COMMENTARY

Whistleblowing without names is hearsay

DAVID HEALY

Abstract

Peter Gøtzsche's proposal to provide anonymity to certain people reporting bad practices within the pharmaceutical industry, regulatory apparatus or health systems is superficially appealing but likely to generate more problems in the longer run than it might solve in the short term. We need to analyse what features of our systems generate problems and correct those, rather than rely on insiders to report on the resulting problems, as all these reports do is offer a false sense of security that things are safer now that one problem has been identified.

Keywords: *Anonymity, hearsay, whistleblowing, access to data, adverse events*

Peter Gøtzsche, in his Comment "Anonymous authorship may reduce prescription drug deaths" in this journal [1], is concerned about a serious problem. Prescription drug death may now be our leading cause of death [2], and life expectancies are falling in developed countries [3]. I imagine few readers of a medical ethics journal will disagree that we have serious problems in healthcare today. It is, however, one thing to recognise that something is badly wrong, but attempting a concrete solution of the problem requires a very clear specification of what it is that is wrong. The view we arrive at, if any, will need to command wide enough assent among those who are concerned, to lead to action. In addition, if we get to a point of taking concrete action, based on precedent, we will likely make things worse rather than put them right.

I think Peter's proposal to provide anonymity to whistleblowers will make things worse. His examples of things that are wrong point to superficial difficulties and do not nail what the underlying problem is. I'm going to nitpick his examples, not for the sake of it, but to bring out why the solution he proposes is wrong.

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One set of his examples centres on Andrew Mosholder of the United States Food and Drug Administration (FDA). Peter says in his Comment: "When the FDA's safety officer Andrew Mosholder concluded that the drugs increased the risk of suicide among teenagers, the FDA prevented him from presenting his findings at an advisory meeting, and suppressed his report" [1]. But, in fact, Mosholder had earlier recommended approving Prozac and Paxil for children in the face of negative trials of these drugs.

Rumour has it that Mosholder was prevented from presenting an analysis of suicidal events and Selective Serotonin Reuptake Inhibitors (SSRIs) at an FDA meeting in February 2004, that had been convened to look into this issue. In fact, the meeting had been convened months previously. Many others had analysed the data in the interim. Mosholder's analysis added nothing to these other analyses. It may well have been legitimate, on bureaucratic grounds, to withhold his presentation. In any case, despite this withholding, everyone at the meeting who wanted it had access to his analysis – FDA employees are pretty adept at getting things into the public domain when they want.

Why pick this nit? There is an impression that the FDA deal in science, and they should be transparent. They don't deal in science. They are bureaucrats who apply regulations. Their only contribution to health lies in the regulation of the wording of advertisements. Their primary concern is to have all boxes ticked so that when things go wrong, they can't be blamed. When all the evidence is in, it may be possible to work out if regulatory developments around Covid vaccines offer a good example of this dynamic.

There is a bunch of people other than the FDA, whose job it is to do the science on drugs. This bunch comprises a number of different people, with a range of expertise, but physicians are the primary group. If the science is not "being done" and this means not just carrying out the research, but doing it in a manner that conforms to the norms of science which requires public scrutiny of the data, the fault lies with this group. The fact that for three decades physicians have tolerated a complete lack of access to data from studies on medicines and almost all the medical literature is ghost written, suggests that this group will not step up to the plate any time soon. This is a problem that will not be solved by providing anonymity for bureaucrats.

Another set of Peter's examples centres on journalism. He outlines a rather trivial instance of what could be called

"cancel culture", where views that don't fit mainstream thinking are silenced. Again, this has nothing much to do with science, it only offers an instance of the operations of a distribution channel through which certain views come to dominate in the public domain.

These examples are important not in themselves but for the question they pose. To whom would an editor of a medical or medical ethics journal offer anonymity? Bureaucrats, journalists, non-clinical scientists, clinicians?

Would anonymous authorship help?

That is the next question.

Any journal presented with an article to be published anonymously or under a pseudonym, would almost certainly turn to their lawyers, who, in turn, would advise against publication.

If an anonymous publication is introduced in expert testimony in a legal setting, the courts would throw it out. Naming the author would lead to the reprisals the proposal seeks to avoid.

Academic journals are not a part of science; they are a business aimed at making a profit. Their mission is not keeping people safe. Most of these journals are embedded in conglomerates that have pharmaceutical company executives on their boards, with conglomerate executives sitting on pharmaceutical company boards.

Even the few medical journals that are not part of a conglomerate, such as the *BMJ,* will rarely take articles on prescription drug hazards that might threaten their business interests. This problem is getting steadily worse.

Most importantly, there is little or nothing any journal could gain from an anonymous whistleblower who has no documents. The documents are what make a leak notable and useful; and getting documents to a journalist or an academic who can write things up is not difficult. Why would a whistleblower want to add a dramatic gesture to a substantive act?

Anonymous whistleblowing without documents is hearsay and hearsay, as companies gleefully tell us, is of no judicial or scientific value.

Anonymous whistleblowing also has no news value. Appearing in any medical journal, it would sink out of sight. It might have some value if a major news source like the *New York Times* took it; but an outlet like this would likely not think a pharma story, short of a story as gross as the Sacklers, owners of Purdue Pharma*, is important enough to cover. Even then, any story is likely to make our current problems worse by conveying an impression that the rotten apple has been found and thrown out of the barrel, when our real problem is the rotten barrel.

Rather than an answer to our problems, anonymity is, in my view, central to the problem. In his embrace of randomised controlled trials (RCTs) and Evidence Based Medicine (EBM), Peter has helped create the problem we now have. RCTs celebrate anonymity and companies use this to frame accounts of prescription drug hazards to which doctors' and patients' names are attached as worthless. Regulators help in this by stripping physician and patient names from all reports of adverse events, effectively transforming them into hearsay, since anonymous participants cannot be brought to court to testify. These anonymous reports are worth far more to industry than any cozying up between regulators and companies that Peter is concerned about.

Regulators, like the FDA, have thousands of reports of deaths on individual drugs to their Adverse Event Reporting system, most of them likely caused by the drug, but the regulators routinely state they have never even established a causal link to a drug (or vaccine)[4]. What is left unstated is that the causal link cannot be made, primarily because these reports are anonymous.

Peter has been scathing about drug companies, but if there are reports of adverse events made to them, companies are legally obliged to assess these. After accessing a person's medical records, they can and do decide their drug has caused the problem even when doctors say it probably hasn't, and they change drug labels accordingly, albeit in ways that naïve doctors fail to interpret [2, 5].

In contrast, doctors are lily-livered when it comes to putting treatment hazards on the map, or blowing whistles on corrupt practices in either pharmaceutical or health service corporations. With rare exceptions, most of what we know about specific problems comes from courageous people working within industry, not from doctors.

What our healthcare problems need is for people to stand behind their experiences and reports and be named. If physicians stood together in reporting adverse events, the way pilots do by refusing to fly until aberrant systems change, they could resolve our current problems. At present, physicians have a privileged life, with status and money, and no backlash when they stonewall in the face of calls on their courage or decency.

The issues are most clear at inquests. Coroners can ascribe a cause of death to a street drug but not to a prescription drug. Doctors, advised by their insurers, betray families at a time of extreme need, and blame underlying diseases rather than a drug for the death [6]. The idea that medicine involves bringing good out of the use of a poison simply does not compute for insurers or managers or politicians. This is not going to be solved by anonymity.

As things are developing, the managers who now run health systems, depend on gold standard evidence from RCTs that "greenwash" medicines. These RCTs by making drugs appear effective and safe are increasingly leading to a replacement of doctors with cheaper prescribers. Doctors as we knew them are increasingly being replaced by nurses and others

as front line clinical staff. They are going out of business because they have accepted the idea that drugs are wonderfully effective and extraordinarily safe. Perhaps, at some point soon, when health systems have replaced doctors, our systems will find a way to recognise the harms that treatments can cause; but it is difficult to see how any solution will be able to work without a named person to stand behind each claim that a drug has caused this individual that specific harm.

Anonymity is not likely to be part of that. If we offer anonymity to the weak and scared, there will be no way to stop the strong and brazen from using it to destroy the credibility of someone like Peter and anything that has his name attached to it.

Note: The Sackler family, owners of Purdue Pharma, denied wrongdoing in the opioid addiction and deaths of several thousands of Americans who got addicted to their prescription drug OxyContin, which the company had marketed as a harmless painkiller.

References

1. Gøtzsche PC. Anonymous authorship may reduce prescription drug deaths. *Indian J Med Ethics.* 2022 Jul-Sep; 7(3) NS: 189-193. DOI: https://doi.org/10.20529/IJME.2022.041
2. Healy D. *Shipwreck of the Singular. Healthcare's Castaways.* Toronto: Samizdat; 2021.
3. Hiam L, Dorling D. The end of great expectations? The pandemic inquiry must account for stalling life expectancy before the pandemic. *BMJ.* 2022 May 5 [cited 2022 Jun 25];377: e071329. Available from: https://www.bmj.com/content/377/bmj-2022-071329
4. Wise J. Covid-19: UK makes first payments to compensate injury or death from vaccines. *BMJ.* 2022 Jun 24[cited 2022 Jun 25]; 377: o1565.Available from: https://www.bmj.com/content/377/bmj.o1565
5. Healy D. *Let them eat Prozac.* New York: New York University Press; 2004.
6. Healy D. Morgan v Morgan: The Future of the NHS? *davidhealy.org.* 2021 Aug 15[cited 2022 Jun 25]. Available from: https://davidhealy.org/morgan-vs-morgan-the-future-of-the-nhs/

COMMENT

Gift authorship: Look the gift horse in the mouth

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Abstract

Unmerited authorship in research papers is widely acknowledged to constitute research misconduct. In different contexts, it has been called "gift", "honorary", or "guest" authorship. Although several attempts have been made to address the issue, it remains a significant problem in research. In this paper, we discuss accepted criteria that qualify a person to be an author on a research publication and define what constitutes "gift authorship". We also look at the scenario in India and try to identify the circumstances that have fostered this practice in academia in the country. Finally, we discuss the adverse effects of this practice on the research enterprise as a whole, and possible remedial measures.

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Introduction

The question of who qualifies for authorship on a research publication has been a controversial and vexatious issue for long [1]. It came into sharp focus in the aftermath of sensational cases of research fraud in the 1970s and 80s. The Darsee [2], Slutsky [3], Pearce [4] and Soman [5] cases are prominent examples of research papers that contained data that were fabricated. However, what was shocking was the number of high-profile co-authors who denied any knowledge of the veracity of the data in those papers that they were supposed to have co-authored [1]. While these authors were only too ready to take credit for the publications, they did not seem to feel they needed to be held accountable when the data were called into question.

In response to these and several other similar scandals, the International Committee of Medical Journal Editors (ICMJE), which was then known as the 'International Steering Committee of Medical Editors', proposed authorship criteria in 1978 [6], which have since been amended several times. The current ICMJE criteria (updated in Dec 2021), which are widely accepted today, state that authorship should be based on fulfilment of the following four conditions [7]:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or