

## EDITORIALS

# Confronting the medical devices jungle

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The report by the International Consortium of Investigative Journalists (ICIJ) on the international medical device industry (1) adds to the growing documentation of health scandals in India in recent years. A comprehensive picture emerges of manufacturers selling untested products at usurious rates; criminally negligent doctors and medical establishments; and a regulatory system focused on the industry's growth with little regard for patient safety.

A few months before the Implant Files, the documentary *The Bleeding Edge* (2) told the stories of women and men in the United States who had suffered terribly from untested and substandard medical devices. In addition to J&J's hip implant, they included Bayer's contraceptive coil which doctors could insert but not remove; defective breast implants, and a vaginal mesh that tore through tissue. Patients expressed outrage that not only did their doctors implant these devices that ravaged their bodies, but they also refused to acknowledge the harm inflicted. The doctors were clearly motivated not by their patients' welfare but the kickbacks they received from the medical device industry.

These voices resonate in India where there will be thousands of victims of faulty implants, but few who manage to be heard.

Since October last year, Johnson & Johnson's toxic metal-on-metal ASR hip implant has been in the news. Indian victims of these implants have suffered horrifying tissue damage and severe illnesses necessitating major medical and surgical interventions. With the help of civil society organisations, they have been fighting to get the company to pay for reparative surgery, and proper compensation for the harm inflicted on them (3,4).

### Medical devices and you

Medical devices are not restricted to such major products. According to the Medical Devices Rules, 2017 (5), a medical device is an "instrument, apparatus, appliance, software, material, or other article" used for "diagnostic or therapeutic purposes." So they include everything from syringes, condoms and blood glucose testing machines, to long-term implants such as intrauterine devices, stents and pacemakers, and are used at all levels of health services, from the primary health centre in rural India to the super-speciality hospital in Mumbai. The medical devices industry represents 4-5% of the \$96.7 billion healthcare industry in India (6).

Are these devices being evaluated properly for safety and efficacy before being let loose on the market and into people's bodies? Are they being used rationally and ethically? Once they are on the market, are they being monitored for safety and withdrawn promptly if they are found to be dangerous? Are manufacturers held responsible for treating patients injured by their implants, and are they made to give compensation for harm?

To all these questions, the answer is, regrettably, "No."

### Toxic nexus

The Implant Files and other recent reports on the medical device industry in India together expose the underbelly of a corrupt medical profession. Surgeons who prey on transgender people, offering cheap breast implant surgery in filthy conditions – in the knowledge that few will complain when things go wrong (7). Medical researchers who are paid millions to conduct and publish shoddy studies which become the basis of a device's approval (8). Doctors who accept freebies to promote a medical device – though the Code of Medical Ethics specifically forbids doctors from accepting gifts from the industry. Professional bodies which earn crores by advertising the company's product through live demonstration "training" surgeries conducted on poor patients and without follow-up (9).

Indeed, we have seen, again and again, that the doctor-industry nexus in medical devices in India colours healthcare at every level all the way up the food chain from provider to manufacturer, and regulation is ineffective at best.

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Medical device companies spend crores in India on seminars and “product giveaways” to get doctors to use their products. The ICIJ report describes how one company, Medtronic, used an innovative campaign to expand the cardiac device market to poor Indians (10) through a “healthy heart” initiative in collaboration with small hospitals. Patients rounded up through company-sponsored cardiac screening camps were offered Medtronic stents and pacemakers at inflated prices. And a company-funded agency offered patients loans to pay for these overpriced devices.

Another extortionate practice was exposed in 2017, when cardiac stents were brought under the National List of Essential Medicines and subjected to price control. It was learned that the stents were being sold to patients at up to 1,000% mark-up, with manufacturers, distributors, hospitals and even doctors all taking their cuts along the way (11). Some cardiologists would advocate the more expensive foreign-made stents though there is no evidence of their superiority. But patients are rarely in a position to make informed choices on this matter, and are unlikely to question the doctor’s decision on a matter of life and death.

Many people have paid these exorbitant rates for cardiac stents that they believed saved their lives. How many also received unnecessary interventions because their doctor got a kickback from the company?

In the jungle of medical entrepreneurs in India, it is easier to understand – though not justify – how doctors of unknown credentials manage to conduct surgeries in unhygienic settings, leaving patients with infections and damaged bodies. But the ICIJ was also informed by doctors at the country’s top government hospital that 20% of hip replacement surgeries that they conducted were revisions for faulty implants (12). In other words, botched surgeries were an open secret but no one called for investigation. Do doctors and their associations not feel morally obliged to make a noise about this state of affairs? Certainly, professional associations of cardiologists, orthopaedic surgeons, and other specialists have not uttered a word on any of the emerging scandals – though they are implicated in every one of them. The regulatory bodies of the medical profession, the Medical Council of India and its state bodies, have also remained silent throughout.

### **Medical devices: approval by default**

Faulty or wrongly used medical devices can maim and kill. Yet, the approval process is perfunctory at best, in effect serving industry interests. It depends almost entirely on international regulatory practices, which in turn are controlled by industry.

The United States Food and Drug Administration’s medical device division is essentially in the control of device manufacturers whose fees contribute one-third of the division’s budget (13). In Europe, efforts to set up an independent authority under the European Medicines Agency were quashed by industry, arguing that it would slow down approval, stifle innovation, and increase prices, without improving safety (14).

In the US, very few devices approved since regulation first started in 1976 have been subjected to trials, and few high-risk medical devices approved in the US have good quality research-based proof of efficacy and safety (15). Most approvals depend only the manufacturer’s evidence that the device is “substantially equivalent” to a similar already approved product or “predicate device” – even if the predicate device has been withdrawn from the market. In Europe, private “notified bodies” certify medical devices for a fee with regulators in a largely observational role (14).

### **The Medical Devices Rules, 2017: Cosmetic changes**

It is this body of evidence that India uses to grant approval to new medical devices. Before 2018, those medical devices that came under the authority of the Central Drugs Standard Control Organisation (CDSCO) received automatic approval as long as they were already approved in the US, Europe, Japan, Canada or Australia.

The Medical Devices Rules, 2017 (5), which came into effect on January 1, 2018, introduced a system categorising medical devices according to the level of risk they posed to patients. Only Class C and D devices, for which the risk is deemed “moderate high” and “high” respectively, require pilot trials for preliminary information and pivotal trials for evidence of the device’s effectiveness and on adverse events.

But this requirement is meaningless. The Rules also state that Class C and D devices that have been approved by authorities in Australia, Canada, Japan, European Union or the US – some of which approve devices without research – may be imported and marketed without any requirement for conducting local clinical trials. Furthermore, the Rules do not even specify that devices submitted for approval under this option must be approved and used in the country of the manufacturer.

### **The scandal of post-market monitoring and action on injury reports**

Post-marketing surveillance is critical for medical devices, especially given the limited amount of information gathered in pre-marketing research. However, monitoring for medical device injury reports started only in 2014 in India, and only from 13 centres across the country, with little reporting, if any from the major metropolises. The ICIJ counted just 556 injury reports in India in 2018, most from the smaller centres (16). And at least until 2014, the CDSCO did not even track international device recalls.

In the case of the Johnson & Johnson hip implant, the company renewed registration for its toxic implant even after it was withdrawn in Australia in 2009. And though the product was withdrawn worldwide in 2010, the CDSCO cancelled its licence only in 2012, and issued a medical device alert on ASR implants only in 2013 (17).

Though the company was required to register and track each implant, details were available of only some 1,200 of the 4,700 people who had received an ASR hip implant. The remaining 3,500 patients must somehow be traced and followed for implant-related injuries.

### So where do we go from here?

The ICIJ and other reports confirm our worst fears about technologies in medical practice in India. Medical devices are approved without proper evaluation. They are marketed and used unethically. There is almost no follow-up of medical devices for adverse events. If at all a device such as an implant is withdrawn, patients may never learn of it. And finally, mechanisms for compensation for injury are weak.

There are, of course, instances of regulatory bodies acting in the public's interest. One such example is the inclusion of stents in the National List of Essential Medicines and bringing them under price control. In the case of J&J's faulty stents, the court has responded, though less forcefully, to demands for compensation. Such actions have been prompted by a strong civil society movement. However, none of the players in the medical devices market – from medical professional to manufacturer – has faced substantive regulatory action.

The medical devices we use are woven into the fabric of our lives. It is imperative that devices be approved based on a rational and transparent system of evaluation. Regulators must ensure long-term monitoring of all implants for adverse events; respond promptly to reports of injuries of device failures, take action against violations by medical professionals and others, and ensure compensation for harm. The voices of implant victims and civil society organisations are loud and clear.

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