

# Mass Tort Ads

*Sowing Confusion or Educating Potential Victims?*

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Late-night and daytime television viewers are surely familiar with the ads soliciting patients for mass tort litigation involving an allegedly dangerous drug or device. “If you or a loved one took Xarelto and suffered internal bleeding,” intones a concerned and somewhat urgent voiceover, “you may be entitled to substantial compensation.”

Among the drugs most recently appearing in those ads are several novel anticoagulants—dabigatran (Pradaxa), rivaroxaban (Xarelto), and apixaban (Eliquis)—rolled out between 2010 and 2012 as alternatives to the problematic warfarin (Coumadin).

The first of the new anticoagulants to come on the market was dabigatran, and soon thereafter reports of uncontrolled bleeding were leading to lawsuits. Approximately 4,000 lawsuits claiming harm were largely settled in June 2014 when manufacturer Boehringer Ingelheim offered claimants \$650 million while admitting no wrongdoing. The drug remains in use, and 560,887 prescriptions for it were sold in the last quarter of 2014 (in that same period, 80.2 million prescriptions were sold for warfarin, 1.75 million for rivaroxaban, and 609,301 for apixaban).

Just a month after the settlement on dabigatran, there was a large uptick in lawsuits claiming harm from rivaroxaban, noted Rustin Silverstein, whose firm tracks mass tort advertising and its relationship to product

liability lawsuits and prescriptions filled. “It’s not an accident that [legal ads targeting] Xarelto started a month after the Pradaxa settlement was announced,” he said. “I think the calculation was, ‘Wow, that was a big payout; what’s the next thing?’ And there was Xarelto.”

Silverstein said 70,000 rivaroxaban mass tort litigation ads have been broadcast since the beginning of 2015, at an estimated cost of more than \$23 million. There are approximately 1,800 lawsuits now in federal court, all of them being organized into a multiple-district litigation based in New Orleans.

Mass tort advertising is now also targeting apixaban, which came on the market in 2012. A fourth of the so-called direct oral anticoagulants, edoxaban, was approved by the Food and Drug Administration (FDA) in January 2015. Mass tort television advertising against all types of products has doubled during the past 5 years, Silverstein estimated, now totaling more than \$150 million a year.

Emergency physician Frank Peacock, MD, is irked by the advertising and its potential effect on patients receiving anticoagulation therapy, who he believes may be frightened into stopping their medication. In fact, he has seen it happen. He treated a patient in the emergency department (ED) who had been prescribed rivaroxaban for atrial fibrillation but soon after saw a mass tort advertisement that scared her, so she quit receiving her anticoagulant.

“She shows up in my ER freaked out, having not taken the drug for 4

days and at risk of stroke,” recalled Dr. Peacock. “I spent an hour talking with this lady trying to help her understand the risks and benefits of the situation she’d gotten into.”

## SCARE TACTICS?

Dr. Peacock was curious whether there were other patients who had been scared off their anticoagulant prescription and had had a bad outcome, so he asked rivaroxaban maker Janssen Pharmaceuticals, with which he has worked carrying out postmarket research on the drug. The company gave him a list of more than 20 patients who had clotting events after stopping the medication because of a mass tort advertisement. Two of the patients died, the company said in an e-mail in response to questions from *Annals*.

Some Xarelto legal ads do include a caveat to talk to a physician before deciding whether to stop receiving the drug, and some do not. Dr. Peacock questioned why lawyers do not have to follow the same rules for advertising the risks and benefits of drugs that pharmaceutical companies do. Paul Rheingold, a veteran litigator in mass torts, said that regulation of legal advertising has typically been shot down by higher courts on freedom of speech grounds.

“There are no guidelines [for mass tort ads] and the goal is for lawyers to get cases,” he said.

Law firms pursuing mass torts have ventured into more sophisticated marketing techniques in recent years, both Silverstein and Rheingold said, including buying the names of potential victims from third parties that sponsor the advertising. “An aggregator will call and say, ‘I have 100 Xarelto leads’” and ask \$50,000 for them, said Rheingold. “There must be dozens, if not hundreds, of entrepreneurs running that type of approach. They don’t screen them....

[T]hey're not likely to turn out to be good Xarelto cases."

Although those excesses of mass torts may be unseemly, plaintiffs' attorneys argue that there are also plenty of serious, responsible attorneys working mass torts to perform the important societal function of helping powerless individuals who have been harmed by a giant pharmaceutical company's product get medical help and compensation for their injuries.

Thomas Moore, senior scientist for the Institute for Safe Medication Practices, argues that there is nothing inaccurate about the advertising, and if it makes patients more aware of the risks of the anticoagulants they are receiving, that is a good thing. He sees it as a counterbalance to the onslaught of drugmakers' ads touting their products.

"Patients need to know more about the risks and benefits of the drug and have a hard, careful conversation with their physician and not be swayed by advertising in either direction," Moore said.

Brian Barr, colead counsel for the plaintiffs in the Xarelto multidistrict litigation, asked why it is necessary to advertise an anticoagulant drug directly to consumers in the first place, given that physicians are the ones who need to weigh risks and benefits of prescribing. Worse yet, patients are not informed when risks about a drug are identified after it is on the market. "The only way a person who takes the drug has the ability to learn they may have been harmed is by seeing legal ads," he said. If there is a postmarket risk identified, "the pharmaceutical companies say their obligation is to warn the doctor, not the patient. They send 'Dear Doctor' letters."

## REGULATING RISKY DRUGS

In theory, the legal system provides a useful check on bad drugs harming patients, products that slip through cracks in the FDA's

approval and postmarketing surveillance system. The Institute for Safe Medicine Practices reported in September 2015 that there were 525 direct reports to the FDA of serious injury from rivaroxaban in 2014, the most of any drug.

That is one reason the direct oral anticoagulants have been targeted by plaintiffs' lawyers: anticoagulants, including the 60-year-old warfarin, regularly show up near the top of lists of risky drugs and those that potentially cause harm. Calibrating the tricky balance between clotting and bleeding is bound to result in unwanted outcomes in either direction.

"They're just risky drugs by the nature of what they do," said emergency physician Ryan Radecki, MD, MS, who wrote a recent review of the latest evidence on the new anticoagulants for *ACEP Now*.

The novel anticoagulants were embraced as a welcome alternative to warfarin, which is difficult and time consuming to manage, requiring regular blood tests at an anticoagulation clinic or physician's office. As approved by the FDA, dabigatran, rivaroxaban, and apixaban do not require regular blood tests to calibrate dosage, do not require dietary restrictions, and present a lesser risk of brain bleeds than does warfarin. That does not mean they are risk free, as the reports of gastrointestinal bleeding can attest.

The drugs are managed "on a razor's edge," said Moore. "Too much, you have a bleed; and not enough and you've got a stroke."

So careful use of the entire class of anticoagulants is key, and that has not always happened, said Ann Wittkowski, PharmD, director of anticoagulation services at the University of Washington Medical Center in Seattle. That means some of the bad outcomes from the new anticoagulants might be "not a drug failure but a

prescription failure." "There were early-adopter prescribers who may have jumped the gun, attempting to use these new drugs in the wrong dose or in the wrong patients, resulting in adverse outcomes," Dr. Wittkowski said. (Dr. Wittkowski provides some detailed guidance on use of the new anticoagulants in a Medscape article<sup>1</sup>, and her clinic maintains anticoagulant management guidelines online.)

That was particularly the case with dabigatran, which has a higher degree of renal clearance than other direct oral anticoagulants. So people older than 75 years or with reduced kidney function might end up with more of the drug in their systems.

Meanwhile, dabigatran maker Boehringer Ingelheim said in an e-mail that it "stands resolutely behind Pradaxa." The firm cited several factors that can lead a company to settle lawsuits, as it did to the tune of \$650 million. "A large driver in [Boehringer Ingelheim's] decision to settle was the fact that the litigation diverted time and focus from research and patient care," the e-mail said.

The 3 newer anticoagulants are touted as needing no blood-level testing, although critics say that results in uneven levels throughout the day, leading to less effective protection against clotting and increased risk of bleeding. Dr. Peacock disagreed, saying that rivaroxaban is taken at dinnertime on purpose, so if an increased level of the drug poses a bleeding risk it will happen at night when it is less dangerous. Increasing the likelihood that patients will use the medication as directed with simpler dosing is worthwhile, Dr. Peacock argued. In any event, apixaban is being seen as less problematic because of its twice-daily dosing.

These small differences in dosing and how the drugs are metabolized require a thorough knowledge on the part of a prescribing physician to

evaluate their suitability for each patient. That evaluation should take into account both the potential risks from the disease itself and alternative drug treatments, anticoagulation specialists say. Both Dr. Peacock and Dr. Wittkowski see potential benefits from direct oral anticoagulants when looking at the alternatives, such as warfarin's higher risk of brain bleeds.

Still, Moore is skeptical about all the warfarin alternatives, arguing that the FDA should not have let their manufacturers develop them with an emphasis on patient ease of use, reducing physician oversight. "We think the ease of use idea is a bad idea," said Moore. "This treatment is too risky."

## ANTICOAGULANTS IN THE ED

For emergency physicians, the most likely scenario for choosing anticoagulant therapy is someone's receiving a new diagnosis in the ED of a thrombosis or pulmonary embolism. Dr. Peacock argued that instead of admitting them into the hospital to receive intravenous heparin or subcutaneous enoxaparin sodium, some portion of these patients could be sent home with rivaroxaban, which ramps up much more quickly than warfarin.

"These new drugs work immediately, so why do I put you in the hospital? I probably shouldn't," Dr. Peacock said. Some patients identified in the ED with atrial fibrillation could also go home with a novel anticoagulant, he said.

Given the risky territory, many physicians have simply kept to the

sidelines in these early years of use of the newer anticoagulants, sticking with the devil they know, warfarin. Dr. Peacock said there will be helpful guidance for emergency physicians soon because the original clinical trial data continue to be plumbed for insights on more nuanced use of the drugs.

Emergency physicians may also encounter patients who are receiving anticoagulant therapy and have had an injury that is causing bleeding, and need an antidote to stop it. If it is warfarin, there's vitamin K, plasma, and prothrombin complex concentrates. With the new drugs out on the market for a few years, most EDs should have by now developed protocols for treating bleeding in the presence of any of the anticoagulants, said Dr. Radecki. However, a specific reversal agent for Pradaxa called Praxbind (Boehringer Ingelheim) was approved in late 2015, and an application for approval of Andexanet Alfa (Portola Pharmaceuticals), a reversal agent for the other new drugs, was being reviewed by the FDA in late 2015. A third "universal" reversal agent, Ciraparantag (PER977, Perosphere Pharmaceuticals), was in late phase testing.

Patients, possibly bewildered by both pharmaceutical company ads touting the drugs and law firms warning of the risks, will need clear explanations about why an anticoagulant is being prescribed in their particular situation. "Most times a patient is initiated on an anticoagulant medication for a chronic medical condition, they're having a detailed

conversation about risks, and then the relative pros and cons of the various options," said Dr. Radecki. "For some patients, I'm sure communicating the uncertainty for safety for these new medications will influence them to choose an older option."

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## REFERENCE

1. Fiore M, Wittkowsky AK. The New Anticoagulants: Indications and Risks. *Medscape* July 24, 2014, Available at, <http://www.medscape.com/viewarticle/828669>.