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The Walking Wounded calls for a rethink of what we most value

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Starting with Karl Marx, many thinkers have pointed out that the creative potential of the capitalist economic system comes at a cost – the lack of inherent ethical scruples to limit the inexorable logic of profit and growth.

ABC TV's Four Corners' exposé of the scandal about a defective medical hip replacement device known as “ASR” is a case in point. [The Walking Wounded](#) examines the case of a surgical treatment widely used to treat painful arthritic conditions, mainly in elderly people.

Designed, manufactured and marketed by DePuy (a subsidiary of Johnson & Johnson, the world's largest medical device company), nearly 100,000 people received the implants over a six-year period. More than 5,000 of them were from Australia.

Originally launched in 2003, defects were soon apparent to many of the surgeons using the device. Some called for its withdrawal. But sales continued until 2009, and it was not until a year later that the company announced a worldwide recall.

Legal actions

In Australia, a class action has been launched on behalf of hundreds of patients whose implants failed. It follows a US case fought and won by Bill Kransky, who was awarded \$US8 million from the company for damages he suffered as a result of the defective device.

The facts of the Australian case have yet to be tested but those of the US case seem straightforward.

The evidence of harm, including pain, disability and possibly even neurological disease and genotoxicity resulting in (some suggest) [increased cancer risk](#), was apparently available, but suppressed.

No clinical trials were carried out before the product was launched. Rather, DePuy obtained fast-track authorisation from the US regulator, the Food and Drug Administration (FDA), to market its full hip replacement version of the ASR on the questionable basis that it was “substantially equivalent” to other brands of metal-on-metal hip.

Those who drew attention to the problem were ignored. Company executives met behind closed doors to decide how to manage the bad publicity – in every way except the most obvious one: by withdrawing the product, apologising to those injured and offering compensation.

More transparency

This disturbing case raises important questions both for government regulators and ordinary citizens. In particular, we have to ask why the scandal happened in the first place and what can be done to prevent recurrences.

The answer to the second question is straightforward. A complex regulatory system has already been developed for pharmaceutical agents, and it clearly needs to be extended to medical devices, including bioprosthetic devices, such as joint replacements.

Despite being much maligned, the drug industry is one of the most rigorously regulated sectors of the economy. It operates under elaborate and intricate codes of conduct. In contrast, the regulation of medical devices, both internationally and in Australia, is [cumbersome and inadequate](#). It’s clearly time for that to change.

In addition – this applies equally to pharmaceuticals and devices – while all clinical trials have to be publicly registered, there is no requirement for the data they generate to be made publicly available.

In the interests of public safety, and to allow full assessments of claims made about the safety and efficacy of devices and medicines, it should be mandatory for all clinical data obtained about any medical product to be accessible for independent review.

Rethinking priorities

The question of why this scandal took place in the first instance is more difficult. How could (if it is proved to be true) one of the largest and most respected companies in the world systematically and deliberately place profit above the protection and care of some of the neediest and most vulnerable members of society?

We must recognise the dangers posed by the drive for commercial success and innovation when it is unconcerned with patient safety. But more generally we must reverse the replacement of social responsibility and ethical vision with a crude commitment to making money.

And we must stop celebrating businesspeople for their achievement in accumulating large amounts of money, regardless of the social cost.

Maybe this sounds hopelessly naïve, but the integrity of social institutions – including the health and educational systems – depends on it.

Ultimately, the pathology that generates scandals like that of the ASR prostheses does not lie in deficiencies in government or in the court system but in society and culture. It is to society and culture that we must look for a solution.