The Johnson & Johnson Files

Praise for the Book

'This is the finest of investigative journalism: shoe-leather reporting from hospital wards, company boardrooms and government offices; listening to traumatised patients, deciphering their records; lifting the veil of corporate deceit and untangling the web of regulatory failures. In *The Johnson & Johnson Files*, Kaunain Sheriff tells the remarkable story of how a global giant cynically plays the local game, twists rules, cuts corners and endangers lives – all for profit. Meticulously researched and elegantly written, this must-read book is a cautionary tale for patients and a powerful wake-up call for our health-care system.'

- Raj Kamal Jha, Chief Editor, The Indian Express

The Johnson & Johnson Files

The Indian Secrets of a Global Giant

Kaunain Sheriff M.



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For Ammi and Fareeha, my constant source of strength



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Preface

One evening in February 2018, the city bureau of *The Indian Express* was its usual hive of activity when Ritu Sarin, a legend in investigative journalism, walked in. There's something about her presence that makes people sit up and take notice, even without her saying a word.

She came over to my desk for a quick chat, and honestly, even a short conversation with her feels like a golden opportunity. Having led some of the biggest investigative projects, her insights are pure gold – every word she says is a lesson in journalism you don't want to miss.

That evening, she got straight to the point. 'There's a new project I want to discuss with you,' she said, her voice calm but firm. The topic? The unregulated medical device market.

I blinked, trying to process her words. At that point, my expertise as a health reporter was rooted in city-level stories, patient tales and hospital challenges. The regulatory maze of medical devices? That was uncharted territory. When she asked me how much I knew about the issues in this space, I hesitated, then admitted honestly: 'I have not covered medical devices much, especially the regulatory side, but I'll look into it and get a few leads.'

She smiled and then came the twist. 'This project,' she said, 'is part of a global investigation led by the Pulitzer-winning International Consortium of Investigative Journalists (ICIJ).' Her words hit me like a lightning bolt. A collaboration involving 260 journalists worldwide to expose the flaws in a \$400 billion industry? It sounded like the kind of story that could shake the industry and change lives.

The moment I left the bureau, my mind was racing. Where do I start? When it came to health stories, I had a reliable first stop: All India Institute Of Medical Sciences Delhi (AIIMS), India's most prestigious health institution. The sprawling campus, with its maze of corridors and teeming OPDs, was a place where you could find leads on almost any health issue. The very next evening, at 4.30 p.m., I had an appointment with a surgeon who had over 30 years of experience.

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As I entered his office, the air smelled faintly of disinfectant and old paper – a mix that always felt oddly reassuring. The surgeon looked up from a stack of case files. I began explaining the project, but his initial response was a raised eyebrow and a question: 'Why this topic?'

The scepticism in his voice was hard to miss. 'This isn't something we talk about much,' he added, leaning back in his chair. 'Not in conferences, not even in private meetings.' His words painted a picture of an issue buried deep beneath layers of silence. But I wasn't about to give up. I pressed him for leads, though I left that day with little more than his vague interest in the topic.

A week later, the phone rang. It was the surgeon. 'Come by. I have something to share,' he said, his tone now serious. When I walked into his office again, he greeted me with a PowerPoint presentation titled 'Industry Influence in Total Knee Arthroplasty'.

It laid out some glaring facts – there were over 150 types of knee implants on the market and the fierce competition often led to corners being cut. The presentation raised tough questions about the industry's priorities: Were they genuinely innovating or just focused on profits?

I couldn't resist asking, 'Has any device ever performed so badly that it was recalled?'

His response was immediate: 'Yes. The DePuy hip implant. It was a metal-on-metal [MoM] device.'

Now, even as someone new to the medical device industry, I recognized the name DePuy. It's a massive subsidiary of Johnson & Johnson. To explain the problem, the surgeon grabbed a piece of paper and started sketching. He drew a rough diagram of the implant, showing how it had failed.

'What about the patients?' I asked, leaning forward. 'How many were affected?'

He sighed. 'I didn't use that implant myself, so I wouldn't know. That's something you'll have to dig into.'

And just like that, my investigation into the Articular Surface Replacement (ASR) hip implant scandal began – in room 5001 of the AIIMS OPD.

Since the ASR recall was primarily reported by journalists in Mumbai in 2012 – due to actions taken by local government authorities – and later in Delhi during 2017–2018, after the central government formed an expert committee to investigate the issue, revisiting this high-profile medical device recall presented a unique challenge. The

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goal was to examine the entire event through the lenses of patient safety, regulatory actions and most importantly, whether justice was delivered to the affected patients.

When I began delving into these stories layer by layer, the findings were startling. Starting in August 2018, *The Indian Express* published over half a dozen investigative stories on the ASR recall. Then, in November 2018, *The Indian Express*, in collaboration with the ICIJ, published The Implant Files.

This was another major collaboration with the ICIJ, following explosive investigations like the Panama Papers and Swiss Leaks, which exposed how the world's elite tucked away their riches in offshore havens. But this time, the lens wasn't on money – it was on bodies. And the findings? Disturbing. *The Indian Express* published over twenty-one hard-hitting stories, with the ASR scandal prominently featured in the series.

The first story appeared on 24 August. At exactly 8.23 p.m., as I refreshed my inbox, an email popped up with the subject line: 'Johnson & Johnson faulty implant surgeries'. I clicked it open, and my heart sank. The email was from Lata Pillay, who had read our story and decided to share her husband Dinesh Pillay's ordeal. 'I felt very happy after reading today's article in *The Indian Express*,' she wrote. 'Finally, there's some hope for justice – for compensation for all the suffering.' Her words were laced with equal parts relief and desperation.

Dinesh, she explained, had undergone surgery in Pune and had been battling constant pain and complications ever since. His was just one of the several stories of suffering, but it painted a vivid picture of the human toll behind the statistics. I've included Lata's original email, detailing her and Dinesh's ordeal, below:

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Subject of the email: Johnson & Johnson faulty implant surgeries.
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Dear Sir,

I am Lata Dinesh Pillay from Pune, Maharashtra.

This has reference to your article on the front page of Indian Express of today i.e 24th Aug 2018. The article named 'Johnson & Johnson buried key facts on faulty hip implant surgeries, kept regulator in dark'. I was actually looking for this opportunity to complaint against Johnson & Johnson. I have tried calling them at Chennai office in 2016 after

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the third operation as my husband was still suffering from the severe pain.

Let me narrate the whole issue.

My husband Mr Dinesh Pillay, age 50 years was operated for THR in the year 2007. Even after the operation he was not okay. He could not walk even for 1 km at a time. Due to this he could not join any of the job. In the year 2012 he had a very severe pain in the operated hip and thigh. On getting the x-ray done, we got to know that the stem of the implant had broken. Due to which my husband had high fever and infections. Due to which, he had to undergo the revision immediately. The revision was done by replacing the ceramic implant. It was very difficult to remove the broken piece of the stem. To remove this, surgeon had to make a fracture in his thigh bone. After which the revision was done by inserting a long ceramic implant. After the revision, he was unable to walk until 5 months. Since then he is suffering with severe pain in the thigh. After again consulting the surgeon, x-ray was done. Which showed that the pain was due to the loosening of the stem and the fracture that was done while removing the broken implant. This is due to the faulty implant that was supplied by Johnson & Johnson. If the implant was of the good quality, my husband's operation would have been succeeded.

Till now he has to get the x-rays followed by bone scan done twice or thrice a year whenever he has unbearable pain, and keep a regular follow-up with the surgeon. However, it has become beyond our affordable status to continue with the treatment.

I felt very happy after reading today's article in the India Express today as I can see there are some hope for getting justice in way of compensation for the sufferings.

Awaiting any update on this matter.

Thanks and regards,

Lata Dinesh Pillay

A few weeks later, on 6 September 2018, another email arrived at 10.26 a.m. This one was gut-wrenching. A husband recounted how his wife had endured a painful revision surgery after her initial implant failed. The tragedy didn't end there – she didn't survive.

During The Implant Files investigation, I highlighted Dinesh's

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case because it involved a rare instance of 'live surgery' – a questionable practice where medical devices are demonstrated to surgeons during live procedures – raising serious ethical concerns. However, I couldn't highlight the other case because the family couldn't confirm the exact implant used.

It got me thinking: how many families in India are in the same position? Most people trust their doctors completely and don't think to ask questions like, 'Which implant are you using? Why this one? How long does it last? What are the risks?'These aren't questions people are used to asking in the chaos of hospital visits, where decisions are made quickly and consent forms are signed without much thought.

But here's the thing – these questions matter. They demarcate the difference between a successful recovery and years of suffering. Unfortunately, most families don't know this until it's too late. And to make things worse, manufacturers – and even the system as a whole – don't make it easy to get clear answers.

It was during this time that I realized the importance of revisiting my previous journalistic work and compiling it into an investigative book. Patient safety deserved a deeper, more comprehensive examination. And so, this book was born.

When it came to exposing the cracks in our system, no story was more compelling – or urgent – than how the ASR hip implant scandal unfolded in India. It's a tale of trust betrayed and lives upended. What happened – and what should never have happened – must be recounted not just to document the past but to ensure it's not repeated. This story needs to be unravelled layer by layer because it reveals the glaring loopholes in a system that is meant to protect, not harm.

Yet, while revisiting this issue, we cannot ignore an important fact: medical devices, especially hip implants, have been transformative for countless people. These are the miracles of modern medicine. But then there are the exceptions, the outliers – those rare cases where the very device meant to restore a life ends up devastating it instead. Identifying these outliers isn't just important, it's critical. And this book delves into one such case, holding it up as a mirror to the system.

But this isn't just a story about a company or a faulty device. It's about something far bigger. This unprecedented medical device recall offers a stark reminder of the need to put patient safety above profits, bureaucracy and negligence. Through this lens, I examine the broader systemic issues that demand our attention – and action.