

# CIVIL JUSTICE RESPONSE AND DRUG, DEVICE AND BIOTECHNOLOGY

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# IN THIS ISSUE

Plaintiffs' attorneys are spending billions of dollars saturating the airwaves with advertisements that target prescription drugs and medical devices for lawsuits. Many of these ads are misleading and alarmist; some have led to the deaths of frightened consumers who stopped taking their medications after seeing such commercials. In 2019, Tennessee and Texas enacted first-of-its-kind legislation regulating ads for legal services. Critics of the new laws claim they violate plaintiff lawyers' free speech rights while proponents find them important to protect public health.

# Alert: Deceptive Plaintiff Lawyer Advertising is Harmful to Public Health... and States are Taking Action



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- 2 -

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- 3 -

After suffering from a deep vein thrombosis, a 45-year old man was prescribed life-saving medication by his doctor. Negative lawsuit ads about the product led the man to discontinue the medication without consulting his physician. The man suffered a pulmonary embolism and died.<sup>1</sup>

Unfortunately, this person's story is not unique. For example, in 2016, the U.S. Food & Drug Administration received 61 reports from health care professionals whose patients discontinued or reduced their use of blood thinners after viewing lawsuit advertisements.<sup>2</sup> Six of the patients died.<sup>3</sup>

This year, Tennessee then Texas enacted first-of-its-kind legislation to regulate misleading practices often found in plaintiff lawyer mass tort advertising.<sup>4</sup> The laws take effect on July 1 and September 1, 2019, respectively.

This article discusses the problems with plaintiff lawyer advertisements that target prescription drugs and medical devices for litigation. It then analyzes the new Tennessee and Texas laws. The article concludes by briefly responding to opponents' claims that regulating misleading lawsuit advertising violates the First Amendment.

#### The Problem with Misleading Lawsuit Ads

Lawsuit advertisements that target prescription drugs and medical devices contain sensationalized information about the risks associated with those products. The advertisements often begin by flashing words like "medical alert" or "health alert."<sup>5</sup> The ads then attempt to bolster their credibility by incorporating images of government agency logos such as the FDA logo.<sup>6</sup> Because the ads look legitimate, consumers may believe they are watching a public service announcement or receiving sound advice from a medical professional. What viewers are actually watching is fearmongering by plaintiff attorneys seeking to convince them to file lawsuits.

The information conveyed in lawsuit commercials may be unreliable. For

<sup>&</sup>lt;sup>1</sup> Paul Burton & W. Frank Peacock, A Medwatch Review of Reported Events in Patients Who Discontinued Rivaroxaban (XARELTO) Therapy in Response to Legal Advertising, Heart Rhythm Case Reports, v. 2, issue 3, 248-49 (May 2016), at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC541 9767/.

<sup>&</sup>lt;sup>2</sup> See Cary Silverman, Bad for your Health: Lawsuit Advertising Implications and Solutions, U.S. Chamber Inst. for Legal Reform (Oct. 2017), at 25 (citing Letter from Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, U.S. Food & Drug Admin. to Hon. Andy Harris, M.D., U.S. House of Rep. (2017)), at

https://www.instituteforlegalreform.com/research/ bad-for-your-health-lawsuit-advertisingimplications-solutions.

<sup>&</sup>lt;sup>3</sup> Id.

<sup>&</sup>lt;sup>4</sup> Tenn. Pub. Chap. 2019-116 (H.B. 352) (to be codified at Tenn. Code §§ 47-18-5601 et seq.), at <u>https://legiscan.com/TN/text/SB0352/id/1998216/T</u> <u>ennessee-2019-SB0352-Chaptered.pdf;</u> S.B. 1189, 86th Leg. (Tex. 2019) (to be codified at Tex. Gov't Code §§ 81.151 et seq.), at <u>https://legiscan.com/TX/text/SB1189/id/2024451/T</u> <u>exas-2019-SB1189-Enrolled.html</u>.

<sup>&</sup>lt;sup>5</sup> Silverman, *supra* note 2, at 1-2.
<sup>6</sup> *Id.* at 13.



**CIVIL JUSTICE RESPONSE AND DRUG, DEVICE AND BIOTECHNOLOGY JOINT NEWSLETTER** June 2019

example, in 2015, lawsuit advertisements told viewers that taking the anti-nausea drug Zofran during pregnancy could increase the risk of birth defects including cleft lip and cleft palate.7 Viewers were told to call "1-800-BAD DRUG" to potentially obtain "Substantial Compensation."<sup>8</sup> The FDA, however. found insufficient scientific evidence to support the claims, and a subsequent study confirmed that no connection exists between Zofran and birth defects.9

Lawsuit advertisements typically do not disclose the likelihood that a person will experience an adverse effect associated with product.<sup>10</sup> Without this the critical information, viewers are unable to weigh the risks and benefits of treatment, or the impact of discontinuing or reducing the use of a medication or having a medical device removed.

Most lawsuit ads conclude with fine print that is too small and too briefly shown for viewers to read. This text often informs

https://www.youtube.com/watch?v=nfG6d3blrQs. <sup>8</sup> Id.

<sup>9</sup> See FDA, Response to Citizen Petition of James P. Reichmann, Docket No. FDA-2013-P-0048 (Oct. 27, 2015) (denying citizen petition requesting that FDA reclassify Zofran to reflect a higher degree of risk when taken during pregnancy and to warn OB/GYNs that use of Zofran during pregnancy can lead to adverse maternal or fetal outcomes after closely review all available scientific literature and other http://zofran.monheit.com/wpdata), at content/uploads/2016/02/Citizen Petition Denial R esponse from FDA CDER to Mr James P Reichm ann Redacted.pdf; see also Marlena S. Fejzo et al.,

viewers that the advertisement is for legal services, that the sponsor is not an attorney but a company that specializes in generating "leads" for law firms, and that any legal work may be handled by others. Callers are sometimes routed to foreign call centers, who take basic information to screen claims. Very few of the ads advise viewers to speak with their doctors before discontinuing or reducing use of a prescription medication.

Lawsuit ads intentionally leave viewerswho may be potential plaintiffs and jurorswith the impression that a particular product is a "bad drug," and may suggest that it has been recalled, even when the product remains FDA-approved.

#### How Significant is this Problem?

Lawyer spending on television advertising has grown at a rate six times faster than all other television ad spending.<sup>11</sup>

2018, the American Tort Reform In Association estimated that \$226 million was

Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes in the United States, 62 Reproductive Toxicology 134-37 (July 2016) (finding women who took Zofran during pregnancy for extreme morning sickness reported fewer miscarriages and pregnancy terminations and higher live birth rates than women who did not take the drug, and finding no support that Zofran increases the risk of birth defects), at https://www.ncbi.nlm.nih.gov/pubmed/27151373.

https://www.instituteforlegalreform.com/uploads/si tes/1/TrialLawyerMarketing.pdf.

<sup>&</sup>lt;sup>7</sup> See Zofran Birth Defect Warning 1-800-BADDRUG Ad, at

<sup>&</sup>lt;sup>10</sup> See Silverman, supra note 2, at 12.

<sup>&</sup>lt;sup>11</sup> Ken Goldstein & Dhavan V. Shah, *Trial Lawyer* Marketing: Broadcast, Search, and Social Strategies, U.S. Chamber Inst. for Legal Reform (Oct. 27, 2015), at



- 5 -

spent on television ads for legal services in the third quarter of 2018 alone.<sup>12</sup> Total spending on legal advertisements (television, radio, and Internet) may reach \$1 billion annually.<sup>13</sup>

Advertisements for lawsuits against manufacturers of prescription drugs and medical devices make up the largest share of legal services advertising on television.<sup>14</sup>

#### What are the Consequences?

One in four people who take prescription drugs have reported they would stop taking their medication *immediately,* without consulting a doctor, if they saw a lawsuit advertisement involving the drug.<sup>15</sup>

One recent study found that when viewers were shown two television commercials soliciting lawsuits targeting a reflux drug one that purported to be a public service warning and another that clearly disclosed its purpose as a lawsuit advertisementthose who viewed the ad presented as a health alert were less likely to fill a new prescription or refill an existing prescription.<sup>16</sup>

An earlier survey of psychiatrists who treat patients for schizophrenia and bipolar disorder reported patients stopping their medication or reducing their dosages without consulting them first. "More than half attributed these actions to lawsuit ads."<sup>17</sup>

The American Medical Association has recognized that patients are more likely to discontinue prescribed medications after seeing television advertisements that "emphasize side effects while ignoring the benefits or the fact that the medication is FDA approved."<sup>18</sup>

The targeted advertisements compromise the doctor-patient relationship. Patients who view negative advertisements perceive them as "medical advice, and they are often

<sup>&</sup>lt;sup>12</sup> See Am. Tort Reform Ass'n, Local Legal Services Television Advertising—2018 Quarter 3 (Dec. 2018), at <u>http://www.atra.org/wpcontent/uploads/2019/01/ATRA\_Q3\_Legal\_Services</u> \_Ad\_Spending\_Report.pdf.

<sup>&</sup>lt;sup>13</sup> See Silverman, supra note 2, at 1.

<sup>&</sup>lt;sup>14</sup> *Id.* at 6.

<sup>&</sup>lt;sup>15</sup> See Lisa Rickard, Warning: Lawsuit Ads May Be Harmful to the Health of Americans, The Hill, June 23, 2017, at <u>https://thehill.com/blogs/congressblog/judicial/339057-warning-lawsuit-ads-may-be-</u> harmful-to-the-health-of-americans.

<sup>&</sup>lt;sup>16</sup> See Jesse King & Elizabeth Tippett, Drug Injury Advertising, Yale J. of Health Pol'y L. & Ethics (forthcoming 2019), at https://papers.ssrn.com/sol3/papers.cfm?abstract i d=3220066.

<sup>&</sup>lt;sup>17</sup> Silverman, *supra* note 2, at 3.

<sup>&</sup>lt;sup>18</sup> Jessica Karmasek, AMA: Lawyer Ads Are Alarming Prescription Drug Users, Jeopardizing Health Care, Forbes.com, July 21, 2016 (quoting Russell W. H. Kridel, M.D., an AMA board member), at <u>https://www.forbes.com/sites/legalnewsline/2016/0</u> 7/21/ama-lawyer-ads-are-alarming-prescriptiondrug-users-jeopardizing-health-

<sup>&</sup>lt;u>care/#140e8e52369e</u>; see also Am. Med. Ass'n, Attorney Ads on Drug Side Effects H-105.985, Resolution 208, A-16 (June 2016), at https://policysearch.ama-

assn.org/policyfinder/detail/Attorney%20Ads%20on %20Drug%20Side%20Effects%20H-105\_0%52uri=%25AMADoc%25HOD\_105\_0%5 xml

<sup>105.985?</sup>uri=%2FAMADoc%2FHOD-105.985.xml.



in direct contradiction to that of their physicians," according to a North Carolina board certified vascular surgeon who testified before Congress.<sup>19</sup> This leads patients to distrust their doctors and refuse sound medical advice-believing that the person giving them the advice had prescribed a drug that could harm them.

#### What is the Solution?

Tennessee and Texas recently enacted legislation regulating deceptive practices that are common in mass tort advertising.<sup>20</sup>

Both laws include provisions that ensure that viewers will understand that they are seeing a legal advertisement. All lawyer ads must indicate that thev are paid advertisements for legal services. An ad may not be presented as a "medical alert," alert," "public "health service announcement," or other similar phrase.

The new laws also prohibit legal services ads from using the term "recall" when a product has not been recalled by a government agency or through an agreement between a manufacturer and government agency. And the laws forbid the displaying of a government agency logo in a manner that suggests an affiliation with the agency. These provisions apply to lawsuit ads targeting any products that are regulated by federal or state agencies (e.g., consumer products and automobiles), not just prescription drugs and medical devices.

When a lawsuit ad involves a prescription drug, both laws require that ad to warn viewers not to stop taking the medication without first consulting a physician. In addition, the Tennessee law requires legal services ads to disclose that the subject drug or medical device remains FDA-approved (unless, of course, it has been recalled).

Both laws include provisions to make sure that these disclosures are not merely flashed in fine print, but that viewers are able to hear and read the required information.

There is an important distinction regarding the scope of the two laws. The Tennessee law applies to all advertisements, including radio, television, Internet, websites, all other newspapers, billboards, and written, electronic, or recorded information.<sup>21</sup> The Texas law applies only to "television advertisements" for legal services.<sup>22</sup>

The laws also vary in how they will be enforced. A violation of the Tennessee law is

<sup>&</sup>lt;sup>19</sup> Testimony of Shawn H. Fleming, M.D., Novant Health Vascular Specialists, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Regarding Responsibilities Ethical Attorney Advertising." June 23, 2017, at https://www.govinfo.gov/content/pkg/CHRG-115hhrg29776/html/CHRG-115hhrg29776.htm.

<sup>&</sup>lt;sup>20</sup> Tenn. Pub. Chap. 2019-116 (H.B. 352) (to be codified at Tenn. Code §§ 47-18-5601 et seq.); S.B. 1189, 86th Leg. (Tex. 2019) (to be codified at Tex. Gov't Code §§ 81.151 et seq.).

<sup>&</sup>lt;sup>21</sup> See Tenn. Code § 47-18-5601(1).

<sup>&</sup>lt;sup>22</sup> See Tex. Gov't Code § 81.151(a).



CIVIL JUSTICE RESPONSE AND DRUG, DEVICE AND BIOTECHNOLOGY JOINT NEWSLETTER June 2019

an unfair or deceptive act or practice under the state's consumer protection law.<sup>23</sup> As such, Tennessee's attorney general can investigate potential violations and enforce the law. In addition, individuals injured due to a misleading advertisement for legal services may bring a private action against the ad's sponsor.

While the Texas law similarly provides that a violation of the Act is a deceptive act or practice, it limits enforcement to the consumer protection division of the attorney general's office or a district or county attorney.<sup>24</sup> The Texas law also includes a safe harbor that protects the sponsor of an ad from liability when it submits the ad to the advertising review committee of the State Bar before running the ad and the Bar finds that the ad complies with the law.<sup>25</sup>

Texans for Lawsuit Reform (TLR) issued this statement after the Texas bill was enacted:

The Texas Senate sent a strong message today that our state will not tolerate lawyer advertising practices that unnecessarily alarm Texans and create threats to public health to generate clients," TLR General Counsel Lee Parsley said. "It's unacceptable that Texans have suffered adverse health consequences or died because they were frightened into discontinuing use of a necessary medication by an advertisement for legal services....<sup>26</sup>

#### **Consistent with the First Amendment**

The Tennessee and Texas laws are likely to face First Amendment challenges.<sup>27</sup> A Nashville plaintiff attorney who reportedly intends to challenge the Tennessee law has said the law "unfairly singles out lawyers and denies them their First Amendment rights, while placing no such limitations on pharmaceutical company or health care provider advertisements."<sup>28</sup> A Texas Trial Lawyer Association board member called the Texas law "an unconstitutional restraint on commercial free speech."<sup>29</sup>

The U.S. Supreme Court, however, has long recognized that while states cannot bar attorney ads, "[a]dvertising that is false, deceptive, or misleading of course is subject to restraint."<sup>30</sup> The Court has upheld restrictions on attorney advertising that unduly influence injured people<sup>31</sup> or misled

<sup>&</sup>lt;sup>23</sup> See Tenn. Code § 47-18-5605.

<sup>&</sup>lt;sup>24</sup> See Tex. Gov't Code § 81.155(a)-(b).

<sup>&</sup>lt;sup>25</sup> See Tex. Gov't Code § 81.155(c).

<sup>&</sup>lt;sup>26</sup> Press Release, Texans for Lawsuit Reform, Statement on Senate Passage of SB 1189 (Apr. 11, 2019), at <u>https://www.tortreform.com/press-</u> release/statement-on-senate-passage-of-sb-1189/.

<sup>&</sup>lt;sup>27</sup> Maureen Leddy, *Tenn., Texas Move to Restrict Content of Legal Services Advertisements*, Trial News (Am. Ass'n for Justice) (June 6, 2019).

<sup>&</sup>lt;sup>28</sup> *Id.* (quoting Gerard Stranch).

<sup>&</sup>lt;sup>29</sup> *Id.* (quoting Craig Eiland).

<sup>&</sup>lt;sup>30</sup> Bates v. State Bar of Ariz., 433 U.S. 350, 383 (1977).

<sup>31</sup> *See Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 464-65 (1978) (upholding restriction on soliciting patients at hospitals or accident sites).



**CIVIL JUSTICE RESPONSE AND DRUG, DEVICE AND BIOTECHNOLOGY JOINT NEWSLETTER** June 2019

the public.<sup>32</sup> Because the Tennessee and Texas laws target misleading ads that often influence people who are ill or elderly, they do not violate the First Amendment.

Even when attorney advertising is arguably protected speech, the Court has found that narrowly tailored restrictions are permissible where there is a substantial interest in protecting the public.<sup>33</sup> Laws that ban misleading lawsuit advertisements in response to reports of patient injuries and deaths do just that.

First Amendment objections from the plaintiffs' bar and lead generators also ring hollow since the Tennessee and Texas laws are far less intrusive than the FDA's regulation of pharmaceutical marketing. Direct-to-consumer advertisements for prescription drugs must present a fair balance between the potential benefits of a drug and its potential side effects. Manufacturers may not make exaggerated claims, cannot selectively present research or studies, and cannot use graphics or headlines in a way that is misleading.<sup>34</sup> In contrast, lawsuit ads use these practices to convey misleading information, and have not faced scrutiny from the FDA, Federal Trade Commission, or state bar associations.

Tennessee and Texas have simply mandated the minimum oversight necessary to protect the public. Their laws target specific misleading practices that would be illegal if used in advertisements associated with any other product or service.

#### Conclusion

Plaintiffs' attorneys and lead generators use fearmongering ads to generate as many lawsuits as possible. The lawsuits stemming from these ads are intended to pressure businesses to settle mass tort cases regardless of the merits. The side effect, however, is that some viewers stop taking their prescribed medication or do not seek medical care that could help them. The public suffers the consequences of deceptive commercials for legal services. Tennessee and Texas are the first states to prohibit common misleading practices in lawsuit advertisements. Other states should follow.

<sup>32</sup> Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 650 (1985) (upholding discipline when attorney ad for medical device litigation said "no recovery, no fee" when client would be required to pay litigation expenses); see also Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980) ("[F]or commercial speech to come within the First

Amendment, it at least must concern lawful activity and not be misleading.").

<sup>33</sup> See Fla. Bar v. Went for It, Inc., 515 U.S. 618, 626-29 (1995) (upholding Florida Bar rule that prohibited lawyers from sending direct mail to victims and their relatives within 30 days of an accident or disaster). <sup>34</sup> See generally 21 C.F.R. § 202.1(e)(5)-(7).



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