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# DRUG AND MEDICAL DEVICE LITIGATION

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WORLDWATCH

# DRUG AND MEDICAL DEVICE LITIGATION

## PANEL EXPERTS

### AUSTRALIA

**Greg Williams**
Group Lead Partner – Disputes
Clayton Utz
T: +61 2 9353 4798
E: gwilliams@claytonutz.com

**Greg Williams** is an experienced practitioner with over 25 years' experience in Australia's premier product liability practice. He has been involved in the defence of product liability claims and class actions involving pharmaceuticals and medical devices, financial services and automobiles. He has significant experience in running large complex matters to a contested hearing. He was a member of the team that defended the Australian Vioxx class action.

### UNITED STATES

**Hildy Sastre**
Partner
DLA Piper
T: +1 305 702 8847
E: hildy.sastre@us.dlapiper.com

**Hildy Sastre** is one of the nation's most highly regarded trial lawyers, having first-chaired dozens of high-stakes cases for Fortune 100 companies across the country – often in some of the most plaintiff-friendly jurisdictions. She frequently serves as trial counsel in bellwether and first-impression cases and has extensive experience defending multinational corporations in consolidated proceedings and national multidistrict litigation. Ms Sastre has secured numerous defence verdicts for clients facing significant high-risk litigation throughout the US.

### SINGAPORE

**Tony Yeo**
Managing Director
Drew & Napier
T: +65 6531 2512
E: tony.yeo@drewnapier.com

**Tony Yeo** is the managing director of Drew & Napier's intellectual property department, and a director in the dispute resolution department. He also heads the firm's healthcare & life sciences practice. He is currently representing leading biotech and pharmaceutical companies such as Sanofi-Aventis, AstraZeneca and Novartis, government statutory boards such as Sentosa Development Corporation and the Health Promotion Board, as well as listed companies such as PT Bayan Resources Tbk and Manhattan Resources Ltd.

### ITALY

**Christian Di Mauro**
Partner
Hogan Lovells
T: +39 (02) 720 2521
E: christian.dimauro@hoganlovells.com

**Christian Di Mauro** brings 25 years' experience as both a product litigator and product regulatory specialist. He acts in the full spectrum of product-related disputes, including commercial and supply chain litigation, product liability, mass torts, class and collective actions. He counsels on the entire product risk lifecycle, covering crisis management, product safety and quality issues, recalls, regulatory engagement and product-related investigations. His sector focus spans life sciences alongside technology, chemicals, cosmetics and food.

CANADA

**Byron Shaw**
Partner
McCarthy Tetrault
T: +1 (416) 601 8256
E: bdshaw@mccarthy.ca

**Byron Shaw**'s practice includes corporate and commercial litigation, class actions and public law litigation. He regularly acts for corporations, individuals and government agencies in commercial litigation before the courts and private arbitration panels. He has considerable expertise in class action defence of financial institutions and product liability claims against manufacturers and distributors of pharmaceutical, medical device and consumer products and services. He also litigates and advises public and private entities on constitutional and administrative law.

**CD: How are you seeing regulatory expectations evolve for drug and medical device manufacturers, particularly as agencies increasingly rely on informal guidance, adaptive oversight or 'soft law' approaches?**

AUSTRALIA

**Williams:** Australia's medicine and medical device regulator, the Therapeutic Goods Administration (TGA), has long had a compliance framework which encourages voluntary compliance through education and prioritises enforcement actions based on risk. It publishes guidance documents on a wide range of topics to assist compliance. However, I do not see that this framework has in any way weakened the TGA's standards or reduced its resolve to take enforcement action where necessary. Rather, the TGA is expanding the areas where it engages in enforcement actions and in recent years has, for example, achieved a record penalty outcome against a global medical device company for quite a technical breach of its regulatory obligations.

SINGAPORE

**Yeo:** Regulatory agencies in Singapore are moving away from static, prescriptive rules toward more flexible, principles-based approaches to oversight that blend safety and quality control with flexibility and guidance. This is reflected in the growing use of guidance instruments, especially for governing emerging developments such as the use of artificial intelligence (AI) and the applications of precision medicine in healthcare. In 2025, the Health Sciences

Authority (HSA) published its 'Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices – A Life Cycle Approach', to provide clarity on the regulatory requirements across the product lifecycle. The HSA has also moved toward adaptive oversight. Following its May 2025 public consultation, the Health Products (AI Standalone Mobile Application – Exemption) Order 2026 took effect on 13 February 2026, which initiated the establishment of a regulatory sandbox for class A and B AI software as a medical device (AI-SaMDs) developed by public healthcare entities, and signalled the HSA's willingness to experiment with tiered, risk-proportionate frameworks. While these tools afford flexibility, manufacturers must treat the underlying guidelines as de facto compliance benchmarks, with continuous post-market vigilance expected.

ITALY

**Di Mauro:** Regulators and courts increasingly expect manufacturers to demonstrate a lifecycle compliance culture that includes quality management, proactive surveillance, vigilance, corrective actions, clinical evidence updates and clear risk communication. By way of example, the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) framework requires manufacturers to implement and keep updated a post-market surveillance system as part of the quality management system, and the Medical Device Coordination Group (MDCG) established by article 103 of Regulation (EU) 2017/745. The growth of 'soft law' also matters because formally non-binding guidance is becoming a practical benchmark for expected conduct. The MDCG guidance expressly states that its views are not legally binding and that only the European Court of Justice can give binding interpretations of European Union (EU) law.

> **"The volume of drug and device litigation has not necessarily increased significantly, but the focus and nature of the claims has evolved."**
>
> *Byron Shaw, McCarthy Tetrault*

CANADA

**Shaw:** Canada's statutory framework remains relatively open-textured, leaving room for

discretionary oversight and soft law in the form of administrative guidance applied by enforcement agencies. Drugs and medical devices are federally regulated under the Food and Drugs Act and medical devices regulations, but manufacturers must also pay close attention to Health Canada's informal guidance. While the Food and Drugs Act prohibits false, misleading and pre-authorisation promotion, Health Canada's administrative guidance recognises that manufacturers may provide accessible, non-promotional information to healthcare professionals and the public. Health Canada's guidance applies across a broad range of products, including prescription and non-prescription drugs, vaccines, natural health products and medical devices, in both traditional and digital media.

UNITED STATES

**Sastre:** We are seeing a pronounced shift from prescriptive rulemaking toward adaptive, principles-based oversight. The US Food and Drug Administration's (FDA's) increased reliance on guidance documents, pre-certification frameworks and real-world evidence pathways means manufacturers face evolving compliance targets that lack the procedural safeguards of formal rulemaking. For product liability practitioners, this creates a complex landscape. Plaintiffs' counsel increasingly argue that 'soft law' instruments set a de facto standard of care, while manufacturers contend these are aspirational rather than binding. Parties should consider potential litigation impacts when considering informal guidance and factor that into decision making.

**CD: To what extent is the rise of AI enabled devices and digital health technologies creating new exposures for manufacturers? How are regulators in your region addressing the complexity of software based medical products?**

SINGAPORE

**Yeo:** The increasing integration of AI into medical products and digital technologies primarily increases exposures for manufacturers in the realms of cyber security, data privacy, product liability and regulatory enforcement. Software failures and data integrity are increasingly becoming areas of vulnerability for manufacturers. Software defects, biased training data and adversarial attacks are emerging vulnerabilities, with the Cyber Security Agency of Singapore reporting a rise in healthcare ransomware incidents from 12 to 18 percent in 2023. Singapore's regulators are responding to the complexity of software-based medical products through a layered software or digital-specific framework that combines rules and technical guidance and supervised experimentation. The HSA's SaMD guidelines embed secure device design and lifecycle

change management expectations, while the AI-SaMD sandbox requires ISO 13485 self-attestation, clinician supervision, chairman of medical board and chief executive endorsement, HSA notification, and patient disclosure. The HSA's 'Artificial Intelligence in Healthcare Guidelines', published in March 2026, further codify expectations on fit for purpose design, representative datasets, algorithmic robustness and clear documentation.

ITALY

**Di Mauro:** AI-enabled devices and digital health products are creating a meaningful expansion of exposure for manufacturers in Italy, mainly because liability risk now sits at the intersection of medical device law, AI governance, cyber security, privacy, professional liability and product liability. Digital health in Italy is not governed by one single statute, but software as a medical device is regulated through the MDR, the IVDR and Legislative Decrees No. 137/2022 and No. 138/2022, with the Ministry of Health as the competent authority for medical devices. Italian Law No. 132/2025 on AI also addresses healthcare AI and requires, among other things, that AI systems used in healthcare support prevention, diagnosis, treatment and therapeutic choice without displacing the physician's decision.

CANADA

**Shaw:** Health Canada has taken an active and flexible approach to regulating digital health technologies, including mobile apps, telemedicine, software as a medical device and AI-enabled products. Amendments to the Food and Drugs Act in 2019 introduced a risk-based framework for advanced therapeutic products, allowing regulators to address novel technologies that did not fit neatly within existing rules. In 2021, Health Canada, the US FDA and the UK's Medicines and Healthcare products Regulatory Agency also identified 10 guiding principles for 'Good Machine Learning Practice'. These guiding principles are intended to provide users with clear, relevant information about intended use, performance, training data, limitations, updates and how to raise concerns. At the same time, manufacturers and healthcare providers must navigate strict privacy requirements governing personal health information. There are numerous pieces of provincial and federal legislation that place meaningful limits on the collection, use and storage of personal information and personal health information, which require careful analysis and compliance planning.

UNITED STATES

**Sastre:** AI-enabled devices and digital health technologies are fundamentally reshaping the litigation landscape. Unlike traditional medical

devices with static functionality, software-based products that learn and adapt post-market create novel questions around foreseeability, duty to update and causation. The FDA's evolving framework for software as a medical device attempts to address this, but the regulatory architecture still lags the technology. In our practice, we are advising on documentation strategies that capture algorithmic decision-making processes – critical evidence when defending against claims that an AI-driven recommendation caused patient harm. Regulators are increasingly expecting manufacturers to demonstrate ongoing algorithm monitoring, which creates both compliance obligations and a potential litigation record-keeping issue. The intersection of cyber security vulnerabilities with patient safety adds yet another key consideration for manufacturers.

**"Italy remains an opt-in jurisdiction, and personal injury and product liability claims are still often brought as individual actions."**

*Christian Di Mauro, Hogan Lovells*

AUSTRALIA

**Williams:** AI has a wide range of health applications, but like any new technology, it comes with increased risk. It is very likely that AI enabled devices and technologies can be the subject of claims for damages under the Australian Consumer Law, whether that be a strict liability claim for a defective product or a claim based on a failure to provide services with due care and skill. In October 2025, the Australian government published 'The Review of AI and the Australian Consumer Law', proposing amendments to clarify the regulation of AI under the Australian Consumer Law. Separately, in 2021 the TGA's enabling legislation was amended to create a new regime for the regulation of software as a medical device, including by creating categories of software which require little or no regulation. The TGA has published guidelines about its regulation of software which were updated in February 2026 to deal with AI.

**CD: Across your jurisdiction, what shifts are you seeing in mass tort and class action strategies, including the balance between personal injury claims and emerging 'economic loss only' models?**

ITALY

**Di Mauro:** Italy remains an opt-in jurisdiction, and personal injury and product liability claims are still often brought as individual actions. Italian collective redress, however, has become much more relevant after the 2019 class action reform and the 2023 implementation of the EU Representative Actions Directive. General class action is now in the Code of Civil Procedure and may be used to protect homogeneous individual rights against enterprises or public service operators, including through compensatory or injunctive relief. Separate representative actions under the Consumer Code may be brought by qualified consumer organisations for breaches of specified EU-derived consumer protection rules, including product liability, pharmaceuticals, medical devices, food safety, data protection and unfair commercial practices. In life sciences, we are seeing claimants test both traditional personal injury theories and broader collective strategies. A notable Italian example involved medical breathing devices, where in 2023 the Court of Milan ordered a multinational company to complete safety corrective actions concerning devices allegedly posing serious risks to patients with sleep disorders and respiratory diseases.

CANADA

**Shaw:** In Canada, most personal injury product liability claims continue to proceed as class actions, particularly in provinces that have not amended their class proceedings legislation to require 'predominance' and 'superiority', thresholds that can make certification more difficult. Claims based solely on economic loss models, without actual injury, have been defeated by manufacturers of pharmaceutical products both at certification and on summary judgment. Canadian courts have historically imposed relatively strict limits on recovery for pure economic loss in negligence, especially where the alleged harm is speculative or unaccompanied by physical injury. The scope of pure economic loss, however, is likely to receive significant attention in the coming year. The Supreme Court of Canada has agreed to hear

> **"Software failures and data integrity are increasingly becoming areas of vulnerability for manufacturers."**
>
> *Tony Yeo, Drew & Napier*

an appeal in an automotive class action addressing whether a latent defect, absent physical injury, can support a negligence claim for pure economic loss. The court's ruling has the potential to impact claims against manufacturers in all industries, including pharmaceutical products and medical devices.

AUSTRALIA

**Williams:** There is now High Court authority in motor vehicle claims confirming the availability of 'reduction in value' damages under the Australian Consumer Law for vehicles which breach the consumer guarantee of acceptable quality. Reduction in value damages are recoverable without proof of actual loss. The measure of such damages is the difference between the price a purchaser paid for a product and the price they would have paid had they known the true nature of the product, including any potential for repair. It is likely that this theory of damage will be used to either expand the number of claimants in a product liability claim beyond those who have actually suffered damage, or to bring claims in respect of allegedly defective products where the consequences are too limited or transient to found a claim for damages. We will see claims for reduction in value damages for a range of other consumer goods, including therapeutic goods. We are aware of two claims, involving implantable medical devices, in which reduction in value damages have been claimed.

UNITED STATES

**Sastre:** The US mass tort ecosystem is undergoing significant strategic evolution. We are seeing plaintiffs' firms invest heavily in 'economic loss only' models, particularly consumer protection and warranty-based claims, that allow them to aggregate large putative classes without proving individualised physical injury. This lowers barriers to entry and increases settlement pressure. Simultaneously, traditional personal injury multidistrict litigations (MDLs) remain robust, but bellwether strategies are shifting as courts experiment with different case-selection methodologies. Early, aggressive engagement with case management – particularly science-driven Rule 702 challenges and rigorous application of ascertainability and predominance requirements – remains the most effective tool for containing exposure in an environment where plaintiffs continue to push creative aggregation theories.

SINGAPORE

**Yeo:** In Singapore, representative actions remain relatively uncommon. That said, there have been some notable recent examples – albeit not in the drug and medical device space – such as the 2026 case *Kupetz, Jonathan and others v Terraform Labs Pte Ltd and others*, which dealt with a representative action relating to the crash of the Luna cryptocurrency token and algorithmic

stablecoin TerraUSD. Given the increasingly global nature of litigation and Singapore's position as a global hub, it is possible that representative actions may become more common in the future. Under Singapore law, there is no general exclusionary rule against claims for pure economic loss under the tort of negligence. The general test applies. The threshold inquiry is that of factual foreseeability, followed by a two-stage test comprising proximity and policy considerations. When assessing proximity in cases involving pure economic loss, the twin criteria of voluntary assumption of responsibility and reliance may more appropriately apply, although the court may also refer to other factors where relevant to determine the issue of proximity, such as in the 2025 case *Astrawati Aluwi v Lo Yew Seng and anor.*

## CD: What trends are you observing in the use of scientific and expert evidence in litigation?

UNITED STATES

**Sastre:** Expert evidence remains the decisive battleground in drug and device litigation. We are observing courts applying Rule 702 with increasing rigour, particularly scrutinising general causation methodologies in pharmaceutical cases. Plaintiffs are turning to novel epidemiological approaches and AI-assisted literature reviews to overcome evidentiary thresholds, while defence teams are

leveraging sophisticated biostatistical analyses and regulatory science to challenge unreliable methodologies. The trend toward court-appointed experts in complex MDLs is accelerating, which can benefit well-prepared defendants. Investing early in the science, working closely with medical and scientific advisers to understand the data before it becomes litigation evidence, gives parties a significant strategic advantage when expert challenges and summary judgment motions become ripe.

SINGAPORE

**Yeo:** Under the Rules of Court 2021, no expert evidence may be used in court unless the court has approved it. As far as possible, parties must agree on and appoint a single common expert. The objective of this general rule is to save time and costs. In practice, it is often difficult for parties to agree on and appoint a single common expert. In the past, this has been especially difficult in highly technical matters such as patent disputes, although in a very recent case, a single common expert was appointed in a patent dispute in court. Over time, we expect that we will gradually see more reported cases where parties will agree on and appoint a single common expert.

AUSTRALIA

**Williams:** Expert evidence plays a critical role in Australian litigation. Because Australian trials are almost always before judges rather than juries, experts' evidence is closely tested and experts may be cross-examined at length, sometimes for multiple days. Each party is usually permitted to call its own expert. However, those experts must abide by the expert witness code of conduct, which states that their paramount duty is to the court rather than the party who has called them, limiting lawyers' influence over their reports. It is also common for experts to give evidence in conclave. Competing experts on a particular topic sit in the witness box together, which often moderates more extreme opinions. One interesting recent development is the use of experts unaligned to the parties to assist the court with scientific or technical issues. In the *Roundup* class action, the court appointed an eminent scientist as an 'assessor' who sat on the bench with the judge and assisted the judge to understand and interpret the scientific evidence about causation.

CANADA

**Shaw:** In Canada, courts and counsel are increasingly scrutinising experts' use of AI, particularly following recent decisions sanctioning lawyers who relied on AI-generated authorities containing hallucinations. In some jurisdictions,

including Ontario, experts must now swear that they have verified the authenticity of every authority, document and record cited in their reports. Recent case law has also reinforced the existing evidentiary standards governing the admissibility of expert evidence, especially with respect to an expert's qualifications and the proper scope of their opinions.

ITALY

**Di Mauro:** Scientific and expert evidence is becoming more central in Italian drug and device litigation. Italian civil procedure remains party-driven, where the claimant must prove the facts underlying the claim, and the court generally bases its decision on the evidence submitted by the parties, subject to specific statutory exceptions. In product liability cases, the claimant typically must prove defect, damage and causation, although particular regimes such as article 2050 of the Civil Code may shift or ease aspects of the evidentiary burden. The court-appointed expert, or CTU, is often decisive in complex health and life sciences disputes. Italian courts may appoint a CTU when the dispute requires specific technical knowledge, and each party may appoint its own party expert, or CTP, to engage with the CTU's work. The CTU is an auxiliary of the judge, owes duties to the court, and is expected to answer technical questions rather than make legal determinations. Although the CTU's report is formally not binding on the judge, in practice judges often follow the CTU's conclusions in technically complex disputes.

**"Regulators are increasingly expecting manufacturers to demonstrate ongoing algorithm monitoring, which creates both compliance obligations and a potential litigation record-keeping issue."**

*Hildy Sastre, DLA Piper*

**CD: How are broader societal issues – such as reproductive healthcare debates, environmental chemical exposure and heightened scrutiny of corporate conduct – shaping the volume and nature of drug and device litigation in your jurisdiction?**

SINGAPORE

**Yeo:** We have experienced a steady increase in the volume of pharmaceutical related patent litigation in Singapore in recent years. However, it is

not clear whether this increase is attributable to any particular development in broader societal issues.

AUSTRALIA

**Williams:** Australia has a well-established plaintiff bar which is skilled at exploiting public sentiment to drive interest and engagement from potential claimants and place pressure on defendants. However, the Australian system is perhaps less susceptible to external pressures than some others and there are recent examples of defendants – in drug and device cases and other types of cases – successfully defending class action litigation. The plaintiff bar also recognises that drug and device cases are more complex and costly and have a greater degree of risk than some other kinds of litigation which will sometimes moderate lawyers' willingness to run such cases.

CANADA

**Shaw:** The volume of drug and device litigation has not necessarily increased significantly, but the focus and nature of the claims has evolved. There has been an increasing trend toward 'industry' class actions in which plaintiffs name all or most manufacturers of a product in an industry in a single case or set of cases. In addition, we have seen an increase in claims commenced by governments, particularly at the provincial level. Canadian provinces have enacted special legislation targeting manufacturers of tobacco, opioids and vaping products. These statutes allow governments to recover healthcare costs directly from manufacturers and distributors of certain products and facilitate claims by creating legal presumptions and modifying the burden of proof. These types of laws have withstood several constitutional challenges, including in a recent Supreme Court of Canada decision in 2024 upholding the validity of provisions authorising national government classes for opioid cost recovery.

**"One interesting recent development is the use of experts unaligned to the parties to assist the court with scientific or technical issues."**

*Greg Williams, Clayton Utz*

ITALY

**Di Mauro:** In Italy, broader societal issues are reshaping life sciences litigation by expanding the factual and reputational context in which product disputes arise. The most direct increase in litigation risk is not necessarily in classic drug and device personal injury claims, but in the overlap between health, consumer protection, environmental exposure, data protection, environmental, social and governance and corporate communications. This means manufacturers must think about litigation risk not only as a question of defect and causation, but also as a question of trust, transparency and consistency between public statements and internal compliance evidence. Finally, corporate conduct is under much closer scrutiny, particularly around sustainability, health-related claims, social responsibility claims and consumer transparency. Italian courts and the Italian Competition Authority have already scrutinised greenwashing and sustainability-related communications, including a July 2025 Milan Court decision in a class action concerning allegedly misleading environmental claims and Italian Competition Authority sanctions involving green claims.

UNITED STATES

**Sastre:** Broader societal currents are unmistakably influencing the litigation pipeline. Post-Dobbs reproductive healthcare debates have generated new waves of pharmaceutical litigation around contraceptives and fertility treatments. Perfluoroalkyl and polyfluoroalkyl substances and other environmental chemical exposure claims are expanding from traditional toxic tort frameworks into product liability theories targeting consumer goods manufacturers. Meanwhile, heightened scrutiny of corporate conduct – fuelled by social media, environmental, social and governance-focused investors, and aggressive state attorneys general, means that internal corporate decisions once considered routine may now carry potential litigation risk. Reputational and regulatory exposure increasingly precedes formal litigation. Companies that treat product stewardship as a holistic enterprise risk management function, rather than siloing legal compliance from public affairs and government relations, are often better positioned to navigate this environment. CD