POOR QUALITY MEDICINE IMPACTING PATIENT SAFETY

New Delhi, Friday, March 11, 2016: The Hon'ble Supreme Court heard two Public Interest Litigations (PIL) filed by Dinesh Thakur seeking the Court's intervention to improve the standard of regulation governing the Indian Pharmaceutical industry.

The First Petition filed under Article 32 of the constitution versus The Union of India, through Ministry of Health & Family Welfare (MoHFW), Central Drugs Standard Control Organization (CDSCO), Drugs Consultative Committee (DCC) & Comptroller & Auditor General (CAG) – sought to bring to table three specific issues:

1. ***Issue pertaining to illegal drug approvals:*** Illegal drug approvals granted by CDSCO to drugs which are not sold anywhere else in the world and the failure of MoHFW to investigate the approvals despite giving the Parliamentary Standing Committee on Health & Family Welfare a written commitment that such investigations would be conducted.
2. ***Issue pertaining to changes in India's drug regulatory structure***: Recommendations of MoHFW appointed Expert Committee headed by Dr. Katoch to study the functioning of the CDSCO.
3. ***The measures to be undertaken in order to regulate the quality of drugs being made in India for Indians and exported to foreign countries:*** Tackling the problem of sub-standard drugs by addressing several different issues. For example, most Indian generics sold in India or exported to lesser regulated markets in Asia and Africa are not required to undergo bioequivalence or stability studies despite expert committee recommendations to make such testing mandatory. Another important issue is the creation of a drug recall system in India whereby nationwide drug recalls can be co-ordinated anytime a govt. laboratory in any state, detects a Not of Standard Quality (NSQ) drug. This PIL also aimed to reform the manner of investigation, prosecution and sentencing in all cases pertaining to NSQ drugs. .

The Second Petition versus The Union of India, through MoHFW, challenged the constitutionality of Rules under the Drugs & Cosmetic Rules, 1945 by which the Central government sub-delegates to 36 different state licensing authorities the power to grant or renew licenses for manufacture of certain class of drugs. The aim of this petition was to centralise the issuance of all manufacturing licences with the Central Government.

Expressing his disappointment on the decision of the court in not admitting the PILs, Dinesh Thakur, said "The Supreme Court declined to admit either of the petitions that address a substantive issue on the quality of medicine and patient safety. We are committed to the cause of putting patients first and will continue to advocate the need for better regulations in the Indian Pharmaceutical Industry."

Dinesh has spent considerable time working towards improving the regulatory standard of Indian pharmaceutical industry. He has worked with his legal and research team to file over 125 applications under the Right to Information Act, 2005 with various State and Central authorities to access information on the manner in which drug regulations are being implemented in India.

The deficiencies discovered during the course of his research have substantial bearing on the quality of medicine consumed by not only Indians but citizens of other countries who import Indian made medicines. Such substandard medicine can have a very serious adverse effect on public health; they not only fail to cure the ailment as intended but in several cases can cause increased resistance to infectious diseases thereby endangering public health.

Dinesh S. Thakur is a public health activist, who was the whistleblower responsible for prosecution of Ranbaxy Laboratories, once India's largest pharmaceutical company in a US court for selling substandard and adulterated drugs in the US Market. For more information, please visit: http://dineshthakur.com/