

What Is Bill Gates Up To? Irregularities in the Conduct of Studies Using HPV Vaccines in India

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After having read the 72nd report of the Department Related Parliamentary Standing Committee on alleged irregularities in the conduct of studies using HPV vaccines by Path in India, it was startling to see Bill Gates bobbing his head up and down and smiling ingratiatingly on prime time television while the Prime Minister lectured him in Hindi on his plans for the country. Public memory fades quickly and politicians of all hues wait for this memory to fade so as to carry on regardless of the effect of their policies on the health of the nation.

In 2010, "the entire world was shocked by media reports about the deaths of female children in Andhra Pradesh after being administered the HPV vaccines. The project was reportedly funded by the Bill & Melinda Gates Foundation." The role of government agencies including ICMR and DCGI in approving these trials, the misuse of the government funds "for a private project of dubious nature", the use of the logo of the NRHM to give it respectability and official endorsement, the approval of the trials by the National Ethical Committee, came under scrutiny by Parliament. Hugely perturbed "the Central Government directed an enquiry be conducted by the premier investigation agency, the state governments were advised not to carry out further vaccinations in the interim period."

The committee appointed to investigate

"found the entire matter very intriguing and fishy... the monopolistic nature of the product being pushed and the unlimited market potential... are all pointers to a well-planned scheme to commercially exploit a situation... and would have generated windfall profits for the manufacturers by way of automatic sale, year after year without any promotional or marketing expense. The American organization Path resorted to subterfuge. The interest, safety and well beings of subjects were completely

jeopardized by Path.

Thus as early as 2006, the main objective of Path was to facilitate the introduction of the HPV vaccine *Gardasil* into government funded immunization programme in India."

The experts in the enquiry committee when asked, opined that "the design of the project itself was faulty. In the survey documents there was no column for serious adverse events even though much before the trials started, severe allergic reactions and other considerable side effects were well-known. Because ICMR was worried about bad publicity in case of side effects, Path did not provide for "urgent expert medical attention in cases of serious adverse events", which were known or expected. There was no preparation to handle serious developments like cardiac arrest and seizures occurring at the sites of vaccine administration. There existed no insurance cover for the children.

The Committee took a serious note of the fact that "both the Ethics Committees existed as a formality" and that there was "a clear dereliction of duty". The credibility of the Universal Immunization Programme "was used to promote private, foreign interest" and recommended "practices of diverting public funds for advancing interest of a private agency should never be allowed in future."

The Committee found that the project was "reportedly funded by Bill and Melinda Gates Foundation" and that the "vaccines were donated by the manufacturers."

When the Committee desired to know "whether criminal enquiry was initiated against Path", no answer was forthcoming. Commenting on the action taken report "the Committee was amazed at the audacity of DCGI to merely repeat various steps to be taken as if they were new additional measures. Except for slight amendment in the informed consent form, there was nothing new in the action taken report. No accountability had been fixed."

Commenting on the American organization Path, the Committee was concerned that it set up an office without getting the required mandatory approvals / permissions. The Committee found it "surprising that security and intelligence agencies did not raise an eyebrow on a way a foreign entity entered India through the backdoor." The Committee found the actions of Path "a serious breach of trust, of medical ethics, and a clear cut violation of the human rights of these girl children."

The Parliamentary Standing Committee questioned the decision of ICMR to promote the drug in the Universal Immunization Programme in 2007 itself, before the vaccine was approved in India in 2008.

The Committee also affirmed the general guidelines of CDSCO that no trial can be conducted on children until trials are conducted on adults to determine efficacy and safety. The project envisaged vaccination of about 30,000 children in the age group of 10-14 years. What made things even more worrying was the deaths of children after receiving the vaccine. These were dismissed as "unrelated to vaccination without in-depth investigation."

On informed consent the ICMR acknowledged that

"there were gross violations of norms in Andhra Pradesh. 9543 consent forms were signed, 1948 had thumb impressions, while hostel wardens signed 2763 forms.

In Gujarat 6217 were signed and 3944 had thumb impressions. Very large number of parents / guardians were illiterate and could not even sign in their local language. The wardens / teachers / head-masters were not given written permissions by the parents / guardians to sign on behalf of their girls. On many forms, witnesses had not signed. Neither the photographs, nor the photo ID cards of the parents / guardians / wardens is pasted in the consent form. On many forms, investigators had not signed. On some forms, signature of the parents / guardians is not matching with their names. The date of vaccination in some forms was much earlier than the date of signatures.”

The DG, ICMR admitted “that many consent forms were filled up by the principal on behalf of the students, he admitted gross violations in the recording of serious adverse effects also.” The Committee concluded that the consent forms were carelessly filled up “and were incomplete and inaccurate”, full of “grave irregularity”.

High officials admitted that the presence of ICMR in the Project Advisory Committee indicated “conflict of interest” and therefore ICMR had moral responsibility for the numerous irregularities reportedly committed. This dereliction of duty went to the extent of ICMR “apparently acting at the behest of the manufacturers”. For example, “States were not even capable of monitoring the adverse effects.” The machinations of Path came in for “the strongest condemnation”.

The Drugs Controller General of India (DCGI) came in for scathing criticism as well.

“DCGI played a very questionable role... remained as a silent spectator even when its own rules and regulations were being so flagrantly violated.”

The Parliamentary Standing Committee found instances of conflict of interest in the composition of the Enquiry Committee. There was no disclosure by the members of the Enquiry Committee or by the experts. The Committee found that an individual availed the hospitality of the trial sponsors during a visit to Seoul to attend a conference, which fact was not disclosed. On enquiry, the Committee found that the conflict of interest though, “serious matter” was treated in a “casual manner”.

The success of vaccine manufacturers and promoters in getting away with myriad illegalities in the marketing of the HPV vaccines and its endorsement by the Prime Minister of India, ultimately paved the way for the secretive clearance of the COVID vaccines in India. Serious adverse events were kept top secret. Perhaps the number people who died due to vaccine related reasons will never be known. The sudden inexplicable deaths of young persons proximate to the taking of the vaccine will probably never be investigated.

The judiciary is loath to even allow any enquiry perhaps on the assumption that a judicial review could possibly lead to vaccine hesitancy.

In the meanwhile, the large numbers of COVID vaccine related deaths remains India’s best kept secret. But, that is another story; and there are excellent studies done which are waiting in the wings to be reported but cannot find a willing publisher. Such is the nature of freedom of the press in India.

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