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Dangerous Trend

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The tremors created by the Public Interest Litigation filed in the Supreme Court related to clinical trials of some biotech drugs will take a long time to subside. The PIL had its beginnings in another much-publicized complaint against Shantha Biotechnics by an unknown NGO, Anikethan, to the biotech regulator GEAC, a year ago. For the PIL, by yet another equally unknown Mumbai-based NGO, ADOPH, has borrowed heavily from the complaint to GEAC.

Being the first pure play biotech company, Shantha had to face the brunt of the problems associated with the government regulator's learning process in handling recombinant pharma products. The complaint raised by Anikethan related to procedural issues about the involvement of regulatory agencies. In fact, Shantha' regulatory process has been taken as the benchmark for future evaluation of such products by the regulator. However, some grey areas in the process, which became public knowledge during the long-winding regulatory approval path of the streptokinase drug has become the fodder for targeting the company through selective use of this data.

In fact, the crux of the PIL filed against Biocon over the clinical trials of its insulin drug is an offshoot of the same procedural issue: whether GEAC approval for each stage of the trial is required or not, after having got the clearance from all the other regulatory agencies involved. The regulator GEAC has clearly stated that the procedural lapse in Shantha's case did not involve any mala fide intention. The approval process for any drug stretches for years and these are
subjected to very stringent and evolving guidelines. In most cases, regulators approve use of these trial drugs on individuals who are left with very few alternatives and the acceptable mortality rates are based on risk-benefit analysis.
There is an urgent need to share with the public the benchmark rates for adverse effects of the trials of various drugs to

ensure that selective use of this data does not stymie the development process of many potential life-saving biotech drugs.

What is interesting is that our society has a very ambivalent attitude towards all regulatory agencies. Regulatory mechanisms is an evolving field and in the last 15 years or so, the various regulatory agencies have gone through a very difficult learning process and many have come out with flying colors. And whenever any such regulatory agency highlights some "deficiencies" in the process followed by companies, these have become the fodder for their opponents for a negative campaign. At the same time, a well articulated view point by the regulator, clearing an organization or company, has by and large been attributed as a "motivated" decision by rivals affected by these happenings. As a result any clean chit given to a company by a regulator is rarely taken at its face value by rival players.

Biotech is now becoming a victim of this syndrome. The technology has the potential to provide many path-breaking solutions to several serious issues facing the humanity. The complex nature of the technology has foxed every one, including the regulators.

Many of the hurdles created by the lack of full understanding of the benefits and also the possible side-effects could be tackled only if all stakeholders work together in a spirit of cooperation. Transparency should become the cornerstone of the clinical trials process (except the commercial details) to allay public fears over the drug development process in the biotech sector.