Prof. Anton J.M. Loonen, MD, PharmD, PhD Clinical NeuroPsychoPharmacologist

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Roosendaal, March 19th, 2018

Cochrane Central Executive St Albans House 57-59 Haymarket London SW1Y 4QX United Kingdom

Dear Sir, Madam.

Please be informed that this matter concerns Prof. Dr. Peter C. Gøtzsche, the director of the Nordic Cochrane Centre. Mr. Gøtzsche and I acted as experts during a court session at the District Criminal Court of Gelderland (the Netherlands) in 2016. The suspect was a 34-year old woman who was accused of killing her 8 year old son and 6 year old daughter. Mr. Gøtzsche provided an expert opinion on behalf of the defense using reports submitted by me, and I was in turn asked by the court to give my comments to this expert opinion. I was very surprised about the content of his opinion, and also the level of his qualifications to be able to offer an expert opinion in this case; I expressed my serious concerns about both matters. Mr. Gøtzsche's theoretical education and clinical expertise in Psychiatry, Neuropsychopharmacology, and Clinical Pharmacology mean that he is insufficiently qualified to write this report. Mr. Gøtzsche had neither examined the suspect nor had he studied the criminal files himself. His report was exclusively based on a translation of my report and its addendum. It became evident to me later that, as could be expected, this translation showed imperfections. His report contained several incorrect statements and, in addition to these, numerous allegations against the treating physicians and myself.

Mr. Gøtzsche's expert opinion was presented on the company stationary of the Nordic Cochrane Centre with your standard motto 'Trusted evidence. Informed decisions. Better health.' It was also signed by him as follows: "Peter C Gøtzsche, Professor, DrMedSci, MSc, Director of the Nordic Cochrane Centre, Rigshospitalet". Apparently, the Nordic Cochrane Centre endorsed Mr. Gøtzsche's findings in that criminal case. This is, however, questionable for me because, to my knowledge, the Cochrane organization is not active in this domain of individual forensic psychiatry, the domain which was entirely the subject of his expressed criticisms. Moreover, the director of the Nordic Cochrane Centre is perhaps financially not entirely independent, since a considerable fee was paid for the report in question, and consequent publicity might promote the selling of Mr Gøtzsche's books (which do - according to your previous statement - not always give the views of the Cochrane Organization). I would like to know: (i) whether the Nordic Cochrane Centre was familiar with the opinion in question, (ii) whether it is correct that the Nordic Cochrane Centre endorsed Mr. Gøtzsche's findings, and (iii) whether this conduct is in line with Cochrane's policy on conflict of interest. Can you please inform me about the Nordic Cochrane Centre's position on these matters?

It is also apparent to me that the defense and/or Mr. Gøtzsche shared my expert opinion with a Dutch newspaper ('De Volkskrant'), despite the fact that the report was confidential. I would also like to know: (i) what the policies of the Cochrane Central Executive in this regard are, (ii) whether the Nordic Cochrane Centre and Central Executive were familiar with this, and (iii) whether they support this kind of sharing of confidential information by one of its directors. Can you please also provide your views in these matters?

In January 2018, two years after the court session, Mr. Gøtzsche filed a complaint against me at the disciplinary court because of my expressions. Together with this complaint, several confidential files were shared. This complaint was filed by Mr. Gøtzsche as director of the Nordic Cochrane Centre (appendix). I would further like to know: (i) whether the Nordic Cochrane Centre and Central Executive were familiar with this complaint and (ii) whether it is correct that the Nordic Cochrane Centre also intended to file this complaint against me.

I look forward to hearing from you. If you need any further information, please feel free to contact me.

Yours sincerely,

Anton

Document K: Peter Gøtzsche's reponses inserted into original 11th April 2018 e-mail from Mark Wilson

Peter Gøtzsche's comments in italics inserted 18 April 2014

Dear Peter,

As you know, following my e-mails to you of 15th and 20th March (attached) and our meeting of 21st March in Lisbon (Minutes attached), I have been considering three issues:

 A formal complaint by E. Fuller Torrey from the Stanley Medical Research Institute (of 1st and 2nd March) that you failed to make the necessary distinction between your personal academic views and those of Cochrane as an organisation related to a request on 16th February for unpublished data on the TIPS clinical study relating to the benefits and harms of psychiatric drugs.

2. A Tweet from Anton Pottergard (8th March) accusing you of illegitimately using your "Cochrane affiliation when inviting for deprescribing symposium, alongside [the International Institute for Psychiatric Drug Withdrawal] and cochrane-email for signup. In our immediate response to Mr. Pottergard we tweeted: "Cochrane takes seriously all feedback from our community, and we have shared your comments with senior leadership for further action. If you would like to submit a formal statement directly, please use our website: http://cochrane.org/contact." No further response has been received.

3. A letter from Professor Anton Loonen (19th March) asking a series of questions related to your involvement in a 2016 criminal case in the Netherlands, a subsequent media report in a Dutch newspaper, and your filing of a complaint against him in the Regional Disciplinary Court for Healthcare at Eindhoven in January 2018.

I've carefully considered the documentation related to these complaints, your explanations and responses during our meeting in Lisbon, and concluded that you have breached both Cochrane's Spokesperson Policy (and the additional requirements and undertakings you made in July 2015) in the letter to the Stanley Medical Research Institute (1), and your mandating of a Dutch attorney to submit a complaint against Professor Loonen with the Regional Disciplinary Court for Healthcare (3), but not in the flyer relating to the seminar held at the Hotel Nyborg Strand which was the subject of the tweet (2).

In case 1, through the use of Cochrane headed paper, the use of your name and title in the signature description at the bottom of the letter as Director of the Nordic Cochrane Centre, and the language used in the request for data (where consistent use of the words 'we' and 'our' would reasonably lead any reader to assume that the request is from the Nordic Cochrane Centre and the views expressed in the request are those of the NCC) you have failed to abide by the Cochrane Spokesperson Policy, which requires you to "state clearly that you are speaking in a personal or other professional capacity unless you have been expressly authorized to represent Cochrane _; and that: "If you do use your Cochrane affiliation along with another title then it is incumbent upon you to state unequivocally and clearly that the views are your own and not those of Cochrane. This cannot be implied, but must be stated explicitly."

I have not broken the Spokesperson policy and I am not obliged to adhere to any additional requirements. See my detailed reply about this in relation to Torrey sent to the Governing Board and you on 16 April. You acknowledge that it is clear that the request comes from the Nordic Cochrane Centre, of which I am the director, and I can of course authorize myself to speak on behalf of my centre. Apart from this, any views I expressed in my letter are shared by my researchers at the Centre. So there cannot be any problem.

In case 3, through the use of the Nordic Cochrane Centre's address (and not your own personal address) in the signed power of attorney to Dr Bijl to act on your behalf in the formal complaint to the Regional Disciplinary Court for Healthcare in Eindhoven you failed to abide by the same requirements of the Spokesperson Policy.

The Spokesperson policy is about ensuring that what individual people say or write is not misinterpreted as if it were official Cochrane policy. There can be no doubt in this case that I am addressing a lawyer on behalf of myself. I have therefore not broken the Spokesperson policy.

In case 2, though it would be preferred and helpful to use a non-Cochrane address in future for registration of seminars and meetings you organize relating to the use of psychiatric drugs, you did not use your Cochrane title, Cochrane logo or otherwise sufficiently associate Cochrane with the event. However, the complaint highlights the need in such cases for you to make clear in future that the seminar/discussion is not an official Nordic Cochrane Centre event.

I do not agree. As our advertisement clearly says, we do a Cochrane review on withdrawal of depression pills and the seminar was about this. It was therefore relevant for our Cochrane activities, among other things because we learn from our interactions with psychiatrists, which was the focus group for our seminar. Cochrane is also about advocacy and about helping patients, which is what we try to do.

In cases 1 and 3 you also failed to adhere to the undertakings you made and the addditional requirements made of you in July 2015 which were set out at that time and again on 6th January 2017 (you have my e-mail and attachments already). These required you: "because of the continued controversy inn 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 ["Professor of Clinical Research Design and Analysis, University of Copenhagen"]" Both cases concern that issue, and you therefore had a clear and unambiguous obligation to use this title and make clear the distinction between your academic research in this area and your role as Director of the Cochrane Nordic Cochrane Centre. This you did not do. In our meeting in Lisbon you said that the Cochrane Governing Board in Geneva in April 2017 explicitly rescinded these requirements and agreements made by the Cochrane leadership in 2015 during a 'Board only' session that I was not attending. I have checked with the Board Co-Chairs to clarify this and they say that such a decision was not taken by the Board at that time; the Minute of the Board-only session does not record such a decision; and I have not been instructed by the Co-Chairs or the Board no longer to apply these requirements to you. They are, therefore, still in force.

These provisions are clearly no longer in force. As I explained at the Centre directors' meeting in Seoul, there cannot be separate rules for me and other rules for everybody else in Cochrane. We should all abide by the same rules. This is what I told the Governing Board in Genève before I left the room and there was general agreement about this. Apart from this, my researchers, who also write articles about psychiatric drugs, cannot use any other affiliation than the Nordic Cochrane Centre, so also for this reason it would be inappropriate to have separate rules for me. It would look odd that the Nordic Cochrane Centre is their address, and I, as the only one, use another address, and readers would think that I no longer work at the centre. This would be misleading and we do not want our scientific articles to be misleading.

I made detailed minutes after the Board only session and it was very clear that I am allowed to use the Nordic Cochrane Centre's letterhead also for non-Cochrane issues, as long as I respect the Spokesperson policy, which I do. This was what I was told when I was allowed into the room again after this issue had been discussed. It is not my fault that the minutes from the Board only session are very short, only 16 words, related to this particular item. Since this was the Board's decision, it means that the special provisions for me are no longer in force. Whether or not you were instructed by the Board to stop making these requirements of me is immaterial. Furthermore, your comments above do not reflect what I said at the meeting between you, me, Joerg and Karsten on 21 March in Lisboa. The minutes you sent me say:

"(PG) I was told at the Centre Directors meeting that there can't be separate rules for me and not everyone else. In Geneva, the Board agreed that I could use the letterhead and Cochrane affiliation as long as I make it clear these are my personal views. This means the additional agreements have been annulled and MGW has not been informed. The Minutes from the 'Board only' time say this.

(JM) We didn't explicitly discuss the case, but the Board discussed and agreed it doesn't make sense to prevent people using the letterhead but they should abide by the Spokesperson Policy and make it clear explicitly when it is not a Cochrane view. There are Minutes from the 'Board only' time to confirm. Maybe we can find a way to resolve the three concrete cases which would make me happy. I can fully understand Mark's position: it is his job to protect the brand."

Thus, I said: "This means the additional agreements have been annulled", which is correct and which Joerg confirmed, both in Genève and again in Lisboa.

A key point in all of this, and in earlier complaints, which has been overlooked, is that affiliation is not representation. The nominal factual relationship with the Nordic Cochrane Centre does not at all mean that I, or any of my researchers, speak in the name of Cochrane as a spokesperson, nor have we ever given that impression. That impression is the result of the very partial interpretation by a number of our scientific and political opponents, but unfortunately you and your staff have followed the same line of reasoning when you have erroneously claimed, again and again, that I have broken the Spokesperson policy.

Having consulted Rob Scholten and Lotty Hooft, Co-Directors of Cochrane Netherlands, I am also concerned that though you became involved in a Dutch criminal case and then a medical practitioner dispute using your Nordic Cochrane Centre affiliation, you did not inform them or warn them of your actions, and possible publicity or impact on Cochrane in the Netherlands. Whilst this is not a requirement of the Spokesperson (or any other existing) Cochrane Policy, I would have expected that you would have abided by the guidance in that policy related to involvements with the media of other countries, given that this was such a more serious intervention in the Netherlands than a simple interview with a Dutch journalist. The Policy points out that: "it is common courtesy and best practice, if you are speaking in a country or have been interviewed by media within a country with a Cochrane presence and are referring to Cochrane to to inform the Director responsible for Cochrane activities in that country at the earliest convenience".

I talk to journalists virtually every day, from many countries, and cannot possibly inform my colleagues about all this. Often, I do not even know if and when they will go public. Some of the other Cochrane directors also often speak with the media, and they also do not inform colleagues in other countries. We do not think this is important. I was an expert witness in a double homicide case. The homicides would very likely not have happened, were it not for the use of a depression pill. My role for the defense was favourably described in Dutch media, and there were questions in Parliament. My interventions were very positive for the Cochrane brand, so there was no problem as seen from the Cochrane perspective.

As we discussed in Lisbon (see the attached Minutes), my conclusion is that in future you must abide at all times by the original requirement established by Cochrane's leadership in its letter of 9th June 2015, namely, that you "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'"; and that you ensure you abide at all times in the future with the obligations in Cochrane's Spokesperson Policy (and specifically those set out above). Failure to do so will result in disciplinary action, which may include as the JJune 2015 letter signaled the de-registration of the NNordic Cochrane Centre. We discussed at the close of our meeting in Lisbon that setting up your own separate, personal organization (be it a foundation, Institute or other legal body) from which to research and campaign on these issues may help you to clarify your roles, research and activities far more easily.

It was clearly agreed by the Board in Genève that I am entitled to use the Nordic Cochrane Centre's letterhead, which decision must be respected by you. I consider it totally out of proportion, appalling and highly disrespectful of my work that you threaten me with closing my centre.

I have attached my intended responses to Dr Torrey and to Mr Pottergard, as promised in Lisbon. If you have any comments you would like to make about them before I send them later this week then you are welcome to send those comments to me. I have already considered the points made in your draft responses you sent me on 18thMarch in formulating these replies.

In your email from Wednesday 11 April at 14.23, of 13,000 words with 9 attachments, you gave me a deadline of only two days after you had yourself had six weeks to think about the letter from Torrey. I consider that this is not due process and furthermore disrespectful of my work, and I asked you not to write to Torrey and Pottegård after such a short deadline. I explained, also to the Board, that during those two days I would be fully occupied with meetings and would not have time to respond before the weekend. Nonetheless, I responded to the Board and you early Monday morning on 16 April.

However, I am not able to finalize a response to Professor Loonen because I am not yet in a position to answer all of the questions in his letter. In relation to that dispute, therefore, can you please let me know the answers to the following questions:

There is no hurry, as the court case Loonen and I were involved with as expert witnesses took place two years ago. In his letter to you from 19 March, Loonen stated:

"I was very surprised about the content of his opinion, and also the level of his qualifications to be able to offer an expert opinion in this case; I expressed my serious concerns about both matters. Mr. Gotzsche's theoretical education and clinical expertise in Psychiatry, Neuropsychopharmacology, and Clinical Pharmacology mean that he is insufficiently qualified to write this report. Mr. Gotzsche had neither examined the suspect nor had he studied the criminal files himself. His report was exclusively based on a translation of my report and its addendum. It became evident to me later that, as could be expected, this translation showed imperfections. His report contained several incorrect statements and, in addition to these, numerous allegations against the treating physicians and myself."

Loonen gives himself an authority he does not have. It is up to the court – not Loonen - to decide whether I have qualifications for being an expert witness. The court ruled that I had. Indeed, I have strong qualifications. I have done research in this area since 2007 and currently have 5 PhD students and a psychiatrist in my staff. The issues I raised in my expert report were highly relevant for the court case.

Loonen notes that my expert opinion was presented using the letterhead of the Nordic Cochrane Centre and he asks whether the Centre endorsed my findings in my expert report, and whether my conduct is in line with Cochrane's policy on conflict of interest.

My expert report was written for the court and as far as I know, it has not been made public. Thus, this is not a matter of how the public perceives it, and there cannot be any confusion in relation to the Spokesperson policy. Further, Loonen's questions are irrelevant. The reason that I was approved as an expert witness is related to my work at the Nordic Cochrane Centre and it was therefore natural that I used this letterhead. This has nothing to do with whether or not my Centre endorsed my findings, and I am entitled to use my Centre's letterhead (see above). No one has or had any reason to doubt that what I stated in my expert report was my own opinion. This is what being an expert witness is all about; it is not about policies. Further, I cannot see how it could be a conflict of interest to defend a woman who was seriously harmed by the depression drug she was taking and developed symptoms that predispose to violence and homicide. Loonen did not acknowledge this in this expert report or in court.

Loonen states that his expert report was confidential. This is not correct and we were not asked by the court to sign any confidentiality agreements. There were plenty of journalists present and I do not know if or how they got access to Loonen's report.

Loonen states that, in January 2018, two years after the court session, I filed a complaint against him at the disciplinary court. A Dutch lawyer filed the complaint on my behalf, to the Regional Disciplinary Court for Healthcare at Eindhoven. The background for this complaint is that Loonen behaved so badly during the court proceedings that he was officially reprimanded several times.

In the middle of the court proceedings, Loonen was asked to leave the room and he asked if a journalist was present. Loonen contacted the press, and a newspaper printed an article where Loonen, among other things, called another expert witness, Selma Eikelenboom, for a "charlatan". Eikelenboom complained to the Regional Disciplinary Court for Healthcare at Eindhoven. The Court found Loonen's statements offensive, unfair and consciously directed towards Eikelenboom and reprimanded him. The Court furthermore found that Loonen, as a judicial expert, in an improper way had wanted to influence the criminal process, which involved particularly serious and punishable offenses. The Public Prosecution Service concluded that Loonen's offense was criminal according to criminal law.

Also in the middle of the court proceedings, Loonen asked the judges for permission to distribute a paper in Dutch he had written. Permission was granted. During the lunch break, before the proceedings were resumed, someone translated the paper for me orally. It started this way:

"Concerning the person Prof Dr Peter C Gotzsche. The court should be aware of the fact that Mister Gotzsche (recently) has become a controversial figure ... Of importance is also the official statement with which the Cochrane organization dissociated itself from the content of his book 'Deadly psychiatry and organized denial' (translated into Dutch as Dodelijke medicijnen en georganiseerde misdaad). It remains to be seen whether Mister Gotzsche is entitled to write this letter to defence counsel De Haas in the capacity of director of the Nordic Cochrane Centre and on the stationery of that organization. Furthermore, Mister Gotzsche is trained as an internist and by profession an epidemiologist (Clinical Research Design and Analysis) and he does not work as a physician/clinical pharmacologist in the individual psychiatric patient care. His great scientific merits are beyond all doubt. Therefore, it is all the more tragic to see that on occasion, as seen from a scientific perspective, his remarks in recent writing (as in this letter [which was my expert report]) are neither here nor there. This leads me to suspect the course of a disease, as a result of which he has seriously become disinhibited. Naturally doctors may fall ill much like anybody in which case the health system unfortunately proves to be more than little capable to protect these ill people against themselves. It should be noted that this is merely my opinion. I otherwise do not know Mister Gotzsche and I have never examined him, but in my professional opinion I feel he ought to be."

I am proud of my expert report, in which I provide serious criticism of Loonen's expert report. I complained to the court about his outrageous, unethical and unprofessional statements, saying it would be unfair to give his paper any importance in the proceedings. The judges

accepted my complaint and disregarded Loonen's defamatory paper. I later complained about Loonen's grossly inappropriate conduct to the University of Groningen with which he is affiliated, and the Rector arranged a meeting with Loonen where Loonen was told that his conduct was inappropriate. The University wrote to me:

"In the meeting which took place on 26 February 2018 the Rector and mr. S.R. van Dijk talked for more than one hour with professor Loonen. They have conveyed the concerns of the Rijksuniversiteit Groningen with regard to the conduct of professor Loonen and have brought to his attention that he, like every special appointed professor, must behave in a responsible manner and must prevent the university from suffering possible damage as a result of his behavior. Professor Loonen has indicated that he understood our concerns and would take into account the interests of the university in future statements."

a. Did you submit your expert opinion in the Dutch criminal trial "on the company stationary of the Nordic Cochrane Centre ... signed as follows: 'Peter C Gotzsche, Profeessor, DrMedSci, MSc, Director of the Nordic Cochrane Centre, Rigshospitalet'? (https://emea01.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftranslate.google.co.uk%2Ftranslate%3Fhl%3Den%26sl%3Dnl%26u%3Dhttps%3A%2F%2Fuitspraken.rechtspraak.nl%2Finziendocument%253Fid%253DECLI%3ANL%3ARBGEL%3A2016%3A1715%26prev%3Dsearch&data=02%7C01%7CMWilson%40cochrane.org%7C9324e4049748439e67b308d594bd1602%7Cb6c2e21e4db74533916398c1451c1caa%7C0%7C0%7C636578462211145502&sdata=wd1DWMIQMi1hVlNsiKZELpU4oatZ5z9ytblKDqbJ8tl%3D&reserved=0)

See above.

b. Did you receive payment for the expert medical legal report you gave in the criminal case; and if you did, was it received by you personally or did you pass it to your employer, the University of Copenhagen?

I cannot see any relevance of this question.

c. Did you share Professor Loonen's confidential expert opinion with the *De Volkskrant* newspaper?

It was not confidential, see above. I do not know how the journalists became aware of the issues but there were plenty of journalists present during the proceedings and a lot of talking went on during the breaks, some of which Loonen initiated himself.

Thank you for providing answers to these questions. Can I ask you to send me your replies within seven days (by 18th April), and I'll then be able to revert back to you with any final conclusions, then finalize a reply to Professor Loonen and close these issues off. I will then raise with the Co-Chairs and David your request to remove the statement by the Cochrane leadership of 18th September 2015 from the Cochrane website (http://www.cochrane.org/news/statement-cochrane).

I very much hope you will remove this outdated message, as it is very harmful for our work and also causes yourself a lot of unnecessary work. People learn from each other and this message has been much abused to create pseudo-problems. I have protected you by only

informing you about a minority of all these abuses.

Please do not send any replies to Torrey, Pottegård or Loonen before I have agreed to them. In case you and I cannot agree, the Collaboration Agreement between you and me from February 2017 describes what should happen next.

This Collaboration Agreement contains the following:

Cochrane, its Chief Executive Officer (CEO) and its Central Executive will:
6. Recognize the NCC as the leader and co-ordinator of Cochrane activities and principal representative of Cochrane in Denmark, and consult with its Director(s) on any activities affecting Denmark and those countries where the NCC manages an Associate Centre/Affiliate.

It is clear from this that you must consult with me when people complain about me.

11. Upon the request of the Centre Director, engage with, advise and support the Director and his/her staff in their work, including addressing problems or complaints, and helping with conflict resolution.

I have not seen much in terms of supporting me so far in relation to people complaining about me. Your actions have often harmed not only me but the whole Nordic Cochrane Centre. A member of the Governing Board sees it this way in relation to the recent complaints:

The independence of Cochrane could be tarnished by this action by its CEO. We all know that the pharmaceutical industry and its lobbies, both visible and covert, are reacting aggressively to articles and books about the gross overmedication and overprescription of psychiatric drugs. Your [my] publications and public appearances have been particularly effective in sparking a very necessary public debate concerning this harmful practice not justified by most scientific evidence. If Cochrane is perceived as being influenced by these defensive campaigns by industry, even if they are carried out by people with no apparent direct financial interests, the reputation of Cochrane could be seriously harmed. I seriously hope this does not happen.

Dispute Resolution and Performance Management

22. In the event of a dispute between the CEO and the NCC Director on Cochrane-related business or

issues, both will make every good faith effort to resolve it amicably within six weeks. The CEO and/or

the Centre Director may call upon the Centre Directors' Executive to advise on the resolution of the

dispute.

As you know, and as Joerg Meerpohl witnessed on two occations in Lisboa, I tried to resolve the current issues amicably and also asked you not to make too much out of the complaints.

23. If, following attempts at a resolution of the dispute, the Cochrane Director remains opposed to the

decision, he/she may appeal it to the Cochrane Governing Board. If the Centre Director's position is

supported by a majority of the Cochrane Centre Directors' Executive, then this will be made clear to

the Governing Board. The decision of the Governing Board will be final.

I have not contacted the Cochrane Centre Directors' Executive and it is not mandatory. I you and I cannot reach an agreement on the above and on my comments sent to the Board and you on 16 April, I will appeal your decisions to the Cochrane Governing Board.

Please do not hesitate to call me if you would like to discuss any of these points in more detail.

Best wishes,

Mark

Mark G. Wilson Chief Executive Officer

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