

A Typical Example of the Loot of MNCs Practiced against Patients in India

The promoters of imperialist globalisation and its economic policies of liberalization have been consistently harping about the so-called virtues of corporate management, corporate ethics and corporate social responsibility etc. But all these claims are proved to be nothing but empty talk purely intended to hood-wink people with false claims in order to facilitate trans-national corporations of the monopoly capital to loot the people in their heinous pursuit of earning super-profits.

That the rulers, governments and governmental regulatory bodies that have to protect people from deceit and day-time robbery of imperialist transnational corporations too are a part and parcel of this loot is also becoming more and more clear to the people day by day in their day to day experiences.

Presently such a typical case of brand and loot played by a transnational pharmaceutical giant Johnson & Johnson through its Indian subsidiary Deputy by aggressively selling its failed ASR hip implants to patients in Indian market through its distributors in 2009, even after the Australia withdrawn it (ASR implant) from the market;

In India more than one lakh joint replacement surgeries are carried out annually. Of those an estimated 70,000 to 80,000 are knee replacements and 20,000 to 30,000 are hip replacements.

The Drug Controller General of India (DGCI) granted permission to import and market Deputy's ASR hip implant in 2006. At that time the company has been aggressively promoting its ATS implant as a long lasting, durable and ideal choice for younger candidates opting for hip-replacement. It claimed that while most orthopedic implants wear off after a period of 10 to 15 years necessitating a revision surgery, the company claimed that its ASR implant with a promised life span of 20 to 25 years and pushed it in the markets. With simple logic claimed that its ASR implant consisting of the femoral head and stem and the socket (acetabular cup) promised more longevity as both are made of metal compared to the metal-on-polythene implants which were widely in use then.

From 2006 to 2010, Deputy Medical Private Ltd., Mumbai, the Indian subsidiary for Johnson & Johnson imported a total of 15,289 ASR implants in to India. While the price of a single MoM implant could be anywhere between Rs 90,000 and 1.2 lakh, the cost of the procedure ranges from Rs.2.5 lakh to Rs 4 lakh.

When the Australian Orthopedic Association of National Joint Replacement Registry had red-flagged the early revision surgery rate of the implant, Australia withdrew it from the market in 2009. A Joint registry in U.K announced that 12% to 13% of patients are in need of a revision surgery within 5 years of getting ASR implant. This finally triggered a global recall of the company in August 2010.

By this time 4,700 ASR surgeries had been carried out in India and 4,500 patients were implanted with the ASR implant from Deputy, the subsidiary of Johnson and Johnson.

Some of the patients who were implanted with the ASR of implants (MoM implants) complained of suffering from severe pain and are bed-ridden. But their doctor who studied the X-rays of the patients told them that their implant was absolutely fine and that their pain is a psychologist one.

But as the implant left large quantities of metal debries in the body it leaching of metals mainly cobalt and chromium caused severe pain, neuropathy, fluid accumulation and metal poisoning in the patients.

Knowing fully-well of all these faults of its A.T.S implant besides its highly failing rate J&J had recalled its ATS implant in August 2010 from global market.

But neither J&J nor its Indian subsidiary Deputy had taken up any corrective action to reach the affected patients in India and advising them to undergo a revision surgery. The J&J has conspi-cuously neglected those affected patients and their sufferings by concealing the crucial information about its faulty ASR implant which is not short of any criminal negligence on its part.

It is being claimed that through social media and internet etc every person throughout the globe can know any information and any news immediately.

But surprisingly neither the patients, who are mostly the users of internet and other social media, nor the rulers of India, nor the regulatory agencies, nor the doctors, could alert the suffering patients with the news of high failure rate of ATS implants nor the damage caused to the patients.

This is not a mere over sight of the 'news' about MoM implants failure but an intentional criminal neglect and a systematic conspiracy played by all concerned in this game who had willfully ignored their responsibility towards patients.

It was the commissioner of Food and Drugs Administration of Maharashtra (FDA) Mahesh Zogade who first gave the alert against ASR implant of J&J by lodging an FIR for not making a series effort to inform

patients about their defective implant. He also reported the issue to the central Drugs standard control organization (CDSCO) asking to take corrective action about this.

Even then, either the CDSCO or the FDAs in other states have not plunged into action against errant company to make it liable for its faulty devices. It took 2 years for the CDSCO to put out a 'medical device alerts' on its website. It took more than six years to obtain an 'expert committee report' on the faulty hip implants manufactured by the subsidiary of Johnson and Johnson. And though the expert committee report was submitted in February, 2018, it has been put up only in public domain after 6 months in the last week of August 2018. This too had occurred after the CDSCO has been under attack for not being pro-active is seeking compensation for patients who got faulty hip implants.

Thus the government had neglected the issue for around eight years to take any concrete stand in obtaining relief to the aggrieved patients despite being engaged with the company. The affected patients allege that the government presently is taking steps to 'eye-wash' them, by making the governmental panel of union health and family welfare ministry to asking the company to pay a minimum of Rs.20 lakh each to every patient as compensation. Aggrieved and suffering patients allege that the government panel set up for the assessment process was "non-transparent and biased towards the pharma giant". They claim that the governments action is too hasty and are distressed to see the government continuing to closely consult with J&J, while patients who have suffered grievous injuries have not been consulted even a single time.'

The allegations of the patients are not only just but are correct too. Such a callous negligence of the governments and rulers of their responsibility towards the patients (victims) is not new. Such a gross callous negligence was exhibited by our rulers and successive governments are well known towards the victims of Bhopal gas disaster created by the union carbide corporation of U.S.A.

While J&J has paid hefty compensation to patients in other parts of the world following a global recall of ASR hip implant device in 2010, it did nothing to the patients in India leaving them out. Even after the advise of FDA of Maharashtra to CDSCO to take corrective action nobody stopped the act through a class action suit for example. The J&J has agreed to pay \$2.5 billion as compensation to nearly 8,000 patients in the US. But it has not taken the responsibility to pay compensation to the Indian patients.

It is argued that since in India the drugs and cosmetics act, 1940, which also regulates medical devices has not expressly provide for compensation of adverse and serious reactions, such a legal loophole has made the regulators (both central and state) weak in seeking compensation from the errant company and to make it liable for its faulty devices. Such arguments hold no water. As a sovereign country Indian government can always work out a mechanism to book J&J like bringing out an ordinance for instance and make it liable.

But such a course of action was not taken by our rulers and governments intentionally since they are working with an unheard zeal to make the country, the best for the transnational corporations to do easy benefits in India even at the cost of lives of Indian people including the sick patients.

On the other hand the J&J did whatever it can to evade its responsibility and avoid any help to the grievously suffering patients. It claims that it had sent an "urgent field safety notice" dated August 24, 2010 to surgeons informing them about the higher than expected revision rates involving ASR, directing them to stop implanting the ASR devices and provide for details about the reimbursement process and the ASR Help-line. But the surgeons state that they were not in receipt of any such notice either from J&J or any such alert notice from CDSCO. Some surgeons state that the implant maker got in touch with them about three to four years after the global recall and when they tried to get in touch with their patients they were unable to reach them to alert. The ASR helpline that was supposed to have provided Deputy was of no help in anyway to the patients. The patients claim that the company was not at all cooperative and complain when they reached out to the helpline the response they get was "call back when you have severe problem" and they rudely said to the patients contracted them that "nagging problem was not a big enough problem". Thus the company deliberately evaded from its liability and responsibility.

Even after the exposure of its heinous crime of concealing the information about its totally faulty ASR hip-implants and looting the patients of India amply, J&J has never attempted to redeem from its crime and come to the aid of patients affected by its faulty ASR hip-implants causing them grievous pain, suffering and injury. It had shut-down its ASR helpline in 2017. It had reached only 275 patients in India out of 4,500 patients implanted with its faulty ASR hip-implants; and has fanded for their revision surgeries. But it has not paid compensation even to a single patient.

Moreover it has been arguing that it has been unable to reach the patients since their information has not been provided to it by the joint registry of hip-implantation established by the Indian Society of Hip and Knee Surgeons (ISHKS). Such an argument is not maintainable and holds no water since it can obtain the data and trace the patients from the distributors of ASR Hip implants sold by them. The Indian authorities as usual have

intentionally failed to challenge the unsubstantiated argument of J&J to the detriment of the interests of the aggrieved patients.

Even the medical professionals who ought to be the gate keepers of health care system had failed to be the guardians of patient's interest, by remaining silent.

All parties concerned the J&J, the regulators, doctors, hospitals and consumer groups have failed in their responsibility to bring justice to the suffering patients.

As Mr.Zagde, the erstwhile commissioner of FDA of Maharashtra explains, this sheer negligence of CDSCO the governmental regulator reflects the "deep-seated necrotic rot commandeered by the pharmaceutical industry" totally controlled by the transnational corporations is correct.

While the company has its commercial motive of earning super profits, the doctor were afraid of back-lash that they might had to face if they had willingly revealed that the implant has chosen was a faulty one. The deep routed doctor-pharma nexus, huge kick backs on devices and pharma sponsorship for conferences and seminars had kept the doctors to be silent about the faulty ASR hip-implants of J&J subsidiary making them indifferent to the interests of their patients; Despite over 6000 doctors have discussed widely about the issue during their annual conference of Indian orthopedic Association (IOA) in 2016.

The clout of J&J with the Indian rulers and governmental regulatory agencies made them to be knowingly and willfully negligent of their responsibility to bring justice to the aggrieved suffering patients.

From the time of Bhopal gas disaster all along the rulers and governments are in active service of the interests of the criminal transnational corporations of imperialism, at the cost of lives of people of India exposing their comprador class nature to their imperialist masters.

This has been the root-cause of this necrotic sort commandeered by the Johnson & Johnson company in pharmaceutical sector.

Serving to the interests of imperialism even at the cost of lives of Indian people has been the class nature inherent in the Indian system.

Unless and until this rotted system of governance is uprooted and replaced with a socialist system without exploitation, inequality and private property, it is highly impossible to arrest such loot practiced by the Johnson & Johnson Company on its patients or other imperialist trans-national companies in India for that matter.

People of India must be made aware of the machinations and crimes practiced by imperialist transnational companies in looting them besides making them aware and conscious of the very necessity of rooting out the rotted present day system of anti-people interests and establishing a people's democratic system in our country.

This task has to be taken immediately by all whose objective in people's interests, particularly at the present time where the protection of laws is made more important than the protection of the people and their lives!
