Academic rigour, journalistic flair

If your health practitioner has used a syringe, tongue depressor (to look at your throat), pacemaker, stethoscope, X-ray or MRI scan, blood test, dental filling or joint implant to treat you, you’ve encountered a product from the medical technology industry.

That industry is diverse, ranging from high-tech patent-rich global corporations to small businesses that operate only in Australia. It is claimed to employ more than 19,000 people in Australia and have a turnover of around A$12 billion in 2012/13. Operating margins have been around 25%.

Many of the businesses are represented by the Medical Technology Association of Australia (MTAA). This industry body is for manufacturers of products regulated by the Commonwealth government. Use of those products is typically funded wholly or in part by the taxpayer. There are strict requirements around their certification, import and sale.

MTAA members include Johnson & Johnson Medical, 3M Healthcare and Medtronic Australasia.
The MTAA is quietly influential. Quiet because its activity as an industry advocacy body is often only known to policymakers and specialists. Quiet because it has not sought to capture the mass media.

It’s influential because it persuaded the government, in responding earlier this month to the Review of Medicines and Medical Devices Regulation (aka Sansom Review), to reject the recommendation to establish mandatory registries for use of high-risk implantable devices such as hip joints.

Those registries would be overseen by the Therapeutic Goods Administration (TGA), the industry-funded national drugs and devices regulator.

The MTAA explained its opposition to the registries as a cost concern for industry and an inhibitor of innovation, claiming that establishment and maintenance of the registries would be extremely expensive.

We need to be wary of such advocacy. Some of the businesses are large and profitable. Some have faced law suits for selling defective devices.

DePuy International, a subsidiary of global giant Johnson & Johnson, for example, sold faulty joint implants. This resulted in harm to individuals and to the national economy through hospitalisation for remedial surgery and loss of productivity. These harms were not fully addressed through billion-dollar class actions in Australia and overseas.

The Sansom Review had accordingly recommended that data in the registries would be used for an active program to analyse and report on problems with devices.

Sansom also recommended the TGA actively share registry and other monitoring data with overseas medical device regulators. Transparency in what’s going wrong is a foundation for health practice. It would offset the TGA’s past weaknesses in this area.

MTAA priorities

MTAA spending on advocacy – whether through representations to MPs, briefings of journalists, submissions to inquiries such as the Harper Review on competition policy, or membership of official working groups – is not publicly available.

Its annual report does not detail the number of health and industry ministers who were met, the backbenchers visited or officials who were encouraged to see the world through the eyes of the MTAA’s largest members.

The MTAA emphasises self-regulation under the Medical Technology Industry Code of Practice. It has been lobbying against external regulation that its dominant members regard as burdensome.

At the same time, like any other industry body, it seems keen to ensure that non members are regulated. Capturing non members might foster trust in the industry (inhibiting Sansom-style inquiries), as smaller enterprises leave the market when unable to comply with regulatory costs.
The MTAA has sought to persuade the Commonwealth to raise minimum prices for devices on the 
**Prostheses List**. This means member companies could charge more for prostheses such as knee and 
hip implants, pacemakers, cardiac stents and heart valves.

Use of such devices is no longer exceptional medical practice. An ageing population means that more 
of us will need prostheses in future, both for comfort and so we can keep working and thereby pay 
taxes.

The Association has also advocated for reimbursement of currently unfunded innovative medical 
technologies, such as wireless **cardiac monitoring**.

In making sense of the advocacy, it is useful to remember that while the TGA regulates health 
products to try (with **uneven success**) to **prevent harms**, it does not require all goods to be **efficacious**. 
The gatekeepers are instead the economists within the Department of Health and the Independent 
Hospital Pricing Authority (IHPA).

**How does the MTAA influence?**

The MTAA’s **MedTech Industry Blueprint**, which outlines the group’s policy challenges and goals, 
ticks advocacy boxes such as strengthening Australia’s research capability, building a skilled 
workforce, enhancing Indigenous health and fostering access to emerging markets in the Asia Pacific 
region. We cannot tell the persuasiveness of that document.

What we can see, however, is the MTAA actively contributing to official inquiries, with for example 
submissions to the Harper Competition Policy inquiry, the Review to Strengthen Independent 
Medical Research Institutes (RSIMRI), the Review of Medicines and Medical Devices, the National 
Diabetes Strategy and the Tasmanian Green Paper.

In practice, the MTAA gets more traction by shaping the terms of debate through participation in 
official working parties and advisory groups. These entities are unrecognised by non specialists but 
increasingly – through hollowing out of capacity within government – do the heavy lifting in policy 
development and prioritisation.

When making sense of regulation and advocacy in Australia, we should accordingly be looking at 
benefices such as the Independent Hospital Pricing Authority Stakeholder Advisory Committee, the 
Prostheses List **Advisory Committee** and National Joint Replacement Registry Consultative 
Committee rather than the Daily Telegraph or Senator Derryn Hinch. Persuasion in these areas is less 
transparent than desirable.