

A joint statement by State Peak Health Consumers organisations:



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MEDIA RELEASE

## DUTY OF CARE OR BUYER BEWARE?

Despite the TGA's most recent media release claiming progress in the battle for a just resolution to the pelvic mesh crisis, according to a coalition of state health consumer bodies, little has changed since the Senate Inquiry into Pelvic Mesh handed down its recommendations in 2018.

"The historic win in court last week was the result of civil action taken by injured women – not due to any actions pertaining to the 13 recommendations from the Senate Inquiry" according to CEO of Health Issues Centre, Danny Vadasz.

"No credit is due nor cost borne by any regulators or health authorities. The fact that women had to turn to the courts for vindication is itself an indictment on the failure of the health system to accept its share in the burden of responsibility."

The TGA's claims that it has simplified the consumer reporting process, investigated data sharing, strengthened post-market monitoring and co-designed information leaflets may have some impact however, according to Danny "these initiatives don't address the fundamental flaws in a system that road-tests devices in human guinea pigs and then uses passive surveillance (otherwise known as "market monitoring") to see how much damage has been done."

"Basically the TGA's focus on better informing consumers and inviting self-reporting of adverse outcomes is an abrogation of their duty of care and a shift of responsibility to consumers ("buyer beware").

"Nor do these initiatives address the injustice inflicted on thousands of women over decades of system failure.

“As well as medical device manufacturers, both state and federal Governments have a responsibility as guardians of the health system to those who have been harmed.”

“We call on state and Federal Governments to enact a 7 point commitment that includes:

1. Provision of dedicated and integrated state based services to attend to the physical, emotional, financial and social damages caused by mesh;
2. Establishment of a retrospective register of implanted mesh devices to enable life-long monitoring of the health of mesh recipients;
3. Launch of a major outreach effort to identify and offer assessment to all women who have received mesh implants;
4. Free ongoing treatment and rehabilitation of all those injured;
5. Facilitating free access by individuals to their mesh hospital records;
6. Reimbursement of retrospective and underwriting all future costs of mesh related surgery including (where warranted) the costs of overseas surgery;
7. A judicial inquiry into the conduct and culpability of mesh manufacturers with a view to requiring them to establish and fund a Mesh Injury Compensation Fund (similar to the James Hardie Asbestos Compensation Fund) for the express purposes of addressing all injury associated claims.

“While we applaud efforts to prevent further prospective injury we cannot ignore and abandon those women whose lived experiences have educated the health system at their personal cost.”

**CONTACT:** Heather Potter: 0431 856 598 or Danny Vadasz: 0419 419 988

**Health Consumers Alliance of SA**  
**Health Issues Centre (Vic)**  
**Health Consumers Queensland**  
**Health Consumers' Council (WA)**  
**Health Care Consumers Association (ACT)**  
**Health Consumers New South Wales**  
**Health Consumers Tasmania**