Drug Tests in India Face Questions; Biotech Co's Conducting Illegal Trials

By Indrajit Basu UPI Business Correspondent

CALCUTTA, India, Nov. 22 (UPI) -- The opportunities are huge, multinationals are eager, and India has the skills. And these along with its huge population that's genetically diverse make India the most fertile ground for multinational companies to outsource clinical drug tests and save huge costs. More importantly, this is one sort of outsourcing which the western world workers aren't likely to protest.

But even as global drug giants are flocking into the country for testing of new drugs on humans, it is also a sort of outsourcing that, fear Indians, is perhaps making the country the greatest source of human guinea pigs for the global drug industry.

Two of India's top biotech companies, Hyderabad-based Shanta Biotech and Bangalore-headquartered Biocon India have come under scrutiny after a local non-government organization, Aadar Destitute and Old People Home the Supreme alleged recently that these were "openly" conducting illegal clinical trials of new drugs on unsuspecting patients.

Aadar charged these two companies for conducted improper clinical trials of Streptokinise -- a new clot-busting drug used in heart attacks -- last November without requisite permissions (of the Genetic Engineering Appproval Committee), as a consequence of which eight people lost their lives.

But the Streptokinise wasn't an isolated one. In 2003 Monthly Index of Medical Specialities, an independent pharmaceuticals journal in India revealed that more than 400 women across India were subjected to clinical trials without consent for a drug called Letrozole, which was copied (with permission) by Sun Pharmaceuticals, a large Indian generic drug company, from a patented product of the same name of Novartis.

It was alleged by yet another social outfit that Sun Pharmaceuticals used Letrozole for treating conception problems while Novartis' original was introduced globally for solely treating breast cancer and not for any other use in any country, including India.

And in 2001, another trial that made headlines involved the clinical trial of nordihydroguaiaretic acid, a chemical with anti-cancer properties, which was tested by a regional cancer-treatment center in the Indian state of Kerala for a U.S.-based researcher then associated with Johns Hopkins Hospital in the United States. The drug was allegedly tried on 26 unsuspecting cancer patients, two of whom died. Subsequently, a 60-year-old woman was again included for a trial for which the testing center provided five doses of the experimental drug, worth $200, free. The woman's condition turned critical as well by the fifth dose.

Indeed, these incidents indicate that in the absence of adequate regulations and proper laws, a developing country eager to cash in on the opportunities of globalization can be used for indulging in rash and risky practices. A survey of 200 health researchers globally that was commissioned by the former U.S. National Bioethics Advisory Commission and published in February's revealed that a quarter of clinical trials conducted in developing countries did not undergo ethical review.

But in India unethical and illegal clinical trials are rampant and are conducted without fear because, as says Dr Arun Bal, president of the Association for Consumers' Action on Safety and Health, "there is no law to safeguard the interests of volunteers involved in clinical trials. And, though the Indian Council of Medical Research has laid down guidelines for conducting trials, there is no mechanism in
Still the potential for the outsourcing of clinical trials is too tempting for India to ignore.

According to the industry group Pharma Research, the business of pharmaceutical and medical device clinical trials is a $15 billion per year business in the United States and $40 billion globally. An industry study from Business Communications Company of Connecticut, says that United States-based spending on clinical trials is growing fast; at about 12 percent per year that should generate $26.5 billion by 2007.

Moreover, the cost of new drug development is enormous. Boston's Tufts Center for the Study of Drug Development, the leading research center of new drug regulation economics, calculates that total pre-and-post-approval research including clinical trials averages $897 million per drug. But the time required for the trials process -- which may take 10 years - is both a major factor in costs and an impediment to releasing beneficial new drugs. The costs are especially challenging to smaller drug companies.

Whereas, costs in India are a fraction of that and according to a study by Rabo India Finance, a subsidiary of the Netherlands-based Rabo Bank, "More than 40 percent of drug development costs are incurred in clinical trials and India offers immense savings -- about 60 percent -- on that aspect."

India's also has a huge patient population also offers vast genetic diversity, making the country "an ideal site for clinical trials". For example, India has the largest pool of diabetic patients, with more than 20 million citizens suffering from the ailment -- small wonder that insulin is one of the most researched drugs in the country.

Besides this, the country offers other critical facilities, such as nearly 700,000 specialty hospital beds, 221 medical colleges and skilled English-speaking medical staff.

Small wonder then almost all top names, including Novo Nordisk, Aventis, Novartis and GlaxoSmithKline, have started running clinical drug trials in India lately, while some, such as Eli Lilly and Pfizer, which started much earlier, continue testing.

Also, a variety of both India-based and global contract/clinical research organizations that specialize in outsourced clinical trials management are working to expand India's clinical-trials business. These include Quintiles, Omnicare, PharmaNet and Pharm-Olam (all U.S.-based).

On the upside this is leading to the country raking in the money. Industry sources say that in 2002, clinical trials were reckoned to have generated $70 million in revenues for India. This could grow to $200 million by 2007 and anywhere between $500 million and $1 billion by 2010.

Nevertheless, rattled by the recent deaths and the public outcry, India's regulators have started sitting up. In what could be seen as a clampdown on clinical research in the country, the Drug Controller General of India announced in September that it is working out a policy which demands accreditation of clinical research outfits for obtaining approval on any kind of tests conducted on humans.

It is also crafting out a set of standard procedures for all kinds of clinical tests conducted for different drugs. And most importantly, The Drug and Controller General of India said that by this year end it will put in place inspection systems to track the progress of drug trials from beginning to end.

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