

Access to Justice – Litigation Funding and Group Proceedings  
Victorian Law Reform Commission  
GPO Box 4637  
Melbourne Vic 3001

**By email: [law.reform@lawreform.vic.gov.au](mailto:law.reform@lawreform.vic.gov.au)**

29 September 2017

Dear Commissioners

**Access to Justice – Litigation Funding and Group Proceedings – June 2017**

Thank you for the opportunity to provide a submission to the Victorian Law Reform Commission's Access to Justice – Litigation Funding and Group Proceedings Consultation Paper, dated July 2017 (the **Consultation Paper**).

This submission has been prepared by a group of Australian companies and businesses who have an interest in the matters under consideration by the Commission:

- Johnson & Johnson Family of Companies – comprising Johnson & Johnson Medical, a medical devices and diagnostics business; Janssen, a leading researched based pharmaceutical company; and Johnson & Johnson Pacific, known for its portfolio of leading consumer health brands;
- Smith & Nephew- a global medical technology business with leadership positions in Orthopaedic Reconstruction, Advanced Wound Management, Sports Medicine and Trauma & Extremities, Smith & Nephew has around 15,000 employees and a presence in more than 100 countries;
- Stryker manufactures medical devices and medical equipment including reconstructive, medical and surgical, and neurotechnology and spine products. Stryker products and services are available in over 100 countries around the world; and
- Zimmer-Biomet - designs, manufactures and markets orthopaedics products, including knee, hip, shoulder, elbow, foot and ankle artificial joints and dental prostheses. The company has operations in more than 40 countries around the world and sells products in more than 100 countries.

Appendix 1 to this submission provides more detail on each entity that supports this submission.

In the ordinary course of our businesses, we frequently appear (both as plaintiff and respondent) in the Australian judicial system in a diverse range of matters including contract, employment, consumer protection, product liability and intellectual property. We have been, and are, involved in matters litigated on an individual basis as well as those conducted as representative proceedings. We recognise that that legal system must produce fair and just outcomes.

We welcome the opportunity to comment on the matters raised by the Consultation Paper and how those matters may impact both the business community generally and more specifically, our own industries.

### ***General Comments concerning the Consultation Paper***

We have not commented on each of the questions asked in the Consultation Paper. We have restricted our comments to matters which we feel are of particular relevance to either healthcare or the business community generally – those are:

- 1 Contingency Fees
- 2 Litigation Funding
- 3 Certification

We have been provided with a copy of the submissions made by the US Chamber Institute for Legal Reform (ILR)<sup>1</sup>. We broadly endorse the submissions made by the ILR save as noted or qualified below.

### ***Contingency fees***

- 26 Would lifting the ban on contingency fees mitigate the issues presented by the practice of litigation funding?
- 27 If the ban on contingency fees were lifted, what measures should be put in place to ensure:
  - a) a wide variety of cases are funded by contingency fee arrangements, not merely those that present the highest potential return
  - b) clients face lower risks and cost burdens than they do now in proceedings funded by litigation funders
  - c) clients' interests are not subordinated to commercial interests
  - d) other issues raised by the involvement of litigation funders in proceedings are mitigated?

In considering contingency fees, we note the Commission's comment at paragraph 2.38:

*"The terms of reference ask whether lifting the ban [prohibiting solicitors from charging contingency fees] would assist in mitigating issues presented by the practice*

---

<sup>1</sup> US Chamber Institute for Legal Reform Submission to the Victorian Law Reform Commission "Litigation Funding And Group Proceedings", September 2017

*of litigation funding; they do not call for the Commission to review whether the ban should be lifted.”*

The third party litigation funding “issues” that are presented as requiring mitigation are:

- case selection – the limited range of cases selected for funding;
- costs – the actual amount of the funding fee; and
- client interests – the subordination of the client’s interests to commercial objectives.

Indeed, these are significant and material matters that should be reviewed and appropriately managed. However, if the ban prohibiting solicitors from charging contingency fees were lifted, the result is that, at best, another party is introduced that faces exactly the same issues and, at worst, those issues are exacerbated: the potential for conflict of interest are sharpened and introduced far earlier. “Damages based billing” is, simply put, litigation funding under a different name.

Turning to the Commission’s specific questions, we submit:

- 1 There is no evidence or data that would support a conclusion that lifting the ban prohibiting solicitors from charging contingency fees would assist in mitigating issues presented by the practice of litigation funding. There is undoubtedly considerable academic debate<sup>2</sup> and consideration of the pros and cons of lifting the ban by the legal industry.<sup>3</sup> What is noteworthy is that each potential “advantage” of allowing contingency fees to be charged (including expansion of access, lower costs and management of conflicts) is met with a risk of an equal or greater “disadvantage” (being that there is no expansion of access, there may be higher costs and even greater conflicts of interest). For instance, note the summary table provided by the Law Council of Australia (Table 1).<sup>4</sup>

---

<sup>2</sup> For example, Michael Legg, ‘Litigation nation – Revisiting contingency fees, litigation funding and class actions in Australia’ (2012) 20 *Torts Law Journal* 61, 70; Andrew Watson and Michael Donnelly, ‘Financing Access to Justice: Third Party Litigation Funding and Class Actions in Australia’ (2014) 55 *Canadian Business Law Journal* 17, 3; Peter O’Donahoo and Tim Maxwell, ‘Contingency Fees and Access to Justice in Australia’ (2014) 81 *Defense Counsel Journal* 272, 275; Michael Legg, ‘Litigation Funding in Australia: Identifying and Addressing Conflicts of Interest for Lawyers’ (2012) *US Chamber Institute for Legal Reform*; Michael Wheelahan, ‘Not just a business: The debate around contingency fees’ [2016] 137 *Precedent* 46; Adrian Walters, ‘Contingency fee arrangements at common law’ (2000) 116 *Law Quarterly Review* 371-377; Stewart Jay, ‘The dilemmas of attorney contingent fees’ (1988) 2 *Georgetown Journal of Legal Ethics* 813; Vince Morabito, ‘Federal class actions, contingency fees and the rules governing costs’ (1995) 21 *Monash University Law Review* 231, 245; S Clark and C Harris, ‘The push to reform class action procedure in Australia: Evolution or Revolution?’ (2008) 32 *Melbourne University Law Review* 775, 810; A Walters, ‘Contingency fee arrangements at common law’ (2000) 116 *Law Quarterly Review* 371; Michael Legg, ‘Contingency fees – Antidote or poison for Australian civil justice?’ (2015) 39 *Australian Bar Review* 244, 245;

<sup>3</sup> For example, Productivity Commission Inquiry Report No. 72, *Access to Justice Arrangements* (5 September 2014), Vol 2, 625; Law Council of Australia, ‘Percentage based contingency fee agreements – Final Report’ (May 2014), Victorian Law Reform Commission, *Civil Justice Review*, Report No 14 (2008) 685.

<sup>4</sup> Law Council of Australia, ‘Percentage based contingency fee agreements – Final Report’ (May 2014) 20-21.



- 2 In a commercial environment, where funders have economic rather than philanthropic goals, there are no realistic legislative options to mandate that funders are required to accept cases that fall below their assessments for acceptable risk and return. Equally, there is no evidence that solicitors being able to charge contingency fees would mean that a greater range of cases were funded.
- 3 While the argument may be made that solicitors being able to charge contingency fees would create market tension with traditional funders and lead to lower costs for clients,<sup>5</sup> this is not a foregone conclusion. It is not unreasonable to expect a higher fee being charged for a matter that a traditional funder is unwilling to fund. It is also not unreasonable to think that a law firm listed on the Australian Stock Exchange would apply markedly different criteria to case selection or fees, to those applied by traditional funders.

---

<sup>5</sup> Victorian Law Reform Commission, *'Access to Justice – Litigation Funding and Group Proceedings Consultation Paper'* (July 2017) 116 [8.29].

Table 1 – From “Percentage Based Contingency Fee Agreements”, Final Report of the Working Group, Law Council of Australia, May 2014, pp.20-21

Advantages of contingency fee agreements	Disadvantages of contingency fee agreements
<p>Create a more level playing field – potentially opens litigation (including representative actions) that third party litigation funders presently undertake under contingency fee agreements, to competition from lawyers.</p> <p>Act as an incentive:</p> <ul style="list-style-type: none"> <li>• for early assessment of clients' prospects of success;</li> <li>• to vigorously and innovatively pursue cases that have a reasonable prospects of success.</li> </ul> <p>Act as a disincentive to instituting unmeritorious or vexatious proceedings.</p> <p><i>Maintenance</i> and <i>champerty</i> (both as a crime and tort) have been legislatively abolished in the ACT NSW Vic and SA- and are arguably abolished at common law.</p> <p>Both the historical justification and public policy considerations for the prohibitions (on <i>maintenance</i> and <i>champerty</i>) have changed</p>	<p>Removing the financial impediment to litigation may give rise to an increase in unmeritorious litigation (often referred to as US style litigation).</p> <p>Concerns about contingency fee arrangements are historically wedded in prohibitions against <i>maintenance</i> and <i>champerty</i>. These prohibitions were founded on reasons including:</p> <ul style="list-style-type: none"> <li>• concerns about 'wanton and officious intermeddling';</li> <li>• fears about the fairness of the bargain struck between the funder and intended litigant; and fears the maintainer may be tempted to act unethically for personal gain.</li> </ul>
<p>Unlike litigation funders- solicitors are regulated by <i>legal profession legislation</i> and rules of professional conduct, which provide safeguards against unethical conduct.</p> <p>Furthermore, solicitors may more diligently and effectively screen prospective cases, being reluctant to bear the risks of a case that does not have a reasonable chance of success.</p>	<p>Conflicts of interest- may encourage lawyers to</p> <ul style="list-style-type: none"> <li>• settle at a time that maximises fees (early or later prolonging a case but that is inconsistent with client's interests/ expectations unethical behaviour, with solicitors being tempted to either, in order to maximise their fees.</li> <li>• pressure clients to accept less favourable/advantageous settlements.</li> </ul>
<p>Promotes freedom of contract, providing clients with the ability to choose the fee arrangement that is most suitable to their circumstances.</p>	<p>Power imbalance between solicitor and client may result in a client agreeing to a contingency fee arrangement which does not best suit their interests.</p>
<p>Promotes access to justice for civil action plaintiffs that have meritorious claims and who otherwise have no means of funding litigation, in particular those with strong cases but who are otherwise unable to afford legal assistance.</p>	<p>May encourage litigation, resulting in increased costs and delay to the justice system.</p>
<p>Provides an alternative to the traditional time-billing model which has been criticised by the judiciary, clients and lawyers alike.</p> <p>Represents a pure form of billing- clients pay upon the successful outcome of their case. Fees are thus, result (or output based) rather than based on hourly rates and billing in accordance with scales that are billed on 'input' rather than 'output'.</p> <p>Potentially provides greater clarity, certainty and simplicity regarding the fees for which a client is ultimately liable in a successful action.</p>	<p>Concern that, while contingency fee arrangements are by definition proportionally tied to the damages amount, they may not necessarily be reasonable if lawyers receive large fees that bear no reasonable reflection of:</p> <ul style="list-style-type: none"> <li>• the work required on the case;</li> <li>• the period of time that the awyers carry the costs of the action until finalisation; and</li> <li>• the risk lawyers take that the claim will succeed and they will be paid.</li> </ul>

- 4 We note and support the ILR’s submissions concerning the real and sensible conflicts of interest that would arise as a consequence of introducing contingency fees arrangements.
- 5 In circumstances where:
  - a. there is no evidence or data that would support a conclusion that lifting the ban prohibiting solicitors from charging contingency fees would assist in mitigating issues presented by the practice of litigation funding; and
  - b. there is a real and genuine likelihood that those issues would be exacerbated by lifting that ban,we do not support the proposition that lifting the ban would assist in mitigating the issues which arise through litigation funding.
- 6 Lifting the ban on solicitors being able to charge contingency fees and at the same time leaving unresolved the current issues concerning third party litigation funding, will take Australia down a path of US litigation culture, where the class action/mass action system is seriously dysfunctional: a legal system in which class actions produce no benefits for class members, lawyers reap millions of dollars in fees and the system is transformed into an abusive mechanism which becomes a magnet for advertising-driven, poorly investigated (and often patently invalid) personal injury claims.
- 7 There are a range of options available that could be readily implemented to properly mitigate the issues presented by third party litigation funding. We endorse the ILR’s recommendations in this respect.
- 8 We do not support the lifting of the ban. However, in order to address question 27, the minimum threshold for both third party litigation funders and solicitors charging contingency fees, should be licensing pursuant to the regime identified by the ILR<sup>6</sup>. In addition, strict regulations should be implemented which limit advertising of legal services: Court approval of any advertising would be appropriate and one way to manage such risk.

---

<sup>6</sup> US Chamber Institute for Legal Reform Submission to the Victorian Law Reform Commission “Litigation Funding And Group Proceedings”, September 2017, pp27-30.



- 9 From a Healthcare perspective, a system that is predicated on lawyers making profit through contingency fees will lead to significant and harmful advertising. As was submitted to the Productivity Commission's 2014 Report in Access to Justice,<sup>7</sup> a likely outcome of such a system is predatory advertising by lawyers deliberately focusing on a person's concern over their health and that of their friends and relatives in order to generate business. Taking advantage of this concern is not acceptable, nor is it appropriate that such advertising may influence consumers to change their treatment regime without proper consultation of their healthcare professionals.

Three examples are illustrative of the issue and may assist the Commission in this respect. The first relates to a survey conducted in 2007 in the United States:<sup>8</sup>

The survey, which was conducted among 402 psychiatrists who treat patients with schizophrenia and bipolar disorder, showed that, even when patients were responding well to their prescribed antipsychotic treatment, many requested a medication change because these drugs are featured in law firm advertisements. Other patients stopped taking their medication, often without telling their psychiatrist, for the same reason.

"Many of our patients already struggle with accepting their illness and staying on their prescribed treatment, and now they are experiencing new levels of fear due to the increasing incidence of these jarring advertisements," said Dr. Ralph Aquila, assistant clinical professor of psychiatry, Columbia College of Physicians and Surgeons; director, residential community services, St Luke's-Roosevelt Hospital Center, New York, NY. "This irresponsible advertising is hindering the progress of therapy for many of these patients and disrupting the important relationship between them and their healthcare providers. Plaintiffs attorneys need to consider the consequences that these advertisements may have on patients."

The findings from this survey, which was commissioned by the National Council for Community Behavioral Healthcare and Eli Lilly and Company, are consistent with a Harris Interactive(R) poll of 250 physicians commissioned by the U.S. Chamber of Commerce in 2003(i) that examined how pharmaceutical litigation impacts prescribing decisions across disease states. However, this new survey went one step further by asking psychiatrists to examine the potential impact of this type of litigation on patient care. These new findings have implications for doctors who treat serious and persistent mental illnesses, and confirm trends in clinical practice that many people in the mental health community have observed, but have not been quantified until now.

The second example, while not advertising, concerns two Australian Broadcasting Commission's *Catalyst* programs aired in October 2013 collectively

---

<sup>7</sup> Johnson & Johnson, Response to Productivity Commission's Draft Report on Access to Justice Arrangements (April 2014)

<sup>8</sup> Rockville, Md., 'Relapses Seen As Patients Abandon Treatment in Response to Negative Law Firm Ads' (June 2007) accessed from <https://investor.lilly.com/releasedetail.cfm?releaseid=248836>.

titled “Heart of the Matter” reporting on the use of statins, provides an interesting and instructive analogue.<sup>9</sup> While the Audience and Consumer Affairs Unit of the ABC investigated the episodes and determined that there had been a breach of impartiality, it acknowledged:

There is an inherent danger when any program presents criticisms of medical practices or advice that people will act without consulting experts or fully considering the consequences. That is not a reason to avoid these controversial subjects if they are in the public interest (<http://about.abc.net.au/wp-content/uploads/2014/05/Catalyst-Heart-of-the-Matter-ACA-Investigation-Report.pdf>).

The “inherent danger” the Audience and Consumer Affairs Unit is referring is the “potential for people to decide not to take prescribed medication”. Both episodes have been removed from the *Catalyst* website, and corrections posted on the ABC’s “Corrections Page”.

It has been reported that a Heart Foundation survey at the time (of 1,000 patients) found that 10% had ceased taking their prescribed medication because of the program.<sup>10</sup>

Finally, attached to this submission are some relevant and recent materials concerning the United States’ experience with legal advertising and its impact on healthcare:

- (a) a paper titled “A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising”. This 2016 study noted that beginning in 2014, advertising appeared on the radio, television and print media directed towards patients who may have suffered an adverse clinical event while taking rivaroxaban. That study concluded that legal advertising resulted in some patients stopping their therapy and experiencing adverse clinical events, such as stroke; and
- (b) a letter from the Chairman of the Congress of the United States House of Representatives, Committee on the Judiciary, dated 7 March 2017.

---

<sup>9</sup> ABC News, ‘ABC’s Catalyst Program on statins, heart disease breached impartiality standards, investigation finds’ (May 2014) accessed from <http://www.abc.net.au/news/2014-05-12/abcs-catalyst-program-breached-impartiality-standards/5447242>).

<sup>10</sup> Ibid.



It is also worthy of mention that in June 2016, the American Medical Association, the premier national physician organization in the United States, adopted a policy in response to such matters <https://www.ama-assn.org/ama-adopts-new-policies-final-day-annual-meeting>):

### **Warnings Urged For Lawyer Ads Targeting Medications**

With TV viewers inundated by ads warning about the dangers of pharmaceuticals, the AMA today recommended that such advertisements come with a warning that patients should first consult with a physician before discontinuing medications.

"The onslaught of attorney ads has the potential to frighten patients and place fear between them and their doctor. By emphasizing side effects while ignoring the benefits or the fact that the medication is FDA approved, these ads jeopardize patient care. For many patients, stopping a prescribed medication is far more dangerous, and we need to be looking out for them," said AMA Board Member Russell W. H. Kridel, M.D.

If the ban were lifted, strict regulations should be implemented which limit advertising of legal services: such advertising may not be prevalent now, but when partnered with a large financial incentive of a contingency fee may result in disastrous consequences. Consider, for example, how a non-misleading or non-deceptive advertising campaign around the MMR or polio vaccination (eg "is your child displaying any of these symptoms?") may impact public healthcare – both the human cost and the costs to the healthcare system of an epidemic.

### ***Litigation funding***

#### Current regulation of litigation funders and lawyers

- 3 Should different procedures apply to the supervision and management of class actions financed by litigation funders compared to those that are not?
- 4 How can the Supreme Court be better supported in its role in supervising and managing class actions?

#### Disclosure to court

- 10 In funded class actions, should the plaintiff be required to disclose the funding agreement to the Court and/or other parties? If so, how should this requirement be conveyed and enforced?
- 12 In the absence of Commonwealth regulation relating to capital adequacy, how could the Court ensure a litigation funder can meet its financial obligations under the funding agreement?

#### Settlement

- 17 How could the interests of unrepresented class members be better protected during settlement approval?
- 18 What improvements could be made to the way that legal costs are assessed in class actions?
- 20 Is there a need for an independent expert to assist the Court in assessing funding fees? If so, how should the expert undertake this assessment?
- 22 In class actions, should lawyers and litigation funders be able to request that the total amounts they receive in settlement be kept confidential?

- |    |   |
|----|---|
| 23 | How could the management of settlement distribution schemes be improved to:<br>a) ensure that individual compensation reflects the merits of individual claims<br>b) ensure that it is completed in a manner that minimises costs and delays? |
|----|---|

As noted above, the Commission now has the opportunity to make meaningful steps in reform and regulation to resolve the issues concerning third party litigation funding. There are a range of options available, and that could be readily implemented to properly mitigate the issues presented by third party litigation funding. We endorse the ILR's recommendations in this respect and in particular, support its recommendation that where litigation funding is being used (in any form), that there is notification the Court and to the defendant of that fact.

From our own experiences in representative proceedings, we note and submit:

- 1 We note the ILR's submission that an independent third party could add value to settlement negotiations. However, there will likely be challenges with ensuring such third party is fully advised and informed and able to provide that objective and timely advice.
- 2 Where an independent third party would, in our opinion, add real value to the Court and to group members, would be in the analysis of the mechanism and cost of distributing any settlement (that is, expertise in management of procurement of such services). With respect to those plaintiff law firms who attempt to transition their role from legal expert to scheme administrator, we submit that there are third parties who are far better resourced and experienced to handle such matters (and indeed, can handle those matters at reasonable, not lawyer, rates).
- 3 The Commission may wish to inquire as to the feasibility of compulsory reporting and publication of distributions made to group members, the time taken for such distributions and the amounts charged. This data would be useful to determine the value that is actually derived to each group member and would allow a transparent means of comparison between law firms. Indeed, consideration may be given to ensuring that no funds are awarded to any other party before group members are compensated.

### ***Certification***

- |    |  |
|----|--|
| 13 | Should the existing threshold criteria for commencing a class action be increased? If so, which one or more of the following reforms are appropriate?<br><br>(a) introduction of a pre-commencement hearing to certify that certain preliminary criteria are met |
|----|--|



- (b) legislative amendment of existing threshold requirements under section 33C of the Supreme Court Act 1986 (Vic)
- (c) placing the onus on the plaintiff at the commencement of proceedings to prove that the threshold requirements under section 33C are met
- (d) other reforms.

15 Should a specific legislative power be drafted to set out how the Court should proceed where competing class actions arise? If not, is some other reform necessary in the way competing class actions are addressed?

We endorse the ILR's recommendations in concerning certification and management of competing actions.

In addition, we note that the United States process concerning certification is still evolving and improving. We draw the Commission's attention to the recent passing in Congress of the Fairness in Class Action Litigation and Furthering Asbestos Claim Transparency Act of 2017 which was a bill (inter alia) to prohibit federal courts from certifying class actions (<https://www.congress.gov/bill/115th-congress/house-bill/985?q=%7B%22search%22%3A%5B%22fairness+in+class+action+litigation%22%5D%7D>) unless:

- in a class action seeking monetary relief for personal injury or economic loss, each proposed class member suffered the same type and scope of injury as the named class representatives;
- no class representatives or named plaintiffs are relatives of class counsel, except in a private securities litigation brought as a class action subject to the Securities Act of 1933 or the Securities Exchange Act of 1934; and
- in a class action seeking monetary relief, the party seeking to maintain the class action demonstrates a reliable and administratively feasible mechanism for the court to determine whether putative class members fall within the class definition and for the distribution of any monetary relief directly to a substantial majority of class members.

And further that the certification must include a determination that the entirety of the cause of action from which the particular issues arise satisfies all the class certification prerequisites. We endorse the submissions of the ILR noting the challenges which are generated in the absence of some form of initial 'certification' by the Court<sup>11</sup>, and further note that the current class action regime is not well suited to matters concerning personal injury: matters in which individual causation will need to be carefully and deliberately considered.

<sup>11</sup> US Chamber Institute for Legal Reform Submission to the Victorian Law Reform Commission "Litigation Funding And Group Proceedings", September 2017, p 37.



Yours faithfully

PP 

George Power

Legal Director, Johnson & Johnson Medical on behalf of the submitting parties as noted on page 1

## Appendix 1

- Johnson & Johnson Family of Companies – comprising Johnson & Johnson Medical, a medical devices and diagnostics business; Janssen, a leading researched based pharmaceutical company; and Johnson & Johnson Pacific, known for its portfolio of leading consumer health brands.
- Smith & Nephew - Smith & Nephew is a global medical technology business with leadership positions in Orthopaedic Reconstruction, Advanced Wound Management, Sports Medicine and Trauma & Extremities, Smith & Nephew has around 15,000 employees and a presence in more than 100 countries
- Stryker manufactures medical devices and medical equipment including reconstructive, medical and surgical, and neurotechnology and spine products. Stryker products and services are available in over 100 countries around the world.
- Zimmer-Biomet – designs, manufactures and markets orthopaedics products, including knee, hip, shoulder, elbow, foot and ankle artificial joints and dental prostheses. Operations in more than 40 countries around the world and sells products in more than 100 countries.

Appendix 2 - "A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising".



# A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising



Paul Burton, MD, PhD, FACC,\* W. Frank Peacock, MD, FACEP†

From the \*Cardiovascular and Metabolism Medical Affairs, Janssen Pharmaceuticals Inc, Raritan, New Jersey, and †Baylor College of Medicine, Houston, Texas.

## Introduction

Rivaroxaban (XARELTO) is an oral Factor Xa inhibitor anticoagulant. Studied in over 85,000 patients,<sup>1</sup> it was initially approved by the FDA in 2011 and is indicated to treat or prevent thrombosis in a variety of clinical settings; and when appropriately prescribed, for example in patients with atrial fibrillation, rivaroxaban has similar anticoagulant efficacy, with a lower risk of intracranial hemorrhage, as compared to the historical standard of warfarin.<sup>1</sup>

It is well established that anticoagulant therapy is associated with an increased risk of hemorrhage, regardless of the specific anticoagulant. Therefore, in the risk–benefit balance, an appropriate anticoagulation prescription occurs in the setting of increased thrombotic risk that justifies the increased bleeding risk. This is an important consideration, as the mitigation of the thrombotic risk attained by the use of an anticoagulant is terminated if the anticoagulant is stopped. Importantly, current evidence<sup>2</sup> does not suggest a rebound of thrombotic risk upon anticoagulation discontinuation; rather, the patient simply resumes the thrombotic risk that existed prior to anticoagulant initiation, and the lack of rebound thrombosis with rivaroxaban is supported by longitudinal studies.<sup>2</sup> However, in a patient at risk for a thrombotic event, premature discontinuation of any oral anticoagulant may increase the risk of thrombotic events, as outlined in The United States Prescribing Information for all of the newer non-warfarin anticoagulants (<https://www.xarelto-us.com/shared/product/xarelto/prescribing-information.pdf>; [http://packageinserts.bms.com/pi/pi\\_eliquis.pdf](http://packageinserts.bms.com/pi/pi_eliquis.pdf);

<http://bidocs.boehringer-ingenelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing%20Information/PIs/Pradaxa/Pradaxa.pdf>; <http://dsi.com/prescribing-information-portlet/getPICContent?productName=Savaysa&inline=true>). As a class, the novel oral anticoagulants have rapid onset of action and short half-lives; as such, it is important to avoid abrupt cessation.

Rivaroxaban is currently the subject of a class action litigation. Beginning in 2014, advertising has appeared on television, on the radio, and in print media directed toward patients who may have experienced adverse clinical events while on rivaroxaban. Described here are a series of serious medical events reported in 28 submissions of 31 individual patients to Medwatch (The FDA Safety Information and Adverse Event Reporting System; <http://www.fda.gov/Safety/MedWatch/default.htm>).

## Case report

Overall, based on the available data, the mean age of the patients was 72 (range, 45–90), and 13 patients were male. All were prescribed rivaroxaban and subsequently discontinued their anticoagulant without consulting their physician after viewing negative rivaroxaban legal advertising.

In the majority of these cases (23/31, 75%), patients experienced a stroke or a transient ischemic neurologic event; 2 patients had persistent residual paralysis. One patient, a 45-year-old man receiving rivaroxaban for treatment of a deep vein thrombosis, stopped the drug and died of a subsequent pulmonary embolism, and 1 female patient, receiving rivaroxaban for stroke prevention, stopped the drug and died of a massive stroke (Table). All these cases were considered to be serious medical events by the health care professionals that submitted the reports.

## Discussion

There are obvious numerous and significant limitations to this report. These include the limited description of clinical

**KEYWORDS** Rivaroxaban; Stroke; Atrial fibrillation; Legal advertising (Heart Rhythm Case Reports 2016;2:248–249)

Funding source: Janssen Pharmaceuticals Inc. Conflicts: Dr Burton works for Janssen Pharmaceuticals Inc, and owns stock in Johnson and Johnson, which markets rivaroxaban in the United States. Dr Peacock is a paid consultant for Janssen Pharmaceuticals Inc. **Address reprints and correspondence:** Dr Paul Burton, Cardiovascular and Metabolism Medical Affairs, Janssen Pharmaceuticals Inc, 1000 Route 202, Raritan, NJ 08869. E-mail address: pburton@its.jnj.com.



**KEY TEACHING POINTS**

- Novel oral anticoagulants provide a new treatment option for a variety of thrombotic conditions, including nonvalvular atrial fibrillation.
- These drugs have rapid onsets and short half-lives and should not be prematurely discontinued.
- Legal advertising concerning XARELTO (rivaroxaban) has resulted in some patients stopping XARELTO therapy and experiencing adverse clinical events, such as stroke.

patients ceased their anticoagulant and suffered an adverse event that was not reported. Finally, while the language in these forms clearly states that patients viewed legal advertising and stopped their rivaroxaban, this cannot be definitively known. However, it is clear that some patients are intimidated enough by the ongoing legal campaign to stop their anticoagulant, and thus suffer an adverse event.

These cases serve to highlight the importance of following anticoagulant prescribing information, and that physicians should emphasize that patients should not stop anticoagulants without medical consultation. Continued partnership between drug manufacturers, physicians, regulators, and patients is necessary to provide sufficient education to ensure that these important medical events do not occur.<sup>3</sup>

**Table** Summary of clinical outcomes following abrupt rivaroxaban termination as reported to Medwatch

Case	Age	Sex	Anticoagulant indication	Consequence of stopping anticoagulant	Event reported
1	NR	F	NVAF	TIA/possible stroke	September 2014
2	80	F	NVAF	DVT of arm	November 2014
3	80	M	NR	Stroke	December 2014
4	NR	M	NVAF	Stroke	January 2015
5	NR	NR	NR	Stroke	January 2015
6	80	F	NVAF	Stroke	March 2015
7	NR	M	NR	Stroke	March 2015
8	55	M	NVAF	Cardiac thrombosis	April 2015
9	NR	NR	NR	Stroke	April 2015
10	NR	M	VTE	Cerebral and lower limb thrombosis	April 2015
11	60	M	NVAF	Stroke	April 2015
12	NR	NR	NR	Stroke in 2 patients	May 2015
13	NR	F	NVAF	DVT	June 2015
14	NR	F	VTE	Pulmonary embolism	June 2015
15	45	M	VTE	Death due to pulmonary embolism	June 2015
16	90	M	NVAF	Stroke	June 2015
17	NR	NR	NR	Stroke in 3 patients	June 2015
18	NR	NR	NR	Thrombosis	June 2015
19	69	F	NVAF	TIA	July 2015
20	NR	F	NVAF	Stroke	August 2015
21	NR	NR	NVAF	Stroke	September 2015
22	NR	F	NVAF	Death following stroke	September 2015
23	NR	M	VTE	Thrombosis	September 2015
24	NR	NR	NR	Stroke	October 2015
25	NR	M	AF	Stroke	November 2015
26	70	M	NR	Stroke	November 2015
27	90	M	AF	Cardiomyopathy/TIA	December 2015
28	NR	M	AF	Stroke	December 2015

AF = atrial fibrillation; DVT = deep vein thrombosis; NR = not reported; NVAF = nonvalvular atrial fibrillation; TIA = transient ischemic attack; VTE = venous thromboembolism.

characteristics of the individual cases within the Medwatch submissions, such as prior medical history, clinical risk (eg, CHADS2 score), the lack of ability to follow up on an individual case basis, the potential for bias in the reporting mechanism that cannot be controlled, and an unknown denominator of the “at-risk” population. Further, it is not known how many patients abruptly ceased rivaroxaban and did not experience a clinical event, nor is it known how many

## References

1. Sarich TC, Peters G, Berkowitz SD, et al. Rivaroxaban: a novel oral anticoagulant for the prevention and treatment of several thrombosis-mediated conditions. *Ann N Y Acad Sci* 2013;1291:42–55.
2. Mahaffey KW, Hellkamp AS, Patel MR, et al. End of study transition from study drug to open-label vitamin K antagonist therapy: the ROCKET AF experience. *Circ Cardiovasc Qual Outcomes* 2013;6:470–478.
3. Have Atrial Fibrillation? Blood Thinners Can Prevent Strokes, Save Lives. Available at (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm467201.htm>). Accessed December 20 2015.

Appendix 3 – Letter from the Chairman of the Congress of the United States House of Representatives, Committee on the Judiciary, dated 7 March 2017



BOB GOODLATTE, Virginia  
CHAIRMAN

F. JAMES SENSENBRENNER, JR., Wisconsin  
LAMAR S. SMITH, Texas  
STEVE CHABOT, Ohio  
DARRELL E. ISSA, California  
STEVE KING, Iowa  
TRENT FRANKS, Arizona  
LOUIE GOHMERT, Texas  
JIM JORDAN, Ohio  
TED POE, Texas  
JASON CHAFFETZ, Utah  
TOM MARINO, Pennsylvania  
TREY GOWDY, South Carolina  
RAUL R. LABRADOR, Idaho  
BLAKE FARENTHOLD, Texas  
DOUG COLLINS, Georgia  
RON DESANTIS, Florida  
KEN BUCK, Colorado  
JOHN RATCLIFFE, Texas  
MIKE BISHOP, Michigan  
MARTHA ROBY, Alabama  
MATT GAETZ, Florida  
MIKE JOHNSON, Louisiana  
ANDY BIGGS, Arizona

JOHN CONYERS, JR., Michigan  
RANKING MEMBER

JERROLD NADLER, New York  
ZOE LOFGREN, California  
SHEILA JACKSON LEE, Texas  
STEVE COHEN, Tennessee  
HENRY C. "HANK" JOHNSON, JR., Georgia  
JUDY CHU, California  
TED DEUTCH, Florida  
LUIS V. GUTIÉRREZ, Illinois  
KAREN BASS, California  
CEDRIC L. RICHMOND, Louisiana  
HAKEEM S. JEFFRIES, New York  
DAVID CICILLINE, Rhode Island  
ERIC SWALWELL, California  
TED LIEU, California  
JAMIE RASKIN, Maryland  
PRAMILA JAYAPAL, Washington

ONE HUNDRED FIFTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON THE JUDICIARY

2138 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6216

(202) 225-3951  
<http://www.house.gov/judiciary>

March 7, 2017

Linda A. Klein  
President  
American Bar Association  
321 North Clark Street  
Chicago, IL 60654

Dear Ms. Klein:

The American Medical Association (AMA) recently adopted a resolution supporting a legislative or regulatory “requirement that attorney commercials which may cause patients to discontinue medically necessary medications have appropriate warnings that patients should not discontinue medications without seeking the advice of their physician . . .” The AMA’s resolution notes that “[t]elevision commercials that seek plaintiffs regarding new medications are rampant on late-night television,” that “[o]ften potential complications are spoken about them in an alarming way,” and that “[a]s a result of these ads, some patients have endangered themselves by stopping prescribed medications without speaking to a physician.” The AMA resolution concludes that advertisements “are ‘fearmongering’ and dangerous to the public at-large because they do not present a clear picture regarding the product.” Dr. Russell W.H. Kridel, M.D., member of the AMA’s Board of Trustees, explained the need for such commercials to advise patients to consult with a physician before discontinuing medications by noting that:

The onslaught of attorney ads has the potential to frighten patients and place fear between them and their doctor. By emphasizing side effects while ignoring the benefits or the fact that the medication is FDA approved, these ads jeopardize patient care. For many patients, stopping prescribed medication is far more dangerous, and we need to be looking out for them.<sup>1</sup>

Indeed, much of this advertising is designed to frighten patients. After emphasizing the potential side effects of an FDA approved and doctor prescribed medication, one advertisement urges patients to call 1-800-BAD-DRUG<sup>2</sup> -- a less than subtle suggestion that the drug in question is

<sup>1</sup> <https://www.ama-assn.org/ama-adopts-new-policies-final-day-annual-meeting>

<sup>2</sup> <https://www.ispot.tv/ad/793E/pulaski-and-middleman-xarelto-and-pradaxa-warning>

inherently harmful. Another commercial holds itself out to be a “medical alert,”<sup>3</sup> while another one states unequivocally that the FDA approved drug is “dangerous.”<sup>4</sup> One even depicts a patient being loaded into an ambulance.<sup>5</sup> It is little wonder that patients are confused and concerned about such medications and decide to discontinue taking their doctor-prescribed and often lifesaving medication. These deceptive advertisements have had deadly consequences.

A recent article published in the Heart Rhythm Journal reveals that numerous patients have ceased using their anticoagulant without consulting a physician after viewing negative legal advertisements. Based on incidents reported to the FDA Safety Information and Adverse Event Reporting System, the article summarizes these serious cases, including two deaths, as follows:

In the majority of these cases (23/31, 75%), patients experienced a stroke or a transient ischemic neurologic event; 2 patients had persistent residual paralysis. One patient, a 45 year-old man receiving rivaroxaban for treatment of a deep vein thrombosis, stopped the drug and died of a subsequent pulmonary embolism, and 1 female patient, receiving rivaroxaban for stroke prevention, stopped the drug and died of a massive stroke. All these cases were considered to be serious medical events by the health care professionals that submitted the reports.<sup>6</sup>

These reports are extremely alarming and bring into clear focus the rationale for the AMA’s resolution. Their recommendation ensures that legal advertising is not deceptive and that patients are not scared into discontinuing their prescribed medication. Legislation, however, should not be needed. The legal profession, which prides itself on the ability to self-regulate, should consider immediately adopting common sense reforms that require all legal advertising to contain a clear and conspicuous admonition to patients not to discontinue medication without consulting their physician. They should also remind patients that the drugs are approved by the FDA and that doctors prescribe these medications because of the overwhelming health benefits from these drugs. Given the cases noted above, lives depend on it.

Because of our concern about patient safety, we would appreciate your informing the Committee about the steps the ABA is taking to review this matter and amend the Model Rules of Professional Conduct to require common sense reforms like these.

---

<sup>3</sup> <https://www.ispot.tv/ad/Afkx/the-sentinel-group-xarelto-and-pradaxa-alert>

<sup>4</sup> <https://www.ispot.tv/ad/ANKO/guardian-legal-network-users-of-xarelto-or-pradaxa>

<sup>5</sup> <https://www.ispot.tv/ad/AGIM/the-driscoll-firm-xarelto-and-pradaxa-linked-to-internal-bleeding>. This commercial prominently displays the Driscoll firm’s website address, [settlementhelpers.com](http://settlementhelpers.com), which brings one to a page that contains numerous trusted logos including the logo of the American Bar Association, thereby implying an endorsement by the ABA.

<sup>6</sup> [http://www.heartrhythmcasereports.com/article/S2214-0271\(16\)00014-2/abstract](http://www.heartrhythmcasereports.com/article/S2214-0271(16)00014-2/abstract)

Thank you for your attention to this important patient safety issue. We look forward to your response by March 21, 2017.

Sincerely,

A handwritten signature in blue ink that reads "Bob Goodlatte". The signature is written in a cursive style with a large initial "B" and a long horizontal stroke at the end.

Bob Goodlatte  
Chairman