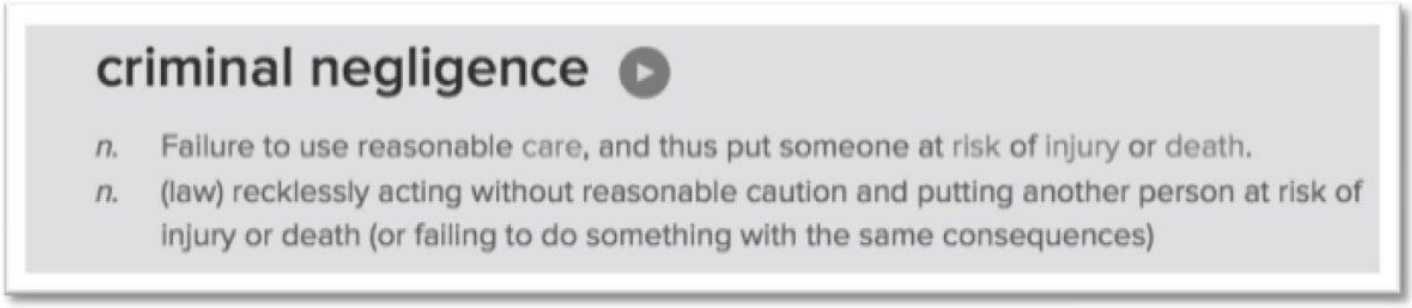
08/09/2021

Regulation or Racket? UK Drug Regulator Never Inspected the Pfizer Vaccine Study Data

Documents

As populations around the world face coercion to submit to COVID-19 gene-based 'vaccination', including being locked out of employment and medical care, while reports of deaths following vaccination soar, a scandal regarding the legitimacy of COVID vaccine authorization processes is unfolding.

EXCLUSIVE TO DOCTORS FOR COVID ETHICS: A second Freedom of Information request seeking regulatory transparency has revealed that the UK medical regulator never inspected Pfizer's COVID-19 clinical trial data, joining the Australian regulator in rubber-stamping Pfizer's vaccine.



Following the exclusive revelation on this website that a Freedom of Information request to the Australian drugs regulator (the Therapeutic Goods Administration or TGA) approved the Pfizer-BioNtech mRNA vaccine in record time, yet never sighted Pfizer's patient-level data (IPD), another regulatory scandal is breaking.

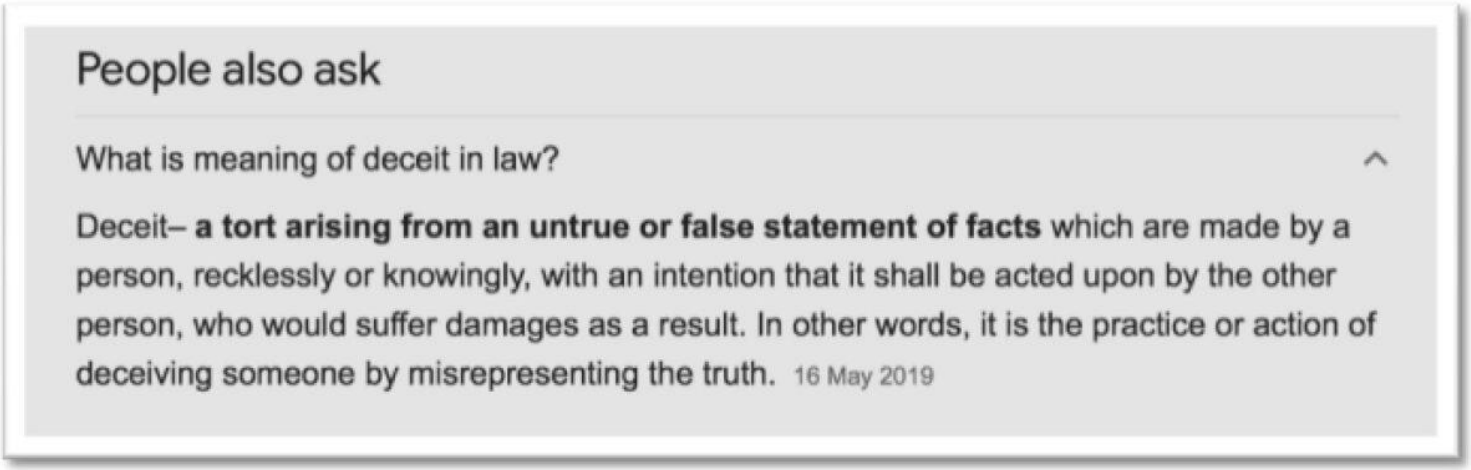
The TGA story was published here in June, asking basic questions regarding the TGA's probity in performing their most fundamental task: validating clinical trial data submitted by Pfizer. Instead of verifying the data, the TGA simply rubber stamped the Pfizer vaccine, accepting on face value Pfizer's misleading claim that their product showed "95% efficacy to prevent COVID-19 infection".

Since then, worldwide data, particularly in the UK and Israel (but also in smaller countries such as Iceland and Gibraltar where vaccination rates approach 100% yet cases are still rising), have shown disappointing real world effectiveness, in contrast to Pfizer's claims. Given Pfizer's legal history of healthcare fraud it was imperative that the drug

regulators verify the drug manufacturers' submission data prior to COVID vaccine approval.

The TGA failed to do so, but what about the other drug regulator held in high regard around the world – the UK's MHRA?

Doctors for Covid Ethics can reveal that the MHRA never validated Pfizer's trial data either.



Freedom of ~~Information~~ Obfuscation

On 7th June 2021, a Freedom of Information (FOI) request was submitted to the MHRA, seeking documentation relating to the temporary authorization of the Pfizer (BNT162b2) and AstraZeneca (ChAdOx1) COVID-19 vaccines. Specifically, the FOI (FOI 21/632) sought:

1. Any documents requesting access from the sponsor [Pfizer and AstraZeneca] to the raw data (patient-level anonymised data or equivalent patient-level data).

2. Confirmation as to whether the MHRA holds the patient-level data (approximately 70,000 records) from these applications or whether these were restricted from access or assessment by the sponsor. If they were supplied, the format in which these records were supplied and how they were hosted at the MHRA (e.g. paper, or electronic database – specify format such as MySQL, MsSQL databases, csv, excel files).

3. Any documents confirming that a process for analysing the raw data from the sponsor was undertaken, and the result of that process (e.g. meeting minutes or equivalent) including the qualifications (and names if appropriate) of the committee (if any) which has undertaken the review of the raw data.

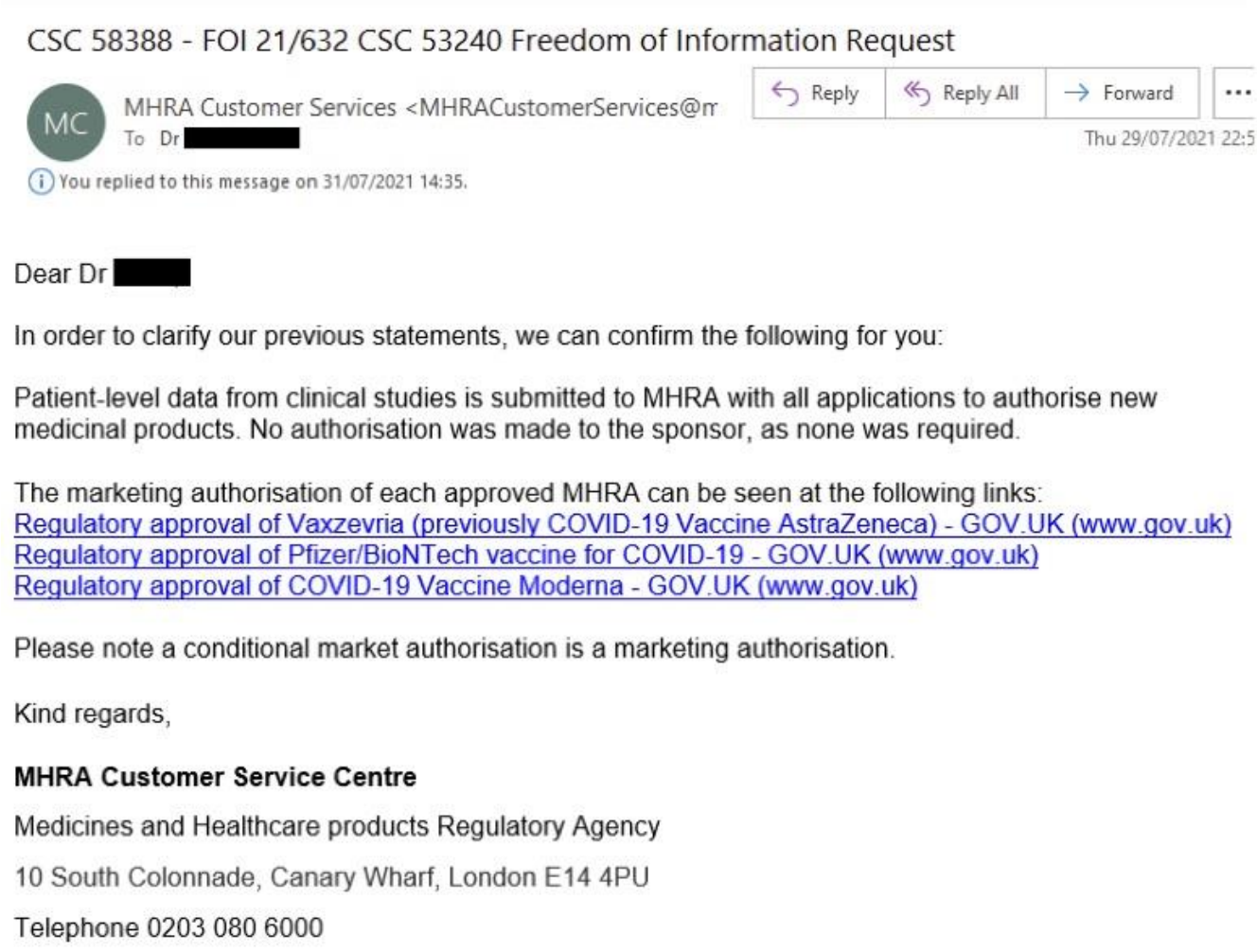
Rather than answering any of the questions or supplying documentation, however, the MHRA responded with generalities regarding usual process, and devolved their responsibilities to Public Health England, providing for a tangled web of deflection. See the MHRA's initial response to the FOI request here, and the FOI applicant's follow-up reply seeking specific answers rather than obfuscation here.

In addition to citing standard practice and noting that "the sponsor" ie *Pfizer*, "had access to the raw data", the MHRA directed the FOI applicant to an earlier committee meeting with the Commission on Human Medicines (CHM), held on 24th December 2020. Minutes from that meeting reveal that the CHM had been told: "Results from the **MHRA analysis of raw data** from the interim analysis showed VE of 91% (CI 63, 98) in the period from day 14 after the first dose to when dose 2 was given. Results from an **independent analysis by Public Health England of the full Pfizer dataset** were also discussed."

A document summarising the CHM meeting is here.

However, based on their FOI responses, the MHRA appears not to have analyzed any raw data at all. In an email dated 29th July 2021, following the FOI applicant's second request for assurances that the MHRA had conducted its own data analysis, the MHRA stated:

"In order to clarify our previous statements, we can confirm the following for you: Patient-level data from clinical studies is submitted to MHRA with all applications to authorise new medicinal products. No authorisation was made to the sponsor, as none was required. " The MHRA then directed the applicant to public posts regarding COVID vaccine authorization on government websites.



CSC 58388 - FOI 21/632 CSC 53240 Freedom of Information Request

MC MHRA Customer Services <MHRACustomerServices@m

To Dr [redacted]

Reply | Reply All | Forward | ...

Thu 29/07/2021 22:5

You replied to this message on 31/07/2021 14:35.

Dear Dr [redacted]

In order to clarify our previous statements, we can confirm the following for you:

Patient-level data from clinical studies is submitted to MHRA with all applications to authorise new medicinal products. No authorisation was made to the sponsor, as none was required.

The marketing authorisation of each approved MHRA can be seen at the following links:
Regulatory approval of Vaxzevria (previously COVID-19 Vaccine AstraZeneca) - GOV.UK (www.gov.uk)
Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk)
Regulatory approval of COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)

Please note a conditional market authorisation is a marketing authorisation.

Kind regards,

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 0203 080 6000

This reply was clearly inconsistent with the CHM minutes of 24th December.

The Big Lie

Given that the MHRA had deflected to the CHM meeting as evidence that "the clinical trial data were analysed as they would be for any marketing authorisation", a further Freedom of Information request was submitted on 31st July 2021 – this time to Public Health England. The second FOI request related to the purported "independent analysis… of the full Pfizer dataset" by PHE, as cited at the CHM meeting.

The response was swift and negative.

Re: Freedom of Information request

Thank you for your request received on 31 July 2021 addressed to Public Health England (PHE). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that PHE partly holds the information you have specified. I have answered your questions in the order raised.

Request

I am writing to request all documents relating to the "Independent analysis by Public Health England of the full Pfizer dataset" as referenced in the Commission on Human Medicines meeting held on 24th December 2020 (extract attached).

The documents should include, but not be limited to

(1) The executive summary of the analysis
(2) The full summary of the analysis

In accordance with Section 1(1)(a) of the FOI Act, PHE can confirm it does not hold this information. There was no executive summary or full summary of the analysis as suggested by your request.

Under Section 16 of the FOI Act, public authorities have a duty to provide advice and assistance. Accordingly, the paper presented to the Commission on Human Medicines meeting held on 24 December 2020 has been published at the link below:

The PHE response goes on to state "In accordance with Section 1(1)(a) of the FOI Act, PHE can confirm it does not hold this information**. It is not the case that PHE had access to the full Pfizer dataset**."

In other words, the MHRA (the UK drug regulator that is tasked with ensuring safety of new drugs) failed to analyze the Pfizer data itself. Furthermore they claimed to have given this job to Public Health England who stated categorically that they had no access to the data, let alone having conducted data validation or analysis.

The full document relating to the Public Health England FOI is available here.

The bottom line is that this is the second of the big four drug regulators (MHRA, TGA, EMA, FDA) who have never inspected nor assessed the validity of Pfizer's "miracle" data.

Which begs the question – who, outside of Pfizer, has verified and analyzed Pfizer's trial data? Why should the public take Pfizer's word on the results of their own investigations, when tens of billions of dollars in profits are at stake? What is the true role of medical regulators if their approach to "any marketing authorisation" is to outsource data validation to a body that fails to even obtain, let alone inspect, the manufacturer's data?

And why was the Commission on Human Medicines told that Public Health England had undertaken an "independent analysis… of the full Pfizer dataset" when that was not the case?

The answers to these questions are critical to public health and public safety from COVID-19 vaccines. The plausibility of Pfizer's claims regarding their trial data had already come into question prior to these FOI results, based both on numerical inconsistencies and scientifically untenable assertions in Pfizer's documentation of their findings.

An analysis by professors of immunology, biochemistry, toxicology and pharmacology, for instance, has detailed "unlikely claims and contradictions" in Pfizer's clinical trial reporting. This includes sudden and uniform onset of immunity across all vaccine recipients on day 12 following injection, which is "not at all a biologically plausible outcome". Moreover, according to Pfizer's documentation, the sudden-onset immunity occurred before, not after, neutralising antibodies appeared, whose levels only began rising 9 days later, reaching maximal levels on day 28, more than two weeks after clinical immunity is claimed to have set in. Further discrepancies have been noted numerically, with different analyses of the same data by Pfizer containing inconsistent numbers which "cannot possibly be reconciled; one must be false. Since, as discussed, the sudden onset of immunity implied by [the results] lacks any biological plausibility, it is most likely that it is this data set which was fabricated."

With anomalies this stark, against Pfizer's history of setting records in the billions for criminal fines and settlements over fraud and unsafe medical products, including conducting unauthorized clinical trials, and in light of the lack of regulatory transparency and failures of regulatory oversight documented here, COVID vaccine recipients are entitled to ask: Did Pfizer fabricate their data for the COVID-19 mRNA vaccine?

Is deceit an element of crime?

Can you sue someone for deceit?

In order to sue for deceit, you need to show that not only was there a lie, but that you believed it. And that you did something as a result of believing it. If you never believed the lie, then you weren't deceived. **You can only sue for deceit if the person successfully deceived you.** 2 Jul 2015

MHRA FOI (A): Link to the full document

1. MHRA_FOI_1Download

MHRA FOI (B): Link to the full document

2. MHRA_FOI_2Download

Commission on Human Medicines meeting, December 24th, 2020: Link to the full document

3. CHM 24 Dec 2020 – Final Summary MinutesDownload

PHE FOI: Link to the full document

4. PHE_FOIDownload

fraud noun

Save Word

\ ˈfrȯd \

Definition of *fraud*

1 a : DECEIT, TRICKERY

specifically : intentional perversion of truth in order to induce another to part with something of value or to surrender a legal right

// was accused of credit card *fraud*

b : an act of deceiving or misrepresenting : TRICK

// automobile insurance *frauds*