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COMMENT

Anonymous authorship may reduce prescription drug deaths

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Abstract

Anonymous sources are used by journalists when it is important to protect whistleblowers from repercussions. Healthcare is heavily influenced by vested interests which are often financial, but academic prestige and protection of guild interests also play a major role. If anonymous authorship is not allowed, many potential whistleblowers would prefer to keep quiet, even though their stepping forward would serve the public interest and might save many lives, particularly by reducing prescription drug deaths. This is especially important since drugs are the third leading cause of death in the Western world.

Keywords: *authorship ethics, anonymity, whistleblower, transparency,* prescription drug deaths

Introduction

I am a staunch supporter of transparency and accountability in everything humans do, which includes mentioning names, and I have explained why [1]:

> *"My preference is to mention names because people should be held responsible for their actions and arguments. If they do something laudable, they would be disappointed if they were anonymous, but it must work both ways. If I concealed the names when people did something reproachable, or sustained an erroneous belief, I would be inconsistent, and my readers would try to guess anyway who they were. Science is not about guesswork, which is another reason why I prefer to mention names. However, it is fair to point out that when I name a person for something he or she should not be proud of, there are thousands of others who have done the same or share the same beliefs."*

However, this general rule comes with exceptions. Healthcare is heavily influenced by vested interests, which are often financial, but academic prestige and protection of guild interests also play a major role.

If anonymous authorship is not allowed, many potential whistleblowers will prefer to keep quiet about what they know, even though it would serve the public interest and might save many lives if they stepped forward. This is because they know pretty well what the consequences could be of speaking out [2].

Fate of whistleblowers

It is usually highly stressful to become a whistleblower and cases in the West take five years, on average, to be resolved [3]. In a book about his own whistleblowing, Peter Rost, a global vice president of marketing for Pfizer, explained that "Pharmacia's lawyer clearly thought that anyone who tried to resolve potential criminal acts within the company and keep his job was a mental case." [4]

Rost described how things went for 233 people who blew the whistle on fraud [4] — 90% were fired or demoted, 27% faced lawsuits, 26% had to seek psychiatric or physical care, 25% suffered alcohol abuse, 17% lost their homes, 15% got divorced, 10% attempted suicide and 8% went bankrupt.

Unfortunately, as far as I know, it is only in the United States that whistleblowers may get rewarded to a substantial degree that allows them not to worry — at least not financially — that they might never get a job again.

I have pointed out in my writings over the years that drug companies beat all other industries in terms of serious crime, bribery and corruption. Furthermore, drug regulatory agencies are also complicit in why we have a broken system for drug use [2]. Drug regulators are consistently willing to award the benefit of scientific doubt to manufacturers rather than patients and they have become more permissive in recent decades. This has resulted in increasing numbers of drug withdrawals after marketing, followed by reports to the regulatory agencies of serious adverse events [2].

An example of egregious regulatory permissiveness was the case of rofecoxib (Vioxx), an arthritis drug. Based on its mode of action, it was expected that rofecoxib would greatly increase the risk of thrombosis, and the United States Food and Drug Administration (FDA) had serious concerns about the drug when it came to them for approval [2]. However, despite worrisome evidence in the application, the FDA

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approved rofecoxib for marketing in May 1999, stating that they lacked "complete certainty" that the drug increased cardiovascular risk [5]. It was removed from the market in 2004, but by the company, Merck (see more below), not by the FDA.

Another example is rosiglitazone (Avandia), a diabetes drug [2]. It also increases the risk of thrombosis and was taken off the market in Europe but not in the United States. The story about this drug was summarised in an editorial in *The Lancet* as one of "death, greed, and corruption". Fraud was also an issue. In 1999, the company, then known as SmithKline Beecham, completed a trial that found more cardiac problems with rosiglitazone than with pioglitazone, but stated in an internal email that "These data should not see the light of day to anyone outside of GSK [GlaxoSmithKline]."[6] Instead of publishing the trial's results, GSK spent the next 11 years trying to cover them up.

The industry is not effectively regulated, and drug regulators indulge in protracted and amicable negotiations with the industry, instead of acting promptly when there is a danger to public health. This explains why the culture within the FDA has been described as one of intimidation and fear and overly industry friendly. I give some examples below.

The FDA has accepted safety data it knew were fraudulent, and — on many occasions — data that clearly showed the drug was not safe [2]. It approved telithromycin (Ketek), an antibiotic that causes liver failure. When deaths with liver failure started to accumulate, the FDA held an emergency meeting among senior managers. At this meeting, in which it did not include its safety officers, it announced that the drug was safe — but by referring to a study that it knew was fraudulent [7]. The FDA's Commissioner, Andrew von Eschenbach, prohibited FDA scientists from discussing Ketek outside the agency [2]. Despite the knowledge that the drug was dangerous, the FDA did not deregister Ketek.

When FDA scientists find signs of serious harms, they are often overruled and intimidated by their superiors, and bullied into silence. Their superiors may have their own interests in pleasing drug companies to the detriment of patients; for example, many bosses at regulatory agencies obtain extremely well-paid jobs in the industry after they retire or leave.

There is evidence suggesting that the temptation of insider trading can result in the agency overruling the recommendations of its own experts and advisory committee not to approve a drug [2]. The situation was so bad that, in 2009, eight FDA scientists wrote to President Obama about widespread corruption in the FDA at the highest levels, including several commissioners [8].

In 2012, it was revealed that the FDA had installed spyware on the computers of five scientists who had alerted the agency about safety problems to no avail and had therefore approached politicians for redress [2, 8]. This came to light only because thousands of confidential documents from the scientists' computers were posted on a public website, apparently by mistake, by a private document-handling contractor [8].

When FDA reviewers and independent researchers found in 2004 that the drug companies had concealed cases of suicidal thoughts and acts caused by depression pills, by labelling them "emotional lability", the FDA bosses suppressed this information [2]. 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. When the report was leaked, the FDA's reaction was to conduct a criminal investigation into the leak [9].

David Graham, associate director in the FDA's Office of Drug Safety, showed in 2004 that Vioxx (rofecoxib) increases serious coronary heart disease. However, his study was pulled at the last minute from *The Lancet* after Steven Galson, director of the FDA's Center for Drug Evaluation and Research, raised allegations of scientific misconduct with the editor. Galson and his co-supervisors raised these allegations even though they knew they were untrue [2, 10]. The study was later published, but just a week before Merck withdrew Vioxx from the market, senior officials at the FDA questioned why Graham had studied the harms of Vioxx when the FDA had no regulatory problems with it, and wanted him to stop, charging him with doing "junk science".

There were hearings in Congress after Merck pulled the drug from the market, but Graham's superiors tried to prevent him from testifying, by stating to Senator Chuck Grassley, chair of the committee, that Graham was a liar, a cheat, and a bully not worth listening to [10]. Graham needed congressional protection to keep his job after threats, abuse, intimidation and lies that culminated in his sacking from the agency. It turned out that people who had claimed to be anonymous whistleblowers, and had accused Graham of bullying them, were higher-ups at the FDA management. An email showed that an FDA director promised to notify Merck before Graham's findings became public so that Merck could prepare for the media attention.

Merck selectively targeted doctors who raised questions about Vioxx and pressured some of them through deans and department chairs, often with the hint of loss of funding [2]. A few days after Eric Topol had testified for a federal jury that Merck's former chair, Raymond Gilmartin, had called the chair of the clinic's board of trustees to complain about Topol's views on Vioxx, his titles as provost and chief academic officer at the medical school in Cleveland were removed [11].

Lawsuits against Merck have uncovered details about how the company systematically persecuted critical doctors [2]. A spreadsheet contained information about doctors and the Merck people who were given the responsibility of following them, and an email said: "We may need to seek them out and destroy them where they live." There was detailed

information about the outcomes of the harassment, such as "neutralized" and "discredited". As just noted, the FDA behaved in the same way as the drug company did, using spyware on the computers of whistleblowers and firing them [2, 8].

The fraud committed by Merck and Pfizer in their trials of rofecoxib and celecoxib, respectively, have cost patients and their relatives dearly. I have estimated that these two drugs have killed around 200,000 people globally [2].

The Vioxx story illustrates that threats can be particularly malignant when scientists have found lethal harms with marketed drugs that the companies have successfully concealed. These include death threats and frightening telephone calls from the company warning that "very bad things could happen", cars stationed near the researcher's home through the night, a ghoulish funeral gift, or an anonymous letter containing a picture of the researcher's young daughter leaving home to go to school [2]. These are mob behaviours.

In 2006, internal Lilly documents leaked to the *New York Times* demonstrated the extent to which the company had downplayed the harms of its psychosis drug Zyprexa (olanzapine) [2]. Lilly instigated legal action against a number of doctors, lawyers, journalists, and activists to stop them from publishing the incriminating leaked documents on the internet [12]. After the company obtained an injunction, the documents disappeared. Lilly continued to deny that Zyprexa causes diabetes, even though the label since 2003 had carried an FDA warning that hyperglycaemia had been reported with the use of this drug. I have estimated that already by 2007, Zyprexa had killed 200,000 people [2] most of whom should never have received the drug [1].

A whistleblower may even have the whole state against him, as happened with Stanley Adams when he reported Roche's vitamin cartel to the European Commission in 1973 [2, 13]. Willi Schlieder, Director-General for Competition at the Commission, leaked Adams' name to Roche. Adams ended up in a Swiss prison, charged with — and later convicted of — crimes against the state by giving economic information to a foreign power. Roche seems to have orchestrated the police interrogations and when Adams' wife was told he could face 20 years in prison, she committed suicide. Adams was treated as a spy, court proceedings were held in secret, and he was not even allowed to attend his wife's funeral.

It is getting worse

Scientific debates where everyone is free to air even their wildest ideas without fearing repercussions are essential for the advancement of science, but they have become more difficult. It is a fact that when people become afraid of something, they are all too easily willing to abandon their ethical principles in return for some sense of security, however false or unsubstantiated that security might be.

We have seen this in abundance during the Covid-19 pandemic, which has created worldwide panic that has resulted in the introduction of many undocumented interventions, some of which were later shown to have been harmful [14].

The public debate quickly became painted in black and white because people needed something to believe in. Researchers who questioned the prevailing belief that the coronavirus was much more contagious and much more deadly than influenza were harassed and ridiculed, particularly on social media. Researchers who were concerned that the vaccines had been developed so quickly that there were no animal experiments and no data on long-term harms, even though some of them involved a totally new principle (the use of mRNA) were called anti-vaxxers [14]. It was considered heretical to question the mandatory use of face masks, even though a meta-analysis I conducted of the randomised trials of the use of face masks for preventing influenza-like illness (including the Danish trial for preventing Covid-19) failed to find an effect (risk ratio = 0.96, 95% confidence interval = 0.81 to 1.13, P = 0.63) [14]. A subsequent huge randomised trial of face mask use in Bangladesh carried out from November 2020 to April 2021 did not demonstrate an effect of face masks for Covid-19 either. The small effect, a 1% difference in infections, could be explained by the fact that physical distancing was practised by 29% in intervention villages and only by 24% in the control villages [15, 16]. Nonetheless, governments in the whole world mandated their citizens to dress like bank robbers.

Academic bullying and *ad hominem* attacks in relation to discussions about how we should handle the pandemic created groupthink, have caused serious reputational harm, and led some scientists to self-censor and avoid publishing data that could potentially have reduced death rates [14, 16]. Some researchers even refused to talk to journalists anonymously.

Professor John Ioannidis of Stanford University, the world's most cited medical researcher, became the subject of one of the worst witch-hunts in recent medical history, described by journalists Jeanne Lenzer and Shannon Brownlee in *Scientific American* [17, 18].

Next, *Scientific American* committed editorial misconduct [19]. The editors uploaded "corrections" to Lenzer and Brownlee's papers on the journal's homepage, several of which were errors committed by themselves, and others were false or irrelevant. They violated the first rule of journalistic integrity by publishing accusations without asking the accused for their responses. Lenzer and Brownlee tried to correct the false "corrections" but the editors denied them even this opportunity. The inappropriate "corrections" triggered an outpouring of hate mail and false claims about Ioannidis and the integrity of Lenzer and Brownlee as journalists.

It was so bad that Jeffrey S Flier, former Dean at Harvard

Medical School, wrote to the editors asking them to take proper action [19]:

> *"By printing a lengthy correction to their article, while refusing to permit them the opportunity to address the inaccuracies therein, Scientific American has needlessly besmirched the reputations of two distinguished and accomplished journalists who deserve a great deal of credit for their work over the years, including efforts to expose problematic issues in biomedical science."* [19]

Flier also noted that, "By bowing to the mob that has been attacking Ioannidis with false accusations that distort the totality of his work, *Scientific American* has lent support to behaviors that violate the norms of ethical scientific conduct." [19]

When it was found that the corona vaccine from AstraZeneca in rare cases causes an autoimmune coagulation disorder involving the thrombocytes, which can be fatal, a researcher wrote in an email to me that she had found the same autoantibodies induced by a totally different vaccine. However, she did not dare publish this observation, saying "because of the climate at my workplace, I would have to do it anonymously." I suggested we could publish together, with her being anonymous, but she did not take the offer.

Abuse of the peer review system

While anonymity may be necessary in the case of whistleblowers to protect them when, for example, they expose serious harms of drugs, anonymity for peer reviewers is not acceptable. Nowhere in healthcare is the issue of anonymity misused more than in the peer review process. Drummond Rennie, previous editor at the *New England Journal of Medicine* and *JAMA* and the initiator of the four-yearly peer review congresses, has argued convincingly that a fair system is either one where both the author and the peer reviewer are anonymous or one where they are both named [20]. The open system clearly wins [20]. If both the peer reviewers and the authors were anonymous, it would still be easy for peer reviewers to abuse their position, and the authors would not be able to find out, for example, if they were on a drug company's payroll, were heavily conflicted in other ways, or contradicted what they had themselves published earlier.

Yet, virtually every medical journal in the world operates with a system where only the peer reviewer is anonymous. Everyone with a long research career has been exposed to misconduct related to this unilateral system. Peer reviewers have stolen research ideas while posing so many obstacles for the authors that they made certain that they would publish first.

I have published numerous papers considered "controversial", which always meant that my results threatened vested interests. Many of my best papers proved impossible to publish in specialty journals because of guild interests and I often felt I had been exposed to an anonymous hangman who did the dirty job for the editors of inventing unwarranted criticism of my methods, allowing them to summarily reject my papers. Very often, I suspected the editors hadn't read my paper. Whenever I responded to the peer reviews, despite the flat rejection, that the reviews had no merit, or that the comments were erroneous, I got nowhere. It was not a question of science but of abuse of power.

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The problem with peer reviewers abusing their power in the guise of anonymity is common; but this could be much reduced if their identity were known.

Publishing anonymously could save many lives

The use of anonymous sources is common in newspaper articles and TV documentaries, eg: "His real name is not Lars, but his identity is known to us." It has also proved necessary to conceal the identity of witnesses in murder cases where criminal gangs are involved. If we didn't do this, many such cases would not lead to conviction and even more people might get murdered.

I am therefore a bit surprised that some academics argue that anonymous publishing of scientific papers, letters or commentaries should never be allowed. We should at least give it a try and evaluate the results after a while. The Council of Science Editors writes about anonymous authorship:

> *"In extremely rare cases, when the author can make a credible claim that attaching his or her name to the document could cause serious hardship (e.g., threat to personal safety or loss of employment), a journal editor may decide to publish anonymous content."* [21]

It is well known that managers at hospitals and universities often break the law by issuing gag orders, which also frustrate journalists when they face a stone wall of silence because employees won't talk for fear of losing their jobs [22].

I also have reservations about journal editors. They are often busy clinicians who are full of conflicts of interest, and my main worry is whether we can trust editors to respect

anonymity. There are examples where editors on a drug company's payroll have leaked confidential information to the company. This risk could be avoided if the anonymous author is not even known to the editor because the manuscript is submitted by another person.

This should not be seen as deception of the readers but as whistleblower protection. In most cases, the anonymous author could declare conflicts of interest without running a risk of becoming identified, (for example by stating: "I worked for (name of company, hospital, drug agency or other institution) when these events happened and have no other conflicts of interest.")

I have little doubt that the use of anonymous sources could contribute greatly to public health. It is particularly important to be able to offer anonymity when needed for people working at drug regulatory agencies. The track record of drug regulators is bad, but there are many good and honest people who would be willing to warn us about hidden, serious drug harms, if they did not run a personal risk by speaking out.

We should never forget that the business model of drug companies is organised crime; that our prescription drugs are the third leading cause of death after heart disease and cancer in the Western world; and that most of those who died didn't need the drug that killed them [1, 2].

Here, I have documented the corruption in drug regulation, and I suggest that many lives could be saved by allowing conscientious people in drug regulatory agencies to report their observations of regulatory misconduct or corruption anonymously.

There is now a UK charity, Collateral Global, which allows anonymous authorship [23]. It is dedicated to researching, understanding, and communicating the effectiveness and collateral impacts of the mandated non-pharmaceutical interventions made by governments worldwide in response to the Covid-19 pandemic.

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