# **SLUG: COMMENT**

# **TITLE:** **Storm in a teacup? General implications of the Cochrane crisis**

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The expulsion of Peter Gøtzsche from the Cochrane Collaboration had all the signs of a storm in a teacup at first glance. Gøtzsche’s writing in his earlier popular book ([[1]](#footnote-1)) on the unstated dangers of psychotropic drugs that are coming into the market for the mentally ill had the finesse of a bull in a china shop. He has used all kinds of populist phrases to describe the authoritarianism of professional expertise: worst of all, calling the leaders of the psychiatric profession “silverbacks”, to liken them to alpha male gorillas who ran the profession. While this book’s perspective was informally referred to ([[2]](#footnote-2)) as an element in a trail of reasons, apparently going as far back 2003, the last flap of the butterfly’s wing that caused the storm was Gøtzsche’s “excessive" criticism of the Cochrane review of the human papilloma virus vaccine for adolescent and young adult women which promised to cut down the incidence of cervical cancer. So, it is indeed understandable that Gøtzsche was sacked because of his outspoken, loose cannon style. And that is how the “proper” voice of the Cochrane board described him ([[3]](#footnote-3)): arrogant, self-indulgent, irresponsible and excessively polemical in his statements. These were the personal stylistic reasons that accompanied the substantive reason for the sacking: that his pronouncements put millions of patients at risk. Good riddance, I thought!

Gøtzsche responded by writing a public letter ([[4]](#footnote-4)) that charged the Board with acting in a dictatorial manner, that with his expulsion, “the Cochrane Collaboration has entered an unchartered territory of crisis and lack of strategic direction. A recovery from this dire situation would call for the dissolution of the present board, new elections and a broad-based participatory debate about the future strategy and governance of the organization”. So far, it seems like a typical power play between the “Haves” and the “Wanna Haves”, ho hum!

What is at stake? On the one hand, if the Cochrane Board is right, Gøtzsche’s pronouncements, under the garb of Cochrane authority unethically misleads doctors and the people at large by misinforming them about false flaws in these drugs, thus putting many young girls at risk of preventable cervical cancer. On the other hand, if Gøtzsche’s right, the Cochrane reviews of the HPV vaccines are faulty. These vaccines can cause serious iatrogenic disability ([[5]](#footnote-5)).

Gøtzsche’s argument against psychotropic drugs is that the system of production and marketing them pushes flawed products that harm the mentally ill: including increasing the risk of chronic diseases, having debilitating side effects and failing at its primary curative purpose.

Gøtzsche’s charge is that these problems arise because the Cochrane Review Board which had started out as a noble institution to ensure the truth of medical research is corrupted by the pressure of pharma. So, the storm in this teacup has some potentially serious repercussions on our lives. Psychiatrists continue to prescribe new drugs in blind faith. Doctors in the news nonchalantly recommend HPV vaccines in mainstream newspapers even as late as October 1st ­­ 2018 after the storm has erupted ([[6]](#footnote-6)). How do we decide what to do?

While the Cochrane charge against Gøtzsche and the latter’s original announcement of his termination seem a run of the mill power battle, a later publication by Gøtzsche and his colleagues shows the matter in a different light ([[7]](#footnote-7)). This substantive essay describes clearly the intentional and structural roadblocks that go against any independent evaluation of a Cochrane review. It also highlights the shortcomings of the review. The main issues summarized:

* Public confidence in vaccines needs reliable assessment. The Cochrane review is no longer reliable.
* Clinical study reports that are kept by manufacturers contain more information than journal publications but are harder to access. The Cochrane review of the HPV vaccine studies didn’t use the manufacturers’ clinical study reports. They were not allowed access to this data.
* In general regulators did not have the full data and the manufacturers place restrictions on the dissemination of industry data.
* European Medicines Agency too did not initially permit free access of data to Gøtzsche and his colleagues, and when they ultimately did, the data was incomplete, scattered and difficult to use. Only half of potentially eligible reports for a systematic review of HPV vaccines had been delivered to the authors of the essay cited after three years of their efforts: this data was incomplete and contained extensive redactions (blanked sentences to ensure pharma knowledge secrecy).
* The process for releasing clinical study reports should be improved to make it faster and more complete.

This paper is far more convincing than the statements that exchanged blame and underlines the real problem for the doctor who prescribes and recommends based on the faith in the system.

Clearly the doctor must be well informed. But how many of our doctors have the time to be well informed, and what happens to this ‘well informedness’ if their continuing education is by the medical representative of precisely the pharmaceutical companies that have pushed these vaccines and drugs into the market? How do mere mortals find out what the truth is here when even the privileged authors Jorgensen, Gøtzsche, Doshi and Jefferson say that it is difficult to get information from the regulatory agencies and the manufacturers?

So then, this is the size and extent of the crisis: Cochrane, the global watchdog of effective and efficient drug discovery and use has now been crippled with inefficacy and inefficiency.

The problem clearly seems to be that of a pharmaceutical industry (as any other industry) which seeks to find ways to profit from its business. Naturally it tries to sell more medicines. And as with any other industry it finds loopholes to do so. The problem with medicine is that it is not a simple sale between a buyer who knows what she wants and a seller who is open about the information. In medicine, the ignorant patient, i.e., the ‘buyer’ trusts, and is at the mercy of, the doctor, who prescribes what he thinks the buyer needs, *often based on ‘knowledge’ he receives from the seller’s representative*. Not only this, the buyer is often in a catastrophic or critical situation where he must accept the doctor’s prescription, or expect to suffer a dire and painful future if she refuses medical advice! This then is the larger trap we are in with respect to our approach to medical care and health. Despite obvious ‘villains’, the situation is larger than individual wrong doing or corporate greed alone. This is the medical culture we are born into.

It bodes ill that this knowledge-industry-specialist medical culture we live in has fully taken the health of people into its hands. Medicine has become increasingly specialized and remote, yet it reaches into our daily lives with terrifying alacrity to promote health, to prevent disease and to cure our bodies with its alien expertise. If it fails, and it has so often, we have no recourse. Industry wants to profit and grow and, in the process, is losing sight of its primary responsibility as part of medicine: not to harm people knowingly while selling them cures for their illnesses. Governments seems on the one hand to depend blindly on the specialists, and on the other, to encourage pharmaceutical industries to do whatever they want to, to boost economic growth indices. And in the middle of this global morass of interests and priorities, the watchdog institution the Cochrane Collaboration has dealt itself a potential death blow, abetted by pharma pressure. How do we retrieve our wellbeing from this dead end?\*

While our medical culture struggles to find its feet, there is no doubt that we must listen to the likes of Gøtzsche and his colleagues. These are the few experts who remember their responsibility to the people and fight institutional failure and corporate greed. For those like them, it is a fundamental ethical responsibility to do so. For those like us, people, patients, caregivers it is a matter of survival and wellbeing.

What then is the professional responsibility of a doctor in this uncertain situation? The average Indian patient will continue to put his life in the doctor’s hands in implicit and explicit trust. But perhaps we should begin to think for ourselves a little more; find ways to survive, as a people, this trap we are in. Perhaps we need to strengthen models of local knowledge and sharing of insights, depending on ethical critics like Gøtzsche and colleagues, to find ways to survive this unhealthy regime of health care. It is here that organizations like Medico Friend Circle of India need to continue to prove their role as places of exchange and mediation between expertise and activism.

***Acknowledgments****: I am grateful to the discussion of this topic on the mfc egroup by people more knowledgeable than I. I also thank Anita Jain for the prompt and warm response to my request for article reprints. Errors are mine.*

\* ***Note***

For an earlier and more general version of this argument, see the “Introduction” in Zachariah A, Srivatsan R, Tharu S, editors. *Towards a critical medical practice: Reflections on the dilemmas of medical culture today*. Hyderabad, India: Orient Blackswan; 2010. Pp 392.

**References**

1. Peter Gøtzsche. *Deadly psychiatry and organized denial,* Copenhagen: People’s Press, 2015. [↑](#footnote-ref-1)
2. See: <https://www.statnews.com/2018/09/16/expulsion-cochrane-peter-gotzsche-medicine/> Accessed on October 5, 2018 [↑](#footnote-ref-2)
3. “Cochrane’s Editor in Chief responds to BMJ EBM article criticizing HPV review”, <https://www.cochrane.org/news/cochranes-editor-chief-responds-bmj-ebm-article-criticizing-hpv-review> Accessed on October 5, 2018. [↑](#footnote-ref-3)
4. 14 September 2018, “A moral governance crisis: the growing lack of democratic collaboration and scientific pluralism in Cochrane”. Referred to as on the Cochrane Nordic website, but has since been taken down. Not accessible on 5 October 2018. [↑](#footnote-ref-4)
5. Postural orthostatic tachycardia syndrome (POTS) and complex regional pain syndrome (CRPS), are two .documented side-effects of the vaccine. The disagreement between Gøtzsche and the Board is the relative risk and benefit. ([BMJ 2018;362:k3694 doi: 10.1136/bmj.k3694](BMJ%202018;362:k3694%20doi:%2010.1136/bmj.k3694), Published 24 September 2018) [↑](#footnote-ref-5)
6. See for example the article in The Hindu dated 1st “October 2018 titled Why early detection is key to deal with women's cancers” which carries a box recommending the use of HPV vaccines to prevent cervical cancers. At: <https://www.thehindu.com/sci-tech/health/breast-cancer-awareness-month-more-reluctance-less-reluctance/article25094170.ece> Accessed on October 4, 2018. [↑](#footnote-ref-6)
7. Jørgensen L, P Doshi, P Gøtzsche, T Jefferson, Challenges of independent assessment of potential

   harms of HPV vaccines””, BMJ2018;362:k3694 doi: 10.1136/bmj.k3694 (Published 24 September 2018). Accessed on 04 October 2018. [↑](#footnote-ref-7)