

National Institutes of Health say that such studies should involve, in principle, adult, healthy volunteers. To what extent underfed volunteers can be called healthy is a moot question. Worse, it is not clear if they were adequately informed about what they were getting into.

A monograph on Citalopram says, "The possibility of a suicide attempt is inherent in depression and may persist until remission occurs. Therefore, high-risk patients should be closely supervised throughout therapy with Citalopram hydrobromide and consideration should be given to the possible need for hospitalisation. In order to minimise the opportunity for overdose, prescription for Citalopram should be written for the smallest quantity of drug consistent with good patient management." Clearly giving Citalopram to 'healthy' people seems to present a risk. Giving it to underfed, poor people, seems to be an even worse choice.

The Sun Pharma company says the trial was part of Phase IV post-marketing surveillance (PMS). However, PMS is done on patients who have been prescribed the drug for the said condition.

The same monograph on Citalopram says that, "to date, no information is available on the pharmacokinetic or pharmacodynamic effects of citalopram in patients with severely reduced renal function." Did the patients have a history of renal dysfunction? Did the company check?

A WHO guideline on bioequivalence studies reads, "Health monitoring, before, during and after the study must be carried out under the supervision of a qualified medical practitioner licensed in the jurisdiction in which the study is conducted." The Sun Pharma medical director is quoted in the papers as saying 'How can we be held responsible?'

The researchers claim to have taken informed consent. This is meaningless when the research subject is non-literate, poor and otherwise weak in bargaining power.

Sun Pharma claims to be subjecting every batch or export consignment to bioequivalence studies, albeit at the insistence of the importer. The guidelines do not mention such a practice which is both absurd and fraught with dangers.

Soon after this controversy, Sun Pharma advertised in the newspapers asking for volunteers for trials. Is the public entitled to know what these trials are for and which ethical guidelines are followed? If they are for bioequivalence will the Drug Controller explain why we need bioequivalence studies for every export consignment? If Parliament could pass a law from the Right to Information in public affairs for the country, what about the right of the public at large to know what kind of trials are going on and on whom and for what purpose?

The recent post-liberalisation hype is to project India as a favored destination for clinical trials. But our very advantages — a large population, genetic diversity and low costs — are compounded by: poor or no regulatory laws, and ignorance on research ethics and law among the public and even health professionals.

The application fee for phase I clinical trials will be Rs 50,000 and the fee for both phase II and phase III trials, is just Rs 25,000 each. Many companies will of course get "informed

consent" of illiterate poor people, and probably women, and will be targeted with drugs known and unknown. Citalopram is just an indicator.

Chinu Srinivasan, Rohit Prajapati, Kiritbhai Bhatt, Tupti Shah, Masoor Saleri, People's Union for Civil Liberties, Baroda..

Ethical use of animals in scientific research

A number of articles have appeared in the press recently regarding a visit to the National Institute of Immunology (NII), New Delhi, by an inspection team of the Committee for the Prevention of Cruelty in Scientific Experiments on Animals (CPCSEA). The articles were extremely critical of the condition of the monkeys kept in the NII and its use of animals in scientific research. One article stated that the CPCSEA had recommended closure of the primate house at the NII, in effect terminating all research at the Institute involving these animals.

Delhi Science Forum (DSF), a non-profit public interest organisation of scientists, technologists and social scientists working in areas of science and technology policy, is extremely concerned at these developments at NII which are but the latest of a series of similar actions by CPCSEA in different institutions. These actions reveal disturbing trends in the structure and functioning of CPCSEA and also have serious implications for the future of scientific research in India.

DSF designated a three-member team to visit NII and examine the issue covering not only the conditions and use of animals at NII but also the functioning of the CPCSEA. DSF spoke with CPCSEA team members and sought their views but was unable to obtain a copy of the team's report from either the team or CPCSEA.

Contrary to the allegation that animals are kept in overcrowded enclosures, DSF found that the 207 primates at NII are kept in 13 large outdoor enclosures (5 more are under construction) and additional indoor enclosures for observations and rotation, with small chambers in some outdoor enclosures with provision for heating or cooling depending on season. Enclosures are cleaned four times a day, about an hour after each feeding period. NII also has operating theatres and three full-time veterinarians. Therefore, the animal facilities at NII provide ample space, are in good condition, and are well-maintained.

Against the allegation that over 90% of the monkeys are infected with TB, NII records and DSF's observations show that only 2 adult monkeys out of 207 have TB, and these, along with one female's infant, are in quarantine, under observation and treatment. NII records show that all incoming monkeys are quarantined and tested for TB, such testing also being conducted regularly for all the monkeys, with infected monkeys being treated and painlessly put to sleep as per approved procedure if not cured.

Among the more sensational allegations was that the monkeys at NII were undernourished. DSF examined the monkeys' dietary and nutritional status besides feeding practices at NII. Monkeys at NII are fed four times a day, with special pelletised feeds, channa, bread with vitamin and other nutritional supplements (both additional for pregnant and lactating animals), fruits and vegetables. Monkeys at NII thus obtain more than the internationally recommended standard of 70-

100 kCal/kg of bodyweight per day.

NII has Standard Operating Procedures for care of animals and their use in experiments which are monitored and overseen by NII's Ethics Committee. DSF found not only that conditions and treatment of animals at NII were satisfactory but also that records were basically sound, properly maintained and procedures broadly conforming to international standards were being followed. Of course, there is always room for improvement and NII scientists and managers appeared open and willing to discuss any measures that may be recommended in this regard.

Not all the CPCSEA team members agree with the opinions as reflected in sections of the press and reiterated by some members to DSF. This makes the non-availability of the team report all the more serious and, if action is being taken or contemplated based on such unsubstantiated individual opinions, this raises grave concerns about pre-determined, motivated and biased functioning of CPCSEA.

DSF explicitly recognises the necessity for regulation of use of animals in scientific research to ensure ethical and proper treatment of animals and pursuit of research in accordance with clearly prescribed rules. The fact that the CPCSEA is a statutory body, with rules governed by law, is a positive aspect not only ensuring compliance but also benefiting scientific research and practice. The rules under the relevant Act are also broadly as endorsed by the scientific community in India and abroad.

While the CPCSEA as constituted gives representation to scientific departments and the research community, apart from animal rights activists, in practice and in the manner it functions, the latter have virtually taken over the CPCSEA and its various bodies, and have subverted the statutory body. CPCSEA today appears to act not to regulate the use of animals in scientific research but to completely stop it now and prevent it in future.

Some fundamental defects in the constitution of the CPCSEA under the relevant Act urgently require to be addressed. The NII episode, as well as previous ones at JNU, Indian Institute of Science, AIIMS, National Institute of Nutrition and other research institutions in both the public and private sectors, brings out sharply that the CPCSEA now appears to be functioning as police, prosecutor, judge and hangman, resulting in arbitrariness and lack of transparency and accountability.

The CPCSEA should be overhauled, and its advisory, inspection and other bodies completely reconstituted, with due representation of the scientific community apart from those with concerns for animal welfare. Inspection reports should be shared with the concerned institution for greater transparency, to enable peer review and full participation of research institutions in the regulatory process. CPCSEA should be brought under the ministry of science and technology with proper structures and mechanisms for transparency and accountability.

In the case of NII, no action should be taken on the basis of this inspection team's report since the entire process has been deeply flawed and vitiated.

Finally, DSF calls upon the scientific community to vigorously debate these issues, evolve a consensus and work towards a thorough overhaul and reform of this important regulatory body.

Delhi Science Forum, D-158, Lower Ground Floor, Saket, New Delhi 110017 Email:ctdds@vsnl.com

Abortion pill or murder marketed?

I draw your attention to the distribution and marketing of Mifepristone and Misoprostol by Sun, Cipla and Zydus Alidac Pharmaceuticals. These drugs for abortion are supplied to practising gynaecologists to be given to patients after obtaining their consent. The money is to be collected from the patient by the physician, who in turn turns it over to the drug representative. This is highly irregular, unethical and illegal and cannot be equated with drug dispensing by primary physicians at their dispensary.

Second, the drug is meant for the medical termination of pregnancy (MTP). This must be done according to the MTP Act, 1971, only by an *approved physician, in an approved centre and for approved conditions* (Threat to mother's life, congenital anomalies, rape induced pregnancy and pregnancy due to contraceptive failure, the last only in the case of married women).

According to the promotional literature, the pill is to be distributed for abortion at home. This is contrary to the provisions of the MTP Act. It makes no difference that in the consent form circulated by drug companies and to be signed by the patient, the patient agrees to take the pill in the physician's clinic. According to the MTP Act, a gynaecologist's consulting chamber is not recognised for the purpose of MTP. In any case, the abortion takes place at home and is not in conformity with the MTP Act. The possibility of failure and profuse bleeding is substantial and would expose the patient to grave risks, especially in rural settings. The risk is greater for unwed women for whom pregnancy is looked down upon, and who may therefore not contact proper services and may abort and bleed at home. Besides, the pill is being distributed through qualified and unqualified medical practitioners in the country, though under the MTP Act only a practitioner registered with the appropriate Medical Council can terminate a pregnancy. This is virtually marketing murder for paltry monetary gains with the open connivance of medical professionals.

Also, the distribution of full-text articles reproduced from the *New England Journal of Medicine*, *British Journal of Obstetrics and Gynaecology* and the *Journal of American Medical Women's Association* as promotional material, with or without the permission of the journals and the authors, is unethical. It amounts to lending the name by authors for promotion of brand/drug and amounts to 'association' under the MCI Act.

This marketing strategy to promote the abortion pill as an 'in-house' abortion method is dangerous and will claim hundreds of lives in the prevalent health care scenario in India. Unsafe abortion under the garb of MTP is already claiming many lives in the country.

Dr S G Kabra, Indian Institute of Health Management Research, 1, Prabhu Dayal Marg, Sanganer Airport, Jaipur 302 011