

Clinical trial research is no crime

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What's the point? The Bill is regressive Scott Rothstein/shutterstock.com
The penalties for error in the proposed Drugs and Cosmetics (Amendment) Bill are extremely unreasonable

It is not news that clinical research in India has taken a hit. The year 2013 saw a precipitous drop in the number of clinical trials conducted in India, and 2014 has been little better.

As regulators attempt to resuscitate a clinical trial industry, vital to India's role as a global leader of scientific innovation, the Drugs and Cosmetics (Amendment) Bill, 2013, imposing unnecessary penal consequences on trial investigators, is still pending before the Rajya Sabha.

The risk of such penalties will force investigators to quit conducting clinical research, pushing the industry to almost certain economic death and depriving patients across India of any chance of obtaining potentially life-saving experimental treatments. It is imperative that the new government, with its avowed commitment to economic progress, does not proceed with this Bill.

Under section 4ZE of the Bill, any clinical researcher (including the sponsor, institution or investigator and anyone who works on their behalf) who fails to conduct a clinical trial in accordance with "the conditions of permission" imposed by the central licensing authority would be punishable with a minimum of two years' imprisonment and a fine of ₹5 lakh. Additionally, under section 4ZG of the Bill, any researcher who fails to provide compensation to a subject suffering a trial-related injury shall be punishable with "imprisonment which may extend to two years and a fine which shall not be less than twice the amount of the compensation".

Concerns over penalty

Prominent researchers have said they will stop conducting clinical trials if section 4ZE and its counterparts become law. They believe that such penal provisions will lead to arbitrary prosecution. In their eyes, the risk of an unfounded two-year prison sentence is simply too high.

Dilip G Shah, the secretary-general of the Indian Pharmaceutical Alliance, agrees with these researchers. He stated during his November 2013 deposition before the Committee on Health and Family Welfare that “the penal provisions are without adequate safeguards and prone to abuse”. He also stated his belief that the penal provisions would discourage foreign and domestic investment in the pharmaceutical industry.

These concerns have merit. The Bill treats investigators who intentionally ignore central licensing authority requirements no differently from those who are committed to ethical practices but have inadvertently misinterpreted the often ambiguous clinical trial conditions imposed by the authority.

Misinterpretation by well-intentioned practitioners will likely be a common occurrence because the language of protocols and corresponding “conditions of permission” are vague, as they must be, to apply to a wide variety of trial events and research participation conditions.

Need for greater fairness

To prevent the mass exodus of investigators from the clinical trial industry, to resuscitate India’s dying clinical trials industry, and to ensure that patients in India can choose to access new, cutting-edge potential therapies, the Bill containing these proposed penal provisions should not be revived in the new session. If there is to be a new Bill — the need for which is not exactly clear — then it should reflect a more fair and rational policy. Instead of imposing strict liability, the penal provisions should require that prosecutors demonstrate wilful misconduct on the part of an investigator.

Further, prosecution should be reserved only for material violations of approved study designs, when those violations directly cause harm to participants. Finally, any revised penal provisions should avoid the use of minimum mandatory penalties. Such penalties prevent the judicial system from imposing sentences that reflect the unique culpability — or lack of culpability or— of each individual defendant. Prosecutors can then focus on investigators who are truly bad actors.

If an investigator is non-compliant due to simple interpretation errors, he or she should be offered additional clinical trials training and education — not prison. The previous government is being criticised for acting unwisely and precipitously in many aspects of the regulations affecting clinical trials in India.

The regulations have strangled clinical research in India and have deprived the citizens of India of any chance to enrol in clinical trials of potential life-saving therapies. The time has come for more rational, more measured and more productive policies, and we should start by burying this amendment Bill, once and for all.

Barnes is co-chair of the Harvard University Multi-Regional Clinical Trials Center, Naqvee and Das are with LexCounsel Law Offices, and Shah is a legal fellow at Harvard MRCT