

Drug makers accused of trying to hide test results

Tom Whipple Science Editor

Pharmaceutical companies are lobbying to block the public release of clinical trial data in a move that campaigners say puts patient safety at risk.

A European transparency initiative is proposed to ensure that when regulators approve new drugs the full data from the trials would be publicly released, rather than just a summary published in a medical journal.

The proposal comes after high-profile cases in which independent researchers found that drugs such as Tamiflu or the antidepressant Seroxat were more dangerous or less effective than pharmaceutical companies had claimed.

In the case of Seroxat, a GlaxoSmith-Kline drug, the full study reports had been restricted. When researchers accessed the papers, they found that the drug was linked to self-harm and suicide in teenagers — even though the drug company's summary of the research had said that it was safe and effective.

Campaigners have said that while all companies are ostensibly on board with the reforms, some are now asking to be allowed to redact so much data before the release that it would effectively lead to the removal of all useful information.

The pharmaceutical companies say that they are doing this to ensure that details of patients involved in the trial remain confidential.

Other scientists argue that the approach effectively renders the whole exercise pointless.

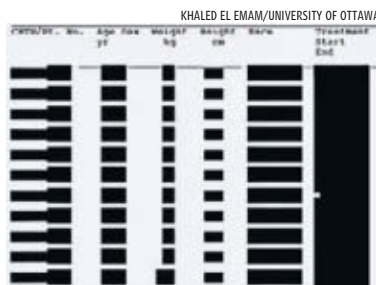
"Healthcare professionals cannot reliably inform patients of the potential benefits and potential harms of medicines when the underlying clinical trial data is kept secret," said Peter Doshi, from the University of Maryland school of pharmacy, who has campaigned for the release of all data. "Without raw data, we are left vulnerable to trusting at face value journal articles that may, in truth, be little more than marketing dressed up as peer-reviewed science."

Tom Jefferson, a British researcher based in Rome who works for the respected Cochrane Collaboration, a volunteer health organisation, said that there was a moral, as well as a practical, necessity to change the regulations. He said that the transparency initiative would be undermined if much of the data were redacted.

"If you carry out an experiment on a human you have certain responsibilities," Mr Jefferson said. "One of those is that you shouldn't suppress data."

Both scientists said that it should be possible to make the patients anonymous without rendering the research useless. "Journals have articles ten to fifteen pages long," Mr Jefferson said. "The underlying data set is tens of thousands of pages long. This means they can present the product in the best possible light — which is what they've been doing. We've got abundant, overwhelming evidence this is the case."

Research released this year showed



Bad medicine

Seroxat

"Study 329" has taken on a totemic status in the battle for transparency. This trial in the 1990s by Smithkline Beecham, now GSK, into the antidepressant paroxetine, also known as Seroxat, helped to establish a drug that made the company billions. The trial showed that the side effects of the drug were minimal. It transpired, though, that the study had been ghostwritten and had downplayed serious risks of the drug, which was also shown to be ineffective for adolescents.

Tamiflu

The British government spent half a billion pounds stockpiling the antiviral Tamiflu as preparation for a potential flu pandemic, but it emerged that most of the trials into the drug were never made public. It was also claimed that Tamiflu prevented pneumonia — but an analysis of the full data, eventually released, showed that many of these pneumonia cases had never been verified, and where they had there was no significant effect.

that when industry sponsors medical trials of its own drugs they are backed 97 per cent of the time.

This is why the European Medicines Agency, a London-based umbrella organisation for national regulators, is working to introduce a voluntary code for the release of all data as drugs come to market, so that other researchers can reassess it as necessary.

Researchers involved in the discussions have told *The Times* that several companies want a strict approach to make this data so anonymous that, when applied to real-world examples, such as the Tamiflu research, it removes virtually all the information.

A spokesman for the European Federation of Pharmaceutical Industries and Associations said it was working to "balance responsible reporting for public health benefit and safeguarding patient confidentiality".

Professor Doshi said that it was imperative that the data remained usable. "After years, we finally have a system that's soon to go live and make trial data public," he said. "But at the last minute, there's a move that could render the system useless."

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Swept off his feet This kitesurfer took advantage of strong winds to produce a spectacular display off Lyme Regis, Dorset

Comet with 10,000-mile alcopop tail offers clue to origins of life on Earth

Oliver Moody Science Correspondent

As comets go, C/2014 Q2 Lovejoy has a lot to be said for it. The space rock delighted stargazers in January when it reached the closest point to the Sun on its 19,000-year orbit, briefly lighting up the night skies over Earth with its eerie bluish-green tail.

More strikingly, it now turns out that Lovejoy makes more alcohol in a year than the whole of France. Nasa astronomers have discovered that it spews out the equivalent of 500 bottles of wine each second. Combined with thousands of tonnes of sugar and water, its wake is in effect a 10,000-mile streak of deconstructed alcopops.

It is the first time that scientists have found traces of ethyl alcohol on a comet, although the revelation is not unexpected. The *Philae* and *Rosetta*



Comet C/2014 Q2 Lovejoy produces more alcohol in a year than France

mission to Comet 67P/Churyumov-Gerasimenko has added to a growing body of evidence that the frozen rocks can harbour complex organic compounds such as amino acids, fuelling speculation that some may carry the starter kits for DNA and proteins.

Stefanie Milam, an astrochemist at Nasa's Goddard Space Flight Center in

Maryland and one of the authors of the study, said that the boozy comet might add weight to suggestions that one of its peers could have brought the rudiments of life to Earth. She said: "About 3.8 billion years ago, when many comets and asteroids were blasting into Earth and we were getting our first oceans, life didn't have to start with just simple molecules like water, carbon monoxide and oxygen."

"Now you can see where sugars start forming, as well as more complex organics such as amino acids — the building blocks of proteins — or nucleobases, the building blocks of DNA. These can start forming much easier than beginning with molecules with only two or three atoms."

Writing in *Science Advances*, they hailed "an important step toward our understanding of the origin of life on Earth".

Ban on forces at jailed Marine protest

Neil Johnston

Members of the armed forces have been told that they cannot attend a rally in support of a Royal Marine who was jailed for murdering a Taliban insurgent.

More than 1,000 people are expected to join a demonstration in Parliament Square tomorrow for Sergeant Alexander Blackman, 41, who was sentenced to life imprisonment in November 2013.

A campaign led by his wife, Claire, 43, says that the killing was manslaughter not murder because of a failure of lead-

ership at the highest level which left his unit dysfunctional. So far £750,000 has been raised for his legal bills.

Organisers say that servicemen and women have been threatened with disciplinary action if they attend the event, which is timed to coincide with the anniversary of the Royal Marines. Ministry of Defence rules mean that members of the military cannot attend any "political" demonstrations.

Sergeant Blackman was serving with 42 Commando, based in Plymouth, when he shot dead a wounded Taliban

prisoner in Helmand province in September 2011. John Davis, a former Royal Marine helping to organise the event, said: "We speak to the guys daily and I'm aware that orders have been going out daily that they must not attend a political protest, but this is not a political protest, it's a show of support."

An MoD spokesman said that serving members of the military were routinely reminded not to attend political protests, including any against decisions "taken by the legal system or the government".