last decade that might affect the assessment of the effects of plain packaging in Australia" was to be done by a "joint team" (i.e. PMI-IPE-UZH) "based on PMI material and information". It is certainly not the lack of resources, nor the lack of time, that made Kaul and Wolf opt for the "easier" and "very simple, purely time-series analysis" that was "not controlling for anything else". This sounds like a *post-hoc* decision with an undeclared – although quite obvious - motivation.

Diethelm and Farley have re-analysed the data used by Kaul and Wolf, adding explanatory variables coded to represent the regulatory interventions mentioned by the two professors ("the information of the taxes, other policy interventions, banning smoking outdoors -- or indoors"). When these regulatory variables are added to the statistical model, the data exhibit a plain packaging effect, which is statistically significant for adults[30]. Diethelm and Farley's results also

[29] Reference 30 and Reference 30a

[30] Reference 85

show significant effects associated with the 2012 tax increase of 25% on cigarettes and with the introduction of smoke-free policies, which are each associated with a significant decrease of smoking prevalence in the Australian population.

4. MARCH 2014 - KAUL AND WOLF'S FIRST WORKING PAPER PUBLISHED ON UZH WEBSITE

Between 23 and 25 March 2014 [exact day unknown to us], Kaul and Wolf publish their original Working Paper 149 "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis"[31] on the website of the Department of Economics of the University of Zurich.

The paper starts with the following abstract:

> *A key stated objective of the Australian Plain Packaging Act 2011 is to influence smoking prevalence, in particular of minors. We use the Roy Morgan Single Source (Australia) data set on minors, (that is, Australians aged 14 to 17 years) over the time period January 2001 to December 2013 to analyze whether there is evidence that this goal has been achieved. We carry out a statistical trend analysis to study the (possible) effect of plain packaging on smoking prevalence of minors in Australia. More specifically,* ***we fit a linear time trend that explains well the fact that observed smoking prevalence has declined steadily over the last 13 years****. Two informative analyses help to draw conclusions on the (actual) effect of plain packaging on smoking prevalence of Australian minors. First, we look at the year of data before plain packaging was introduced, which happened in December 2012. Second, we compute confidence intervals around the estimated treatment effects (that is, around the deviations from the fitted trend line) from 12/2012 on.* ***Both analyses fail to find any evidence for an actual plain packaging effect on Australians aged 14 to 17 years. Several reasonable variations to our methodology are discussed. All of these would only result in findings even more indicative of an absence of any plain packaging effect.***

[31] Reference 4 (original version)

Kaul and Wolf explain the choice of their simple linear model as follows:

> *We model a simple linear time trend. [...] ... see Figure 2 for a graphical display.* ***It can be seen that the linear trend generally fits the observed data well****. The individual deviations of the observed data from the fitted line are typically quite large, which is unavoidable given the unstable development of observed smoking prevalence over time (for the reasons discussed above). Globally, however,* ***the fit of such a simple linear time trend is surprisingly good****, given the long time period and the numerous regulatory changes in tobacco control policies over this period.*

Figure 2 to which the authors refer when they say that "it can be seen that the linear trend fits the observed data well", is shown below:

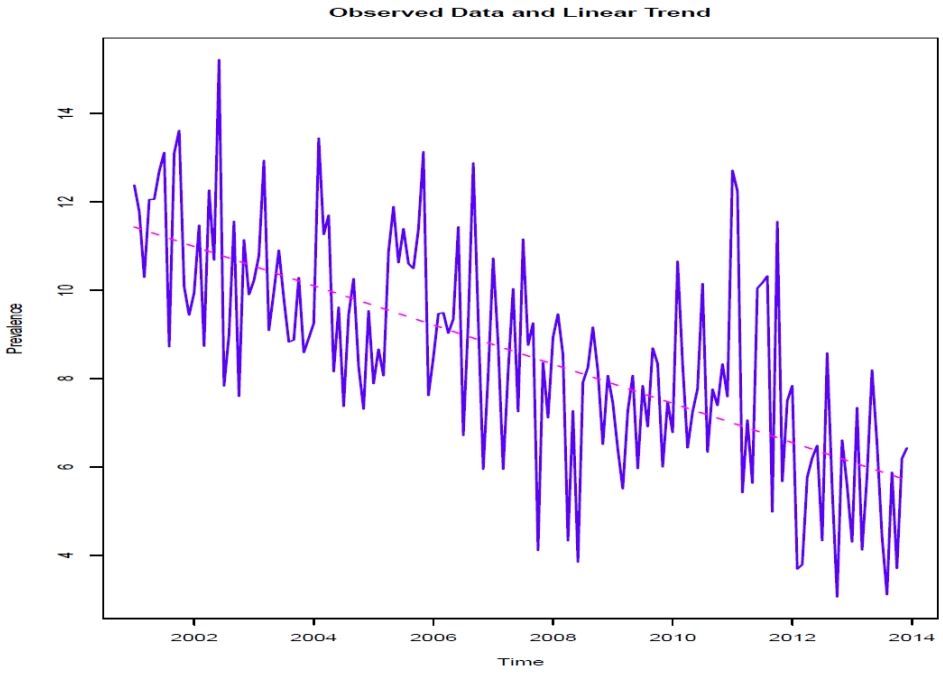


Figure 2: Time series plot of observed prevalence with fitted linear time trend.

Kaul and Wolf end their paper with the following conclusion:

> *Altogether, we have applied quite liberal inference techniques, that is, our analysis, if anything, is slightly biased in favor of finding a statistically significant (negative) effect of plain packaging on smoking prevalence of Australians aged 14 to 17 years. Nevertheless, no such evidence has been discovered. More conservative statistical inference methods would only reinforce this conclusion.*

In the authors' credentials, Wolf is presented as belonging to the Department of Economics at the University of Zurich and Kaul is presented as belonging both to the Institute for Policy Evaluation (IPE), Saarland and to the Department of Economics, Saarland University. The title of the paper has a footnote that reads: "Philip Morris International provided the funding for this research. At no time did we provide Philip Morris International with access to the underlying data."

The working paper is posted on the SSRN (Social Sciences Research Network) website on 26 March 2014[32].

NOTES

This paper has serious limitations and the authors' conclusion is severely misleading. As will be shown by several commentators and critics (see below), the rudimentary method of analysis used by the two professors was inadequate and lacked statistical power. At best they could have concluded that their results were unconclusive.

The paper contains no indication of its limitations. In particular, the authors do not mention the limitations discussed during their Chantler Review hearing, such as the fact that the simple univariate time series analysis was controlling nothing else but time. Instead, the authors claim that they have applied "quite liberal inference techniques" and found no evidence of a plain packaging effect, adding that "more conservative statistical inference methods would only reinforce this conclusion".

The authors explain that they fitted "a linear time trend that explains well the fact that observed smoking prevalence has declined steadily over the last 13 years". A linear time trend does not explain such a decline. This is a circular reasoning, using the definiendum to "explain" the definiens: a (downward) linear time trend is something that, by definition, declines steadily over time. This is also a way of stating without justification that prevalence has declined linearly in Australia over the study period. This is obviously not true and has been shown not to be true, notably by Wakefield et al. in two papers, the first published in the American Journal of Public Health in August 2008[33], and the second in the Bulletin of the World Health Organization on 18 March 2014[34]. Indeed, key tobacco control measures of scientifically established effectiveness were implemented during that period. Notably Wakefield et al. showed in their second paper that the 25% cigarette tax increase of 2010 and the gradual introduction of smoke-free policies in Australia's states and territories from 2006 until 2010 had a significant impact on smoking prevalence.

Kaul and Wolf will later revise their working paper 149, adding a section on power analysis and a section on robustness checking, both intended to strengthen the robustness of their results.

[32] Reference 16d

[33] Reference 4b

[34] Reference 4a

We see below that their power analysis leads to a significant overestimate of the real power of their statistical method.

In the light of the contract between the UZH and PMI, the working paper appears to breach important rules of integrity in scientific research laid out in the 2008 *Principles and procedures* of the Swiss Academies of Arts and Sciences (SAAS).[35] The highest principles of veracity and transparency do not seem to have been fully observed. The SAAS states that:

> *Scientific research is based on the elaboration and exchange of knowledge.* ***Veracity, self-discipline and self-criticism are therefore essential for behaviour of integrity in the field of science.***

It looks like these essential requirements of scientific integrity have been neglected in this working paper. As shown above, self-criticism was not only absent, but replaced with a statement that presented the authors' methodology as "biased in favor of finding a statistically significant (negative) effect of plain packaging". Self-discipline seems also lacking, as the authors, without any explanation, did not apply the approach spelled out in the project proposal, which clearly indicated that "regulatory changes would [...] be coded in a way that the relevant information can be included in a statistical analysis".

Furthermore, the SAAS principles and procedures specify that the "person who, through his personal scientific work, has made an important contribution to the planning, the realisation and the evaluation or checking of the research work must be listed as author", qualifying as "dishonest behaviour" the "deliberate non-mention of participants who have made significant contributions". Given PMI's overwhelming role in the research, which was under the company's control throughout all four phases, up to and including the decision whether or not to publish the final paper and in what format, a member of the PMI team involved in the project should have been one of the co-authors of the paper in order to fulfil, at least in a minimal way, the SAAS principles.

5. MARCH 2014 – PHILIP MORRIS INTERNATIONAL ISSUES A MEDIA RELEASE

On the same day, Philip Morris International issues a media release[36] with the title "Researchers Find No Evidence Plain Packaging 'Experiment' Has Cut Smoking". The release makes the following statements:

[35] Reference 0c

[36] Reference 5

The plain packaging experiment in Australia has not deterred young smokers, *professors from the Department of Economics at Zurich University and the University of Saarland found in a report released today [...].*

The study undertook a statistical analysis of smoking prevalence data for Australians aged 14-17 years old. It used the same data chosen by anti-smoking groups, as well as techniques that were biased in favour of finding evidence of a significant effect of plain packaging on reducing youth smoking, but as the study concludes, no such evidence has been discovered.

Professor Wolf and Professor Kaul explained: "We used statistical methodology that gave every possible leeway for detecting a possible plain packaging effect. Nevertheless, the data does not support any evidence of an actual effect of the Australian Plain Packaging Act on smoking prevalence of minors." [...].

Plain packaging in Australia has not reduced smoking rates and has had no impact on youth smoking prevalence.

NOTES

The initial statement ("The plain packaging experiment in Australia has not deterred young smokers") is presented as fact that has been established by the UZH study.

PMI' release starts by persuading the reader that Kaul and Wolf's results are robust: the two professors used "the **same data chosen by anti-smoking groups**" and "techniques that were **biased in favour of finding evidence** of a significant effect of plain packaging on reducing youth smoking"; they used "statistical methodology that gave **every possible leeway for detecting a possible plain pack aging effect**". Under such circumstances, if "no such evidence has been discovered", if "the data does not support any evidence of an actual effect of the Australian Plain Packaging Act on smoking prevalence of minors," this can be only because the plain packaging measure was ineffective. This allows PMI to conclude that "Plain packaging in Australia **has not** reduced smoking rates and **has had no** impact on youth smoking prevalence."

No mention is made of potential limitations of the Kaul and Wolf's study.

Although collaborating closely with PMI, the two professors have raised no objections against this way of presenting their findings, which they later described as a "fair characterization of their results".

Also note that, according to them, it is "the data" that does not support any evidence of a plain packaging effect. No reference is made to the limitations of the statistical method used by the

two professors. In their quotation, they falsely imply that the statistical method they used was the best to extract all possible evidence contained in the data.

6. MARCH 2014 - UK NHS FEARS THAT MISLEADING FINDINGS MAY REACH THE MAINSTREAM MEDIA

The news is picked up on 26 March 2014 by the UK National Health Service (NHS), with an article published on its website under the heading "Plain cigarette packaging doesn't work, says industry funded study"[37] (this title will be later changed - see below). The NHS reports that "Based on the trend analyses, the researchers said they failed to find any evidence for an actual plain packaging effect on reducing smoking in young people." The NHS also reports on how the researchers interpreted their findings:

> *Based on the trend analyses, the researchers said they failed to find any evidence for an actual plain packaging effect on reducing smoking in young people.*
>
> *Conclusions in the press release based on the trend analysis and tobacco sales figures indicated that "plain packaging in Australia has not reduced smoking rates and has had no impact on youth smoking prevalence".*

The NHS concludes its news item with the following criticism:

> *The research does not appear to have been peer reviewed, meaning it has not been scrutinised by experts in the field for methodological rigor, or to check if the conclusions are reliable. This significantly increases the risk that misleading findings can reach the mainstream media and public before it has been properly scrutinised.*
>
> *Based on this data alone, it is difficult to make any firm conclusions on whether the plain packaging affected prevalence rates.*
>
> *While the researchers stated that there was no access to the analysis of the data by the tobacco company, it raises questions – and eyebrows – that this research has been released to the press without being peer reviewed by independent experts.*

[37] Reference 6

7. MARCH 2014 - KAUL AND WOLF REPLY TO THE NHS

The NHS news provokes a reaction by Kaul and Wolf. On 28 March 2014, they publish a reply on the website of the Institute for Policy Evaluation (IPE)[38]. Their main point relates to the title of the NHS news item. They write:

> *While we always welcome other researchers' comments on our work, we kindly ask them to carefully read our work first before publicly criticizing it. To start with, the NHS comment is titled "Plain cigarette packaging doesn't work, says industry funded study". This title is an incorrect summary of our results and therefore is misleading. Being experienced empirical researchers, we took care to point out that we "fail to find any evidence for an actual plain packaging effect", which is not the same as claiming we find evidence for no plain packaging effect. In other words, the absence of evidence for an effect should not be misconstrued as evidence for no effect. Either the author(s) of the comment is/are not aware of this fundamental distinction or the study's claim are deliberately inflated in order to question our credibility.*

Kaul and Wolf make some clarification point about the methodology of their study (it is not a cross-sectional but a time-series analysis) and ensure that, while this is an industry-funded study, "**freedom of research has been guaranteed**".

Noting that NHS article also questioned the reliability of their study because it is not peer-reviewed, Kaul and Wolf replied that this is "standard in research because peer-review takes time and findings are typically communicated in working papers in order to allow for a methodological debate and to disseminate findings at an early stage." However, they say that they will be "submitting [their] study to a peer-reviewed outlet in due time", adding that "Given the straightforward nature of the data and the statistical methodology, we do not expect changes to the basic findings during the reviewing process."

NOTE

The sentence "Freedom of research has been guaranteed" is not consistent with the Annex 1 to the Contract between PMI and UZH (the Project Proposal), in which the two professors place their research under the control of Philip Morris.

The authors did not "allow for a methodological debate": they allow their findings to be immediately used in the policy-making debate by PMI. Despite their commitment to submit their study "to a peer-reviewed outlet", this will never be done. They announce that, in any case,

[38] Reference 7

they do not expect the peer-review of their study to change its basic findings, which is a way of claiming that their paper has the same weight as a peer-reviewed publication.

8. MARCH 2014 – NHS: "DOESN'T WORK" CHANGED TO "NO EVIDENCE THAT PLAIN PACKAGING WORKS"

Shortly after Kaul and Wolf's reaction, the NHS changes the title of the article to "No evidence that plain cigarette packs work, says industry funded study"[39]. The rest of the text remains unchanged except that the study is described as "a repeated cross-sectional study (time-trend analysis)" instead of simply a "cross-sectional study".

9. MARCH 2014 – CANCER COUNCIL VICTORIA (AUSTRALIA) CRITICIZES KAUL AND WOLF PAPER

On 26 March 2014, Cancer Council Victoria (CCV) issues a note entitled "Comments on Kaul & Wolf 'The (possible) effect of plain packaging on the smoking prevalence of minors in Australia: a trend analysis'"[40], in which they state that the Kaul and Wolf's study is "seriously flawed conceptually":

> *The report is seriously flawed conceptually. It is based on the straw man principle that plain packaging could be expected to immediately lead to a detectable reduction in adolescent smoking prevalence. No other tobacco control intervention has achieved that and neither is this the expectation of governments or credible researchers.*
>
> *The process of smoking uptake in adolescence is gradual, beginning with the first puff of a cigarette and then a period of experimentation of sharing puffs and cigarettes which can last some years. If left unarrested, this experimentation gradually becomes more regular in nature and ultimately progresses to the commencement of daily smoking and an escalation of the number of cigarettes smoked each day. At the point of daily smoking, adolescents begin to resemble adult smokers. Any intervention that exerts an impact on adolescent smoking will naturally take many years to become detectable because the change needs to occur early in the period of uptake to divert adolescents from becoming regular smokers as they age into adulthood.*

[39] Reference 8

[40] Reference 9

CCV criticizes the statistical model used by Kaul and Wolf, which ignores the "many other tobacco control interventions that have been implemented during the period under study", notably "the particularly large tobacco excise increase in April 2010";

> *With the comprehensive approach adopted by the Australian government, many tobacco control interventions have occurred over the recent period, including a large excise increase in April 2010, strengthening of smoke-free laws, large scale mass media campaigns, rotating graphic health warnings, and the implementation of cigarette display bans, all of which have contributed to declining smoking prevalence over many years. [...]*
>
> ***It is a breathtaking error of logic that the authors demand to find an immediate reduction in this crude measure of prevalence after plain packaging, while not also requiring the same immediate drop in prevalence from the many other tobacco control interventions that have been implemented during the period under study*** *– for example, the introduction of graphic health warnings in early 2006, the tobacco excise increases that occurred in 1999–2001 and the particularly large tobacco excise increase in April 2010. It is not excusable that the authors were unaware of these policies because they note the existence of "numerous regulatory changes in tobacco control policies over this period".*

CCV also raises the issue of the limitations resulting from small monthly sample sizes and points out the inadequacy of a simple trend line over the 13-year of observation:

> *The small monthly sample size prohibits any credible analysis of change over a short period of time. The authors describe the sample as being between 200 to 350 adolescents per month, (although they neglect to point out the sample size in the last several years has been reduced to closer to 200 per month). The authors entire analysis is based on the fact that they have been able to fit a trend line to the measure of smoking over the 13-year period examined. This is not a test of plain packaging but a simple description of how much on average smoking prevalence has declined over the 13-year period. It would be truly concerning if any ongoing survey in Australia could not yield this basic descriptive parameter, since there has been such a large gradual decline in smoking over this 13-year period due to the aforementioned ongoing tobacco control policies and program efforts.*

Finally, CCV criticizes the great over-interpretation of the meaning of unstable monthly prevalence estimates:

The authors acknowledge that monthly observed smoking prevalence is unstable because of the small sample size each month and the fact that the sample composition changes each month. Despite this, their analysis of deviations from the trend line is expressly focussed on the size of the deviations that occur each month from this longer term trend, in the year prior to and after plain packaging implementation. In other words, they have greatly over-interpreted the meaning of the monthly prevalence estimates, both in their "naïve" analysis and in their so-called "more informative" descriptive analyses, the data points for which are summarised in Figures 3 to 5. In their "naïve" analysis they point the reader to the fact that "… the twelve numbers pre 12/2012 are almost a mirror image of the twelve numbers post 12/2012" (p.4). The "more informative" analysis that focusses on confidence intervals merely serves to underline the basic concern that the monthly data series have extremely wide confidence intervals and are too variable for credible analysis in the short term.

NOTES

By observing that "the small monthly sample size prohibits any credible analysis of change over a short period of time," CCV raises the issue of the lack of statistical power of Kaul and Wolf's first study.

When it says that "it is not excusable that the authors were unaware of these [regulatory] policies", CCV does not know that in fact the authors *were* aware of these policies and had considered it "crucial" to include them in their statistical analysis. The Project Proposal (see item 1. above) was quite explicit about it:

"[..] document regulatory interventions in order to identify significant changes to the regulatory environment in prior years, including tax and price increases as well as changes in tobacco control policies. These regulatory changes would then be coded in a way that the relevant information can be included in a statistical analysis."

CCV's critique of Kaul and Wolf's first paper gives a hint of what reviewers would be likely to say if the two professors submitted it to a peer-reviewed journal.

10. MARCH 2014 – STEVE BANNON'S *BREITBART*: NEW DATA PROVES PLAIN PACKAGING HAS FAILED

On 27 March 2017, the US extreme right-wing[41] website, Breitbart (whose executive chairman was Steve Bannon) reports on the UZH study under the heading in capital letters: "NEW DATA PROVES PLAIN PACK CIGARETTES DOESN'T DISSUADE YOUNG SMOKERS AND FUELS THE BLACK MARKET"[42]. The UZH study is discussed at the end of the article: "A study also released this week by professors from the University of Zurich and the University of Saarland in Germany indicates that plain packaging has failed to effect a reduction in tobacco consumption among 14 to 17 year olds."

11. MARCH 2014 – THE *NEW ZEALAND HERALD*: "PLAIN PACKS DERIDED AS NOT WORKING"

On 31st March 2014, The New Zealand Herald, the country's largest newspaper, publishes an article entitled "Plain packs derided as not working"[43], in which it reports that "The tobacco industry has ramped up efforts to persuade New Zealand against plain packaging, by circulating research claiming to show the policy has not worked in Australia." The article refers to Philip Morris:

> *Philip Morris, the manufacturer of Marlboro cigarettes, has drawn attention to "three separate data sets that demonstrate plain packaging has not reduced smoking rates in Australia". Two are company-funded surveys of smoking prevalence, by Zurich University and by policy consultancy London Economics. The third is industry sales data, released by the company, showing a 0.3 per cent rise in the volume of tobacco delivered to retailers last year.[...]*
>
> *Philip Morris Australia and New Zealand corporate affairs director Chris Argent said that since plain packaging took effect in Australia, "**hard data shows that the measure has not reduced smoking rates and has had no impact on youth smoking prevalence**".*
>
> *"The plain packaging 'experiment' in Australia has simply not worked."*
>
> *The two surveys tracked prevalence - one of them looking specifically at youth - before and after the introduction of plain packaging.*

[41] https://mediabiasfactcheck.com/breitbart/
[42] Reference 10
[43] Reference 11

NOTE

Here again, it is "hard data" that "shows" that plain packaging has not reduced smoking.

We note also that the introduction of plain packaging in Australia is presented as an "**experiment**" (a recurring theme in the tobacco industry's narrative), which the UZH study shows "has simply not worked".

12. APRIL 2014 – SIR CHANDLER'S REVIEW DEPOSITED IN THE UK HOUSE OF COMMONS

On 3rd April 2014, Sir Cyril Chandler deposits his independent review on standardized packaging of tobacco in the UK House of Commons[44,45]. Summarizing his findings, Sir Chantler writes:

> *The aim of standardised packaging is to reduce the tobacco package's visual identity and appeal as an advertisement for the product. There is very strong evidence that exposure to tobacco advertising and promotion increases the likelihood of children taking up smoking. Industry documents show that tobacco packaging has for decades been designed, in the light of market research, with regard to what appeals to target groups. Branded cigarettes are "badge" products, frequently on display, which therefore act as a "silent salesman". Tobacco packages appear to be especially important as a means of communicating brand imagery in countries like Australia and the UK which have comprehensive bans on advertising and promotion.*

[44] https://depositedpapers.parliament.uk/depositedpaper/2274243/details

[45] Reference 12

The tobacco industry argues that all of its marketing activity, including packaging, aims solely to persuade existing adult smokers to switch brand and never targets children or new smokers. However, in my opinion, whatever their intent, it is not plausible that the effect of branded packaging is only to encourage brand switching amongst adult smokers, and never to encourage non-smokers from taking up smoking. I have heard no coherent argument as to how this purported separation occurs in practice and in my opinion a "spillover effect" is highly plausible whereby packages that are designed to appeal to a young adult, also, albeit inadvertently, appeal to children. It seems to me that children and non-smokers are not, and cannot be, quarantined from seeing tobacco packaging and in my view once they are exposed to this packaging, they are susceptible to its appeal whether it is intended to target them or not. In the light of these and other considerations set out in my report I believe that branded packaging contributes to increased tobacco consumption.

Sir Chantler then presents the following conclusion:

Having reviewed the evidence it is in my view highly likely that standardised packaging would serve to reduce the rate of children taking up smoking and implausible that it would increase the consumption of tobacco. I am persuaded that branded packaging plays an important role in encouraging young people to smoke and in consolidating the habit irrespective of the intentions of the industry. Although I have not seen evidence that allows me to quantify the size of the likely impact of standardized packaging, I am satisfied that the body of evidence shows that standardised packaging, in conjunction with the current tobacco control regime, is very likely to lead to a modest but important reduction over time on the uptake and prevalence of smoking and thus have a positive impact on public health.

Sir Chantler indicates that he took into account the views from both sides of the issue:

In carrying out the Review, I have met with opponents of standardised packaging including representatives from the major tobacco companies. I have also met with tobacco control experts many of whom strongly advocate standardised packaging. I have been sent a considerable volume of evidence from both sides of the debate which my team and I have reviewed carefully. We sought further information where we considered it relevant.

The Kaul and Wolf working paper is not specifically cited in sir Chantler's report. Sir Chantler makes the following observation among his concluding points:

The specific evidence base, centred on the Stirling Review and update, is relatively modest, and put forward in awareness of its limitations due in particular to constraints on study design. But it points in a single direction, and I am not aware of any convincing evidence pointing the other way. [...] Whilst standardised packaging may have a modest effect, it is the nature of public health measures that small effects mount up at a population level.

13. APRIL 2014 – SNOWDON: WHY DID SIR CHANTLER EXCLUDE THE KAUL AND WOLF STUDY?

On 11 April 2014, Christopher Snowdon publishes an article on his blog, Velvet Glove, Iron Fist, entitled "The missing packs data"[46] , in which he expresses his astonishment that Kaul and Wolf's study is not referenced in the Chantler report:

When the Chantler report on plain packaging was published last week, one piece of evidence was conspicuous by its absence. At first I assumed that the empirical research on teen smoking rates from the University of Zurich had been published too late to be included, but I was wrong. It transpires that Chantler's team not only had access to the study, but had spoken personally to its authors, Dr Ashok Kaul and Dr Michael Wolf.

Chantler had every reason to be interested in this research. It is the only study to date that addresses the question upon which all else hinges - does plain packaging help reduce the smoking rate amongst minors?

Summarizing Kaul and Wolf findings, Snowdon says that "plain packaging was shown to have had no discernible impact whatsoever...". Referring to the hearing of Kaul and Wolf by the Chantler's team, Snowdon says that "At this meeting, Dr Kaul described that the methodology they used allowed maximum leeway for finding some effect from plain packaging. Alas, there was none...". He concludes his paper with a question that he leaves to his readers: "Why was the only empirical, real world evidence about underage smoking rates after plain packaging excluded?"

Snowdon's concerns were echoed by Breitbart in an article published on 20 April 2014 entitled "Britain's Implementation of Plain Cigarette Packs Could Lead to an Obama-esque Loss for the Taxpayer"[47]:

[46] Reference 13

[47] Reference 13a

Perhaps the more disquieting evidence was offered by Dr. Ashok Kaul and Dr. Michael Wolf from the University of Zurich. They analysed Australian data for January 2011 to December 2013 for fourteen to seventeen year olds and concluded that "both analyses fail to find any evidence for an actual plain packaging effect on Australians aged 14 to 17 years".

Kaul and Wolf flew over from Zurich to London on the 20th March and had a meeting with Christopher Cox who described himself as "a secondee from the Department of Health... supporting Sir Cyril Chantler in his review... Sorry that Sir Cyril himself can't make this meeting... we will give him a full briefing in the light of what you tell us."

Dr. Kaul told Chris Snowdon, Director of Lifestyle Economics at the Institute of Economic Affairs that "the Chantler review team claims that our work was considered in reaching the conclusions of the review."

It appears in this case to have been discarded.

The article then describes what would await the UK government if it adopted plain packaging:

Should plain packaging get green-lit in the UK, what awaits when tobacco exporting companies take the government to the World Trade Organisation may cost the British taxpayer £millions in compensation. The move seems to be in conflict with the WTO's 1986 Uruguay Round on Trade-Related Aspects of Intellectual Property Rights where "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements." [...]

Plain packaging remains a contentious issue and at this stage it may be too early to draw any conclusions as to its efficacy. With the evidence still unclear and huge costs to governments at risk, taxpayers and free market, free trade proponents must keep an eye on the public purse, and their own.

Breitbart quotes is taken from Article 20 of the TRIPS agreement.

NOTES

Christopher Snowdon, who describes himself as a "libertarian writer and researcher"[48], is the Director of the Lifestyle Economics unit of the Institute of Economic Affairs (IEA), a well-known British neo-liberal think tank that accepts money from the tobacco industry.[49,50]

[48] https://www.christophersnowdon.com/

[49] https://tobaccotactics.org/wiki/christopher-snowdon/

[50] https://tobaccotactics.org/wiki/institute-of-economic-affairs/

The way Breitbart presents the issue facing the UK government if it adopts plain packaging resorts to two classical tactics of the tobacco industry: *creating doubt*[51] - the issue remains "contentious" - and expressing this uncertainty as a risk for governments with huge financial consequences, i.e. using *the chilling effect*[52].

The quote "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements." in the Breitbart article is taken from Article 20 of the TRIPS agreement, which will be at the heart of the Australia-plain packaging dispute at the WTO.

14. APRIL 2014 – SNOWDON PUBLISHES AN INTERVIEW OF KAUL ON HIS BLOG

On 15 April, Christopher Snowdon publishes an interview of Kaul on his blog, Velvet Glove, Iron Fist[53]. Snowdon asks Kaul to comment about the 'small sample size' critique raised against their paper. Kaul's reply:

> *Despite the relatively small sample sizes, the power of our methodology against a meaningful immediate effect on smoking prevalence is not tiny. [...] In a nutshell, our approach would detect a non-negligible effect of plain packaging on smoking prevalence of minors in Australia with a pretty high probability - despite the small sample size. Criticizing the 'small sample size' is therefore quite absurd.*

Kaul then adds:

> ***The empirical evidence** so far does not support the conclusion of a short-term effect. Of course, short-term effects are important for policy makers around the world who would like to choose their regulatory policies from a set of alternatives that have been proven to be effective - plain packaging is so far not part of this set.*

NOTE

It's worth noting that, for Kaul, their UZH study on minors provides ***the*** empirical evidence.

[51] See for instance Doubt is Their Product, by David Michaels, Oxford University Press, Inc. 2008

[52] Reference 0p1

[53] Reference 14

15. APRIL 2014 – *THE LANCET*: KAUL AND WOLF MISREPRESENTED EVIDENCE

Online on 10 April 2014, and then in print on 19 April 2014, a letter is published in The Lancet by A. Laverty et al. under the title "Standardised packaging and tobacco-industry funded research"[54].

Noting that "tobacco industry misrepresentation of the evidence in order to try to block public health interventions by manipulating policy making and public opinion is well documented", the authors write:

> *Recently, Philip Morris International funded an analysis of smoking among Australian adolescents aged 14–17 years showing 'an absence of any plain packaging effect'. We have reviewed the data presented in Ashok Kaul and Michael Wolf's paper and conclude that in view of the short time span since the measure was introduced, the variability in the measure, and the small sample size, this is neither an unexpected nor a meaningful conclusion.*

Laverty et al. make the following analysis:

> *At the time standardized packaging was introduced, smoking prevalence was 6%. […] a reduction of 1.25% in the year after plain packaging compared with the year before would be required to be statistically significant using this analysis. Against the background decline of 0.44% per year, this would equate to a fall of 1.69%; nearly a four-fold increase in the rate and far exceeding the likely effect.* ***We are surprised that Kaul and Wolf do not mention this rather obvious limitation in their discussion of the results****.*

The authors conclude their letter by observing that "the lesson from Australia is that the tobacco industry's struggle against standardized packaging will not cease and it is essential to guard against continued misrepresentation of the evidence."

54 Reference 15

16. MAY 2014 – KAUL AND WOLF POST A REVISED VERSION OF THEIR WORKING PAPER ON MINORS

In May 2014, Kaul and Wolf post on the website of the Department of Economics of the University of Zurich a revised version of the working paper 149[55]. The "Goal and Basic Setup" section of the revised paper is almost 4 times longer than the original version. What has been added is mainly a selective review of the literature on the expected effects of plain packaging. At the end of the section, the authors address the critique raised by Laverty et al. in their letter to The Lancet:

> *As a reaction to an earlier version of this paper, Laverty et al. (2014) state that "in view of the short time span since the measure was introduced, the variability in the measure, and the small sample size" failing to find any evidence for a plain packaging effect "is neither an unexpected nor a meaningful conclusion". Based on reasoning that is not explained in (sufficient) detail, they further claim that a reduction of 1.25 percentage points "would be required to be statistically significant using this analysis". However, this claim is unjustified, since our approach actually allows to identify an effect much smaller than 1.25 percentage points with reasonable power already.*

The revised paper contains the same data analysis as the original paper. The authors added a Power Analysis section (3.3) and a Robustness Check section (3.4). The figures and tables at the end of the paper are the same as in the original paper, with three additions: Figure 8 (time series plot of observed prevalence with two fitted linear trends) and Tables 2 and 3 (power of the two inference methods against various plain packages effects).

NOTE

Later it will be shown that the power analysis used by Kaul and Wolf to refute the Lancet critique is flawed. The critique remains unchallenged.

[55] Reference 16

17. JUNE 2014 – *THE AUSTRALIAN*: TEENAGE SMOKING IN AUSTRALIA DID NOT DECREASE

On 21 June 2014, the right-leaning[56] newspaper The Australian publishes an article[57] under the heading "Why Stephen Koukoulas is plain wrong on cigarette", in which the author refutes the Australian government's claim (citing its economic adviser Koukoulas) that plain packaging has been effective in curbing youth smoking.

The article starts with a comparison with climate science: "In this case too, as with climate change, 'the science was settled': plain packaging would 'reduce the consumption of tobacco by about 6 per cent and the number of smokers by 2 to 3 per cent'." It then argues that "basic economics shows that instead of lowering tobacco consumption, plain packaging may increase it, and the risk of cancer with it." The article goes on to say that the available evidence does not support the government's claims, referring to Kaul and Wolf's first working paper:

> *An econometric analysis by researchers at the University of Zurich is a case in point. Using a broad range of methods, the researchers conclude that* ***plain packaging has not reduced the incidence of teenage smoking in Australia****. True, the study was funded by Philip Morris ; however, it is methodologically rigorous, and its results are consistent with those of earlier research.*

18. JUNE 2014 – KAUL AND WOLF'S SECOND WORKING PAPER PUBLISHED ON UZH WEBSITE

On 30th June 2014, Kaul and Wolf's second paper on plain packaging appears on the website of the Department of Economics of the University of Zurich. Its title: "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis"[58]. The paper uses the same statistical methodology as the first paper, with a much larger sample size (700,000+ participants against 41,000+ for the first paper), covering ages from 14 and above.

The abstract gives the following summary of the paper:

[56] https://mediabiasfactcheck.com/the-australian/

[57] Reference 17

[58] Reference 18

A stated objective of the Australian Plain Packaging Act 2011 is to reduce smoking prevalence. We use the Roy Morgan Single Source (Australia) data set over the time period January 2001 to December 2013 to analyze whether this goal has been achieved in the first year since the implementation. In particular, we carry out a statistical trend analysis to study the (possible) effect of plain packaging on smoking prevalence. Two informative analyses help to draw conclusions on the (actual) effect of plain packaging on smoking prevalence in Australia. First, we look at the year of data before plain packaging was introduced, which happened in December 2012. Second, we compute confidence intervals around the estimated treatment effects.

Our main results can be summarized as follows. First, if a statistical significance level of 5% is required, then there is no evidence at all for a plain packaging effect on smoking prevalence. Second, if one is willing to accept a relatively low level of statistical significance (that is, 10%), then there is evidence for a very short-lived plain packaging effect on smoking prevalence, namely in December 2012 only (after which smoking prevalence is statistically indistinguishable from its pre-existing trend).

A formal power analysis demonstrates that the power of our inference methods is remarkably high.

As in the first paper, Kaul and Wolf use a simple linear time trend as their model. They provide the following explanation:

We start by modeling a simple linear time trend. [...] ... see Figure 2 for a graphical display. We also include a local, nonparametric trend that does not make any assumptions on the parametric form of the trend (like linear or quadratic). Such a nonparametric trend provides a good local fit and avoids the problem of misspecification. ***It can be seen that the (global) linear trend is not a very satisfactory fit to the observed data: it is somewhat too high early on and in the final years while somewhat too low in the middle****.*

Despite its flexible nature, the nonparametric fit resembles a straight line in the second two thirds of the observation period, which is the interval of main interest to us. For simplicity, and for ease of reproducibility of our results by other researchers, we match the nonparametric trend in the second two thirds of the data by fitting a linear time trend from 07/2004 on. [...] The results are displayed in Figure 3. It can be seen that in the last two thirds of the period, the linear trend is, for all practical purposes, indistinguishable from the nonparametric trend.

Figure 3 which the authors use to infer their assumption of linearity "in the last two thirds of the period" is shown below:

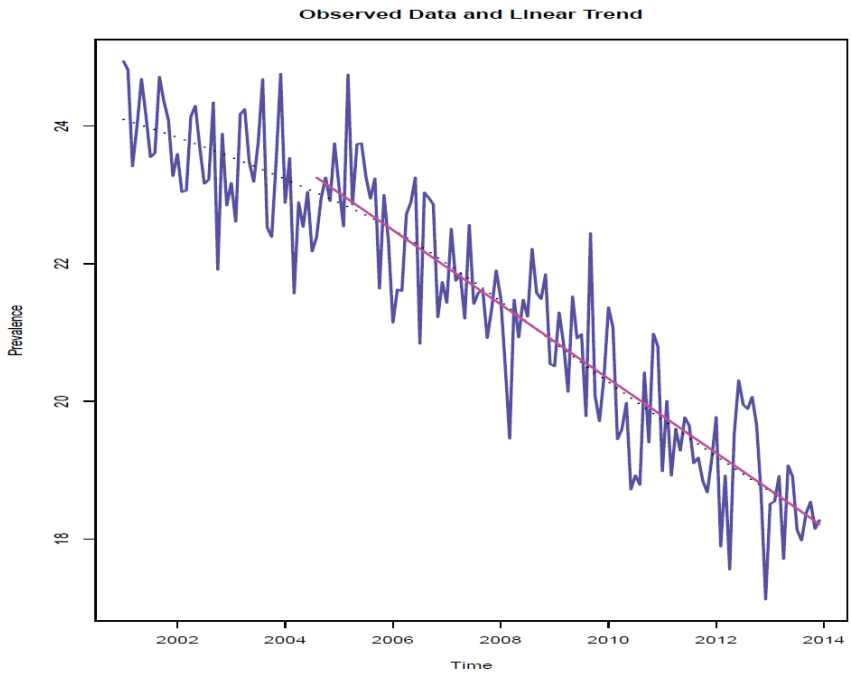


Figure 3: Time series plot of observed prevalence with fitted linear trend based on the observations from 07/2004 on (solid line). In addition, a fitted nonparametric trend has been added

In the first section of the paper ("Goal and Setup"), Kaul and Wolf explain that "in most of the paper, we employ a statistical approach more favourable to finding a plain packaging effect, namely by asking whether there is a plain packaging effect in any specific month", adding that they have performed a formal power analysis which demonstrates that their approach can identify even small reductions in smoking prevalence with reasonable power.

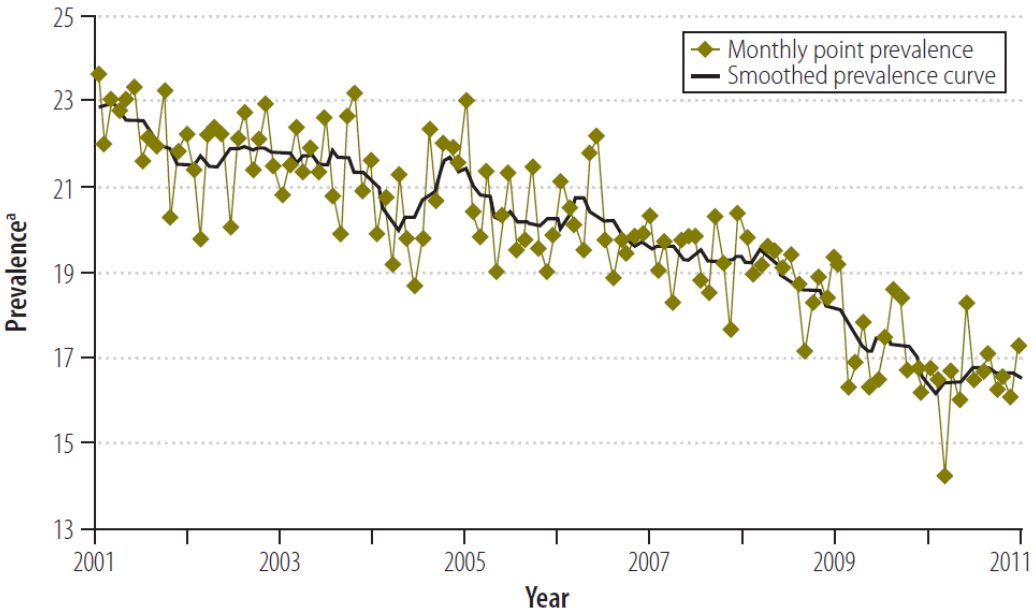
The paper is posted on the SSRN website on 1st July 2014[59].

[59] Reference 18b

NOTES

It is worth contrasting Figure 3 above used by Kaul and Wolf as their intuitive proof that smoking prevalence follows a linear trend with the figure used by Wakefield et al. to illustrate the evolution of smoking prevalence from January 2001 to June 2011:

Fig. 1. **Monthly smoking prevalence among Australian adults, January 2001 to June 2011**



[a] Smokers per 100 respondents.

In the figure proposed by Wakefield at al., although smoothed smoking prevalence shows a downward trend over the entire period, its year-to-year evolution does not appear to be linear.

The comments on the lack of compliance with the rules of integrity in scientific research set out in the 2008 *Principles and procedures* of the Swiss Academies of Arts and Sciences (SAAS)[60], which were made in the notes on Kaul and Wolf's first paper, also apply here.

[60] Reference 0c

19. JULY 2014 – IPE ISSUES A MEDIA RELEASE ANNOUNCING THE SECOND KAUL AND WOLF PAPER

On 1st July 2014, an IPE media release is published by Business Wire on their website[61], **in six languages** (English, French, German, Italian, Dutch, and Spanish). Business Wire is an American press release agency specialized in disseminating full-text releases "to news media, financial markets, disclosure systems, investors, information web sites, databases, bloggers, social networks and other audiences"[62]. The same media release is also published, at the same time, on the website of the UK edition of the Reuters news agency[63] and, the same day, on the website of IPE[64,65]. The release announces that research on smoking prevalence in Australia following plain packaging was published the previous day:

> *Yesterday, two researchers from the IPE Institute for Policy Evaluation Saarland & Department of Economics at Saarland University and from the Department of Economics at the University of Zurich have released a paper entitled "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis" which was commissioned by Philip Morris International.*
>
> *The experts conducted a statistical trend analysis of smoking prevalence among Australians aged 14+ between January 2001 and December 2013, with the objective of determining whether there was evidence for a plain packaging effect on smoking prevalence at any time during the 13 months from December 2012 through December 2013.*

[61] Reference IPE-1
[62] https://en.wikipedia.org/wiki/Business_Wire
[63] Reference IPE-2
[64] Reference IPE-3 (print of IPE "News" webpage)
[65] Reference IPE-4

The release quotes “Dr Ashok Kaul, the lead author of the report”:

> *Using standard analytic techniques that are easy for other researchers to replicate, we found no solid evidence for a plain packaging effect in any month. […]*
>
> *Based on our analysis, one could, at most, claim an effect on smoking prevalence among the total Australian population in December 2012 only, that is, an effect that lasted no more than one month. From January 2013 on, even very powerful statistical techniques no longer can pick up any change from the pre-existing trend.*

The release explains that “In conducting their analysis, the experts relied on data collected by and available for purchase from Roy Morgan Research, a well-known Australian research firm”.

The contact for the release is Kaul, in his capacity as Research Director of IPE.

Looking at the properties of the PDF document containing the media release published on IPE’s website, one sees that its author is “**Sparrow, Ryan**”[66]. Research on LinkedIn reveals that Ryan Sparrow is Head of Regulatory Communications (Global) at Philip Morris International in Lausanne[67]. He describes his experience at PMI as follows:

> - *Developed the global structure and led crisis communications.*
> - *Responsible for the development and implementation of international strategy in coordination with local teams to shape the public affairs environment on regulatory issues.*
> - *Advise on the development of opinion research strategies leading to the improved design, execution and tracking of global and market level government affairs and communications campaigns.*
> - *Build global capacity throughout the organization by utilizing a comprehensive campaign approach in coordination with legal, government affairs, policy and marketing.*

NOTES

One sees that the diffusion of the second paper by Kaul and Wolf is massive and international. There is a well-orchestrated effort to promote it immediately after its publication on the website of the University of Zürich, leaving no time for the scientific debate to take place, but

[66] Reference IPE-4a

[67] Reference IPE-4b

positioning it immediately in the on-going political debate and in litigation as a key piece of evidence of the ineffectiveness of plain packaging.

The authorship of the PDF of IPE's media release strongly suggests that it was written or edited by PMI. We will see later another example that reinforces this assumption. This would not be surprising when seen in the context of Annex 1 to the Contract between PMI and UZH.

20. JULY 2014 – PHILIP MORRIS'S OPEN LETTER TO MICHAEL MOORE

On 2nd of July 2014, PMI issues an "open letter"[68] to Michael Moore, the CEO of Public Health Association of Australia, in response to a press release[69] of PHAA of 18 June 2014 entitled "Big Tobacco's desperation reaches new heights". The press release quotes Moore:

> *If the tobacco industry has nothing to hide, why would it refuse to release reports on which it bases claims about trends in Australia and apparent efforts to reduce the impact of plain packaging with cheap, youth-friendly brands. […] The tobacco companies are clearly desperate to prevent its introduction in countries such as the UK, Ireland, New Zealand and France – all of whose governments have supported plain packaging. […] They are reduced to seeking publicity for reports making bizarre claims about trends in Australia which they refuse to release for independent analysis.*

In the open letter, PMI asks whether Moore was referring to "the analysis by renowned consulting firm London Economics", "the KPMG analysis of the Australian tobacco black market", ending this list of publicly available studies with the Kaul and Wolf working paper on minors:

> *Perhaps, […] you were referring to the analysis of adolescent smoking prevalence by experts from the Universities of Saarland and Zurich which 'failed to find any evidence for an actual plain packaging effect on minors'. Perhaps you missed that paper when it was published* ***in the prestigious University of Zurich Department of Economics Working Paper Series*** *[…]. Had you seen this publicly available report, you would know that* ***despite conducting multiple analyses of publicly available youth smoking prevalence data and structuring them in a way that was most likely to find that plain packaging reduced smoking, the experts could find no evidence of a plain packaging effect****.*

[68] Reference 23

[69] Reference 24

The study by consulting firm London Economics[70] (An analysis of smoking prevalence in Australia, Final, November 2013) was commissioned by Philip Morris International and the KPMG analysis[71] (Illicit Tobacco in Australia, 2013 Full Year Report, 3 April 2014) was prepared in accordance with "terms of reference agreed between British American Tobacco Australia, Philip Morris Limited and Imperial Tobacco Australia Limited, and KPMG". The KPMG report starts with an "important notice": "PMG LLP wishes all parties to be aware that KPMG LLP's work for the Addressees was performed to meet specific terms of reference agreed between the Addressees and KPMG LLP and that there were particular features determined for the purposes of the engagement. **The Report should not therefore be regarded as suitable to be used or relied on by any other person or for any other purpose**."

21. JULY 2014 – CRITIQUE OF KAUL AND WOLF'S FIRST PAPER PUBLISHED IN *TOBACCO CONTROL*

On 7 July 2014, Tobacco Control, a scientific journal belonging to the BMJ group, publishes an article[72] entitled "Tobacco industry-funded research on standardized packaging: there are none so blind as those who will not see!". Its authors are Pascal Diethelm ("Diethelm") of OxyRomandie, a Swiss tobacco control NGO, and Martin McKee ("McKee"), of the London School of Hygiene and Tropical Medicine.

The authors observe first that the Kaul and Wolf study on minors lacks statistical power to detect the level of change of prevalence that could be expected among minors following the introduction of plain packaging:

[70] Reference 25
[71] Reference 26
[72] Reference 27

The study looks at the "prevalence of smoking among Australians aged 14–17 years", taking monthly prevalence estimates from a marketing survey [...]. The purpose of standardised packaging is, as the authors acknowledge, to discourage smoking initiation and encourage quitting. Measures of prevalence cannot distinguish those who took up smoking after standardised packaging was introduced from those who took it up previously, with the former likely to comprise only between one-quarter and one-third of the age group.

The data used in the study show that the prevalence of smoking in Australia in the 14–17 years age group was 5.6% in 2012. The lack of power of the study is then apparent and has been documented by others. If it is assumed that the introduction of standardised packaging would have negligible effect on quitting rates in the 14–17 years age group, a reasonable assumption, as few adolescents readily stop smoking, as "they are dependent on nicotine, even before they become regular or daily smokers", and considering a scenario in which standardised packaging reduced smoking uptake by 10%, a result that would amply justify the measure, this would result in a decrease in prevalence of 0.2%, down to 5.4%. According to the power calculations included in their revised working paper, even using the generous 90% confidence level employed by the authors, the study would fail to reliably detect any decline in prevalence that was less than 1.0 percentage point. [...] In particular, it would be hardly more efficient than flipping a coin for the detection of the 0.2% decrease in prevalence mentioned above."

The authors also find that a "serious issue" with Kaul and Wolf's paper on minors is that "the arguments of the authors rely entirely on their assumption of linearity, which is unfounded." They independently computed the average annual observed prevalence over the entire observation period and established that the linearity assumption did not hold.

Diethelm and McKee then conclude:

> *Given these serious limitations, it might be expected that the authors would include some caveats. Yet they did not, enabling their tobacco industry sponsor to proclaim "researchers find no evidence plain packaging 'experiment' has cut smoking". Indeed, on the contrary, they insist that their analysis is very robust. In the conclusion, they argue that their approach, "if anything, is slightly biased in favour of finding a statistically significant (negative) effect of plain packaging on smoking prevalence of Australians aged 14 to 17 years". Moreover, they are quoted in the press release by Philip Morris International as saying "We used statistical methodology that gave every possible leeway for detecting a possible plain packaging effect. Nevertheless, the data does not support any evidence of an actual effect of the Australian Plain Packaging Act on smoking prevalence of minors".*
>
> *The headlines that this paper has generated have thus been highly misleading. However, they are entirely in keeping with the narrative being advanced by the tobacco industry and those who speak on its behalf.*

NOTE

It could be noted that, in this paper, Diethelm and McKee assume that the statistical power values presented by Kaul and Wolf are correct. As will be shown below, they are highly overestimated. It turns out that Kaul and Wolf's method is not better than flipping a coin for detecting a decrease of smoking prevalence of up to 1.25 percentage point (i.e. from 5.6% to 4.35%), which would be obtained if plain packaging had reduced smoking *uptake* by more than 50% among minors in Australia within its first year of implementation, a highly unrealistic assumption.

22. JULY 2014 – *THE LANCET* PUBLISHES KAUL AND WOLF'S RESPONSE

On 19th July 2014, The Lancet publishes Kaul and Wolf's response[73] to the letter by Laverty et al. that criticized their paper on minors. Kaul and Wolf use of the power results from their revised paper. They refute Laverty et al.'s claim "that a reduction of 1.25 percentage points 'would be required to be statistically significant using this analysis'" by arguing that their statistical analysis can detect the effect of small prevalence reductions, and even a 0.5 percentage point reduction is detectable with a power 0.65, which is "not unreasonably low." Kaul and Wolf add that "The data we have worked with are publicly available, and our analyses are described in detail and can be replicated."

[73] Reference 28

This was a strange statement, that seemed to be inconsistent with the footnote they had on the first page of their paper that said: "At no time did we provide Philip Morris International with access to the underlying data."

It will later be shown that the power values on which Kaul and Wolf rely are much higher than the true values and that the data they have worked with are not "publicly available", but "available for purchase from Roy Morgan Research", as is said in the media release of IPE.

23. JUNE 2014 – THE UK GOVERNMENT LAUNCHES A CONSULTATION ON STANDARDIZED PACKAGING

Following up on a first consultation on standardised packaging of tobacco products[74], which took place form 16 April 2012 to 12 August 2012, the UK Government publishes a second consultation on the introduction of regulations for plain packaging of tobacco products on 26 June 2014, with a closing date for submissions on 7 August 2014[75,76]. The four major tobacco multinationals submitted responses.

24. AUGUST 2014 – KAUL'S AND PHILIP MORRIS'S RESPONSE

On 5 August 2014, Kaul sends an email to the UK Department of Health to which is attached a copy of the second UZH paper[77]. This is presented as follows in Kaul's email:

[74] Reference 29a
[75] Reference 29
[76] https://tobaccotactics.org/wiki/plain-packaging-in-the-uk-second-consultation/
[77] Reference 29b

I would like to submit my attached paper entitled: "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis" for consideration in the ongoing UK consultation process on standardised packaging of tobacco products. The paper appeared In the University of Zurich Department of Economics Working Paper Series [ISSN 1664-7041 (print) ISSN 1664-705X (online)] as Working Paper No. 165.

The paper is co-authored with my colleague [REDACTED] from the University of Zurich who I copy in.

I also wanted to point your attention to our companion paper entitled: "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis". It appeared in the same Working Paper Serles as WP No.149. It was presented to the Chantler review team earlier this year. However, it was not referenced in the Chantler report.

Both papers were funded by Philip Morris International.

We would be grateful if our research would be taken into consideration in the consultation process in the UK.

In its response[78] to the UK consultation[79], sent two days later (7 August 2014), Philip Morris refers to the Kaul and Wolf studies in a section placed under heading "The Data Emerging from Australia". It is reproduced below *in extenso*:

[78] Reference 29c

[79] Reference 29

a) Youth smoking prevalence trend analysis

In March 2014, Professors Kaul and Wolf from the University of Zurich and the University of Saarland made public a study, funded by PMI, which analyzed whether there was evidence for a significant effect of "standardised packaging" on smoking prevalence among minors (Australians aged 14 to 17 years) during the 13 months from introduction of "standardised packaging" in December 2012 through December 2013. In conducting their analysis, the professors relied on data covering the time period from January 2001 to December 2013, based on a total sample size of 41,438 survey responses. The data were collected by Roy Morgan Research, an independent Australian research firm that regularly collects data on a range of consumer products. Public health experts and the Australian government regularly rely on Roy Morgan Research data. The professors' analysis did not find evidence of an actual 'standardised packaging' effect.

PMI submitted this study as part of a review into "standardised packaging" of tobacco products conducted by Cyril Chantler (the "Chantler Review"), and the two experts met personally with the Chantler Review team to discuss their work. Neither the Chantler Review nor the IA 2014 [Department of Health Impact Assessment conducted in 2014] so much as mentions the study.

b. Overall smoking prevalence trend analysis

A second study by Kaul and Wolf, made public in June 2014, analyzed whether "standardised packaging" had had any significant effect on smoking prevalence among Australians aged 14 and above. The total sample size over the entire period was around 700,000; the average annual sample size around 54,200 surveys.

In both studies, using standard techniques for statistical analysis and applying the standard statistical significance level of 5%, the experts found no evidence that "standardised packaging" had had an effect on smoking prevalence among Australians aged 14 to 17 years old (in the case of the March study) or Australians aged 14 and above (in the case of the June study). ***Kaul and Wolf confirmed that if there had been an effect in reality (including of the magnitude predicted by Pechey and the DH), it would have been reflected in the data. According to the study, however, no effect was found.***

NOTES

There is a subtle syllogism at play in PMI's last argument. The two premises are explicitly stated, and the conclusion is left to the reader to deduce. The major premise is a logical implication "If there had been an effect, the data would have shown it". The minor premise is "No effect was found in the data". The conclusion, which is left implicit, is "Therefore there was

no effect"[80]. This argument boils down to the allusion that Kaul and Wolf confirmed that plain packaging has no effect, without saying so.

It may also be noted that, in PMI's submission, Kaul is not presented as research director at IPE, a consulting firm, but as professor at the University of Saarland. This may be misleading as suggesting that the University of Saarland was involved in the project, which was not the case. On the website of the university, the one of the pages giving information about Kaul[81] shows under heading "**Consulting**" the project "The Effects on Smoking Behavior of the 2011 Plain Packaging Act for Tobacco Products in Australia: A Statistical Analysis" whose client is PMI.

25. AUGUST 2014 - BRITISH AMERICAN TOBACCO'S RESPONSE

British American Tobacco also mention the two papers by Kaul and Wolf in their response to the consultation[82] (dated 7 August 2014):

> *The Roy Morgan population survey data, which shows that there has been no change in the pre-existing trend in youth or adult smoking since the introduction of Plain Packaging. Analysis of this data by expert economists:*
>
> *[•] failed to find any evidence for an actual effect of Plain Packaging on Australians aged 14 to 17 years; and*
>
> *[•] failed to find any sustained impact of Plain Packaging on existing smoking prevalence trends generally.*

The first bullet point refers to Kaul and Wolf's first paper (on minors), and the second to their second paper (on Australians aged 14+).

Attachment 1 to BAT's response is the "Gibson report"[83], prepared by consulting firm SLG Economics Ltd and commissioned by BAT through a thirds party (Herbert Smith Freehills LLP). The report contains a section dealing with the analysis of Roy Morgan Research data for 14-17 year olds, in which the author presents his own results, which do not show "any statistically significant

[80] If we designate the statement "There was an effect" by A and the statement "An effect was shown in the data" by B, the major premise is "A implies B", the minor premise is "not A" and the conclusion is, logically, "not A", which results from the equivalence between "A implies B" and "not B implies not A".

[81] Reference 30

[82] Reference 31

[83] Reference 32

impact of the introduction of plain packaging on reported tobacco usage". Then a reference is made of the Kaul and Wolf's first paper:

> *This data was also reviewed by Kaul and Wolf in a University of Zurich working paper who found the same result - that there is no statistically significant evidence of an effect of plain packaging on tobacco consumption.* ***Kaul and Wolf also considered various variations to their analysis and showed that these would reinforce their conclusion that plain packaging has had no impact on smoking by 14-17 year olds****.*

26. AUGUST 2014 - IMPERIAL TOBACCO'S RESPONSE

In their response to the UK consultation[84] (date 7 August 2014), Imperial Tobacco mention only the Kaul and Wolf study on minors. They emphasize that this study was not included in the Chantler Review:

> *Remarkably, the only piece of published real-world data about underage smoking rates in Australia that was available to the Review was not even mentioned in the Report. This was despite its authors visiting the review team in London to talk through their findings.* ***The study by statisticians Dr Ashok Kaul and Dr Michael Wolf strongly suggested that there had been no increase in the rate of decline of smoking prevalence amongst 14-17 year olds*** *between December 2012 (when the legislation came into force) and December 2013 (when the most recent data ended).*

Imperial Tobacco then quote the interview with Kaul that Snowdon published on his blog in April (see 14, above) and conclude that the "decision by the Chantler Review not to mention **the only real world figures** on smoking prevalence available at the time is inexplicable."

27. AUGUST 2014 - JTI'S RESPONSE

In its response to the UK consultation[85] (dated 6 August 2014), JTI summarize the state of knowledge about the effect of the introduction of plain packaging in Australia: "No evidence of any positive impact". They then explain:

[84] Reference 33
[85] Reference 34

After 18 months, the evidence actually emerging from Australia reinforces the fact that plain packaging does not work:

- *studies by the Universities of Zurich and Saarland have found that plain packaging has had **no effect on smoking prevalence**, either among minors or adults; [...] (bold in the original)*

JTI also criticize the Chantler Report, which "wrongly dismisses [...] a number of studies / important data / expert analysis 'pointing the other way' often with no or very limited explanation, including for example:"

[...] the Universities of Zurich and Saarland studies, which undertake a statistical trend analysis to examine the possible effect of plain packaging on smoking prevalence of minors and adults in Australia. The studies related to data from pre and post the introduction of plain packaging in Australia, and found that plain packaging had no effect on smoking prevalence, either among minors or adults. Professors Wolf and Kaul met with one of the members of the Chantler Review Team to discuss the results of their study in relation to minors (as their study in respect of adults was not published at the time), but no reference to this study or their meeting is included in the Chantler Report; [...]

NOTES

The four responses (from PMI, BAT, Imperial and JTI) all present the results of the Kaul and Wolf studies as evidence of the ineffectiveness of plain packaging in a rather assertive way:

PMI	"Kaul and Wolf confirmed that if there had been an effect in reality (including of the magnitude predicted by Pechey and the DH), it would have been reflected in the data. According to the study, however, no effect was found." Note: These are the two premises of a phantom syllogism whose conclusion is "Thus, there was no effect" - it deceives the reader into concluding "there was no effect", without explicitly stating it.
BAT	"The Roy Morgan population survey data [...] **shows** that there has been no change in the pre-existing trend in youth or adult smoking since the introduction of Plain Packaging."
Imperial	"The study by statisticians Dr Ashok Kaul and Dr Michael Wolf **strongly suggested** that there had been no increase in the rate of decline of smoking prevalence amongst 14-17 year olds."
JTI	"The studies related to data from pre and post the introduction of plain packaging in Australia, and found that plain packaging **had no effect** on smoking prevalence, either among minors or adults."

We are not aware of any public reaction of Kaul and Wolf against this presentation of their results. This is to be contrasted with their reaction to the NHS news item of 26 March 2014 (see 6. and 7.), in which they said: "we took care to point out that we 'fail to find any evidence for an actual plain packaging effect', which is not the same as claiming we find evidence for no plain packaging effect. In other words, the absence of evidence for an effect should not be misconstrued as evidence for no effect."

The Contract between UZH and PMI (see 2.) stipulates that "Neither Party nor its Personnel shall, without the prior express written approval of the other Party, [...] use the others Party's name or that of any of its Personnel name or any trade name, trademark or service mark or brand imagery belonging to that Party and/or its Affiliates in any press release, any form of advertising, or any of its business communications (internal or external) except those necessary to provide the Services." Accordingly, PMI must have obtained the "express written approval" of UZH to use its name and that of Kaul and Wolf in its response to the UK consultation.

28. AUGUST 2014 – THE IEA PUBLISHES A BRIEFING DOCUMENT ON PLAIN PACKAGING

The Institute of Economic Affairs, a free-market think tank (see 13.), publishes it "Briefing 14:02"[86] entitled "Plain packaging – Questions that need answering", whose author is Christopher Snowdon. The briefing document presents the arguments against plain packaging, related to smoking prevalence, illicit trade, intellectual property rights, impact on retailers, etc. The Kaul and Wolf studies are mentioned in the section "Evidence: smoking prevalence":

> *Two studies by Dr Ashok Kaul and Dr Michael Wolf have confirmed that there was no impact from plain packaging on the longterm trend in smoking prevalence. These statisticians met Sir Cyril Chantler's team but their evidence was not included in the Chantler Review—a significant oversight.*

29. OCTOBER 2014 – *BEOBACHTER*: "ZURICH PROFESSOR CONDUCTS RESEARCH FOR BIG TOBACCO"

On 28 October 2014, the German-language Swiss magazine Beobachter (Observer) publishes an article on its website with the following title: "Zurich professor conduct research for Big Tobacco" ("Zürcher Professor forscht für Big Tobacco")[87].

[86] Reference 35

[87] Reference 36

Michael Wolf and his colleague Ashok Kau1 have been keeping the big cigarette manufacturers in a good mood for a few months now. The two professors from the University of Zurich (Wolf) and the University of the Saarland (Kaul) have been studying the effects of so-called 'plain packaging'. This radical measure was introduced by the Australian government in 2012 primarily to protect young people. [...]

The two researchers concluded from their research that there was no evidence that plain packaging had any influence on the smoking behaviour of 14- to 17-year-old Australians. Wolf and Kaul published the results of their study as a working paper at the University of Zurich in spring 2014.

What is piquant about Wolf and Kaul's publication is that it was paid for by the tobacco multinational Philip Morris International. Wolf and Kaul point this out and emphasize that they "did not provide Philip Morris International with access to the underlying data" at any time. Wolf also stresses to Beobachter that he and Kaul used "objective scientific methods to analyze the data".

The article summarizes the reaction from the University of Zurich:

The University of Zurich sees no problem in the fact that one of its faculty members is conducting research on behalf of the tobacco industry: "The working paper complies with university guidelines", writes the university's media office in response to an inquiry from Beobachter. Media spokeswoman Nathalie Huber also emphasizes that Philip Morris "did not influence the content of the working paper in any way" - a statement that cannot be found in the paper itself.

The University invoked a "confidentiality agreement" to deny the journalist access to its contract with PMI:

As problem-free as Wolf's research work is for Philip Morris, according to the media office, the University of Zurich does not want to disclose the contract between the scientist and the tobacco multinational. ***A "confidentiality agreement" precludes publication of the contract****.*

30. DECEMBER 2014 – "TOBACCO MULTINATIONAL MAY 'REVIEW' EXPLOSIVE STUDY"

On 24 December 2014, Beobachter (Observer) publishes in its magazine an article with the following title: "Uni Zurich: Tobacco multinational may 'review' explosive study" ("Uni Zürich: Tabakmulti darf brisante Studie «überprüfen»"), whose author is Thomas Angeli[88]. The article summarizes the situation in the first two paragraphs:

> *Nothing was left to chance: the "Service Agreement" concluded by the University of Zurich with Philip Morris in July 2013 is 17 pages long. In it, the Faculty of Business and Economics and Philip Morris International Management AG (PMI) set out the conditions for a study on so-called plain packaging in Australia (Beobachter No. 22): What are the implications of an Australian law that allows cigarettes to be sold only in neutral packages with warnings and dissuasive images? The Zurich statistics professor Michael Wolf and his colleague Ashok Kaul from Saarland University were asked to investigate this.*
>
> *Wolf and Kaul were soon able to present their results - and since then they have been quoted often and with pleasure by the tobacco industry when it comes to averting government intervention in cigarette sales anywhere in the world. No wonder, because their findings are grist to the tobacco lobby's mill: they declare that there is no evidence whatsoever that neutral packs have any influence on the smoking behavior of 14- to 17-year-old Australians.*

Under sub-heading "Restricting buyers' freedom of choice", Angeli explains that he obtained a copy of the contract and "parts of the project description" and summarizes their key parts:

> *At the request of Beobachter, the university management has now released the contract and parts of the project description - and they are quite something. The two researchers already indicate in the project description that they are just as critical of the Australian law as the tobacco multinational itself. The measure causes "very high costs for the cigarette industry and consumers", they write. The law is "a serious restriction of intellectual property rights" and "drastically limits consumers' freedom of choice".*

[88] Reference 37

In the contract, the world's largest tobacco company agreed to the right to consult the study "for review and comment" 30 days before publication. In doing so, the university undertakes to "take said comments into account in good faith". In other words, the cigarette multinational assumed the right to check the study results before publication - and the University of Zurich allowed it.

Angeli asked the opinion of Professor Markus Müller, the co-initiator of the "Zurich Appeal for the Preservation of Scientific Independence". Here is his reaction, quoted in the article:

"A violation of the freedom of research", outraged the Bernese professor of constitutional law Markus Müller. [...] "With such formulations, funders influence research."

The journalist reports that **Professor Wolf explained that the tobacco company only corrected "typographical errors and linguistic trifles (which are immaterial in terms of content)."** For its part**, PMI has added that it "at no time influenced the research results or raised objections to them or restricted publication"**.

Angeli observes that "However, PMI also played it safe when it came to media contacts: if journalists approach the researchers, they are contractually obligated to inform Philip Morris so that the company can 'coordinate' the information."

Finally, the journalist points out some incoherence among the parties ("the parties involved disagree") concerning the provenance of the data.

Wolf and Kaul correctly state in their "Working Paper" that the study was financed by PMI and explain that they did not grant PMI access to the underlying data "at any time". This was not even necessary - some of the data came from PMI itself. A corresponding reference only appeared in a revised version of the study.

On his blog (angelisansichten.ch), Angeli provides further information in an article posted on 27 December 2014 under the title "University of Zurich allows 'review' of a study by Philip Morris" ("Universität Zürich lässt «Review» einer Studie durch Philip Morris zu")[89]. He indicates that he "was able to inspect (**but not copy**!) the contract between the University of Zurich and PMI".

As the Contract between UZH and PMI "raises the question of research freedom and whether [its] provisions are compatible with it", Angeli asked German political psychologist Thomas Kliche of the University of Magdeburg-Stendal, and received the following answer:

> *Corruption in science works mostly informally, through anticipation of expectations. The scientists, who are smart people, research institutes and university managements know what the clients expect, even if this is not explicitly stated in the contract. […] The real key point is not the threat of a whip, i.e., the contract, but the carrot: funding from tobacco death vendors. It has been shown that they have systematically infiltrated research worldwide for decades and have financed and covertly funded misleading studies that deflected attention from lung cancer. So, the problem is that here the funds are obviously not awarded by ethically driven people, and the recipients know this.*

31. DECEMBER 2014 – THE *NEUE ZÜRCHER ZEITUNG* PUBLISHES AN INTERVIEW OF WOLF

On 27 December 2014, the Neue Zürcher Zeitung (also know as NZZ) publishes an interview of Professor Michael Wolf, under the heading "Philip Morris did not influence the content" («Philip Morris hat keinen Einfluss auf die Inhalte genommen»)[90]. The article starts with the following introduction: "The accusations are serious. The tobacco company Philip Morris International AG (PMI) pays for a study by the University of Zurich and is contractually guaranteed a say." We reproduce below key extracts from Wolf's interview by the NZZ:

[89] Reference 38
[90] Reference 39

Mr. Wolf, the accusations against you and your colleague Ashok Kaul are serious.

I do not see it that way. In a response letter, we refuted the criticism in "The Lancet" that the result was neither unexpected nor meaningful on the basis of the data analyzed. The data did not come from Philip Morris. They were obtained from a leading market research institute in Australia, Roy Morgan Research. Prevention researchers also use it. PMI only paid for the purchase of the data, but ***never had access to it****.*

As the saying goes, "Don't bite the hand that feeds you!" Don't funders like PMI influence research with such "service agreements" and violate research freedom?

Doesn't this argument apply to all contract research, i.e. also to that of anti-tobacco organizations? More research can be done through such third-party funding. The important thing is that scientific freedom is guaranteed. And it was in our case! ***We were not restricted in our independence in any way during our research****. We work with standard methods and a recognized data set. [...]*

However, they could also obtain third-party funding from companies that are not directly affected by the research.

This is rather rarely the case in practice, regardless of the industry. In my opinion, there is nothing to be said against obtaining third-party funding from companies that are directly affected by the research, ***as long as both transparency of funding and independence of research are guaranteed****.*

How have you ensured that your freedom of research remains granted?

Restrictions on research freedom are, in our opinion, not compatible with the university's third-party funding guidelines. However, the contract with PMI was in line with these guidelines. Frankly, we saw no reason for further safeguards. Philip Morris was clear from the beginning that we would not be interfered with in our work. And that was never a problem.

Philip Morris is contractually guaranteed a say in a "service agreement". In this way, the Group does influence the content.

Philip Morris did not influence the content. In my experience, it is quite common for the client, whether public or private, to receive a study draft for review.

[...]

Doesn't that put your reputation as a scientist at risk?

No, as long as there is transparency with the client, the methodology and the data, as in this case, I see no problem. In principle, I will continue to do studies on behalf of corporations.

NOTES

Many of the statements made by Professor Wolf in his interview by the NZZ are either factually incorrect or in contradiction with Annex 1 to the Contract between PMI and UZH, i.e. the Project Proposal jointly submitted by the University of Zurich and IPE to Philip Morris on May 22, 2013, which he co-signed.

In his answer to the journalist's first question, Professor Wolf claims that Kaul and he have refuted the criticism in The Lancet, which contended that the result of their first paper "was neither unexpected nor meaningful". They have not. Their rebuttal of this criticism contained an error that invalidated their point[91]. The results of their first paper are, at best, unconclusive, as The Lancet correctly pointed out.

The journalist's asked whether "funders like PMI influence research [...] and violate research freedom?" In his answer, Professor Wolf uses the classical "whataboutism" argument, suggesting that "anti-tobacco organizations" may also be influenced by their funders. He then asserts that "scientific freedom" was "guaranteed" in their case, and that "they were not restricted in our independence in any way during our research".

In fact, the proposal did the opposite of guaranteeing "scientific freedom": it severely curtailed the independence of the two professors by placing their research under the control of Philip Morris. The tobacco company was contractually allowed to supervise the research work during the four phases of the project. Philip Morris reserved the right to decide at the end of each phase what will be done in the next phase and could decide at the end whether to publish an external report and in what form. The Project Proposal indicates that such supervision was achieved by "regular meetings of PMI team members and [IPE and UZH's] team members, regular conference calls, and frequent email communication", which were "inevitable for reaching our project goals", and by Kaul and Wolf's producing reports "for PMI internal use only" at the end of each phase.

In response to the third question, which deals with the notion of conflict of interest, Wolf says that he sees nothing wrong with conflict of interest "as long as both transparency of funding and independence of research are guaranteed". However, here we have a case of conflict of interest where transparency and independence are both lacking. The University of Zurich was still invoking the confidentiality agreement contained in the Contract to refuse its access to journalist Angeli of Beobachter. As we have just seen, the Project Proposal reveals the high degree of dependence, **even subservience**, that the two professors accepted from PMI by placing their research under the control of the tobacco multinational.

There is also a lack of transparency in the Contract between UZH and PMI: the participation of German consulting firm IPE, in which both Kaul and Wolf have a vested interest, is not mentioned. The contract is silent on the fact that this will be a collaborative project between the UZH and IPE, in which IPE will have the main stake. As will be seen later, IPE (and Kaul and

[91] Reference 102

Wolf as members of IPE) played a considerable role in the WTO dispute against Australia, in which four countries (Cuba, Dominican Republic, Honduras, and Indonesia) claimed that the introduction of plain packaging in Australia was in breach of WTO agreements. Kaul and Wolf were the key experts of the Dominican Republic.

The introduction of the *Principles and procedures* on Integrity in scientific research[92], the Swiss Academies of Arts and Sciences (SAAS) starts with the following statement:

> *Integrity is a positive asset in our personal life and in society in general. Scientific behaviour of integrity is therefore of prime importance in all research activity. We understand scientific integrity as the commitment of researchers to adhere to the basic rules of good scientific practice. Honesty and sincerity, self-discipline, self-criticism and fairness are indispensable for behaviour of integrity. They form the basis for all scientific activity and are prerequisites for the credibility and acceptance of science.*

Given the project proposal he submitted to PMI with his co-author, which outlined the nature of the collaboration between UZH and the tobacco manufacturer, Wolf's statement to the NZZ seems at odds with the basic principles of SAAS. It is apparent that in this collaboration the "requirements for the credibility and acceptance of science" were not met.

32. JANUARY 2015 – OXYROMANDIE ASKS FOR THE RETRACTION OF KAUL AND WOLF'S PAPERS

On 29 January 2015, Pascal Diethelm, the president of OxyRomandie, sends an email to Professor Michael Hengartner, the rector of the University of Zurich[93], with two attachments: a letter addressed to him and an annex to the letter[94].

In the letter, Diethelm, on behalf of OxyRomandie, asks that UZH retract Kaul and Wolf's two working papers, explaining why as follows:

[92] Reference 0c
[93] Reference 40
[94] Reference 41

You will see in the Annex the list of errors which we have identified with these two papers. They are extremely serious. Taken individually, most of them are sufficient to invalidate the findings of the papers. Collectively, they are damning. We also document in the Annex some serious issues which throw further doubt about the credibility and integrity of the science involved in their preparation.

The publication of these two papers, which were funded and supervised by tobacco multinational Philip Morris, occurs at a critical time when a number of countries are considering the adoption of plain packaging, a smoking prevention measure recommended by the WHO Framework Convention on Tobacco Control1. A few days ago, the UK Government announced that it would proceed with plain packaging legislation and a vote will be taken in the UK parliament before May of this year.

The tobacco multinationals present these two papers as key pieces of scientific evidence that plain packaging is not effective, in their effort to counter the public health policy of these countries. They take advantage of the authority conferred to these papers by the fact that they are published by the University of Zürich. For instance, in its response to the UK Department of Health's consultation on the introduction of regulations for standardised packaging of tobacco products, Japan Tobacco International refers to these studies as "studies by the Universities of Zürich and Saarland."

As long as the two papers remains on the website of the University of Zürich, the tobacco multinationals will continue to argue that these papers receive the endorsement of your academic institution.

We do not ask that these papers be retracted because we do not like their conclusions. We ask the University of Zürich to retract them because they are erroneous beyond repair and because, dealing with an important subject in public health, they interfere with the public health policy of other countries, with consequences that could affect the health of millions of people. We are simply asking the University to assume its responsibility in this matter.

Diethelm observes that while errors are always possible, the errors found by OxyRomandie "are not randomly distributed but they all go in the same direction, towards reinforcing the conclusion of a lack of evidence, i.e. they all play in favour of the commercial interest of the financial sponsor."

The Annex contains a detailed description of 7 "errors" and 7 "issues" OxyRomandie found in the workings papers:

"Errors":

- "Erroneous and misleading reporting of study results"
- "Power is obtained by sacrificing significance"
- "Inadequate model for calculating power which introduces a bias towards exceedingly large power values"
- "Ignorance of the fact that disjunctive grouping of two tests results in a significance level higher than the significance level of the individual tests"
- "Failure to take into account the difference between pointwise and uniform confidence intervals"
- "Invalid significance level due to confusion about one-tail vs. two-tail test"
- "Invalid assumption of long term linearity"

"Issues":

- "Avoiding evidence by post-hoc change to the method"
- "Unnecessary technicality of the method, hiding the methodological flaws of the papers"
- "Very ineffective and crude analytic method"
- "Non standard, ad-hoc method"
- "Contradiction and lack of transparency about the way data was obtained"
- "Conflict of interest not fully declared"
- "Lack of peer review"

Diethelm concludes the letter with the following appeal:

> *We think that the above raises the fundamental question of the integrity of science. The University of Zürich should not let the tobacco industry corrupt science and should protect itself against those who want to take advantage of its influence and reputation, not hesitating to put science at the service of money and not heeding the mission entrusted to this public institution, a mission which consists in particular in disseminating a culture founded on scientific knowledge and raising public awareness of the responsibilities that teachers assume towards society.*

In an email sent on 30 January 2015[95], Professor Hengartner acknowledges the receipt of Diethelm's message and said that he will get back to him "once we had the opportunity to have a detailed read and analysis of the critique presented in Annex 1."

[95] Reference 42

NOTES

It should be noted that when Diethelm sends this letter and its annex to the rector of the UZH, he is not aware of the Project Proposal submitted in May 2013 by Kaul and Wolf to Philip Morris. He has also not seen the contract between the university and PMI: He only knows of its existence from Angeli's article in the Beobachter and on his blog. He does not know the debates that took place in the WTO panels that examined the complaints against Australia by four countries (Cuba, Dominican Republic, Honduras and Indonesia) for having introduced plain packaging of tobacco products. In these debates, it was revealed that Kaul and Wolf's research on plain packaging suffered from serious flaws that even go beyond Diethelm's criticism.

The concluding paragraph of Diethelm's letter reproduces a translation of the statement made by the High Court of Justice of Geneva in December 2003 in its final judgment on the so-called "Rylander affair"[96]:

> *"Genève a bien été la plate-forme d'une fraude scientifique sans précédent dans la mesure où Ragnar Rylander a agi en sa qualité de professeur associé de l'Université, profitant de son rayonnement et n'hésitant pas à mettre la science au service de l'argent, au mépris de la mission confiée à cet établissement de droit public qui consiste en particulier à diffuser une culture fondée sur les connaissances scientifiques et à faire prendre conscience de la responsabilité que les enseignants assument envers la société."*
>
> *("Geneva was indeed the platform for an unprecedented scientific fraud, insofar as Ragnar Rylander acted in his capacity as an associate professor at the University, taking advantage of its influence and reputation, not hesitating to put science at the service of money, not heeding the mission entrusted to this public-law institution, a mission which consists is in particular in disseminating a culture founded on scientific knowledge and raising public awareness of the responsibilities that teachers assume towards society.")*

Finally, it could be noted that in his email of 30 January, professor Hengartner refers to "Annex 1". There is no "Annex 1" attached to OxyRomandie's letter, but simply an "Annex". "Annex 1" is the document attached to the contract between UZH and PMI.

33. FEBRUARY 2015 – ARTICLE BY LAVERTY ET AL. "USE AND ABUSE OF STATISTICS"

On 2 February 2015, a paper entitled "Use and abuse of statistics in tobacco industry-funded research on standardised packaging"[97] is published on the website of Tobacco Control, a

[96] Reference 42a
[97] Reference 43

specialized scientific journal of the BMJ Group. The lead author Dr Anthony Laverty, and another author (Hilary Watt) are from the Department of Primary Care & Public Health, Imperial College London. The other authors are from the NIHR Respiratory Biomedical Research Unit at Royal Brompton and Harefield NHS Foundation Trust and Imperial College, London (Nicholas Hopkinson), the London School of Hygiene and Tropical Medicine (Martin McKee), and OxyRomandie (Pascal Diethelm).

The authors of the paper indicate that two "core issues" with Kaul and Wolf's working papers on plain packaging in Australia need to be considered: "The first is that the introduction of standardised packaging is not expected to have a sudden impact on smoking prevalence, but rather to impact on the rate of smoking uptake. The second is that both papers are not in fact powered to detect any plausible impact."

The "sudden-effect" model adopted by Kaul and Wolf in the Monte-Carlo simulations they use to compute the power of their statistical method is found "implausible": first, "[a] sudden decline in smoking prevalence was not envisaged in [the Australian] legislation, with any effect expected to be predominantly around initiation of smoking rather than rates of quitting." Furthermore, the authors explain that "The nature of addiction is such that any impact on quitting is likely to take place over several years and a small increase in the rate of decline may be more realistic than an immediate dramatic fall in prevalence." When a gradual effect model is used in the Monte Carlo simulation, the resulting power values are much lower and show that Kaul and Wolf's two papers did not have sufficient power to be conclusive.

Laverty et al. also raised the issue of the ad-hoc nature of the approach used by Kaul and Wolf, illustrating it with the following example:

> *For the second paper on adults, the authors also amended the overall definition of significance used to calculate power (ie, they remove December 2012 from their analysis, which avoids overall significance favouring standardised packaging (by the definition that they use to calculate power, based on significance on any one of several tests). Such amendments raise additional concerns about the ad hoc nature of the approach used in these working papers.*

In their (first) paper on minors, Kaul and Wolf defined the plain packaging period (PP-period) as extending from December 2012 to December 2013. This was a logical choice: After a 3-month transition period, plain packaging entered in full effect on 1st December 2012 in Australia and the survey data used in the analysis was available up to 31 December 2013. Using the same 13-month period in their study on adults, their approach indicates a plain packaging effect. By shortening the PP-period to January-December 2013, the plain packaging effect disappears.

Laverty and al. describe how the tobacco industry is making use of Kaul and Wolf's working papers:

> *Both of these working papers have been heavily publicised by the tobacco industry, continuing a tradition of misrepresenting evidence. The publication of the adult paper on the website of the University of Zürich was accompanied by a media release issued by the Institute for Policy Evaluation, which had been commissioned by Philip Morris International to carry out the study. This claimed that "The experts found no evidence for a standardized packaging effect on smoking prevalence using standard techniques for statistical analysis, in particular requiring a statistical significance level of 5%, which is the standard in applied research." Several major tobacco companies have additionally referred to these papers in their response to the UK consultation on standardised packaging, for example, Philip Morris Limited submitted that:*
>
> > *"In both studies, using standard techniques for statistical analysis and applying the standard statistical significance level of 5%, the experts found no evidence that 'standardised packaging' had had an effect on smoking prevalence among Australians aged 14 to 17 years old (in the case of the March study) or Australians aged 14 and above (in the case of the June study). Kaul and Wolf confirmed that if there had been an effect in reality [...] it would have been reflected in the data. According to the study, however, no effect was found."*

Laverty et al. conclude that "There is a continuing need to guard against such misrepresentations of the evidence as other countries look to Australia to inform their own policies of standardised packaging. "

34. FEBRUARY 2015 – *LE COURRIER* (GENEVA NEWSPAPER): "STRONG SUSPICION OF FRAUD"

On 13 February 2015, the Geneva-based newspaper Le Courrier publishes an article by Laura Drompt under the title "Strong suspicion of fraud" within quotes[98]. Below are key excerpts from it:

[98] Reference 44

Has the University of Zurich let itself be fooled? In a letter sent on January 29, the anti-smoking association OxyRomandie urged the university to retract two studies funded by Philip Morris International. The university affirmed to take the accusations seriously and confirmed to Le Courrier yesterday that an external expert has been commissioned to look into the papers and OxyRomandie's criticism.

The studies by Professors Michael Wolf (University of Zurich) and Ashok Kaul (Saarland University, Germany) aimed to assess the impact of plain cigarette packaging ("plain packaging") imposed in Australia since 2012. Based on data provided in part thanks to funding from Philip Morris International, the studies concluded that unbranded packs have had no impact on smoking prevalence in Australia, the first country to impose such a measure.

[...]

For Pascal Diethelm, President of OxyRomandie, these two studies come at the worst possible time, as they are now being used by the tobacco lobbies to prevent other countries from adopting the concept of plain packaging. In Great Britain, for example, where Parliament is due to decide on the issue in May.

But these papers are not just ill-timed: they are also tainted by errors and omissions, already identified in scientific articles. The latest was published in the journal "Tobacco Control", from the British Medical Journal group. Co-authored by Pascal Diethelm and several specialists in public health and respiratory research, it notes that the statistical model chosen is not optimal. "These two studies have been widely diffused by the tobacco industry, perpetuating a tradition of evidence misrepresentation", the article insists.

[...]

The authors' dispute

Criticism had already surfaced last December, when a journalist from the "Beobachter" revealed certain clauses binding the two scientists concerned and Philip Morris International. The company had the right to check and comment on the study before publication, and the researchers were obliged to declare any contacts made by the media. In response to the newspaper's criticism, Michael Wolf, interviewed by the "Neue Zürcher Zeitung", replied: "It's important that scientific freedom is guaranteed. And we do!" The scientist further affirmed that he had "in no way been restricted in the course of the research" and had worked "with standard methods and a recognized data register".

[cont'd]

External expertise

Contacted by telephone yesterday, Michael Hengartner, Rector of the University of Zurich, said he "takes the situation very seriously, in view of the severe accusations made". "I have made contact with Professor Wolf, a renowned and respected statistician, who takes responsibility for his work. He affirms that his paper is absolutely correct and follows the usual rules. To clarify the situation, we have decided to commission an external expert to analyze these criticisms in detail. If any serious technical faults or ethical problems were to be found, we would of course have a duty to correct them."

The same article was published the next day (14 February 2015) by two French-speaking newspapers, Le Nouvelliste[99] (Valais) and L'Express[100] (Neuchâtel).

35. FEBRUARY 2015 – *THE GUARDIAN*: "ROW OVER MARLBORO-FUNDED RESEARCH"

On 14 February 2015, the British newspaper The Guardian publishes an article by Jamie Doward entitled: "Row over Marlboro-funded research that undermined plain cigarette packs"[101]:

A bitter academic row has triggered calls for a leading university to withdraw two key scientific papers sponsored by "big tobacco" and used to make the case against the introduction of selling cigarettes in plain packets.

The papers, published by the University of Zurich, analysed the impact of plain packets in Australia. Their findings were widely disseminated in the media and used by the tobacco lobby to make the case that the health initiative had no discernible effect on smoking rates among the young in Australia, and therefore should not be introduced in the UK.

But now a group of academics has written to the university calling for the papers, funded and supervised by Philip Morris International (PMI), which makes Marlboro cigarettes, to be withdrawn.

[99] Reference 44a
[100] Reference 44b
[101] Reference 45

In his letter to Dr Michael Hengartner, the university's rector, Pascal Diethelm, president of OxyRomandie, a Swiss anti-smoking organisation, lists seven errors that he and his team say they have identified. "They are extremely serious," Diethelm says. "Taken individually, most of them are sufficient to invalidate the findings of the papers. Collectively, they are damning."

The two papers were written by Ashok Kaul and Michael Wolf, who have robustly defended their work, which was cited as key evidence by tobacco manufacturers in submissions to the Department of Health's consultation on plain packaging.

On the back of their findings, PMI issued a press release stating: "The plain packaging experiment in Australia has not deterred young smokers, professors from the department of economics at Zurich University and the University of Saarland found in a report released today."

However, Diethelm claims the errors go towards "reinforcing the conclusion of a lack of evidence, ie, they all play in favour of the commercial interest of the financial sponsor".

The row has been taken up by others. A group of doctors recently declared on the BMJ website that "both of these papers are flawed in conception as well as design, but have none the less been widely publicised as cautionary tales". Diethelm's letter calls on the university to take the papers down from its website. "We ask the University of Zurich to retract them because they are erroneous beyond repair and because ... they interfere with the public health policy of other countries..."

In both papers, which were not peer-reviewed, Kaul and Wolf acknowledge that PMI provided funding. However, they do not reveal that the company demanded sight of the study before publication and the right to put forward suggestions.

Dr Nicholas Hopkinson, senior lecturer in respiratory medicine at Imperial College London – who criticised the papers on the BMJ website – described Zurich University's collaboration with PMI as a "stain" on its reputation.

In a response to the criticisms, which they describe as "spurious" and "defamatory", the two authors said: "As the authors of the working papers – committed to an open, free and objective scientific debate – we will not withdraw them from public scrutiny."

36. FEBRUARY 2015 – KAUL AND WOLF'S REPLY TO OXYROMANDIE CRITIQUE

In a mail sent on 14 February 2015 to Diethelm[102], Professor Hengartner makes the following announcement:

> *The university executive board has requested Professor Wolf to answer the critique that you submitted in your letter. Prof. Wolf has provided us with his answers earlier this week. I am attaching Professor Wolf's reply to this mail. Professor Wolf mentioned to me that his reply has also been published on his collaborator's web site: http://www.ipe-saarland.de/deutsch/news/*
>
> *We now will request an external statistics expert to look over the working papers, your critique, and Professor Wolf's reply. We are confident that we can get the expert's feedback in a timely manner.*

The email contains a copy of the "Public reply to the letter with subject 'Request for retraction of two papers published on UZH website' by Pascal A. Diethelm" dated 11 February 2015 on the letterhead of the University of Zurich[103] and a copy of the "Reply to the ANNEX 'Errors and issues with Kaul and Wolf's two working papers on tobacco plain packaging in Australia'" also dated 11 February 2015[104]. Both documents are jointly signed by Kaul (with two affiliations: Institute for Policy Evaluation (IPE) Saarland and Department of Economics, Saarland University) and Wolf (with one affiliation: Department of Economics, University of Zurich).

The UZH appears to be opting for a narrow approach to the problem raised by OxySuisse by reducing it to a technical matter that could be settled by an "external statistics expert" who would "look over the working papers, your critique, and Professor Wolf's reply". No mention is made of scientific integrity or of ethical and deontological considerations.

Key points of Kaul and Wolf's "public reply" to Diethelm's letter of 29 January 2015 are shown in the following quotes:

[102] Reference 46
[103] Reference 47
[104] Reference 48

The letter by Mr. Diethelm, President of OxyRomandie, to the Rector of the University of Zurich makes grave allegations against us and two working papers that we wrote on the effects of plain packaging in Australia. [...] It is alleged that the two papers are "erroneous beyond repair" and that the errors "all go in the same direction, towards reinforcing the conclusion of a lack of evidence [that plain packaging is effective]". Mr. Diethelm concludes that "one can presume the existence of a bias". He labels our science as "corrupt" and claims that we "put science at the service of money". Mr. Diethelm calls for the withdrawal of the papers because they "interfere" with the public health debate on the effectiveness of plain packaging.

Notes

Kaul and Wolf misrepresent what Diethelm says in his letter to the rector of UZH. He does not refer to Kaul and Wolf, but to the tobacco industry, when he says that "The University of Zürich should not let the tobacco industry corrupt science and should protect itself against those who want to take advantage of its influence and reputation, not hesitating to put science at the service of money." He does not say that the two working papers were interfering with the "public health debate": he says that the two papers, as they are presented by tobacco multinationales, are used to "interfere with the *public health policy* of other countries". Of course, as the Project Proposal shows, Kaul and Wolf served the interests of Philip Morris from the very beginning, and understandably, criticism directed against their sponsor is taken by the two professors as criticism against them personally.

Indeed, as we outline in our reply to the annex to Mr. Diethelm's letter (attached to this document), the anonymous authors of the OxyRomandie critique (i) have shown a surprising lack of basic statistical knowledge and (ii) have made a series of false statements about the content of our working papers. Furthermore, the authors of the annex have chosen to hide in anonymity, since the annex is signed only by "OxyRomandie". We deem such conduct to be unprofessional and below the standards of any credible scientist.

As academics, we welcome substantive criticism of the approaches and methods applied in our work, and of the validity of the conclusions drawn. Indeed, such criticism is an important part of the scientific process that furthers the objectives of research – in this case in the effectiveness of plain packaging. To that end, as part of the standard academic process in our field, "working papers" are published precisely to allow criticism by peers – hopefully, informed and constructive criticism.

Notes

Criticism of the fact that the annex has not been signed has the character of a *red herring*. Unsigned annexes are normally assumed to have been written by the signatory of the main document. In any case, Diethelm, being the president of OxyRomandie, is legally responsible for what is written by his association.

The two professors claim that "'working papers' are published precisely to allow criticism by peers – hopefully, informed and constructive criticism" does not reconcile with the precipitation with which they inserted their papers in the political decision-making process. They and their sponsor left no time for the scientific review process to take place. They did not wait even a single day before presenting them as the definitive answer on the effectiveness of plain packaging, spreading the message worldwide through press agencies such as Reuters and Businesswire.

As we explain in the attached reply, our chosen methods are standard techniques for assessing the impact of a policy like plain packaging. Moreover, many of our methods, including those criticized by OxyRomandie, were chosen because they tend towards finding a plain packaging effect. Hence, our choices favor the position of proponents of plain packaging. It is curious to us that OxyRomandie should criticize us for applying standard evaluation techniques, in particular those that are deliberately intended towards a favorable finding that plain packaging reduces smoking.

Notes

Kaul and Wolf insist that their methods "tend towards finding a plain packaging effect". In PMI's media release following the publication of their first paper, they are quoted as saying that they "used statistical methodology that gave every possible leeway for detecting a possible plain pack aging effect." This claim provides Philip Morris with the narrative it needed: "The statistical methodology used by the two professors was the best to find an effect if there was one. Since no effect was found, this provides strong evidence that plain packaging is ineffective as a tobacco control measure."

Our two working papers provide the first publicly available empirical assessment of whether plain packaging has reduced smoking in Australia. With the effectiveness of plain packaging under intense public scrutiny, they make an important contribution to the ongoing debate, using objective scientific methods.

Notes

Kaul and Wolf reveal here what made their two papers crucial for their sponsor. The dataset they used, the Roy Morgan Single Source survey data, is considered a high-quality data source, with a large sample size (over 700'000 observations in the second working paper). They use this fact to claim that their papers provide "the first publicly available empirical assessment of whether plain packaging has reduced smoking in Australia" and that, consequently, they have the potential of making "an important contribution to the ongoing debate". There is indeed, at the time, no other "empirical assessment" of the effectiveness of plain packaging in Australia.

Had their approach been methodologically sound, these papers would have been an important contribution, as their findings could be interpreted as a rebuttal of the pre-implementation research results which predicted that the effectiveness of plain packaging would be manifest already in its first year of implementation.

It is nevertheless misleading to present the two papers as an "empirical assessment". They are indeed empirical (as they are based on observable data), but they are not an *assessment*. The "fundamentally flawed" methodology used by the authors produced results that were *at best* inconclusive. As will be observed by Australia at the WTO hearings, it appears that "The 'no evidence' result was effectively preordained. The analysis was simply not capable of finding the very thing it claims it set out to find which renders the results of the analysis meaningless."[105]

In their "Reply to the Annex 'Errors and issues with Kaul and Wolf's two working papers on tobacco plain packaging in Australia'", the two professors address each of the 7 "errors" and 7 "issues" raised by OxyRomandie. This is presented in **Appendix 1**[106] together with OxyRomandie's comments on the two professors' reply.

37. FEBRUARY 2015 – OXYROMANDIE WELCOMES THE DECISION OF UZH

In an email he sent on the same day (14 February 2015)[107], Diethelm thanks Professor Hengartner on behalf of OxyRomandie for the way he is treating the issue. He adds:

[105] Reference WTO-4, p. 455

[106] Available at https://tnt.oxysuisse.ch/tntdossier.php?n=2-A1

[107] Reference 49

Please be assured that our only motivation in this affair is the protection of the integrity of science, of public health and of the high respectability of your academic institution. We have strictly no personal resentment against prof. Wolf and Kaul, who are esteemed scholars. We simply fear we are facing a case where science is being engineered by a powerful tobacco multinational and believe this was our duty, as an organization dedicated to tobacco control and as concerned citizens, to draw this case to your attention.

We are looking forward to receiving the statistical expert's conclusions which we will consider in the most constructive way. As we are not experts ourselves, we have relied heavily on critiques which appeared in the peer reviewed literature and are very open to a professional assessment of our own critique.

38. FEBRUARY 2015 –"JUST THE FACTS", PHILIP MORRIS'S COMMENTS ON ITS WEBSITE

On 14 February 2015, Philip Morris publishes a new article on its website in its "Just the Facts" section, under the title "Independent, Quality Research on Plain Packaging: Our Commitment"[108].

The article makes implicit reference to OxyRomandie's criticism of Kaul and Wolf's studies, without mentioning the association: [109] [110]

PMI is interested in an informed debate about the impact of plain packaging and is committed to supporting experts to conduct quality, independent research that evaluates the effect of imposed logo bans on tobacco products as a means to reduce smoking prevalence.

In line with our standard practice, the research studies we commission clearly communicate our funding, and the researchers with whom we work retain full academic freedom both when conducting a study and making their findings publicly available.

[108] Reference PMI-5

[109] Link to Kaul and Wolf's working paper 149 on UZH website (Reference 16)

[110] Link to Kaul and Wolf's working paper 165 on UZH website (Reference 18)

PMI is interested in an informed debate about the impact of plain packaging and is committed to supporting experts to conduct quality, independent research that evaluates the effect of imposed logo bans on tobacco products as a means to reduce smoking prevalence.

In line with our standard practice, the research studies we commission clearly communicate our funding, and the researchers with whom we work retain full academic freedom both when conducting a study and making their findings publicly available.

To help accurately inform the debate about the Australian plain packaging policy experiment, we asked Professor Wolf of the University of Zurich, a leading academic in the fields of econometrics and applied statistics, as well as Professor Kaul of the Institute of Policy Evaluation (IPE) to evaluate whether plain packaging has contributed to already declining smoking rates in Australia. The results of this evaluation are available here and here.

PMI and the researchers have disclosed since the start that the study was funded by PMI, and the report itself cites both the source of the funding (on page 1 of the study) and of the data.

The funding was approved by the University of Zurich under its guidelines for third-party funding.

The researchers retained complete freedom to conduct and publish the research as they saw fit. As Professor Wolf [1] has stated, PMI did not influence the results of the study.

Having a data-driven, substantive policy debate is fundamental to informed decision making. ***Professors Kaul and Wolf's study is a robust evaluation and reflects the quality of their research****. In the interest of a transparent academic debate, they have also made publicly available critical comments on their work and their reply to such comments.*

We recognize that industry-funded studies are subject to higher scrutiny than most, yet it is a pity that to certain vocal anti-tobacco lobbyists, the source of funding continues to be more important than the substantive findings, which show a lack of evidence that Australia's logo ban has reduced smoking rates.

[Footnote:]

[1] NZZ, 26/12/2014: «Philip Morris hat keinen Einfluss auf die Inhalte genommen»

NOTE

This commentary is a typical illustration of the doublespeak of the cigarette company. The Project Proposal, which was supposed to remain secret, shows that Philip Morris had full control of the study, over each of its four phases, getting internal reports from the two professors and deciding what would be done in the next phase. This is in complete contradiction with the statement that "The researchers retained complete freedom to conduct and publish the research as they saw fit" and with the quoted statement by Professor Wolf saying that "PMI did not influence the results of the study". The quotation is extracted from Wolf's interview with the NZZ (see item 30. above).

39. FEBRUARY 2015 – IPE ASKS OXYROMANDIE TO STOP ITS "DEFAMATORY CAMPAIGN"

On 16 February 2015, the Institute for Policy Evaluation (IPE) issues a media release on their website[111] summoning OxyRomandie and its president to "stop their defamatory campaign against us and the University of Zurich". Under the heading "**Rhetoric trump science?**", this what one can read:

> *Prof. Kaul from the IPE Institute for Policy Evaluation Saarland & Department of Economics at Saarland University and Prof. Wolf from the Department of Economics at the University of Zurich – ask the anti-smoking organization OxyRomandie and its president Mr. Diethelm to stop their defamatory campaign against us and the University of Zurich.*
>
> *OxyRomandie and its president have every right to advocate for a policy they support, but they should not have to resort to inflammatory rhetoric and unsubstantiated claims, which do nothing to advance an important academic debate.*
>
> *As we have demonstrated in our detailed reply to OxyRomandie, the authors of OxyRomandie's critique of our work (i) show a surprising lack of basic statistical knowledge and (ii) make a series of false statements about the content of our two working papers. [...]*
>
> *We regret that instead of engaging on the scientific substance of our reply, OxyRomandie apparently has decided to seek refuge in further aggressive rhetoric, now claiming that there is a "strong suspicion of scientific fraud". Such conduct should be beneath any serious academic, and we ask OxyRomandie to withdraw these baseless accusations.*

[111] Reference 51

[cont'd]

To be sure, tobacco is an unpopular industry and plain packaging a controversial political topic, but the data are the data and standard statistical methods remain the same regardless of the topic to which they are applied. We therefore welcome the initiative of the University of Zurich to ask an external expert to make an assessment of our studies and the criticisms leveled against them.

NOTE

It is true that Diethelm, the author of OxyRomandie's critique of Kaul and Wolf's work, cannot claim a level of statistical expertise even remotely approaching Professor Wolf's impressive curriculum vitae[112] in this field. Nevertheless, he has co-authored four research papers which criticise Kaul and Wolf's studies on plain packaging and even refute their conclusions, papers which have all been published in peer-reviewed journals, whereas Kaul and Wolf's papers have not to this day.

40. FEBRUARY 2015 – SWISS TELEVISION REPORTS ON THE AFFAIR IN THE *19H30* NEWS

On 16 February 2015, French-speaking Swiss television covers the case of the two studies carried out by the University of Zurich on behalf of Philip Morris on its "19H30" news programme, under the title "A University of Zurich study on cigarettes is said to be biased"[113]. Here is a full transcript of the news segment:

Daniel Rochebin (Anchor) - At a time when anti-smoking campaigns are in full swing, a controversy is erupting over the influence of cigarette manufacturers: a study published by researchers at the University of Zurich is said to be biased. The independence of scientists is being questioned. The University and Philip Morris are bound by a contract with astonishing clauses. Nathalie Bougeard, Anne Fournier.

[112] Reference 2b

[113] Reference 52

Nathalie Bougeard (journalist) - Here's the problem. A study on plain cigarette packs. The brand becomes almost invisible, with shock images predominating. Governments that adopt them hope that they will discourage smoking, which annoys the tobacco industry. Based on data supplied in part by Philip Morris, this research by the University of Zurich concludes that there is no proof that this concept has any effect. Cigarette companies have taken up this argument, as it suits them. However, several groups of scientists have criticised this work. This economist, a former WHO collaborator, is one of them.

Pascal Diethelm - I think this study is wrong and misleading. It's not totally false. In fact, the professors said "we found nothing" because they couldn't find anything.

Nathalie Bougeard - What is being criticised is the design of the study, the choice of data and the statistics used. The authors have responded to all these comments, justifying their choice. To get to the bottom of this specialist dispute, the Rector of the University of Zurich decided to appoint an external expert.

Professor Hengartner - Look, this is the classic problem. If we look at this internally and say it's perfectly clean, we're going to be reproached: well, you're trying to hide the whole thing, you're protecting your professor. ***By having a clear opinion, we're convinced that everyone will be able to see and be convinced that there's nothing there****.*

Nathalie Bougeard - Except that there is another concern in this story: the link between the authors of this study and Philip Morris. An 11-page contract signed in 2013. A collaboration worth 9,000 francs a month to the University of Zurich. If he had to do it all over again, the Rector would not sign the agreement as it stands.

Professor Hengartner - There are two or three clauses that I would change. But essentially, I think that professors should have the right, the freedom to collaborate with industry, yes.

Nathalie Bougeard - Here's a problematic clause: the link between Philip Morris and the University must remain secret. Or another: the cigarette company can check the work before publication, and corrections must be taken into account. Another example: scientists must inform the company of any contact, for example with journalists, in order to coordinate information.

Pascal Diethelm - What the university has done: it has sold academic freedom to a tobacco company, and that's what makes it totally intolerable.

Nathalie Bougeard - Determining whether the researchers were influenced by this link with the tobacco company: the beginning of the answer with the expert report, expected in a few weeks' time.

41. FEBRUARY 2015 – PHILIP MORRIS SENDS A LETTER TO LE COURRIER OF GENEVA

On 17 February 2015, Geneva-based newspaper *Le Courrier* publishes a letter from Philip Morris reacting to the article published on 14 February under the title “Strong suspicion of fraud”[114]. The letter is signed by Julie Soderlund, Vice President Communications, Philip. Here it is in its entirety:

Here it is in its entirety (original in French):

> *It was with some consternation that we read the article entitled "Strong suspicion de fraude" published in your edition of 14 February and picked up by various regional newspapers. In it, you unreservedly relayed the defamatory and unfounded statements made by an anti-smoking organisation in French-speaking Switzerland against the University of Zurich for having carried out a scientific and objective study, albeit financed by our company. This funding has always been clearly stated in the research report. We were therefore very surprised that your newspaper should be used as a platform for such serious accusations, with far-reaching consequences for the people and the institution targeted by these violent attacks, without even seriously checking the facts or allowing differing, or even opposing, opinions to be expressed.*
>
> *The fact that the University of Zurich has decided to carry out research on a subject that certain parties do not like in no way justifies criticism of the authors of this work, whose scientific rigour and academic independence are widely recognised. It is one thing for tobacco to be the subject of controversy, but we do not accept that the integrity of external partners, in this case the academic world, should be called into question on the basis of spurious and ideological accusations.*

The Courrier issued the following editorial response:

[114] Reference 44c

The Courrier has taken due note of Philip Morris International's reaction to the article published on 14 February. The editorial team would like to point out that several paragraphs were devoted to the responses of Professor Michael Wolf and the Rector of the University of Zurich, who were therefore given the necessary space to express their line of defence. Le Courrier believes that the public interest in the issue of smoking fully justifies opening its columns to debate on the scientific study in question, which has been called into question in one of the most reliable medical journals.

The editorial team will be following the outcome of this case closely and will not fail to relay the results of the independent investigation requested by the rectorate of the University of Zurich.

42. FEBRUARY 2015 - OXYROMANDIE SUBMITS ITS COMMENTS ON KAUL AND WOLF'S REPLY

On 19 February 2015, Diethelm, on behalf of OxyRomandie, sends a letter to Professor Hengartner[115], enclosing his comments on Kaul and Wolf's letter and their reply[116]. In the letter, Diethelm gives the following explanation:

[115] Reference 53

[116] Reference 54

Additionally, I should like to make the following statement, to allow you to fully understand our position. Apart from the "errors" and "issues" listed in our initial Annex, we consider the studies produced by prof. Kaul and Wolf biased on one further account, which is fundamental: they are sponsored by Philip Morris, a tobacco company. As you know, there is a growing body of literature documenting the evidence that studies funded by the drug industry are up to four times more likely to produce positive results than those with other sources of funding. This is called the "funding effect". In case of a company like Philip Morris, the funding effect takes an extreme form. Internal tobacco industry documents reveal that one of the key criteria used by Philip Morris to fund external scientific research proposals is that they be "consistent with Philip Morris business objectives". Not surprisingly, research studies sponsored by the tobacco company always produce positive results for the sponsor.

I have personally reviewed tens of thousands of tobacco industry documents and have looked at hundreds of reports of external research projects funded by Philip Morris. I have not seen a single instance of them that produced a result made public which was not consistent with the company business interests. This feat is achieved using an array of manipulative and fraudulent techniques, which are well described by professor of history Robert Proctor at Stanford University in his recent book Golden Holocaust. The extent of the company's fraudulent behaviour, executed with the complicity of other tobacco companies, has been qualified as "racketeering" by a US federal court, a judgment upheld by the US Supreme Court in 2010.

One of the methods used by the company is the careful selection of research topics so as to avoid results which could be detrimental to its business interests and to approach "sensitive" topics from an angle which ensures that the result will not lead to a bad surprise. As D. Michael says in his article in the Washington Post, "It's not the answers that are biased, it's the questions." Generally, with Philip Morris, it's both. Research sponsored by the tobacco industry is inherently biased.

Diethelm then expresses his worries about a declaration made by the UZH rector on Swiss television: [117]

[117] See item 39. above

I should like also to express our concern about what you said in the interview you gave on RTS (19:30, 16 February). You stated that by requesting the opinion of an external expert, "everybody will see and will be convinced that there is nothing." (« En ayant une opinion claire, nous sommes convaincus que tout le monde va voir et va pouvoir être convaincu qu'il n'y a rien. ») This is a public declaration of what you are expecting from the external assessment: that OxyRomandie's critique be found unjustified. Our first reaction when we learnt that you had appointed an external expert was to applaud. We now fear that our satisfaction with this decision of yours might have been a bit premature. Indeed, your public statement of what result you are expecting from the expert assessment – which the University of Zürich is commissioning – may now be considered as being part of the terms of reference of the "external" expertise.

Finally, Diethelm concludes his letter with the following plea:

We also insist that our request to you is not just based on narrow technical aspects of Kaul and Wolf's working papers. To be complete, the assessment needs to cover their ethical and deontological implications, which go beyond the contents of the two papers and notably extends to the way they were used, with the authors' explicit or tacit approval, by the tobacco industry to undermine an important public health policy decision by the UK government.

Attached to Diethelm's letter to prof. Hengartner of 19 February are OxyRomandie's comments to Kaul and Wolf's reply to their 7 "errors" and 7 "issues"[118]. A detailed account of these comments is given in **Appendix 1**[119].

43. FEBRUARY 2015 – OXYROMANDIE PUBLISHES A CLARIFICATION ON ITS WEBSITE

On 20 February 2015, OxyRomandie publishes a clarification on its website[120] concerning the interpretation of its critique and retraction request.

[118] Reference 54

[119] Available at https://tnt.oxysuisse.ch/tntdossier.php?n=2-A1

[120] Reference 55

Some titles in the French-speaking Swiss press recently reported on OxyRomandie's request to the rectorate of the University of Zurich for the retraction of two scientific articles published in 2014 by Professors Kaul and Wolf on the university's website. The article published in Le Courrier on 14 February 2015 entitled "L'uni de Zürich suspectée de fraude" apparently served as a reference for the other articles. This article quotes our statements as follows:

> *A total of seven errors have been notified to the rectorate of the University of Zurich. OxyRomandie believes that these "are probably not the result of chance, as they all point in the same direction, denying the effectiveness of the standardised package, which is the result desired by the financial sponsor". Pascal Diethelm adds that the case "seems to him to violate fundamental rules of integrity" and sees in it "elements that create a strong suspicion of scientific fraud".*

To dispel any misinterpretation of our comments, we would like to make the following clarification. Neither OxyRomandie nor its president are questioning the scientific integrity of Professors Kaul and Wolf, even though we remain convinced that their two articles are marred by errors and are biased in their conclusions (which the expert report currently in progress should demonstrate). We have never stated that these errors and this bias in the results were deliberate on the part of the two professors. We specifically stated in our letter of 29 January to the Rector that this bias could be "conscious or unconscious".

On the other hand, OxyRomandie considers that the way in which Philip Morris presented the results of the two studies is scientifically incorrect. This presentation is seriously misleading and we strongly suspect that the tobacco company has intentionally misrepresented the results of the research by Professors Kaul and Wolf, particularly in the response that the tobacco multinational submitted to the UK government during the consultation on standardised cigarette packaging.

Insofar as the University of Zurich and Philip Morris are bound by a contract which specifies that any communication on the studies of the two professors may not take place without prior agreement between the two parties, we consider that this erroneous use of the results of the studies engages the responsibility of the University of Zurich.

In addition to the errors and biases mentioned above, the results of Professors Wolf and Kaul have been seriously distorted by the tobacco multinational, which has presented them as proof of the ineffectiveness of plain packaging. Even though Philip Morris claims that Kaul and Wolf confirmed this erroneous version of their results, and even though the professors repeated (in their response of 11 February) that this presentation of their results by the tobacco company gave them a faithful characterization, we believe that it remains very likely that this misleading presentation of their results was made without their knowledge by Philip Morris and that their consent was only tacit.

NOTE

OxyRomandie opts for a policy of appeasement by applying the principle of charity to the two professors, to avoid being sued for defamation, without compromising the substance of its criticism.

44. FEBRUARY 2015 - THE UZH RECTOR ADDRESSES TWO ISSUES RAISED IN OXYROMANDIE'S LETTER

On 21 February 2015, Professor Hengartner sends an email to Diethelm[121] in which he confirms that OxyRomandie's comments on Kaul and Wolf's reply have been sent to the external expert for consideration. He also addresses two issues raised in Diethelm's letter of 19 February 2015:

> *1. In your original letter, you provided me with a document documenting multiple technical and statistical errors in two working papers by Kaul and Wolf. You suggested in your letter that this accumulation of errors is likely the result of fraudulent activity by the authors. You made a point in your letter that you asked for a retraction of these papers because of the presence of these serious errors, and not because of the conclusion presented in the paper ("We do not ask that these papers be retracted because we do not like their conclusions. We ask the University of Zürich to retract them because they are erroneous beyond repair…").*
>
> *Your accusations against one of our professors were very serious, and we took them very seriously. We asked the authors to reply to your critique. They readily did so. We provided you with their reply. The authors also proactively published their reply onto their web site (http://www.ipe-saarland.de/deutsch/news/). As such, the facts are now in the public domain, and anyone versed in the art of statistics should be able to determine for themselves whether your critique is substantiated or not.*
>
> *Because of the seriousness of your accusations, we decided that we would not passively wait for the scientific community to come to a conclusion, but to ask an external expert, not associated with the authors or with UZH, to evaluate the case. We expect to get an analysis within the next few weeks. We will provide you with the expert's report, and will make the report publicly available. We are hopeful that the report will help us determine whether the papers are, as you stated, "beyond repair" and whether there is a pattern of errors that could indeed suggest unethical behavior.*

[121] Reference 60

[cont'd]

In your new letter, you now raise a new issue. You condemn the working papers of Kaul and Wolf fundamentally, irrespective of the correctness of their results, because of the fact that the study was financed by a tobacco company. I am bemused that you come up with this argument at this point of the evaluation process. While it is your right to do so, I hope that you understand that your request that "the assessment needs to cover their ethical and deontological implications, which go beyond the content of the two papers and notably extend to the way they were used, with the authors' explicit or tacit approval, by the tobacco industry to undermine an important public health policy decision by the UK government" goes far beyond what you initially criticized, and certainly is not a task that an external statistics expert will be able to address. It unfortunately also suggests that you already decided definitively that the results of the working papers cannot be accepted, no matter what the external expert will report. I hope that this hypothesis is wrong, and that you will, as you had indicated in a previous email, consider the statistical expert's conclusions "in the most constructive way". Indeed, you added: "As we are not experts ourselves, we have relied heavily on critiques which appeared in the peer reviewed literature and are very open to a professional assessment of our own critique." I hope that this statement still holds.

This brings me to my second point.

2. In your letter, you express concern regarding my few words on TV. Let me be more extensive and precise here, since you clearly misunderstood my message, which I admit had to be short since it was a TV interview, and was done in a language that I am quite rusty in. First, let me point out that we do not need an external expert to determine whether your accusations are correct or not. We have many statistics experts at UZH who can do this. The reason that we decided to task an external expert with the analysis is to insure that the evaluation can be performed completely independently, and will also be accepted as such by a neutral observer. Second, the question of independence is only relevant if the report exonerates, partially or completely, the accused. If the report confirms your critique, then it would hardly matter whether the expert was internal or external. In summary, the only reason to have an external rather than an internal expert is in the case that the accusations would in the end not be substantiated, in which case such a statement will have more weight from an independent source than from a source linked, directly, or indirectly, to the accused. This is the message that I tried to convey.

[cont'd]

I share your lack of expertise in statistics, and I can assure you that I have no expectation regarding the outcome of the external review, except that it will hopefully shed light into this story. I am greatly disappointed by your lack of trust in me and in the University of Zurich as an institution, and I am deeply offended and insulted -- albeit at the same time somewhat amused -- by your insinuation that I would ask an external expert to be untrue to his own code of conduct and instruct him to give me a biased report tailored to my liking. Indeed, such a move would be not only completely unethical, but also foolish, both for me and for the expert: the working papers, your critique and the authors' reply are in the public domain. There is no way to hide anything. Not for the authors, not for the independent expert, not for me, not for you.

Mr. Diethelm, I treated, and continue to treat, you and your association with trust, openness and respect. I believe that you are a serious organization, trying to do your best to accomplish your laudable mission of preventing and reducing smoking. I would appreciate if you would treat me and my institution with the same trust and respect.

NOTES

We have reproduced Professor Hengartner's text almost entirely, as it addresses the key issues in a particularly detailed and thoughtful way.

The rector says that Diethelm, by emphasizing the inherent unethical aspect of funding academic research by a tobacco company, raises a new issue. This issue is not new, but on the contrary omnipresent in Diethelm's letter of 20 January 2015 to the rector, even if it is not explicitly stated in direct terms. Diethelm says in his letter:

The tobacco multinationals present these two papers as key pieces of scientific evidence that plain packaging is not effective, in their effort to counter the public health policy of these countries. They take advantage of the authority conferred to these papers by the fact that they are published by the University of Zürich.

This raises an important ethical and deontological question for UZH. PMI can be predicted to exploit the results produced by the two professors to advance its commercial interests, which are recognized to be inherently incompatible with public health. Indeed, at its High Level Meeting on the Prevention and Control of Non-communicable Diseases in September 2011, the UN General Assembly adopted a declaration in which it "recognize[d] the fundamental conflict of interest between the tobacco industry and public health"[122]. UZH seems to have ignored the ethical implications of its contract with PMI.

[122] Reference 0n

Furthermore, the rector writes:

> *I hope that you understand that your request that "the assessment needs to cover their ethical and deontological implications, which go beyond the content of the two papers and notably extend to the way they were used, with the authors' explicit or tacit approval, by the tobacco industry to undermine an important public health policy decision by the UK government" goes far beyond what you initially criticized, and certainly is not a task that an external statistics expert will be able to address.*

No, this does not go far beyond what Diethelm have initially criticized: it is in fact the point specifically addressed under "Error #1" in the Annex to the letter of 29 January 2015, which deals with the way Kaul and Wolf's results were used by Philip Morris, with their (tacit?) consent, and by other tobacco companies, to oppose the UK public health policy regarding the implementation of plain packaging. When he says that this not a task that an external statistics expert will be able to address, the rector merely recognizes that the mandate given to the external expert will be confined to the narrow technical and statistical aspects of OxyRomandie's criticism, and will not adequately cover the question of scientific integrity and the broader ethical and deontological issues raised by the association (unethical aspect of doing research for a tobacco company, erroneous and misleading reporting of the results, contradiction and lack of transparency about the way data was obtained, conflict of interest not fully declared, lack of peer review).

Professor Hengartner says that UZH "are hopeful that the report will help us determine whether the papers are, as you stated, 'beyond repair' and whether there is a pattern of errors that could indeed suggest unethical behavior". He is also outraged by Diethelm's disapproval of his statement on Swiss television that he expected the expert report to convince everyone "that there is nothing there" (see above).

Non-compliance with the Principles and procedures of the SAAS

It could be observed that, in the present case, the University of Zurich does not seem to apply the Principles and procedures of the Swiss Academies of Arts and Sciences (SAAS) related to integrity in scientific research[123]. The SAAS procedural recommendations specify various procedural steps shared between the different persons or panels: an ombudsperson, an integrity protection commissioner, a factfinding panel and a decision-making panel, who intervene case by case. The members of the integrity protection organisation are independent in respect of the handling of cases of scientific misconduct. Under "Partiality" the Principles and Procedures give the following instruction:

[123] Reference 0c

At the beginning of each phase of the procedure, both the incriminated person and the person making the allegation will be informed of the composition of the responsible panel. They are free to refuse the presence of partial individuals on the panel, and if this refusal is found to be justified the composition of the panel will be changed accordingly.

No panel was set up, or at least OxyRomandie was not informed of the composition of any such panel. It appears that the University of Zurich dealt with the matter either in accordance with internal rules that were not made known to OxyRomandie, or on an *ad hoc* basis.

45. FEBRUARY 2015 - DIETHELM REPLIES TO PROFESSOR HENGARTNER'S EMAIL

On the same day he received Professor Hengartner email (21 February 2015), Diethelm sends his reply to the rector[124]. After thanking him for his "long and comprehensive response", Diethelm makes the following clarification:

First, although we raised serious concerns with Kaul and Wolf's papers, we never used the word "fraud" or "fraudulent" against the two authors. For those papers to be fraudulent would mean that the errors and bias we revealed be ***intentional*** *or the result of* ***serious negligence****. In the letter, I specifically said that the errors could be conscious* ***or not.*** *Many published papers contain errors and are biased, but only a very small fraction of them are truly fraudulent. You know as well as I do that many of our cognitive biases can betray us.*

The "funding effect" is very often the result of a cognitive phenomenon which takes place at the unconscious level. There is a large body of literature on our cognitive limitations in this respect [...]

If there is something fraudulent in the affair, it is most likely on the side of your partner in the project, Philip Morris, and its way of reporting the results of the study, with the allegation that this was confirmed by the two authors.

[124] Reference 61

Second, my observation about studies sponsored by the tobacco industry being biased is to be understood collectively, not at the level of individual papers. [...] This kind of inherent bias of tobacco sponsored studies is well known and well documented. This is why reputable scientific journals like the British Medical Journal refuse to publish papers sponsored by the tobacco industry (see http://www.bmj.com/content/347/bmj.f5193).

Our observation about the public expression of your expectation concerning the result of the expertise you have commissioned was by no means intended to insult you, but was meant to seek a clarification on this point. We apologize if this has offended you but we hope you can understand our worry. We note that this was not your intention to communicate your expectations to the external consultant. Let me confess that we have our own reasons to be on our guards, based on our past experience. In the Rylander case which we denounced (this professor at the University of Geneva who was secretly employed by Philip Morris for 30 years and who conducted fraudulent studies denying the harmful effects of secondhand smoke), the first report - produced internally by the university - exonerated the professor completely, because it looked at the issue in such a narrow way that guaranteed nothing would be found. From this lesson, we applauded when we learnt about your decision to mandate an **external** expert. However, from this same lesson, we are wary that the scope of the assessment might be too narrow and might miss some of the key ethical and deontological questions, which probably fall outside the mandate of an expert statistician. We have noted with satisfaction your commitment when you declared to the newspaper Le Courrier: « Si des défauts techniques sérieux **ou des problèmes éthiques** devaient être constatés, nous aurions bien entendu le devoir de les corriger. » (“If serious technical faults or **ethical problems** were to be identified, we would of course have a duty to rectify them.”) (our emphasis) We indeed think that it is important that the ethical and deontological side of the case be fully examined.

Then, Diethelm explains the nature of OxyRomandie’s motivation:

Be assured, Dear Prof. Dr. Hengartner, that we have the highest esteem and respect for you and for your academic institution. I am sorry if what I said in my previous email gave you a different impression. OxyRomandie's motivation, and my personal motivation, is twofold. To make sure the cause of public health is not betrayed by the perverse tactics of the tobacco industry, which does not hesitate to corrupt science to achieve its aims, using an array of highly sophisticated techniques which they have developed over the last seventy years, and to protect the academic institution against such tactics. I am sure both of us share the same view on this. OxyRomandie's way of approaching these issues, being an advocacy organization, is rather direct and perhaps even brutally frank at times, differing from what is customary in the academic debate. But beyond this difference of form, what counts is the substance of the matter and our common will to get as closely as we can to the truth, and learn from it. All this in a spirit of trust, openness and mutual respect.

46. FEBRUARY 2015 – DIETHELM REQUESTS A COPY OF THE CONTRACT BETWEEN PMI AND UZH

On 25 February 2015, Diethelm sends an email to Professor Hengartner[125] asking whether he could provide OxyRomandie "with a copy of the contract between the University of Zurich and PMI."

47. MARCH 2015 – UZH RECTOR ACKNOWLEDGES DIETHELM'S TWO EMAIL AND TAKES ACTION

On 4 March 2015, Diethelm sends an email to Professor Hengartner[126] asking him for an acknowledgment that he has taken note of his previous two requests (his emails of 21 and 25 February). The first request was for the peer reviewers' comments to be communicated to the external expert, in case Kaul and Wolf have submitted their first paper to a peer-reviewed journal. The second was to get a copy of the contract between the University of Zurich and PMI "(assuming the University of Zurich has a rule that grants citizens free access to its administrative documents, we should like to invoke it)".

On the same day (4 March 2015), Professor Hengartner replies to Diethelm[127], thanking him "for the long reply on Feb 21, which I positively took notice of".

[125] Reference 62
[126] Reference 63
[127] Reference 64

I discussed your second request with Mr. Akeret (in cc'), head of our legal department, yesterday on the occasion of our weekly meeting. Mr. Akeret confirmed that this is possible and will he send you the contract shortly.

Your first request is more unusual, but I understand your intent. I will contact Professor Wolf and see what the status of the paper is and whether reviewer comments have come in. If yes, it should indeed be possible to send these to the external statistical expert. I will let you know what I find out.

48. MARCH 2015 – THE UZH SENDS A COPY OF THE CONTRACT TO OXYROMANDIE

On 4 March 2015, Mr. Akeret, head of UZH legal department, sends the contract to the rector, UZH, with a copy to Diethelm, OxyRomandie[128]. The email contains a scanned copy of the Services Agreement (see item 2. above).

On 5 March 2015, Diethelm emails Mr. Akeret (with copy to the rector)[129], making the following remark:

Upon examination of the contract, it seems we are missing some of its attachments, notably Schedule 1 and its Annex or Annexes, which are necessary to fully understand it. We should like to receive these documents as well, so as to have a complete copy of the contract.

On the same day (5 March 2015), Professor Hengartner sends Diethelm the following reply[130]:

I am not sure what sure what schedule 1 is. I will check with my legal department.

The Annex is simply the research proposal. We do not hand out research proposals from our professors, as they contain trade secrets, including for example their research plans for the coming years. In the same vein, we do not hand out manuscripts or unpublished data. Please note that this is a standard policy that is shared by essentially all (perhaps even all -- I do not know of any exception) institutions of higher learning. What I can offer you is to send you the summary/abstract page of the research proposal, in order to allow you to get a general idea of its content. Let me know if that is of interest to you.

[128] Reference 65
[129] Reference 66
[130] Reference 67

On 6 March 2015, Diethelm sends an email to Professor Hengartner[131], thanking him for his "kind consideration of our request", adding:

> *I understand your rule about research proposals and would leave it to prof. Wolf to decide whether he wants to disclose his proposal or not, as a way of promoting optimal transparency. I note that an extract of the Annex is already published on the blog of journalist Thomas Angeli from Beobachter at address http://angelisansichten.ch/wp-content/uploads/2014/12/Project-Proposal.pdf. We would be glad to receive a copy of the summary/abstract page of the research proposal as you suggest, if it is different from the page obtained via the above link. We are still interested in obtaining the Schedule, defined under item 1.1 of the contract as an attachment to the Agreement* ***which forms part of it****.*

The summary/abstract page that is shown on the blog of the journalist from Beobachter[132] is not a scanned copy of the original, but a transcribed copy. Angeli explained in an email to Diethelm[133]: "The university wouldn't let me photocopy the document. So I made a transcript. The document published on my blog is the transcript."

On the same day (6 March 2015), Professor Hengartner emails a brief reply to Diethelm[134]:

> *The abstract is indeed the text that you refer to in your mail below.*
>
> *I have in the mean time obtained a scan of Schedule 1, which I attach to this mail.*

Schedule 1[135] is a very short document containing a single four-line paragraph, which is reproduced in its entirety below:

> *SCHEDULE 1*
>
> *Services*
>
> *The services shall be performed as described in the "Project Proposal: Intervention Analysis: the Effects of Plain Packaging for Tobacco Products on Smoking Behavior in Australia," (the* ***"Project Proposal")*** *attached as Annex I to this schedule. For the avoidance of doubt the terms of the Project Proposal are hereby incorporated as material terms of this Agreement.*

[131] Reference 68
[132] Reference 69 and Reference 69a
[133] Reference 70
[134] Reference 68a
[135] Reference 1b

NOTES

The document called Schedule 1 which is referred to in the Contractl[136] establishes that the Project Proposal is the "Annex 1" to which the Services Agreement refers. Furthermore, Annex 1 is indicated as being "incorporated as material terms of this Agreement".

Professor Hengartner also confirms in his email that the "summary/abstract page of the research proposal" he proposed to make available to Diethelm is the same as the page that UZH allowed Angeli to transcribe. Finally, the title of the Project Proposal indicated in Schedule 1 is strictly identical to the title on the document received by OxySuisse in May 2023.

This page ("Page 4 of 17") of the project proposal disclosed by the university gives no indication of the tight control exercised by Philip Morris over the two professors' research. In this respect, it is misleading and could be seen as an attempt to conceal the true nature of the link between the UZH and Philip Morris.

49. MARCH 2015 – KAUL AND WOLF'S FIRST PAPER IS NOT PEER-REVIEWED

In the email he sends on 6 March 2015 to Diethelm[137], Professsor Hengartner encloses a quotation from an email Professor Wolf has sent him, in which he explains:

> *What my coauthor Ashok Kaul meant by his statement* [in their conversation with the Chantler Review Team] *is that we were waiting for informal feedback from some colleagues (at the time of the interview). He clearly did not make any statement saying that we had submitted the paper to a scientific journal. We had not in fact (and still haven't for several reasons), and this can be easily proven/checked if needed.*

NOTE

The question asked by C. Cox of the Chantler Review team to Kaul and Wolf was: "Is there a plan to publish in a journal?" and Kaul's answer was "Yes, we are thinking about it, we finished that a couple of weeks ago so the usual process is extended and we wait for feedback. We have published all our papers in peer-reviewed journals so there is no reason to stop here." In the context of the question they were asked, the answer suggested that they were already engaged in the "usual process" of submitting their paper to a peer-reviewed journal. Almost one year later, they have not submitted it to a peer-reviewed journal ("for several reasons") – and have not to this day, making this paper the only one of their papers that was not published in a journal.

[136] Reference 1

[137] Reference 71

50. APRIL 2014 –UZH HAS RECEIVED THE EXPERT'S REPORT

On 8 April 2015, Professor Hengartner sends an email to Diethelm[138] informing him that the university has received the expert's report and inviting him to discuss the matter directly over the phone:

> *We have now received the report from the external statistics expert. I would appreciate if we could find a time either to meet in person or to discuss over the phone the findings of the expert. Since my schedule is unfortunately quite full these days, I will unfortunately not be able to come in the near future to Geneva (I will be there mid-May, but I am sure that we both wish to move forward on this topic before then). I would be happy to invite you to lunch or dinner in Zurich. Alternatively, a 30 minute phone call might also work.*
>
> *The goal of our discussion would be to come, to the extent possible, to a common understanding/agreement regarding what the expert says and does not say, in order to avoid a public squabbling on this issue between our two organizations. I would of course send you the report prior to our discussion.*
>
> *I must admit that I would also appreciate meeting you independently of the current affair, simply to learn more about your organization and the issue of tobacco control in general and the challenges that you face on this issue. But many this discussion should be reserved for another occasion, depending on how much time we will have.*

NOTE

The tone and contents of this email are particularly amicable. The rector seems to be putting UZH and OxySuisse on an equal footing when he invites the association's president to lunch or dinner in Zurich with the goal coming "to a common understanding/agreement regarding what the expert says and does not say, in order to avoid a public squabbling on this issue between our two organizations." It is worth noting that the 2015 annual budget of the UZH was over CHF 1.3 billion, while that of OxySuisse was less than CHF 1,500. Also note the rector's personal interest in learning more about OxySuisse and the issue of tobacco control. While the rector's expression of consideration for OxySuisse and its advocacy work is probably sincere, it is not far-fetched to assume that it could also be an attempt to appease the association and its president so that they are more willing to accept the expert's conclusion without further public quarrel.

[138] Reference 72

51. APRIL 2014 – DIETHELM ACCEPTS THE RECTOR'S INVITATION TO MEET IN ZURICH

On the same day (8 April 2015), Diethelm replies to the rector[139], accepting his invitation:

> *I thank you for your confidence and the concerted way you are approaching the question I submitted to you on behalf of OxyRomandie. I would be pleased to come to Zurich to discuss the matter directly with you. [...] I agree that a face-to-face discussion would be best to find a common ground on how to present the results from the expert report in a mutually satisfactory way. I have a good feeling that it is both possible and desirable.*

Eight days later (on 16 April 2015), Diethelm re-sends his message to Professor Hengartner[140] (which he initially sent "from a location in Thailand were Internet access was at best erratic"), adding a *nota bene,* in which he asked for a copy of the report from the external statistical expert, so that he can "study it carefully before our meeting".

In the *nota bene*, Diethelm indicates that he has attached to his email "a paper I recently published on the Rylander case in a French journal with a side bar documenting how the University of Geneva handled the issue and the lessons learnt from the affair, which might interest you." The paper appeared in the January 2015 issue of French journal *Science et pseudo-sciences*. Its title was "The Rylander case: An example of scientific fraud perpetrated by the tobacco industry"[141]. Drawing the rector's attention to the story told in the side bar is clearly meant to be a message to him, by establishing a parallel between what has happened at the University of Geneva 15 years ago and the situation with the report from the external statistical expert:

[139] Reference 73
[140] Reference 74
[141] Reference 74a

The University's attitude

The University did respond to the request for an investigation made by the two anti-smoking campaigners at their press conference in March 2001.However, the result was far from their expectations. In fact, the enquiry's report, delivered less than three months later, instantly became a central piece of incriminating evidence in Rylander's lawsuit for libel against them. A godsend for the plaintiff, the report concluded: "The commission did not find, in the documents it examined and the interviews it conducted, any evidence to support the conclusion that Professor Rylander was guilty of scientific fraud". In addition to exonerating the professor, the investigators invited the University of Geneva "to resist the temptation to give in to the song of certain sirens who seem to have found, in the radical criticism of the tobacco industry's actions, a way of focusing, if not monopolising, public opinion". They suggested that Professor Rylander was the victim of two anti-smoking fanatics who wanted to sacrifice him on the altar of their convictions - a thesis that Rylander's lawyer repeated again and again in his closing arguments.

It was not until ten months after the final judgement in December 2003 that the University of Geneva finally produced a new report on the case, whose conclusions refuted those of the initial investigators, summing up Rylander's actions as follows: "[...] the concealment of the true extent of the links of dependence in relation to the tobacco industry and the alignment of his activities as a researcher and expert in the field of tobacco smoke with the strategic objectives of the industry constitute an attack on the scientific integrity that the public and his peers have a right to expect from a university researcher." However, for the University, the tobacco industry was first and foremost to blame: "Prof. Rylander's breaches of scientific integrity only make sense in the context of the strategy designed and implemented by the tobacco industry to sow doubt about the toxicity of tobacco smoke, particularly for non-smokers. The fate of an individual should not blind us to the fact that the most unforgivable guilt lies with an institutional and commercial force, the tobacco industry, whose objectives and interests are at odds with both public health and medical science". In October 2004, the University of Geneva issued a press release in which it stated that it would draw the necessary lessons from this affair and thanked Pascal Diethelm and Jean-Charles Rielle for having "played an essential role in its elucidation".

The last point made by Diethelm in the *nota bene* is an update on the implementation of plain packaging in the world and a reminder of the on-going international legal cases in which the two UZH papers could be used against plain packaging:

> *Since we submitted our request to you on 29 January this year, parliaments of three countries have adopted plain packaging as a tobacco control measure: the United Kingdom, Ireland and France (where the measure still needs to be examined by the French Senate but with very little risk that it will be changed). The urgency there was in settling the issue which we raised is no longer as pressing as it was at the time of our submittal. Fortunately, Kaul and Wolf's results were not sufficient to inflect the decision of lawmakers in these three countries. However, the papers can still play a significant role in the courts in which the tobacco industry currently challenges the measure, namely two arbitration courts which have to determine to what extent plain packaging is a breach of bilateral investment treaties (BIT) (between Philip Morris and Uruguay, using the BIT between Switzerland and Uruguay and between Philip Morris and Australia, using the BIT between Hong Kong and Australia), and the complaint brought by Ukraine against Australia before the World Trade Organization. It is very likely hat in such legal contexts, the tobacco industry will use the two papers as key pieces of evidence.*

52. APRIL 2015 – RECTOR UZH SENDS THE EXTERNAL EXPERT'S REPORT TO DIETHELM

The report of the external statistics expert[142] is sent to Diethelm on 16 April 2015 attached to an email from Professor Hengartner[143], in which the rector asks him to treat the report "for the time being -- with the promised confidentiality". The author of the report is Ben Jann, who is professor of sociology at the Institute of Sociology, University of Bern[144]. Entitled "Methodological Report on Kaul and Wolf's Working Papers on the Effect of Plain Packaging on Smoking Prevalence in Australia and the Criticism Raised by OxyRomandie", the report is dated 10 March 2015. It is 46 pages long. Professor Jann describes his mandate in the Introduction as follows:

[142] Reference 75
[143] Reference 76
[144] Reference 77

On February 16, 2015 I was asked by Vice President Prof. Schwarzenegger of University of Zurich to provide a methodological assessment of two working papers by Prof. Kaul and Prof. Wolf on the effect of plain packaging on smoking prevalence in Australia and the criticism raised against these working papers by OxyRomandie.

The materials on which I base my assessment include:

- *Working paper no. 149 on "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis" by Ashok Kaul and Michael Wolf (Kaul and Wolf 2014b).*
- *Working paper no. 165 on "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis" by Ashok Kaul and Michael Wolf (Kaul and Wolf 2014a).*
- *Letter by Pascal A. Diethelm on behalf of OxyRomandie to the President of University of Zurich, including the annex "Errors and issues with Kaul and Wolf's two working papers on tobacco plain packaging in Australia" [...] dated January 29, 2015 (provided by Prof. Schwarzenegger).*
- *Public reply to the letter of Pascal A. Diethelm, including a reply to the annex of the letter of Pascal A. Diethelm, by Ashok Kaul and Michael Wolf [...] dated February 11, 2015 (provided by Prof. Schwarzenegger).*
- *Letter by Pascal A. Diethelm on behalf of OxyRomandie to the President of University of Zurich, including the document "Comments on Kaul and Wolf's reply to our Annex", dated February 19, 2015 (provided by Prof. Schwarzenegger).*
- *Forthcoming comment on the "Use and abuse of statistics in tobacco industry-funded research on standardised packaging" by Laverty, Diethelm, Hopkins, Watt and Mckee (Laverty et al. forthcoming) (provided by Prof. Schwarzenegger).*
- *Monthly data on sample sizes and smoking prevalences, January 2001 to December 2013, for minors and adults, as displayed in Figures 1 and 2 in Kaul and Wolf (2014a,b) (provided by Prof. Schwarzenegger).*

He was paid 8'000 Swiss francs (standard rate) to produce the report, which he did in slightly more than three weeks.

Professor Jann made the following comments on "*Issue #6: Conflict of interest not fully declared*" raised by OxyRomandie:

OxyRomandie accuses Kaul and Wolf of not having been fully transparent about the role of PMI. Kaul and Wolf did declare that PMI provided funding. In my opinion, this clearly identifies the papers as industry sponsored research. Whether PMI, by contract, had the possibility to comment on the papers prior to planned publication or not, does not really appear essential to me. ***Things might be different if the contract gave PMI a right of veto against publication*** *(which does not seem to be the case according to the quote from the contract presented by OxyRomandie).*

In general, the problem with industry sponsored research might not be so much that single studies are biased or flawed. A much bigger problem, in my opinion, is that industry funding biases the selection of studies that are conducted and that unfavorable results are often withheld, leading to publication bias. ***In the present case it does not seem that PMI could have withheld publication if results would have been unfavorable, but we do not really know****.*

Many of Professor Jann's other points are discussed in OxyRomandie's comments on his report, issued on 21 May 2015 (see item 51. below).

NOTES

Professor Jann was asked to provide a *methodological* assessment of the two working papers and of OxyRomandie's criticism. In his letter of 29 January 2015[145] (third item on Jann's list of materials), Diethelm raised the following concern:

The publication of these two papers, which were funded and supervised by tobacco multinational Philip Morris, occurs at a critical time when a number of countries are considering the adoption of plain packaging, a smoking prevention measure recommended by the WHO Framework Convention on Tobacco Control. A few days ago, the UK Government announced that it would proceed with plain packaging legislation and a vote will be taken in the UK parliament before May of this year.

The tobacco multinationals present these two papers as key pieces of scientific evidence that plain packaging is not effective, in their effort to counter the public health policy of these countries. They take advantage of the authority conferred to these papers by the fact that they are published by the University of Zürich. For instance, in its response to the UK Department of Health's consultation on the introduction of regulations for standardised packaging of tobacco products, Japan Tobacco International refers to these studies as "studies by the Universities of Zürich and Saarland."

[145] Reference 41

In the Annex to his letter, Diethelm makes the following observation as a matter of introduction:

> *Kaul and Wolf's studies were the product of a contract apparently concluded between the two professors, their respective universities (University of Zürich and University of Saarland), the marketing consulting firm IPE Institut für Politikevaluation GmbH and Philip Morris International.*
> *[…]*
> *Based on this contract, we take it for granted that Kaul and Wolf have given their consent to the communication on the studies issued by the other parties, notably Philip Morris International and IPE Institut für Politikevaluation GmbH, the marketing consulting firm of which Kaul is the Director.*

The point identified as Error #1 of the Annex deals with the erroneous and misleading reporting of the results of Kaul and Wolf's study by PMI and other tobacco companies. In their reply to OxyRomandie's criticism, the two professors say that the way PMI presented their findings in media releases and in the company's response to the UK consultation is "a fair characterization of their results"[146], thus endorsing the misrepresentation of their results by their tobacco sponsor.

The above points show that OxyRomandie's criticism, while concentrating on technical aspects of Kaul and Wolf's studies, are not confined to methodology but include broader considerations of scientific integrity, notably the way the studies' results were reported by the two professors and used by the tobacco sponsor in its communication and argumentation against plain packaging.

In his letter of 19 February 2015 (fifth item on Jann's list of materials), Diethelm explained:

> *We also insist that our request to you is not just based on narrow technical aspects of Kaul and Wolf's working papers. To be complete, the assessment needs to cover their ethical and deontological implications, which go beyond the contents of the two papers and notably extends to the way they were used, with the authors' explicit or tacit approval, by the tobacco industry to undermine an important public health policy decision by the UK government.*

Unfortunately, the task assigned to Professor Jann by UZH seems to be limited to the "narrow technical aspects of Kaul and Wolf working papers".

Professor Jann's remark on *Issue #6: Conflict of interest not fully declared* takes on a very different tone when confronted with Annex 1 to the Contract between PMI and UZH (the

[146] Reference 48

Project Proposal). Now we know that *things are indeed different* as the contract "gave PMI a right of veto against publication" and that "PMI could have withheld publication if results would have been unfavourable". The "problem" is indeed "much bigger".

53. MAY 2015 – DIETHELM MAKES HIS FIRST COMMENTS ON THE EXTERNAL EXPERT'S REPORT

On 5 May 2015, Diethelm sends an email to Professor Hengartner[147] in which he thanks him for the "very nice lunch" they had on Friday 1st May. He then makes some comments on the external statistics expert's report:

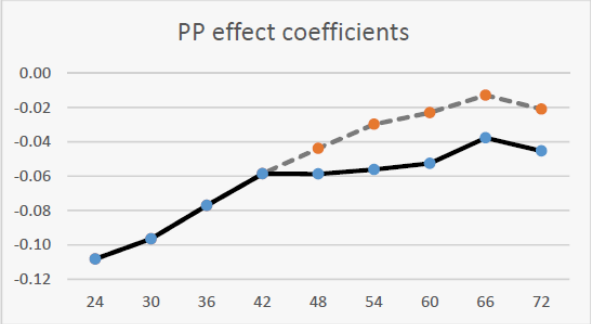
> *As I said, we are quite pleased with prof. Yann's methodological report, even if we have comments and reservations on several points, including key points. However, we can agree on how to handle its findings and recommendations without opening a further discussion on its details in our public communication. The broad lines and main points of the report are sufficiently clear. We will send you later our details comments, but my time schedule is so full that they will only be ready mid-June, at the earliest. The University will probably not want to wait any further before issuing its reaction to Prof. Jann's report and we understand.*
>
> *Concerning the request I submitted to you for some detailed analysis of the data, I'd like to clarify that this is simply meant to show that, contrary to what prof. Kaul and Wolf claim in their second paper, the data they used, provided it is properly used, exhibit a fairly strong plain packaging effect and that their conclusion could consequently be highly misleading.*
>
> *I have attached to the present mail our own calculations using the logistic regression approach (with the R package). If our figures are correct (i.e. if prof. Yann can confirm them), the marketing data used by the two professors provides clear and indisputable evidence of a plain packaging effect – this has important public health repercussions. This would clearly imply the need to issue a corrigendum on the website of the University of Zurich. I would be grateful if you could transmit this to prof. Jann, as before proceeding further, our results need to be triple checked.*

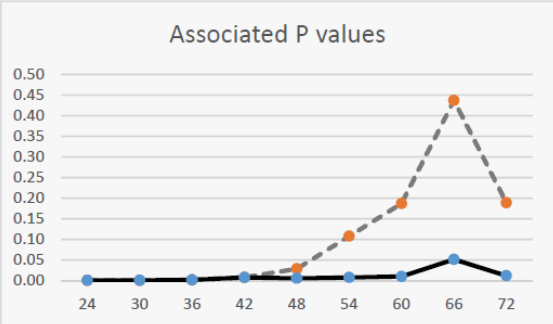
[147] Reference 78

OxyRomandie's "own calculations", attached to Diethelm's email, are shown on one sheet[148], which is reproduced below:

Logistic regression - Estimated coefficients for PP effect (plain packaging) and tax effect (tax increase) and their respective P values

	PP effect alone		Tax effect + PP effect				Combined	
Length of period (months)	PP effect	P value	Tax effect	P value	PP effect	P value	PP effect	P value
24	-0.10821	0.00074 ***					-0.10821	0.00074 ***
30	-0.09648	0.00080 ***					-0.09648	0.00080 ***
36	-0.07708	0.00202 **					-0.07708	0.00202 **
42	-0.05860	0.00799 **					-0.05860	0.00799 **
48	-0.04387	0.02870 *	-0.04915	0.04120 *	-0.05876	0.00588 **	-0.05876	0.00588 **
54	-0.02986	0.10800	-0.05391	0.00897 **	-0.05617	0.00782 **	-0.05617	0.00782 **
60	-0.02310	0.18700	-0.05652	0.00568 **	-0.05259	0.01021 *	-0.05259	0.01021 *
66	-0.01294	0.43700	-0.05049	0.01260 *	-0.03774	0.05160 .	-0.03774	0.05160 .
72	-0.02102	0.18900	-0.05635	0.00402 **	-0.04537	0.01212 *	-0.04537	0.01212 *





Dashed line: PP effect alone;continuous line: PP effect + tax effect when applicable

54. MAY 2015 – DRAFT UZH STATEMENT ABOUT THE EXTERNAL EXPERT'S REPORT SENT TO DIETHELM

On the same day (5 May 2015), Professor Hengartner sends an email to Diethelm with, attached, the "draft statement that we plan to send selectively to the journalists that have asked us actively for an update", adding that "We do not plan to actively communicate beyond that small group of individuals, but would send the same statement to further individuals upon request." The rector then explains:

[148] Reference 78a

As discussed, we see little point in a public confrontation with Oxyromandie, but have a duty to inform, as previously promised, the media of what the external expert found.

Comments from your side regarding the wording of our communique are welcome. You mentioned in particular that you would welcome a reaffirmation of the statement that "the absence of evidence of an effect is not evidence of an absence of an effect." I cannot promised that we will take up your suggestions, but I can promise that we will consider them in good faith. In return, I hope that you will be able to give a positive feedback/comment regarding our response and evaluation process to the media that might contact you, and that you will update the status of this issue on your web site in an appropriate manner.

I would appreciate if we could get feedback from you by the end of this week (I understand that you are very busy, but as you suspected, we would like to wrap this up, lest the media think that we are trying to buy time/hide bad news). I will inform you in advance of the date on which we will communicate with the media, so that you can prepare for their very likely call.

The draft statement that is joined to Hengartner's email is dated 4 April 2015[149]. It is in German. Here is an English translation of the full text:

An independent expert report on two working papers by Prof. Kaul, Saarland University, and Prof. Wolf, University of Zurich, on the effect of plain packaging on smoking in Australia is now available. Prof. Ben Jann of the University of Bern was commissioned by UZH to investigate the accusations made by "OxyRomandie". The organization accused the studies of methodological flaws and demanded that the University of Zurich remove the two working papers from its website.

In his 46-page expert report, Prof. Jann concludes that the Working Papers do not contain any significant methodological errors. He assesses the approach of Prof. Kaul and Wolf as comprehensible, although there might have been better evaluation methods. According to Jann, the data analysis methods used, the data basis, and the hypothetical assumptions have also been described with sufficient transparency so that the studies can be replicated by other researchers.

[149] Reference 78a

[cont'd]

From the University of Zurich's point of view, the accusations that the Working Papers are flawed have thus been refuted. Based on the expert's recommendation, the university management has decided to leave the Working Papers on Prof. Wolf's website, to refer to the controversial discussion there, and to make the expert's report public.

The University of Zurich also states that scientific freedom of research was guaranteed for both Working Papers and that the tobacco company Philipp Morris did not exert any influence on the content of the papers.

NOTES

The draft statement is quite explicitly saying that OxyRomandie's accusations against the two professors are unfounded, that the working papers produced by Kaul and Wolf "do not contain any significant methodological errors", and, finally, that "scientific freedom of research was guaranteed" and that the "tobacco company Philipp Morris did not exert any influence on the content of the papers".

Reading the Project Proposal, one realizes how false this latter claim is. It will be shown below that all the other claims made in the UZH statement are similarly false. Kaul and Wolf working papers are flawed, they contain serious methodological errors, which the external statistics expert has *not* refuted in his report but has simply minimized or even replicated in his own calculations. This is shown in two peer-reviewed papers written by Diethelm and Farley, who re-analysed the data used by Kaul and Wolf with a state-of-the-art statistical methodology and applying the approach that Kaul and Wolf themselves had planned to apply in the Project Proposal (which they considered "crucial"). They obtained radically different results, which refuted the findings of the two professors.

Finally, the UZH's statement does not consider the ethical and deontological aspects of the case. No reference is made to the conflict of interest inherent in working for a tobacco multinational on a subject motivated by public health considerations. The statement remains also silent on the way the sponsor of the studies, Philip Morris, used and abused the results of the two professors, with their approval, since they allowed themselves to be quoted in Philip Morris press releases and in submissions to government consultations in a highly distorted manner, without any protest on their part (on the contrary, they described such use and quotations as a "fair characterization of their results", as we have seen above).

This draft statement could be taken as indicative of UZH's desire to bury the matter once and for all.

55. MAY 2015 – DIETHELM REACTS TO THE DRAFT UZH STATEMENT

On 6 May 2015, Diethelm sends an email reply to the rector[150], in which he indicates that he is far from satisfied with the draft statement prepared by UZH. Here is a large extract of his email:

> *[...] Although I think that the draft statement conforms to what one would normally expect of a very large institution which, understandably, is highly concerned about protecting its reputation [...] I would indeed have expected a statement with a bit more teeth, in particular following our conversation on last Friday.*
>
> *While I admit that we were wrong in some of our more technical criticisms (and right in others), our key concern remains unchallenged. Your partner in the project, Philip Morris, has clearly misrepresented the study results in its public communication and in its submission to the UK government, using the name of the University of Zürich to give scientific credibility to their disinformation. This was our key point when we raised the issue and we have re-iterated it numerous times since then [...]. I fear that not addressing this issue could expose the University of Zurich to the criticism of having adopted the "ostrich policy" with regard to the key accusation of OxyRomandie. This is why I would indeed recommend that the University explicitly takes its distance with respect to this improper use of Kaul and Wolf's results by the tobacco multinational (with which the University is linked by a contractual agreement). In particular the statement "**Kaul and Wolf confirmed that if there had been an effect in reality..., it would have been reflected in the data. According to the study, however, no effect was found**" in PMI's response to the UK consultation on plain packaging is clearly doubly false (Kaul and Wolf have probably not confirmed this statement, which is itself false) and is thus misleading and should not be left without objection. This is a question of the University's responsibilities towards society. For us, it is the crucial point of the whole affair.*
>
> *Also, by evoking only euphemistically the serious limitations found in the two papers by prof. Jann, the University of Zurich leaves this task entirely to us. I understand the difficulty you have as an institution to deal with comments criticizing the work of a faculty member. We will assume our role here, while remaining always respectful of you and the University, for which we have the highest esteem, and will use our freedom of expression to ensure that institutional political correctness will not be at the detriment of public health, and in particular of the public health policy of a sovereign state such as the UK.*

[150] Reference 79

Finally, when the University says that Philip Morris has had no influence on the contents of the two papers, I am again afraid that you will unfortunately project the image of an institution which is fooling itself and practices self-persuasion. [....] The tobacco industry has developed highly sophisticated manipulation techniques over the last 50 years and it is hard for anyone dealing with it to escape from their influence – most often unconsciously. The fact is that the industry has a record of having funded studies whose results are nearly 100% favourable to their commercial interest (I am still looking for an exception). A landmark article (attached) entitled "Why review articles on the health effects of passive smoking reach different conclusions" done in the late 90s concluded that "the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry." This may well apply today to studies on the effect of plain packaging.

Diethelm ends his email by saying that the present mail is a first reaction and that he will get back to the rector by the end of the week with further comments.

The "landmark article" mentioned in the last paragraph quoted above is the 1998 paper by DE Barnes and LA Bero LA entitled "Why review articles on the health effects of passive smoking reach different conclusions"[151], whose finding was: "In multiple logistic regression analyses controlling for article quality, peer review status, article topic, and year of publication, the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry."

56. MAY 2015 – OXYROMANDIE'S "LATEST" COMMENTS ON THE EXTERNAL EXPERT'S REPORT

After having sent several "final" versions of OxyRomandie's comments on the report of the external statistics expert, Diethelm sends the "latest" version of these comments[152] attached to an email he addresses to the rector on 25 May 2015[153]. In his email, Diethelm draws Professor Hengartner's attention that his reanalysis of Kaul and Wolf's second paper, if confirmed, would constitute a rebuttal of their findings. He also alerts him of the sensitive turn taken by the issue, as BAT and Philip Morris have just announced that they are suing the UK government over plain packaging. [154]

[151] Reference 79a

[152] This version will be further revised. Only the final version is included as exhibit.

[153] Reference 80

[154] Reference 80a

See attached the latest revision of our reaction to prof. Jann's report. The substance of our comments remains identical to those found in earlier versions which I sent you. However our reanalysis of prof. Kaul and Wolf's data on adults has been substantially strengthened and establishes now on what we believe is very solid ground that the introduction of plain packaging in Australia is associated with a reduction of smoking prevalence. Our results achieve a high level of statistical significance. If they are confirmed, they would constitute a rebuttal of the two professors' findings and, above all, of Philip Morris's presentation of their results.

I intend to submit for publication a paper which will be co-authored by a former WHO colleague who is a high calibre professional statistician. The critique of peer reviewers will provide us with a further check on the validity of our approach.

The issue is becoming increasingly sensitive, as it has been just announced that BAT and Philip Morris are suing the UK government on plain packaging. See http://www.nytimes.com/2015/05/23/business/international/tobacco-plain-packaging-philipmorris-british-american-cigarettes.html?_r=0. Clearly the effectiveness of the measure will be a central argument in the forthcoming trial.

57. JUNE 2015 – OXYROMANDIE'S FINAL COMMENTS ON THE EXTERNAL EXPERT'S REPORT

On 11 June 2015, Diethelm sends OxyRomandie's final[155] comments on the report of the external statistics expert[156]. In his email[157], Diethelm describes the latest changes made to OxyRomandie's comments:

[155] OxyRomandie will issue a new final version of these comments in December 2015.

[156] Reference 81

[157] Reference 82

The main differences between this version and the previous one are as follows:

- *Our re-analysis has been moved to the back as an Annex to the main document. As we are currently working on a paper to be submitted for publication in a peered-reviewed journal, this preliminary analysis will likely undergo significant improvements.*
- *We slightly altered our position under Comments on 4.2 Error #2: Power is obtained by sacrificing significance and under Comments on 4.3 Error #3: Inadequate model for calculating power which introduces a bias towards exceedingly large power values*
- *We significantly strengthened our position under Comments on 4.7 Error #7: Invalid assumption of long term linearity. We found publications (of which prof. Kaul and Wolf were aware) which establish that tobacco control measures have had an effect on smoking prevalence in Australia, making less acceptable the two professors' assumption that smoking prevalence was driven by a pre-existing linear trend independent of tobacco control measures.*

OxyRomandie's comments on the report of the external statistics expert start with the following introduction:

We consider that prof. Jann's reanalysis is a vast improvement over the approach used by prof. Kaul and Wolf in their two papers. In a complementary way, prof. Jann reveals what was weak or lacking in the approach used by the two professors. We also applaud his attempt at presenting an objective and balanced treatment of the issue, which again, by reflection, shows how the two professors could have addressed the issue, had they been more careful.

This being said, we nevertheless respectfully fear that prof. Jann has fallen into the pitfall of accepting uncritically some of the key assumptions on which prof. Kaul and Wolf base their analysis, assumptions which are highly questionable and on which the results of the analysis depend critically, and has repeated some of the same mistakes in his own reanalysis.

To illustrate what we mean, we have also performed our own reanalysis of the data, using an approach which seeks to disentangle the confounding effect of other tobacco control measures, allowing the effect of plain packaging to be seen more clearly. We think that our comments below will be best understood if the reader looks at our reanalysis, which is presented in the Annex. It will be noted for instance that, using the same data, we arrive at a conclusion which contradicts prof. Kaul and Wolf's findings.

Diethelm's emails of 25 May and 11 June 2015 will be left unanswered by Professor Hengartner.

58. JUNE 2015 – PHILIP MORRIS SUBMITS ITS RESPONSE TO NORWAY'S HEARING ON PLAIN PACKAGING

On 17 March 2015, Norway published for consultation its proposal to introduce plain packaging in its tobacco control law[158]. The hearing deadline was 9 June 2015. On 8 June, Philip Morris Norway AS et PM Tobakk Norge AS submit their response[159], an 8-page document in which they argued as follows:

> *We encourage the Department to consider the data from the Australian states attached as Appendix 6, the available data on tobacco consumption attached as Appendix 7, and studies submitted as Appendix 8 that show that the standardised packs have not had the desired effect in Australia.*

Philip Morris's submission includes about 30 annexes[160], including the two UZH working papers: the second working paper (study on 14+) is attached as Annex 8.4 and the first working paper (on minors) as Annex 8.5. Annex 8[161] is entitled "Studies that find no evidence for the effect of plain packaging". It consists essentially of a table in which four studies are presented, two of which are the UZH studies. The table is preceded with the following comment:

> *Two of the studies in the table below were funded by Philip Morris International ("PMI"). However, the studies were conducted on an independent basis by researchers from the University of Zurich (Switzerland) and the University of Saarland (Germany).*

In the table, the two UZH studies are commented as follows:

> *In both studies, using standard techniques for statistical analysis, and the standard statistical significance level of 5 per cent, the experts found no evidence that 'plain packaging' had had any impact on the prevalence of smoking among Australian youth between 14 to 17 years (in the March study) or Australians aged 14 and over (in the June study).*

[158] Reference 83
[159] Reference 83a
[160] Reference 83b
[161] Reference 83c

The other two "studies" include an accepted manuscript of a paper by N. McKeganey and C. Russell, of the Glasgow-based Centre for Drug Misuse Research, to appear in International Journal of Drug Policy, shown as Annex 8.2[162] and a report by the Democracy Institute, a think tank based in Washington and London, authored by its founder, P. Basham, shown as Annex 8.3[163]. Both the Centre for Drug Misuse Research, later renamed Centre for Substance Use Research, and the Democracy Institute have links with the tobacco industry[164]. In their accepted manuscript, McKeganey and Russell declare that they received no funding from the tobacco industry. However, they later (2016) issued a corrigendum in which they declared that, in 2014, McKeganey "prepared a report that was included in the Annex to the British American Tobacco (BAT) response to the UK Government consultation on plain packaging"[165].

The Democracy Institute report, entitled "An Australian lesson: The plain packaging experiment is a failure" is a selective review of a set of reports and newspaper articles to support its thesis that the introduction of plain packaging in Australia failed. The review relies mainly on reports produced by neo-liberal/libertarian think tanks (Washington Legal Foundation, Democracy Institute) and by institutions commissioned by the tobacco industry (London Economics, UZH) or with a common interest with the industry (Australasian Association of Convenience Stores). The UZH studies are covered as follows:

[162] Reference 83d

[163] Reference 83e

[164] For CSUR, see https://tobaccotactics.org/article/centre-for-substance-use-research-csur/ and for the Democracy Institute, see https://tobaccotactics.org/article/democracy-institute/.

[165] https://doi.org/10.1016/j.drugpo.2015.09.004

[...] last summer, researchers from the Institute of Policy Evaluation Saarland & Department of Economics at Saarland University and from the Department of Economics at the University of Zurich conducted a statistical trend analysis of smoking prevalence among Australians (aged 14 and older) between January 2001 and December 2013. The objective was to determine whether there was evidence for a plain packaging effect on smoking prevalence at any time during the 13 months from December 2012 through December 2013.

Using standard statistical analysis techniques, these experts found no evidence for a plain packaging effect on smoking prevalence. As explained by lead author, Ashok Kaul:

> *[W]e found no solid evidence for a plain packaging effect in any month. Only when using statistical techniques biased in favour of finding a plain packaging effect could we detect weak evidence for a one-time effect on smoking prevalence in December 2012 itself, after which smoking prevalence is statistically indistinguishable from the pre-existing trend.*
>
> *Based on our analysis, one could, at most, claim an effect on smoking prevalence among the total Australian population in December 2012 only, that is, an effect that lasted no more than one month. From January 2013 on, even very powerful statistical techniques no longer can pick up any change from the pre-existing trend.[17]*

[17] Ashok Kaul et al. "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis," University of Zurich Department of Economics Working Paper Series, 1 July 2014, http://www.econ.uzh.ch/static/workingpapers.php?id=844.

The paper by McKeganey and Russell cannot be described as a study "that find no evidence for the effect of plain packaging", as it concludes, on the contrary, that no such research with the necessary level of quality existed (the paper was finalized in March 2015):

In the face of what seems likely to be the further extension of the plain packaging policy beyond Australia, Ireland, and the United Kingdom, there has always been the necessity to ensure that high quality research is being planned and conducted to evaluate the effectiveness of plain packaging in reducing smoking prevalence in a given population set against any unintended health, social and economic consequences. Although seemingly obvious to state, we must be mindful that evidence of changes in smoking prevalence do not permit conclusions about the causes of such changes, and that only research that has been designed to quantify the causal role of various factors can inform conclusions about the role of plain packaging. We must be mindful that no such research of this kind has yet been reported, and so no person has an evidence base from which to contend that plain packaging has reduced or increased smoking in any jurisdiction.

The last sentence stating that "no person has an evidence base from which to contend that plain packaging has reduced or increased smoking in any jurisdiction" implies *a fortiori* that, lacking such an evidence base, failing to find evidence of a plain packaging effect, as Kaul and Wolf did, is equally unconclusive. Thus, at the same time as Philip Morris produces the two UZH studies in its response to Norwegian consultation, it also produced a paper rejecting their conclusions, for their failure "to quantify the causal role of the various causal factors that can inform conclusions about the role of plain packaging."

Other tobacco companies have used the two UZH studies in their submission to the Norwegian consultation. For instance, in its response[166], JTI makes the following statement:

Plain packaging has not worked in Australia

5.9 Claims have been made about the health-related impacts of plain packaging in Australia, the only country in the world to have introduced such legislation. Plain packaging in Australia came into force in December 2012. At 30 months since the implementation, the actual evidence emerging from Australia reinforces the fact that plain packaging does not work:

(a) Studies by the Universities of Zurich and Saarland have found that plain packaging has had no effect on smoking prevalence, either among minors or adults.[33]

[166] Reference 83f

[cont'd]

[...]

[33] See "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis", University of Zurich, Department of Economics, Working Paper No. 149, May 2014. Available via: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2414430 and "The "Possible" Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis", Working Paper No. 165, June 2014. Available via: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2460704.

NOTES

Philip Morris's submission to Norway's consultation on plain packaging illustrates how the company uses the two UZH papers: the papers are used directly in Philip Morris's arguments, and indirectly in reports produced by think tanks and authors affiliated with the tobacco industry.

The submission by JTI illustrates how "absence of evidence of an effect" becomes "evidence of absence of an effect": the "studies by the Universities of Zurich and Saarland **have found that plain packaging has had no effect** on smoking prevalence, either among minors or adults."

59. AUGUST 2015 – UZH ISSUES A STATEMENT ON THE EXPERT REPORT BY PROF BEN JANN

The external expert report, together with a statement from UZH, is sent "to all members of the media who had contacted us regarding the working papers by Kaul and Wolf" in early August. At least, this is what the rector of UZH told Diethelm in an email he sent him on 17 December 2015. The statement, dated 4 August 2015, is not sent to Diethelm (he learnt about it when receiving it attached to an email Professor Hengartner's sent him on 17 December 2015). It turns out that three of the five journalists to whom the statement was supposedly addressed did not receive it. The statement[167] reads as follows (original in German):

[167] Reference 84

An independent expert report on two working papers by Prof. Kaul, Saarland University, and Prof. Wolf, University of Zurich, on the effect of plain packaging on smoking in Australia is now available. Prof. Ben Jann from the University of Bern was commissioned by UZH to investigate the allegations made by "OxyRomandie". The organization accused the studies of methodological flaws and demanded that the University of Zurich remove the two working papers from its website.

In his 46-page expert report, Prof. Jann concludes that the working papers do not contain any significant methodological errors. He considers Prof. Kaul and Wolf's approach to be comprehensible, although there may have been better evaluation methods. According to Prof. Jann, the data analysis methods used, the data basis and the hypothetical assumptions have also been described with sufficient transparency so that the studies can be replicated by other researchers. In the reviewer's opinion, the controversial parts of the papers can be clarified in the usual scientific discourse.

For the University of Zurich, the accusations that the working papers are flawed have thus been refuted. Based on the expert's recommendation, the university management has decided to leave the working papers on the website of the Institute of Economics, to refer to the controversial discussion there and to make the expert report public. If the available studies by Prof. Kaul and Prof. Wolf, based on the available data, were unable to establish any evidence for the effectiveness of the plain packaging measure, this does not mean that an effect can generally be ruled out. Nor does it mean that the ineffectiveness of plain packaging has been scientifically proven.

The University of Zurich also states that scientific freedom of research was guaranteed for both working papers.

It is worth comparing this final version of the UZH statement with its draft that was the rector presented to Diethelm on 4 April 2015[168]:

Draft of 4 April 2014	*Final version of 4 August 2014*	*Comment*
	"In the reviewer's opinion, the controversial parts of the papers can be clarified in the usual scientific discourse."	Added at the end of the second paragraph
	"If the available studies by Prof. Kaul and Prof. Wolf, based on the available data, were unable to establish any evidence for the effectiveness of the plain packaging measure, this does not mean that an effect can generally be ruled out. Nor does it mean that the ineffectiveness of plain packaging has been scientifically proven."	Added at the end of the third paragraph
"The University of Zurich also states that scientific freedom of research was guaranteed for both Working Papers and that the tobacco company Philipp Morris did not exert any influence on the content of the papers."	"The University of Zurich also states that scientific freedom of research was guaranteed for both working papers."	The second clause "and that the tobacco company Philipp Morris did not exert any influence on the content of the papers" has been removed in the final statement.

NOTE

It will be seen below that OxyRomandie was not happy at all with this statement, stating that it is written in "waffling language". The suppression of the clause stating that Philip Morris did not exert any influence on the content of the papers could be taken as a thinly veiled admission that UZH was aware that such interference has indeed taken place.

[168] Reference 78a

60. AUGUST 2015 – IPE ISSUES A "PRESS STATEMENT BY PROF. KAUL AND PROF. WOLF"

On August 5, just one day after the release of the statement by UZH, a press statement is published on the website of IPE[169]. Under the title "Independent expert report regarding Kaul/Wolf working papers: no basis for Oxyromandie's defamatory campaign – Press statement by Prof. Kaul and Prof. Wolf", the statement gives the following account of the external expert's report:

> *OxyRomandie claimed that there is a "strong suspicion of scientific fraud" in two of our working papers on the potential effects of plain packaging of tobacco products in Australia. The University of Zurich had asked the independent expert Prof. Ben Jann (University of Bern, Switzerland) to assess the allegations leveled against us. The independent expert report by Prof. Jann is now available. As is clear from the conclusions of the independent expert report, there was no basis for Oxyromandie's defamatory campaign:*
>
> - *There are no fundamental "errors" or "issues" justifying the retraction of the papers.*
> - *Freedom of scientific research was ensured at all times.*
> - *Any disagreements, as the independent expert has said, "can be resolved through usual scientific discourse."*
>
> *On the contrary, some of OxyRomandie's claims and methods seem "entirely unclear" to the expert Prof. Jann. Accordingly, we hope that from now on Oxyromandie will refrain from its excessively aggressive rhetoric and personal attacks.*

The statement then provides quotations from Jann's report for each of the seven errors and seven issues raised by OxyRomandie in a way that suggest that they were all refuted in Jann's report.

Looking at the properties of the PDF file containing the press statement originally published on IPE's website (which is available on the Web Archive), one sees that its "Author" is "Olbrich, Till" and that the associated "Company" is "Philip Morris International". This name rings a bell: looking at the Contract between PMI and UZH, one sees that it was signed on behalf of the tobacco multinational by "Till Olbrich" in his capacity as VP & General Counsel[170]. This strongly suggests that the statement was written or edited by PMI.

[169] Reference IPE-6 and Reference IPE-6b

[170] Reference IPE-6a

NOTES

It should be observed that the release of this press statement by the two professors was well coordinated with the release of the statement by UZH, showing a high degree of cooperation between UZH, PMI, IPE and the two professors. This was done without OxyRomandie and Diethelm being informed (they received the declaration from the UZH more than four months later).

The fact that the two professors' press statement was written or edited by PMI is not surprising when seen in the context of Appendix 1 of the Contract.

61. NOVEMBER 2015 – DIETHELM AND FARLEY REFUTE KAUL AND WOLF SECOND WORKING PAPER

Tobacco Prevention and Cessation, a peer-reviewed journal recently created by the European Network for Smoking and Tobacco Prevention (ENSP) publishes in its November 2015 issue a paper by P. Diethelm and T. Farley entitled "Refuting tobacco-industry funded research: empirical data shows a decline in smoking prevalence following the introduction of plain packaging in Australia"[171]. The abstract reads as follows:

> *INTRODUCTION - Legislation to introduce plain packaging of tobacco products, advocated as an important tobacco control policy in the Framework Convention on Tobacco Control, has been vigorously attacked by the tobacco industry on the grounds that it results in no measurable impact on smoking rates. This claim is based on two industry-funded working papers that examined trends in smoking prevalence in Australia.*
>
> *OBJECTIVE - To assess the effect of plain packaging on smoking prevalence in Australia, taking into account key tobacco control measures introduced over the period 2001-2013, which could potentially act as confounders, with the aim of investigating the findings of the industry-funded papers.*

[171] Reference 85

[cont'd]

METHODS - Monthly smoking prevalence and sample sizes from repeat cross-sectional surveys were reconstructed from the working paper by reverse engineering of the industry presented data and analysed as a time series using logistic regression. Indicator variables reflecting comprehensive smokefree policy, graphic health warnings, 25% taxation increase, and introduction of plain packaging were constructed from official information.

RESULTS - Smoking prevalence in Australia declined from 25% to 18% over the 13 year period examined – an overall 28% relative reduction or an average annual reduction of 2.8% (95% confidence interval 2.6% - 2.9%). A significantly improved fit was obtained by the full model which included terms for tax increase (4.8%, 2.7% - 6.8% reduction), comprehensive smoke-free policy (4.5%, 1.7% - 7.2% reduction) and plain packaging (3.7%, 1.1% - 6.2% reduction) in addition to an adjusted average annual reduction of 1.7% (1.3% - 2.2%).

CONCLUSIONS - A significant decline in smoking prevalence in Australia followed the introduction of plain packaging, after adjusting for the impact of other tobacco control measures. This conclusion is in marked contrast to that of the industry-funded analysis.

The paper exposes some flaws of Kaul and Wolf's second paper. For instance, their decision to truncate the data by cutting off the first 42 months of observation is considered unjustified:

Although the statistical model we obtained is not very elaborate, controlling for only two key tobacco control measures, besides plain packaging, it provides a much better fit to the data than the crude linear model used by Kaul and Wolf, as shown by the improvement in the goodness of fit statistic indicated above. This is also visually verified by looking at the nonparametric Loess trend in Figure 1. Kaul and Wolf observed the discrepancy between the Loess trend and the time trend in the first three years. Rather than questioning the validity of their linear model, they simply cut off the first 42 months of observation, retaining only months 43-156 for their analysis. Our results show that this decision was not justified.

Diethelm and Farley report that their results exhibit a larger decrease of prevalence after the introduction of plain packaging than anticipated by the experts:

> *If further data confirm the observed decline in smoking prevalence noted in the 14 months from November 2012, this would indicate that the measure is associated with a stronger effect than anticipated. The Australian government only envisaged that plain packaging would "in the long term, as part of a comprehensive package of tobacco control measures, contribute to efforts to reduce smoking rates" Experts who commented on the measure before its implementation predicted that it would take more than two years to achieve its full impact.*

Finally, Diethelm and Farley conclude that their findings refute the results obtained by Kaul and Wolf in their second paper:

> *Our results do not support Philip Morris's assertions that there was no decrease in smoking prevalence after the introduction of plain packaging in Australia. The conclusion reached by Kaul and Wolf in their two papers was based on a subtle circular reasoning. They posited that the decrease of smoking prevalence observed in OECD countries, including Australia, follows a "pre-existing" linear trend which is independent of tobacco control policies. Starting from the hypothesis that all tobacco control measures are ineffective, they arrived at the conclusion that there was no evidence of the effectiveness of one of them, plain packaging.*
>
> *Using the same data set as Kaul and Wolf, we have shown in this paper that with the more realistic assumption that tobacco control measures can be potentially effective – as was shown by Wakefield et al. - we arrive at the conclusion that three key tobacco control measures that were introduced during the 13-year period under study, namely comprehensive smoke-free policies, the large tax increase of April 2010 and plain packaging, were all associated with a clear and statistically significant reduction in smoking prevalence. This suggests consequently that all these measures were effective. In particular, the reduction in smoking prevalence that followed the introduction of plain packaging appears to have been even greater than expected.*

62. DECEMBRE 2015 – IPE PUBLISHES REPORT FUNDED BY PMI

On 1st December 2015, IPE issues a press release[172] in the News section of its website,[173] which is announced as follows:

> *(Saarland, Germany) The IPE Institute for Policy Evaluation Saarland has conducted a study on the occasion of the third anniversary of plain packaging. In December 2012, the Australian Government implemented plain packaging for tobacco products in order to curb smoking. But three years later, governmental data and related research show that neither the rate of smoking, nor tobacco consumption have declined as a result of plain packaging.*
>
> *The study was commissioned by Philip Morris International.*

The press release is signed by Ashok Kaul, on behalf of IPE. The authors of the IPE report, entitled "Three years of plain packaging for tobacco products in Australia - Have the Expectations Been Met?"[174], refer to the two UZH studies to support of their answer "no" to the question in the title.

> *Focusing on Australia as a whole, empirical evidence based on Roy Morgan Single Source (RMSS) data suggests that plain packaging has not reduced smoking rates. RMSS has two important advantages over NDSHS [the Australian National Drug Strategy Household Survey]:*
>
> *Firstly, the annual sample size is twice as large as that of NDSHS (about 50,000, as opposed to the 24,000 of NDSHS).*
>
> *Secondly, the survey is conducted on a monthly basis, which allows for a more refined analysis of smoking rates before and after plain packaging. RMSS23 has therefore been used by several tobacco control researchers to analyze smoking behavior in Australia. Kaul and Wolf (2014a) conducted a trend analysis based on RMSS taking the existing decline in smoking behavior into account. They find no evidence of a plain packaging effect on the rate of smoking; that is, the implementation of plain packaging is not associated with a statistically significant reduction in the rate of smoking.*

[172] Reference IPE-7
[173] Reference IPE-7a
[174] Reference IPE-7b

Whereas the NDSHS data provide no useful information on the impact of plain packaging on smoking rates, neither the governmental state-level data nor the RMSS data employed by Kaul and Wolf (2014a and 2014b) indicate a decline in the rate of smoking of adults or minors that could legitimately be attributed to plain packaging. Instead, Australian state-level data and research by McKeganey and Russel (2015) suggest that smoking rates may actually have increased in the first year after the implementation of plain packaging. Consequently, the combined evidence supports the conclusion that plain packaging has not reduced smoking rates. Furthermore, state-level data indicate that only after the drastic increases in Australia's tobacco taxation in 2013 and 2014 did smoking rates continue to decline.

[…]

Using monthly RMSS data and applying a statistical trend analysis, Kaul and Wolf (2014b) specifically analyze whether plain packaging has reduced smoking rates of 14–17 year olds. They find no evidence of a plain packaging effect.

No contribution of Wolf is mentioned in the report, although he is IPE's senior adviser and one of the key IPE experts who assist the Dominican Republic in its complaint against Australia before the WTO.

NOTE

While, in their two UZH papers, Kaul and Wolf approach is fundamentally based on the assumption that smoking prevalence decreases uniformly over time, following a "pre-existing" linear trend, independent of tobacco control measures, in this report, Kaul has no problem attributing to "the drastic increases in Australia's tobacco taxation in 2013 and 2014" the fact that smoking rates continued to decline.

63. DECEMBER 2015 – DIETHELM WRITES TO THE RECTOR UZH ON BEHALF OF OXYROMANDIE

On 15 December 2015, Diethelm sends an email to the rector of UZH in follow-up to their correspondence in May 2015[175]. His email is accompanied by three attachments:

- OxyRomandie's letter to the rector, dated 14 December 2015[176]
- OxyRomandie's final comments on the expert's report[177]
- Paper by P Diethelm and TM Farley, "Refuting tobacco-industry funded research: empirical data shows decline in smoking prevalence following introduction of plain packaging in Australia"[178]

In the letter, Diethelm expresses his disappointment about the way UZH has communicated about the affair:

> *In April of this year, you kindly sent me a copy of the expert's report, asking me to treat it with confidentiality, which I did. You also indicated that the University of Zürich would soon release a media statement to communicate your comments to the journalists who had covered this topic.*
>
> *We have patiently waited for this statement to be issued, respecting our commitment of confidentiality. A few weeks ago, it was brought to our attention that a link to the expert's report had been discretely added on the pages of the two working papers on the UZH website.1 Furthermore, we also learnt that a press release had been posted on the website of IPE Institut für Politikevaluation on 5 August, which makes a distorted presentation of the expert's evaluation.*
>
> *We are disappointed about the way the University of Zürich has communicated on this issue. We were expecting better, particularly as you indicated in your email of 5 May to me that the University had "a duty to inform, as previously promised, the media of what the external expert found."*

[175] Reference 86
[176] Reference 87
[177] Reference 88
[178] Reference 85

[cont'd]

We have patiently waited for this statement to be issued, respecting our commitment of confidentiality. A few weeks ago, it was brought to our attention that a link to the expert's report had been discretely added on the pages of the two working papers on the UZH website.1 Furthermore, we also learnt that a press release had been posted on the website of IPE Institut für Politikevaluation on 5 August, which makes a distorted presentation of the expert's evaluation.

We are disappointed about the way the University of Zürich has communicated on this issue. We were expecting better, particularly as you indicated in your email of 5 May to me that the University had "a duty to inform, as previously promised, the media of what the external expert found.

Diethelm draws the rector's attention to the recent publication by IPE of a report commissioned by PMI "perpetuating the denial of the effectiveness of plain packaging" adding that OxyRomandie is "glad that at least this collaboration with the tobacco multinational no longer implicates the University of Zürich." Referring to OxyRomandie's final comments on the external expert report, Diethelm concludes his letter as follows:

After having carefully read the expert's evaluation, we consider that the essential part of our critique remains unchallenged. We persist in our assessment that the two working papers suffer from serious flaws and design misconception that are collectively damning and make them defective beyond repair.

In spite of our reservations, we agree with the expert's conclusion that the University of Zürich "add a note on the website providing the working papers or directly within the working papers) stating that these studies have been discussed controversially (including references to relevant documents)." The note should also draw the readers' attention to their defective nature and to the misleading character of their conclusions. As of today, no such note has been added. This needs to be done as a matter of urgency.[4] Furthermore, we respectfully request that, as part of the "references to relevant documents", a link be included to a copy of our comments on the expert's report, together with a link to the Diethelm-Farley article, which refutes the working papers. We also ask that the announcement of such additions be made on the homepage of the UZH website.

We still think it of crucial importance that the University of Zürich take its distance with respect to the use made by the tobacco sponsor of the two defective working papers and publicly denounce the misrepresentation of their results, notably in the tobacco multinational's submission to the UK government in response to the 2014 consultation on plain packaging. The contract that links the University to Philip Morris International gives the University the right to do so.

Failing to assume its responsibility, the University of Zürich would set an extremely worrying precedent, institutionalizing the complicity of an academic establishment in the manipulation of science by a corporate sponsor. This would imply that as long as the corporate sponsor pays, he owns the results of the studies produced by the university, which are considered purely as deliverables, and this ownership extends to the point of being able to distort and misrepresent the findings, without the university feeling any obligation or responsibility to intervene to prevent or stop the disinformation. Such an approach to partnership between the private sector and the university would wide open the door to all kind of abuses and would inevitably undermine public confidence in academic research.

We trust the University of Zürich will not let the science it produces become the prey of the tobacco industry, an inherently immoral industry. We again urge you to take the necessary corrective action.

[4] As you probably know, tobacco multinationals are currently waging large lawsuits against several countries, attacking their decisions to introduce plain packaging. They use the working papers of the University of Zürich as "proof" of the ineffectiveness of the measure.

NOTE

The external expert's request to "add a note on the website providing the working papers or directly within the working papers) stating that these studies have been discussed controversially (including references to relevant documents)" has been ignored by UZH. Diethelm's request that "as part of the 'references to relevant documents', a link be included to a copy of [OxyRomandie's] comments on the expert's report, together with a link to the Diethelm-Farley article, which refutes the working papers" was similarly ignored.

64. DECEMBER 2015 – OXYROMANDIE FINAL "FINAL" COMMENTS ON THE EXTERNAL EXPERT'S REPORT

To Diethelm's email of 15 December to the rector of UZH is attached the last "final" version of OxyRomandie's comments on the external expert's report[179]. Here is the summary provided by OxyRomandie of its comments:

> *We consider that prof. Jann's re-analysis is an improvement over the approach used in the two working papers under consideration. We also applaud his attempt at presenting an objective and balanced treatment of the issue.*
>
> *We note that prof. Jann is very critical of the two studies. He considers that the design on which they are based is "weak" and that their co-authors could have been "more careful in pointing out this weakness." He further observes that the two co-authors failed to discuss the limitation of their approach. He adds that it is "hard to find truly convincing arguments" for the key assumption on which their analysis is based, analysis which he finds "somewhat confusing" and even "inconsistent" at places. Prof Jann also agrees "that it is odd to exclude December 2012, as plain packaging came into effect in December 2012" referring to a key decision in the study on adults. He states that "better test approaches exist than the one used by Kaul and Wolf," contradicting the claim made by the two professors that no method would achieve better results than theirs.*
>
> *While we agree with prof. Jann's critical remarks, we nevertheless respectfully fear that he has failed to identify more crucial defects of the papers, by leaving unchallenged some of the key unfounded assumptions on which the co-authors base their analysis. He has used these invalid assumptions in his own re-calculation of their results, thus replicating their errors.*
>
> *A re-analysis of the data used in the study on adults has been carried out by P. Diethelm and T.M. Farley, using state-of-the art statistical methodology. They arrived at results which contradict the findings of the two professors, thus refuting their main conclusion. Diethelm and Farley's re-analysis has been published in a peer reviewed journal.[1]*

[179] Reference 88

[cont'd]

Out of the seven errors and seven issues we identified in the two working papers, prof. Jann's report provides answers to two of them which we accept; OxyRomandie has no hesitation withdrawing these two points. However, for the remaining 12 points, his explanations do not provide sufficient answers, as he either simply replicates and thus endorses the errors they contain or, when acknowledging them, he unconvincingly minimizes and relativizes their significance.

The essential part of our critique remains therefore unchallenged. We persist in our assessment that the two working papers suffer from serious flaws and design misconception that are collectively damning and make them defective beyond repair. Yet it is these very two papers that are exhibited by Philip Morris[2],[3] and other tobacco companies as the evidence that plain packaging did not work in Australia.

We still think it of crucial importance that the University of Zürich take its distance with respect to the use made by the tobacco sponsor – their partner – of these two defective studies and publicly denounce without ambiguity the misrepresentation of their results, notably in the tobacco multinational's submission to the UK government in response to the 2014 consultation on plain packaging. The contract that links the University to Philip Morris International gives the University the right to do so. Its status as a public academic institution makes it a moral obligation.

We think that, failing to assume its responsibility, the University of Zürich would set an extremely worrying precedent, institutionalizing the complicity of an academic establishment in the manipulation of science by a corporate sponsor. This is implying that as long as the sponsor pays, he owns the results of the studies produced by the university, which are thus considered purely as deliverables, and his ownership extends to the point of being able to distort and misrepresent their findings, without the university feeling any obligation or responsibility to intervene to prevent or stop the disinformation. Such an approach to partnership between the private sector and the university would wide open the door to all kind of abuses and would inevitably undermine public confidence in academic research.

We reiterate what we said in our letter of 29 January: this affair poses the fundamental question of the integrity of science. The University of Zürich should not let the tobacco industry corrupt science and should protect itself against those who want to take advantage of its influence and reputation, not hesitating to put science at the service of money and not heeding the mission entrusted to this public institution. A mission which consists in particular in disseminating a culture founded on scientific knowledge and raising public awareness of the responsibilities that teachers and academic researchers assume towards society.

[cont'd]

[1] Diethelm P and Farley TM. Refuting tobacco-industry funded research: empirical data shows decline in smoking prevalence following introduction of plain packaging in Australia. Tob. Prev. Cessation 2015;1(November):6 doi: 10.18332/tpc/60650 Available from: https://doi.org/10.18332/tpc/60650

[2] Philip Morris Limited. Response to the Consultation on "Standardised Packaging" 7 August 2014. Available from: http://www.pmi.com/eng/tobacco_regulation/submissions/Documents/UK%20-%20%20Standardised%20Packaging%20Submission%20PML.pdf

[3] Philip Morris Annex 8.1. Overview of the studies showing that there is no evidence that plain packaging has had the desired effect.pdf. Consultation on proposals for introducing standardized tobacco packaging and implementation of Tobacco Convention Article 5.3 in Norway. Available from: https://www.regjeringen.no/no/dokumenter/horing-av-forslag-til-innforing-av-standardiserte-tobakkspakninger-og-gjennomforing-av-tobakkskonvensjonen-artikkel-5.3-i-norge/id2401022/?uid=4d145cdb-ecc1-46d6-90db-653df39c6f09#

NOTES

OxyRomandie's comments remain valid today. However, after the recent disclosure of Annex 1 to the Contract, they now seem to be taking the *principle of charity* to the extreme by their treatment of two professors' research, its use by PMI for propaganda and argument in the legal arena, and UZH's attempt (successful at the time) to bury the matter.

The external expert found that he arrived at the same results as the two professors by redoing the same calculations on the same data using the same software. He did not fundamentally question their methodology, but merely noted a few shortcomings. He refrained from elaborating on the improper, let alone fraudulent, use of the two professors' findings by their corporate sponsor, and instead provided the following general explanation:

I am very sceptical of whether researchers can be held responsible for monitoring the use and interpretation of their results by others. This would be an obligation that is impossible to fulfil and it would strongly discourage researchers from publishing anything. Of course, we can expect researchers to pay attention to a correct representation of their results in press releases or similar materials, if they are given the chance to do so. But we cannot make them responsible for what is published by others and we cannot expect them to actively watch out for material misinterpreting their results.

This is a disconcerting assertion, which advocates the moral resignation of researchers in the face of dishonest use of the results of their research, particularly by those who commission them. In this case, the external expert overlooks the fact that what he calls "others" is in fact the tobacco company that commissioned the studies in question, i.e. a partner of the UZH in the project, who signed a contract with the university stipulating that any communication by either party may not take place without the express authorization of the other party.

In the external expert's defence, it was difficult for him to know this, as neither the Contract nor its Annex 1 was among the documents made available to him. It can be assumed that if he had been aware of these elements, it would have placed his assessment in a very different perspective.

One of OxyRomandie's criticisms was that the lack of proof of the effectiveness of plain packaging was falsely presented by Philip Morris and the tobacco companies as proof of its ineffectiveness, often quoting one or the other of the two professors. The external expert rejected this criticism:

> *I agree that some of the quotes provided by OxyRomandie read as "evidence for no effect" instead of "no evidence for an effect". However: (1) The difference between the two formulations is subtle and my experience is—based on teaching statistics—that people without statistical training are typically not aware of the difference. Of course, it is better to always use the correct formulation, but I do not think that it really makes a big difference [...].*

There is no need to be a statistician to understand the difference between the two formulations, which are the building blocks of the classical *ad ignorantiam* argument. The target audience of Kaul and Wolf's papers and of their sponsor's communication include policy decision makers and public health experts who know the logical difference between "evidence for no effect" and "no evidence for an effect". Using the first formulation when only the second is valid is clearly misleading, and even more so when it is endorsed by respected university professors who are supposed to fully understand the difference.

The external expert's comments on this point suggest that the researchers must refrain from interfering with the use of their results by those who have funded them: the sponsors own the results and do what they like with them. They can decide to present "no evidence of an effect" as "evidence of no effect", this is their right. **Such a policy of disengagement of the researcher has perhaps the advantage of reassuring potential private partners wishing to fund the research carried out by the university on their behalf: the university will leave them free to use the results as they see fit. The cost for society is, however, enormous: the integrity of science and academic responsibility become meaningless terms.**

For the detailed presentation of the external statistics expert's methodological assessment and of OxyRomandie comments, the reader is referred to Reference 88.

65. DECEMBER 2015 – OXYROMANDIE POSTS A STATEMENT ON ITS WEBSITE

On the same day Diethelm sent his email to the rector of UZH, OxyRomandie posts a statement on the association website.[180] The statement echoes many of the points raised in the email and its attached letter. OxyRomandie expresses its concern that the UZH may adopt the "ostrich policy" in dealing with this affair:

[180] Reference 89

OxyRomandie calls on the University of Zurich to stop burying its head in the sand in this case

OxyRomandie has the unpleasant impression that the University of Zürich has tried to cover up this affair – by following a line that is often the one adopted by the financial sponsor of these studies when the latter is confronted with a question that puts it in difficulty: no comment, no communication, total silence. In February, when the rector announced the evaluation by an external expert, he promised to communicate the results to the media who covered the case at the time. This has not been done. On the contrary, the University of Zürich has surreptitiously added a link to the expert's report on the archive pages of the website where the studies in question are located, with the utmost discretion and without saying anything to OxyRomandie. On the other hand, it seems that the German marketing research company IPE Institut für Politikevaluation has been informed, since there is a press release dated 4 August on its website which comments on this report and gives a link to download it.
[...]
If the University of Zurich refuses to take responsibility for this affair by continuing the policy of burying its head in the sand that it seems to have adopted so far, it may constitute a very serious precedent, by institutionalizing the complicity of an academic institution in the manipulation of science by a private company. As soon as a financial sponsor pays for research work carried out by the university, it would become the owner of the result of that work and would have the right to use that result as it saw fit, including misrepresenting and misleading it. The responsibility of the academic researcher would cease as soon as his or her "product" is delivered to the sponsor. Such an approach to public-private partnership would open the door wide to abuse and would inevitably sabotage the public's right to trust in academic research.

66. DECEMBER 2015 – THE RECTOR OF UZH RESPONDS TO DIETHELM'S EMAIL AND LETTER

On 17 December 2015, Professor Hengartner sends an email to Diethelm, thanking him for his mail and for the attached letter and documents. He then explains:

> *UZH did send, as I had promised you, the report, together with a statement from UZH, to all members of the media who had contacted us regarding the working papers by Kaul and Wolf. The documents were sent in early August. This communication with the media also prompted the authors' statement on the IPE's web site, which you refered to in your letter.*
>
> *I conclude from your letter that our communication department failed to send these documents also to you. This is obviously not right, as you certainly were our most important contact in this issue. I thus fully understand your surprise and irritation at discovering the link without having been informed directly, and I would like to apologize for this failure on our part.*
>
> *I fully share your point of view that UZH must distance itself from anybody who is misusing results that are generated by our scientists. I attach the statement that was sent in August to this mail. You will see that we do indeed, in the second to last paragraph, explicitely point out that the failure of Kaul and Wolf to find an effect does not mean that there is no effect, and also explicitely point out that absence of evidence is not evidence of absence.*

67. JANUARY 2016 – DIETHELM TO HENGARTNER: MOST JOURNALISTS DID NOT RECEIVE THE UZH STATEMENT

On 4 January 2016, Diethelm replies to Professor Hengartner's email of 17 December 2015[181], making the following comments:

> *I have waited until now to reply to your email as I needed to check with journalists whether they had received the UZH statement last August. Well, it seems your communication department had intended to sweep the affair under the rug, they could not have done it better. This is the answers I received from the journalists:*
>
> - *Thomas Angeli, Beobachter: "I checked my e-mail, my 'trash' and 'spam' and I find nothing … it's the first time I see this statement."*
> - *Sophie Davaris, Tribune de Genève: "I found no trace of this communication in August."*
> - *Laura Drompt, Le Courrier: "I was in Cuba in August. A search in our archives gives no indication of that such a mail was received."*
> - *Jean-Luc Wenger, Vigousse: "The message was indeed received on 4th of August while I was on holidays."*
> - *Natalie Bougeard, RTS: "I had some exchange with the University of Zürich this summer and they send me their statement."*
>
> *Concerning the statement itself, with due respect, it appears as an instance of what we call in French "langue de bois" (wooden language). If the intent is to state that the UZH is distancing itself from the misrepresentation of the study results (which are themselves false) by multinational Philip Morris, the company which commissioned the research, then I'm afraid this message will be incomprehensible to most readers. On the other hand, one would hope it to be trivially true that the university must distance itself from* ***anybody*** *who is misusing the results generated by its scientists – the contrary would be quite worrying. What we are expecting in the present affair is that the University clearly, explicitly and publicly take its distance with the way its partner* ***Philip Morris*** *abusively represented the flawed UZH studies, notably in its submissions to the UK and Norway, deliberately misleading governments in their elaboration of public health policy. Failing to do so, the University could be considered as an accomplice in the multinational's fraudulent behaviour.*

[181] Reference 90

He then draws the rector's attention to a recent tweet that illustrates how tobacco companies are exploiting the UZH studies on plain packaging in their propaganda.

> *A few days ago (on 28 December), Imperial Tobacco posted on Twitter the attached message. Such misleading communication is facilitated by the lack of reaction of the university with respect to the defects of the studies and by the absence of a clear public statement in which the UZH condemns their exploitation to falsely deny the efficacy of plain packaging.*

The tweet by Imperial Tobacco[182] used the UZH second study to debunk the "myth" that "plain packaging has significantly reduced smoking rates in Australia":

Diethelm then expresses his concerns about the way the matter is being handled by UZH and indicates the actions that OxyRomandie would be taking as a result:

[182] Reference 91a

We respectfully fear that the University of Zürich has failed so far to assume its responsibility in this affair to the extent deemed by the seriousness of the public health issue at stake. Consequently, OxyRomandie has decided to write to the governments of the UK and of Norway to correct the misleading use made by Philip Morris of the UZH studies in their responses to their consultations on plain packaging. We will also participate in the on-going consultation of the government of Singapore on plain packaging to warn them on the false and misleading character of the two UZH studies and of their misrepresentation by Philip Morris International and the other tobacco companies.

This email and all subsequent emails sent by Diethelm to the rector will be left unanswered.

68. FEBRUARY 2016 – OXYROMANDIE RESPONDS TO THE CONSULTATION OF SINGAPORE

On 13 February 2016, OxyRomandie submits its comments[183] in response to the Public Consultation Paper on Potential Tobacco Control Policies conducted by the Ministry of Health, together with the Health Promotion Board and the Health Sciences Authority of the Republic of Singapore.[184] In its submission, the association alerts the Singaporean Ministry of Health about the "flawed UZH studies funded by Philip Morris":

5. As part of [its] engagement, OxyRomandie has recently denounced research into the effectiveness of plain packaging done by the University of Zürich (UZH) on behalf of Philip Morris International. The studies published in 2014 as "working papers" on the website of the university are widely used by Philip Morris International and all the other tobacco multinationals, which present them as providing "evidence" that the introduction of plain packaging in Australia produced no effect on smoking prevalence, both in teenagers and in all smokers.

6. For instance, in its response to the UK Department of Health's consultation on plain packaging, British American Tobacco (BAT) states that "the evidence to date from Australia shows that more than 18 months after its introduction, Plain Packaging has not had any effect on smoking behaviours beneficial to public health," referring to the findings of the UZH studies.

[183] Reference 92

[184] Reference 92a

[cont'd]

7. Similarly, JTI declared in its submission to the UK consultation that after 18 months, "the evidence actually emerging from Australia reinforces the fact that plain packaging does not work", again citing the two UZH studies, adding that they "have found that plain packaging has had no effect on smoking prevalence, either among minors or adults."

8. In its submission, Philip Morris also refers to the UZH studies, saying that "the experts found no evidence that 'standardised packaging' has had an effect on smoking prevalence among Australians," adding that they "confirmed that if there had been an effect in reality ... it would have been reflected in the data."

6. For instance, in its response to the UK Department of Health's consultation on plain packaging, British American Tobacco (BAT) states that "the evidence to date from Australia shows that more than 18 months after its introduction, Plain Packaging has not had any effect on smoking behaviours beneficial to public health," referring to the findings of the UZH studies.

7. Similarly, JTI declared in its submission to the UK consultation that after 18 months, "the evidence actually emerging from Australia reinforces the fact that plain packaging does not work", again citing the two UZH studies, adding that they "have found that plain packaging has had no effect on smoking prevalence, either among minors or adults."

8. In its submission, Philip Morris also refers to the UZH studies, saying that "the experts found no evidence that 'standardised packaging' has had an effect on smoking prevalence among Australians," adding that they "confirmed that if there had been an effect in reality ... it would have been reflected in the data."

9. More recently, in its submission to Norway's consultation on proposals for the introduction of standardized tobacco packaging and implementation of Tobacco Convention Article 5.3,9 Philip Morris International included an Annex 8.1 entitled "Overview of the studies showing that there is no evidence that plain packaging has had the desired effect," in which four "studies" are listed, comprising the two UZH working papers and two reports by think tanks with links to the tobacco industry.

[cont'd]

10. The two UZH working papers – which have not been published in a peer-reviewed journal - appear to be the only "scientific publications" on which Philip Morris relies to support its claim that plain packaging had no effect on smoking prevalence in Australia.

11. However, OxyRomandie likes to point out that these papers suffer from a number of fatal deficiencies:

a. They are methodologically flawed.

b. Their conclusions are false.

c. If this were not enough, Philip Morris and the other tobacco companies further grossly misrepresent their findings.

13. It is not unreasonable to expect that Philip Morris International will again refer to the two UZH studies in its response to the present consultation. Consequently, OxyRomandie feels a duty to share with the Ministry of Health, the Health Promotion Board and the Health Sciences Authority the knowledge it possesses about these studies outsourced by Philip Morris to the University of Zürich and to warn them about their defective character, their misleading nature and the misuse made of their results by the tobacco multinationals.

14. OxyRomandie also considers it important that the attention of the Ministry of Health, of the Health Promotion Board and of the Health Sciences Authority be directed to the fact that these studies have been refuted and that a re-analysis of their data – which is of high quality - has produced results contradicting their conclusion and providing strong evidence that a significant reduction of smoking prevalence was associated with the introduction of plain packaging in Australia, even when accounting for other potentially confounding factors.

OxyRomandie then draws the Singaporean Ministry of Health's attention to the Diethelm-Farley refutation of UZH results, pointing out that their peer-reviewed paper shows that the introduction of plain packaging in Australia was associated with a significant reduction of smoking prevalence:

When analysed properly, with state of the art statistical methodology, the data on which these studies are based show a statistically highly significant effect associated with the introduction of plain packaging: a 3.7% decrease of smoking prevalence was observed during the first year after the introduction of plain packaging in Australia when taking into account the possible confounding effect of other tobacco control measures, such as the large tax increase of April 2010 and the introduction of strict smoke free policies in 2006-2007.

Finally, OxyRomandie points out the Diethelm-Farley results are robust:

There are many possible assumptions involved in the statistical analysis of a plain packaging effect given the data at hand (which is treated as a time series). Crucial assumptions relate to the statistical model: they express whether the plain packaging measure is studied in isolation or whether other tobacco control measures which might have a confounding effect are taken into consideration and included in the model. In their paper, Diethelm and Farley included the key tobacco control measures implemented during the 13-year period of analysis and let the method known as "stepwise logistic regression" select the model that best fit the data. Other assumptions concern the onset of the period of analysis, and the starting and ending month of the plain packaging period.

To illustrate this point about robustness, OxyRomandie refers to the following table:

Evaluating effect of plain packaging on smoking prevalence in Australia with RMSS survey data
(Using logistic regression analysis)

Start of period of analysis	Model	Plain package period											
		Nov.12-Dec.13			Dec.12-Dec.13			Nov.12-Nov.13			Dec.12-Nov.13		
		Prevalence reduction (%)	p-value	Best fit[1]	Prevalence reduction (%)	p-value	Best fit*	Prevalence reduction (%)	p-value	Best fit*	Prevalence reduction (%)	p-value	Best fit*
Jan.01	time+pp	3.70	0.0031		3.65	0.0045		3.75	0.0033		3.71	0.0047	
Jan.01	time+smoke.free+pp	4.64	0.0004		4.57	0.0063		4.68	0.0004		4.61	0.0007	
Jan.01	time+tax+pp	2.57	0.0470		2.55	0.0534		2.61	0.0478		2.60	0.0542	
Jan.01	time+smoke.free+tax+pp	3.66	0.0061	√	3.63	0.0076	√	3.67	0.0067	√	3.66	0.0083	√
Jul.04	time+pp[2]	1.62	0.2320		1.57	0.2550		1.68	0.2220		1.64	0.2430	
Jul.04	time+smoke.free+tax+pp	3.43	0.0317	√	3.33	0.0390	√	3.45	0.0320	√	3.36	0.0393	√

(1) Best fit using Akaike information criterion (AIC)
(2) Gray-shaded cells: model and time frame used by study of the University of Zürich funded by Philip Morris

The table is accompanied by the following comments:

20. It should be noted that all the different combinations of assumptions show a reduction of smoking prevalence (range 1.57% - 4.68%) associated with plain packaging. All of these prevalence reductions are statistically significant, except in the particular case where other tobacco control measures besides plain packaging are excluded from the analysis (at the cost of ignoring previously published studies exhibiting the importance of such control measures) while the first 42 months of observations are arbitrarily cut off. This is the combination of assumptions which were chosen for the second UZH working paper (on adults).

21. The results in the above table show that the findings of Diethelm and Farley remain when using all realistic and justifiable assumptions, achieving high statistical significance with the models that best fit the data.

NOTES

The table used to illustrate the robustness of the Diethelm-Farley results shows that all combinations of assumptions indicate a prevalence decrease associated with the introduction of plain packaging. However, when making the *least justifiable* assumption (prevalence depends on time only) combined with arbitrarily cutting off the first 42 months of observation, the decrease of prevalence ceases to be statistically significant. This is the assumptions used by Kaul and Wolf.

It will be shown later that, in their evaluation report, the Singaporean authorities have considered and then rejected the Kaul and Wolf paper, with the following explanation:

The studies arguing that the introduction of standardised packaging in Australia did not have the effect of reducing smoking prevalence or of changing smokers' attitudes towards smoking were not published in any peer-reviewed journal, appear to be methodologically flawed and have been subject to significant criticism in peer-reviewed scientific literature, including a reanalysis (of data from one of the studies) that showed a decline in smoking prevalence following introduction of standardised packaging in Australia.

69. FEBRUARY 2016 – AUSTRALIA PUBLISHES POST-IMPLEMENTATION REVIEW OF PLAIN PACKAGING

On 26 February 2016, the Australian Office of Impact Analysis announces on its website[185] the releases the Post-Implementation Review (PIR) of Tobacco Packaging. The review material consists of a report and three appendices. The report[186], entitled "Post-Implementation Review Tobacco Plain Packaging", and describes its purpose as follows:

> *This document is the Post-Implementation Review (PIR) for the Tobacco Plain Packaging Act 2011 (the TPP Act) and associated regulations (the tobacco plain packaging measure). It has been prepared by the Department of Health (the Department) in accordance with the Australian Government's applicable administrative policy for Post Implementation Reviews as administered by the Office of Best Practice Regulation (OBPR). [...] This PIR assesses the effectiveness and efficiency of the tobacco plain packaging measure to meet its objective in order to determine if it is an appropriate regulatory intervention.*
>
> *The PIR report summarizes its findings as follows:*
>
> *While the full effect of the tobacco plain packaging measure is expected to be realised over time, the evidence examined in this PIR suggests that the measure is achieving its aims. This evidence shows that tobacco plain packaging is having a positive impact on its specific mechanisms as envisaged in the TPP Act. All of the major datasets examined also showed on-going drops in national smoking prevalence in Australia. These decreases cannot be entirely attributed to plain packaging given the range of tobacco control measures in place in Australia, including media campaigns and Australia's tobacco excise regime. However, analysis of Roy Morgan Single Source Survey Data shows that the 2012 packaging changes (plain packaging combined with enhanced graphic health warnings) have contributed to declines in smoking prevalence, even at this early time after implementation. The analysis estimated that the 2012 packaging changes resulted in a "statistically significant decline in smoking prevalence [among Australians aged 14 years and over] of 0.55 percentage points over the post-implementation period, relative to what the prevalence would have been without the packaging changes".[9]*

[185] Reference 93
[186] Reference 94

[cont'd]

In light of all of this evidence, the PIR concludes that tobacco plain packaging is achieving its aim of improving public health in Australia and is expected to have substantial public health outcomes into the future.

[9] Appendix A, T. Chipty, Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia (January 2016), para. 6.

The PIR relied on the study of the impact of the plain packaging measure on smoking prevalence conducted by Dr Tasneem Chipty, of Analysis Group, Inc., who was engaged by the Australian Department of Health "to analyse the Roy Morgan data covering the period from 1 January 2001 to 30 September 2015 to see if a contribution from plain packaging could be detected at this early stage". Her study is attached as Appendix A to the PIR report[187]. Dr Chipty used the Roy Morgan data, that is the same data used by Kaul and Wolf. Under heading "Smoking prevalence and consumption data" and sub-heading "Roy Morgan Sigle Source Survey Data", the PIR report summarizes her findings as follows:

103. While plain packaging is a long term measure, the full effects of which are not expected to be realised so soon after its implementation, available data shows that smoking prevalence has declined sharply in the period following the introduction of the 2012 packaging changes. To ascertain what contribution, if any, the 2012 packaging changes made to these declines, the Department engaged Dr Tasneem Chipty of Analysis Group, Inc.,to analyse the Roy Morgan data covering the period from 1 January 2001 to 30 September 2015 to see if a contribution from plain packaging could be detected at this early stage.

104. Both of the 2012 packaging changes are designed to reduce smoking levels and to work in concert with each other. Indeed, one of the aims of plain packaging is to make graphic health warnings more effective. As noted by Dr Chipty, due to the timing of the 2012 packaging changes it is not possible to identify separately the effects of tobacco plain packaging and enlarged and updated graphic health warnings on smoking prevalence without making restrictive assumptions. The analysis undertaken was, however, able to estimate the impact of both measures working in concert from other aspects of Australia's comprehensive approach to tobacco control, such as excise increases. [...]

[187] Reference 94a

106. To estimate the impact of the 2012 packaging changes on the declines in smoking prevalence after implementation a "before-after" regression analysis of the Roy Morgan data was performed. The analysis disentangles the effects of multiple factors that may simultaneously be influencing observed smoking prevalence rates and "identifies the effect of the [2012] packaging changes by comparing smoking behaviour before the policy to smoking behaviour after" implementation. The regression analysis accounted for the rollout of other tobacco control measures (such as the 2006 introduction of graphic health warnings and the various excise increases), socio-demographic factors (such as gender, marital status, age, education, income and work status), and a trend over time.

107. Dr Chipty's analysis estimated that the 2012 packaging changes reduced average smoking prevalence among Australians aged 14 years and over by 0.55 percentage points. This result was statistically significant. The model predicts that without the 2012 packaging changes average smoking prevalence in the post-implementation period would have been 17.77% as opposed to 17.21% with the 2012 packaging changes."

The PIR report then makes the following observation:

111. In addition to the analysis commissioned by the Department, a subset of the same Roy Morgan data up to December 2013 was also analysed in industry-commissioned working papers by Professors Kaul and Wolf.[124] The papers conclude that there had been no impact of plain packaging on 14-17 year olds and that there had been no lasting impact of the tobacco plain packaging measure on those aged 14 years and older. These papers have been the subject of significant criticism by other academic experts, including in peer-reviewed journals.[125] For example, criticisms include the low statistical significance of the analytical methods used.[126]

[124] A. Kaul and M. Wolf, 'The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis' (Working Paper No. 149, University of Zurich, Department of Economics, 2014), p. 1 states that "Philip Morris International provided the funding for this research"; A. Kaul and M. Wolf, 'The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis' (Working Paper No. 165, University of Zurich, Department of Economics, 2014), p. 1 states that "Philip Morris International provided the funding for this research".

[cont'd]

[125] For example see A. Laverty, P. Diethelm, N. Hopkins, H. Watt and M. McKee, 'Use and Abuse of Statistics in Tobacco Industry-funded Research on Standardised Packaging' (2015) 24 Tobacco Control pp. 422-424; OxyRomandie, 'Errors and Issues with Kaul and Wolf's Two Working Papers on Tobacco Plain Packaging in Australia' (29 January 2015) <http://tobaccotactics.org/images/2/25/20150129-oxyromandie-letter-to-rector-uzh-annex.pdf>; Cancer Council Victoria, 'Comments on Kaul & Wolf "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis" (26 March 2014) <https://www.cancervic.org.au/downloads/tobacco_control/2013/Cancer_Council_Victoria_comments_on_Kaul_Wolf.pdf>.

[126] A. Laverty, P. Diethelm, N. Hopkins, H. Watt and M. McKee, 'Use and Abuse of Statistics in Tobacco Industry-funded Research on Standardised Packaging' (2015) 24 Tobacco Control pp. 422-424. See also Cancer Council Victoria, 'Comments on Kaul & Wolf "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis" (26 March 2014) <https://www.cancervic.org.au/downloads/tobacco_control/2013/Cancer_Council_Victoria_comments_on_Kaul_Wolf.pdf>.

The PIR then refers to the Diethelm-Farley re-analysis, indicating that its findings are consistent with Dr Chipty's results:

112. A recent peer reviewed article also re-analysed the data Professors Kaul and Wolf relied upon using "a more appropriate statistical method",[127] including accounting for the potential effect of other key tobacco control measures. The article found that the conclusions of Professors Kaul and Wolf (that there had been no decrease in smoking prevalence after the introduction of tobacco plain packaging), were incorrect and based upon "subtle circular reasoning".[128]

113. The authors conclude that the 2012 packaging changes were in fact associated with a "clear and statistically significant reduction in smoking prevalence" and that the impact of the measure "appears to have been even greater than expected".[129] These findings are consistent with the findings of Dr Chipty's analysis, which made use of more recent Roy Morgan data up to and including September 2015 (an extra almost two years of data) and also found a statistically significant drop associated with the 2012 packaging changes.

[cont'd]

[127] P. Diethelm and T. Farley, 'Refuting Tobacco-industry Funded Research: Empirical Data Shows a Decline in Smoking Prevalence Following the Introduction of Plain Packaging in Australia' (2015) 6 Tobacco Prevention & Cessation p. 3.

[128] Ibid, p. 9.

[129] Ibid.

As a follow-up to her report, Dr Chipty was "asked by Australia's Department of Health to convert the estimated reduction in smoking prevalence into an estimated reduction in the number of smokers attributable to the packaging changes."[188] She produced an addendum to her report,[189] in which she provided the following estimate:

> *[...] over the post-implementation period, I estimate that the packaging changes resulted in an average of 108,228 (=3,434,299 - 3,326,071) fewer smokers. These individuals would have continued to smoke, initiated smoking, or relapsed absent the packaging changes.*

According to her estimate, the introduction of plain packaging has reduced the number of smokers by over 100 thousand. This corresponds to saving tens of thousands of lives, as it is estimated that up to two-thirds of deaths in current smokers can be attributed to smoking[190].

The Australian Department of Health engaged Siggins Miller Consultants Pty Ltd (Siggins Miller) to, inter alia, "undertake stakeholder consultation and to conduct a cost benefit analysis of the tobacco plain packaging measure". Appendix B of the PIR is the consultancy firm's report presenting the findings of the consultation process[191], while Appendix C presents an analysis of the costs and benefits of the measure[192].

In Appendix B, Siggins Miller note the strong contrast between the views of public health stakeholders and the views of the tobacco industry, retailers and non-health related NGOs. The consulting firm makes the following observation:

[188] Reference 94a1
[189] Ibid.
[190] Reference 0p2
[191] Reference 94b
[192] Reference 94c

The tobacco industry has made prevalence the centrepiece of its opposition to the measure, asserting that the government cannot show a proximal drop in smoking rates to establish that tobacco plain packaging has met its objectives. Government and public health stakeholders note that governments did not expect that the prevalence of smoking would drop immediately following the introduction of tobacco plain packaging in the short timeframe covered by the PIR. They note tobacco plain packaging was part of a comprehensive approach to assist with continuing the trend in the reduction of smoking rates.

To the question as to whether the plain packaging measure could discourage young people from taking up smoking, Siggins Miller provides the following summary of its finding:

Tobacco company stakeholder/s, retailers, tobacco packaging manufacturers and non-health related NGO stakeholder/s who provided a negative or unsure rating commented on smoking incidence and prevalence, asserting that if there are no significant reductions in these figures since the introduction of tobacco plain packaging then the measure must not have been successful. These groups cited the following sources [...]:

- *A 2015 report by SLG economics which included analysis of Roy Morgan Research data was cited as showing that direct evidence of smoking prevalence in Australia pre and post the introduction of tobacco plain packaging does not find any statistically significant effect of tobacco plain packaging on reported usage by 14 to 17 years. In the same SLG* ***report a May 2014 University of Zurich working paper by Kaul and Wolf was cited as reinforcing that tobacco plain packaging has had no impact on smoking by 14 to 17 year olds***.

The 2015 report by SLG Economics mentioned by Siggins Miller is a report commissioned by British American Tobacco, entitled "Review of Evidence on the introduction of Plain Packaging of Tobacco Products in Australia"[193]. This report concludes that "The direct evidence from the Australian experience suggests that even when combined with other tobacco regulation measures, introducing plain packaging is unlikely to be an effective policy for meeting public health objectives in other jurisdictions." It bases its findings on "four independent surveys comparing smoking prevalence, attitudes to smoking, quitting and smoking behaviour before and after the introduction of plain packaging in Australia in December 2012". One of the surveys is the Roy Morgan Research data also used by Kaul and Wolf. SLG Economics makes its own analysis of the data, using an approach very similar to the one adopted for the UZH studies (no regulatory measure taken into consideration):

[193] Reference 94d

7.1 Analysis of Roy Morgan Research data for 14-17 year olds

The RMR dataset for 14-17 year olds has been analysed using least squares regression14 for each of the data series (FMC, RYO, pipes and cigars). The regression results [...] show no systematic relationship or significant association between the surveyed levels of FMC, RYO, pipe or cigar smoking and the introduction of plain packaging15. None of the regression models show any statistically significant impact of the introduction of plain packaging on reported tobacco usage.

This data was also reviewed by Kaul and Wolf in a University of Zurich working paper who found the same result - that there is no statistically significant evidence of an effect of plain packaging on tobacco consumption. ***Kaul and Wolf also considered various variations to their analysis and showed that these would reinforce their conclusion that plain packaging has had no impact on smoking by 14-17 year olds.*** *[...]*

7.2 Analysis of Roy Morgan Research data for adults

Kaul and Wolf have repeated their analysis of the RMR data for adults and failed to find any sustained impact of plain packaging on existing smoking prevalence trends.

7.3 Summary of evidence from Roy Morgan Research data

This direct evidence of smoking prevalence in Australia pre and post the introduction of plain packaging does not find any statistically significant effect of plain packaging on reported tobacco usage by adults or 14-17 year olds.

In its submission to the PIR consultation process, Philip Morris also made reference to the Roy Morgan data and to the two UZH studies:

c. Roy Morgan Single Source

The most robust data set with respect to smoking prevalence is from Roy Morgan Single Source (RMSS). RMSS is a commercially available data set designed and collected by Roy Morgan Research, a leading Australian research agency. Roy Morgan Research collects its data via approximately 54,000 interviews with Australians aged 14 years and older each year. The long data history allows for the identification of robust smoking prevalence trends against which to assess the actual post-implementation data. RMSS has also been used by public health advocates who advise the Australian government, and the Australian government is working with Roy Morgan Research to administer the NDSHS.

Two published research papers relying on RMSS data show how these data can be analysed to identify (or not) evidence for an effect of plain packaging. In the first of their analyses, Professors Kaul and Wolf of the Universities of Saarland and Zurich searched for evidence of a plain packaging effect on smoking prevalence among Australians aged 14 to 17 – they found none. In the second, they analysed RMSS data from Australians aged 14 years and older – and again could find no evidence of a lasting plain packaging effect.

NOTES

The report on the consultation process (Appendix B) observes that "the tobacco industry has made prevalence the centrepiece of its opposition to the measure", for which it used the two UZH studies as key pieces of evidence. In its submission, Philip Morris makes a direct reference to the two studies, which are also used in the report of a consulting firm commissioned by British American Tobacco.

The reader may also note the technique used by Philip Morris to presents the two UZH studies as scientifically credible. The studies use a "robust data set" which allows for the "identification of robust smoking prevalences". The fact that the data set is also used by "public health advocates" and by the Australian government itself further strengthen that sense of robustness. All of this creates a *priming* effect that leads the reader to assume, by a mechanism of cognitive transposition, that such robustness also applies to the statistical analysis which use the data, and, consequently, to its results.

70. APRIL 2016 – ANGELI IN *BEOBACHTER*: SMOKE PETARDS FROM THE UNIVERSITY OF ZURICH

On 15 April 2016, journalist Thomas Angeli from the German-language Swiss magazine Beobachter published an article reflecting the status of the UZH-PMI affair[194]. Here are the most important parts of the article:

Whenever a government anywhere in the world threatens to introduce cigarette packs without a logo, the tobacco lobby often likes to pull out two studies from the University of Zurich. On behalf of the cigarette multinational Philip Morris International, Zurich economics professor Michael Wolf and his colleague Ashok Kaul from Saarland University investigated whether young people in Australia smoke less since the introduction of the so-called plain packaging: tobacco companies have to omit the logo on the packet and instead print photos of diseased organs.

Philip Morris compensated the researchers with several tens of thousands of francs. Their conclusion: It cannot be proven that this cigarette packaging has an influence on whether the proportion of young smokers decreases (see Beobachter no. 26/2014). Since then, this finding has been used by the tobacco lobby as the main proof of the ineffectiveness of "neutral" packaging.

Prevention experts doubt the statements of the two economists and are demanding that the University of Zurich retract the two studies. [...]

In 2015, the University of Zurich therefore had the two studies by Wolf and Kaul reviewed by Ben Jann, a professor of sociology at the university of Bern. The professor criticized the design of the studies and said he was "not happy with all aspects". In particular, Jann criticized the fact that Wolf and Kaul had based their studies on the assumption that the proportion of smokers among young people would have fallen even without the introduction of plain packaging. There would have been "more meaningful designs", Jann wrote in his report. "The point is: we simply don't know how the trend would have developed without the measure." However, he does not believe that the studies are flawed in terms of their methodological approach. Jann therefore recommended adding a note to the studies stating that they are controversial. However, this note is still missing on the University of Zurich website.

[194] Reference 95

[cont'd]

The two "working papers" are now coming under further pressure. Prevention expert Diethelm has re-analyzed the available data himself, together with co-author Timothy Farley, who has "no connection whatsoever to the anti-tobacco movement", as Diethelm emphasizes. Their findings fundamentally contradict those of Wolf and Kaul. In their peer-reviewed article published in a specialist journal, they show that the proportion of young smokers in Australia has fallen significantly since the introduction of neutral packaging.

This finding is supported by a study conducted by the Australian government. "The analysis shows that changes in packaging (neutral packs in combination with increased graphic health warnings) have led to a decrease in smoking prevalence. " Nevertheless, the University of Zurich does not want to distance itself from the controversial studies. The accusations that they were flawed have been refuted by the expert opinion of Professor Ben Jann, the media service reports, and there is "no reason" for a retraction.

The debate is likely to continue, as the Institute for Policy Evaluation in Wiesbaden, where Kaul is the scientific director and Wolf is part of the "Research Network", has now followed up. Neutral packaging "did not reduce the proportion of smokers", according to a study published at the end of 2015. Incidentally, it was financed by an old acquaintance: tobacco multinational Philip Morris International.

NOTE

Angeli is also the co-president of Lobbywatch. According to Wikipedia, "Lobbywatch is a journalistic online platform for transparent politics in Switzerland. Founded in 2014, the association is recognised as a non-profit organisation and is based in Bern."[195]

71. MAY 2016 – UK HIGH COURT DISMISSES TOBACCO INDUSTRY CHALLENGE TO STANDARDISED PACKAGING

On 19 May 2016, the UK High Court of Justice issued the judgment by Mr Justice Green in the application for judicial review brought by tobacco manufacturers against the The Standardised Packaging of Tobacco Products Regulations 2015.[196] The tobacco manufacturers "represent the major part of the world's supply of tobacco products": British American Tobacco (BAT), Philip

[195] https://de.wikipedia.org/wiki/Lobbywatch

[196] Reference 96

Morris, JT International, Gallaher, and Imperial Tobacco. The application for judicial review is a legal mechanism enabling people or companies to challenge the lawfulness of a decision or other conduct by a public body.

Justice Green judgment is 386 pages long and comprise exactly 1000 paragraphs. The last paragraph, which is the shortest, reads:

> *1000. In conclusion I reject the Claimants' submissions.*

In the introduction section of the judgement, "some of the central issues which arise in this litigation" are summarized. The first one, which the judge considers "**at the core in this litigation**" is the "**intrinsic value of the Claimants' evidence"**:[197]

> *(5) The intrinsic value of the Claimants' evidence*
>
> *18. A core issue in this litigation concerns the intrinsic quality of the evidence submitted during the consultation, but also in the course of this judicial review. A remarkable feature of the WHO Convention (the FCTC) is that it marks out the tobacco companies as entities which have deliberately sought to undermine national health polices and it translates this considered position into a strong recommendation to the contracting states that, in effect, they apply great circumspection when assessing evidence submitted to them by tobacco interests. The FCTC position is said to be "evidence based", a claim that the tobacco companies submit is "manifestly" absurd. The FCTC contains at its heart two propositions of real significance for the present case. The first is that tobacco use is an "epidemic" of global proportions which exerts a catastrophic impact upon health. The tobacco companies do not dispute or seek to undermine the universal medical consensus as to the profound harm caused by smoking. The second, and most controversial in the context of the present proceedings, is that* ***the tobacco companies have over multiple decades set out, deliberately and knowingly, to subvert attempts by government around the world to curb tobacco use and promote public health****.*

[197] The quotations that will follow are quite long and extensive. However, they all appear to be related, directly or indirectly, to the Kaul and Wolf papers and their refutation by Diethelm and Farley, which seem to have played a core role in the judge's considerations on the "intrinsic value of the Claimants' evidence".

19. The first proposition is the premise for most of the substantive provisions of the FCTC which set out to curb smoking and tobacco consumption. The second proposition is based upon the experience of the US courts in litigation involving the tobacco companies in the course of which the tobacco companies were, after protracted interlocutory disputes about discovery and privilege, required to divulge truly stupendous quantities of internal documentation (exceeding 50 million pages). This material has now been placed in the public domain and is searchable on-line. The WHO has produced its own practical guide to searching the material. The analysis conducted of these documents by bodies such as WHO, and by the US courts, has led to some stark and, from the perspective of public health, unpalatable conclusions: in particular ***that the outward facing public statements of the tobacco companies are contradicted by their own inward facing private deliberations and analyses****. One instance of this concerns the claim by the tobacco companies that they do not market their products towards children. This proposition (repeated in this litigation) has been rejected in the US courts and by the WHO upon the basis, inter alia, of internal tobacco company documents. The FCTC requires that contracting states should exercise vigilance when dealing with the tobacco companies and should ensure that they act with accountability and transparency. The FCTC does not however spell out in detail how those principles should translate into the national laws and practices of the contracting states.*

20. In these proceedings I have analysed the conclusions of the WHO and the US courts because they bear upon the dispute between the Secretary of State and the tobacco companies as to the reliability of the evidence submitted by the tobacco companies in the course of the pre-legislative consultation, but also in this litigation. ***Put bluntly the Government says that the intrinsic quality of the tobacco company's evidence is inferior as not being in compliance with methodological best practice accepted worldwide by the scientific and technical research communities. These include such matters as: the importance of peer review of research results; the independence of researchers and experts from vested interests; the cross-referability of the reports of experts instructed by the tobacco companies against the internal documents of the tobacco companies themselves; the qualifications and competence of tobacco company experts to opine upon particular topics; and the practice of the tobacco company experts of ignoring or dismissing the pre-existing and adverse literature****. To say that the parties disagree fundamentally about these matters is an understatement.*

21. In my judgment the Government was entitled to conclude that the tobacco companies' evidence did fall below acceptable standards during the consultation. The conclusions which have arisen from the US courts about the sharp discord between what the tobacco companies think inside their own four walls and what they then say to the outside world (especially through experts), are so damning and the evidence of the discord so compelling and far reaching that it is not at all surprising that the WHO concluded that there was an evidence base upon which to found their recommendations to contracting states to apply vigilance and demand accountability and transparency in their dealing with the tobacco companies.

22. In coming to this conclusion I have not applied any sui generis rule which singles out the tobacco companies for particular and adverse treatment. The requirement that experts should act with transparency and accountability is hardly surprising. It is in fact the cornerstone of the "best practice" regimes applied by regulators worldwide when they seek to evaluate empirical evidence advanced by companies (outside the field of tobacco control) under investigation. [...]

23. I have accordingly sought to apply these principles to all of the evidence before me, from whatever source. I have applied the sorts of methodological standards that in my judgment are world-wide norms and which make sense to apply to the present facts. As a generality, ***the Claimants' evidence is largely: not peer reviewed; frequently not tendered with a statement of truth or declaration that complies with the CPR [Civil Procedure Rules]; almost universally prepared without any reference to the internal documentation or data of the tobacco companies themselves; either ignores or airily dismisses the worldwide research and literature base which contradicts evidence tendered by the tobacco industry; and, is frequently unverifiable****. I say "largely" because the quality of the evidence submitted to this Court (which included all of that tendered during the consultation) was sometimes of remarkably variable quality. Some of it was wholly untenable and resembled diatribe rather than expert opinion; but some was of high quality, albeit that I am still critical of it, for instance, because it ignores internal documents or was unverifiable.*

24. It was submitted to me that the experts instructed by the tobacco companies were highly skilled and experienced professionals. Some of the work that they have produced for the purpose of this litigation (and in particular the empirical work) is indeed extraordinarily sophisticated. However, ***as was observed in the US Courts the simple fact that an expert has a high pedigree or is a Harvard professor or a Nobel Prize winner is not a reason not to apply to their work exactly the same rigorous standards as are applied to the work of others. The report of a Nobel Prize winner as presented to a Court might be a remarkably good piece of work but if it lacks peer review or ignores contradictory internal documents or is unverifiable, its probative value may nonetheless be substantially diminished****. Nobel Prize winners should in any event be strong adherents of the very highest of international research best standards; and if they fail to live up to these standards a Court must say so and act accordingly.*

25. A point referred to repeatedly by international regulators, who routinely have to address empirical analyses of great complexity authored by individuals of stature and experience and who are leaders in their fields, is that ***transparency, accountability and verifiability are critical****. The more detailed and sophisticated the evidence tendered the greater the need for the regulator or decision maker to be able to de-construct that evidence right down to the tips of its roots in order to be able to evaluate its core structure and the assumptions upon which it is predicated and to assess them against all the available data.*

26. In this case the evidence submitted by the Claimants' experts is not capable of being verified nor its underlying assumptions tested. It has been subjected to sustained criticism by the experts instructed by the Secretary of State and these criticisms extend not only to the substantive conclusions but especially to its methodological integrity.

*27. Nonetheless, I endeavoured to conduct an exercise for myself in order to determine whether the methodological criticisms launched at the Claimants' experts were justified. This entailed taking each criticism (**for instance that a piece of research was not peer reviewed**, or was outside the expert's normal field of competence, or **included assumptions which were not backed up with evidence**, or **which ignored the existing literature base**, or which appeared to arrive at a conclusion which ran counter to internal documents of the tobacco companies) and checking its accuracy against the other documents in the voluminous Court file. **My conclusion was that, where I was able to conduct a proper cross-check, it was a validly made criticism**. It is notable that the Claimants have not materially challenged the detailed and highly particularised methodological criticisms made of their expert evidence. Rather they attack the criticism at source, contending that the "best practice" principles advocated by the Secretary of State are irrelevant, misguided or flawed and that accordingly criticisms based upon these principles simply do not strike home.*

28. In my judgment the best practice principles are just that - "best" practice. They are tried and tested across the international scientific, medical, social science, legal and economic communities. These principles fall, neatly, under the broad heading of "transparency" referred to in the FCTC; and they are logical forensic tools to be applied by a Court to evaluate evidence. Applying these standards I have rejected the Claimants' challenge to the manner in which their evidence has been treated.

Justice Green dedicates several paragraphs under subheading "**Independence & bias / conflict of interest**":

283. The importance of independence is obvious: a researcher who has no affiliation which could give rise to a conflict of interest is less likely to be subject to bias. Independence can be compromised by any sort of financial relationship with a person or party who seeks a particular result. This can extend from the provision of research funding to fees for the preparation of expert reports. But bias can arise from less overt and far more subtle sources. So for instance academics have long recognised the concept of "confirmation bias" which is said to arise when a decision maker seeks only to collect or give credit to evidence which leads to (the confirmation of) a particular preferred result. Such confirmation bias can be subconscious; it need not indicate a deliberate intent to distort an evidence collection or decision making process. […].

284. Independence is not an absolute requirement; in normal litigation where expert evidence is required experts are instructed by parties and they may be very well paid to present an opinion to the Court. The quality of that evidence cannot be automatically discounted simply because it is advanced on behalf of those who are parti pris. The same will apply to evidence submitted in the course of a consultative process. Consultees advance their point of view and frequently support that with expert evidence. Expert opinion evidence is thus submitted in a multiplicity of different circumstances ranging from consultations through regulatory proceedings to litigation. A common question therefore is how such opinion evidence is to be evaluated especially given that in the context of scientific and technical research (much of which is conducted by academics with no compromising affiliations) a premium is placed upon independence.

285. The problems associated with a lack of independence can be overcome. Where there is full disclosure of the facts giving rise to the actual or perceived lack of independence those who subsequently come to read or rely upon the research output can evaluate the research through the optic of possible bias and predisposition. ***The more acute the possible bias the more extensive might need to be the extent of the disclosure****. A researcher who receives a research grant from an interested party which served only to defray research costs may be in a different position to an individual who stands personally to gain through the receipt of a substantial fee. Disclosure of the nature and extent of the interest may therefore be important but it is not a complete answer. Sometimes the expert evidence might concern a subject matter which is of great complexity and which is, thereby, exceedingly difficult for a Court or decision maker to unravel so that the mere fact that the author has declared an interest does not equip a reader with the tools needed to determine whether in* actual fact *the research output is affected or distorted by that declared interest.*

This is certainly true of the research which is before this Court, whether it derives from pre-existing literature sources or from the new research conducted by experts instructed by the parties, such as the regression analyses. In the present case both sides accuse the other of bias or predisposition. Chantler rejected the suggestion that tobacco control experts were biased as "absurd" (Chantler Report paragraph [6.9]; see paragraph [113] above). In my view I would not wholly dismiss the proposition that tobacco control experts might, albeit subconsciously, feel so strongly about the correctness of their cause that their opinion might be influenced by that view. ***It is for this reason that whilst independence is a relevant factor it is not necessarily the determinative factor and adherence to other quality control practices such as peer review and/or benchmarking against internal documents can play an important and possibly crucial role in providing the guarantee that the research output is of the highest quality****.*

The “important and possibly crucial role” played by **peer review** is then treated by Justice Green, using as illustration the studies by Kaul and Wolf:

> *287. Peer review is the process by which an authored work is submitted to the scrutiny of others for constructive criticism. It is a process of intellectual democratisation whereby anyone can access the research and evaluate it. Not infrequently a previously unknown researcher or Ph.D student emerges from a non-mainstream academic institution who manages to puncture the previous orthodoxy and thereby contribute to the debate. The underlying premise is that “sunlight bleaches” - by exposing research results to scrutiny their strengths and deficiencies are highlighted and this not only enables the original researchers to go back and improve the work but it also enables other researchers to build on the peer reviewed platform. The process of peer review is routine in the editorial practices of the better scientific and technical publications. Material that is not peer reviewed will not by definition be of inferior quality but* ***since the practice of peer review is so widespread an absence of peer review may be a legitimate reason for querying the integrity of that research; and even more so if it is deliberately not peer reviewed. The advantages of peer review are obvious: it imposes upon researchers an incentive to ensure that their material is intellectually and evidentially robust; it enables proposals for publication to be criticised and thereby improved; and it ensures that as thinking on an issue evolves it does so with the weight of academic and scientific opinion in support. It is a process which enables concerns relating to an absence of independence to be mitigated****. The advantages can be seen by considering how research results would evolve without the process. It would mean that errors or weaknesses or bias in original research risk not being identified and there is correspondingly diminished incentive for researchers to get it right first time around.* ***If research that has not been peer reviewed is then used as a platform for subsequent researchers to build upon it can lead to errors being self-perpetuated****. Mr Derbyshire, for the Secretary of State, put the point in the following way:*
>
> *“…the degree to which the data used and the analyses of it has been independently or widely scrutinised should be considered. Such consideration helps counteract the conflict of interest issues referred to above. The analyst or decision-maker is able to place greater weight on data and analysis that describes transparently what work has been done and any issues arising (such* ***as conflicts), has been peer reviewed and has been published for critique by a wider audience. Wider scrutiny can help ensure all analysis is being considered and there is not selective reporting of favourable findings and non-reporting of unfavourable results****. Such scrutinised analysis is more informative than a non-peer-reviewed, opaque analysis seen only by a few people”.*

288. The Claimants reject this analysis. They submit that the fact that their evidence is exposed in litigation and subject to judicial review is a superior process to peer review. I fundamentally disagree. I have, in this litigation, had the opportunity to test the proposition thoroughly. I set out my conclusions in relation to Ground 3 and as to the sort of process that would have to occur to enable a Court adequately to resolve disputes of this type at paragraphs [630] – [648] below. ***Courts do not have the time or resources to take research away and then spend months unpicking and reverse engineering it so that it can be re-performed using different and improved assumptions, even assuming that the Court has the technical ability to do so****. In judicial review the argument might not even focus upon the actual nuts and bolts merits as opposed to issues such as margin of appreciation. In the present case nearly 30 expert reports have been tendered and relied upon, predominantly from the Claimants. For the most part the evidence was simply used in written submissions and as cross references in footnotes to the written submissions and only a modest proportion was in actual fact highlighted during the course of oral argument. These reports however cover an enormous array of different issues and many seek to build upon prior research a significant portion (but not all) of which is not peer reviewed or from independent researchers. It is an almost impossible task for a Court in such circumstances to assess the accuracy of the entirety of a vast body of evidence such as this. In fact this case serves to highlight the importance of the Court having available to it methodological tools, such as research best practice guidelines and principles, with which to assess the evidence.*

289. I give below one illustration of how the process of peer review can result in an iterative and incremental perfection of results. This is found in the exchange between the parties as to the relative reliability of different data sources. In his first report Professor Mulligan (for the Claimants) was critical of the 2014 Impact Assessment for failing to consider data sources that measured smoking prevalence frequently enough to permit a valid comparison of rates of prevalence immediately prior to, and following, the introduction of standardised packaging in Australia. Professor Mulligan relied, in particular, upon two pieces of research by Messrs. Kaul & Wolf8 ("Kaul & Wolf"). There is evidence that this research was funded by the tobacco industry. In this research the authors sought evidence of an effect brought about by standardised packaging upon smoking prevalence in Australia and found none. Professor Mulligan points out that the researchers modelled the trend of smoking prevalence in Australia prior to introduction of standardised packaging and considered the degree to which prevalence fell faster than that trend following standardised packaging. Professor Mulligan attributed substantial weight to the Kaul & Wolf Reports. He rejected the criticisms made of that work in the 2014 Impact Assessment for an alleged lack of statistical "power". Professor Mulligan pointed out that Kaul & Wolf did not control for changes in cigarette prices and accordingly even if standardised packaging had exerted no impact upon prevalence one would then have expected Kaul & Wolf to observe a decrease in prevalence beyond trend but since they observed no decrease beyond trend at all this suggested that standardised packaging had an, unanticipated, upward effect upon smoking prevalence.

290. In his second report Professor Mulligan returned to this theme. He, once again, relied upon Kaul & Wolf to undermine the data sources relied upon in the 2014 Impact Assessment. Other experts instructed by the Claimants also relied upon this same research.

*291. **Kaul & Wolf have, however, subsequently been peer reviewed by Diethelm & Farley**. These researchers were critical of the conclusions arrived at by Kaul & Wolf. They sought to re-work the data relied upon and concluded that, properly understood, it demonstrated the opposite conclusion to that arrived at by Kaul & Wolf**. The episode demonstrates the importance of peer review**. It is especially important if a vested interest seeks to rely, and build upon, research that it has funded because rigorous peer review minimises the risk that non-independent research results are perpetrated by other non-peer reviewed researchers with the consequence that a growing body of un-reviewed research gains traction. **I have subjected this particular episode to more detailed substantive analysis at paragraphs [619] – [624] below**. Ms Demetriou QC, in her closing submissions, then subjected Diethelm & Farley to her own forensic criticism. No doubt, other (independent) researchers may take the work of Diethelm & Farley and subject it to additional review and over time the process of peer review might result in a perfected analysis. **If, at the end of the day, it is established that the data relied upon initially by Kaul & Wolf disproves the proposition the Claimants seek to assert then it will do no more than demonstrate the critical importance of a proper peer review process being applied to precisely the sorts of evidence which are in issue in this case**. I am not (remotely) in a position to decide who is right and who is wrong. I can, however, conclude from this that the process of peer review is an important one with serious implications for the issues arising in the present litigation.*

Justice Green indicates that he subjected "this particular episode" (Kaul and Wolf being peer-reviewed by Diethelm and Farley) to a more detailed substantive analysis. We reproduce below the paragraphs where this is done:

*619. **The absence of peer review**: The quantitative evidence was almost wholly free from peer review and was not subjected to any systematic, fully transparent, process of verification which could have acted as a proxy or substitute. An illustration of the benefits of a process which subjects complex quantitative analysis to external peer review is found in the approach of the parties to the research of Kaul & Wolf (see paragraph [291] above). The Claimants' experts relied upon this research which suggested that the available data from Australia demonstrated that standardised packaging led to adverse health results. It appears (see quotation below) that this research was funded by Philip Morris. The Secretary of State however relied upon a subsequent research paper by Diethelm & Farley, "Refuting tobacco-industry funded research: empirical data shows decline in smoking prevalence following introduction of plain packaging in Australia" (November 2015). This set out to "correct" Kaul & Wolf and to provide an assessment which they said was "independent" of the tobacco industry. Under the methodology used monthly smoking prevalence and sample sizes from repeat cross-sectional surveys were reconstructed from published working papers using an original reverse-engineering technique that achieved (they said) nearly 100% accuracy. This was analysed as a time series using logistic regression analysis. Indicator variables were chosen reflecting comprehensive smoke-free policies, graphic health warnings, a 25% taxation increase, and the introduction of plain packaging. The result was that smoking prevalence declined from 25% to 18% over the 3 year period – an overall 28% relative reduction or average 2.8% (95% confidence interval 2.6% - 2.9%) annual reduction. A significantly improved fit was obtained by the full model which included terms for tax increase (4.8%, 2.7% - 6.8% reduction), a comprehensive smoke-free policy (4.5%, 1.7% - 7.2% reduction) and plain packaging (3.7%, 1.1% - 6.2% reduction) in addition to an adjusted average annual reduction of 1.7% (1.3% - 2.2%).*

620. The conclusion was expressed in the following way:

"Conclusions:
A significant decline in smoking prevalence in Australia followed introduction of plain packaging after adjustment for the impact of other tobacco control measures. This conclusion is in marked contrast to that from the industry-funded analysis".

621. The authors sought not to overstate the result:

"While it is not possible to conclude that the decrease in smoking prevalence was caused by plain packaging, it remains that the new tobacco packaging policy constitutes, at least partly, one of the most plausible explanations for the observed decrease. Another factor which may have also induced a decrease in smoking prevalence is the enlarged and enhanced health warnings, which appeared on cigarette packs conjointly with the requirement for standardized packaging. It is however difficult to completely separate these two measures from each other as the larger health warnings are an integral part of the new pack design.

If further data confirm the observed decline in smoking prevalence noted in the 14 months from November 2012, this would indicate that the measure is associated with a stronger effect than anticipated".

622. The researchers declared that they were free from any conflict of interest and did not have any specific grant from any funding agency in the public, commercial or not-for-profit sectors. The researchers took the evidence base used by Kaul & Wolf and subjected it to a full regression analysis. It is worth setting out the background to this in full:

"The multinational tobacco companies are intensively opposing the measure on several fronts, notably using international trade law and bilateral investment treaties to challenge Australia and threatening the other countries with large lawsuits and the spectre of billion-dollar financial compensations. One key legal argument used by these companies invokes the principle of proportionality, which requires that any limitation on the exercise of rights and freedom may be made only if it is suitable to achieve its aim. In spite of mounting evidence to the contrary, they claim this condition is not met in the case of plain packaging, contending that evidence of effectiveness of the measure is lacking.

[cont'd]

They even go further, resorting to the classical ad ignorantiam argument, shifting from absence-of-evidence to evidence-of-absence. In their response to the UK Department of Health's consultation on plain packaging, British American Tobacco (BAT) states that "the evidence to date from Australia shows that more than 18 months after its introduction, Plain Packaging has not had any effect on smoking behaviours beneficial to public health," referring to the Roy Morgan population survey data as evidence. Similarly, JTI declared in its submission to the consultation that after 18 months, "the evidence actually emerging from Australia reinforces the fact that plain packaging does not work", citing two studies by A. Kaul and M. Wolf published on the web-site of the University of Zurich, which "have found that plain packaging has had no effect on smoking prevalence, either among minors or adults" and a report by a UK consultancy company, all three funded by Philip Morris. A closer inspection reveals that the Roy Morgan population data cited by BAT designates the same two studies. In its response to the consultation, Philip Morris also refers to these studies, saying that "the experts found no evidence that 'standardised packaging' had had an effect on smoking prevalence among Australians," adding that they "confirmed that if there had been an effect in reality ... it would have been reflected in the data.

These two studies are presented by one of their authors as the only papers on plain packaging "based on real-world data." The authors also claimed that their methodology is the most apt at finding an effect associated with plain packaging: "Altogether, we have applied quite liberal inference techniques, that is, our analysis, if anything, is slightly biased in favor of finding a statistically significant (negative) effect [...]. Nevertheless, no such evidence has been discovered. More conservative statistical inference methods would only reinforce this conclusion." The two papers, which use nearly identical approaches, have been criticized for their methodological flaws. Most critiques related to the first study (on minors), except Laverty et al. who looked at the second study (on adults). None was based on a re-analysis of the data used by the authors. In this article, we complement these critiques by re-analysing the data set used in the paper on smoking prevalence in adults using a more appropriate method of analysis.

The two authors further assume that in Australia, like in "all the OECD countries," there is a continuous downward trend in smoking prevalence which is best modelled by a declining straight line. They explain that "we see essentially the same line in all countries" regardless of whether they have "heavy anti-smoking measures" with a "minus 0.4 percentage point effect per year." Accordingly, this decline in prevalence observed over the past 15 years across OECD countries is the result of a "pre-existing" continuous and uniform trend. Two studies published in peer-reviewed journals contradict this assumption and strongly suggest that the evolution of smoking prevalence over periods which largely overlap the period considered by Kaul and Wolf was associated with the introduction of tobacco control measures.

[cont'd]

Our objective hence was to assess the effect of plain packaging on smoking prevalence among adults in Australia based on the same data as Kaul and Wolf using a more appropriate statistical method and accounting for the potential effect of other key tobacco control measures".

623. It was observed that when Kaul & Wolf noticed that there were discrepancies in their data (the so called discrepancy between the Loess trend and the time trend for the first three years): "Rather than questioning the validity of their linear model, they simply cut off the first 42 months of observation, retaining only months 43-156 for their analysis." And also:

"The conclusion reached by Kaul and Wolf in their two papers was based on a subtle circular reasoning. They posited that the decrease of smoking prevalence observed in OECD countries, including Australia, follows a "pre-existing" linear trend which is independent of tobacco control policies. Starting from the hypothesis that all tobacco control measures are ineffective, they arrived at the conclusion that there was no evidence of the effectiveness of one of them, plain packaging.

Using the same data set as Kaul and Wolf, we have shown in this paper that with the more realistic assumption that tobacco control measures can be potentially effective – as was shown by Wakefield et al - we arrive at the conclusion that three key tobacco control measures that were introduced during the 13-year period under study, namely comprehensive smoke-free policies, the large tax increase of April 2010 and plain packaging, were all associated with a clear and statistically significant reduction in smoking prevalence. This suggests consequently that all these measures were effective. In particular, the reduction in smoking prevalence that followed the introduction of plain packaging appears to have been even greater than expected".

624. In her closing submissions Ms Demetriou QC skilfully subjected Diethelm & Farley to sustained criticism. I am not in this judgment expressing a conclusion on who is right and who is wrong. The criticisms of Kaul & Wolf seem persuasive. However, ultimately this episode demonstrates that much of the evidence in this area is as yet undercooked. It has not been subject to peer review or to any proxy process whereby it can be robustly tested.

The claimants filed an appeal on 17 grounds, which were all rejected, in a judgement issued on 30 November 2016[198]. The standardized packaging measure came into force on 20 May 2017, after UK Supreme Court refused permission to tobacco companies to appeal against the law.[199]

NOTE

It should be noted that, although the judge states that he is not expressing "a conclusion on who is right and who is wrong" between Kaul and Wolf, on the one hand, and Diethelm and Farley, on the other, his lengthy quotation from Diethelm Farley's article, which extends over three pages of his judgment, while not quoting a single line from Kaul and Wolf papers, speaks for itself.

72. MAY 2016 – WORLD NO TOBACCO DAY: "GET READY FOR PLAIN PACKAGING"

The theme of the 2016 edition of WHO's World No Tobacco Day, which happens each year on 31 May, is "Get Ready for Plain Packaging"[200]. In her video address dedicated to the event, Dr Margaret Chan, Director-General of WHO, makes the following point:

[198] Reference 96b
[199] Reference 96c
[200] Reference 98

This year in World No Tobacco Day, WHO is calling on governments to get ready for plain packaging of tobacco products. Who encourages governments to implement plain packaging for a very good reason: It works! The evidence has earned it a solid place in any comprehensive approach to tobacco control. The evidence tells us that plain packaging reduces the attractiveness of tobacco products, it kills the glamour, which is appropriate for a product that kills people, it restricts tobacco advertising and promotion, it limits misleading packaging and labelling, and it increases the effectiveness of health warnings. The evidence explains why plain packaging was included in guidelines to the WHO Framework Convention on Tobacco Control. The evidence explains why governments, like those in Australia, France, Ireland, and the United Kingdom have passed plain packaging laws. The evidence from countries with these laws explains why plain packaging has become a global movement. Let me say it again: it works. Let me say the obvious: because it works so well to control tobacco use, plain packaging has been the target of a massive tobacco industry misinformation campaign, dating as far back as 1993. WHO has stood up against this campaign, replacing falsehoods with facts. In the end, the voice of a public agency like WHO has far more credibility than the voice of an industry with such a long history of deceit. In fact, the extent of industry opposition to a control measure adds to the evidence of its effectiveness.

In the days surrounding the events, a number of French-speaking press titles evoke the UZH-PMI affair. In its edition of 25 May 2016, French satirical weekly, Le Canard enchaîné[201], a well-respected newspaper featuring investigative journalism, includes in its columns an article entitled "Philip Morris fumes over plain packaging"[202]:

[201] See https://en.wikipedia.org/wiki/Le_Canard_encha%C3%AEn%C3%A9

[202] Reference 99

Plain packaging (all cigarette packs same olive-green colour and the same format) would be ineffective in the fight against smoking. At least, that's what is claimed by two studies carried out in 2014 by the prestigious University University of Zurich. Studies that the tobacco tobacco industry is using to try to counter the measure, which came into force into force on 20 May in France.

If they are to be believed, plain packaging has not not reduced smoking rates in the countries where it has been imposed. What's more, "its introduction has led to record levels of illicit trade", we read on the website of the manufacturer of the cowboy's cigarette.

The cigarette maker doesn't cut corners.

But, as it says in small print at the bottom of the page, these studies were financed by the giant Philip Morris. They are published by the University of Zurich (UZH), because the university and the tobacco industry (sales of 70 billion in sales) have signed a secret partnership agreement in July 2013. The contract, of which Le Canard has a copy, makes the Swiss university (20,000 students) into a mere service provider, despite the fact that no fewer than twelve Nobel Prize winners have come from its ranks.

The cigarette company chooses its consultants, who are paid 9,000 Swiss francs a month (8,200 euros) and holds exclusive intellectual property rights over the university's productions. "Not only is this study riddled with gross errors, but the figures show exactly the opposite, i.e. a decline in smoking, explains Pascal Diethelm, President of the anti-smoking association OxyRomandie. And Philip Morris is using these figures in its negotiations with the health authorities."

The authors of the two studies, one of whom is a professor at UZH, also work for the Institut für Politikevaluation (IPE). Strangely enough, this institute, based in Saarbrücken (Germany), which evaluates the impact of public policies, communicates only on plain packaging. And nothing else. Pascal Diethelm suspects that the IPE is a front for Philip Morris, in the same way as INBIFO was in Cologne in the 1980s, the secret laboratory of the cigarette company, run at the time by the renowned medical professor Ragnar Rylander.

He knew all about the ravages of smoking, but was paid to keep quiet. Without coughing...

The Swiss newspaper Le Temps reports on the UZH-PMI affair on its website on 26 May 2016[203]. It asked a professional statistician to express his point of view:

[203] Reference 99a

So how do you make up your mind? According to Frédéric Schütz, an expert in statistics at the University of Lausanne, "the study conducted by the University of Zurich has statistical problems that are very typical of the mistakes that can be made". For example, the fact that the researchers chose to favour certain data by using too few years.

The article concludes with the following observation: "Since the controversy became public, the University of Zürich has not commented on the subject."

The affair is also the subject of articles in newspapers 24Heures and Tribune de Genève on 1st June 2016[204], and of Swiss satirical weekly Vigousse on 3 June 2016[205].

73. AUGUST 2016 – IPE PARTICIPATES IN WHO'S CONSULTATION ON GLOBAL NCD ACTION PLAN

On 31 August 2016, Kaul, on behalf of IPE, sends an email to WHO as part of the Web-based Consultation on Updating Appendix 3 of the WHO Global NCD Action Plan 2013-2020[206], with the following contents:

[...] regarding plain packaging (PP), most of the scientific literature has focused on the effect of PP on perceptions and appeal. My own research has dealt with actual behavior. Since the introduction of standardized packaging for tobacco products in Australia in 2012, I have carried out extensive research to evaluate the (potential) effectiveness of this measure. My professional experience includes working as a scientific expert — commissioned by one of the complainant parties, namely the Dominican Republic — in the WTO dispute on plain packaging. In addition, I have published empirical working papers on the topic:

[204] Reference 99b and Reference 99c
[205] Reference 99d
[206] Reference 100

- *Kaul A and Wolf M (2014a). The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis. University of Zurich Department of Economics Working Paper Series. May 2014; Available at: http://www.econ.uzh.ch/static/workingpapers.php?id=828.*

- *Kaul A and Wolf M (2014b). The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis. University of Zurich Department of Economics Working Paper Series, June 2014. Available at: http://www.econ.uzh.ch/static/workingpapers.php?id=844.*

Most recently, I have conducted a brief empirical study summarizing the effectiveness of plain packaging in Australia, three years after its implementation (Three Years of Plain Packaging Products in Australia — Have the Expectations Been Met?); please find the corresponding report attached. [...]

In light of the scientific evidence, I conclude that the implementation of plain/standard packaging and/or large graphic health warnings on all tobacco packages should not be included in the list of specific interventions on Tobacco Use under Appendix 3 of the WHO Global NCD Action Plan 2013-2020.

Kaul makes no mention that the studies were funded by Philip Morris. He signs his letter as "Chair of Public Policy, Saarland University, Germany".

74. NOVEMBER 2016 – KAUL AND WOLF PROPOSE TO CHANGE STANDARD OF PROOF IN WTO DISPUTES

On 11 November 2016, the journal *The Theory and Practice of Legislation* (TPLeg) publishes on its website an article entitled "Standard of proof in WTO dispute settlement proceedings: an applied statistical perspective"[207]. Its authors are professors Ashok Kaul and Michael Wolf, together with Manuel Schieler, a fulltime consultant at IPE – Institute for Policy Evaluation. All three authors declare their affiliation with IPE. In addition, Kaul and Wolf indicate affiliation with the Department of Economics of the University of Zurich, while Kaul and Schieler indicate their affiliation with the Department of Economics of Saarland University. According to his Linkedin profile[208], Schieler left Saarland University in October 2014 to become consultant at IPE.

[207] Reference 113

[208] Reference IPE-xe

Here is the abstract of the paper:

> *This paper proposes a statistical framework for establishing prima facie evidence in WTO proceedings in which empirical evidence and statistical analysis play an important role. As our main contribution, we suggest a general guideline for the choice of the significance level in a statistical analysis, in order to meet the requirements for establishing prima facie evidence of a claim. We consider a fundamental asymmetry between whether a complainant's initial claim is positive or negative. Statistically, a positive claim is one in favour of the alternative hypothesis, whereas a negative claim is one in favour of the null hypothesis. To account for this asymmetry, we suggest using different significance levels for positive and negative assertions, respectively. For positive claims, we suggest using the most commonly applied significance level of 5%. For negative claims, we suggest the less strict (but still commonly accepted) significance level of 10%. Choosing a less strict significance level in the case of a negative claim than in the case of a positive claim accounts for another fundamental asymmetry between the two possible outcomes of a statistical hypothesis test: rejecting the null hypothesis or not. Our framework helps to define reasonable hurdles in WTO proceedings to substantiate claims using statistical methods while leaving enough leeway for the panel and the Appellant Body to make adjustments on a case-by-case basis.*

The paper refers to "WTO proceedings", with emphasis on the *Australia – Tobacco Plain Packaging* WTO dispute:

> *The statistical framework presented can be applied to, but is not limited to, any WTO proceeding with empirical questions. In a typical application, complainants challenge new policies for being inconsistent with existing WTO agreements by providing empirical evidence thereof. The 2005 World Trade Report identifies two common areas of application for quantitative economic analysis in a number of WTO provisions. The first area concerns the effect of a policy measure (or its removal) on trade flows. The second area concerns the effect of imports on competing domestic products or their producers. A recent example of the former is Australia – Tobacco Plain Packaging, a WTO dispute on the introduction of the health-related measure 'plain packaging' (PP) in Australia. In December 2012, the Australian Government implemented plain packaging for tobacco products in order to curb smoking. The new measure banned cigarette brand logos on packs and therefore no longer allowed differentiation among tobacco products. Consequently, in WTO Dispute Settlements DS441, DS434, DS435, DS458 and DS467, a number of countries challenged Australia's new policy. In this context, complainants' potential claims could be 'PP leads to unfair competition' (positive claim) or 'PP is not having its intended (health-related) effect' (negative claim).*

To deal with what they refer to as the "asymmetry between positive and negative claims" in the context of the WTO dispute, the authors propose the following approach:

> *For positive claims, we suggest using the most commonly applied significance level of 5% (which is equivalent to a confidence level of 95%). In this case, evidence for an inconsistency with a provision of a covered agreement is provided by rejecting the null hypothesis that there is no inconsistency. The complainant should be asked to present such evidence at a low significance level and thus incur a low probability of a Type I error. [...]*
>
> *For negative claims, finding evidence for an inconsistency with a provision of a covered agreement is literally impossible. This task would be similar to finding evidence for no effect. Instead, a statistical test can only provide no evidence for an effect (by not rejecting the null hypothesis). To impose a reasonable hurdle on the complainant, a test should provide the most possible leeway for an 'effect' to appear. This objective can be achieved by increasing the significance level. We therefore suggest the higher (but still commonly accepted) significance level of 10% for the case of negative claims.[...]*
>
> *Our suggestions deal with providing prima facie evidence during the initial step of a WTO proceeding, in which empirical evidence and statistical analysis play an important role. We suggest extending the underlying logic and propose significance levels for the defendant's rebuttal as well. The defendant is then faced with two options. First, he can provide evidence against the complainant's claim by also using the significance level of 5% for positive claims and the significance level of 10% for negative claims.*

In a long section entitled "A primer on statistical hypothesis testing", the authors introduce the concept of the power of a hypothesis test. They write: "A power analysis relies on numerical methods (such as simulation methods) to approximate the power of a test under a certain scenario for the true state of nature. For the specification of such a scenario in practice, one must understand how the power of a test depends qualitatively on certain input parameters." The input parameters they consider comprise the significance level of the test, the effect size, the sample size, and the variability of the population.

The paper ends with a Disclosure Statement:

> ***No potential conflict of interest was reported by the author***.

NOTES

The Kaul-Schieler-Wolf (KSW) paper proposes a new way of interpretating the *p*-value of a statistical test in the context of WTO proceedings.

The authors start with the following observation:

> *In WTO dispute settlement proceedings, the complainant 'must make out a prima facie case by presenting sufficient evidence to raise a presumption in favor of its claim'. Consequently, the initial burden of proof rests with the complainant.*

They then indicate their objective:

> *If the evidence presented is empirical, such as the outcome of a statistical test, it is unclear what constitutes a 'sufficient' hurdle to establish prima facie evidence. This paper proposes a statistical framework that formalises such a hurdle.*

The authors' aim is thus to propose ***a statistical framework that formalises how prima facie evidence is established***.

They introduce a change of terminology, calling the null hypothesis the *negative claim* ("a claim that the null is true is a negative claim (non-existence of an effect)") and the alternative hypothesis the *positive claim* ("a claim that the alternative is true is a positive claim (existence of an effect)"). They use the context of "*Australia– Tobacco Plain Packaging*, a WTO dispute on the introduction of the health-related measure 'plain packaging' (PP) in Australia" to give the following example of negative claim: "PP [plain packaging] is not having its intended (health-related) effect". While admitting that "finding evidence for a negative claim is impossible through using the tools of statistics", they nevertheless propose a "framework [...] to substantiate [positive or negative] claims *using statistical methods*". (emphasis ours)

Their approach is exclusively based on the significance level:

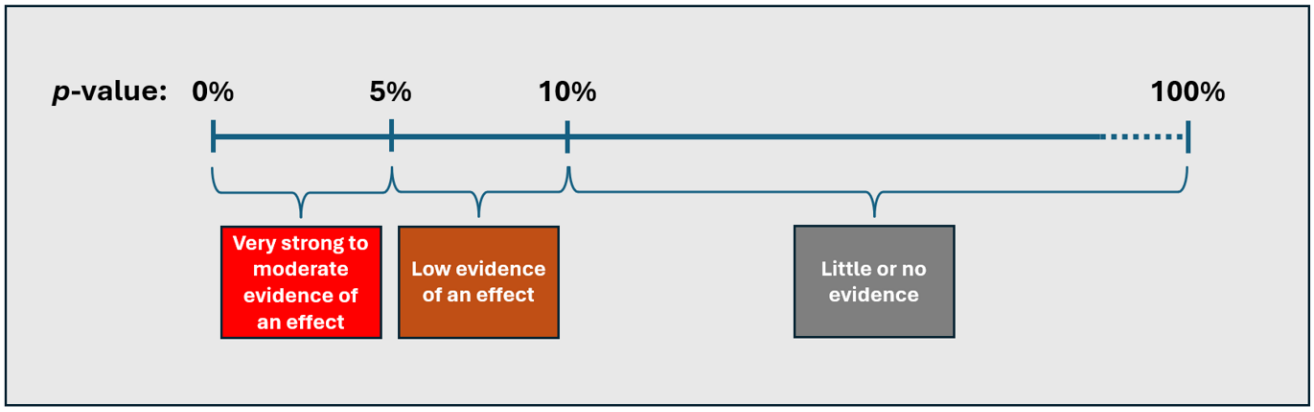
> *[...] we suggest using different significance levels for positive and negative assertions, respectively. For positive claims, we suggest using the most commonly applied significance level of 5%. For negative claims, we suggest the less strict (but still commonly accepted) significance level of 10%.*

The 10% significance level is motivated as follows:

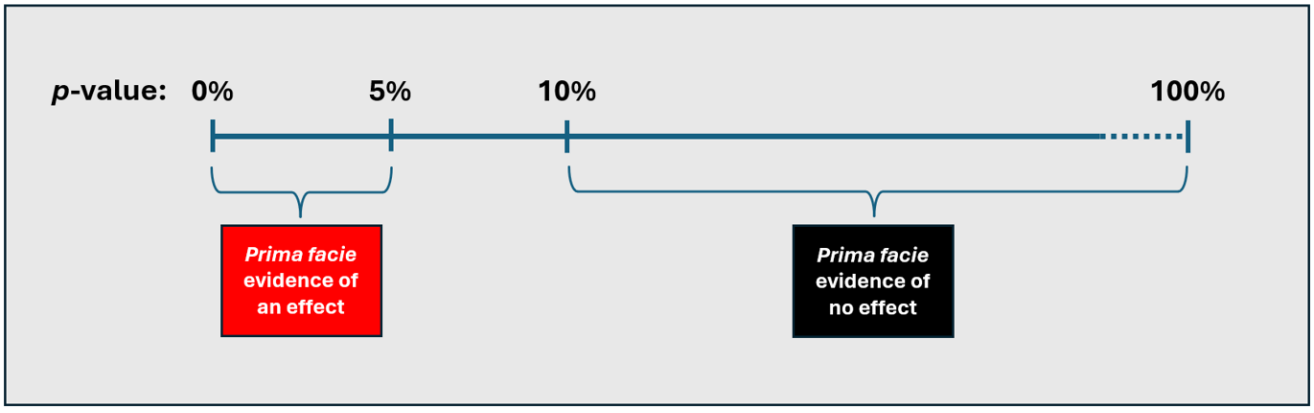
To impose a reasonable hurdle on the complainant, a test should provide the most possible leeway for an 'effect' to appear. This objective can be achieved by increasing the significance level. We therefore suggest the higher (but still commonly accepted) significance level of 10% for the case of negative claims.

The authors imply that if an effect does not appear when applying the "less strict" 10% significance level, in the context of WTO proceedings this is to be taken as *prima facie* evidence of the absence of an effect. The following figure shows how their approach differs from the standard interpretation of significance level[209]:

Standard interpretation of a statistical test



The Kaul-Schieler-Wolf (KSW) proposal



A few months before the publication of the KSW paper, the American Statistical Association published a statement in which they warned about the common misuse and misinterpretation of the *p*-value and clarified several widely agreed upon principles underlying the proper use and interpretation of the *p*-value[210]. The approach proposed by KSW seems to ignore several of these principles:

[209] For the "standard" interpretation of the *p*-value of a statistical test, see for example Reference 113a
[210] Reference 113b

1. P-values can indicate how incompatible the data are with a specified statistical model

In the online supplemental paper to the ASA statement, Greenland et al. explains[211]: "Every method of statistical inference depends on a complex web of assumptions about how data were collected and analyzed, and how the analysis results were selected for presentation. The full set of assumptions is embodied in a statistical model that underpins the method. This model is a mathematical representation of data variability, and thus ideally would capture accurately all sources of such variability. Many problems arise, however, because this statistical model often incorporates unrealistic or at best unjustified assumptions."

No mention is made by KSW of this limitation, which is particularly in the WTO "*Australia - Tobacco Plain Packaging*" case: Kaul and Wolf, and IPE, used an inadequate model in their statistical analysis of the Australian survey data, making their results and in particular the associated *p*-values uninterpretable.

3. Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold.

[...] *Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis. Pragmatic considerations often require binary, "yes-no" decisions, but this does not mean that p-values alone can ensure that a decision is correct or incorrect. The widespread use of "statistical significance"* [...] *as a license for making a claim of a scientific finding (or implied truth) leads to considerable distortion of the scientific process.*

The proposal by KSW breaches this principle, as it concentrates on the *p*-value, which is presented as a key device that complainants can use to provide prima facie evidence of their claims before WTO Panels or the Appellate Body, notably in the context of the "*Australia – Tobacco Plain Packaging*" dispute.

[211] Reference 113c

> ***4. Proper inference requires full reporting and transparency***
>
> [...] *Whenever a researcher chooses what to present based on statistical results, valid interpretation of those results is severely compromised if the reader is not informed of the choice and its basis. Researchers should disclose the number of hypotheses explored during the study, all data collection decisions, all statistical analyses conducted, and all p-values computed. Valid scientific conclusions based on p-values and related statistics cannot be drawn without at least knowing how many and which analyses were conducted, and how those analyses (including p-values) were selected for reporting.*

In the case of the working papers produced by Kaul and Wolf, transparency was lacking: most of the methodological decisions they made were only internally reported to Philip Morris at different phases in the research process. The tobacco company could decide what to do in the next phase and could, at the end, decide whether to publish or not. None of this was publicly documented. All of this has a crucial impact on the interpretation of the research results. This shows that without transparency, *p*-values may be misleading.

> ***6. By itself, a p-value does not provide a good measure of evidence regarding a model or hypothesis.***
>
> *Researchers should recognize that a p-value without context or other evidence provides limited information. For example, a p-value near 0.05 taken by itself offers only weak evidence against the null hypothesis.* ***Likewise, a relatively large p-value does not imply evidence in favor of the null hypothesis****; many other hypotheses may be equally or more consistent with the observed data. For these reasons, data analysis should not end with the calculation of a p-value when other approaches are appropriate and feasible.*

The KSW proposal says that a *p*-value greater than 10% can be taken as prima facie evidence of the absence of an effect in WTO proceedings when the complainants need to prove that the policy they challenge was ineffective. This is a breach of this ASA principle.

If the approach advocated by Kaul, Schieler and Wolf had been adopted by the WTO panels and Appellate Body, one can see how Kaul and Wolf's results from their second plain packaging paper (on 14+) could be used to argue that they provide evidence of the ineffectiveness of plain packaging, legitimating the way their sponsor, PMI, has consistently presented them. Indeed, the results of Kaul and Wolf's second paper, on the general population, is described as follows in the press release issued by IPE (which was drafted by PMI)[212]:

[212] Reference IPE-1

The experts found no evidence for a plain packaging effect on smoking prevalence using standard techniques for statistical analysis, in particular requiring a statistical significance level of 5%, which is the standard in applied research. Only when the experts structured their analysis in a way that favoured finding an effect, in particular, by requiring a statistical significance level of 10% only, could they detect "evidence for a very short-lived plain packaging effect on smoking prevalence, namely in December 2012 only (after which smoking prevalence is statistically indistinguishable from its pre-existing trend)."

[...]

As explained by Prof. Dr. Ashok Kaul, the lead author of the report:

> Using standard analytic techniques that are easy for other researchers to replicate, we found no solid evidence for a plain packaging effect in any month.
>
> Only when using statistical techniques biased in favour of finding a plain packaging effect could we detect weak evidence for a one-time effect on smoking prevalence in December 2012 itself, after which smoking prevalence is statistically indistinguishable from the pre-existing trend.
>
> Based on our analysis, one could, at most, claim an effect on smoking prevalence among the total Australian population in December 2012 only, that is, an effect that lasted no more than one month. From January 2013 on, even very powerful statistical techniques no longer can pick up any change from the pre-existing trend.

The purpose of the authors' proposal is obviously to convince WTO panel members to interpret results such as the above as proof of the ineffectiveness of the introduction of plain packaging in Australia: in December 2012, there was a "very short-lived plain packaging effect" at an inconclusive 10% significance level, and afterwards, the absence of evidence of an effect at the same 10% significance level can be assumed by the panels as proof that there was no effect.

The Dominican Republic, one of the complainants in the WTO dispute, produced before the WTO panels a report prepared by the IPE team (Kaul, Wolf and two IPE consultants) which contained results very similar to those of Kaul and Wolf' UZH papers[213]:

[213] Reference WTO-9

43. The Dominican Republic first submitted, through IPE, a statistical trend analysis of smoking prevalence using the RMSS dataset. The trend analysis consists of (1) estimating the time trend of smoking prevalence for the pre-TPP implementation period (before December 2012); (2) predicting the prevalence rate that would have been obtain in any given month following the implementation of the TPP measures on 1 December 2012, in the absence of the TPP measures using the pre-TPP implementation trend; and (3) determining whether the difference between the observed prevalence and the estimated counterfactual prevalence is different from zero by computing confidence intervals.

44. The trend analysis is undertaken by estimating either a quadratic time trend for the January 2001-March 2014 period or a linear trend model for the January 2006-March 2014 period. In both cases, IPE concludes that there is no statistical difference between observed smoking prevalence of the full population and the estimated counterfactual prevalence of the full population with the exception of the month of December 2012, implying overall that the post-implementation trend did not shift. Similar results are found when the analysis focuses only on minor population and young adult population.

It seems likely that the analysis presented in the IPE report was an extension of that used in Kaul and Wolf's two UZH working papers[214].

The affiliation of the authors with IPE, the consulting firm hired by the Dominican Republic to help them in the WTO dispute against the introduction of plain packaging is an obvious conflict of interest. The fact that Kaul and Wolf were directly involved in writing the IPE reports for the Dominican Republic makes the conflict of interest even more blatant. Both professors were paid by Philip Morris (and are likely still paid via IPE) to conduct studies that provide results which are favourable to the tobacco multinational. As PMI has a significant commercial interest in the outcome of the WTO dispute, this is another similarly blatant conflict of interest. Nevertheless, the authors ("the author"?) report no "potential conflict of interest". This is a clear breach of scientific integrity.

The two professors attempt to change the standards of interpretation of scientific and epidemiological results in a way that would be benefit the tobacco industry is not unprecedented. In the 1990s, Philip Morris attempted to change the standards for interpreting the results of epidemiological studies that estimated the increased health risks of people exposed to passive smoking compared to unexposed individuals[215]. They asked law firm Shook, Hardy and Bacon, of Kansas City, to produce guidelines they called "Good Epidemiological Practice" (GEP), with the objective of discrediting epidemiologic results with relative risks of less than 2. If these guidelines had been adopted by the scientific community, they would have

[214] The linear trend model described in the WTO document is similar to Kaul and Wolf's original model used in their second paper, in which the authors cut off the first 42 months of observation, as the early part of the data did not fit with the linearity assumption. An even larger truncation has been done here, excluding the first five years (the period of analysis starts from January 2006 instead of January 2001). The results are nearly identical as those of the UZH paper. When a quadratic component is added, the IPE analysis covers the full period of observation period.

[215] Reference 0r

nullified in one fell sweep a large body of research findings on the harmful effects of passive smoking, including the EPA's review of these research findings and the International Agency for Research on Cancer's large-scale epidemiological study, all of which concluded that exposure to passive smoking had statistically significant adverse effects (lung cancer and cardiovascular disease) with, however, relative risks of less than 2.

75. APRIL 2017 – *COCHRANE*: "STANDARDISED PACKAGING MAY REDUCE SMOKING PREVALENCE"

On 27 April 2017, the Cochrane Library[216] publishes on its website a new Cochrane Review entitled "Tobacco packaging design for reducing tobacco use". In a press release[217] in seven languages (English, German, Italian, Malay, Polish, Russian, and Spanish), the Cohrane Library announces that "New evidence finds standardized cigarette packaging may reduce the number of people who smoke", providing the following summary:

> *A number of countries have implemented, or are in the process of implementing, standardized tobacco packaging. Australia was the first country in the world to implement standardized packaging of tobacco products. The laws, which took full effect there in December 2012, also required enlarged pictorial health warnings.*
>
> *A team of Cochrane researchers from the UK and Canada have summarized results from studies that examine the impact of standardized packaging on tobacco attitudes and behaviour. They have published their findings in the Cochrane Library.*
>
> *The author team found 51 studies that looked at standardized packaging. The studies differed in the way they were done and also what they measured. Only one country had implemented standardized packaging at the time of this review,* ***so evidence that tobacco use prevalence may have decreased following standardized packaging comes from one large observational study****.*

The full Cochrane Review[218] provides a "plain language summary" of it "key results" as follows:

[216] See https://www.cochranelibrary.com/?contentLanguage=eng
[217] Reference 101
[218] Reference 101a

We found 51 studies involving approximately 800,000 participants. These studies varied considerably. Some studies focused on the effect of standardised packaging in Australia, and included looking at overall smoking levels, whether smokers altered their behaviour such as by cutting down the number of cigarettes they smoked, and whether smokers were making more quit attempts. We also included experiments in which people used or viewed standardised tobacco packs and examined their responses, compared to when they were viewing branded packs. We also included studies that assessed people's eye movements when they looked at different packs and how willing people were to buy, and how much they were willing to pay for, standardised compared to branded packs.

Only five studies looked at our key outcomes. One study in Australia looked at data from 700,000 people before and after standardised packaging was introduced. This study found that there was a half a percentage point drop in the proportion of people who used tobacco after the introduction of standardised packaging, compared to before, when adjusting for other factors which could affect this. [...]

Under heading "**Primary outcomes: changes in tobacco use**", the review reports on its findings:

Primary outcomes: changes in tobacco use

We found five published studies which examined changes in tobacco use. Three were from Australia, assessing the impact of standardised packaging legislation implemented in 2012 (Diethelm 2015; Miller 2015; Scollo 2015). Two were experimental studies from the UK (Maynard 2015; Moodie 2013).One study examined changes in prevalence (Diethelm 2015) and four studies examined changes in tobacco consumption among smokers (Maynard 2015; Miller 2015; Moodie 2013; Scollo 2015). No studies examined changes in relapse and tobacco uptake.

Changes in tobacco use prevalence

Diethelm 2015 assessed the effect of standardised packaging on smoking prevalence among 700,000 adults (aged 18+) in Australia, with the aim of investigating the findings of a tobacco industry funded paper which was not published in the peer-reviewed literature (Kaul 2014). Kaul 2014 concluded that standardised packaging had no effect on reducing smoking prevalence. The study used serial cross-country weekly surveys with a random sampling design and were nationally representative of Australia. For the period from January 2001 to December 2013 (one year after mandatory full implementation of standardised packaging), prevalence figures were extracted and computed from data presented within Kaul and Wolf's working paper, adjusted for the following policies introduced over the 13-year period: graphic health warnings (but not the enhancement of health warnings introduced alongside standardised packaging in 2012), smoke-free policies, and tax increases on tobacco products. A separate unpublished report from the Australian Government (Chipty 2016) also uses the same data as Diethelm 2015 and Kaul 2014. Given that they rely on the same data set, we have incorporated findings from Chipty 2016 and Kaul 2014 in our analysis of Diethelm 2015.

These findings are further elaborated in the Results section of the report:

Prevalence

The one included study assessing the impact of standardised tobacco packaging on smoking prevalence in Australia (Diethelm 2015) found a 3.66% reduction in odds (P = 0.0061) when comparing before to after the implementation of standardised packaging, adjusting for confounders (= -0.0372, 95% confidence interval (CI) -0.0638 to 0.0106; n = 700,000). This is consistent with a drop in the proportion smoking from 19% to 18.5%, i.e. a 0.5 percentage point drop in smoking prevalence around the time of the change. Two further unpublished papers make use of the same data set and hence are classed as additional references under Diethelm 2015. A paper written for the Australian government (Chipty 2016) detected very similar findings, despite using slightly different methodological approaches; the authors found a statistically significant decline in smoking prevalence of 0.55 percentage points over the post-implementation period, relative to what the prevalence would have been without the implementation of standardised packaging. A separate paper written for the tobacco industry (Kaul 2014) did not detect an effect attributable to standardised packaging; there are three key differences in their methods which may have led to these different conclusions. Firstly, ***Kaul 2014 chose to model the overall time trend for a shorter period of time (from July 2004 onwards, rather than from 2002); they state they have done so because the trend appears non-linear in the first two years compared to later years. However, the analysis in Diethelm 2015 makes some allowance for this by the inclusion of additional covariates and hence Diethelm's final model (unlike that of Kaul) is not a simple linear time trend****. Secondly,* ***Kaul 2014 excludes December 2012 from their analyses (when standardised packaging came into effect), whereas both Diethelm 2015 and Chipty 2016 include this month; this appears to be a post hoc decision made in the Kaul 2014 analysis****. Thirdly, Kaul 2014 primarily analyses residuals, rather than estimation of the trend before and after the implementation of standardised packaging, which Diethelm 2015 and Chipty 2016 have done.*

Given the consistency in findings between Diethelm 2015 and Chipty 2016 *and given that Diethelm 2015 is the primary reference for this study (as the only peer-reviewed published reference analysing this data set),* ***our conclusions on this outcome are based on those presented by Diethelm 2015****.*

On the same date (27 April 2017), the British newspaper The Guardian covers the publication of the Cochrane Review with two articles, the first under the title "Plain cigarette packaging could drive 300,000 Britons to quit smoking"[219] and the second entitled "Standardised cigarette packaging is on its way, but will it reduce smoking?"[220], in which the following summary of the review is given:

> *A new systematic review of all the studies investigating the impact of standardised packaging has been published by the Cochrane review, a global independent network that produces reviews of important health topics to aid informed decision making. It identified 51 peer-reviewed studies that in some way looked at standardised packaging. The review particularly focused on associations between the use of standardised packaging and changes in the prevalence of smoking, be it the number of people starting smoking, the number of people stopping, or the number of people relapsing back to smoking after attempting to quit.*
>
> *Of the 51 studies they found, only 5 had looked at these particular outcomes in relation to the introduction of the packaging changes. All of these were conducted in Australia, where standardised packaging was introduced at the end of 2012. The largest of these studies assessed the prevalence of smoking in 700,000 Australians up to one year after the introduction of standardised packaging. This study found that smoking prevalence had dropped after the introduction of the packaging, although the difference was small – an absolute difference of around 0.5%.*
>
> *The authors of the review are cautious not to draw too firm conclusions, partly because they are largely based on just this one study, and also because it's extremely difficult to assess the impact of a nationwide policy change. When standardised packaging was introduced in Australia, legislation also changed related to the pictorial warning on cigarette packets. Therefore it's almost impossible to tease out whether changes in smoking behaviours are due to standardised packets, the new pictorial health warnings, or some combination of the two. They do point out that routine data on smoking gathered by the Australian government back these findings up.*

NOTE

The "large observational study" providing "evidence that tobacco use prevalence may have decreased following standardized packaging" referred to in the Cochrane Library's press release is the Diethelm-Farley study. The UZH study was rejected as suffering from serious methodological limitations. The authors of the review observe that Kaul and Wolf may have obtained a different result from Diethelm and Farley because they opted for simply modelling

[219] Reference 101b
[220] Reference 101c

the time trend, while Diethelm and Farley have included additional covariates and in their final model, which "(unlike that of Kaul) is not a simple linear time trend".

76. NOVEMBER 2017 – PUBLICATION OF DIETHELM AND FARLEY'S REANALYSIS OF UZH STUDY ON MINORS

Tobacco Prevention and Cessation, a peer-reviewed journal, publishes in its November 2017 issue, Diethelm and Farley's re-analysis of the first UZH study on the effect of plain packaging on minors in Australia. Its title is "Re-analysing tobacco industry funded research on the effect of plain packaging on minors in Australia: Same data but different results". Here is the abstract of the paper:

> ***Introduction**: Our objective was to re-analyse the data used in an industry-funded working paper to study the effect of plain packaging on youth smoking prevalence in Australia, allowing for other tobacco control measures introduced over the period 2001-2013, and using a more appropriate method of analysis.*
>
> ***Methods**: Monthly smoking prevalence and sample sizes from repeat cross-sectional surveys were reconstructed from the working paper by reverse engineering of the industry-presented data, and analysed as a time series using logistic regression. Power analysis presented in the industry-funded working paper was re-calculated.*
>
> ***Results**: Smoking prevalence among minors in Australia declined from 11.6% to 5.6% over the 13-year period examined; an overall 52% relative reduction or an average annual reduction of 5.5% (95% confidence interval 4.6% to 6.4%). There was a 12.1% (-4.8% to 26.2%) relative reduction in smoking prevalence when plain packaging was introduced, though the reduction was not statistically significant. Re-calculated power values were much lower than those reported in the industry-funded paper, confirming the inconclusiveness of its findings, as pointed out in previous critiques.*
>
> ***Conclusions**: Our findings suggest a decline of smoking prevalence in minors following the introduction of plain packaging in Australia. They differ substantially from those presented in an industry-funded study on the effects of plain packaging on smoking prevalence in minors in Australia, which used the same data.*

In their re-analysis of Kaul and Wolf first working paper, Diethelm and Farley's looked at the power of their results, which was at the centre of the two professors' response to the Lancet criticism:

Our results confirm what Laverty and colleagues [11] had pointed out: given the data at hand, and the small sample sizes, ***Kaul and Wolf's method lacked sufficient power for detecting the likely impact of PP on smoking prevalence amongst minors*** *in Australia during the first year after the measure was implemented. With the PP effect level that could be plausibly expected (0.5 percentage point absolute decrease of prevalence),* ***their method actually had a much greater probability of not finding an effect than of finding one****. It is therefore not surprising that they did not find any evidence of a PP effect. Our results contradict Kaul and Wolf's statement that 'if anything' their analysis was 'slightly biased in favor of finding a statistically significant (negative) effect of plain packaging on smoking prevalence of Australians aged 14 to 17 years'.[5]*

The best that could be said of their analysis is that it was inconclusive. Furthermore, while emphasizing that their analysis did not discover evidence of a PP effect, Kaul and Wolf added that '[m]ore conservative statistical inference methods would only reinforce this conclusion'. Table 1 [not reproduced here] shows that the power figures, associated with the more 'conservative' 95% confidence intervals, are all lower than those associated with their 'liberal' 90% counterparts; contrary to their assertion, more conservative approaches are in fact less conclusive.

[5] Kaul A and Wolf M. The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis. University of Zurich Department of Economics Working Paper Series. May 2014. Available at: http://www.econ.uzh.ch/static/workingpapers.php?id=828 (accessed August 2017)

[11] Laverty AA, Watt HC, Arnott D, et al. Standardised packaging and tobacco-industry-funded research. The Lancet 2014; 383(9926):1384. doi: 10.1016/s0140-6736(14)60499-2

Diethelm and Farley conclude their paper as follows:

> *On the same day Kaul and Wolf's first working paper was posted on the website of the University of Zürich, Philip Morris International issued a press release entitled 'Researchers Find No Evidence Plain Packaging "Experiment" Has Cut Smoking'[23], in which the two UZH researchers were quoted explaining: 'We used statistical methodology that gave every possible leeway for detecting a possible plain packaging effect. Nevertheless, the data does not support any evidence of an actual effect of the Australian Plain Packaging Act on smoking prevalence of minors.' In the response it submitted a few months later to the UK government's consultation on standardized packaging[24], PMI went even further and presented the results of the UZH study as follows: '(...) using standard techniques for statistical analysis and applying the standard statistical significance level of 5%, the experts found no evidence that "standardised packaging" had had an effect on smoking prevalence among Australians aged 14 to 17 years old [...]. Kaul and Wolf confirmed that if there had been an effect in reality [...], it would have been reflected in the data. According to the study, however, no effect was found'. This strong statement was logically equivalent to saying that Kaul and Wolf's study had actually proved that plain packaging was not effective.*
>
> *Our results showed that this conclusion was unjustified:* ***Kaul and Wolf's results on minors are at best inconclusive****. Their method applied to the Roy Morgan survey data on minors lacked power to produce a significant conclusion:* ***the critique by Laverty at al.[11] is thus confirmed****. Furthermore, Kaul and Wolf were mistaken when they claimed that more 'conservative' approaches than their 'liberal' method would reinforce their findings: we saw that such approaches are actually weaker.*
>
> *Contrary to Kaul and Wolf's conclusions, our logistic regression analysis suggests a plain packaging effect in the expected direction, although this is not statistically significant, the data set on minors being too small and thus lacking the power needed to reach a firmer conclusion.*

NOTE

It could be noted that B. Jann, the external statistics expert, reached a similar conclusion as Diethelm and Farley in his Methodological Report on Kaul and Wolf's Working Papers:[221]

[221] Reference 75, p. 15

Bound to a strict interpretation of significance tests (employing a usual 5% significance level), we would conclude from these results that there is no convincing evidence for an effect of plain packaging on smoking prevalence, neither for minors nor for adults and irrespective of whether we use two-sided tests or one-sided tests. However, if we employ a more gradual interpretation of statistical results without resorting to strict (and somewhat arbitrary) cutoffs, ***we can acknowledge that the effects at least point in the expected direction****. For example, using a one-sided test, the p-value from the logistic regression for minors is p = 0.062, which is not far from the conventional 5% level.*

77. FEBRUARY 2018 – SINGAPORE RELEASES CONSULTATION PAPER ON TOBACCO CONTROL MEASURES

On 5 February 2018, the Ministry of Health of Singapore releases its Public Consultation Paper on Proposed Tobacco Control Measures in Singapore[222]. One of the proposed measures is the introduction of plain packaging for tobacco products. The report evaluates extensively the evidence *against* plain packaging:

[222] Reference 103

4.4 Evaluation of evidence against standardised packaging

In the course of evaluating the evidence for the efficacy of the SP Proposal, the Government reviewed various reports and studies with findings that did not support the conclusion that standardised packaging would be an effective measure in meeting its stated policy objectives. […]

The Government […] notes that a team of Cochrane researchers from the United Kingdom and Canada had, in 2017, summarised results from studies that examined the impact of standardised packaging on tobacco attitudes and behaviour and concluded that the evidence to support the effectiveness of standardised packaging in affecting tobacco use prevalence was of low "grade" because the studies reviewed were not randomised controlled clinical trials.[71]

*However, as observed by Professor Chia and Associate Professor Miller, it would be difficult (if not impossible) to evaluate the impact of population-level interventions such as standardised packaging through randomised controlled clinical trials. Moreover**, the Cochrane researchers did in fact conclude that the evidence suggested that standardised packaging may have the effect of reducing smoking prevalence**.*

The Government's attention has also been drawn to materials which claim that Australia's plain packaging measure had failed to reduce smoking prevalence in Australia. These materials included reports commissioned by the tobacco industry, one other study by experts linked with the tobacco industry, and a literature review on standardised packaging and health warnings.

Briefly, the evidence against standardised packaging as set out in these reports and studies is as follows:

- There is no proof that the introduction of plain packaging in Australia has had the effect of reducing smoking prevalence. Smoking prevalence was on a linear downward trend among both adults and adolescents prior to the introduction of plain packaging and there is no evidence that the measure affected the rate of decrease.[73]

[…]

[cont'd]

Having carefully considered the various reports and studies that suggest that the Australian plain packaging measure has not been effective, and having taken into account the assessment of Professor Chia and Associate Professor Miller on these reports, the Government is of the view that ***these reports should be accorded limited weight. This is because, on an overall assessment and based on criteria that include the independence of the authors and peer-review status, the quality of evidence supporting the effectiveness of standardised packaging and enlarged graphic health warnings significantly exceeds that of the evidence against the same****. In summary, the Government notes that:*

- The evidence for standardised packaging is based on studies conducted over a considerable period of time and amongst many different groups of people. The totality of the evidence set out in Parts 4.2 and 4.3 above and the consistency of their conclusions are a strong indicator that standardised packaging is likely to be an effective measure.

- The studies arguing that the introduction of standardised packaging in Australia did not have the effect of reducing smoking prevalence or of changing smokers' attitudes towards smoking were not published in any peer-reviewed journal, appear to be methodologically flawed and have been subject to significant criticism in peer-reviewed scientific literature, including a reanalysis (of data from one of the studies) that showed a decline in smoking prevalence following introduction of standardised packaging in Australia.[79] In contrast, the Post-Implementation studies from Australia consist of a substantial body of federal and local surveys evaluating the early impact of Australia's standardised packaging measure and supporting the conclusion that Australia's standardised packaging measure had begun to show its intended impact of reducing the appeal of tobacco products, increasing the noticeability of graphic health warnings and reducing the ability of tobacco product packaging to mislead about its harmful effects.

The Government and its experts have also carefully reviewed the studies underlying the Australian Post-Implementation Review and share the view that their methodologies are sound and their findings can be relied upon.

[cont'd]

[71] McNeill A, Gravely S, Hitchman SC, Bauld L, Hammond D, Hartmann-Boyce J. Tobacco packaging design for reducing tobacco use. Cochrane Database of Systematic Reviews. 2017, Issue 4. Art. No.: CD011244.

[73] Kaul A, Wolf M. The (possible) effect of plain packaging on smoking prevalence of minors in Australia: A trend analysis. 2014. Available at: http://www.econ.uzh.ch/static/workingpapers.php?id=828; Kaul A, Wolf M. The (possible) effect of plain packaging on smoking prevalence in Australia: a trend analysis. 2014. Available at: http://www.econ.uzh.ch/static/workingpapers.php?id=844.

[79] Diethelm PA, Farley TM. Refuting tobacco-industry funded research: Empirical data shows decline in smoking prevalence following introduction of plain packaging in Australia. Tobacco Prevention & Cessation. 2015; 1:6.

The above evaluation refers to "the assessment of Professor Chia and Associate Professor Millea" on "the various reports and studies that suggest that the Australian plain packaging measure has not been effective". In their report, entitled "Review of literature and research on the policy impact of standardised packaging for tobacco products"[223], Chia and Millea make the following commented on the Kaul and Wolf's studies:

The Australian PIR [post-implementation review] also reviewed the prevalence of tobacco use based on several surveys:

a. [...]

b. Another industry-commissioned analysis by academics Kaul and Wolf used a smaller and shorter subset of the Roy Morgan data and concluded that there had been no impact on 14-17 year olds and no lasting impact on those 14 years and above. However, ***the Australian PIR pointed out the significant flaws and criticisms by other academic experts, and that there was a recent peer-reviewed article that re-analysed the same dataset with a more appropriate statistical method and found that there was a "clear and statistically significant reduction in smoking prevalence" and that the impact of the measure "appears to have been even greater than expected"****.*

[223] Reference 103a

NOTE

The "recent peer-reviewed article that re-analysed the same dataset with a more appropriate statistical method" refers to the first paper (November 2015) by Diethelm and Farley.

78. MARCH 2018 - IPE SIGNS THE GLOBAL COALITION LETTER AGAINST PLAIN PACKAGING

On 20 March 2018, a coalition of 62 organizations publish on the website of the Property Rights Alliance[224] an open letter to Dr. Tedros A. Ghebreyesus, Director-General of WHO, under the heading "5 Years of Failure: Global Coalition Letter Against Plain Packaging"[225]. The letter contains the following statement:

> *Plain packaging in Australia has been a complete failure and has not met its overall policy objective to reduce smoking incidence. The latest independent research on the impact of plain packaging in Australia, using data paid for by the Commonwealth government, finds "no statistically significant difference in effectiveness of the graphic health warning as a result of the policy being introduced—if anything that effectiveness declined.*

The letter terminates by engaging in a *slippery slope* argument about the consequences of the adoption of plain packaging for tobacco products:

> *After Australia implemented the policy, other industries have been targeted around the world: alcohol, sugary beverages, fatty foods, even toys. These industries employ millions and any regulation that would deny key IP assets would have a devastating global economic impact. The trademark value alone of only twelve companies associated with these sectors is estimated to be more than $1.8 trillion.*
>
> *The costs of plain packaging are enormous: the loss of the innovation incentive to the economy and society are inestimable, the mutilation of established international IP law is unprecedented, and the market carve-out to illicit actors, including terrorists, is reprehensible. It is beyond reason that such a policy continues to be pursued, even after it has failed to achieve its intended goal.*

[224] "Property Rights Alliance (PRA), an affiliate of the Tholos Foundation, stands as an advocacy organization dedicated to the protection of innovation, intellectual property rights, and physical property rights around the world." - https://www.propertyrightsalliance.org/about/

[225] Reference 104

The costs of plain packaging are enormous: the loss of the innovation incentive to the economy and society are inestimable, the mutilation of established international IP law is unprecedented, and the market carve-out to illicit actors, including terrorists, is reprehensible. It is beyond reason that such a policy continues to be pursued, even after it has failed to achieve its intended goal.

Finally, the signatories conclude by urging "the WHO and governments around the world to stop infringing on intellectual property rights with plain packaging policies."

An analysis of the 62 signatories[226] reveal that they consist for the great majority of them (46 out of 62) of neo-liberal/free-market think tanks which are members of the Atlas Network[227]. Among the others are 3 small private consulting companies and 4 one-person organizations/blogs.

The letter is signed by Ashok Kaul on behalf of IPE – Institute for Policy Evaluation. The logo of IPE appears of the first page of the letter.

NOTES

At the time of signing the letter, Kaul held the position of "Senior Research Affiliate in Econometrics and Applied Statistics" at the University of Zurich. Signing the open letter on behalf of the IPE shows that both Kaul and IPE are actively engaged in the fight against plain packaging. This, together with its close links to PMI, shows that the consulting firm acts as an arm of the tobacco industry in its campaign against plain packaging.

This letter also provides a good illustration of the role played by neo-liberal think tanks in opposing governmental regulations, which the tobacco industry uses very effectively in its fight against plain packaging.

79. JUNE 2018 – AUSTRALIA WINS TOBACCO PLAIN PACKAGING DISPUTE AT THE WTO

On 29 June 2018, the British newspaper The Guardian publishes an article entitled "'Resounding victory': Australia wins tobacco plain packaging dispute"[228]. The day before, on 28 June 2018, the World Trade Organization published the Reports of the Panels reporting the WTO decision on the dispute between Australia and four countries, which the Guardian summarized as follows:

[226] Reference 104b

[227] See https://en.wikipedia.org/wiki/Atlas_Network

[228] Reference 104

Australia has triumphed in a major trade dispute over its tobacco plain packaging law, with World Trade Organisation judges rejecting a complaint brought by Cuba, Indonesia, Honduras and the Dominican Republic.

The WTO panel said Australia's law improved public health by reducing the use of tobacco products, rebuffing claims that alternative measures would be equally effective. It also rejected the argument that Australia had unjustifiably infringed tobacco trademarks and violated intellectual property rights.

Initially, there were five complainants (Ukraine, Honduras, Dominican Republic, Indonesia, and Cuba), which requested the establishment of panels to examine their objections. The five panels were composed of the same three panellists: Mr. Alexander Erwin, chair, from South Africa (Minister of Public Enterprises, 2004-2008), Mr. François Dessemontet, from Switzerland, (former Dean of the Faculty of Law, University of Lausanne), and Ms. Billie Miller, from Barbados (Deputy Prime Minister, 1994-2003)[229,230]. In May 2015, Ukraine withdrew from the dispute. The panellist produced a consolidated report that grouped the four remaining complaints.[231]

Extracts from key documents related to the Australia-plain packaging disputes at the WTO are shown in **Appendix 2**[232] to this chronological record. The appendix starts with a summary of the case provided by the McCabe Centre for Law and Cancer[233], which presents the decision of the panels as follows:

The Panel rejected all of the complainants' claims that Australia's measure is inconsistent with WTO rules. The Panel confirmed Australia's tobacco plain packaging measure is making a meaningful contribution to improving public health.

The Dominican Republic presented as exhibits five reports by the Institute for Policy Evaluation (IPE):

- "Empirical Assessment of Australia's Plain Packaging Regime" (Exhibit DOM-100: IPE Report, 7 October 2014)
- "Updated Empirical Assessment of Australia's Plain Packaging Regime" (Exhibit DOM-303: IPE Updated Report, 14 September 2015)

[229] Reference 17 and Reference WTO-7, 1.27, page 66. Note that in the WTO reports, "the panel" and "the panels" are used interchangeably in the singular and the plural, as, formally, they were several panels (one for each complainant), which were all composed of the same three panellists.
[230] Reference WTO-23
[231] Reference WTO-18
[232] Available at https://tnt.oxysuisse.ch/tntdossier.php?n=2-A2
[233] Reference WTO-1

- "Updated Empirical Assessment of Australia's Plain Packaging Regime" (Exhibit DOM-361: IPE Second Updated Report, 27 October 2015)
- "Updated Empirical Assessment of Australia's Plain Packaging Regime" (Exhibit DOM-375: IPE Third Updated Report, 8 December 2015)
- "Summary of Findings: Empirical Assessment of Australia's Plain Packaging Regime" (Exhibit DOM-379: IPE Summary, 1 February 2016)

These five reports have the same four authors, two of whom are professors Kaul and Wolf. The reports are cited over 30 times by the Panel. The way the panellists describe the first IPE report (Exhibit DOM-100)[234] suggests that the statistical analysis its authors used is very similar to Kaul and Wolf's working papers, with identical results:

> *The trend analysis consists of (1) estimating the time trend of smoking prevalence for the pre-TPP implementation period (before December 2012); (2) predicting the prevalence rate that would have been obtain in any given month following the implementation of the TPP measures on 1 December 2012, in the absence of the TPP measures using the pre-TPP implementation trend; and (3) determining whether the difference between the observed prevalence and the estimated counterfactual prevalence is different from zero by computing confidence intervals.[40]*
>
> *The trend analysis is undertaken by estimating either a quadratic time trend for the January 2001-March 2014 period or a linear trend model for the January 2006-March 2014 period. In both cases, IPE concludes that there is no statistical difference between observed smoking prevalence of the full population and the estimated counterfactual prevalence of the full population with the exception of the month of December 2012, implying overall that the post-implementation trend did not shift. Similar results are found when the analysis focuses only on minor population and young adult population.[41]*
>
> *[40] See IPE Report, (Exhibit DOM-100), pp. 26-27.*
>
> *[41] See IPE Report, (Reference DOM-100), pp. 28-35, 105-116, 119-156, and 181-199.*

The only two differences are that a quadratic trend was also tested in addition to the pure linear trend used in Kaul and Wolf's UZH papers, and that the plain packaging period was extended by three additional months, from January to March 2014.

The panellists summarize the fundamental assumption on which IPE's approach is based as follows[235]:

[234] Reference WTO-9, paragraphs 43 and 44, page C-18
[235] Reference WTO-9, paragraph 10, page C-3

The IPE Report submitted by the Dominican Republic contends that there is a secular downward trend in smoking prevalence in Australia and other high income countries, which are presumably, at least in part due to a combination of demographic shifts (change in the composition of population, education, etc.) as well as other factors entirely unrelated to tobacco control interventions (such as a general trend towards a healthier lifestyle and away from smoking).[7]

[7] See IPE Updated Report, (Exhibit DOM-303), paras. 43-46; and IPE Third Updated Report, (Exhibit DOM-375), paras. 193-201.

The same assumption is made by Kaul and Wolf in their two working papers. They claimed that smoking prevalence followed a linear trend independent of tobacco control measures in all OECD countries ("we see this line in all the OECD countries, it looks very similar across all countries and in some countries we had heavy anti-smoking measures, in other countries we didn't, but we see essentially the same line in all countries"[236]). Australia's expert disagrees[237]:

Professor Chaloupka, in an expert report submitted by Australia, disagrees that (1) tobacco use has been falling consistently in all OECD countries, (2) this decline has been largely linear over time and (3) these downward trends are expected to continue into the future regardless of what happens in these countries. According to Professor Chaloupka trends in tobacco use differ considerably across OECD countries and that assuming a linear downward trend over time is overly simplistic and fails to fully capture the role of tobacco control policies (or lack thereof) in accelerating (decelerating) any downward trend in tobacco use.

Professor Chaloupka was joined by two other experts in his criticism of the statistical methodology used by IPE:

[236] Reference 3, page 28

[237] Reference WTO-9, paragraph 11, page C-4

Australia's expert, Dr Chipty, rejects the IPE Report's results on the grounds, inter alia, that (1) IPE asserts without support that historical trends will continue into the future in the absence of new regulatory measures; (2) ***IPE does not attempt to evaluate the extent to which past policies contributed to the trend in prevalence****; and (3)* ***IPE's model design makes it less likely, and sometimes impossible, to find a policy effect.*** *[...]*

*Australia also submits another expert report by Professor Scharfstein, who further argues that (1) IPE's assumption that smoking prevalence would have continued to decline at the same rate after December 2012, even if the TPP measures had never been introduced, is entirely unsupported without assumptions or a valid natural experiment; (2) IPE's date restriction (i.e. January 2006) in the linear trend model is derived by simply looking at the data; (3****) IPE's statistical trend analysis lacks statistical rigor by not specifying a null hypothesis to evaluate whether there is a TPP measures' effect****; and most importantly (4)* ***IPE's statistical trend analysis has low statistical power and is inadequate to detect important declines in smoking prevalence after the introduction of the TPP measures****.*

Having carefully considered both sides of the argument, the panel points out the contradictions and weaknesses in the statistical approach used by IPE[238]:

[238] Reference WTO-9, paragraphs 101 and 103, pages C-31 and C-32

Turning to the econometric results based on the RMSS data, we note at the outset that the different conclusions reached by the parties regarding the impact of the TPP measures on smoking prevalence stem from the fact that the parties' experts use different model specification (i.e. different explanatory variables included in the model), estimation approaches and in some cases sample periods. [...]

After a careful review of the econometric reports on smoking prevalence based on the RMSS data submitted by the Dominican Republic's and Indonesia's experts [IPE], we are not persuaded that these econometric results can be taken at face value, mainly because most of their model specifications are unable to detect the impact of tobacco costliness (including excise tax increases) on smoking prevalence. Yet, all parties consider tobacco excise tax to be one of the most effective tobacco control policies. To some extent, the Dominican Republic, Honduras and Indonesia are asking the Panel to conclude that the TPP measures had no impact on smoking prevalence, because its effect is statistically not significant, but to disregard the fact that the same econometric results suggest that excise tax or price increase have also had no impact on smoking prevalence. [...]

In sum, and based on the elements discussed above, we have reservations regarding IPE and Professor List's methodologies and therefore question their results, based on these methodologies, that suggest that the TPP measures had no statistically significant impact on smoking prevalence.

The panel presented its "Overall conclusion on post-implementation evidence on smoking prevalence"[239] as follows:

[239] Reference WTO-9, paragraph 123, page C-38

Overall, based on the most recent data available and econometric evidence submitted by the parties, we find that:

a. There is evidence that overall smoking prevalence in Australia continued to decrease following the introduction of the TPP measures.

b. The downward trend in overall smoking prevalence in Australia appears to have accelerated in the post-TPP period.

c. Although it is impossible to distinguish between the impact of TPP and the impact of enlarged GHWs, there is some econometric evidence suggesting that the TPP measures, together with the enlarged GHWs implemented at the same time, contributed to the reduction in overall smoking prevalence as well as in cigar smoking prevalence observed after their entry into force.

For the panel, the complainants were not able to demonstrate that plain packaging is ineffective for public health. The panellists concluded on the contrary that plain packaging while Australia introduction of plain packaging contributes to Australia's objective of reducing tobacco use[240]:

7.2.5.3.8 Overall conclusion on the degree of contribution of the TPP measures to Australia's objective

7.1024. We have considered above the evidence before us in relation to the contribution of the TPP measures to their objective of improving public health by reducing the use of, and exposure to, tobacco products. We have considered the relevant evidence relating both to the design, structure and intended operation of the TPP measures, and the available evidence relating to their application since their entry into force in December 2012.

7.1025. Overall, we find that the complainants have not demonstrated that the TPP measures are not apt to make a contribution to Australia's objective of improving public health by reducing the use of, and exposure to, tobacco products. Rather, we find that the evidence before us, taken in its totality, supports the view that the TPP measures, in combination with other tobacco-control measures maintained by Australia (including the enlarged GHWs introduced simultaneously with TPP), are apt to, and do in fact, contribute to Australia's objective of reducing the use of, and exposure to, tobacco products.

[240] Reference WTO-7, page 415

In its submissions, Australia (via its experts) strongly criticises the statistical methods used by IPE as being "**fundamentally flawed**"[241]:

> *The IPE report purports to undertake a comprehensive review of empirical data from the Australian market to assess whether tobacco plain packaging has reduced smoking prevalence rates. The authors of the IPE report employ two standard analyses for this purpose: (i) a "statistical trend" analysis, and (ii) a "micro-econometric" analysis. In both analyses IPE investigate a single data set, the Roy Morgan Single Source survey data.*
>
> *20. According to the IPE report, the results for both these analyses are the same: they find no empirical evidence for the conclusion that the implementation of tobacco plain packaging has caused a lasting reduction in smoking prevalence.*
>
> *21. However, as explained in more detail below, the analyses undertaken by IPE are fundamentally flawed.*
>
> - *For one, because of a lack of what statisticians refer to as "power", IPE's statistical trend analysis was not capable of detecting meaningful reductions in smoking prevalence in the period following the implementation of tobacco plain packaging. **The "no evidence" result was effectively preordained**. The analysis was simply not capable of finding the very thing it claims it set out to find which renders the results of the analysis meaningless.*
> - *[...]*

Australia's experts also found that "IPE's statistical trend analysis lacked 'power' to detect meaningful changes in smoking prevalence"[242]:

> *32. Power is of critical importance to analyses of the type that IPE have undertaken. **If there is no chance of detecting a particular result, it is meaningless to declare that one has not been found**. As Professor Scharfstein observes, an implication of power is that failure to find a statistically significant result does not imply that the measure being studied (i.e. tobacco plain packaging) has not had an effect.[1342] It could be that the analysis was not adequately powered to detect the true population effect.*
>
> *33. Indeed, this is precisely the problem with IPE's analysis.*

[241] Reference WTO-4, page 455
[242] Reference WTO-4, pages 456-459

NOTES

Australia's criticism of the IPE's statistical approach (of which Kaul and Wolf are co-authors) add and confirm earlier critiques of the UZH papers, including some of the key errors and issues raised by OxyRomandie, emphasizing notably:

- the inadequacy of the statistical model;
- the lack of justification for the assumption on which it is based (notably the claimed pre-existing linear decrease of smoking prevalence in al OECD countries independent of tobacco control measures);
- the arbitrary character of some decisions (such as starting the linear trend in January 2006);
- and the lack of statistical power.

Concerning the lack of statistical power, Australia observes in its submission that "Power is of critical importance to analyses of the type that IPE have undertaken. **If there is no chance of detecting a particular result, it is meaningless to declare that one has not been found.**"

The lack of power of their statistical method has not refrained Kaul and Wolf, notably in their joint declarations with Philip Morris, to claim that the lack of evidence exhibited by their papers was, on the contrary, highly meaningful, presenting their method was "the one that gives the most leeway to finding an effect, if there had been any"[243], and saying that "even very powerful statistical techniques" would also fail to find an effect.

Finally, it should be noted for Australia, "IPE's statistical trend analysis was not capable of detecting meaningful reductions in smoking prevalence in the period following the implementation of tobacco plain packaging. **The 'no evidence' result was effectively preordained**. The analysis was simply not capable of finding the very thing it claims it set out to find which renders the results of the analysis meaningless."

80. JULY 2019 – "THE CONTROVERSY ABOUT THE EFFECTIVENESS OF THE PLAIN PACKAGING MEASURE"

On 16 July 2019, the journal Marketing Science publishes an advance copy of a paper by researchers from Australia and the Unites States entitled "Assessing the Sales Impact of Plain

[243] Reference 3 – See item 3. above.

Packaging Regulation for Cigarettes: Evidence from Australia"[244]. The authors' purpose was to "assess the impact of legislation mandating the plain packaging of cigarettes in 2012 in Australia on both primary and secondary demand". In the abstract, the say that "Our results suggest a decline in sales due to the PPM of around 67 million units (sticks) per month, representing around 7.5% of the market."

In the Introduction, the researchers explain their approach, making the following observation:

> *In terms of the data and methodology used, those in our study differ from those used in previous research in important ways. Our study is the first to assess the impact on sales (rather than, for example, self-reports). The closest published evidence is an event study by Diethelm and Farley (2015) that examines the impact of plain packaging on smoking prevalence measured with survey data. Although that study is an important step in contributing to our overall understanding of the PPM, the use of survey data could lead to biased estimates of the effects of PPM because respondents' stated behavior could differ from their actual actions.*

They then carried out a literature review of "past work examining plain packaging", looking in particular at studies that used "a monthly omnibus tracking survey conducted by the market research company Roy Morgan", including the UZH studies and the Diethelm-Farley papers:

> *The Australian market research firm Roy Morgan ran a syndicated survey of cigarette smoking prevalence rates on a [monthly] sample of approximately 4,500 respondents aged 14 and older prior and subsequent to the plain packaging measure (as well as other category usage). These data were first analyzed by Kaul and Wolf (2014) under contract for Philip Morris, finding no evidence of a decrease in smoking prevalence attributable to plain packaging. This working paper has attracted considerable controversy partly because of process (it did not acknowledge that Philip Morris had the right to vet its contents or that the terms of the contract with Philip Morris should be kept secret) and partly because of methodological issues (see e.g., Doward 2015). Although a review of the paper commissioned by the University of Zurich suggested that the working paper not be withdrawn (Jann 2015), the review's author did add "Although I am not happy with all*

[244] Reference 106

aspects of the papers (see, e.g., Section2), I do not think that the papers are fundamentally flawed from a methodological point of view. I do not suggest their retraction. There is some space for improvement and some of the interpretations by Kaul and Wolf might be challenged" (Jann 2015, p. 45). In a peer-reviewed paper reanalyzing Kaul and Wolf's (2014) data, Diethelm and Farley (2015) modified some of Kaul and Wolf's (2014) assumptions (e.g., that the trend of smoking prevalence in Australia was occurring independent of previous policy changes) and reached a different conclusion. Using what they considered to be more realistic assumptions, they identified a statistically significant decrease in smoking prevalence of 3.7% coincident with the introduction of plain packaging. In a report for the Australian government, an independent econometric consultant (Chipty 2016) found similar results using these data, a decrease in prevalence of 0.55 percentage points (which, given smoking prevalence at the time of 17.77% amounts to a 3.1% decrease in prevalence rates coincident with the change (0.0055/0.1777 =0.031).

[References]

Kaul and Wolf (2014)	*[same as our Reference 18]*
Doward 2015	*[same as our Reference 45]*
Jann 2015	*[same as our Reference 75]*
Diethelm and Farley (2015)	*[Same as our Reference 85]*
Chipty 2016	*[Same as our Reference 94a]*

The above review of the literature leads the authors to collectively qualify the results of studies which use the Roy Morgan data as a "controversy":

***The controversy about the effectiveness of the plain packaging measure using Roy Morgan data** gives us the opportunity to consider the issue using a further set of data, point-of-sale retail scanner data from Nielsen Research.*

NOTE

Using a different data set, the findings of this study are consistent and reinforce the results obtained by Chipty and Diethelm-Farley.

In their literature review, the authors provide an illustration of one achievement of Philip Morris: With the help of the UZH, the tobacco multinational has managed to create a "controversy" about the effectiveness of plain packaging, where none should have existed. The phrase they use, "The controversy about the effectiveness of the plain packaging measure using Roy Morgan data", has two implications. The first suggests that the Roy Morgan Single Source (RMSS) survey data may not be suitable to estimate the effectiveness of plain packaging. The

second suggests that the studies using the RMSS data to estimate the effectiveness of plain packaging produce controversial results.

PMI intervention contributed to create this false controversy. In reality:

1) The Roy Morgan Single Source (RMSS) survey data is considered suitable to estimate prevalence. It is in fact exceptionally good for that purpose. Here is the conclusion of the WTO panel, after having heard all sides of the argument on this point:[245]

> While we acknowledge that no data are perfect, we agree with Australia that the RMSS data is the most suited available data submitted by the parties to analyse the impact of the TPP measures on smoking prevalence, for two main reasons. First, the RMSS data provide an actual measure of smoking prevalence (based on a population of smokers, recent quitters and non-smokers). Second, the data are available monthly for a long period of time before and after the introduction of the TPP measures.

2) With adequate statistical models (as was done by Chipty[246] and Diethelm-Farley[247]), RMSS data shows that smoking prevalence has further declined after the introduction of plain packaging in Australia. Again, for the WTO panel, which has thoroughly examined the scientific evidence, there is no trace of a controversy on this question:[248]

> [...] we find that the evidence before us, taken in its totality, supports the view that the TPP [tobacco plain packaging] measures, in combination with other tobacco-control measures maintained by Australia (including the enlarged GHWs introduced simultaneously with TPP), are apt to, and do in fact, contribute to Australia's objective of reducing the use of, and exposure to, tobacco products.

We note that, faced with the challenge of plain packaging, Philip Morris has resorted to one of the tobacco industry's oldest tactics, namely to create doubt and establish controversy, which was already set out more than 50 years ago in a famous internal tobacco industry memorandum:[249]

[245] Reference WTO-9, paragraph 99, page C-31
[246] Reference 94a
[247] Reference 85
[248] Reference WTO-7, paragraph 7.1025, page 415
[249] Reference 0t1

> Doubt is our product since it is the best means of competing with the "body of fact" that exists in the mind of the general public. It is also the means of establishing a controversy.

81. MARCH 2023 – DIETHELM ASKS UZH FOR A FULL COPY OF ITS CONTRACT WITH PMI

On 13 March 2023, Diethelm sends an email to the president of UZH[250] to request the full copy of the contract signed in July 2013 between the university and PMI, asking in particular for the annex to the contract, of which he has only one page, in addition to the cover page:

> *I am in the process of writing the full story of the two studies undertaken by the UZH on behalf of Philip Morris International (PMI) in 2014 on the effectiveness of plain packaging for tobacco products. The two studies are published on the UZH website of the Department of Economics:*
>
> - *https://www.econ.uzh.ch/en/research/workingpapers.html?paper-id=828*
> - *https://www.econ.uzh.ch/en/research/workingpapers.html?paper-id=844*
>
> *You will find attached one document which was given to me in 2015 by professor Hengartner. The document is entitled "Project proposal: Intervention Analysis: the Effect of Plain Packaging for Tobacco Products on Smoking Behavior in Australia". It was submitted to Philip Morris by the UZH jointly with the consulting firm IPE – Institute for Policy Evaluation in Saarland, Germany.*
>
> *As you can see, the document which was given to us is very incomplete (title page + 1 text page). Invoking the access to information, I would like to get the full document, which, I am sure, must be in the UZH archives. Any other documents related to these studies, notably the correspondence between PMI and UZH, would also interest us, as we want to be factual, complete and rigorous in our account of this story.*

On 17 March 2023, Diethelm receives an email (in French) from the head of Data Protection Service at UZH, with the following contents:

[250] Reference 107

Your e-mail below, addressed to our director, has been forwarded to me for reasons of competence. We consider your request to be a request for access to information in accordance with the Information and Data Protection Act of the Canton of Zurich.

We will make a search in our archives and with Professor Wolf to see if we can find anything to answer your queries.

82. MAY 2023 – THE UZH PROVIDES DIETHELM WITH A COPY OF THE "PROJECT PROPOSAL"

A package containing several documents with a covering letter from the Head of Data Security at UZH arrives at the office of OxySuisse in Geneva. The letter is dated 11 May 2023[251]. Its main content (in French) is as follows:

We refer to your e-mail of March 13 anni currentis. Attached is the requested "Project Proposal" document, which we have been able to find in our archives. For personal protection reasons, the personal details of the project team have been partially redacted.

The initial "Proposal" for one (only) study eventually turned into two separate studies, precisely the two you listed in your email. There were no further studies. We will then send you other files we have been able to find in our archives on this subject.

I hope you find this information useful, and I'll be happy to answer any questions you may have.

In addition to the Project Proposal, the package contains the copies of several documents of no real significance: two press clippings and a copy of OxyRomandie's letter of 29 January 2015 together with its annex.

[251] Reference 108

83. AUGUST 2023 – FURTHER REQUEST BY DIETHELM

On 6 August 2023, Diethelm sends an email to the head of Data Security at UZH[252], asking for further information. He starts his message by acknowledging the receipt of the documents sent in May and indicates that he was expecting more:

> *I received your letter of 11 May, with a copy of the project proposal dated 22 May 2013 (which, incidentally, is a damning document). In my message of 13 May, I also made the following request: "Any other documents related to these studies, notably the correspondence between PMI and UZH, would also interest us, as we want to be factual, complete and rigorous in our account of this story." Instead of the documents requested, we received copies of two press articles, which are publicly available and already in our possession, as well as a copy of our own document which had been appended to our letter of 29 January 2015 to prof. Hengartner. This does not correspond to what we expected. We were asking for access to the correspondence between PMI and the University of Zürich. We repeat this request here.*
>
> *On reading the document you sent us ("project proposal"), it transpires that Professors Wolf and Kaul had previously signed an agreement with Philip Morris ("UZH undertakes Morris upon execution of this agreement to sign a non-disclosure agreement on substantially the same terms as are contained in the nondisclosure agreement Ashok Kaul and Michael Wolf have already signed"). We request access to these nondisclosure agreements.*

Diethelm's ends his message with an explanation of his motivations and the context in which he submits his requests:

[252] Reference 109

I thank you in advance for your understanding and help in resolving this request. Rest assured that our sole motivation is to defend scientific integrity and in no way to damage the reputation of the UZH. Your prestigious university has been the victim of interference in the scientific process by the multinational Philip Morris. We believe it is important to document all the ins and outs of this affair fully and factually, so that we can learn from it. This is the purpose of the project we are carrying out, which is part of the Tobacco Control Fund's TnT - Transparency and Truth initiative.

It will come as no surprise to you that we are currently in a phase of history where - in the wake of the covid and global warming crises - the scientific process, academic institutions and science itself are under violent attack from certain extremist quarters [...], and where larger sections of the public are sceptical about the relevance of academic work, particularly in human sciences. In such a context, it is even more essential for a university to be exemplary. I'm afraid that this exemplarity was sadly lacking in the way the UZH handled the contract it signed with Philip Morris just 10 years ago. Despite this distance in time, this case remains completely relevant today, because it is emblematic of the capacity of certain large industries to corrupt science and is a perfect illustration of current concerns relating to the commercial determinants of health.

On 7 August 2023, the UZH head of Data Security replied to Diethelm's email[253], saying that they "will check to see if any other documents (including those you mentioned) are available concerning this case", observing, however, that "the case goes back some ten years".

On 14 August 2023, Diethelm sends an email to the head of Data Security[254], asking further questions:

[253] Reference 109a

[254] Reference 109b

The summary/abstract page [of the Project Proposal] had already been given to journalist Thomas Angeli of the Beobachter. It is a very incomplete document that hides the essential points of the project proposal [...], conceals its nature as research subservient to Philip Morris, and says absolutely nothing about the incredible degree of control the company had over the two professors' research work.

As I am in the process of writing a detailed history of this case, concentrating on the factual elements, I would like to understand why it was not possible for prof. Hengartner to give me access to this document in 2015, whereas it is possible in May 2023. If prof. Hengartner's explanations regarding the impossibility of giving me such a document in 2015 are correct, has the law changed since then? I would like to have an explanation to put in the chronological report to help the reader understand this difference in treatment of access to information between 2015 and 2023.

This question was left unanswered.

84. SEPTEMBER 2023 – FINAL EXCHANGES OF EMAIL BETWEEN DIETHELM AND UZH HEAD OF DATA SECURITY

On 5 September 2023, Diethelm received the following email form the head of Data Security at UZH[255]:

In answer to your emails of 6 and 14 August, I can tell you the following:

Between your FOI requests of 2015 and 2023, approximately eight years have elapsed, the weighing of interests as to the extent to which the request is successful must be done at the time of the request. It is therefore quite possible that the case law relating to the principle of transparency has evolved or that the assessment regarding the submission of documents relating to a project that was completed several years ago is now different.

As part of the answer to your request for access to information, we provided you with the documents relevant to the facts as of 11 May anni currentis. We have not been able to find any other documents in our archives (such as the documents you mentioned in addition).

[255] Reference 110

The head of Data Security ends his email with the following injunction, before declaring the case closed:

> *These explanations are for your use only. It is forbidden to distribute this e-mail or to quote from it.*
>
> *This closes the access to information request.*

In an email sent on 9 September 2023[256], Diethelm thanks the head of Data Security for his answer, adding:

> *I take good note that you were unable to find any other documents in your archives (such as the documents I mentioned in my request). This is valuable information for us, and confirms the information along the same lines that we obtained from prof. Hengartner in 2015: the contract that the UZH signed with Philip Morris International in July 2013 consists of two documents, one being the text of the contract itself and the other its Annex 1. We were given these two documents (the second partially redacted), and the UZH has no other documents.*

Diethelm concludes his message by expressing his surprise that the head of Data Protection at UZH forbids him to pass on or quote his last e-mail and asks about the legal basis for such a decision.

NOTE

As Diethelm's last email was left unanswered, he concluded that the decision to prohibit him from quoting head of Data Security's last message has no legal basis.

85. FEBRUARY 2024 – THE TOBACCO INDUSTRY CONTINUES ITS DENIAL, USING THE UZH STUDIES AS REFERENCES

As of February 2024, British American Tobacco continues to claim that "plain packaging does not work" on its website[257]. Under the heading "One of the main reasons why we are against plain

[256] Reference 110a
[257] Reference 111

packaging of tobacco products is because it is not an effective way of reducing smoking levels", the UK tobacco company refers to the Australian example to justify its assertion:

> *We encourage governments and regulators to focus instead on effective interventions, including establishing policies that support smokers to transition to reduced-risk products.*
>
> *Some people think that the colours, designs and trademarks used on cigarette packs make them more appealing, particularly to young people.*
>
> *However, there is no compelling evidence to suggest that plain packs are effective in discouraging young people from smoking, encouraging existing smokers to quit or preventing quitters from taking up smoking again.*
>
> *This is evident from the experience in Australia, the first country to implement plain packaging in December 2012, where the evidence shows that:*
>
> - *there has been no acceleration in the long-term smoking rate decline since plain packaging was introduced;*
> - *[...]*
>
> *The Australian Government's own data shows that after the introduction of plain packaging the decline in the smoking rate slowed — not accelerated — between 2013 and 2019.*

In support of claims concerning the failure of plain packaging in Australia, BAT cites an "expert report of LUISS Business School and Deloitte Financial Advisory, Italy on the impact of plain packaging on smoking in Australia, dated 8 November 2019"[258], which it commissioned.

The BAT expert report reviews "prior analyses of smoking prevalence", which are "all based on the RMSS [Roy Morgan Single Source] database". The first two studies mentioned are the UZH working papers:

[258] Reference 111a and Reference 111b

Kaul and Wolf (2014a)

The first study analysing smoking prevalence using RMSS data is a working paper from the University of Zurich by Kaul and Wolf (2014a). The authors analyse smoking prevalence in Australia in the period from January 2001 to December 2013 on an annual sample of 3,187 minors (aged from 14 to 17). The analysis includes just one year of observation after the implementation of the new packaging regulations, which took place in December 2012. The authors used a linear time trend and found no evidence for any actual effect of Plain Packaging on Australians aged 14 to 17 years in the first year after the introduction of Plain Packaging.

Kaul and Wolf (2014b)

In a similar study, Kaul and Wolf (2014b) analyse smoking prevalence in Australia for the same period using the same dataset, but focusing on the adult population. Their results show that at a relatively lower level of statistical significance (p-value equal or lower than 10%), there is evidence for a very short-lived Plain Packaging effect on smoking prevalence (in December 2012 only), after which smoking prevalence is statistically indistinguishable from its pre-existing trend. At a stronger statistical significance level (p-value lower or equal to 5%), they find no evidence at all for a Plain Packaging effect on smoking prevalence.

Kaul and Wolf's results are presented with no critical comment. The BAT experts' criticism is concentrated on the two papers by Diethelm and Farley:

Diethelm and Farley (2015)

The work of Diethelm and Farley (2015), published in Tobacco Prevention & Cessation, is also based on RMSS data for a sample of adults in the period from January 2001 to December 2013. However, the authors had no direct access to the database. Consequently, their analysis is built on the published work of Kaul and Wolf (2014b), reconstructing the data needed for the analysis from Figures 1 and 2 reported in this paper. This method, as noted in the Cochrane Review, introduces a high risk of statistical errors in its results given that Kaul and Wolf (2014b) provide limited information on how the data was extracted and aggregated.

The results of the analysis by Diethelm and Farley (2015) show a reduction of 3.4% in smoking prevalence in the year after the introduction of Plain Packaging. Apart from the doubts cast on this result by the data collection method and the short period observed, the eventual attribution of this result to Plain Packaging is questionable, given that the estimation model does not include critical control variables, such as price. For these reasons, this study was graded as "low quality" in the Cochrane Review, meaning that their confidence in the effect estimate is limited, and the true effect may be substantially different from the estimate.[19] *Indeed, the authors themselves claim in their paper that "it is not possible to conclude that the decrease in smoking prevalence was caused by plain packaging".*

Diethelm and Farley (2017)

In a following paper, published in Tobacco Prevention and Cessation, Diethelm and Farley (2017) applied the same methodology for the same period (January 2001 to December 2013) using the evidence from Kaul and Wolf (2014a) to analyse smoking prevalence among minors. The study suffers from the same major methodological limitations outlined above for their previous study. Notwithstanding such limitations, their results show that Plain Packaging has not had a statistically significant effect on smoking prevalence among minors.

[19] *McNeill et al. (2017), p. 4-5.*

NOTES

While Kaul and Wolf's results are presented without reservations, Diethelm and Farley's papers are said to suffer from "major methodological limitations". While not saying a word about the lack of critical control variables in the UZH statistical analyses, the BAT experts Diethelm and Farley's results "questionable, given that the estimation model does not include critical control variables, such as price", adding that it is why their study on adults "was graded as 'low quality' in the Cochrane Review".

Contrary to what the BAT experts say, the Cochrane Review found Diethelm and Farley's study superior to Kaul and Wolf's study on adults. Finding serious methodological limitation with the latter, they did not retain it[259]:

[259] Reference 101a

Kaul 2014 chose to model the overall time trend for a shorter period of time (from July 2004 onwards, rather than from 2002); they state they have done so because the trend appears non-linear in the first two years compared to later years. However, the analysis in Diethelm 2015 makes some allowance for this by the inclusion of additional covariates and hence Diethelm's final model (unlike that of Kaul) is not a simple linear time trend. Secondly, Kaul 2014 excludes December 2012 from their analyses (when standardised packaging came into effect), whereas both Diethelm 2015 and Chipty 2016 include this month; this appears to be a post hoc decision made in the Kaul 2014 analysis. Thirdly, Kaul 2014 primarily analyses residuals, rather than estimation of the trend before and after the implementation of standardised packaging, which Diethelm 2015 and Chipty 2016 have done.

Given the consistency in findings between Diethelm 2015 and Chipty 2016 and given that Diethelm 2015 is the primary reference for this study (as the only peer-reviewed published reference analysing this data set), our conclusions on this outcome are based on those presented by Diethelm 2015.

When Cochrane Review gives a grade "LOW" to Diethelm and Farley's study, this is accompanied by a footnote saying:

Based on observational evidence only. Though enhanced pictorial health warnings were implemented at the same time as standardised packaging, making it difficult to separate the effects, we have not downgraded further for two reasons: 1) the low GRADE already reflects the challenges in inferring causality from observational data; and 2) data on non-behavioural outcomes provides plausible mechanisms of effect consistent with the observed decline in prevalence.

The LOW grade relates to the type of evidence obtained from an observational study, which is generally considered by the Cochrane Review to be of lower quality than randomised trials, which is their gold standard. The methodology used by Diethelm and Farley is positively noted: "Appropriate statistical methods were used to examine the effects of a policy using time series data". Using the Cochrane Review GRADE standards, the Kaul and Wolf's study would have been rated at best "VERY LOW", had it not been rejected.

This BAT expert report shows that, as of February 2024, the industry continues to use Kaul and Wolf's working papers in its campaign against plain packaging, misleadingly presenting them as reliable scientific references that show that plain packaging did not work in Australia and is therefore ineffective.

* * *