

Do You Have the Heart? A Cross-Border Comparative Case Study Analysis of Certification Legislation and Motions to Certify Vioxx Class Action Lawsuits in Ontario and the United States

Adrienne Shnier

ABSTRACT: The certification motion is arguably the most important step in a class action proceeding, as the court decides whether a putative class will be certified to allow a class action to move forward. The area of class action litigation is one in which there are commonly concurrent and subsequent proceedings in Canada and the United States, creating a unique opportunity for cross-border comparative analyses of the class proceedings and relevant legislation. In 2006 and 2008, proposed plaintiff classes in the United States and Ontario, respectively, brought comparable certification motions to certify Vioxx class action lawsuits. The certification motion in Ontario was granted, while the US motion was denied. This paper undertakes a comparative analysis of the Ontario Class Proceedings Act (*CPA*), the US *Federal Rules of Civil Procedure (FRCP)*, and certification requirements implications. In particular, the *CPA* requirement for common issues and the *FRCP* commonality and typicality requirements are comparatively analyzed based on the Ontarian and US Vioxx class action certification motion decisions and reasons. This paper further uniquely contextualizes the Vioxx class action certification motion decisions within the structural context and culture in which Vioxx's sponsor, Merck, shaped its promotion in the medical and public narrative, discourse, and ethos, from which regulators, physicians, and the public received information on the drug's risk for adverse events. Considered contextually, the *CPA* legislation seems more equitable, as compared with the comparable *FRCP* legislation. This analysis closes with recommendations to broaden the *FRCP* certification legislation to become more equitable in its requirements.

DO YOU HAVE THE HEART? A CROSS-BORDER COMPARATIVE CASE STUDY ANALYSIS OF CERTIFICATION LEGISLATION AND MOTIONS TO CERTIFY VIOXX CLASS ACTION LAWSUITS IN ONTARIO AND THE UNITED STATES

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A. INTRODUCTION

Certification of a class action is arguably the most important step in a class proceeding since it serves as the point at which the court decides if the action can move forward. The motion to certify class actions is intended to serve the interests of all involved parties, including the plaintiff class, the defendant(s), and the court. The plaintiff class is served by ensuring that the class members' rights and interests are protected and that the representative plaintiff shares and can effectively advocate for their interests. Certification further helps to ensure that the defendant(s) will not be exposed to frivolous actions, and that courts will not incur costly and judicially resource-heavy claims that would be better served as separate actions. If a class is not certified, the action cannot proceed in its current form. Class action certification motions in both Canada and the United States have occurred simultaneously and consecutively with each other, sometimes resulting in different outcomes. One such case is the motion to certify Vioxx classes in Ontario and the United States. This case study showcases Ontario and US Vioxx certification motions as a powerful example of the ways in which proceedings have been differently

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considered internationally, despite having been based on similar claims and shared contextual circumstance.

Vioxx (generic name, rofecoxib; drug class, non-steroidal anti-inflammatory drug (NSAID) and COX-2 inhibitor) was both marketed and manufactured in Canada by Merck Frosst Canada and in the United States by Merck Sharp & Dohme Corp, a subsidiary of Merck & Co (Merck). Vioxx received regulatory approval in 1999 by both Health Canada¹ and the US Food and Drug Administration (FDA)² for the treatment of osteoarthritis, rheumatoid arthritis, dysmenorrhoea, and acute pain.³ Vioxx was withdrawn from both the Canadian and US markets on 30 September 2004. Since its withdrawal, Vioxx has been the subject of individual and class action litigation. Approximately 60,000 lawsuits have been filed against Merck in the United States alone,⁴ including more than 160 class actions.⁵

Vioxx is one of many NSAIDs, a class of drugs that has been called “a horror story filled with extravagant claims, bending of the rules, regulatory inaction, and complacency with what the industry wants even though statements from industry scientists were often logically inconsistent or plainly wrong.”⁶ In a US jury trial concerning Merck’s marketing strategies for Vioxx including the way in which Merck informed doctors about its risks and whether Vioxx caused heart attacks, the jurors unanimously stated on 12 March 2007 that Merck exhibited “malicious, oppressive, and outrageous conduct.” The jury found Merck to be guilty of four counts of fraud in its marketing of Vioxx and failure to warn of its risks.⁷ Prior to its market approval, however, and during the approximately five years that Vioxx was prescribed in both Canada and the United States, its public brand as “the best coxib in the class” was carefully crafted by Merck, its scientists, and the research, medical communications, and

1 Health Canada, “Product Information” (30 September 2004), online: health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=64710.

2 “Drug Approval Package: Vioxx (Rofecoxib) Tablets” (20 May 1999), online: *US Food & Drug Administration* www.accessdata.fda.gov/drugsatfda_docs/nda/99/021042_52_Vioxx.cfm.

3 “Vioxx Product Monograph” *Merck Frosst Canada & Co* (11 August 2004), online: pdf.hres.ca/dpd_pm/00000652.PDF.

4 DrugWatch, “Vioxx Litigation” (2017), online: <https://www.drugwatch.com/vioxx/lawsuits/>.

5 *Tiboni v Merck Frosst Canada Ltd*, 2008 CanLII 37911 (Ont SCJ) [Mignacca].

6 Peter C Göttsche et al, *Deadly Medicines and Organized Crime: How Big Pharma Has Corrupted Healthcare* (London: Radcliffe, 2013) at 20.

7 *Ibid* at 155; Janice Hopkins Tanne, “Merck Appeals Rofecoxib Verdict” (2007) 334 *British Medical Journal* 607.

public relations firms to which it contracted various aspects of the work.⁸ Prioritizing profit over patient safety, Merck systematically distorted the medical information, disseminating it through strategies of neutralization, topical avoidance, and disqualification that prevented physicians and patients from being able to make an informed choice about prescribing and taking Vioxx, respectively.⁹

Vioxx was strategically groomed and marketed to successfully become a blockbuster drug. A drug becomes a blockbuster when it has generated \$1 billion in profits in one year. Vioxx achieved blockbuster status and was widely prescribed by physicians, making US\$2.5 billion in sales for Merck on the US market in the year prior to its withdrawal.¹⁰ Estimates suggest that 15.5 million prescriptions of Vioxx were written for approximately 350,000 people in Canada between 1999 and 2004, while during the same time period, 105 million prescriptions for Vioxx were written for 20 million people in the United States.¹¹ The success of Vioxx sales is owed to Merck's public relations and marketing strategies, which subsequently became the foundations for plaintiffs' negligent design and failure-to-warn claims.

Although many of the now public internal Merck documents originated in the United States, Merck used the promotional documents, strategies, and messaging internationally. Especially in the case of medical journal articles, physicians in Canada and worldwide rely on prominent, respected medical journals for their drug safety and prescribing information. Many of these journals originate in the United States. With the generally increasing trend of pharmaceutical consumption globally¹² and, therefore, the increased risk of exposure to not only adverse events but also harm from potential scientific misconduct as private industry

8 Merck & Co, Inc, "2001 Profit Plan for Vioxx" (1 September 2000) at 3, online: *Drug Industry Document Archive* www.industrydocumentslibrary.ucsf.edu/drug/docs/#id=mxpdo217.

9 Alexander Lyon, "Putting Patients First': Systematically Distorted Communication and Merck's Marketing of Vioxx" (2007) 35:4 *Journal of Applied Communication Research* 376.

10 "Demise of a Blockbuster Drug" *The New York Times* (1 October 2004), online: <https://nyti.ms/2SaUXzS>.

11 Mignacca, above note 5 at para 46.

12 Organization for Economic Co-operation and Development, "Health Status: Pharmaceutical Consumption" (Paris: OECD, 2007), online: stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT# ["Pharmaceutical Consumption" is located in the blue left-hand column under Pharmaceutical Market].

promotes pharmaceuticals in the world market, the time is ripe to analyze class certification in Canada and the United States.

This paper examines the class action legislation and Vioxx motions on certification, specifically pertaining to the common issues as well as commonality and typicality requirements in Ontario and the United States, respectively. The certification step has been described as the most hotly contested certification criterion.¹³ Based on the Ontario common issues and US commonality and typicality legislation, this analysis considers two motions, one in each jurisdiction, for the certification of Vioxx classes. The certification motion in Ontario was granted, while the US motion for certification was denied, suggesting the potential for a friendlier certification environment in Ontario than in the United States. Legislation from Ontario and the United States are suitable for comparison because several Vioxx lawsuits have occurred concurrently and simultaneously on both sides of the border. Both certification motions were also heard and decided under the most recent certification legislation in their respective jurisdictions, providing an opportunity to examine the interpretation and application of most up-to-date legislation.

This analysis is relevant to products liability litigation. The informational ethos, narrative, and discourse created by Merck and its contracted entities to develop its multi-year, multi-faceted marketing strategy to promote sales of Vioxx also created the foundation upon which class action lawsuits against the company have been certified. To illustrate, this critical analysis of certification legislation and motion decisions in Ontario and the United States is complemented and informed by key examples of Merck's conduct in its Vioxx marketing story that help to foster a better understanding of the environment that led to the subject class actions. Finally, this paper concludes with insights and recommendations as the Vioxx case study may serve to inform common issues, commonality, and typicality analyses in future pharmaceutical, and more broadly, products liability, class actions.

13 Janet Walker et al, *Class Actions in Canada: Cases, Notes and Materials* (Toronto: Edmond Montgomery, 2014) at 81.

B. A DOUBLE-EDGED SWORD: THE CREATION OF COMMON ISSUES BETWEEN PLAINTIFFS THROUGH THE CREATION OF A BLOCKBUSTER DRUG

Prior to the approval of Vioxx in 1999, and during its life on the market, Merck and its scientists used a series of strategies, which amount to research misconduct,¹⁴ to systemically conceal the dangers that they knew to be associated with Vioxx. For example, in 1996, Merck scientists knew of the drug's heart attack risk and that it caused thrombosis; however, Merck convinced the scientists who authored the study to change their discussion of these side effects to a sentence that merely neutralized the perception of risk.¹⁵ In 1997, a Merck scientist also insisted that if trial participants were prohibited from taking aspirin during that trial, then patients who were taking Vioxx might suffer more heart attacks, which would "kill the drug."¹⁶

The data fraud¹⁷ and scientific misconduct¹⁸ committed in Merck's Vioxx gastrointestinal outcomes research (VIGOR) study played a key role in allowing Merck to favourably market Vioxx to both doctors and the public. A senior Merck scientist proposed the idea of excluding trial participants with a high risk for cardiovascular events in the VIGOR study, which was then published in the *New England Journal of Medicine (NEJM)* in 2000. This exclusion of participants allowed the difference in cardiovascular events associated with Vioxx to "not be evident" when the drug was compared with its competitors.¹⁹ Moreover, three cases of myocardial infarction were deliberately omitted by Merck from the VIGOR manuscript two days before it was submitted to the *NEJM*.²⁰ Merck

14 Research misconduct has been defined as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." See Stephen L. George & Marc Buyse, "Data Fraud in Clinical Trials" (2015) 5:2 *Clinical Investigation (London)* 161 at 161.

15 Gøtzsche et al, above note 6 at 155.

16 *Ibid.*

17 Data fraud has been defined as "intent to cheat" and "deliberately not reporting" the data; see George & Buyse, above note 14 at 161.

18 Scientific misconduct has been defined as the "selective reporting of results, failure to follow the written protocol, emphasis on secondary rather than primary outcomes, use of improper statistical methods, failure to publish and so on." Gøtzsche et al, above note 6 at 155.

19 *Ibid.* at 155-56.

20 *Ibid.*

scientists also mis-coded a heart attack death and incorrectly attributed two extra deaths to its competitor in the trial, naproxen, to craft a more marketable message in favour of Vioxx.²¹ Inclusion and correct reporting of these cardiovascular events would have undermined Merck's assertion in the article that Vioxx only showed an increased risk for heart attack in already high-risk groups, especially since these omitted heart attacks all occurred in the low-risk participant group.²² Further, Merck did not submit any studies that were designed to evaluate the risk of cardiovascular events while taking Vioxx to the FDA in its new drug application, so the US regulator did not have access to this data on its review of Vioxx for the market.²³ Merck also deceitfully designated an earlier cut-off date for thrombotic events than for gastrointestinal events,²⁴ thereby failing to collect and report all of the necessary data on participants' cardiovascular events while ingesting Vioxx.

In 2001, researchers who were independent from industry analyzed FDA data, documenting that Vioxx doubled the risk of serious cardiovascular events with statistical significance in the VIGOR trial.²⁵ In 2003, Merck published the Assessment of Differences between Vioxx and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness (ADVANTAGE) trial,²⁶ a huge seeding trial,²⁷ in which eight participants suffered heart attacks or sudden cardiac death on Vioxx compared with only one who was taking its competitor drug, naproxen. Despite these findings, three of the Vioxx adverse events disappeared from the publication, which reduced the statistical significance from significant to not

21 *Ibid* at 156.

22 *Ibid.*

23 *Ibid* at 155.

24 *Ibid* at 156.

25 *Ibid* at 157.

26 *Ibid.*

27 A seeding trial is a controversial method of conducting a phase IV clinical trial, where the study operates under the façade of testing a scientific hypothesis, but is actually intended as a marketing tool whereby the sponsoring drug company makes the drug product known to its target prescribing physicians in an effort to alter their prescribing habits. A seeding trial occurs when drug companies sponsor and run a trial involving hundreds of physicians, each of whom recruit only a few patients. Physicians may receive honoraria for their role as investigators in these trials and they may also receive payment from the sponsor for each patient that they enroll. The physician, perhaps unknowingly, plays an essential role in the marketing scheme of the drug product. See Harold C Sox & Drummond Rennie, "Seeding Trials: Just Say 'No'" (2008) 149:4 *Annals of Internal Medicine* 279 at 279–80.

significant. Merck decided that a death from heart attack while on Vioxx should be re-coded as “unknown,” and this was submitted to the FDA.²⁸ In 2004, a meta-analysis was performed by researchers who were independent from Merck. They found an increased risk of myocardial infarction with Vioxx. This connection had been made by Merck in 2000.²⁹ Merck deliberately misinformed both the regulator and physicians of Vioxx’s safety profile and the drug was promoted as safe, despite evidence to the contrary. Merck publicly disseminated drug safety information that it knew to be false or misleading.

Merck’s internal documents provide evidence that it used ghostwriters from medical writing organizations (MWOs) to publish articles on Vioxx in high-impact, reputable medical journals. Medical ghostwriting has been defined as the practice through which a drug company may provide pre-analyzed and interpreted data, conclusions, and/or messages to be written into a manuscript, on which a “guest” author who is a prominent academic physician or researcher agrees to sign their name prior to its submission to a medical journal. There is usually no indication that this ghosting process has occurred and no disclosure of the drug company’s role in the shaping of the data, its interpretation, and the writing of the manuscript. Sometimes an MWO is retained by the drug company to both craft these manuscripts and recruit the guest authors. In these cases, the MWO’s medical writer, or “ghostwriter,” is either unnamed or may be given an acknowledgement at the end of the published article, thanking the individual for their “editorial support.”³⁰ Merck’s internal documents provide evidence that guest authors received anywhere from \$750 to \$2,500 in honoraria payments for agreeing to be named as authors on the ghostwritten papers.³¹

Merck took its structural misrepresentation of Vioxx’s data in published scientific literature one step further by developing its own fake medical journals, some of which include the *Australasian Journal of Cardiology*, *Australasian Journal of Cardiovascular Medicine*, and *Australasian Journal of Bone and Joint Medicine*. Merck published these journals

28 Götzsche et al, above note 6 at 158.

29 *Ibid* at 157.

30 Adriane J Fugh-Berman, “The Haunting of Medical Journals: How Ghostwriting Sold ‘HRT’” (2010) 7:9 *PLoS Medicine* e1000335 at 8–9.

31 Joseph S Ross et al, “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation” (2008) 299:15 *Journal of the American Medical Association* 1800 at 1806.

to appear as if the contained articles were peer-reviewed when, in fact, they were wholly products of Merck to be used as marketing tools. Merck disseminated these journals by paying the academic publisher, Elsevier, to ensure their circulation to its target audiences between 2000 and 2005. The majority of the articles published in these “journals” presented favourable data on Merck’s products, including Vioxx, while failing to disclose this sponsorship and origin of the journal and its articles.³² An Elsevier spokesperson commented that he believed that issues from the *Australasian Journal of Bone and Joint Medicine* alone were distributed to between 10,000 and 20,000 physicians in Australia.³³ It is unclear how many physicians in Canada or the United States received issues from these journals; however, it is conceivable that given our highly globalized world and reliance on international research via the internet, both Canadian and US physicians were exposed to these journal issues and articles. Alternatively, if they were not, they were likely exposed to the same data and messaging from Merck through other mechanisms, such as drug sales representatives, in Canada and the United States.

Drug companies regularly instruct their sales representatives to provide physicians with misleading information about their products in an effort to convince their target physicians to prescribe their product.³⁴ For instance, in February 2001, the FDA discussed the VIGOR study with Merck because of evidence that showed a five-fold increase in myocardial infarction with Vioxx when compared with naproxen. The FDA asked Merck to alert doctors of these results. Instead, the following day, Merck instructed over 3,000 sales representatives, “DO NOT INITIATE DISCUSSIONS ON THE . . . RESULTS OF THE . . . VIGOR STUDY.”³⁵ In addition, Merck disseminated a pamphlet to its sales representatives that exaggerated the benefits of Vioxx, while downplaying its risk by promoting Vioxx as being associated with one-eighth the mortality rate from cardiovascular causes compared with other NSAIDs. This pamphlet included misleading analyses of short-term studies and failed to include

32 Bob Grant, “Elsevier Published 6 Fake Journals” *The Scientist* (7 May 2009), online: www.the-scientist.com/the-nutshell/elsevier-published-6-fake-journals-44160.

33 Natasha Singer, “Merck Paid for ‘Journal’ Without Disclosure” *The New York Times* (13 May 2009), online: <https://nyti.ms/2HzFwo3>.

34 Barbara Mintzes et al, “Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States” (2013) 28:10 *Journal of General Internal Medicine* 1368 at 1370.

35 Gøtzsche et al, above note 6 at 159 [emphasis in original].

any data from the VIGOR study. Also in 2001, Merck issued a press release stating that “Merck reconfirms the cardiovascular safety of Vioxx.”³⁶

Merck’s unwavering promotion of Vioxx in spite of its known serious adverse effect on cardiovascular events is clearly illustrated in one of the PowerPoint presentations that Merck used to train its sales representatives.³⁷ In this presentation, Merck symbolically uses the game of dodge-ball to demonstrate to its employees the ways in which they can handle and diffuse questions from physicians about the adverse cardiovascular events that result from Vioxx. On each presentation slide is the phrase “Dodge Ball” above the drug’s name, “Vioxx (rofecoxib).” Merck provides examples of likely questions that its sales representatives will be asked by physicians: “I am concerned with dose-related increases in hypertension with Vioxx,” “I am concerned about the cardiovascular effects of Vioxx? [sic],” “The competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than Celebrex,” “I am concerned about the safety profile with Vioxx.”³⁸ In the slides, Merck labelled each of these concerns as “obstacles,” numbering them consecutively throughout the presentation. In answer to each of these concerns, Merck visually instructed its sales representatives simply to “DODGE!” these questions with images of dodge-balls on the slides.³⁹ (See Merck’s dodge-ball themed PowerPoint presentation at Appendix 1.)

In 2004, the year that Merck issued a withdrawal of Vioxx from the market, its CEO received over US\$36 million in performance-based bonuses, in addition to his base salary. The CEO was never indicted. In total, an estimated 80 million people were treated with Vioxx. Based on this number and its now known side-effects data, approximately 120,000 were killed by Vioxx’s cardiovascular side effects. This number increases when people who suffered cardiovascular side effects and were not killed are considered. These numbers are likely to be conservative estimates or underestimates.⁴⁰ By 2007, Merck had already spent US\$1.2 billion on legal fees and announced a settlement for its illegal promotion and false statements about Vioxx’s cardiovascular safety as well as its off-label promotion. In 2011, Merck pleaded guilty to a criminal violation of federal

36 *Ibid.*

37 Unknown, “Presentation Re: Dodge Ball,” online: *Drug Industry Document Archive* www.industrydocumentslibrary.ucsf.edu/drug/docs/#id=nghwo217.

38 *Ibid.*

39 *Ibid.*

40 Gøtzsche et al, above note 6 at 160–61.

law and was fined almost \$1 billion in criminal and civil damages due to its illegal promotion and marketing of Vioxx.⁴¹ In 2012, a Canadian class action lawsuit against Merck was settled, followed by a class action settlement in the United States. Merck's conduct, which included the illegal promotion and marketing of Vioxx, contributed to the success of Vioxx as a blockbuster drug. This same conduct subsequently became the foundation for the common issues that were advanced by the proposed plaintiff classes in Ontario and the United States.

C. CERTIFICATION AND COMMON ISSUES LEGISLATION: ONTARIO AND THE UNITED STATES

1) The Importance of Class Action Certification Legislation

The certification stage of a class action lawsuit is an essential requirement that must be satisfied in order for a class action to proceed. The certification requirement serves as a gatekeeper to accessing justice, functioning to either extend or limit proposed plaintiffs' access to justice through inclusion as members in proposed classes, and subsequent access to potential legal remedies that may be so ordered. Class certification has the power to transform legitimate claims, which would otherwise be non-viable due to the cost of litigation, into viable claims in the aggregate.⁴² Key to this process is the transformative nature of certification as it provides an avenue for plaintiffs' rights to be meaningfully exercised through the accumulation of claims in the composite. This is a substantive outcome of certification.⁴³

Certification of a class has advantages for the plaintiffs, the defendant(s), and their counsel. For the plaintiffs and their counsel, a certified class means a broad distribution of the costs of litigation across the class when the high costs of litigation serve as a barrier to advancing a claim, especially in complex cases where damages per plaintiff are minimal and

41 US Department of Justice, News Release, 11-1524, "US Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx" (22 November 2011), online: www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion.

42 Mathew Good, "Access to Justice, Judicial Economy, and Behaviour Modification: Exploring the Goals of Canadian Class Actions" (2009) 47 *Alberta Law Review* 185 at 187.

43 *Ibid* at 225.

where the defendants are better resourced.⁴⁴ For the defendant(s) and their counsel, certification of a class offers some sense of predictability in terms of the identifiable class and, therefore, its potential for and risk of exposure during the action. A defendant may also benefit from the certification of a class action because it creates an opportunity for the parties to settle without the defendant being required to admit liability or be found liable in court. In favour of all parties, the court is tasked with the responsibility of ensuring a fair and efficient resolution. If the court were to shirk this responsibility and permit the certification of ill-conceived class actions, all parties would be disadvantaged by the resultant protracted, costly, and unproductive litigation process.⁴⁵

2) Canadian and US Legislation as Suitable Comparators

Canada and the United States have several similarities that make these countries ideal for cross-border comparisons. For instance, both Canada and the United States are federal states whose federal governments are afforded considerable authority, while still respecting the authority of their respective provincial and territorial or state governments. In the United States, however, federal courts have an expansive ability to intervene in a variety of multijurisdictional matters, including class actions. The US federal judiciary's authority to hear class actions resides in its broad interpretation of interstate commerce as per the Commerce Clause of the US Constitution; therefore, multijurisdictional class actions can be brought in either state or federal courts in the United States.⁴⁶ Alternatively, in Canada, the Federal Court has no jurisdiction to hear matters that typically give rise to class actions. Provincial courts cannot hear multijurisdictional plaintiff classes and federal courts cannot hear class actions unless the claims are made against the Crown.⁴⁷ The inability of the Federal Court in Canada to hear class actions rests on the principle that it does not possess the authority to assert jurisdiction over non-residents of potentially involved provinces. This issue has created a barrier to the development of multijurisdictional class actions in Canada,

44 Walker et al, above note 13 at 55.

45 *Ibid* at 56.

46 SI Strong, "Resolving Mass Legal Disputes through Class Arbitration: The United States and Canada Compared" (2011) 37:4 *North Carolina Journal of International Law and Commercial Regulation* 921 at 924-25.

47 *Ibid*.

whereas the United States has continued its development of multijurisdictional class actions.

3) Certification: Common Issues Legislation under Ontario's *Class Proceedings Act, 1992*

In Ontario, class action legislation has been enacted provincially under the *Class Proceedings Act, 1992 (CPA)*.⁴⁸ On 28 July 2008, Cullity J of the Ontario Superior Court of Justice, as he then was, certified a Vioxx class action in Ontario as against Merck. The representative plaintiffs for the Ontario class were Robert Tiboni, Benny Mignacca, and Elaine Mignacca (the Mignacca class). The Mignacca class was certified under the authority of section 5(1) of the *CPA*, which allows a court to certify a class proceeding on a motion. The 5(1) test that a judge must apply to determine whether a class should be certified contemplates, and is satisfied, if:

- (a) the pleadings or the notice of application discloses a cause of action;
- (b) there is an identifiable class of two or more persons that would be represented by the representative plaintiff or defendant;
- (c) the claims or defences of the class members raise common issues;
- (d) the class proceeding would be the preferable procedure for the resolution of common issues; and
- (e) there is a representative plaintiff or defendant who,
 - (i) would fairly and adequately represent the interests of the class,
 - (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
 - (iii) does not have, on the common issues for the class, an interest in conflict with the interests of other class members.⁴⁹

For the purposes of this paper, section 5(1)(c) regarding common issues will be considered. Section 1 of the *CPA* defines “common issues” as:

- (a) common but not necessarily identical issues of fact, or
- (b) common but not necessarily identical issues of law that arise from common but not necessarily identical facts.⁵⁰

⁴⁸ *Class Proceedings Act, 1992*, SO 1992, c 6 [CPA].

⁴⁹ *Ibid*, s 5(1).

⁵⁰ *Ibid*, s 1.

4) Certification: Commonality and Typicality Legislation in the United States' *Federal Rules of Civil Procedure*

Unlike the Canadian legislative class action regime, the United States has enacted federal class action legislation. On 22 November 2006, Fallon J of the US district court denied the Plaintiffs' Steering Committee's (PSC) motion for class certification (the PSC proposed class).⁵¹ The authority under which judges are able to certify class actions in the United States originates under Rule 23 — Class Actions of the *Federal Rules of Civil Procedure (FRCP)*, which states that:

Rule 23(a) Prerequisites. One or more members of a class may sue or be sued as representative parties on behalf of all members only if:

- (1) the class is so numerous that joinder of all members is impracticable [numerosity];
- (2) there are questions of law or fact common to the class [commonality];
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class [typicality]; and
- (4) the representative parties will fairly and adequately protect the interests of the class [adequacy of representation].⁵²

For the purposes of this paper, Rules 23(a)(2) and 23(a)(3) will be considered.

D. ALLEGATIONS AGAINST MERCK DURING CERTIFICATION BY THE PROPOSED CLASSES IN ONTARIO AND THE UNITED STATES

The PSC proposed class submitted to the court a Master Class Action Complaint for Cases Involving Personal Injury and Wrongful Death, which alleged that

Vioxx was a defective product; that Merck misrepresented the safety of Vioxx and negligently manufactured, marketed, advertised, and sold Vioxx as a safe prescription medication, when in fact Merck knew or should have known that Vioxx was not safe for its intended purpose; and that Vioxx caused serious medical problems, and in certain patients, catastrophic injuries and death.⁵³

51 *In Re: Vioxx Products Liability Litigation (MDL No 1657)*, 239 FRD 450 (ED La 2006) [*Vioxx Products Liability*].

52 *Federal Rules of Civil Procedure*, USC §§ 23(a)(1)–(4) (2017).

53 *Vioxx Products Liability*, above note 51 at 4.

Merck opposed certification of the PSC proposed class. Merck argued that the proposed class members could not be heard together due to their lack of commonality of law. Merck also argued that the claims of the proposed class must be adjudicated using the substantive laws of the states in which the proposed plaintiffs resided, ingested, and were allegedly injured by Vioxx. Merck then argued that certification of the PSC proposed class was inappropriate because each proposed plaintiff's claim involved individual determination of separate and distinct factual issues.⁵⁴ The PSC proposed class also alleged that Merck failed to sufficiently warn physicians, consumers, and the media of the cardiovascular risks of Vioxx and of what Merck knew of the risks associated with the drug.⁵⁵

Similar to the PSC proposed class, the Mignacca class claimed damages in negligence against the defendants or, alternatively, demanded a disgorgement of revenues from the sale of Vioxx in Canada, in line with the principle of behaviour modification.⁵⁶ Product liability claims, typically grounded in negligence, are usually categorized as negligent manufacturing claims, negligent design claims, failure-to-warn claims, and pure economic loss claims.⁵⁷ The claims against Merck regarding Vioxx fit squarely into the negligent design and failure-to-warn categories. The Mignacca class advanced the claim that Vioxx was dangerously defective because of its increased risk of cardiovascular events, including heart attacks and strokes, with consumption.⁵⁸ Furthermore, the Mignacca class advanced the argument that Merck was negligent in its design, development, testing, manufacturing, and selling of Vioxx in Canada, and failed to warn of the cardiovascular risks when they knew or ought to have known of them years before the drug was marketed in Canada. The Mignacca class further alleged that Merck downplayed or concealed the risk of adverse events to physicians, the public, and regulatory authorities. Despite knowing of the cardiovascular risks associated with Vioxx, Merck continued to market and distribute it as safe and effective while the evidence of its risks accumulated.⁵⁹

54 *Ibid* at 5.

55 *Ibid*.

56 *Mignacca*, above note 5 at para 59; Good, above note 42 at 206.

57 Michael A Eizenga & Ashley L Paterson, "The Quintessentials of Product Liability Class Actions" (2015) 34:2 *Advocates' Journal* 21 at 22.

58 *Mignacca*, above note 5 at para 45.

59 *Ibid*.

Justice Cullity identified a total of twelve common issues proposed by the Mignacca class. (Issues 1 to 3 are reproduced and analyzed in Section E(1) of this article.) In particular, Merck raised arguments in opposition of Issue 2 regarding its duty of care and standard of care, as well as Issue 3 pertaining to failure-to-warn. Merck attempted to blur the line between the proposed common issues and individual issues. If Merck had been successful in these arguments, the onus would have been deflected from the company, its knowledge, and its conduct in promoting Vioxx. Both the court and Merck accepted that the onus rested with the drug company to provide information to physicians as prescribed by regulation. If Merck breached this obligation, Cullity J stated that Merck may then be found to have breached its duty and standard of care, whether or not patients or physicians were able to obtain non-Merck information, and whether or not the physician informed the patient of all appropriate warnings.⁶⁰ However, as we are able to see from Merck's creating and shaping of Vioxx's public and medical informational narrative and discourse, Merck failed to provide physicians or regulatory bodies with Vioxx's safety information as it internally knew it, putting all consumers of Vioxx at undue risk for harm.

E. CERTIFICATION: ONTARIO'S COMMON ISSUE CRITERION AS COMPARED WITH THE UNITED STATES' COMMONALITY AND TYPICALLY CRITERIA

1) Establishing Common Issues under Ontario's *Class Proceedings Act, 1992*

In Ontario, the common issues legislation in section 5(1)(c) of the *CPA* contemplates whether "the claims or defences of the class members raise common issues."⁶¹ The common issues analysis for the purposes of class certification stems from a defendant's wrongdoing that has systematically affected all class members, rather than from individual issues, which must be separately investigated as to the specific circumstances of each plaintiff.⁶² Because the purpose of class action proceedings is to resolve common issues on behalf of a class, the order certifying the class will also

60 *Ibid* at para 88.

61 *CPA*, above note 48, s 5(1)(c).

62 Walker et al, above note 13 at 81.

clearly indicate which issues are to be decided on a common basis. Satisfying the common issues requirement is essential to the justification of the presumable costs of a class action. Common issues must be a separate inquiry from the methods that would best resolve the collective class' claims.⁶³

The Mignacca class proposed twelve common issues, the first five of which Cullity J suggested were most important for the certification motion. Of particular interest in this analysis are the first three:

- 1) Was Vioxx defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the defendants? If so, how?
- 2) Did any of the defendants owe a duty of care to the class members? If so, what was the standard of care? Did any of the defendants breach the standard of care? Were any of the defendants negligent? If so, who, when and why?
- 3) Did any of the defendants have a duty to warn the class members of the risks of harm from Vioxx? If so, did any of them fail to warn in a timely manner? If so, who, when and how?⁶⁴

The first common issue proposed by the Mignacca class was generally accepted by the court, relying on *Harrington v Dow Corning Corp.*⁶⁵ *Harrington* provides that this issue of general causation as a common issue is typically raised as “the first step in every products liability case alleging negligent design, manufacture, or marketing.”⁶⁶ Likewise, the United States refers to this same typical first step in products liability actions as “general causation.”⁶⁷ On this basis, Cullity J accepted the negligent design issue as one that was common in nature and could be extrapolated to each member of the class. Merck criticized the first issue by arguing that the court at trial could find Vioxx fit for some uses and not for others and that the evidence shows that Vioxx would be harmful only for certain class members in certain circumstances and, therefore, could only be interrogated on an individual basis.⁶⁸ These arguments were not accepted

63 *Ibid* at 82.

64 *Mignacca*, above note 5 at para 83.

65 2000 BCCA 605 [*Harrington*].

66 *Ibid* at para 42.

67 *Mignacca*, above note 5 at para 85.

68 *Ibid* at para 87.

by Cullity J; however, as we will see, they were accepted by Fallon J in the United States based on the typicality criterion.

In *Singer v Schering-Plough Canada Inc*,⁶⁹ a sunscreen labelling case, Strathy J of the Ontario Superior Court of Justice, as he then was, explained the application of common issues within the certification analysis in Ontario. The certification, and therefore the common issues analysis, is to be undertaken in a purposive and generous manner with an eye to the goals that class actions ought to achieve, including access to justice, judicial economy, sanctioning wrongdoers, and behaviour modification.⁷⁰ The common issues analysis in Ontario is not merit-based; however, a common issues analysis at certification must also be founded in evidence before the court in order to establish the existence of common issues.⁷¹ Furthermore, the proposed common issues must be a substantial ingredient in each class member's claim, with the resolution of a common issue necessary to the resolution of that issue for the class.⁷²

In an effort to avoid frivolous claims by representative plaintiffs, the court requires the provision of a certain minimum evidentiary basis during a certification motion hearing as per the "some basis in fact" (SBIF) test.⁷³ The SBIF test originates in the 1998 case *Taub v Manufacturers Life Insurance Co*,⁷⁴ an apartment building mould case in which the plaintiff produced only her own affidavit, which did not provide any detail regarding the nature of harm or locations of mould in the apartment building, except in her unit. The SBIF test was firmly established three years later in the 2001 case *Hollick v Toronto (City)*,⁷⁵ in which the court agreed with the *Report of the Attorney General's Advisory Committee on Class Action Reform*,⁷⁶ which states that the class representative must establish an evidentiary basis for each of the certification requirements in section 5(1) of the CPA. Representative plaintiffs must show that there is admissible evidence to support their allegations.

69 2010 ONSC 42 [*Singer*].

70 *Ibid* at para 60; *Western Canadian Shopping Centres Inc v Dutton*, 2001 SCC 46 at paras 26–29 [*Western Canadian Shopping Centres*]; *Hollick v Toronto (City)*, 2001 SCC 68 at para 15 [*Hollick*].

71 Walker et al, above note 13 at 82.

72 *Ibid* at 82–83.

73 Eizenga & Patterson, above note 57 at para 2.

74 *Taub v Manufacturers Life Insurance Co*, [1998] OJ No 2694 at para 4 (Gen Div).

75 *Hollick*, above note 70 at para 25.

76 *Ibid* at para 31.

Importantly, the SBIF test requires neither proof of causation nor an evaluation of the merits of the evidence presented to the court at the certification stage. Rather, the test requires that the representative plaintiffs show that their claims have some foundation in fact and, in a products liability case, evidence of commonality across the class such that class certification would be the most efficient mechanism by which to try the claims.⁷⁷ This is often achieved by careful crafting of the class definition and common questions. Similarly to *Singer*, the Mignacca class crafted its common questions in a manner that focused on the conduct of the defendant at the structural level, rather than posing questions that required only a microanalytical approach of the characteristics of the individuals within the class. The latter approach may have otherwise exposed the class to vulnerability, had the defendant argued for individual rather than class litigation as the preferable mechanism for resolution. The posing of common issues is considered to be an exercise burdened with a low evidentiary standard, resulting in a seemingly more favourable product liability class action certification environment for plaintiffs in Ontario.⁷⁸

By relying on the structural and systemic conduct of the defendants, the Mignacca class found common issues based on the common circumstances in which the proposed plaintiffs were prescribed Vioxx by their physicians. In the case of pharmaceutical products, and specifically in the case of Vioxx, common questions concerning design negligence, duty and standard of care, and failure-to-warn would arguably apply en masse to people who consumed Vioxx, given its status as a blockbuster drug. Blockbuster status, as Vioxx achieved, indicates that the drug was prescribed by physicians to, and purchased by, a significant number of people, using far-reaching promotional strategies to reach the ultimate consumers and their physicians. By structuring the common questions in such a way that interrogated the defendants' conduct, the Mignacca class was able to satisfy the court that the common questions would not create conflicting answers among class members. Further, in a class action, success for one must mean success for all; therefore a plaintiff's answer to a common question must be capable of being extrapolated to each member of the proposed class.⁷⁹ Framing of the common issues in a manner that highlighted and relied upon Merck's conduct achieved this result.

77 Above note 57 at 2.

78 *Ibid* at 3.

79 *Singer*, above note 69 at para 140; *Western Canadian Shopping Centres*, above note 70 at para 40; *Merck Frosst Canada Ltd v Wuttunee*, 2009 SKCA 43 at paras 145–46 and

2) Establishing Commonality Under the United States *Federal Rules of Civil Procedure*

Judge Fallon determined that the PSC proposed class met the commonality requirement under Rule 23(a)(2). The commonality criterion in the United States has been defined similarly to the concept of common issues in Ontario's *CPA*. The *FRCP* states that the commonality criterion is satisfied if there are issues of law or fact that are common to the class;⁸⁰ however, not all questions of law or fact that are raised in a class proceeding must be common, and this assessment is one that is qualitative in nature.⁸¹ As with the *CPA*'s common issues requirement, commonality is satisfied if the resolution of at least one issue will affect "all or a significant number of class members."⁸² Additionally, and similarly to Ontario, that some plaintiffs in a putative class might have different claims or require individual assessment does not defeat commonality.⁸³ The relative ease with which commonality is satisfied in the United States seems to mirror that of Ontario. Judge Fallon, who heard the PSC proposed class certification, decided that common questions of fact existed concerning the development, manufacturing, and testing of Vioxx, as well as the ways in which it affects the human body. Judge Fallon further asserted that the common questions raised by the PSC proposed class relate to the concept of "general causation," which would consider whether Vioxx was capable of causing adverse cardiovascular events.⁸⁴

When the certification question regarding the PSC proposed class was decided in 2006, the definition of commonality required that there be legal or factual issues shared between members of the putative class. It was on this basis that Fallon J decided commonality in favour of the PSC proposed class; however, satisfying commonality in the United States has become more difficult for putative plaintiffs since the US Supreme Court's *Wal-Mart Stores, Inc v Dukes*⁸⁵ decision in 2011. Faced with a putative class of approximately 1.5 million Wal-Mart employees who alleged

160; *Ernewein v General Motors of Canada Ltd*, 2005 BCCA 540 at para 31.

80 *Vioxx Products Liability*, above note 51 at 17.

81 Good, above note 42.

82 *Vioxx Products Liability*, above note 51 at 17; see *James v City of Dallas*, 254 F3d 551 at 570 (5th Cir 2001) [*James*]; *Mullen v Treasure Chest Casino, LLC*, 186 F3d 620 at 625 (5th Cir 1999).

83 *James*, above note 82 at 570.

84 *Vioxx Products Liability*, above note 51 at 17.

85 131 S Ct 2541 (2011) [*Dukes*].

that Wal-Mart had discriminatory promotion practices, *Dukes* redefined commonality, swinging the pendulum of favourability to the defence. This new definition made raising a common issue insufficient to obtain class certification and, rather, required that the plaintiffs share in common the “same injury” in order to raise a common issue, the resolution of which would be central to resolving claims made by the class.⁸⁶ *Dukes* also reiterated the *General Telephone Company of the Southwest v Falcon*⁸⁷ decision, that District Courts have the responsibility of engaging in a “rigorous analysis” to resolve any “merits questions” that might influence class certification, despite the fact that the merits of the issues will have to be proven again at trial. Furthermore, the *Dukes* understanding of commonality purports that when the plaintiffs share the “same injury,” all of the claims can be productively litigated together.⁸⁸

Prior to the *Dukes* definition of commonality, a group of consumers who had experienced the same product defect could rely on the common factual issue of an alleged defect or a common legal question of whether the defendant owed and breached its duty of care or negligently failed to warn them of the defect. *Dukes* narrowed the question of commonality from one of structural nature, questioning the conduct of the defendant, to one of individual outcome of the defendant’s conduct, effectively removing a layer of accountability for the defendant’s risk-causing conduct and dividing putative plaintiff classes even before they are certified, when individual circumstance can be resolved at a later time. Consequently, the *Dukes* definition of commonality means that commonality is no longer met at US common law by establishing a common issue of law or fact, which is still required by the black letter law of Rule 23(a)(2) in the US *FRCP*.

3) Establishing Typicality Under the United States *Federal Rules of Civil Procedure*

Unlike in his commonality decision, Fallon J decided that the PSC proposed class failed to satisfy the typicality requirement. Rule 23(a)(3) of the *FRCP* requires the putative class to establish that the claims or defenses

86 *Ibid* at 2551.

87 102 S Ct 2364 at 2372 (1982) [*General Telephone*].

88 *Dukes*, above note 85 at 2551; A Benjamin Spencer, “Class Actions, Heightened Commonality, and Declining Access to Justice” (2013) 93 *Boston University Law Review* 441 at 444–45.

of the representative plaintiff(s) are typical of those of the class. Typicality does not require the claims of the representative plaintiff(s) to be identical to those of the class, but that the essence of the claim's characteristics must be shared. In the subject motion decision, both the proposed representative plaintiffs and the PSC proposed class members alleged various products liability claims against Merck, including negligence, strict liability, failure-to-warn, and defective design.⁸⁹ Judge Fallon echoed Davis J's analysis in *In Re: Baycol Products Liability Litigation*⁹⁰ by determining that despite the fact that the proposed representative plaintiff and the PSC proposed class shared commonality in their products liability claims, their claims also have aspects that must be decided individually, including injury, causation, the application of the learned intermediary doctrine,⁹¹ and comparative fault.⁹²

Judge Fallon applied Davis J's typicality analysis from *Baycol* with equal force to the PSC motion for certification. The typicality analysis stated that the PSC proposed class was not amenable to class certification based on the underlying facts and circumstances under investigation because the PSC proposed class comprised several individuals, each of whom consumed different dosages of Vioxx, at different times, and presumably together with other medications, at least in some cases.⁹³ This analysis, however, does not consider the structurally-determined unidirectional knowledge economy in which these individuals were prescribed and consumed Vioxx. Constrained access to the safety and adverse events information by regulators, physicians, and patients may have served to alter prescribing and consumption decisions.

89 *Vioxx Products Liability*, above note 51 at 18.

90 *In Re: Baycol Products Liability Litigation*, 218 FRD 197 at 205 (D Minn 2003).

91 It has been argued that drug company strategies of promotion are incompatible with the learned intermediary doctrine. Patients rely almost exclusively on their physicians for information about their medications. If patients are exposed to any other drug safety information, it is most likely to be in the form of an advertisement from a drug company. Because physicians receive their information on drug safety and effectiveness from the sponsoring drug companies, the information that the physicians receive serves to promote the medications, rather than providing them with *all* of the necessary information to prescribe in an informed manner. This is true in the case of Vioxx. See Barbara J Tyler & Robert A Cooper, "Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs" (1997) 21:4 *Vermont Law Review* 1073 at 1075.

92 *Vioxx Products Liability*, above note 51 at 18.

93 *Ibid.*

Because the common issues posed by the PSC proposed class were concerned with what Merck knew about Vioxx's cardiovascular risks, when it knew of them, and whether it acted reasonably based on this knowledge, Fallon J held that the claims of the proposed representative plaintiffs were not typical of those of the class. Judge Fallon explained that the PSC proposed class does not satisfy the typicality requirement because of the factual variations between them and the proposed representative plaintiffs. Judge Fallon also found that there was a conflict of state laws issue between the proposed representative plaintiffs and the PSC proposed class members, precluding a finding of typicality.⁹⁴ However, Merck's structural shaping of Vioxx's medical and public narrative and of the discourse that informed the development of the proposed plaintiff class' factual circumstances was not geographically discriminatory, but was purposefully cross-border in nature. For example, Merck's promotion of Vioxx through its ghostwritten and fake journals was intended to reach its targeted physician audiences internationally. According to Fallon J, US courts have generally consistently found that questions of fact in pharmaceutical drug cases do not predominate, stating that "[t]his case is no different."⁹⁵

The PSC proposed class' claims of Merck's failure-to-warn in either strict liability or negligence were rejected as a class-wide issue, because it was determined that these issues turn on individual plaintiff-specific considerations. The plaintiff-specific, individualized questions included those regarding alleged injury from the product, what Merck knew of that injury when that particular plaintiff was prescribed Vioxx, what Merck told physicians and consumers about the risks of Vioxx in the particular Vioxx label that was provided to the specific patient, and other information available at the time that the individual was prescribed Vioxx, given that the label changed several times throughout the five years that it was on the market. Other questions were also raised, including what the individual's physician knew at the time of prescribing Vioxx to that individual and whether that particular physician would have prescribed Vioxx to that patient had the physician been provided with stronger warnings.⁹⁶ However, with access to Merck's internal Vioxx documents, we can now more fully understand its intended and carried out multi-year marketing strategy, which concealed important risks of harm data, making it

94 *Ibid* at 18-19.

95 *Ibid* at 20-21.

96 *Ibid*.

impossible for regulators, prescribers, and the ultimate consumers to have had access to the requisite safety knowledge.⁹⁷ These more narrow, micro-analytical questions deflect attention and, potentially, liability from the company's conduct. This narrowed focus instead positions the particular physician and patient in the proverbial hot seat, suggesting that the physician and ultimate consumer may somehow be in a position of fault, to be held accountable for the marketing strategies undertaken by Merck to sell Vioxx and create brand loyalty among its target audiences in the five years that it was on the market.

Relying on *Baycol*, Fallon J determined that these issues were more appropriately individualized issues, providing that negligence claims are dependent on individual facts per individual plaintiff.⁹⁸ Judge Fallon concluded that “there is no uniform body of representations to which all physicians and putative class members were exposed,”⁹⁹ although Fallon J may not have realized at the time that the layering of representations and promotional strategies for Vioxx by Merck were part of a deliberate and carefully shaped multi-year marketing plan, which is commonly exposed only through the litigation process. Judge Fallon further individualized the certification analysis by citing Rothstein J in the US decision *In Re: Phenylpropanolamine (PPA) Products Liability Litigation*¹⁰⁰ to support his denial of class certification. In this decision, Rothstein J proposed additional factors that further individualized the typicality of the proposed common issues, including plaintiffs’ family histories, demographics, and lifestyle choices.¹⁰¹ This individualization of issues runs directly contrary and contradictory to the intentions of the marketing strategies employed by drug companies to broaden and make more general the population to whom the sponsor’s particular drug can be prescribed.

97 See Justin Biddle, “Lessons from the Vioxx Debacle: What Privatization of Science Can Teach Us About Social Epistemology” (2007) 21:1 *Social Epistemology* 21; Ronald M Green, “Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx” (2006) 35:2 *Hofstra Law Review* 749; Aaron S Kesselheim, Michelle M Mello, & David Studdert, “Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints” (2011) 8:4 *PLoS Medicine* e1000431; Sergio Sismondo, “Ghost Management: How Much of the Medical Literature is Shaped Behind the Scenes by the Pharmaceutical Industry?” (2007) 4:9 *PLoS Medicine* e286.

98 *Vioxx Products Liability*, above note 51.

99 *Ibid* at 21.

100 208 FRD 625 at 631–32 (WD Wash 2002).

101 *Vioxx Products Liability*, above note 51 at 21.

F. CONCLUSION AND FUTURE DIRECTIONS

Ontarian plaintiffs have the ability, based on the common issues criterion, to rely on the defendant's structural and systemic conduct having exposed the proposed class to known harms. In the United States, however, the typicality requirement has precluded such structurally-founded common issues in favour of a more narrow approach. The US typicality requirement, unlike Ontario's certification criteria, has created inherent conflicts among putative class members. In this vein, it seems as though US typicality and commonality law has created a more favourable certification process for the alleged wrongdoers, without affording an equitable chance to proposed plaintiff classes to prove their cases at trial. Unlike the United States, Ontario's class action law does not use the certification stage as an opportunity to assess merit; rather, it requires that at this early stage the proposed class only prove that their claims have some basis in fact. This some basis in fact requirement helps to create a fairer playing field for plaintiffs who have already suffered alleged harms from the defendant's conduct.

The common issues and commonality analyses seem to require a similar level of analysis from the Ontario and US courts, respectively, with the difference of a non-merit-based approach in Ontario and a merit-based approach to resolving the US commonality requirement post-*General Telephone* and reiterated in *Dukes*. The United States requires this merit-based approach, despite the fact that the plaintiff class would, again, be required to prove the merits of its claims at trial, in clear contradiction with the principle of judicial economy, since having to undertake the same interrogation twice increases delays and costs, and decreases the opportunities afforded to the plaintiffs to access recourse through other methods with limited time. This common law understanding in the United States seems to be in contradiction with the black-letter law of the *FRCP*, and this issue requires further research and analysis to determine how the difference between common law and statute has been resolved by US courts certifying class actions.

The US typicality requirement seems to serve the benefit of the defence because it individualizes the fact analyses pertaining to adverse events suffered by plaintiffs and the circumstances in which their adverse events manifested. The US individual-centric focus seems counter-intuitive to negligence claims in this case study, and pharmaceutical negligent design cases in general, because the conduct of Merck was intended to

affect Vioxx's prescribers and potential consumers broadly, suppressing data and misleading prescribers on a large-scale, without true regard for individual use patterns. If the typicality assessment continues in this way, the Ontario certification law seems more amenable to plaintiffs' claims; however, awards tend to be higher in the United States.

The published academic literature on pharmaceutical advertising and its layered management by a sponsoring drug company and its contracted entities has revealed cause for structural analyses with an important focus on its mechanisms of narrative and discourse management.¹⁰² The necessary critical consideration of the pharmaceutical marketing culture that underpins the information disclosed by the companies that, themselves, sponsor, analyze, interpret, and disseminate their data, with the assistance of contracted research and communications companies, potentially weakens the narrow position required by the typicality requirement. In fact, a detailed analysis is extremely important when contextualized within the broader and increasingly well-known culture of pharmaceutical promotion.

Shifting the blame to the millions of individual people who were prescribed and consumed Vioxx is a strategy that drug companies have used and for which they have advocated in order to limit their own liability.¹⁰³ However, since it is the choice of drug companies to develop drugs, collect and interpret data on them, submit applications for drug approval to regulatory bodies, advertise, and publish their data in medical journals, the liability on drug companies should be measured according to their contribution of risk of harm to the consumer. The burden should be shifted back to the drug companies to prove that the information that they provided to regulators, physicians, and consumers did not rely on misleading, falsified, or suppressed data, meant to influence the market and consumers and leading to quantifiable miscalculations of adverse events.

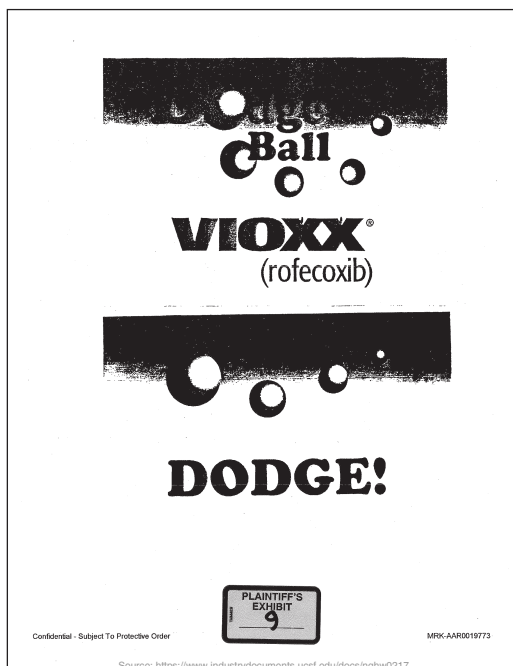
The US courts should reconsider their definitions of commonality and typicality to create a certification environment that is more equitably balanced, as in Ontario, among the proposed plaintiff classes and defendants. This reform will help to rebalance the scales in products liability class action litigation in the United States given the increasing prevalence of litigation concerning pharmaceuticals and the extensive and growing

102 Adrienne Shnier, "Medical Education and Financial Conflict of Interest Relationships with the Pharmaceutical Industry in Canada: An Analysis of Four Areas of Medical Education" (PhD Dissertation, York University, July 2016) [unpublished].

103 Tyler & Cooper, above note 91.

body of literature on unethical and illegal conduct, including data suppression and recoding, which may be used by drug companies to market and sell several classes of drugs to consumers. To this end, Ontarian class actions statute and caselaw should continue to serve the interests of both plaintiffs and defendants with an equitable and balanced application of the certification requirements, and with an appreciation and understanding of the purposefully created context within which classes' issues have developed. The marketing schemes used, including the dissemination of false and misleading safety information to regulators, physicians, and patients by hiding data, creating fake medical journals, ghostwriting medical journal articles, and re-coding severe adverse events as more mild outcomes, are, in fact, structural in nature with systemic effects, and should be recognized as such by the courts.

Appendix 1: Merck's Dodge-Ball Presentation to Sales Representatives
Regarding Physicians' Questions of its Safety Profile



**Dodge
Ball**

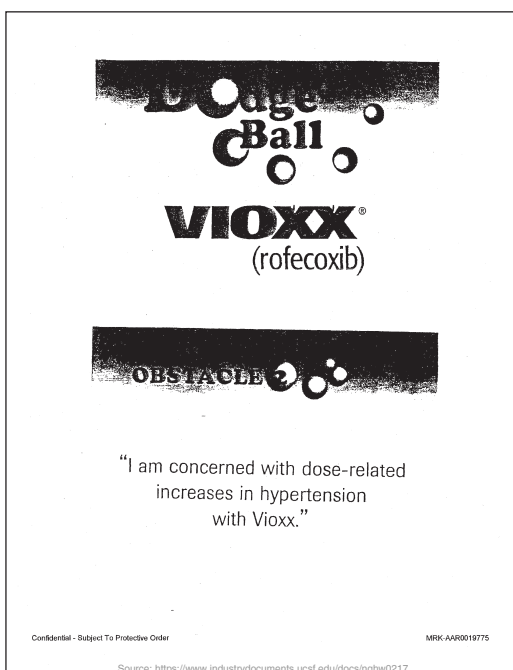
VIOXX[®]
(rofecoxib)

DODGE!

PLAINTIFFS
EXHIBIT
9

Confidential - Subject To Protective Order MRK-AAR0019773

Source: <https://www.industrydocuments.ucsf.edu/docs/hghw0217>



**Dodge
Ball**

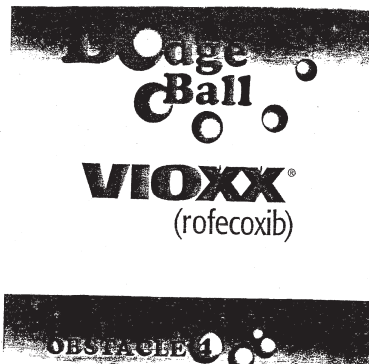
VIOXX[®]
(rofecoxib)

OBSTACLE

"I am concerned with dose-related
increases in hypertension
with Vioxx."

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Source: <https://www.industrydocuments.ucsf.edu/docs/hghw0217>



**Dodge
Ball**

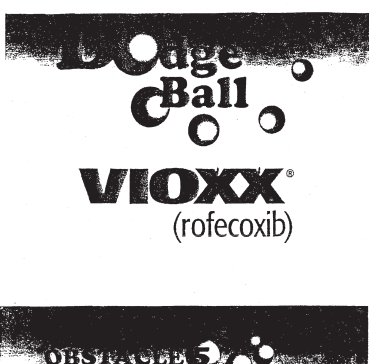
VIOXX[®]
(rofecoxib)

OBSTACLE 4

“I am concerned about the
cardiovascular effects of Vioxx?”

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Source: <https://www.industrydocuments.ucsf.edu/docs/nghw0217>



**Dodge
Ball**

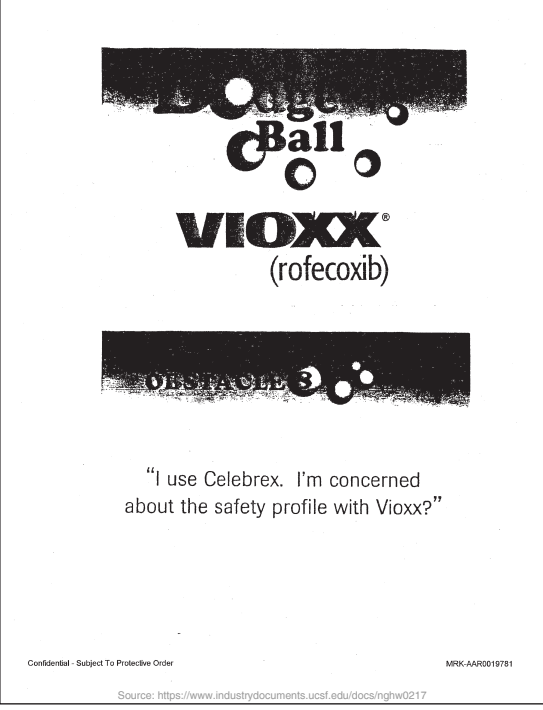
VIOXX[®]
(rofecoxib)

OBSTACLE 5

“The competition has been in my
office telling me that the incidence
of heart attacks is greater with
Vioxx than Celebrex.”

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Source: <https://www.industrydocuments.ucsf.edu/docs/nghw0217>



**Dodge
Ball**


VIOXX[®]
(rofecoxib)

OBSTACLE 3

“I use Celebrex. I’m concerned
about the safety profile with Vioxx?”

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Source: <https://www.industrydocuments.ucsf.edu/docs/nghw0217>



**Dodge
Ball**

VIOXX[®]
(rofecoxib)

DODGE!

Confidential - Subject To Protective Order MRK-AAR0019786

Source: <https://www.industrydocuments.ucsf.edu/docs/nghw0217>

