Title

The good fight

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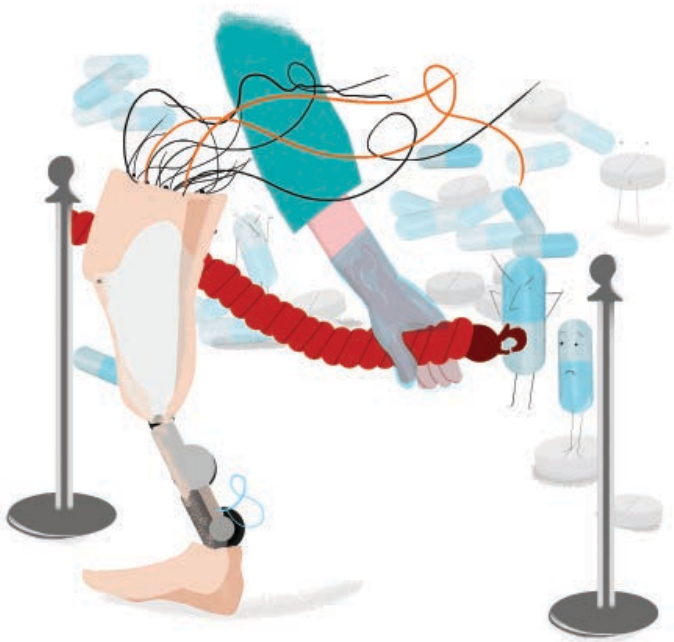
Life and limb

Unsatisfactory oversight of medical devices is harming patients. We must do better, says **Peter Wilmshurst**

A WORLDWIDE investigation into medical implants has found that millions of patients are at risk from poorly tested devices. It is time to face the problem.

If a drug has adverse effects or is ineffective, the medication is changed. But it is more difficult and dangerous to remedy an implanted device, such as a cardiac valve, pacemaker, breast implant or artificial joint. Why then is it so much easier to gain approval for medical devices?

The European Medicines Agency evaluates evidence of efficacy and safety in controlled clinical trials before licensing drugs. Most of the evidence is publicly available. But medical devices can gain a European Conformity (CE) mark for use across the EU from any of dozens of Notified Bodies. These groups issue CE marks for all sorts of devices including light bulbs, toothbrushes and televisions.



JOSIE FORD

Notified Bodies are private firms paid by the device-makers, and the evidence considered is commercially confidential.

The maker of a medical device doesn't usually need to prove it has any therapeutic benefit. A CE mark is often awarded because a device has slight differences from an approved existing device. That may be adequate for a toothbrush, but it has had fatal consequences when minor differences to a medical device have led to unanticipated functional changes.

Makers of drugs and devices have no ethical responsibility to get patients the best treatment. They are beholden to shareholders, and can market products even if competitors have better ones.

We know financial conflicts of interest can influence which drugs doctors prescribe, but conflicts of interest with medical devices are greater. Doctors often

The good fight

Through solidarity and resistance, workers can guide the ethics of tech giants, says **Lilly Irani**

MORE than 700 Google workers have signed an open letter demanding their employer drops Dragonfly, what they call an "effort to create a censored search engine for the Chinese market that enables state surveillance".

Such workers make companies stick to their publicised ethics and push for more robust ethical standards. Their moves are to be admired, as they help us all.

Other examples include some 4000 Google workers who raised the alarm last year over Project Maven, which offered access to a powerful AI to process drone surveillance and target people for killing. And workers at Amazon, Microsoft, Salesforce and Accenture called on their companies to stop providing services to government agencies that criminalise migrants, black and poor people.

Firms like Google, Facebook, Amazon and Apple carry our voices, record our memories and sculpt public attention. But only two kinds of people have a view into the effects of these black boxes – the complex digital systems that shape our lives.

First, marginalised people, such as those living under drone strikes in the Middle East, communities targeted by predictive policing and trans people moving through body scanners, to name but a few. Second, tech workers, who know more from the inside on how the levers work and where companies are taking these technologies.

"Tech workers are coming together and refusing to build 'algorithms of oppression'"

Google has now promised not to build weapons technologies or produce surveillance in violation of international norms. Tech workers are asking for the right to practise these same ethics, refusing to build what have been called "algorithms of oppression".

Individuals acting alone have little ethical agency. Only the

invent medical devices, and they or their institutions own the patents. The inventors often conduct the clinical trials, and EU rules allow devices to be marketed while trials are under way.

Training is then required to implant medical devices, and the procedures can attract high fees in private practice. Device-makers cascade the skills to doctors by paying skilled operators to be part-time trainers, separate from their hospital job. In that role, the trainers are part of the firm's marketing arm. Highly paid opinion leaders may demonstrate a device at a medical conference before thousands of delegates.

I was the principal cardiologist in a trial of a device for closing holes in the heart. In 2007, I expressed concerns about its safety and efficacy, and the manufacturer sued me for libel.

The legal action against me only ended when the manufacturer went into liquidation after it became clear its devices weren't effective. To protect patients, we must make it as difficult to gain approval for medical devices as it is for medicines, and we must outlaw dubious marketing practices. ■

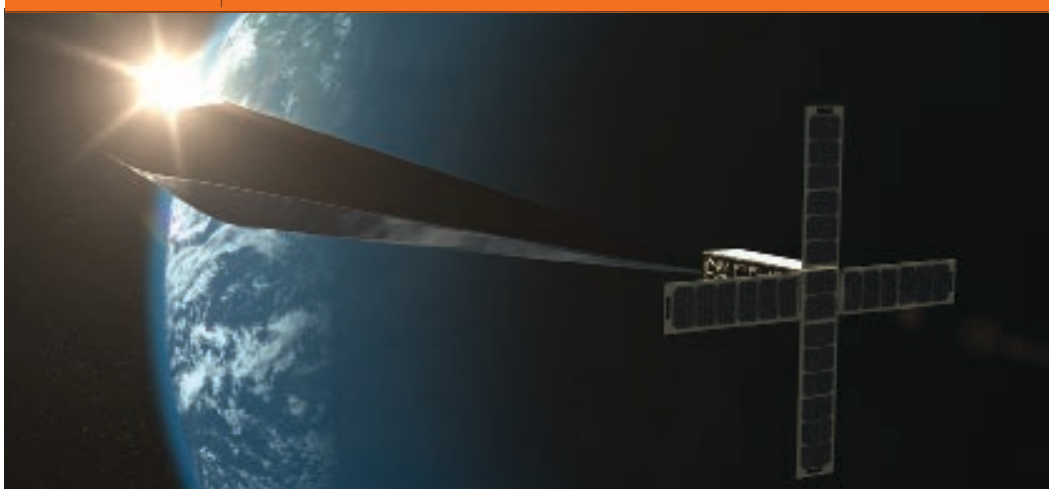
Peter Wilmshurst is a consultant cardiologist at Royal Stoke University Hospital, UK

demands of many thousands can translate an ethical judgement into a democratic reality. And it is resistance in many coordinated forms – refusal to build, work slowdowns, walkouts – that holds firms accountable to their proclaimed ethics.

Only through the solidarity between those who build these systems and those marginalised by them, and the broader support of the public, can we take democratic control of the technologies that shape our lives. ■

Lilly Irani is assistant professor of communication and science studies at the University of California, San Diego

ANALYSIS Space art



TREVOR PAGLEN AND NEVADA MUSEUM OF ART

Space is the ultimate place to exhibit

Chelsea Whyte

FOR the artist as provocateur, the vast night sky is an enticing canvas. The latest attempt to make a mark on the heavens comes from Trevor Paglen, an artist known for outsized works that rely on technological innovation.

His new piece, *Orbital Reflector*, is a giant, diamond-shaped balloon that will inflate once it is in orbit around Earth (artist's rendition pictured above). It was launched aboard a SpaceX Falcon 9 rocket on 3 December, alongside a host of other small satellites.

The 30-metre-long structure is coated in titanium dioxide, which will reflect the sun's light and be visible to the naked eye from Earth's nightside. After a few months, it will re-enter the atmosphere and burn up.

This isn't the first time something shiny has been sent into orbit. In January, space-flight firm Rocket Lab launched a geodesic sphere about a metre wide that reflected light as it circled Earth. It was known as *Humanity Star*, and its creator, Rocket Lab founder Peter Beck, said it was intended to draw people's eye to the night sky and push them to consider their place in the universe.

Putting eventual junk into space without a scientific or technological purpose has riled many scientists, who say these kinds of satellites can interfere with their observations of the sky, but the art community ought to be just as vocal.

However, these glittery pieces aren't particularly original. The decades-old Iridium satellites that connect satellite phones also catch the sun's rays and their glares often reach far beyond the expected brightness of *Orbital Reflector*.

"Astronaut Chris Hadfield's cover of *Space Oddity*, recontextualised a classic in orbit"

Some people have likened reflective space art to graffiti, but even that misses the mark. Earth-bound graffiti is subversive by nature, the message part of the medium. There is nothing that subversive about spending millions of dollars to buy a spot on a rocket with the goal of getting people to simply look up in the dark.

Artists could be doing much more when it comes to orbital exhibits. Astronaut Chris Hadfield demonstrated the power of art in space during his stay on the International Space Station. His photos of Earth's landscapes revealed an impressionistic view of our home planet, while his cover of David Bowie's *Space Oddity*, recorded in orbit, recontextualised a classic.

Space art needn't even reach a large audience. One of the most moving works beyond Earth is something nearly no one has seen with their own eyes. It is an 8.5-centimetre aluminium sculpture called *Fallen Astronaut* that sits in a dusty, mountainous landscape of the moon's northern hemisphere.

The astronaut figurine was made by Belgian painter Paul Van Hoeydonck and placed there by David Scott on the Apollo 15 mission in 1971 to commemorate the astronauts and cosmonauts that died in the course of space exploration. Assuming it isn't hit by an asteroid, the piece will stay on the surface of the moon forever – or at least until the sun expands and consumes the inner solar system, billions of years from now.

As access to Earth orbit grows, it shouldn't merely be restricted to practical applications like communications satellites and scientific experiments – there is certainly space for artists in space. But twinkly lights just don't cut it any more. ■