More drug deaths: Merck and PTC Therapeutics want clinical study reports to be secret

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Lack of access to clinical study reports at drug agencies is immoral. It will result in thousands of unnecessary deaths because clinicians will be kept in the dark about how dangerous many drugs are.[1] As just one example, over half of the deaths and half of the suicides in trials of psychiatric drugs were omitted from the published trial reports, compared to data available in a trial register.[2]

Psychiatric drugs kill many people.[3] A meta-analysis of placebo-controlled trials in patients with dementia showed that antipsychotics kill one patient for every 100 treated for a few weeks.[4] Even though most of the trials had only been presented at conferences and were therefore unpublished, and even though the investigators had contacted the sponsors for more information,[4] the FDA found double as many deaths, two per 100.[5]

By complaining to the European Ombudsman in 2007, I opened the archives of the European Medicines Agency (EMA) of clinical study reports in 2010, despite EMA's unwillingness to do so, claiming they needed to protect commercial interests.[6] But some drug companies try to wind the clock back to the dark ages. In 2013, InterMune and AbbVie – previously Abbott Laboratories – two US drug companies, challenged EMA's new openness policy at the European Court. One of AbbVie's drugs, Humira, a monoclonal antibody that was once the world's topselling drug,[7] can cause life-threatening harms. Nonetheless, at a meeting in Bruxelles in August 2013, AbbVie made it clear that it regarded clinical trial data concerning adverse events as confidential information which it was entitled to keep to itself. This elicited strong reactions from European drug regulators:[8]

Aginus Kalis, head of the Dutch Medicines Evaluation Board, asked Neal Parker from AbbVie: "You are aware that you are working in the healthcare industry ... with patients and human beings?"

Hans Georg Eichler, EMA's senior medical officer, said: "I have been a regulator for many years, and I am totally flabbergasted."

Yet again, two US drug companies are trying to reintroduce secrecy. Merck and PTC Therapeutics have appealed an initial ruling in February 2018 in support of EMA's position that clinical study reports should not be considered confidential.[9] On 11 September 2019, Advocate General of the European Court of Justice, Gerard Hogan, found that disclosure of the documents would harm the companies' commercial interests. The cases are now awaiting a final judgment from the European Court of Justice.[9]

It would be a serious setback for public health if the two US companies prevailed in court. The lack of access to the raw – unfiltered, uncoded and unselected - harms data in clinical trials is a major cause of the horrible situation we are in, documented by several independent studies with different methodologies, that our prescription drugs are the third leading cause of death, after heart disease and cancer.[10-18]

Merck has previously demonstrated a callous disregard for human lives.[1] Scientists at Merck knew all along, even before any clinical trials had been carried out, that the biochemical properties of rofecoxib meant that it must be thrombogenic.[1] However, Merck hid repeatedly that its arthritis drug, rofecoxib (Vioxx), caused heart attacks, and appears to have committed scientific misconduct.[1] Internal company documents and FDA data both showed that heart attacks on rofecoxib were missing in published trial reports.[1] As an example, one of Merck's scientists who had judged that a woman died from a heart attack was overruled

by his boss, “so that we don’t raise concerns.” The cause of death was now called unknown, also in Merck’s report to the FDA.[1]

I have estimated that rofecoxib has killed about 120,000 people.[1] These people could have been treated with another, less deadly drug, or with no drug at all.

In 2006, I saw a TV commercial in the United States on CNN that ended with a very deep voice saying, “Merck, where the patients come first.” I couldn’t help thinking, “Merck, where the patients die first.”[1]

This is a conflict between good and evil. Clinical trials data belong to every one of us, particularly to those patients who have run a personal and unknown risk by volunteering to participate in them.

I encourage doctors to boycott products from Merck, PST Therapeutics, AbbVie and InterMune. Similar products sold by competitors are virtually always available.

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