**The medical devices industry: the sacrifice of science and ethics at the Altar of Mammon /Kubera**

The International Consortium of Investigative Journalists’ report (1) on the international medical device industry adds to the growing documentation of health scandals in India in recent years. A comprehensive picture emerges of manufacturers knowingly selling untested products at usurious rates; criminally negligent doctors and medical establishments; and a regulatory system geared towards the industry’s growth rather than patient safety.

While the investigation documents are revealing of the extent of corruption and malpractice in the healthcare industry and allied professions, there is, unfortunately, nothing surprising about the report’s contents.

Since October last year, Johnson & Johnson’s (J&J) toxic metal-on-metal hip implant has been in the news in India. Indian victims of these implants who have suffered horrifying tissue damage and neurological illnesses have been fighting to get the company to pay for reparative surgery, and compensation on par with that awarded to US patients.

The J&J implant was one of the devices reported on in the July 2018 documentary “The Bleeding Edge”, which told the stories of women and men in the US and the UK who had suffered horrible consequences of untested and substandard medical devices. In addition to J&J’s hip implant, there was Bayer’s contraceptive coil that could not be removed, breast implants that ruptured in the body, a vaginal mesh that tore through tissue, and robotic surgery that maimed. 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 motivated not by their patients’ welfare but their links to the implant industry.

In India, in 2017, it was found that imported cardiac stents were being sold to patients at 10 times the import cost, with hospitals and doctors taking their cuts along the way. Many people have paid these exorbitant rates for cardiac stents that they believed saved their lives. How many received unnecessary interventions because their doctor got a kickback from the company?

**Medical devices and you**

Medical devices are not restricted to such relatively commonly known items. According to the Medical Devices Rules, 2018, a medical device is an “instrument, apparatus, appliance, software, material, or other article” used for “diagnostic or therapeutic purposes”. They include everything from syringes, condoms and test reagents to stents, orthopaedic implants 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.

Are these devices being evaluated properly 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 needed? Have people who suffered injuries been treated and compensated for the harm caused to them?

No, no, no, no and no.

**Nexus of industry and healthcare professionals**

These stories of the medical device industry expose the worst aspects of the medical profession – taking money to act against the interests of those whom it is bound to serve. Medical researchers who are paid millions to conduct and publish shoddy studies which become the basis of a device’s approval; doctors who accept freebies or kickbacks to promote a medical device; professionals preying on transgendered people, offering cheap breast implant surgery in filthy conditions – all in the knowledge that few will complain when things go wrong.

The bulk of the $5.2 billion medical devices market in India comes from foreign-made products, and the ICIJ report found new strategies being tested to extend the reach of these products to poor Indians. Medtronics, the world’s largest medical device company, spent Rs 260 crore in India on seminars and “product giveaways” over four years, to get doctors to use its products. The company tied up with small hospitals across India, to sell cardiac stents to the poor. Patients rounded up through the company-sponsored cardiac screening camps would be offered stents at a discount. For this purpose, a Medtronics-funded agency would offer loans, to be repaid with interest.

In 2017, when the National Pharmaceutical Pricing Authority brought cardiac stents under the National List of Essential Medicines, it found that the stents were being sold at up to 1200% markup from the price at which they were manufactured, with manufacturers, distributors, hospitals and even doctors all taking their cuts. They did this by selling to the hospital or surgeon at a much lower price, letting the hospital/ surgeon profit from the difference between the sale price and the MRP. Some cardiologists would advocate the more expensive foreign-made stents though there is apparently 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. Incidentally, the ICIJ report found that more than half of the 556 device injury reports from India last year were from cardiac stents.

In the jungle of medical entrepreneurs in India, it is easier to understand – though not justify – how doctors of unknown credentials manage to conduct breast implant surgeries in filthy settings, leaving patients with infections and damaged bodies but unwilling to complain. But the ICIJ was also informed by doctors at the country’s top government hospital that 20% of hip replacement surgeries they conducted were revisions for faulty implants. Do doctors not feel obliged to make a noise about this state of affairs? Does this reflect professional apathy? Or fear of some kind of retribution?

**Approval by default**

The medical device industry represents 4-5% of the $96.7 billion healthcare industry in India**.** Yet, theapproval process for marketing these devices in India is perfunctory at best, though not much worse than international practice.

Internationally, the regulatory process for approval of medical devices is essentially controlled by the private sector. In the US, device manufacturers’ fees contribute one-third of the budget of the relevant division of the FDA, and the Agency has indicated that it will use for-profit agencies for setting device standards. Efforts to set up an independent accreditation authority under the European Medicines Agency were quashed by industry, arguing that it would slow down approval, stifle innovation, increase prices, without improving safety (ICIJ).

The vast majority of medical devices, internationally, are cleared without clinical trials proving their safety and efficacy; such trials are mandatory for new drugs.

The flaws were established when the US first started regulating devices. All devices on the market in 1976 were deemed safe, and approved. Since then, less than five percent of medical devices approved by the USFDA have research-based proof of efficacy and safety. Most approvals depend only the manufacturer’s evidence that the device is “substantially equivalent” to a similar already approved product or “predicate device”. The predicate device could be decades old, even off the market. Only devices with major modifications require clinical trials. The same is true in Europe where private “notified bodies” certify medical devices for a fee with regulators playing an observational role.

For-profit notified bodies like TU SUV offer foreign device manufacturers help in navigating the CDSCO’s paperwork. TU SUV advertises that it is an EU-notified body, which would mean it would first certify the medical device in Europe, for a fee, and then help it get automatic clearance in India.

**The Medical Devices Rules, 2018: nothing new**

Before 2018, 10 medical devices came under the CDSCO’s authority. But even these devices received automatic approval as long as they were already approved in the US, Europe, Japan, Canada or Australia. The long-awaited Medical Device Rules are a disappointment.

Under the Rules, 23 categories of devices now come under regulation, categorised according to the level of risk – low (Class A), low moderate (Class B), moderate high (Class C) and high (Class D), with different levels of scrutiny before the CDSCO gives approval.

Class A devices require no evaluation. Class B devices require “prior audit” by a “third party”, or notified body such as TUV SUD. Class C and D devices require “prior audit” and also pilot trials and pivotal trials for efficacy and safety.

However, Class D and D devices that have been approved by authorities in Australia, Canada, Japan, European Union or the US may be imported and marketed without clinical trials.

*(Note: the Rules do not specify that the device must be approved and used in the country of the manufacturer. Some years ago, it was found that many of the cardiac stents in India had not even been approved in the country of their origin.)*

Some devices don’t even require this minimum evaluation. It is legal, in India, to buy second-hand diagnostic equipment online, without certification by a competent accreditation body. This makes up 70% of diagnostic equipment in the private sector.

**Post marketing monitoring of medical devices – an abject failure**

The failure of post-marketing monitoring takes the problem to another level. Medical devices were linked to 1.7 million injuries and 83,000 deaths worldwide over the last decade, a possible underestimate, according to the ICIJ. Monitoring for medical device injury reports started only in 2014 in India, and only from 13 reporting centres across the country. The ICIJ counted 556 injury reports in India in 2018. That would be 5,600 injury reports over the last decade in a country with a sixth of the world’s population.

The Johnson & Johnson story is a good illustration of how the system has functioned. J&J was able to renew registration for its toxic implant even after it was withdrawn in Australia in 2009. And though the product was withdrawn worldwide in 2012, the CDSCO cancelled its licence only in 2012, and issued a medical device alert on ASR implants in 2013. Patients and doctors learned about the international recall from the internet. If things could get worse, as J&J was not made to register each implant, only 1,100 of the 4,700 people who had received an ASR hip implant could be traced.

Indeed, the ICIJ report found that few international device recalls were reported on the CDSCO’s website.

And finally, the company is trying to negotiate a compensation to injured patients which is a fraction of what has been awarded in the US, arguing that the US standard should not apply in India. Device companies are not required by law to compensate for the damage done on Indian patients. Patients feeling differently are welcome to go to the consumer court.

So, the ICIJ report confirms our worst fears about technologies in medical practice. Medical devices are approved without proper evaluation. They are marketed and used unethically. Reports of damage related to their use are not well documented. If at all a device is withdrawn, patients may never get to hear of it. And finally, mechanisms for compensation are so weak as to be non-existent.

*There are of course examples of regulatory bodies acting in the public’s interest, driven by civil society’s advocacy. When the National Pharmaceutical Pricing Authority included stents in the National List of Essential Medicines under price control and cut prices drastically, manufacturers first threatened to stop production, but then backed down. The NPPA also warned hospitals against increasing their cardiac packages to compensate for the price cut. Such stern actions have been prompted by a strong civil society movement against irrational and dangerous drugs, and extortionate pricing in the healthcare industry. Action against the medical profession, on the other hand, is absent.*