Clinical Trails

Why in news?

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A long-drawn legal battle over collusion by the Health Ministry with international NGOs to test experimental drugs on Indians has landed before a Constitution Bench of the Supreme Court.

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What happened?

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- In 2009, a prominent international NGO had launched a $3.6 million **human papillomavirus (HPV) trial** in India and tested two vaccines on 16,000 tribal girls in A.P. and Gujarat, apparently without informed consent from the girls' parents.
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- After allegations were made that the girls had suffered adverse effects, the 72nd Parliamentary Standing Committee Report, **implicated the DCGI** for licensing the vaccines without adequate research on safety and efficacy; **the Health Ministry** for not questioning violations in the licensing process; **the ICMR** for promoting a drug even before it was approved and **the NGO** for setting up a trial without following basic protocol.
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- The committee found **commercial interests were influencing government policy,** and that authorities acted as willing facilitators to the foreign institutions.
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- The committee recommended that henceforth, trials ought to be conducted only in the 330 medical colleges that have emergency facilities.
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- It also sought an investigation into the illegal approval of drugs and of doctors who submitted 'ghost letters' recommending drugs for approval.
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- The NGO and the drug companies involved have dismissed the allegations as baseless and oppose the court's reliance on the report.

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- Because of a legal hurdle, the parliamentary report cannot even be looked at by the Supreme Court. Thus, the issue was referred to a Constitution Bench this week.
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How serious the incident is?

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- In 2005, an important change in the **Drugs and the Cosmetics Act** allowed phase II trials (where the efficacy and safety of an experimental drug is tested) for the first time in India.
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- It allowed drugs discovered abroad by multinational pharmac companies to be tested on Indians.
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- But clinical trials in India have been accompanied by large-scale criminality as doctors, officials and pharma companies understand well enough that India is a cesspool of corruption where clearances can be had for a pittance.
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- While there have been many cases since, the underbelly of India’s clinical trial industry came to the spotlight in 2005 when 3,300 patients were subjected to 90 clinical trials that followed no protocols at a hospital in Madhya Pradesh.
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- In American law, such violations automatically attract the criminal charge of battery. In India, the poor don’t count at all.
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- Clinical trials ought to be done under calibrated statutory regimes. But, despite several crimes of enormous proportion where the poor are tested as guinea pigs, nothing has ever been done.
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Source: The Hindu

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