## The search for the perfect contraceptive

## Rohini Nilekani: Stillborn - a medical thriller: Penguin Books 1998. 168 pages Rs. ZOO.

S. Nilekani turned from reporting f'or a periodical to the 'lonely business' of writing a book. Research into current trends for controlling fertility and studies with the tribals on BR Hills, near Bangalore, provided grist for her mill.

The narrative revolves around Anshul Hiremath who returns from the US to set up a research laboratory to produce an anti-fertility vaccine for women, and Poorva Pundit, an investigative journalist. Nilekani is able to keep the reader interested in the twists and turns of her plot right up to the end.

The narrative jars at places, as when it describes medically incredible situations. As when the principal character has 'some of the bones and most of' my flesh on my left side ... crushed and torn' - she spends just three days in hospital. The unnecessary usage of four-letter words may put some readers off. However, the use of a novel to raise the serious subject of unethical medical practice is much appreciated. The thriller touches upon a number of questions regarding research on vulnerable groups.

The perfect contraceptive. "must be very, very safe. It must be easy to administer... very effective . . . economical. Last, but not the least, it should not need frequent visits to a professional ." he a 1 th Another important prerequisite is reversibility. But there are many pitfalls in the search itself.

Anshul is honest when he tells Poorva: "There is no way anybody can guarantee anything (in research). No medical research would be possible with such a caveat. The element 01' chance will always

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remain. But you have to take this chance consciously and take all precautions." However, when complications jeopardise his research, he suppresses the information. "I area... She had followed... (She) deserve the chance to make corrections if things go wrong. We pregnancy ... " have not created any life-threatening situations for anybody ... "

"How does one get people to volunteer as guinea pigs for the development of something like that (contraceptive) vaccine'?" Poorva Pandit asks her father, a public relations officer for a drug company. "...That's the least of the problems in a country like ours," he replies. "If the incentives are good, if the investigators can convince the volunteers that the risks are nonexistent or low, you can find the people... You can play around a lot with those things. Technically, ethically, even legally, no trial can be conducted without the written, informed consent of the participants. But then our people have so little information! They may not understand all the implications. The doctor is God here."

Poorva asks a retired drug controller (DC) about the requirement of informed consent. "Yes, those rules, at least on paper, are very strict," he replies. "In all these trials, volunteers must sign a form saying: 'I am willing to take this treatment. The risks have been explained to me.' But let me tell you there are many ways around it...After 50 years of independence, not even 50 per cent of our people are functionally literate enough to tell the difference anyway."

Indeed, none of the tribals "seemed aware that the vaccine was not foolproof, and that it could have risks. The men were happy because of the communities," sgan 'harvesting' compensations. The women were getting free contraception." Poorva meets one of the women, Madhamma, who "had taken the contraceptive vaccine twice. The 'doctors' had

promised rations and clothes for the little ones. They had delivered ... Everything had been all right for a while after that... Then she had quit going to the research centre. Her man had gone to work in another tribal ",\*developed all the symptoms of

## The regulation racket

Who should be responsible when trials go wrong? Says the PRO: "The researchers should. The company should. But often in these trials, follow-ups are neglected. So the volunteers may not even make any connection between the problem that has developed and the clinical experiment. And then, you know how it is. Our enforcement agencies can easily turn a blind eye when they want tơ."

That is exactly what happens when the contraceptive fails, babies are born with severe deformities, and women almost die from the complications of pregnancies that should never have occurred "Nobody wants poor tribals to proliferate. So the government is quite content to look the other way. The Drug Control Authority of India has many officers who are pliable on these things."

Adds the retired DC: "The drug controller's office just does not have the resources to keep to the letter of requirements in such cases. They are short on funds, short on staff...Things can and do slip through."

In the course of the novel, Nilekani manages to introduce a number of other related ethical issues as well: Indian pharmaceutical manufacturing practices; population policies; exploitation of multinationals' indigenous medicine. and

rackets, and sloppy legislation that deprives legitimate patients without preventing racketeering.

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