MALLESONS

The Review

Class Actions in Australia 2025/2026

Drugs and devices on trial: A decade of health sector class actions in Australia

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Over the last 10 years, there have been a number of high-profile class actions in Australia against companies relating to consumer health and therapeutic goods, and health services. These proceedings often follow similar claims in the United States. This chapter outlines what we have observed over the decade, and the trends that may influence future class action filing activity.

SNAPSHOT OF CLASS ACTIONS IN THE HEALTH SECTOR

- 20 class actions were filed between February 2016 and June 2026.
- Almost half of these proceedings were commenced in the past 2 financial years: 2024/2025 was the most active year for filings (5 new proceedings), followed by 2025/2026 (4 new proceedings).
- 80% of these class actions followed on from US litigation, regulatory action or product recalls.

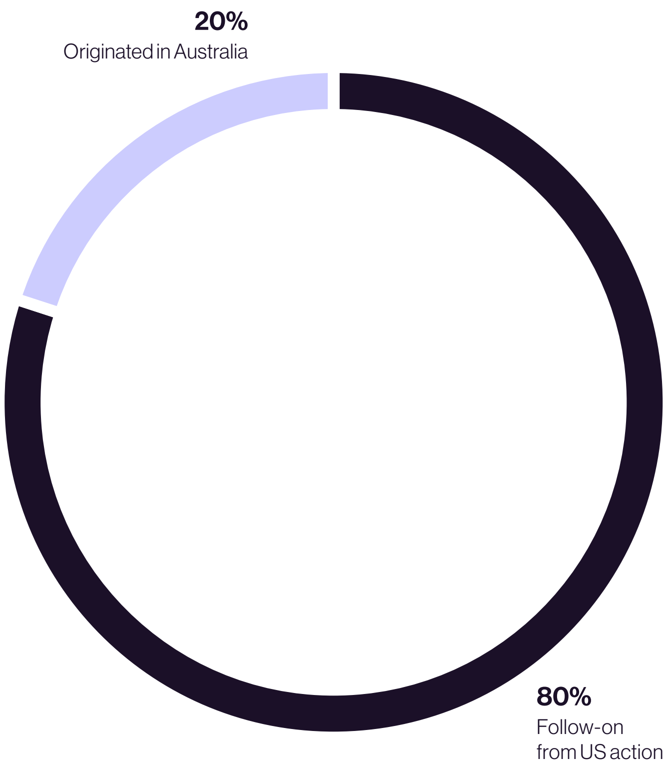
TRENDS OVER A DECADE OF FILINGS

The proceedings filed between February 2016 and June 2026 involved claims alleging negligence and contraventions of the Australian Consumer Law (**ACL**) relating to a diverse range of:

- **consumer health and therapeutic goods**, including sleep apnoea machines, contraceptive devices, joint implants, and over-the-counter medicines, and
- **health services**, including genetic testing for IVF and cosmetic surgery.

While these class actions make up only a small percentage of the class actions filed nationally each year, they have often garnered significant public interest due to:

- the nature of the subject matter (consumer health and therapeutic products), and
- their relationship to actions overseas — a particular feature of class actions in this sector.



The overwhelming majority (approximately 80%) of these class actions were 'follow-on' proceedings, being claims that were commenced in Australia following litigation or regulatory action (including product recalls) that had been taken in the United States.

Only 4 matters (20%) originated independently in Australia. These proceedings cluster into 3 categories:

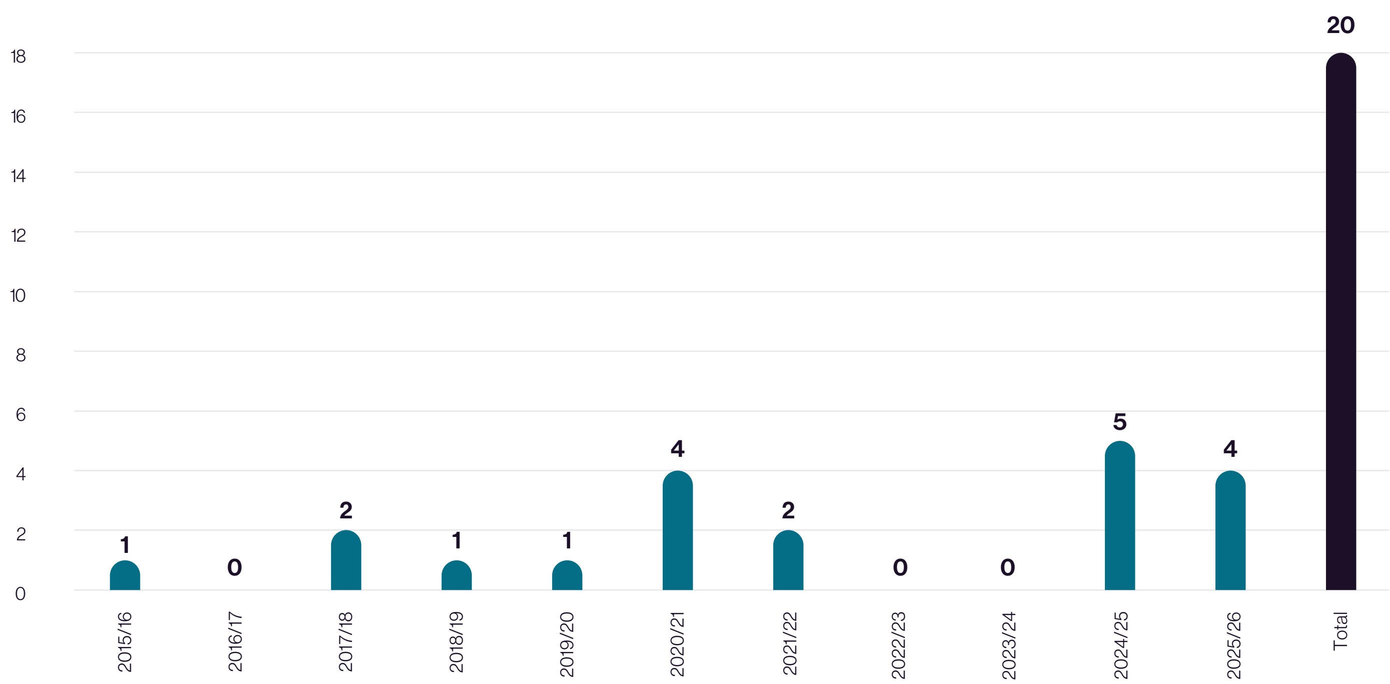
- professional negligence claims against individual practitioners or clinics (the Cosmetic Institute and Dr Lanzer proceedings)
- matters tied to distinctly Australian circumstances with no overseas analogue (the Monash IVF proceedings), and
- claims catalysed by prior domestic regulatory action (the Nurofen proceeding, which followed successful ACCC enforcement action relating to misleading marketing claims that the painkillers had been formulated to target specific types of pain).

Several factors are likely to have driven this pattern.

The United States has traditionally been a more fertile ground for health class actions, where the market — and consequently, the group size — is large, and offers the most significant awards to plaintiffs and returns for plaintiff law firms or funders who take on the risk of commencing proceedings without the risk of an adverse costs order.

By comparison, the Australian health market is small and the risk of bearing the costs of commencing and running test-case proceedings can often outweigh the potential benefits in terms of a monetary award to plaintiffs or their representatives. However, as a common law jurisdiction, similar causes of action to those that have succeeded in the United States are often available in Australia, and the risk of running a class action in Australia is materially reduced after succeeding elsewhere first (as well as there being higher prospects of obtaining a favourable settlement).

Filing trends by financial year



The health sector class actions filed across the decade were not evenly spread. Two distinct waves stand out: 2017/2018 to 2021/2022 and 2024/2025 to 2025/2026, separated by a gap in which no class actions were filed.

The pattern contrasts with the broader Australian class action market, in which proceedings have been commenced at a comparatively steady rate, perhaps suggesting a closer alignment within the health sector to developments overseas than domestically.

The pattern may also be reflective of Australian class action plaintiff firms and funders running one mass tort wave to conclusion before committing to invest in the next. The gap in filings between 2021/2022 and 2024/2025 is consistent with this approach: a first wave of matters resolved during this period, including a stay of proceedings in the American Medical Systems mesh proceedings in 2022, settlement of the TFS Manufacturing mesh proceedings in 2023, and resolution of the Essure, Ethicon and Boston Scientific proceedings in 2024.

The uptick in Court filings in 2024/2025, being the highest single year over the decade, involved matters relating to earplugs, joint replacement devices, breast implants, over-the-counter medication and talcum powder.

Nature of the products and claims

Class actions in relation to medical devices, including sleep apnoea machines and joint implants, account for 45% of filings over the decade, with the remainder split between health services (15%), over-the-counter medicines (35%) and prescription medication (5%).

Of the 17 proceedings where a Statement of Claim is publicly available, 13 plead both negligence and ACL claims, pairing a safety or quality defect allegation with a fault-based claim. The remaining 4 proceedings rely on the ACL alone. Notably, 3 of those were commenced in 2024/2025.

On one view, claims grounded exclusively in the ACL can be easier to make out where the harm is about a product's promised qualities. We expect to see a continued trend in health sector class actions towards labelling, marketing and efficacy-based claims, rather than product safety claims alone.

45%	15%	35%	5%
Medical devices	Healthcare services	Consumer or over-the-counter health products	Prescription medications

OUTCOMES

- 10 of the 20 health sector class actions filed have resolved.
- Of these, 7 settled (including the $56m Monash IVF settlement discussed in The Review 2024/2025) and 2 were stayed or procedurally closed, including the American Medical Systems mesh proceeding, following its US parent company's insolvency.
- The remaining proceeding, Essure, resulted in a win for the defendant. The applicants could not establish the necessary causal link on the balance of probabilities, illustrating the evidentiary hurdle that plaintiffs who run actions in the health sector may face even where a similar claim overseas was successful.

LOOKING AHEAD: OBSERVATIONS FOR 2026 AND BEYOND

We have seen a marked uptick in the commencement of class actions in the health sector, with 9 of the 20 proceedings filed in the past decade having been filed in the past 2 financial years.

Given the continued introduction of new high-profile medical devices and treatments in the United States, we expect this surge to continue in the coming years.

CASE STUDY - ESSURE CONTRACEPTIVE

Case: *Turner v Bayer Australia Ltd* [2024] VSC 760 (Supreme Court of Victoria, Keogh J)

Proceeding: A class action brought on behalf of more than 1,400 group members who received an Essure implant in Australia prior to 31 December 2018.

Allegation: The Essure permanent contraceptive device caused ongoing chronic inflammation resulting in pelvic pain and abnormal uterine bleeding. The device was therefore defective and not of acceptable quality in breach of the *Trade Practices Act 1974* (Cth) and/or the Australian Consumer Law, and the defendants were negligent in designing and manufacturing Essure and in failing to adequately warn of associated risks.

Context: Essure was voluntarily withdrawn from the Australian market in 2017. In the United States, the Food and Drug Administration restricted Essure sales in April 2018, and Bayer ceased distribution of the product by the end of 2018, following more than 26,000 adverse event reports between November 2002 and December 2017. Nearly 39,000 women filed claims in the United States. In August 2020, Bayer resolved the vast majority of those claims for approximately US$1.6b, without admission of liability.

Outcome in Australia: After weighing extensive biostatistical and epidemiological expert evidence, Justice Keogh found that causation was not established on the balance of probabilities. His Honour concluded that the plaintiff's symptoms were more likely explained by an unrelated condition rather than any inherent defect in the device. The claims were dismissed.

Key takeaway: Bayer's US$1.6b settlement in the United States did not translate to success for the group members in Australia. Australian courts will independently scrutinise causation through their own procedural and evidentiary frameworks, relying on case-specific expert evidence. Justice Keogh in this proceeding accepted the defendants' submission that the regulatory history of Essure was 'peripheral to the critical issues requiring determination', and the plaintiff had not established that any regulatory issue 'made any relevant difference' to her case. Practitioners advising on Australian product liability exposure should therefore focus on building a robust, Australia-specific evidentiary record on causation, including biostatistical, clinical and expert evidence, from the outset of any claim or defence, even where there has been overseas regulatory action or significant settlements.

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