

Contemporary
Issues

The Social Cost of Pharmaceutical Mass Tort Litigation

Mary E Bartkus

Policy Brief

FLJS

www.fljs.org

The Foundation for Law, Justice and Society

in association with **the Centre for Socio-Legal Studies**
and **Wolfson College, University of Oxford**

The Foundation for Law, Justice and Society



Executive Summary

- In the United States, claimant lawyers benefit from contingency fees, no cost-shifting, third party funding, liberal pleading and discovery rules, relaxed standards of proof, sub-litigation of procedural issues, and the threat of punitive damages claims made to lay juries ill-equipped to decide scientific, medical, or other complex issues. These elements combine to encourage a claimant lawyer industry to solicit, bring, and attempt to settle before trial large numbers or 'inventories' of claims that can include speculative, baseless, and borderline claims. Large numbers of personal injury claims involving allegations of product liability are brought as individual actions, not as class actions, United States judges having determined through experience that class actions are not appropriate for personal injury actions. Large numbers of individual actions are case-managed by a single federal judge in the federal system and by a single state judge in each involved state jurisdiction. The courts conduct 'bellwether' trials before lay juries, having as a goal the assessment of the strengths and weaknesses of posited categories of cases leading to the eventual resolution of all cases.
- Some other countries with common law traditions, notably Australia and Canada, have continued to experiment with class action treatment of personal injury actions involving allegations of product liability. Few such cases have been tried to conclusion; many have settled before trial, some after many years of multijurisdictional or other procedural litigation.
- When Merck & Co., Inc. withdrew its pain reliever Vioxx® (rofecoxib) in 'the interests of patients' and 'as the responsible course to take', lawyers brought more than 50,000 claims and class actions in the US and hundreds of jurisdictions across six continents. Although Merck won most of the cases heard in the United States, prevailed in jurisdictions around the world, and 'had done everything that might reasonably be expected of it in the discharge of its duty of care', the company spent approximately \$10 billion in withdrawing the medication and defending and resolving litigation and investigations from 2004 through 2016.
- Developing a new medication takes ten to fifteen years on average, and costs an average of \$2.6 billion from drug discovery through regulatory approval. The \$10 billion that Merck & Co., Inc. spent to defend and resolve litigation necessarily was not available to fund the discovery and development of up to four or more new breakthrough life-saving and life-sustaining medications.
- This enormous social cost is instructive as Europe considers a proposed Directive on collective actions that, even in its current form, would appear to permit diverse national class action regimes and procedures and invite forum shopping and costly litigation, including litigation about the application and effect of the Regulations on jurisdiction, recognition and enforcement of judgments, and choice of law.

The Social Cost of Pharmaceutical Mass Tort Litigation

Introduction

No drug for the relief of pain and inflammation has the safety profile of placebo. Long-term use of traditional non-steroidal anti-inflammatory pain relievers (t-NSAIDs), such as diclofenac, ibuprofen, and naproxen, is limited by serious gastrointestinal side effects including bleeds that can be fatal. Those t-NSAIDs inhibit both COX-1 and COX-2. COX-1 mediates the synthesis of prostaglandins responsible for protecting the stomach lining. COX-2 mediates the synthesis of prostaglandins responsible for pain and inflammation. Scientists reasoned that selectively inhibiting COX-2, sparing COX-1, would relieve pain and inflammation with reduced gastrointestinal toxicity compared to t-NSAIDs. They were right.

After years of research and development including clinical trials in more than 10,000 patients, Merck & Co., Inc.'s selective COX-2 inhibitor, Vioxx® (rofecoxib), was approved by the US Food and Drug Administration (FDA) in May 1999 for certain indications including relief of osteoarthritis, and by regulatory authorities worldwide. By the end of 1999, Vioxx was the fastest growing prescription medication for arthritis in the United States and had been launched in forty-seven other countries.

In March 2000, an outcomes research trial, VIGOR, reported the gastrointestinal benefit of rofecoxib over naproxen in rheumatoid arthritis patients. VIGOR, however, reported more thrombotic cardiovascular events in patients on rofecoxib than in patients on naproxen. Merck provided these reports to regulatory authorities, scientists, and clinicians, and issued a press release. Scientists analysing the available data, including clinical trial data, concluded that 'the weight of the evidence was most consistent with a cardioprotective benefit of naproxen and no

prothrombotic effect of rofecoxib'; the data continued to support their interpretation that 'rofecoxib did not increase the risk of cardiovascular thrombotic events in comparison either to placebo or non-naproxen NSAIDs. There was robust public scientific debate over whether the protective effect of naproxen was the best explanation for the findings. Meanwhile, regulators approved updated prescribing information that included the VIGOR study results.

Then, in late September 2004, interim results of the Merck-sponsored placebo-controlled APPROVe study became available: the risk of thrombotic events in patients taking rofecoxib 25mg began to diverge from placebo beginning after eighteen months of daily therapy, and over time the difference became significant.

Although the relative risk seen in APPROVe did not appear elevated during the first eighteen months of use, and Vioxx could have remained on the market with appropriate prescribing information, on 30 September 2004, Merck voluntarily withdrew Vioxx from markets worldwide because it believed withdrawal would 'best serve the interests of patients' and was 'the responsible course to take', given the questions raised by the data and the availability of alternative therapies without similar placebo-controlled data.¹

Whether a similar increased risk would be seen with non-naproxen t-NSAIDs, such as diclofenac and ibuprofen, was 'an as yet unanswered question.'²

Consequences: Litigation and investigations

By late September 2004, Vioxx was available in more than eighty countries with worldwide sales in 2003

of \$2.5 billion, about 11 per cent of Merck's \$22.5 billion in sales for that year. In the US alone, an estimated 105 million prescriptions had been written and about 20 million patients had taken Vioxx. Outside the US, Vioxx was the bestselling arthritis and pain medication, taken by millions more patients.

Shares in Merck & Co., Inc. dropped at the opening bell on the NY Stock Exchange and were down \$12.07, or 26.78 per cent on the day; the company's capitalization consequently was reduced some \$25 billion on 30 September 2004. The US Securities and Exchange Commission, the US Department of Justice, and US Congressional Committees, among others, launched investigations that would last for years. Lawyers filed court actions in the US, Australia, Canada, European countries, and other countries around the world. Physicians prescribed alternative treatments for disappointed patients. Journalists, critics, partisans, and politicians launched narratives and campaigns. Any short sellers were delighted. Scientists, though, were working to illuminate the entire field of NSAIDs over fifteen years.³

As Merck prepared for a first trial by jury in the United States, US lawyers had filed at least 850 court cases in which 2,425 individuals alleged use of the drug caused personal injuries, ninety putative class actions alleging different types of product liability, and thirty-two shareholder actions. The company already had reserved \$675 million solely for its future legal defence costs.

A Texas jury verdict

In August 2005, a lay jury in Angleton, Texas returned a verdict for one claimant in a case about an arrhythmia, which is not a thrombotic event, in the amount of \$253.4 million. The evidence did not support that verdict, and Merck announced its appeal would be 'about fundamental rights to a fair trial'. Although the unsupported verdict would be overturned nearly three years later for lack of evidence, lawyers promptly filed thousands more court actions, activated hundreds of others, advertised for claimants, and discussed with journalists their litigation strategies for France, Italy, the UK, Australia, and other countries.

By the end of 2005, US lawyers had filed nearly 10,000 court cases in which more than 19,000 individuals alleged that use of the drug had caused personal injuries, and 190 class actions alleging different types of product liability. In thirteen of the putative class actions, claimants from other countries sought to represent hundreds of thousands of Vioxx users 'throughout the world', all users 'residing in Europe', or all users residing in each of eleven countries on four continents. Hundreds more from other countries filed individual actions throughout the United States. Others, comparatively more reasonably, filed or activated more than seventy class or representative actions in home countries on four continents and hundreds of individual actions in more than twenty countries. One year later, US lawyers had filed at least 27,400 court cases in which 46,100 individuals alleged that use of the drug had caused personal injuries, and 264 class actions alleging different types of product liability. Numbers also continued to rise outside the US.

The US resolution

By November 2007, juries in the United States had decided for Merck twelve times and for plaintiffs five times; two of the five plaintiffs' verdicts later would be overturned for insufficient evidence and judgment entered for Merck. About 50,000 cases remained to be tried in the US, however, and Merck already had spent \$1.2 billion of \$1.9 billion reserved solely for its own defence costs; there is no cost-shifting in the US for these cases. For pragmatic business reasons, and without admitting liability or causation, Merck agreed to resolve the US heart attack and ischemic stroke personal injury claims for \$4.85 billion, a deal said to be 'favourable' to the company and 'clearly at the low end of general expectations'. On the news Merck's shares rose 5 per cent in New York lunchtime trading. US claimant lawyers would take home some 32 per cent of \$4.85 billion, i.e. more than \$1.55 billion, plus reasonable litigation expenses. Medicare, Medicaid, other government insurers or providers, and private insurers would take their shares of the remaining \$3.3 billion under liens. Qualifying claimants would realize reduced amounts. The *Financial Times* observed:

The drug may well be remembered best in years to come for its effect on the entire pharmaceuticals industry — not just on Merck. Two long-term effects of Vioxx are clear: a new and more cautious handling of drug risks by US regulators, drugmakers, doctors and patients; and a more aggressive defence posture by drugs companies facing mass litigation.⁴

Australian class action judgments for Merck

The US agreement applied only to certain US claims, and US federal and state courts dismissed the actions filed by persons domiciled outside the US on the basis of *forum non conveniens*. Many of those claimants filed actions in their home countries; those claimants and others with actions already underway in home countries were energized by reports of the US settlement, hoping for quick, large, comparable, settlements at home.

In the wake of the announcement of the US settlement, *The Age* reported in Australia:

About 1000 claimants have joined a Federal Court class action [in Australia] ... [Their lawyer] yesterday predicted thousands more would join the class action and that Merck would feel pressure to join mediation talks. 'We believe this will now lead to discussions and resolution of the international claims by Vioxx victims.'⁵

Merck did not 'feel pressure to join mediation talks', nor would its litigation strategy be influenced by media releases and stories. It continued to prepare and defend the international cases based on the evidence, in court. In March 2010, following a forty-three-day trial during 2009 of a class action against Merck and its subsidiary MSD Australia (MSDA), a Justice of the Federal Court of Australia published his 459-page Reasons for Judgment, in which he dismissed, on a class-wide basis, all claims against Merck, finding: '*Merck had done everything that might reasonably be expected of it in the discharge of its duty of care.*'⁶

The Justice also dismissed, on a class-wide basis, all statutory product defect claims, finding in the company's favour on its state of art defence and, for want of causation evidence, all claims involving stroke, unstable angina, transient ischemic attack,

and peripheral vascular disease. He then found against MSDA in favour of the individual applicant, on his personal claim only, under two sections of the Australian Trade Practices Act.

The applicant, the group members, and MSDA appealed. In October 2011, a Full Court of the Federal Court published Reasons for Judgment, granted MSDA's appeal, dismissed the applicant's personal claims, rejected the applicant's and the group's appeals, affirmed the class-wide rulings for MSDA, and awarded full costs to MSDA.⁷ In May 2012, the High Court refused the claimants' applications for special leave to appeal the Full Court's orders and awarded costs to MSD Australia.⁸ The claimants' law firm, listed on the Australian Stock Exchange, announced an AUD 10.5 million loss on its investment in the case.

About three years later, the Federal Court of Australia approved an agreement resolving and dismissing all claims of the remaining 1,660 registered group members for a total payment by MSDA of AUD 542,000 to be distributed among qualifying group members.⁹

These Australian judgments in Merck's favour would influence outcomes in other countries, given the thorough and well-reasoned dismissal of the claims sounding in negligence and of the claims made under a statute modelled on the European Product Liability Directive.¹⁰

State of the science

When the interim results of APPROVe were received in late September 2004, no one knew whether a similar increased relative risk would be seen with non-naproxen t-NSAIDs, such as diclofenac and ibuprofen.¹¹ Based on studies conducted after the withdrawal, it now appears that all of the non-aspirin NSAIDs, with the possible exception of naproxen, have a similar cardiovascular safety profile to Vioxx.

■ In 2006, a meta-analysis of randomized trials showed that 'selective COX-2 inhibitors are associated with a moderate increase in the risk of vascular events, as are high dose regimens of ibuprofen and diclofenac, but that high dose naproxen is not associated with such an excess.'¹²

-
- In 2013, a meta-analysis of individual participant data from randomized trials showed, with regard to vascular risks of NSAIDs, 'clearly that the vascular risks of diclofenac, and possibly ibuprofen, are similar to coxibs, but that naproxen is not associated with an increased risk of major vascular events'.¹³
 - In 2015, the USFDA issued a Drug Safety Communication 'strengthening an existing warning that NSAIDs increase the chance of a heart attack or stroke' and 'requiring updates to the drug labels of all prescription NSAIDs'.¹⁴

This confirms that Merck scientists achieved what they aimed to create and develop in the 1990s: a new anti-inflammatory pain reliever with a similar safety profile to traditional NSAIDs but with an improved gastrointestinal safety profile.

An enormous social cost

When Merck withdrew Vioxx based on an increased relative risk seen in APPROVe in 'the interests of patients' and 'as the responsible course to take', the company's stock dropped nearly 27 per cent; it took a charge of more than \$726 million to effect the withdrawal; physicians prescribed alternative NSAIDs that did not have rofecoxib's gastrointestinal safety data; governments investigated the company; and lawyers launched more than 50,000 claims and class actions in the US and hundreds of jurisdictions across six continents.

Although Merck won most of the cases heard in the United States, prevailed in jurisdictions around the world, and 'had done everything that might reasonably be expected of it in the discharge of its duty of care', the company spent approximately \$10 billion in withdrawing the medication and defending and resolving litigation and investigations from 2004 through 2016.

Developing a new medication takes ten to fifteen years on average, and costs an average of \$2.6 billion from drug discovery through regulatory approval.¹⁵ The \$10 billion that Merck & Co., Inc. spent to defend and resolve litigation necessarily was not available to fund the discovery and development of up to four or more new breakthrough life-saving and life-sustaining medications.

This enormous social cost is instructive as Europe considers a proposed Directive on collective actions¹⁶ that, even in its current form, would appear to permit diverse national class action regimes and procedures and invite forum shopping and costly litigation, including litigation about the application and effect of the Regulations on jurisdiction, recognition and enforcement of judgments, and choice of law. Alternatives to litigation including those proposed by Chris Hodges and colleagues¹⁷ should be debated, and uniform national safeguards against abusive litigation should be required and enforced through regulatory oversight and rigorous judicial case management.

Notes

- ¹ Merck Press Release, 30 September 2004.
- ² FDA Advisory Committee Background Information, January 2005, p. 30.
- ³ C. Patrono and C. Baigent, 'Nonsteroidal Anti-Inflammatory Drugs and the Heart', *Circulation* (2014) 129: 907–16, at 907 ('the whole field of NSAIDs has been illuminated during the past 15 years.').
- ⁴ Christopher Bowe, 'Vioxx storm to have lasting effects', *Financial Times*, 12 November 2007.
- ⁵ Carmel Egan, 'Painkiller victims look set to join class action', *The Age*, 11 November 2007. See also Slater & Gordon Media Release, 'Vioxx Class Action Numbers Surge', 13 November 2007 ('We are keen to talk with the other side').
- ⁶ *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* [2010] FCA 180, 5 March 2010 (italics added).
- ⁷ *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* [2011] FCAFC 128, 12 October 2011 (findings of fact not sufficient as a matter of law to sustain determination of causation in the applicant's favour).
- ⁸ *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* [2012] HCAB 05.
- ⁹ *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* (No 7) [2015] FCA 123.
- ¹⁰ See Mary E. Bartkus, 'The Cost to Society of Pharmaceutical Mass Tort Litigation', 11 June 2019, available at SSRN: <https://ssrn.com/abstract=3402725>. Detailed accounts of litigation in countries are forthcoming.
- ¹¹ FDA Advisory Committee Background Information, January 2005, pp. 30, 34 (whether a similar increased risk would be seen with non-naproxen t-NSAIDs, such as diclofenac and ibuprofen, was 'an as yet unanswered question'; and 'no other non-aspirin NSAIDs or selective COX-2 inhibitors had been studied in this large a patient group for this duration').
- ¹² P. M. Kearny, C. Baigent, J. Godwin, H. Halls, J. R. Emberson, and C. Patrono, 'Do selective cyclo-oxygenase-2 inhibitors and traditional non-steroidal anti-inflammatory drugs increase the risk of atherothrombosis? Meta-analysis of randomised trials', *BMJ* (2006) 332: 1302–8.
- ¹³ Coxib and traditional NSAID Trialists' (CNT) Collaboration, N. Bhala, J. Emberson, A. Merhi, S. Abramson, N. Arber, et al. 'Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials', *Lancet* (2013) 382: 769–79.
- ¹⁴ FDA Drug Safety Communication, 'FDA strengthens warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes', 9 July 2015.
- ¹⁵ J. A. DiMasi, H. G. Grabowski, and R. A. Hansen, 'Innovation in the pharmaceutical industry: new estimates of R&D costs', *Journal of Health Economics* (2016) 47: 20–33.
- ¹⁶ See [https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2018/0089\(OLP\)](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2018/0089(OLP)) (accessed 4 July 2019).
- ¹⁷ C. Hodges and S. Voet, *Delivering Collective Redress: New Technologies* (Oxford: Hart Publishing, 2018); C. Hodges and R. Steinholtz, *Ethical Business Practice and Regulation: A Behavioural and Values-Based Approach to Compliance and Enforcement* (Oxford: Hart Publishing, 2017); C. Hodges, *Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Culture and Ethics* (Oxford: Hart Publishing, 2015).



The Foundation

The mission of the Foundation is to study, reflect on, and promote an understanding of the role that law plays in society. This is achieved by identifying and analysing issues of contemporary interest and importance. In doing so, it draws on the work of scholars and researchers, and aims to make its work easily accessible to practitioners and professionals, whether in government, business, or the law.

Mary E. Bartkus is Special Counsel, Hughes Hubbard & Reed LLP, New York, New York. Previously she was Executive Director & Senior Counsel, Merck & Co., Inc. Views expressed are her own and do not necessarily reflect the views of Hughes Hubbard & Reed LLP or any of its clients, Merck & Co., Inc., or of any other person, entity, or institution. This Policy Brief is sourced to Mary E. Bartkus, 'The Cost to Society of Pharmaceutical Mass Tort Litigation', 11 June 2019, available at SSRN: <https://ssrn.com/abstract=3402725>.

For further information please visit
our website at www.fljs.org
or contact us at:

The Foundation for **Law, Justice and Society**

Wolfson College
Linton Road
Oxford OX2 6UD

T · +44 (0)1865 284433

F · +44 (0)1865 284434

E · info@fljs.org

W · www.fljs.org

The logo for the Foundation for Law, Justice and Society (FLJS) features the letters 'FLJS' in a large, white, serif font. A small white plus sign is positioned between the 'J' and 'S'.

www.fljs.org