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# Clinical trials and the right to information

**Does putting full sets of clinical trial data in the public domain affect a company's commercial interest? It might. But does the public interest not outweigh this? Yes, because if the product is useless or harmful, there should be no commerce in it in the first place.**

Sarah Hiddleston

**T**he scientific study that exposed that expensive anti-depressant drugs including Prozac, used by 40 million people around the world, are no better than sugar pills has brought in its wake many questions about how and why these products were brought into the market. But the story also shows how, when used correctly, right to information laws are powerful tools for correction of abuses, and why such information should remain accessible to those who seek it. Furthermore, it makes a significant case why all trial data should be placed in the public domain for scientific scrutiny, rather than belonging exclusively to the company that generated it.

As it happens, India is about to experience a test case for its 2005 Right to Information Act with regard to data from clinical trials: Multinational major Monsanto's subsidiary Maharashtra Hybrid Seeds Co Ltd is to take the Central Information Commission to court over two orders passed last year compelling the Department of Biotechnology to release data on health and environment safety tests conducted on genetically engineered brinjal, okra, mustard, and rice and the minutes of the meetings of the Review Committee of Genetic Manipulation (RCGM) that approved them for field trials.

The Central Information Commission heard, on April 13, 2007, its first appeal on a submission filed under the Right to Information Act denied to Divya Raghunandan by the Department of Biotechnology. The Commission found that the information, which was denied on the grounds that it could harm Mahyco's competitive interest (section 8(l)(d) of

the Right to Information Act), was a matter of public interest and so, as is clear from provisions of that section, could not be withheld.

When the Department of Biotechnology failed to comply, the Commission heard a second appeal on November 22, 2007. The Commissioner, after going through the Environmental Protection Act (1986) noted: "it is quite clear that genetically engineered organism [sic] or cells are recognised by the government as an item potentially hazardous to public health. It automatically follows that full compliance with these rules is a matter for public interest"

Genetically engineered crops are like drugs in that they both pose potential biohazards to the body. In the same way that drugs are tested for safety and effectiveness so the bio safety of transgenic crops must be determined. Ms. Raghunandan has asked for the proof generated from laboratory, greenhouse, and contained field trials that is required by RCGM before approval for multi-location open-air field trials. These, she submitted before the Information Commission, are difficult to control and open to the elements and wildlife. Mahyco's case, submitted before the Delhi High Court on December 4, is that the information is a matter of commercial confidence and revealing such information before large scale field trials for agronomic advantage are completed could prejudice their chances of filing for a patent.

The question therefore is this: when does public interest in trial data outweigh commercial interest?

Dr Irving Kirsch, professor at the department of psychology at Hull University, and his colleagues in the United States and Canada were able to draw

their conclusions about anti-depressants only because they were working from complete sets of raw test data. Their paper can be read in the open-access Public Library of Science journal, *PLoS Medicine* (<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050045>).

If the researchers had not gone to such lengths to obtain full data from the U.S. Food and Drug Administration (FDA) under the freedom of information act, we would never have known that published data available to the scientific community had not included significant information from unfavourable trials (nine of these were refused by the FDA, data from four of them were obtained from a company website). We would have also been ignorant of the fact that the FDA had not spotted data manipulations from which conclusions were drawn and approved the drug on that basis. Nor would we have known that the companies involved had breached the trust of those who underwent the trials, the doctors who prescribed the medicines, and the patients who took them. Nor that these companies have made massive profits for something that has not stood up in the trials.

What if a product was found not just to be ineffective, but harmful? Just 10 days after Kirsch's results were published, GlaxoSmithKline was found to have withheld clinical trial data from the United Kingdom regulator, the Medicines and Healthcare Regulatory Authority (MHRA), that showed that its anti depressant increased the risk of suicide among teenagers, and that it had known this since 1998.

Does putting such data in the public domain affect a company's commercial

interest: Yes. But does the public interest outweigh this? Yes, because if the product is useless or harmful, there should be no commerce in it in the first place.

Companies claiming that this might affect their intellectual property would do well to remember that this is at the core of the a defined set of criteria through which society gives up its fundamental immediate right to health to grant a right to property. A patent, which gives a company a monopoly in recognition of the risks it undertakes in product development, is awarded if a product is new, involves an inventive step, and has an industrial application - in other words if it is useful.

Most companies already have patents on their products before they move to clinical trials. There could, possibly, be a case for re-examining the timing of the patent grant. But in today's situation companies need not be concerned about losing the competitive advantage they have if the product is genuinely useful — no other company will be able to produce it because they already have the market monopoly guaranteed.

There are many voices in the scientific community calling for public disclosure of full sets of data for review to ensure independent evaluation of data. Perhaps nowhere is this more relevant than in India, where the government courts investment from overseas companies in clinical trials and its own industries seek to develop new products. As the subjects of much experimentation, Indians deserve to have the data generated from trials properly analysed. And for a country with a definite comparative advantage in this field, the government should ensure that it uses this capability to produce world-class products.