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1 December 2016

To:

David McKenna

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RTÉ

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cc: Journalist Rita O'Reilly, [rita.oreilly@rte.ie](mailto: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](mailto: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, Enrica 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 Enrica 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 Enrica 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](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,

A handwritten signature in blue ink, appearing to read 'P. Gøtzsche', with a stylized flourish at the end.

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