
1 December 2016

To:

David McKenna

Head of Broadcast Compliance

RTÉ

david.mckenna@rte.ie

cc: Journalist Rita O'Reilly, rita.oreilly@rte.ie

False statements on Irish national TV (RTÉ) about the Nordic Cochrane Centre in documentary about HPV vaccines

On 14 November, I was interviewed by Rita O'Reilly (rita.oreilly@rte.ie) for more than an hour for a documentary about the HPV vaccines. In e-mails before the interview, O'Reilly had explained:

"We want to interview you in your capacity as director of the Nordic Cochrane Centre regarding the HPV vaccine and specifically your complaint to the EMA [the European Medicines Agency] about maladministration with regards to the safety of the HPV vaccine and your follow-on complaint to the European Ombudsman on the same issue" (9 November)

and

"I will ask you to explain the Cochrane centre on camera and then ask you about the complaint to the EMA, their response and the complaint to the Ombudsman. I will also ask you to outline your concerns about the HPV vaccine's safety" (14 November).

I therefore thought O'Reilly was genuinely interested in learning and broadcasting what was wrong with the way the European Medicines Agency (EMA) had handled the suspected serious harms of the HPV vaccines. O'Reilly was very well prepared and asked me a lot of questions about our complaints to the EMA and to the European ombudsman, and about the science, but by the end of the interview she became very aggressive, and it dawned on me that it didn't matter what I said, as she had a personal agenda she pursued.

The documentary was broadcast on 22 November:

<http://www.rte.ie/player/dk/show/prime-time-extras-30003379/10654255/>

This documentary was extremely one-sided, thereby not reflecting RTÉ's editorial values of being impartial and accurate, and serving the public interest. Everyone - including me - who had concerns about possible serious harms of the HPV vaccines and who believed that more research was needed were described in a way that left the audience with a feeling that they were untrustworthy.

The documentary lasted 18 min and 38 seconds, but O'Reilly used only 12 seconds of her one-hour long interview with me where I said:

"If this is being abused by antivaccine groups, that's their fault. It isn't mine. I have not said anything about this vaccine, whether it is good or bad. Nothing" (from 13.46 to 13.58 min).

Just before this, O'Reilly had explained that the Nordic Cochrane Centre had criticised the EMA's review of a possible link between the vaccine and certain syndromes.

False and defamatory statements

Starting at 14.32, O'Reilly said: "Last month Nordic Cochrane was forced to apologize when it admitted it got it wrong on allegations that the review [the EMA's review of the safety of the HPV vaccines that we criticised] was compromised by conflicts of interest. In one claim it got the wrong person; in another it was simply wrong. It's doubled down in a follow-up complaint to the EU's ombudsman, Emily O'Reilly, chiefly about transparency. It accuses Dr Alteri of having worked for the HPV vaccine manufacturer, Merck, until 2012. Wrong again."

Next, Emerica Alteri, an EMA employee, appeared:

"Merck KGaA is a German company that has absolutely no relationship at all with Merck & Co, which is their American, what is called the American Merck. The two companies parted a hundred years ago or something like that."

1. It is outright false that I and my four colleagues who wrote the complaints have accused Emerica Alteri, an EMA employee, of having worked for the HPV vaccine manufacturer, Merck, until 2012. We did not say this, neither in our complaint to the EMA, nor in our complaint to the ombudsman (see <http://nordic.cochrane.org/research-highlights>) where we said: "we found out that Emerica Alteri from the EMA, who had no restrictions on her participation, nonetheless had conflicts of interest declared on the EMA's website. She was employed by Merck-Serono till June 2012 and her husband has a consulting contract with Merck-Serono for 2016." This is entirely correct, according to Alteri's public declarations on the EMA's website, most recently updated 24 July 2016: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/07/WC500129303.pdf.

2. It is outright false when O'Reilly says in the documentary: "Last month Nordic Cochrane was forced to apologize when it admitted it got it wrong on allegations that the review was compromised by conflicts of interest." We did not get it "wrong on allegations that the review was compromised by conflicts of interest." The review WAS compromised by conflicts of interest and we mentioned several such conflicts of interest, also in our complaint to the ombudsman. During the interview with O'Reilly, I discussed such conflicts at length in relation to Andrew Pollard, the chair of the EMA's scientific committee, and in relation to Guido Rasi, the EMA's executive director, who had not declared that he is inventor of patents. It is therefore wrong of O'Reilly to say otherwise, and since she knew that her statement was false, I believe it is a falsehood. The ombudsman wrote to us on 8 November that she would address our complaint about "the alleged conflict of interest involving a senior EMA staff member." Research has shown that conflicts of interest in relation to the drug industry are important, whether or not they are directly related to the product that is being evaluated.

Given these indisputable facts, I require that:

1. O'Reilly apologizes to me and thereby also to my four colleagues who wrote the complaints to the EMA and the European ombudsman that she propagated false statements on Irish national TV (RTÉ).
2. Irish national TV (RTÉ) publishes my letter on its website and links to it on the page where the documentary is announced, in a way that is equally conspicuous as the title of the programme "Prime Time Extras: HPV Vaccine" and next to that title. The headline could be: "The RTÉ propagated false statements about the Nordic Cochrane Centre in relation to the HPV vaccines and apologizes for this," or a similar headline to be agreed between RTÉ and me.

I look forward to your reply as soon as possible and no later than 7 December.

Sincerely,



Peter C Gøtzsche, DrMedSci, MSc
Director of the Nordic Cochrane Centre, Rigshospitalet
Professor, University of Copenhagen

From: Mark Wilson <MWilson@cochrane.org>
Sent: 06 January 2017 19:56
To: "Peter C. Gøtzsche"
Subject: Spokesperson Policy
Attachments: Letter from the Cochrane leadership; Letter from the Cochrane Co-Chairs & CEO; Re: our meeting about Maudsley yesterday; RE: our meeting about Maudsley yesterday; Letter to the EMA

Dear Peter,

I wanted to write to you following your note of 22nd December (below) to make clear the position so that there is no possible doubt or uncertainty about the application of the Spokesperson Policy, and the subsequent additional requirements related to it, to you. I apologize for the delay in my reply. Your message arrived after I had left for the Christmas and New Year vacation and I have only just returned to work.

You are, as is every Cochrane collaborator, bound to observe the Cochrane Spokesperson Policy as approved (in its latest iteration) by the Governing Board in Seoul (see: <http://community.cochrane.org/organizational-info/resources/policies/spokesperson-policy>). I know that you don't dispute this, though you may disagree with what's in the policy or our interpretation of it. In relation to the latter, the revision passed by the Board was precisely to avoid misinterpretations by adding clarifications and further examples to guide collaborators and Cochrane office holders. Nevertheless, it is the Central Executive team's responsibility to apply the policy (as with all policies) and to provide professional guidance and decision making in its execution. Where my team's interpretation of a policy's application is disputed by a Cochrane collaborator, as you know the dispute is managed through the established accountability lines to me as Chief Executive Officer, and then to Cochrane's Governing Board as the final arbiter of all things.

That is what happened between 2014 and last year in respect of incidents that you are aware of and I don't need to repeat. As a result of these incidents, in meetings and correspondence with the Co-Chairs, David and myself you agreed to adhere to a set of obligations and behaviours in future. These agreements were made between the Cochrane leadership and yourself in lieu of other actions being taken against you as part of Cochrane's management and governance arrangements. These undertakings remain in force. They are set out in the letters to you from the Cochrane leadership of 14th March 2014, 9th June 2015 and the Minutes of our meeting of 7th July 2015 finally agreed by us on 9th September (all attached for your reference). In my e-mail to you of 21st July 2015 I told you that it was important we agree the Minutes of that London meeting because: 'I need to confirm to the Co-Chairs that the requirements set out in our letter of June 9th have, or will be, actioned.' They are:

From the letter of 14th March 2014: 'we would ask that in future you will ensure that when you are presenting your personal views it is clear to any reader or listener that they are your own and cannot be considered to represent the views of the Collaboration; and that you remove from the Nordic Cochrane Centre website references and links to the book.' The letter of 9th June 2015 highlighted that despite this agreement and undertaking you had not done so in May 2015 in a public debate, a BMJ article, a blog and in the Author's reply section of the BMJ website. As Cochrane's Spokesperson Policy was by that time in force you had, therefore breached the policy.

That letter asked you 'publicly to withdraw [the statements made in the BMJ] and to apologize to David, Rachel, Clive and Geraldine.' This was done on 21st July. The letter also asked 'you to no longer use your title of 'Director, Nordic Cochrane Centre' when you are writing and speaking on projects that are not Cochrane reviews or methodology. Instead, we ask that you use your alternate title of "Professor of Clinical Research Design and Analysis, University of Copenhagen".' In our meeting in London on 7th July, at your request and in an act of good faith David and I agreed with you to amend this – as stated in the agreed Minutes:

• '... that Peter could, when presenting scholarly methods research papers, use his "Director, Nordic Cochrane Centre" title; but because of the continued controversy in relation to his views on this particular issue, when he

writes or speaks about psychiatric drugs in other ways or in other fora he should use his University of Copenhagen title.

- They agreed that on other issues and cases that might cause confusion about whether his views are official Cochrane views, Peter's use of the 'Director, Nordic Cochrane Centre' affiliation would still be OK *if* there is a clear disclaimer about these being his own personal views.
- They agreed that in interviews with the media it is safest to say that he is professor at the University of Copenhagen.
- In addition, Peter agreed that he will consult with Julie Wood if he is in doubt about what to do in future in relation to public statements and when and where he should or could use his 'Director, Nordic Cochrane Centre' title.'

These undertakings were reiterated as continuing to apply in our e-mail to you of 22nd August 2016. *I want to stress again that they continue to do so.* In our view, your re-submission to the EMA of 10th October 2016 met the Spokesperson Policy and these specific requirements you have agreed to, in that whilst you used Nordic Cochrane Centre letter-headed paper, you made a clear statement in bold on the first page that: 'The views we express here and our conclusions are based on the facts we present; they are ours and not those of any organisation.' We highlighted this as an acceptable example at the meeting of Centre Directors in Seoul as you know.

However, since then you have been interviewed by Irish television as Director of the Nordic Cochrane Centre despite agreeing that 'in interviews with the media it is safest to say that he is professor at the University of Copenhagen'; and then have written letters of complaint to RTE and the Broadcasting Authority of Ireland on NCC paper without making clear that the EMA submission represents your individual views and not those of Cochrane. You have not consulted with Julie beforehand in relation to the public statements you have made to RTE in the interview or in the statements you have sent them and published on the NCC website. We understand your frustration with RTE's use of your interview in the television programme; but its confusion and mistakes have occurred in part because the RTE journalists saw the EMA submissions as coming from the Nordic Cochrane Centre (as we warned) and then interviewed you as Director of the Nordic Cochrane Centre (when you agreed that this would not happen). Your failure to highlight in your letters of complaint, on Nordic Cochrane Centre letterhead, that the submission was made by you and other researchers in your personal capacity and not as the NCC would still lead RTE and the BAI to assume that the complaint is coming from the Nordic Cochrane Centre and not you personally.

This dispute has, thankfully, not gained media coverage elsewhere. It has highlighted, however, some of the dangers when the Spokesperson Policy and the additional requirements we have agreed are not followed. I therefore want to reiterate again these obligations are still in place. I expect you to honour them, although you disagree with them. I thank you, in advance, for doing so.

Yours sincerely,

Mark

Mark G. Wilson
Chief Executive Officer



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From: "Peter C. Gøtzsche" [<mailto:pcg@cochrane.dk>]

Sent: 22 December 2016 08:34

To: Tom Jefferson <jefferson.tom@gmail.com>; Mark Wilson <MWilson@cochrane.org>

Cc: David Tovey <DTovey@cochrane.org>; Julie Wood <jwood@cochrane.org>; Carl.heneghan@phc.ox.ac.uk

Subject: Re: An a case of acute double standards?