

JOHNSON AND JOHNSON FAULTY HIP IMPLANTS, CURSE TO THE INDIAN PATIENTS

Abhinaya Ramesh

Student, LLM IPL, Christ Deemed to be University, Bangalore.

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ABSTRACT: *The issue that arose because of the Johnson and Johnson Hip implant device, the Acetabular Surface Replacement (ASR) implant which was introduced in India in 2006. The ASR implant import licence was renewed in 2010 just few months before the global recall. Around 4700 acetabular surface replacement surgeries were done in India between those period. The global recall of Johnson and Johnson faulty hip implant was done in August 2010 but it took two years for the Indian regulators, the Central Drug Standard Control Organisation (CDSCO) to ban the import and cancel the licence even after the fact that the regulators, CDSCO which comes under the Ministry of Health and Family Welfare, came to know about the global recall in 2010 itself. CDSCO cancelled the import licence only after a complaint filed by the Food and Drug Agency, Maharashtra. Even after the ban on the import and cancellation of the import licence, more than 50% of the Indian patients who had the implant are still in the dark side about the defective implant and its health complications. Around 4700 Indian patients has underwent the defective implant surgery but since there is an absence of tracking system, more than 2000 patients who had the implants are yet to be traced and the government strives to reach them.¹*

Key Words: *: Acetabular Surface Replacement (ASR), Johnson and Johnson (J & J), Hip implant, Central Drug Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare, Expert Committee, Food and Drug Agency.*

INTRODUCTION:

Johnson & Johnson is an American Multinational company which deals with medical device, pharmaceutical and consumer goods and it has its headquarters in New Jersey. The company has around 250 subsidiaries and has operation over more than 50 countries and its products are sold globally. J & J acquired DePuy in 1998 itself. DePuy manufactures and distributes orthopaedic devices for the bone reconstruction and for mending skeletal damages.

In India, the company got the licence to import the device in 2006 and its licence was renewed in 2010 just few months before the global recall. The Indian Regulators became aware about the global recall in 2010 itself but still they failed to take any action against it and took almost two years to finally ban the import and cancel the import licence. This move by CDSCO came only after a complaint filed by Joint Commissioner of Maharashtra Food and Drugs Agency. The complaint informed the Central regulator that Johnson & Johnson did not take any remedial measures to solve the defective implant and it has also not informed the Indian patients about the faulty implants and its consequences on their health. In the midst of concerns around the world, the Health Ministry set up an expert committee in 2017 to inspect issues emerging out of defective ASR implants in India. The committee looked into the necessary actions or move made by the company to supplant the defective ASR implants, and evaluated the compensation scheme to be given to the individuals who had endured the faulty implant. The committee has also provided certain recommendation to overcome the problems caused by the Johnson & Johnson faulty hip implant.

JOHNSON & JOHNSON HIP REPLACEMENT DEVICE

¹Sumitra Debroy, "Half of Johnsons and Johnsons hip implant users unaware of defects", The Times of India, Sept 2018.

(<https://timesofindia.indiatimes.com/city/mumbai/half-of-jj-hip-implant-users-unaware-of-defects/articleshow/65693215.cms>)- Last visited on Feb 28,2019.

The Articular Surface Replacement device is a metal on metal device with cobalt and chromium as important components. They have been manufactured and distributed by DePuy for a long period of time.² They were manufactured on metal on metal thinking that the implant could be long lasting and help in increasing the ability to move freely. Sadly, for the company the metal on metal configuration has rather caused surprisingly high disappointment rates explicitly in view of metal-on-metal grinding that discharges little amount of metal into encompassing tissue.

DEPUY IMPLANT DEVICE ADVERSE EFFECTS:

DePuy hip implants may cause extreme side effects or reactions such as:

- Metallosis – metal fragment and particle discharge causing morbidity.
- Necrosis – bone and other tissue demise from metallosis poison.
- Osteolysis – bone disintegration due to metallosis toxicity.
- Systemic metallosis – entire body irritation from metal particles.
- Pseudotumors – development of tumour like particles encompassing joints thereby harming them.
- Bone Fracture – debilitating and breakage of bones encompassing the implant.³

Because of these faulty implants, the skin, tissues and bones near the implants gets damaged and affected seriously. Revision Surgery or Reconstructive Surgery is the only solution to this and the Patients who received these metal on metal implant devices may require replacement surgery or reconstructive surgery to repair tissue damage and joint failure caused by the faulty devices. These revision and reconstructive surgeries are most of the time invasive to the body and a lot more agonizing than the primary hip implant surgery. Patients are required to experience longer restoration periods and are presented to extra surgical and recuperation dangers including contamination, aggravation, agony, and idleness in the body parts. Some patients need to experience different medical procedures like multiple surgeries to fix the repair or harm brought about by the DePuy faulty implants.

COMMITTEE FINDINGS:

As indicated by the expert committee report, 4,700 Indian patients were already implanted with the faulty hip implant device of Johnson and Johnson even after the ban on the import. The expert committee said that the ASR implant prompted high wear and tear leading to increase in body chromium and cobalt level which are the main components of the device. This makes them poisonous and leaves organs helpless against damage and harm, as indicated by the committee report. More than 3,600 patients could not be traced and they are still in the dark side, unaware about the defective implant in their body. The committee also found that in some cases, patients with these implants underwent more than one revision surgeries.

THE COMMITTEE RECOMMENDATION:

- The committee has recommended that Johnson and Johnson should be made liable to pay Rs.20 lakhs as base amount to each patient who have received the faulty implant, and this reimbursement programme shall be extended till August 2025.
- A regional and central expert committee should be constituted by the Health Ministry for assessing patients claims with regard to the damages caused to them and the trauma and agony suffered due to the defective ASR device. The regional committee will ascertain whether there is long-lasting permanent disability and damage, and whether such disability/disorder has affected or will affect the patient's earning capacity, and a report will be made by the regional committee and that report will be submitted to the central expert committee.
- The required compensation will be decided or determined by the central expert committee. As per the committee that inspected ASR implants, the base sum ought to be Rs20 lakh, and moreover, the patient ought to be given compensation based on enduring of agony because of financial misfortune due to job loss or other loss and the level of handicap or damage to the patient will also be evaluated for compensation purpose. It has suggested that the maximum sum be at standard with

²Kaunain Sheriff M, How Johnson & Johnson Hip implants system went wrong, The Indian Express, Aug 2018. (<https://indianexpress.com/article/explained/johnson-and-johnson-how-hip-implants-went-wrong-jp-nada-5331779/>)- Last visited on March 02, 2019.

³Depuy hip side effects

(<https://www.drugdangers.com/depu-hip/side-effects/>)- Last visited on March 02, 2019.

the maximum amount for clinical trial related demise and permanent incapacity according to principles and rules of the Drug Controller General of India.

- The company has to take reasonable steps to trace those remaining patients who have been implanted with the defective ASR device but have not been registered with the helpline.
- The patients who have been implanted with the faulty device should be assessed regularly and the health assessment report of these patients should be provided once a year till 2025 to the Health Ministry and necessary follow-ups should be done regularly.
- And a separate registry should be established for trailing the usage/ utilization of risky medical devices and tools. And a separate provision should be included in the Medical Device Rules for the compensation to be allotted if any serious issue or damage is done or caused because of the use of the medical device.⁴

The patients who were traced were not satisfied or happy about the compensation, so the Central expert committee after holding five meetings with the appropriate authorities and the patients who were affected by the implants came up with a compensation formula for evaluating the compensation for each patients who were affected because of this faulty implant. The formula is as follow:

$$\frac{B \times R \times F}{99.37} + \text{Rs.10 lakhs towards non-pecuniary damages.}$$

B is the base amount i.e., Rupees Twenty Lakh

R is the disability level incurred, i.e., the risk factor

F is the age of the patient who underwent the faulty hip implant surgery, i.e., the age factor.

So all the above factors, i.e., base amount multiplied with risk factor in terms of disability caused multiplied with age factor of the victim patient divided with 99.37 and additional ten lakhs will be provided as non-pecuniary damages to the patients who have underwent these implants.⁵

SUPREME COURT DIRECTION TO PIL:

The government was directed by the Supreme court to respond within two months to a public interest litigation filed by a patient who was aggrieved by the faulty hip implant in October 2018. The court sought the report of the expert committee. The PIL request the government to find and trace all the patients who have underwent the hip implant surgery and are victims to this faulty product of Johnson and Johnson without even realising that the implant was a defective one. The plea request is also about taking action against Johnson & Johnson and the government officials who have granted certificate to distribute the faulty implant for commercial purpose and use the device without any proper clinical trial and the PIL seeks a special investigation team to be formed, so that they can take quick action to address the medical concerns of the patients who got the faulty implants.⁶ A Bench driven by Chief Justice Ranjan Gogoi disposed the PIL, that looked for action against the multinational company Johnson and Johnson for manufacturing and creating defective hip implant devices after taking due notice of the means being taken by the government administration to support and help the patients who are suffering because of this implant.

While giving consent to the governments compensation formula, whereby patients will be awarded compensation between Rs.30 lakh and Rs.1.23 crore relying upon their age and the level of disability, the judges requested that the health ministry give wide exposure and publicity to the compensation scheme and additionally requested the expert committee of the health ministry headed by Dr. Arun Agarwal to quickly award the compensation to the patients who underwent the hip implant surgery⁷. The expert committee

⁴ Kaunain Sheriff M, How Johnson & Johnson Hip implants system went wrong, The Indian Express, Aug 2018.

(<https://indianexpress.com/article/explained/johnson-and-johnson-how-hip-implants-went-wrong-jp-nada-5331779/>)- Last visited on March 02, 2019.

⁵ ***PIB Delhi, Health Ministry approves compensation formula for Hip implant cases, Ministry of Health and Family Welfare, Nov 2018.***

(<http://pib.nic.in/PressReleaseIframePage.aspx?PRID=1554266>)- Last visited on March 02, 2019.

⁶ Prabha Raghavan, The Economic Times, Supreme Court seeks Centre's response on faulty hip implants by Johnson & Johnson, Oct 2018.

(<https://economictimes.indiatimes.com/news/politics-and-nation/faulty-implants-for-hip-replacement-supreme-court-seeks-centres-response/articleshow/66082956.cms>)- Last visited on March 03, 2019.

⁷ FE Bureau, Johnson & Johnson hip implants: Supreme Court accepts compensation formula, Financial Express, Jan 2019.

that came up with the compensation formula suggested the utilization of the Indian Disability Evaluation and Assessment Scale (IDEAS) for the assessment and affirmation of disability in patients. The compensation should be able to cope up with the patients cost of living in the future and should also cope-up with their physical and mental suffering.⁸ Johnson and Johnson approached the Delhi High Court on December 2018 to quash the compensation scheme and direct the government to not take any forceful action against the company. The High Court refused to give any relief to Johnson and Johnson since the compensation formula was just and fair. The patients have under-went and will still undergo a lot of trauma which cannot be monetarily compensated but some compensation which is fair and makes their livelihood easy has to be given to them.

The Central Drug Standard Control Organisation order J&J to compensate Rs.74.5 Lakhs to a patient from Maharashtra who had both his hips implanted with the faulty implant and went for revision surgery on his left hip and authority has ordered that the amount has to be paid within thirty days from the date of order of CDSCO.⁹ He is the first Indian patient to get compensation.

ISSUES:

The main warning had been brought up in 2010, when the Maharashtra Food and Drug Administration (FDA) got an anonymous complaint and grievance about a patient enduring an extreme harmful response, prompting a FDA examination and a FIR with Mahim police. When the global recall happened in 2010 just few months after the import licence was renewed in India and CDSCO was aware of it then itself but failed in its duty to cancel the licence immediately. It didn't take action by itself but by a complaint filed by FDA in 2012 asking the regulators of CDSCO to cancel the import licence since the company had not taken appropriate remedial measures or the company has not created awareness about the defective device and asked CDSCO to issue a medical gadget/device alert in order to create awareness among the public including patients about the defective implant and CDSCO issued the alert in 2013, three years after the global recall. Thus there was two years' delay in cancelling the import licence because of which many of the Indian patients became victims to the faulty and defective implants. And CDSCO took another one year to issue alert on the defective implant. Still many patients are unaware about the faulty implant and are yet to come from the dark. CDSCO being the national regulatory body for Indian Pharmaceutical and Medical Devices failed in its duty to act immediately when it became aware about the global recall. It has already been accused of having a collusion with independent medical experts and pharmaceutical companies¹⁰ and the failure on the part of CDSCO to cancel the import licence and take necessary action as soon as it came to know about the global recall which was in 2010 itself just proves the accusation. The unconscionable delay on the part of CDSCO is one of the main reason why the patients list of the implant went up and the impact more tragic.

The other issue is that the company has informed the regulators that around 4,700 Indian patients have received these implants but more than 50% of the patients are yet to be traced. Because of the delay in the cancelling of import licence, there arose a significant impact as Johnson & Johnson told the expert committee appointed by the Union Health Ministry in 2017, that it is unable to trace as many as 3,600 patients who underwent the defective implant surgeries.¹¹ Till 2025 the reimbursement program is open for these

(<https://www.financialexpress.com/industry/hip-implants-supreme-court-accepts-jj-compensation-formula/1441159/>)- Last visited on March 03, 2019.

⁸ **Teena Thacker, J&J faulty hip implants: Compensation for patients approved, Live mint, Nov 2018.** (<https://www.livemint.com/Companies/1spu8RNi7T9jutjHDvexqN/JJ-faulty-hip-implants-Compensation-for-patients-approved.html>)- Last visited on March 03, 2019.

⁹ Bindu Shajan Perappadan, Johnson and Johnson told to pay compensation, The Hindu, March 10, 2019. (<https://www.thehindu.com/news/national/johnson-johnson-told-to-pay-compensation/article26488718.ece>)- Last visited on March 12, 2019

¹⁰ Dave Smith, Collusion discovered between Central Drugs Standard Control Organization (CDSCO), Pharma Firms, International Business Times, 2012. (<https://www.ibtimes.com/collusion-discovered-between-central-drugs-standard-control-organization-cdsko-pharma-697782>)- Last visited on March 4, 2019.

¹¹ Kaunain Sheriff M, Government knew of Johnson & Johnson Faulty hip implants, took almost two years to ban, The Indian Express, Sept 2018. (<https://indianexpress.com/article/india/government-knew-of-johnson-johnson-faulty-hip-implants-took-almost-two-years-to-ban-5342134/>)- Last visited on March 02, 2019.

patients who have received the defective implants. But there is still lack of awareness among the public including some of the patients who have received the implants about the faulty device.

Earlier there was also problem regarding the base compensation decided to be given to the patients who suffered or had these faulty implants. The compensation decided earlier was Rs.20 Lakhs which in the view of many patients were not fair since they suffered a lot of mental and physical trauma. Many lost their livelihood because of these default implants. In US, the compensation awarded was around 2.5 billion dollars to 8,000 patients in 2013 and in Australia where the import of implant was cancelled in 2009 itself, the class action was settled for 250 million dollars plus interest including legal cost. But after five meetings conducted by the central expert committee with the regulators and patients, they increased the compensation by coming up with a formula, where-by the compensation will be between Rs.30 lakhs and Rs.1.23 crore based on the age and disability factors.

SUGGESTION AND CONCLUSION:

It is quite evident that CDSCO has not done its duty effectively. The delay on its part to cancel the licence and issue awareness among the public led to a tragic outcome to many Indian patients. There should be an independent administrative body established which should administer the affairs and check whether government regulating organization like CDSCO which comes under the Ministry of Health and Family Welfare, carry on their duties and functions properly and effectively. Organization like CDSCO should be made to submit yearly report about the imported pharmaceutical and medical devices to this independent administrative body, so that the government organisation would function effectively. Each government regulatory body and organization should carry on their duty constructively and effectively and feel bound by their act.

A lot of people are still unaware about the Johnson and Johnson hip implant controversy and since there is a lack of proper tracking mechanism, awareness among public should be made by advertising about the defective implant in all local and national newspaper and television channels to reach out to patients who are still in the dark side and are unaware about the defective implant in their body. CDSCO act of delay in cancelling the licence made the matter slightly serious, so CDSCO and Johnson and Johnson should be bound to take due diligence in creating this awareness among public and to track the patients.

Johnson and Johnson Acetabular Surface Replacement hip implant was taken as a cure to the pain of many patients but it turned out to be their worst nightmare come true, taking away their livelihood and peace. So from now on, Indian regulators coming under the Ministry of Health and Family Affairs should be more careful in approving import licence of foreign pharmaceutical and medical devices and should do proper clinical trial before allowing any medical and pharmaceutical device both imported and domestic to be used on patients. So proper clinical trial should be done before it is used on patients and the government regulators should not delay in the duties that would result in tragic outcome.