

BR5: Speaking truth to power: how doctors and academics can work with the media to blow the whistle

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BMJ INVESTIGATION

Pfizer's covid vaccine trial: researcher blows the whistle on data integrity concerns

Revelations of poor practices at a Texan company working on a phase III study raise questions about handling of data and regulatory oversight. **Paul D Thacker** reports

Last autumn Pfizer's chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective vaccine to end the pandemic. "As I've said before, we are operating at the speed of science," Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the US.

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase

On its website Ventavia calls itself the largest privately owned clinical research company in Texas and lists many awards it has won for its contract work. But Jackson has told *The BMJ* that, during the two weeks she was employed at Ventavia in September 2020, she repeatedly informed her superiors of poor laboratory management, patient safety concerns, and data integrity issues.

Photographs

Jackson is a trained clinical trial auditor who previously held a director of operations position and came to Ventavia with more than 15 years' experience in clinical research coordination and management. Exasperated that Ventavia was not dealing with the problems, Jackson documented several matters late one night, taking photos on her mobile phone. One photo, provided to *The BMJ*, showed



Fort Worth, Texas (above), location of one of Ventavia's research sites; Albert Bourla (right), Pfizer's chief executive



the study drug (Pfizer's vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told *The BMJ* that drug assignment



Source: [left] Thacker PD. *BMJ*. 2021 Nov 2;375:n2635. <https://doi.org/10.1136/bmj.n2635> PMID: 34728500.

[right] The BMJ. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. <https://youtu.be/RaLxhFiOBYk>

Feature » Drug Marketing

The whistleblowing drama behind Astellas's suspension from the ABPI

BMJ 2019 ; 366 doi: <https://doi.org/10.1136/bmj.l4353> (Published 02 July 2019)

Cite this as: BMJ 2019;366:l4353

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Responses

Deborah Cohen, freelance journalist¹, Shai Mulinari, associate professor², Piotr Ozieranski, assistant professor³

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The Japanese drug company Astellas has had its knuckles rapped for wrongdoing four times in less than three years. Now **Deborah Cohen**, **Shai Mulinari**, and **Piotr Ozieranski** reveal fresh claims about the treatment of an employee who offered to help it clean up its act

When Astellas was reprimanded by the Association of the British Pharmaceutical Industry (ABPI) in June 2016, for “deception on a grand scale which was appalling and shocking” it received the harshest punishment ever levied by

Richard Smith: A successful and cheerful whistleblower

October 10, 2012

 Richard Smith

Peter Wilmshurst is that rare thing—a successful whistleblower. What's more, he's a cheerful one, despite having lost £25 000, faced bankruptcy and the loss of his house, and spent every evening, weekend, and his annual leave for three years successfully defending an egregious libel case.



Most readers of the *BMJ* must be familiar with the libel case of Wilmshurst, a now semiretired cardiologist from Shrewsbury, but let me recap briefly. He was the coprincipal investigator on a trial funded by NMT, an American company, to see whether closing a hole in the heart of patients with migraine would cure their migraine. It didn't. He refused to agree to be an author on a paper published in the journal *Circulation* because the paper was misleading, and he gave an interview to a journalist in the US pointing out the problems in the study. NMT sued him for libel, not in the US, where proving libel is difficult, but in England, where the onus is on the defendant to prove his innocence. NMT probably assumed (rightly in the case of most people) that the financial risk would cause Wilmshurst to cave in. They were wrong, and the case collapsed when NMT went bust.

Circulation has published a very lengthy correction, and two doctors who worked on the study with Wilmshurst are facing hearings with the GMC. One of the authors on the paper, the most distinguished of the several cardiologists, actually died before the study began. Yet that hasn't stopped him being an author on a recently published letter that he cannot have read in response to another letter that he cannot have read about a paper that he cannot have read. Wilmshurst, it is clear, finds this absurdity amusing. Death is no impediment to

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KATHERINE EBAN



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Journalists will never reveal their
sources

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Signal



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Legal aspects of whistleblowing

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What is a whistleblower?

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What is a whistleblower?

What legal protections are available to employees who wish to blow the whistle?

Legal aspects of whistleblowing

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What is a whistleblower?

What legal protections are available to employees who wish to blow the whistle?

What will count as a ‘protected’ or ‘qualifying’ disclosure?

Legal aspects of whistleblowing

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UK Employment Rights Act 1996, section 43B:

“any disclosure of information which, in the reasonable belief of the worker making the disclosure, is made in the public interest and tends to show:

*Criminal conduct, *illegal behaviour, *a miscarriage of justice, *endangerment of health or safety, *damage to the environment, or *concealment of any of these

Legal aspects of whistleblowing

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What is the extent of the assurances of legal protection that journalists may offer their sources?

Legal aspects of whistleblowing

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UK Contempt of Court Act 1981, section 10:

“No court may require a person to disclose...the source of information contained in a publication for which he is responsible, unless it be established...that disclosure is necessary in the interests of justice or national security or for the prevention of disorder or crime.”

Legal aspects of whistleblowing

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Conclusions:

- Make and retain notes and records
- Raise concerns with employer first
- If going to the media, consider carefully whether you would prefer to go on the record or be a confidential source (maybe get some legal advice of your own)
- If anonymised, ask to check the copy before publication

Working with whistleblowers

Stories from the EU

Stories from the EU Research fraud by top psychologist



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Staatsanwaltschaft ermittelt nach Fälschungsskandal gegen Top- Psychologen

Erstellt: 08.04.2021 Aktualisiert: 22.04.2021, 12:29 Uhr

Kommentare

Teilen

Stories from the EU Research fraud by top psychologist – impact

TU DRESDEN BADGE OF HONOR

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The Badge of Honor is awarded to members of TU Dresden who have rendered outstanding services to the university and individual achievements that deserve special mention.



Whistleblowers Martin Holst and Jens Strehle



The courage with which the two whistleblowers pointed out the serious violations of scientific integrity in the context of the PPP study, thus enabling an investigation and disclosure, deserves our highest appreciation. Maintaining academic integrity is key at our university. The responsible actions of the two whistleblowers must therefore be seen as an outstanding commitment to the benefit

of TU Dresden in its entirety.

Stories from the EU Alleged mobbing and mishandling of whistleblowing

BuzzFeed > Recherchen

Neue Vorwürfe von Mobbing und Willkür in der Max-Planck-Gesellschaft

Erstellt: 07.02.2020 Aktualisiert: 02.02.2021, 22:08 Uhr

🗨 Kommentare

Teilen ➦

An einem Luxemburger Institut soll sich eine Direktorin missbräuchlich verhalten. Als ein Mitarbeiter das bei einer Ombudsfrau meldet, wird dessen Identität an die Chefin verraten.



BuzzFeed.de © Sebastian Gollnow / Getty Images

Von Hristio Boytchev / Mitarbeit Pascale Müller

Stories from the EU Alleged mobbing and mishandling of whistleblowing – impact



MAX-PLANCK-GESELLSCHAFT

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Statement

On the Future of the Max Planck Institute for International, European and Regulatory Procedural Law



AUGUST 04, 2022

[International](#) [Research Policy](#)

The Grand Duchy of Luxembourg has informed the Max Planck Society that it wishes to transfer the Max Planck Institute for International, European and Regulatory Procedural Law, which is fully financed by the Grand Duchy, to the University of Luxembourg over a transitional period of three to four years, i.e. until the retirement of the two directors currently in office.

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Konsequenzen nach Mobbing– Vorwürfen am Max-Planck-Institut in Luxemburg

Erstellt: 07.04.2020 Aktualisiert: 28.01.2021, 22:42 Uhr

 Kommentare

Teilen 

Die Max-Planck-Gesellschaft leitet aufgrund von Mobbing-Vorwürfe ein Untersuchungsverfahren am Institut ein. Eine dritte Direktorenstelle soll zunächst nicht besetzt werden.

Stories from the EU Patient story of alternative medicine gone wrong

ARTIKEL

Die Unheilerin

Diese Geschichte endet mit einer Geistheilerin, die eine Hochzeit verhindert. Mit einer Frau, die an Krebs stirbt. Mit einem Schweinskopf, der vor einer Tür liegt. Sie beginnt 2002 mit einer hoffnungsvollen Beziehung.

von Hristio Boytchev

27. November 2017

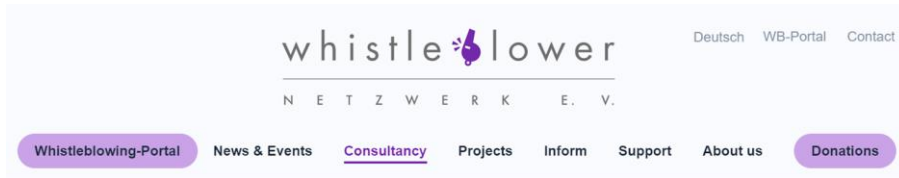


Stories from the EU

Lessons learnt

- Going to the press can be a safety net
- Documentation is key
 - Collect written documentation, write up protocols and send them around
 - Sending complaints to large group internally make it harder to track a potential leak
- Reach out to journalists you trust
- Understand what level of anonymity you need
- Inform yourself

Stories from the EU Ressources for whistleblowers



Consulting for Whistleblowers

You, or any friends of yours, have discovered misconduct in your working environment and don't know how to deal with this? If so, you will find some first non-binding information, as well as the reference data for getting in contact with our consulting team.

Please understand that we cannot answer every inquiry, as we have to restrict our activities to what is currently feasible for us within the framework of our volunteer work.

Before you contact us with data, facts, and questions with respect to your case, please read the relevant texts on this website carefully. Please check whether you are really concerned with whistleblowing, what questions are still open after your perusal, what the long-term objective of your activities is, and what specific support you can expect from us. The better you are prepared, the more effectively can we employ our scarce resources and react to your inquiry to your satisfaction.



[View as a PDF](#)

Whistleblowers can take key steps to protect themselves while having an impact. The following tips were informed by whistleblower attorneys and experts who have worked with thousands of whistleblowers to provide valuable lessons learned.

- **Seek legal and other expert advice early:** Before you make a disclosure (or early in your process before taking risks), consider consulting an attorney experienced in representing whistleblowers. This can help to protect your communications through the attorney-client privilege and help to shield you from legal liability. Also consider contacting an organization that specializes in working with whistleblowers, to help guide you through the process and provide solidarity and support. Many such organizations offer legal representation, and they can potentially serve as a bridge between you those who should be benefiting from your knowledge.

Stories from the EU Legal basis: editorial secrecy in Germany

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Redaktionsgeheimnis

Das Redaktionsgeheimnis umfasst das journalistische Zeugnisverweigerungsrecht wie auch das Verbot, Redaktionsräume zu durchsuchen und Unterlagen zu beschlagnahmen, die sich im Besitz von Journalisten befinden.

Pressefreiheit und Zeugnisverweigerung

Medien sollen zur Meinungsbildung der Gesellschaft beitragen. Deshalb sind Pressefreiheit, Informantenschutz und Vertraulichkeit ein wichtiger Kern journalistischer Arbeit. Die Recherche und die Veröffentlichung von Informationen und Meinungen müssen frei von Eingriffen oder Zensur des Staates sein (Pressefreiheit nach Artikel 5 des Grundgesetzes). Deshalb besitzen Journalisten auch besondere Rechte. Nach Paragraph 53 der Strafprozessordnung sind Vertreter bestimmter Berufsgruppen dazu berechtigt, vor Gericht und bei Ermittlungsbehörden keine Angaben machen zu müssen. Dieses Zeugnisverweigerungsrecht haben auch alle Personen, die Druckwerke, Rundfunksendungen oder Filmberichte vorbereiten, herstellen oder verbreiten. Sie dürfen ihre Informanten schützen und selbst vor Gericht schweigen über Verfasser oder Einsender von Beiträgen und Unterlagen und deren Inhalte. Das gilt jedoch nur für Beiträge, Unterlagen, Mitteilungen und Materialien, die für die Redaktion bestimmt sind.

Beschlagnahmeverbot

In Verbindung mit dem Zeugnisverweigerungsrecht gilt auch das Verbot, journalistische Unterlagen zu Beweiszwecken zu beschlagnahmen. Dies gilt jedoch nur in dem Maße, in dem Medienangehörigen auch das Recht zur Zeugnisverweigerung zusteht. Laut Paragraph 97 der Strafprozessordnung dürfen bestimmte Materialien nicht beschlagnahmt werden. Dazu gehören zum Beispiel Mitschriften oder Aufzeichnungen von Interviews, Dokumente eines Informanten oder von Journalisten selbst recherchierte Materialien und Aufzeichnungen sowie Fotos und Filmaufnahmen. Auch Leserbriefe unterliegen dem Schutz des Beschlagnahmeverbots.

Ausnahmen

Es gibt bestimmte Situationen, in denen das Zeugnisverweigerungsrecht und das

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Legal basis:
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EFJ publishes position on the European Media Freedom Act



European Media Freedom Act EFJ position



- The improvement regarding **protection of sources** of journalists and deployment of any spyware to be in line with International standards;

Stories from the EU

Legal basis: whistleblower directive of EU

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The European Commission decides to refer 8 Member States to the Court of Justice of the European Union over the protection of whistleblowers

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Today, the European Commission decided to refer **Czechia, Germany, Estonia, Spain, Italy, Luxembourg, Hungary and Poland** to the Court of Justice for failure to transpose and notify the national measures transposing the directive on the protection of persons who report breaches of Union law into their legal framework ([Directive \(EU\) 2019/1937](#)).

The directive requires Member States to provide whistleblowers working in the public and private sectors with effective channels to report breaches of EU rules confidentially, establishing a robust system of protection against retaliation. This applies both internally (within an organisation) and externally (to a competent public authority). Member States had to transpose the necessary measures to comply with the Directive's provisions by 17 December 2021.

The directive plays a key role in the enforcement of Union law in a number of important policy areas where breaches of Union law may cause harm to the public interest, ranging from environmental protection, public procurement, financial services, nuclear safety and product safety, to the protection of the financial interests of the Union.



BMJ Investigations Unit (BIU)

BIU MISSION STATEMENT

“To expose the harmful effects of corporate and institutional vested interests and failures in regulation on the health of communities across the US, the UK and around the world. Our findings will support calls for transparency and hold those with power to account, helping ensure medical professionals and the public are able to make decisions guided by rigorous evidence.”



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