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FROM THE PRESS

Deaths in a trial of the HPV vaccine

The death of girls who were a part of a Human Papilloma Virus vaccine trial has raised an alarm about the nature of research in India as well as the value attached by the state to the lives of its citizens.

The trial was being conducted in Andhra Pradesh and Gujarat by the NGO PATH with support from the Indian Council of

Medical Research and local health authorities. They were funded by the Bill and Melinda Gates Foundation. The vaccine is supplied by two companies, Merck Sharpe & Dohme and Glaxo Smith Kline.

When the government stopped the trials, three doses had already been administered to 30,000 participants, mostly tribal girls aged between 9 and 14.

The union health minister, Ghulam Nabi Azad, has denied that the deaths have anything to do with the trials, and as things stand, there is no conclusive evidence of a causal link between the vaccine and the deaths. But the fact that the girls were a part of the trial is reason enough to warrant further investigations.

A committee has been constituted by the union government to investigate the deaths. Further action will depend on the report of the committee.

An investigation in one of the sites in AP, coordinated by the women's health group SAMA, revealed that the trials recruited tribal girls from poor areas. These girls were malnourished. To worsen the situation, consent forms for the trial are in English which even the health care provider administering the vaccine to them may not be able to read, let alone the participants.

Kalpna Sharma, Uninformed consent. The Hindu, April 17, 2010. Aarti Dhar, Brinda: panel may not serve independent probe.

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The Hindu, April 14, 2010. Sanjay Mehdudia. No, Indian girls won't be used as guinea pigs: Azad. *The Hindu*, April 22, 2010. K Majumdar, The cervical cancer bazaar. *Tehelka.com*, March 20, 2010. <http://www.tehelka.com>

/story_main44.asp?filename=Ne200310coverstory.asp (<http://www.tehelka.com>

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The truth about truth tests

The Supreme Court has ruled that narco-analysis, brain-mapping and polygraph tests are illegal unless conducted with the explicit consent of the person to whom these tests are administered. These tests had been banned internationally but were regularly being conducted in India. Among the many people on whom the narcoanalysis test has been used are the accused in the Nithari murder case and Ajmal Kasab who was involved in the attacks in Mumbai in 2008. The Supreme Court ruling will make these techniques less available to investigating agencies.

Not only do these tests violate individuals' right not to incriminate themselves, and their right to privacy, they are also of doubtful scientific validity. The narcoanalysis test requires the administration of sodium pentothal dissolved in water to create a "twilight state" between the conscious and unconscious. But the ramblings of a person in such a state can hardly be considered scientific evidence. Studies have shown that in such a state the person to whom the drug is administered is likely to repeat the interrogator's words or cues, or simply fantasise.

The US outlawed these tests in 1956, judging them to be unreliable. But these methods need to be outlawed not just for being unreliable but more so for violating the basic rights of every individual.

Anonymous, Truth to power. The Indian Express, May 6, 2010.



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Draft Assisted Reproductive Technologies Bill

The Draft Assisted Reproductive Technologies (ART) Bill, 2010, has been submitted to the Union Ministry of Health. It is viewed as long overdue, since India is fast becoming a hub for ART, especially surrogacy. The draft was prepared under the aegis of the Indian Council of Medical Research by a 12 member committee headed by Dr P M Bhargava. The bill seeks to regulate the practice of ART, especially surrogacy, in India. Though there is a sharp increase in cases of surrogacy in India, the sector is unregulated. This has led to complicated situations for all the parties concerned, but especially the surrogate mother. One instance is the case of German parents who had twins through surrogacy in India in February 2008. The twins could not be taken back home as Germany did not recognise surrogacy as a means of parenthood. The parents fought a legal battle for two years while their children lived in Jaipur as stateless citizens.

The draft ART bill, if passed, would prevent such instances. It would make it compulsory for a couple seeking a child through surrogacy to submit documents proving that their country of residence recognises surrogacy as legal and will grant citizenship to the child born through it. Further, the couple will have to identify a local guardian who will provide the necessary care to the surrogate mother during her pregnancy as well as after the delivery till the child is handed over to the surrogate parents. The child will be eligible for Indian citizenship if the foreign parents fail to take custody of the child within one month.

However, the draft doesn't make surrogacy any easier for homosexual couples as it goes by the legal definition of a couple in India which assumes the heterosexual couple as the norm. "...Though homosexuality has been decriminalised in India, it has not been made legal. Till gay and lesbian couples get legal status in India, they can't avail surrogacy," said Dr R S Sharma, member secretary of the committee.

Rakesh Bhatnagar, Germany allows couple to bring surrogate kids home. DNA May 26, 2010. Times News Network, Surrogacy still not an option for Indian gay, lesbian couples. Times of India, May 27, 2010. Kounteya Sinha, Panel drafts law to streamline surrogacy. Times of India May 22, 2010.

Free trade costs lives

The new Free Trade Agreement (FTA) being negotiated between India and the European Union may just make generic drugs more inaccessible to other developing countries. The international NGO Medecins Sans Frontieres (MSF) stated at a press conference in Brussels that 80 % of the antiretrovirals that it uses are sourced from India. MSF representatives feel that the new FTA would put many lives at risk. The draft agreement has more stringent regulations regarding intellectual property rights and their enforcement than those required under international trade rules. This will certainly have an impact on the supply of generic drugs from India to MSF.

The current Indian laws are liberal enough to prevent the granting of patents to changes in existing drugs whether they are improvements in existing drugs, changes in dosage patterns, or changes in combination of drugs. However, the agreement's clause on "data exclusivity" will change the existing liberal laws. It will also create a new problem: clinical trials will have to be repeated for generic drugs before they can be registered. The concept of data exclusivity "not only creates huge financial barriers that act as disincentives to generic companies, but also violates medical ethics, as people would be subjected to the risks of clinical studies for something that is already known," state MSF

Peter Moszynski, India-EU trade deal "threatens access to cheap, generic drugs" BMJ, May 1, 2010. Press Release EU-India Free Trade Agreement: last chance to unblock access to medicines, April 26, 2010, Brussels, MSF homepage
<http://www.doctorswithoutborders.org/press/release.cfm?id=4388&cat=press-release>
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British doctors call homoeopathy witchcraft

The British Medical Association (BMA) has passed a motion questioning the scientificity of homeopathy. Dr Tom Dolphin, deputy chairman of the BMA's junior doctors committee, has gone on record as saying: "Homoeopathy is witchcraft."

The BMA has further questioned the use of homoeopathy in the NHS. The NHS' homoeopathy hospitals in London, Glasgow, Liverpool and Bristol treat a total of 54,000 patients each year at a cost of £ 4 million. A homoeopathy hospital in Turnbridge Wells, Kent, had to close last year as the local NHS stopped funding. The BMA has questioned the allocation of resources by the NHS to homoeopathy, asking the National Institute for Health and Clinical Excellence to examine the evidence base and pass a ruling on the use of homoeopathy by the NHS. The BMA has further asked how expenditure on homoeopathy, which is not scientifically proven, can be justified, especially in times when the health services are strapped for cash.

This motion is supported by Dr Hamish Meldrum, chairman of BMA, though it will be formalised into a policy only after a conference scheduled to take place in June. The BMA's junior doctors' body has argued for a blanket ban on homoeopathy and an end to all placements in the homoeopathy hospitals.

Crystal Sumner, chief executive of the British Homoeopathic Association (BHA), replied to the BMA comment: "Homoeopathy helps thousands of people who are not helped by conventional care.... when people are thinking about making cuts to funding, I think they need to consider public satisfaction, and see that homoeopathy has a place in medicine."

Press Trust of India. No scientific basis? Homoeopathy is witchcraft: UK medical body. The Hindu, May 4, 2010. Laura Donnelly, Homoeopathy is witchcraft, say doctors. The Telegraph, May 15, 2010.

Doctor suspended for false claims

A Mumbai-based doctor, Anirban Chaudhuri, has been suspended by the Maharashtra Medical Council (MMC) for misleading patients by claiming to be a cardiologist and a Member of the Royal College of Physicians (MRCP). Dr Anirban Chaudhuri received his MBBS degree from West Bengal and is registered with the West Bengal Medical Council. He registered himself with the MMC after his shift to Mumbai two years ago, and is affiliated to hospitals in the city's suburbs.

The suspension followed a complaint lodged with the MMC questioning the doctor's credentials. On registering the complaint, the MMC sent Dr Chaudhuri a show cause notice asking him why his name should not be removed from the MMC register. Dr Chaudhuri pleaded guilty and promised to rectify his mistakes at the earliest. A month later, it was brought to the MMC's notice that the doctor's letterhead still claimed that he was a cardiologist and MRCP. This time around the doctor was summoned before the MMC and suspended for two months.

"It's a fact that the act of the doctor amounts to misleading a patient and it is a fit case for being referred to the police. However, under the MMC Act, we don't have the power to approach the police," said an MMC official on the condition of anonymity.

Prafulla Marpakwar 'Cardiologist' suspended for professional misconduct. Times of India, June 2, 2010

Abortion laws get tougher in the US

The US anti-abortion lobby is now using the powers vested in the government to make abortions more inaccessible to its citizens. Already 22 out of 50 states have restrictions that make accessing abortions difficult, with requirements such as mandatory counseling, a waiting period, ultrasonography for non-medical reasons, and so on.

Recently the state of Nebraska passed legislation prohibiting the abortion of fetuses more than 20 weeks old, while Oklahoma passed a bill requiring that women who intend to abort undergo an ultrasound examination in which the image is visible to the woman. Florida is considering a similar law, making ultrasound compulsory, adding an additional expense of approximately \$350 to a woman intending to undergo abortion. Only women who can prove that they were victims of incest, rape or domestic violence will be exempt from paying for the ultrasound.

The increase in anti-abortion legislation is probably a direct outcome of the healthcare reform legislation passed in March. This legislation does not include funding for abortions and will not be providing cover for abortion under health insurance policies that come under it. After passing this legislation, President Obama signed an executive order making federal money unavailable for abortions unless the woman is a victim of incest, rape or her life is in danger.

Ricardo Alonso-Zaldivar, Abortion foes capitalize on health law they fought. Associated Press, May 16, 2010 Janice Hopkins Tanne. US anti-abortion activists use state laws to reduce access BMJ, May 15, 2010.

Patenting life

A team of 24 scientists at the United States-based research organisation J Craig Venter Institute has created artificial life in a laboratory. So far, scientists have manipulated DNA to produce genetically engineered plants and animals. Creating a genome in a laboratory is a new ballgame altogether.

This genome did not come cheap, at a whopping \$30 million upwards spent over 15 years. The *Mycoplasma mycoides* cells, that scientists at JCVI synthesised without using any DNA material were designed in the computer and made in the laboratory. *Mycoplasma mycoides* are parasite bacteria found in cattle and goats. This is the first time that life has been generated without using any living material in a laboratory.

This invention could be used in the pharmaceutical industry, for making biofuels.

This has implications for many other inventions in the field of genetic engineering and biotechnology. But it has its own ethical issues as well. Dr J Craig Venter, the founder of the institute, has cautioned: "We look forward to continued review and dialogue about the important applications of this work to ensure that it is used for the benefit of all." By saying this, he may have silenced questions about the ethical implications of this work.

While JCVI is applying for patents for parts of its work, a voice of dissent has been raised. British scientist John Sulston, who won the Nobel Prize for his work in the area of genome mapping, has expressed his reservations about patenting such an invention. Not the one to mince his words he said, "But the thing is they are using this really rather pretty little experiment, but not one of major importance in itself, to claim an enormous range of possibilities which really would give them control of all bioengineering in the future." Prof Sulston has rubbished the invention saying, "It is in no way artificial life."

John Bingham, Synthetic life: Dr Craig Venter seeking 'monopoly', claims gene pioneer. The Telegraph, May 25, 2010 Chidanand Rajghatta, Man plays creator: Scientists create artificial life in US lab. Times of India, May 22, 2010.

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