Submission No 66

THE PROMOTION OF FALSE OR MISLEADING HEALTH-RELATED INFORMATION OR PRACTICES

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> *"In the United States and Europe today, the third biggest killer after heart disease and cancer is drugs."*
>
> — Peter Gøtzsche,
> Co-founder of the Cochrane Collaboration,
> Leader of the Nordic Cochrane Centre[1]

> *"The Department of Health has not only to promote the interests of the pharmaceutical industry but also the health of the public and the effectiveness of the NHS. There is a dilemma here which cannot be readily glossed over. The Secretary of State for Health cannot serve two masters. The Department seems unable to prioritise the interests of patients and public health over the interests of the pharmaceutical industry."*
>
> — House of Commons Health Committee,
> 2005 inquiry in to
> *The Influence of the Pharmaceutical Industry*[2]

Dear Committee Members,
This communique is written by a concerned citizen, not someone supportive of a melange of alternative medicine snake-oil. I write to you as someone who's always revered science. Indeed, it is for this reason that I studied physics and computing, wherein I received first class honours for my work in logical systems. Yet it is precisely as such a person that I've become horrified by a constant stream of revelations, from highly "respectable" sources including those mentioned above, that have shown medical science might not be as scientific as it purports to be.

The first of the above quotes was taken from the book *Deadly Medicines & Organised Crime*, published this last September, which discusses the present crisis in pharmacology. Doubtless the committee needs no introduction to the Cochrane Collaboration of which Gøtzsche is co-founder, nor to the evidence-based medicine movement of whose existence Cochrane is commonly & proudly held aloft as emblematic.

This communique will be brief, owing to the extreme nature of what the inquiry is considering,

combined with the similarly extreme nature of the medical-industrial complex today, and the very mainstream voices one can readily cite against these. The case is simple: don't do it.

Don't do it because, as Cochrane co-founder Peter Gøtzsche says above, the third biggest killer in the West today is pharmaceutical medication itself. This is a claim he makes in his book whose forwards were contributed —which is to say, its contents endorsed —by Richard Smith, former editor-in-chief at the *British Medical Journal*, and Drummond Rennie, Deputy Editor at the *Journal of the American Medical Association*. Gøtzsche goes on to detail, not just one or two, but myriad reasons to be sceptical of the claims of the pharmaceutical industry. His most alarming statement is that the ten biggest pharmaceutical companies in the world, whose combined profits comprise more than the rest of the *Fortune 500* companies put together, break the law so repeatedly that they meet the definition of organised crime under US "RICO" anti-racketeering legislation.

Dear Committee, it is in this climate in which you seek to create an even *more* privileged place for the medical-industrial complex.

Peter Gøtzsche's book is, of course, not a one off. It is but one of a whole bookshelf one can now assemble, with each book being a monotonous litany of profit-motivated perversions of science that would be dreary if it wasn't all so outrageously important.

Ben Goldacre, for instance, science writer at *The Guardian* and epidemiologist, and the person *New Scientist* called "rationality's rottweiler" [3], detailed his concerns in his book of 2012, *Bad Pharma*[4]. Goldacre summarises his book in the introduction thus:

> *[T]his whole book is about meticulously defending every assertion in the paragraph that follows.*
>
> *Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques which are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don't like, they are perfectly entitled to hide them from doctors and patients, so we only ever see a distorted picture of any drug's true effects. Regulators see most of the trial data, but only from early on in a drug's life, and even then they don't give this data to doctors or patients, or even to other parts of government. This distorted evidence is then communicated and applied in a distorted fashion. In their forty years of practice after leaving medical school, doctors hear about what works through ad hoc oral traditions, from sales reps, colleagues or journals. But those colleagues can be in the pay of drug companies —often undisclosed —and the journals are too. And so are the patient groups. And finally, academic papers, which everyone thinks of as objective, are often covertly planned and*

> *written by people who work directly for the companies, without disclosure. Sometimes whole academic journals are even owned outright by one drug company. Aside from all this, for several of the most important and enduring problems in medicine, we have no idea what the best treatment is, because it's not in anyone's financial interest to conduct any trials at all. These are ongoing problems, and although people have claimed to fix many of them, for the most part they have failed; so all these problems persist, but worse than ever, because now people can pretend that everything is fine after all.*
> ...
> *The true scale of this murderous disaster only fully reveals itself when the details are untangled.*

Stifling discussions of culpability amid the crisis in pharmacology?

This "murderous disaster" surely raises the issue of culpability. There are those, like the former-GP Goldacre, who insist they did everything by the book and have been duped by the pharmaceutical industry alongside patients. There are others, like Gøtzsche, who recognise that the moral and ethical consideration of culpability cannot be swept aside so easily. In that context, how are we, the public of NSW, to interpret the motivation behind the new HCCC powers mooted by this inquiry, which does not seek to have a public discussion along either of these lines, but rather seeks to stifle discussion by all but industry insiders —by exactly the people whose culpability needs to be debated?

Indeed, is the committee seeking to address existing medical crises, perhaps by empowering the HCCC to defend the interests of patients? Does the NSW parliament intend to address Goldacre's "murderous disaster" with as much vigour as it seeks protect the medical establishment from external criticism?

I suspect the Australian Vaccination Network (AVN) is one of the motivators behind this committee's existence. While I don't support everything the AVN says —indeed, probably very little of it —it is naïve to think that the AVN's growing traction has its genesis in anything other than the state of affairs described by people like Gøtzsche, Goldacre, & the House of Commons Committee, as well as a significant minority of other industry insiders. It would be doubly naïve to think that the solution to the threat posed groups like the AVN to the medical-industrial complex is to become *less* open to debate and diversity of opinion and to rely *more* on an authoritarian control of the speech of others.

The terms of reference assume the infallibility of medical consensus. This is "assuming the consequent"

Regarding the inquiry's terms of reference, the "general community['s] mistrust of, or anxiety toward, accepted medical practice" might actually be valid. For instance, for a period in the

history of tobacco smoking, while there was growing awareness in the general community that the habit was unhealthy, there were still medical doctors who were claiming this was untrue. They were paid by the tobacco industry to say this. The case of "regulatory capture" by the pharmaceutical industry of, not only its official regulators, but also the broader medical community, makes our present issue much more subtle and commensurately more dangerous than the tobacco example. In this context, who determines what is a "safe" medical treatment? The spirit of the terms of reference suggest that it will be exactly one side of the debate: the medical establishment.

There is betrayed here a conflation of "accepted medical consensus" with medical fact. There is an underlying assumption here that "accepted medical consensus" is invariably correct. The likes of Peter Gøtzche, Ben Goldacre, the House of Commons Healthy Committee, and others, all suggest that this is over-confidence. Moreover, a publishing niche has emerged in the study of pharmaceutical studies, and there is no longer any doubt that manufacturer sponsorship of drug trials, which is very common, increases the chance of positive outcome by 2-4 times.

Woven throughout the terms of reference is the assumption of an unbiased, rational and *infallible* medical establishment comprising one of the noble pillars of Civil Society. The logician in me needs to point out that to assume this —indeed, to legally enforce it —at the outset of any debate amounts to begging the question, that is, it's an assuming-the-consequent fallacy. And this fallacy is being pushed despite ample evidence already that infallibility is an undeserved assumption. The fact that a crisis in pharmacology exists at all directly implies that most of the medical establishment —let's be frank, this means medical doctors —have been lacklustre in the community's expectation that they should critically evaluate treatments.

What is the *quid pro quo* if the establishment is wrong?

And for these regulations to even begin to make any ethical sense at all, there must at least be built in to them *penalties*, commensurate to the damage inflicted, for any occasions when the mechanisms being explored by the Committee here are used to prolong poor treatment options and withhold better ones. Without this, the committee seeks to create an apparatus of Civil Society with no memory —indeed, which doesn't need one because it's deemed infallible *by definition*.

Is the committee aiming to enhance the NSW government's culpability when it emerges that some therapy or other did more harm than good, and that public discussion of safer options was stifled by the state?

Right to refuse medical treatment?

Moreover, the terms regarding "[t]he publication and/or dissemination of information that

encourages individuals or the public to unsafely refuse preventative health measures" also appear to mock accepted conventional wisdom, not to mention legal precedent, that respect as a human right the individual's right to refuse medical treatment.

Track record of the HCCC

Regarding the question of "the adequacy of the powers of the Health Care Complaints Commission", this must be considered against the history of the HCCC, which the Medical Consumers Association of NSW has summarised unequivocally as an entity whose primary goal is to protect doctors from patients, and not the other way around as the name suggests. This makes its title nothing less than Orwellian in nature, and yet the inquiry is considering giving it more powers.

The inquiry's notion of who is qualified to participate in medical debates is so restrictive that it only includes vested interests and excludes educated outsiders

The terms of reference explicitly seek to

> *"focus on [—and punish, evidently —] individuals who are not recognised health practitioners, and organisations that are not recognised health service providers"*

Again, this leaves only one side of the debate with a permitted voice: that of the industry insiders, vested interests, those whose income stream and evasion of liability is tied up with conflating "accepted medical practice" with efficacy.

For example, I have studied in some detail the problem of psychopharmaceuticals and the evidence-base for them. It turns out this evidence-base is extremely weak, so that the primary dictum of medical ethics — *primum non nocere* (first do no harm) —is certainly not being met. As someone with training in engineering, logic & physics, with a commensurately strong mathematical & rational background, am I to be considered insufficiently trained to comment publicly on a psychopharmacology that deals primarily in the *mathematical, statistical correlations* between arbitrary drug doses and mood questionnaires?

For example, despite what the medical establishment might like believed, David Healy showed[5] that the "serotonin hypothesis" —the claim that low serotonin causes depression — was never directly demonstrated, but only implied by the apparent efficacy of Selective Serotonin Re-uptake inhibitors, a claim now easily described as flawed[6,7,8,9,10,etc]. Extrapolating, however, the industry then came to justify the efficacy of SSRIs in terms of the hypothesis —it had fallen in to a circular argument! In reality, there needn't have been any special status afforded the opinion of neurologists or psychiatrists, for their part of the story was erroneously implied by misjudged statistical and trial-design considerations. In reality, the opinion of anyone trained in a mathematical science was sufficient and would quite likely have lead to a more truthful "accepted medical practice" regarding SSRIs.

On the topic of SSRIs, it's worth noting that the publishing niche that has made patent and undeniable the medical-industrial complex's various biases —profit motive, publish-or-perish pressure on researchers & the prestige journal system to name a few —began with the most egregious example: psychopharmaceuticals. Quoting Gøtzsche once more,

> *"Our citizens would be far better off if we removed all the psychotropic drugs from the market, as doctors are unable to handle them. It is inescapable that their availability creates more harm than good."*[1]

So especially given a pre-existing crisis, is it really the intention of the committee to create a scenario in which the right to debate such socially significant policy matters is so restricted that even natural scientists, mathematicians, logicians & other outsiders well trained in aspects of rational evaluation are prohibited from speaking publicly on the fundamentally mathematical nature of the claims emerging from drug trials? Such an arrangement doesn't so much resemble a Civil Society participating in open debate as it looks like an authority privileging the views of the most vested of interests.

Indeed, since the powerful criticisms of areas psychopharmacology are primarily couched in terms of *statistics* and the (ir)rationality of *trial design*, and following the committee's reasoning and assuming it is sincere, then if anyone is to have a state-privileged opinion in this matter, shouldn't it be statisticians and mathematicians over medical doctors? Will the committee countenance this idea, or is it not in accord with what it is trying to achieve with mooted new HCCC powers?

Conclusion

Dear Committee, what's being considered here is using the HCCC to censor medical dissent in support of the medical establishment, with all the conflicts of interest that entails, and in the midst of a crisis of pharmacology identified by none less than editors of major medical journals and evidenced-based medical groups. At the very least what's being suggested is to outlaw real debate on medical topics, with one party being sole participant, chief financial beneficiary, and adjudicator.

A "science" whose conclusions need government enforcement rather than rational discourse in order to obtain community acceptance is probably not a model of Karl Popper's famous prototype of science. Emboldened by the powers suggested by this inquiry, increasingly it doesn't look like a science at all.

Sincerely,

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[1] Gøtzsche, P, *Deadly Medicines & Organised Crime: How big pharma has corrupted healthcare*, Radcliffe Publishing Ltd, UK, 2013

[2] House of Commons Health Committee, *The Influence of the Pharmaceutical Industry,* Fourth Report of Session 2004–05, Vol. 1, HC 42-I [Incorporating HC 1030-i-iii], http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf

[3] George, A, "Rationality's Rottweiler sinks his teeth in big pharma," *New Scientist*, 2012-10-12, http://www.newscientist.com/article/mg21628850.400-rationalitys-rottweiler-sinks-his-teeth-in-big-pharma.html

[4] Goldacre, B, *Bad Pharma*, 2012, Fourth Estate publishers, London

[5] Healy, D, *The Antidepressant Era*, Harvard University Press, 1997

[6] Kirsch, I, *The Emperor's New Drugs*, Basic Books, NY, 2010

[7] Kirsch *et* al, "The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration," *Prevention & Treatment*, Vol 5, Art 23, 2002

[8] Kirsch & Moncrieff, "Clinical trials and the response rate illusion," *Contemporary Clinical Trials* 28 (2007) 348–351

[9] Kirsch *et al*, "Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration," PloS Med 5(2): e45. doi:10.1371/journal.pmed.0050045

[10] Moncrieff J, Wessely S, Hardy R. "Active placebos versus antidepressants for depression." Cochrane Database of Systematic Reviews 2004, Issue 1. Art. No.: CD003012. DOI: 10.1002/14651858.CD003012.pub2.