

FROM THE PRESS

The case of the controversial cervical cancer vaccine

The advertising campaign by the multinational drug firm Merck promoting its high profile cervical cancer vaccine Gardasil has left Indian households confused and health workers worried. The 15-second commercials on Indian television urge parents to get their young daughters inoculated with the vaccine to protect against cervical cancer which is caused by the human papilloma virus (HPV). But they fail to emphasise key information, and they also create panic.

What is also under wraps is that the vaccine has been mired in controversy in the US since its launch in 2006. The controversy is over its potential side effects, its efficacy and the ethics of administering it to girls as young as nine years of age. According to medical ethicists, advertising prescription drugs on television is unethical enough, but using fear to sell them is worse.

Key information about the safety and risk profiles has not been made available to parents. Reported "serious" side effects include seizures, blood clots, and paralysis. Less serious side effects include fainting, fever and headaches. However, US health officials and Merck have dismissed the adverse events as "unrelated to the vaccine".

Another ethical issue raised is that the vaccine can only prevent, but not treat, HPV infection. Since HPV is sexually transmitted, the vaccine needs to be given before a girl becomes sexually active -- ideally at the age of 11. This has led some to suggest that it might encourage sexual promiscuity post vaccination.

With many unanswered questions, critics say that the Indian health ministry acted in haste to put the Merck vaccine in chemist shops before the results of clinical trials on Indian women (16-23 years) were published. If it was really serious about tackling cervical cancer it should have, instead, promoted the inexpensive Pap test, a screening test that costs Rs 200. The vaccine is exorbitantly priced for the Indian market at Rs 5,800.

The vaccine's long-lasting effectiveness is unclear, as no clinical trial participants have been followed for more than five years. And it does not protect against 30 per cent of HPV strains. This means that even vaccinated women should continue screening by regular Pap tests.

IANS. Cancer vaccine kicks up controversy in India. DNA, December 30, 2008

Drug approved despite violation of Indian drug laws

Questions are being asked about a clinical trial of a cancer drug that led to the drug's approval for infertility treatment in India.

Letrozole is approved for breast cancer treatment in post-menopausal women in 30 countries. Until recently, it was

not approved for fertility treatment anywhere in the world. However, the Drugs Controller General of India (DCGI) recently gave it marketing approval for fertility treatment in pre-menopausal women.

The DCGI is reported to have disregarded warnings by the original manufacturer, Novartis, about the unsuitability of letrozole for infertility treatment in pre-menopausal women. According to CM Gulhati, editor of the *Monthly Index of Medical Specialities India*, the DCGI also ignored rules governing safety of clinical trials.

Letrozole first created a controversy in India five years ago. The Indian drug company Sun Pharmaceuticals was promoting letrozole with infertility specialists, despite the fact that it is illegal to promote a drug's use for an unapproved condition. Reports from these doctors were then used by the company to encourage the off-label use of the drug.

When a *MIMS* report on this practice caused a nationwide uproar, Sun Pharma found a way to get the drug approved by conducting a clinical trial of sorts. This "phase 3 trial" had only 55 participants, though a minimum of 100 are required for phase 3 trials. Further, phase 3 trials of an approved drug for a new indication must be preceded by phase 1 and phase 2 trials, for the same indication, that establish the drug's safety in healthy pre-menopausal women and the dose for treatment. The trial protocol papers do not provide such evidence and the permission is therefore flagrant violation of Indian drug laws, according to Dr. Gulhati.

G S Mudur. Infertility drug trial rules flouted: Govt papers. The Telegraph, September 7, 2008

Kerala debates euthanasia

A law commission in Kerala has recommended the legalisation of euthanasia and assisted suicide as part of the Kerala Terminally Ill Patients Act. The commission has argued that terminally ill patients should have the right to consider euthanasia after taking responsible medical opinion on the prognosis of the illness and the scope for a normal, pain-free life. The commission also wants to delete Section 309 of the Indian Penal Code which makes suicide an offence.

However, the proposal runs counter to a host of Supreme Court rulings that have declared euthanasia or mercy killings homicide, irrespective of the circumstances under which they take place.

Should it be approved, the proposed law would allow terminally ill persons to put an end to their life under medical supervision and also give competent patients the right to refuse treatment, including breathing machines. If patients are incapable of making an informed decision, or have not taken

an informed decision, medical practitioners can evaluate what treatment to offer, or decide to withhold it altogether.

Nirmala Carvalho. Kerala: Communists pushing euthanasia bill. *The Telegraph* (Kolkata), September 21, 2008

Indian doctor pursues unproven stem cell treatment

Leading Australian scientists have issued warnings about the growth of stem cell tourism in India. An Indian doctor speaking at a fund-raiser in Australia reported developing embryonic stem cell lines and using them to treat people with conditions including spinal cord injuries, Parkinson's and motor neurone disease. The doctor claimed that the therapy was safe and reported that it had resulted in improved movement and sensation in limbs in a number of patients.

Critics have stated that use of human embryonic stem cells for such purposes has not been properly tested, and there is no evidence of the procedure's effectiveness and safety. Such practices are dangerous and irresponsible. The doctor's methods need to be subjected to independent scientific scrutiny.

Agencies. Stem cell therapy warning. *The Age*, Australia, October 17, 2008

Tobacco industry puts pressure on the government

The government has succumbed to pressure from the tobacco industry to tone down its plans for pictorial warnings on tobacco products. This information was obtained by an NGO under the Right to Information Act.

Pictorial warnings on tobacco products are intended to increase consumer knowledge of the deadly health effects of tobacco consumption and to encourage people to stop using tobacco. Pictorial warnings also reach across linguistic and cultural barriers.

The central government admits that it is under pressure, not only from the bidi industry, but also from other interested parties. The government stated that the group of ministers entrusted with the responsibility has recommended weaker pictorial warnings on tobacco products. Further, the implementation of this programme has been postponed to May 2009—by when parliamentary elections will be over.

IANS. Government under pressure from tobacco industry. *New Kerala*, December 8, 2008

Insurance coverage refused to visually impaired

Insurance companies are refusing coverage to the disabled. An ex-bank employee who lost his eyesight after an accident approached Reliance General Insurance officials for an insurance policy. He was told that the company had no provision to give insurance cover to visually challenged people. He then went to the state-owned Life Insurance Corporation. LIC rejected his papers as well. He then went to New Delhi and called on the chief commissioner for persons with disability (Ministry of Social Justice and Empowerment) to complain

about LIC's refusal. He has lodged a case against LIC, calling on them to abide by the Persons With Disabilities Act 1995 which does not allow for discrimination against visually challenged persons. He has also called on the Centre to delegate more powers to authorities to execute the provisions of the PWD Act, both in the public and the private sector.

K Shiva Kumar. Visually challenged denied insurance cover. *Express Buzz*, December 3, 2008

India uses controversial brain scan to convict

Indian courts are accepting brain scans as evidence in criminal trials, even though the technique has not been validated by an independent study or peer-reviewed.

A woman accused of poisoning her former fiancé with arsenic was subjected to the Brain Electrical Oscillations Signature test, developed by an Indian neuroscientist. When details of the crime were read out, sections of the woman's brain lit up. The prosecutor successfully argued that this proved "experiential knowledge" of the murder.

Reactions from American experts have ranged from skepticism to outrage. Psychologists and neuroscientists at Northwestern University claim that technologies which are neither properly peer-reviewed nor independently replicated are not credible. This test could very well lead to innocent people being jailed or executed.

India uses controversial brain scan to convict murderer. *International Herald Tribune*, September 8, 2008

Clout of tobacco giants in China and Thailand

Two of the world's biggest tobacco companies tried to undermine anti-smoking efforts in Asia by seeking to influence health policy in China and scientific research in Thailand, according to two new studies. One-third of the world's smokers come from China and Thailand.

British American Tobacco plc, Europe's largest cigarette maker, helped form the Beijing Liver Foundation to reprioritise the agenda of the ministry of public health and to divert the public attention from smoking and health issues to liver diseases. Philip Morris International Inc gained a disturbing and inappropriate influence over teaching at a Bangkok research institute. This is of great concern to the public health community, which is working hard to reduce deaths and disease due to tobacco.

Bloomberg. Philip Morris, BAT sought to influence smoking policy. *Singapore*, December 24, 2008

Autism: to screen or not to screen

A pre-natal test for autism moved a step closer with the announcement by scientists that high levels of the male hormone testosterone in the amniotic fluid surrounding the foetus in the womb may serve as an early warning signal of the condition. Researchers say the discovery raises the possibility

that an amniocentesis test similar to that performed for Down's syndrome could be offered to mothers for autism.

Proponents of screening for autism say that only those at high risk of autism through their family history should be offered the test. Opponents say that the test could lead to the elimination of some of the greatest minds, and that a whole range of individuals who add to the diversity of human nature might be lost.

Jeremy Laurance. The Big Question: Should mothers be offered screening for autism, and what issues would it raise? *The Independent*, December 13, 2008

TV broadcast of assisted suicide in Britain

It is illegal in Britain to aid, abet, counsel or procure suicide. Only a handful of places, including Switzerland, the Netherlands, and some states in the US, allow assisted suicide, and only according to stringent criteria. In the last decade, about 100 Britons have committed suicide at a Swiss clinic called Dignitas, whose slogan is "Die with dignity". The clinic has been accused of profiting in assisting people die.

Recently a man chose have his death broadcasted on Sky Television, in the film, "Right to die!" supported by Digitas. It is said to be the first broadcast on British television of the moment of death in a case of voluntary euthanasia.

This incident added fuel to an already contentious debate. But while the law is clear, its application is murky. Authorities periodically prosecute people who have assisted in suicides in Britain. They are rarely sent to jail, but face many months of distress while waiting to stand trial. Parliament has been reluctant to reconsider its position, and Prime Minister Gordon Brown said that he opposed legislation that would allow assisted suicide.

Sarah Lyal. TV broadcast of an assisted suicide intensifies a contentious debate in Britain. *The New York Times*, December 11, 2008

Reforms in organ transplant practices in China

Organ donation in China has had a terrible reputation as more than 90 per cent of transplanted organs come from executed prisoners. The government has planned reforms in response to foreign criticism. Work on a legal framework for transplants

began in 2006. Financial compensation has now been banned with severe penalties. Transplant tourism is also being tackled.

The Ministry of Health is also trying to set up an opt-in system with people's donation preferences indicated on their driver's license. However, it is expected that the practice of using organs from executed prisoners will continue in the foreseeable future, albeit with written consent for organ removal from the donor.

Official word on Chinese transplants. *The Lancet*, December 6, 2008

Unreliable diagnostic tests sold in developing countries

An inquiry has found that many tuberculosis tests being sold in developing countries were missing more cases than they found. The evaluation of 19 commercially available rapid diagnostic tests, which detect antibodies to tuberculosis bacteria, found that on average they could identify only about a quarter of cases. Most detected less than half and one test identified less than one in a 100 cases. This means that 99 out of 100 TB-infected people would continue to go about their daily lives coughing and infecting people, according to a report by the WHO Special Programme for Research and Training in Tropical Diseases which conducted the research.

The problem is particularly acute in the case of rapid diagnostic tests which have been hailed as the solution to providing affordable and timely point-of-care diagnosis in developing countries. While certain rapid tests on the market are effective, many others do not work effectively or reliably, leaving people with undiagnosed conditions or infections that could be life-threatening. Unfortunately, very few countries actually look at the quality of the products before they are allowed to go on sale.

Experts have called for a global body to regulate diagnostic tests, particularly those used in the control of diseases that disproportionately affect developing countries. Such a body should set standards for tests, provide guidelines for their evaluation, ensure that participating manufacturers adhere to a code of conduct and provide a "seal of approval" for quality products.

Katherine Nightingale. 'Unreliable' diagnostic tests risking lives. www.scidev.net, December 23, 2008

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