THE CASE AGAINST XARELTO®

When Pharmaceutical Companies Value Profit Over People

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First Edition

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INTRODUCTION

WE EXPECT OUR doctors to provide us with reasonable care, including properly warning us about our medications' benefits and risks. If you've suffered a serious complication like internal bleeding after taking the blood thinner Xarelto®, your trust in the healthcare system may feel violated.

If you've had an adverse reaction to Xarelto® after taking it for Deep Vein Thrombosis (DVT) or a stroke, you're not alone. Since its initial U.S. Food and Drug Administration (FDA) approval in 2011, physicians have prescribed Xarelto® to millions of patients. By 2012, patients had reported more than 350 injuries to the FDA,

which they described as "serious, disturbing, or fatal." According to *The New York Times*, the FDA is even questioning whether malfunctioning devices tainted the drug's approval during a clinical trial.[1]

This is hardly the first time pharmaceutical companies' shoddy practices have led to widespread scrutiny. Unfortunately, such practices can lead to patient injury.

What Should You Do If You've Suffered Serious Side Effects from Xarelto®?

If you or a loved one suffered an injury while on Xarelto®, take the following steps:

- **Talk to your doctor** about alternative treatments. Your health should always be paramount.

1 Thomas, Katie, "F.D.A. Asks If Faulty Blood Monitor Tainted Xarelto Approval." *The New York Times. The New York Times*, 22 Feb. 2016. Web. 11 Apr. 2017.

- **Keep all of your records,** including receipts, insurance claim information, even text messages—anything that can help establish a timeline of your injury or illness.

- **Talk to an experienced injury attorney** about your options for obtaining damages.

In the meantime, please read this complimentary guide, so you can familiarize yourself with the side effects and research connected to Xarelto®. Our law firm's goal is to provide you with **comprehensive and easy to understand information** about Xarelto®. Making an informed decision about how to move forward with a potential claim against the manufacturer of this controversial drug will serve you well.

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All You Need to Know about Xarelto®

RESEARCH ON THIS topic often yields complex information about Xarelto®'s chemical composition and the science behind how it works. We've compiled pertinent information you need to know about the drug:

What is Xarelto®?

Xarelto® is the brand name for the drug rivaroxaban, an oral anticoagulant manufactured by Janssen Pharmaceuticals, Inc., a subsidiary of pharmaceutical giant Johnson & Johnson. Designers derived its trade name from the fact that it's a Xa inhibitor (Xa is one of many that control blood clotting). It was the first drug of its kind to hit the market.

The FDA approved Xarelto® in 2011 as an anticoagulant for patients who'd had hip replacement or knee surgery. Several months later, the FDA approved it for stroke prevention in people with nonvalvular atrial fibrillation.

What Risks Are Associated with Xarelto®?

Any doctor will tell you that most treatments have both risks and benefits. Anticoagulant medications, for instance, can lead to an increased risk of bleeding. A 2013 article, "Risk of Internal Bleeding Heightened with

Anticoagulant Therapy," states, "As use of the direct prothrombin inhibitors increased ... there appeared to be an increasing incidence of intracranial hemorrhage and other bleeding events in patients taking anticoagulants. In addition, patients who sustained injuries ... while taking anticoagulants had an increased incidence of bleeding complications because of the medication."[2]

Currently, no reversal agent exists for uncontrolled bleeding linked to Xarelto®. Hemorrhaging can cause such adverse events as fatal brain and stomach bleeds.

Consider, for example, that a patient taking Xarelto® gets into a car accident and suffers internal injuries. Even if paramedics rush this person to the nearest emergency room, doctors may not be able to stop the uncontrollable bleeding, making even minor internal injuries potentially life threatening. Research also

2 Bledsoe, Bryan. "Risk of Internal Bleeding Heightened with Anticoagulant Therapy." *Journal of Emergency Medical Services*. Journal of Emergency Medical Services, 31 Aug. 2013. Web. 11 Apr. 2017.

connects Xarelto® to myriad other negative side effects, including:

- Abnormal liver function
- Reduced platelets
- Dizziness
- Headache
- Bleeding in the brain
- Intestinal bleeding
- Inability to control movement
- Numbness and tingling

What Is the FDA Doing about Xarelto®?

The government tasks the FDA with protecting patient health by monitoring the safety and continued effectiveness for all prescription drugs on the market. Doctors cannot prescribe medications that are not FDA approved. In the latest hiccup, the FDA found that a malfunctioning medical device may have tainted the results of a clinical trial that lead to Xarelto®'s initial 2011 approval. In 2014 the

FDA recalled the device in question because it didn't accurately assess a patient's bleeding risk. A February 2016 legal brief filed by the FDA asks if Johnson & Johnson knew about the malfunction during the clinical trial.[3]

Beyond Xarelto®'s potential serious side effects, the FDA is even questioning the science behind its approval.

Why Would My Doctor Prescribe Xarelto® to Me?

It seems odd that any doctor would prescribe a drug with so many potential risks, but physicians do have reasons for prescribing it. The drug's creators designed the Xa inhibitor to replace warfarin for targeted patient populations. Warfarin requires strict adherence to dietary restrictions and so-called "warfarin clinics," monthly appointments to check blood levels. If patients receive too little warfarin, they're at risk for stroke or pulmonary embolism. If they

3 Thomas, Katie. "F.D.A. Asks If Faulty Blood Monitor Tainted Xarelto Approval." *The New York Times*. The New York Times, 22 Feb. 2016. Web. 11 Apr. 2017.

have too much, however, they're vulnerable to catastrophic bleeding.

For some patients it's difficult to meet warfarin's necessary requirements. Designers created Xarelto® to eliminate the need for repeated trips to the doctor for blood tests. Candidates for Xarelto® may include patients who are compliant with taking daily medications and those who have no serious history of gastrointestinal (GI) bleeding.

Is Legal Action Being Taken against Xarelto® Manufacturer Johnson & Johnson?

The FDA approved Xarelto® for use in certain populations in 2011. By the end of the first quarter in 2012, per the Institute for Safe Medication Practices, victims had already reported 356 incidences of serious or fatal injuries.[4] In response, the FDA placed a so-called "black box warning" on Xarelto®, to alert

4 Courthouse News Service. "Death Blamed on New Blood Thinner." *Courthouse News Service*. N.p., 14 Apr. 2014. Web. 11 Apr. 2017.

consumers about potentially life-threatening side effects.

The statistics surrounding the controversial anticoagulant are alarming:

- In 2015, a XANTUS study found that 2–3% of all patients taking Xarelto® suffered major internal bleeding.
- In the last five months of 2013, pharmaceutical companies paid doctors $20 million to promote blood-thinning medications like Xarelto®.[5]
- As of January 2016, the Judicial Panel on Multidistrict Litigation (MDL) reported 2,826 lawsuits related to internal bleeding pending in MDL Xarelto® Court.

5 Ornstein, Charles, and Ryann Grochowski Jones. "The Drugs That Companies Promote to Doctors Are Rarely Breakthroughs." *The New York Times*. The New York Times, 07 Jan. 2015. Web. 11 Apr. 2017.

Janssen Pharmaceuticals, Inc. and its parent company, Johnson & Johnson (and Bayer, which markets Xarelto® outside of the U.S.), face lawsuits of varying magnitude, based on all of the following grounds:

- They failed to appropriately warn patients of the risks associated with taking Xarelto®.
- The drug companies failed to properly advise physicians on how to stabilize patients in the event of massive internal bleeding.
- Johnson & Johnson, Bayer, and Janssen marketed the drug as a superior alternative to warfarin, even though it had a more dangerous side effect profile.
- The drug manufactures devoted more energy to maximizing profits than they did minimizing the drug's side effects.

Plaintiffs in these nearly 3,000 cases are seeking compensation for their injuries, in

the form of reimbursed medical expenses, lost wages, loss of earning capacity, pain and suffering, and funeral costs (for those who lost loved ones). Many cases also seek punitive damages for gross negligence. These damages seek to punish the pharmaceutical companies and discourage other parties from acting in kind.

Each state has a different time frame for filing personal injury lawsuits, called the *statute of limitations*. Anyone who has experienced adverse side effects or injury from taking Xarelto® should speak with an experienced attorney as soon as possible, to determine their claim's validity and the time periods that govern their ability to file a claim.

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Legal Considerations and Their Implications

Failing to Warn of the Risks

MANY LAWSUITS FILED against large drug companies involve claims that drugmakers failed to warn patients of the risks involved with these medications. Across the U.S., thousands of Xarelto® cases have already been filed.

One case in this litigation involves the widow of a deceased man who had taken Xarelto® to prevent strokes associated with atrial fibrillation. She filed a wrongful death suit on her husband's behalf. In her lawsuit, she says drug manufacturers failed to warn of the internal bleeding risks. Her husband died of a subdural hemorrhage (brain bleed), after doctors were unable to control his symptoms.

Deliberately Concealing Information

Some cases claim that Johnson & Johnson has done more than fail to warn of the medication's risks. In a lawsuit filed in 2016, victims accused the company of deliberately misleading one of the world's most renowned medical journals.[6]

In a legal briefing, lawyers for plaintiffs suing Bayer and Johnson & Johnson wrote that a letter the company published in the *New England Journal of Medicine* omitted critical laboratory data. Editors for the highly regarded

6 Thomas, Katie. "Document Claims Drug Makers Deceived a Top Medical Journal." *The New York Times*. The New York Times, 01 Mar. 2016. Web. 11 Apr. 2017.

publication didn't know of the data's existence until a reporter contacted them to discuss it.

If proven, allegations like these suggest that Bayer and Johnson & Johnson may have cared more about protecting their $2 billion a year net profit from the pill than they cared about patients' lives.

The brief also asks the courts to unseal more than 5,000 records of patients who have filed lawsuits involving Xarelto®. Of those records, 500 involved patient deaths.

Ignoring Their Own Recommendations

Xarelto®'s shaky ties with ethics began with its initial 2011 approval. An investigation into a clinical trial involving 14,000 patients found that the study leading to Xarelto®'s approval may have been faulty. A look at Xarelto®'s history shows that the pharmaceutical companies that peddle the drug have repeatedly ignored FDA advice.

Although the FDA initially approved Xarelto® for postsurgery prophylaxis, doctors have since used it to prevent strokes in those who suffer from a common cardiac irregularity, atrial fibrillation. Since then, Janssen has touted the drug as a safer alternative to Coumadin®, the blood-thinning drug of choice since the 1960s.

The appeal of forgoing warfarin (Coumadin®), along with its strict requirements, led to Xarelto®'s popularity, causing it to become a multibillion-dollar product annually. But this popularity also possibly led the pharmaceutical companies that profited from Xarelto® to conceal some of the drug's most dire side effects.

Johnson & Johnson marketed the drug to doctors based on the convenience of a test-free alternative to warfarin, and it's true that the FDA didn't require it. However, the company's 2011 review of the drug did highly recommend periodic patient testing. According to an internal company report, monitoring, perhaps at the

yearly mark, would be minimally inconvenient to patients and likely to improve their outcomes.

If Xarelto® manufacturers had adhered to these guidelines, there might have been fewer complications and deaths. Directing physicians to engage in annual testing could have saved lives, and the drug would have likely still beat out its competition, warfarin.

Why Did the FDA Approve Xarelto®?

The government tasks the FDA with protecting public health by regulating prescription drugs. Why, then, did it approve such a seemingly dangerous drug?

FDA approval does not mean that a product is absolutely safe from side effects, or that its effectiveness has been confirmed in a clinical trial. The FDA clears some medical products as long as the manufacturer can prove they are substantially similar to a product already on the market. And like every other government entity, the FDA is hindered by budgetary constraints,

while also navigating its dealings with the multibillion-dollar pharmaceutical industry.

The FDA Pushes Back

The FDA may have approved Xarelto® for atrial fibrillation and postoperative prophylaxis, but the drug's manufacturers have tried to get it approved for much more. Ignoring FDA cautions, in 2014 manufacturers pushed for FDA approval for Xarelto® to treat three new diseases: acute coronary syndrome (ACS), peripheral artery disease, and embolic stroke of undetermined source.

Despite multiple attempts and clinical trials, the FDA has never approved Xarelto® for these conditions; the last attempt resulted in a unanimous 10-0 rejection. Additionally, FDA advisory panels are beginning to crack down on how doctors prescribe Xarelto®.

Carelessness and Recalls

Troubles adhering to the FDA standards and failing to warn of potential risks aren't the only issues with the drug's manufacturer. In October 2014, the courts ordered Janssen to recall 13,500 bottles of Xarelto®, after they discovered microbial contamination.

This isn't the first recall in Janssen's history. Just one year prior to the Xarelto® recall, the company was forced to recall 5,000 vials of a popular antipsychotic medication, after they were found to be contaminated with mold.

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Patient Stories

DOCTORS, PATIENTS, AND their advocates are beginning to realize that pharmaceutical companies like Bayer and Johnson & Johnson have too much power. Turn on the TV, and you'll see Xarelto® ads studded with celebrities insisting that taking Xarelto® was the right move for them. The same can't be said for these patients (please note that these are *not* Auger & Auger clients):

Injured Patient 1

Injured Patient 1 is a 37-year-old medical technician from South Florida, who suffered massive blood loss while taking Xarelto®. After her doctors diagnosed her with atrial fibrillation, they placed her on the anticoagulant, which she took as they prescribed. However, during her next menstrual period, she began bleeding profusely and was rushed to the ER and required a two-pint blood transfusion. She joined thousands of other claimants in what's becoming a mass tort action.

Injured Patient 2

Injured Patient 2 is a woman from Georgia whose doctor also prescribed Xarelto® in 2013 for atrial fibrillation. She, too, took the medication as directed. Within two months, she suffered a severe GI bleed that irreversibly damaged her digestive system. This complication is not uncommon: several other claimants have similar stories.

A Wrongful Death

Of the current court cases, several are wrongful death claims. One involves a plaintiff from Georgia, who asserts that his father is dead because Janssen Pharmaceuticals failed to properly warn of Xarelto®'s risks. The plaintiff's father had an accident that triggered uncontrollable, massive internal bleeding. In his complaint, the plaintiff indicated that while the family knew about the bleeding risks associated with Xarelto®, they were unaware that such bleeding would be irreversible.

How the Lawsuit Process Works

All companies have a "duty of care" to those who use their products. If they manufacture, distribute, or market products that injure or harm, they may be liable for negligence. Victims of negligence, including loved ones, are eligible to receive compensation, also called "damages."

When a person brings a claim to court, the law calls it a *tort*. Torts are civil actions, not criminal

ones. To be successful in a personal injury tort case, claimants (or plaintiffs) must prove that they, or a loved one, suffered an injury that led to their damages. These can be economic costs, like medical bills, or general damages like pain and suffering, or loss of consortium.

The plaintiff must prove that the defendant was negligent and that negligence directly or indirectly led to his or her injury. A plaintiff must also prove that he or she suffered an injury or damages. To show damages, evidence such as medical treatment and how the negligence affected the plaintiff will be considered. The burden of proof in a civil case is by "a preponderance of evidence." That means the plaintiff must show it was more likely than not that he or she was injured by the defendant's actions.

When several people are harmed under similar circumstances, it's often beneficial to organize a mass tort action. The courts will

ultimately rule on the merit of a class-action suit based on several factors, such as the following:

- How many plaintiffs are involved?
- Where do they live?
- Are the injuries similar?
- Can the injuries be linked to one likely cause?

Mass tort actions are different from class-action suits, although the two processes are similar. While both bring similarly injured plaintiffs together in similar cases, a mass tort action has separate trials; in a class-action suit, the law treats all the plaintiffs as the same entity. Class-action suits have a single outcome, while mass tort litigation gives attorneys the ability to represent injured parties in individual cases and trials.

What's Happening with the Xarelto Mass Torts?

Mass torts involving Xarelto have evolved into two different civil actions: an MDL that originated in Louisiana and a second mass tort action underway in Philadelphia, PA. Together, these make up over 2,800 cases currently awaiting litigation.

Xarelto lawsuits began "bellwether" trials in 2017. A bellwether trial is a sampling of plaintiffs that sets the tone for the rest and helps ease the court system's case load. As the lawsuits become more publicized, it's likely that more plaintiffs will join the mass tort action. A result in favor of the plaintiffs will almost certainly lead to fewer people being harmed by Xarelto®.

Future Direction and Final Thoughts

WHEN THE ANTICOAGULANT Xarelto® entered the market in 2011, doctors and patients alike viewed the drug with hopeful eyes. Perhaps Xarelto® could be a safer, more easily controlled alternative to Coumadin®. Frustratingly, in the eyes of many experts, the drug fell short of what was hoped for, and many people suffered serious harm from taking this medication.

The information that we've provided is a view of what happens when megacompanies like Johnson & Johnson and Bayer value profits over people's safety. FDA warnings, as well as

doctor-recommended monitoring guidelines, weren't enough to prevent patient harm.

While all anticoagulants carry risk of bleeding and other complications, many Xarelto® patients had no idea that such bleeding could be irreversible.

Prescription drugs are heavily marketed and advertised. With all of the commercials, fancy drug names, paid spokespeople, and long lists of disclosed side effects, it's hard to know what to believe. If you or a loved one take an anticoagulant medication, talk to a doctor about all the risks and benefits. Ask about routine blood checks and the importance of your medication compliance.

Have You Been Injured by Xarelto®?

If you or a loved one suffered harm after taking the prescription drug Xarelto®, you may have lots questions, such as the following:

- Who will pay for my medical bills?

- Am I entitled to compensation for lost wages?
- How will I pay for my future medical care?
- Who will pay for my loved one's funeral expenses?

A qualified attorney who handles Xarelto® claims can help you answer these questions.

You may be entitled to compensation that could reimburse you for economic damages and other claims, such as loss of consortium and pain and suffering.

Your journey to a fair outcome begins with retaining the right lawyers—professionals who understand how to obtain fair compensation for clients; lawyers with systems and processes in place to keep you up to date about your case's status and to be clear about your options.

Auger & Auger has experience fighting and obtaining successful results for clients who have been injured due to others' negligence. Over the

years, our firm has secured **over $50 million** for injury victims and their families.

At Auger & Auger, we offer a free initial consultation with one of our attorneys or professional staff members. A case evaluation allows us to review the specifics of your claim. We take our cases on a contingency-fee basis. We don't get paid unless your case has a successful result.

We're committed to helping the injured get justice. No business should value profit more than people, and you should never have to pay the price for someone else's negligence. To get started with your free initial consultation today, contact us at (800) 559-5741. We're available to talk 24 hours a day, 7 days a week.

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