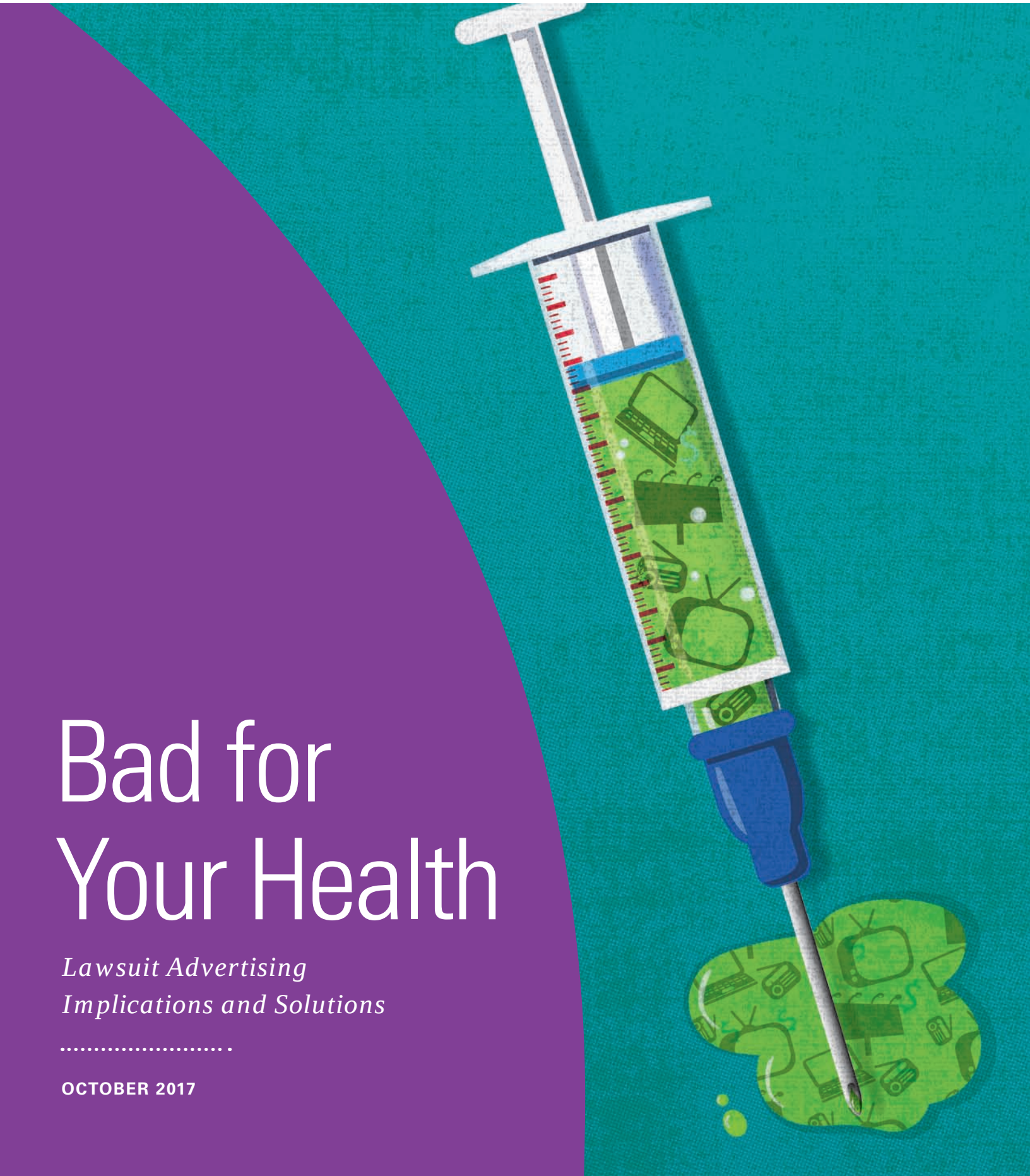
U.S. CHAMBER
Institute for Legal Reform



Bad for Your Health

Lawsuit Advertising Implications and Solutions

OCTOBER 2017

U.S. CHAMBER
Institute for Legal Reform

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Executive Summary

The public is inundated with advertisements on television and the internet soliciting them to file lawsuits. These ads often present prescription drugs and medical devices as dangerous. In dire terms, the ads exaggerate the risks of products that remain approved by the U.S. Food and Drug Administration (FDA) as safe and effective and that doctors prescribe to help their patients. While the purpose of such ads may be to inform injured people of their legal rights, misleading information frightens viewers into stopping their medications and may deter others from seeking treatment. Although these ads pose a public health threat, federal and state authorities have not acted.

The Lawsuit Advertising Surge

According to an analysis by X Ante, which tracks mass tort advertising:

- Spending on television ads for legal services is expected to approach $1 billion in 2017. Nearly six million television ads aired in the first half of the year—a pace that will exceed the number of ads aired in 2016 by over 1.2 million.
- The number of lawsuit ads run on television each year has tripled over the past decade.
- Ads to recruit clients for lawsuits against manufacturers of prescription drugs and medical devices make up the largest share of lawsuit advertising on television, and the number of ads continues to rise.
- Just five law firms and non-attorney marketing companies (also known as "lead generators") sponsor about half of all drug and medical device mass tort ads on television.
- Law firms and lead generators are paying nearly $100 per click on the internet to recruit people for lawsuits.

Misleading Practices

Lawsuit ads targeting drugs and medical devices often mislead the public by:

- Presenting what is an advertisement for legal services as a "medical alert,"

"health alert," or "consumer alert," and incorporating medical symbols in the background.

- Using the FDA logo or the text, "FDA Warning," implying agency affiliation.
- Using the word "recall" in website addresses, names, and headings, when the FDA has never recalled the targeted product and doctors continue to prescribe it regularly to patients.
- Warning that use of the drug or device can result in dire consequences such as heart attack, stroke, death, or birth defects without reliable scientific support or without indicating the rarity of such side effects or complications.
- Burying in illegible fine print or omitting the identity of the sponsor of the lawsuit ad or website.
- Failing to warn viewers that they should not discontinue use of a prescribed medication without consulting their doctor.

Adverse Public Health Implications

There is mounting evidence that misleading information and exaggerated claims made in lawsuit ads prevent people from seeking treatment or lead them to stop taking a prescribed medication without consulting a doctor.

A recent survey of patients who took one or more of twelve medications to treat conditions ranging from diabetes to depression found:

> *"Nearly sixty percent of respondents taking a targeted medication who were shown a lawsuit ad regarding that drug said they would reduce the amount of medication below what their physicians prescribed."*

- Four out of five respondents would be concerned after viewing a lawsuit ad targeting a medication he or she was taking.
- One in four respondents who had taken a prescription drug would stop taking that medication immediately after they viewed an actual lawsuit ad targeting that drug.
- Nearly sixty percent of respondents taking a targeted medication who were shown a lawsuit ad regarding that drug said they would reduce the amount of medication below what their physicians prescribed.
- Over eighty percent of respondents who were taking a drug targeted by a lawsuit ad believed that other people might stop taking the medication after viewing the ad.

An earlier survey of psychiatrists who treat patients for schizophrenia and bipolar disorder indicated similar concerns:

- Psychiatrists reported patients stopping their medication or reducing their dosage without consulting them first. More than half attributed these actions to lawsuit ads.
- Psychiatrists received requests from patients to stop or switch their medication. More than half attributed these requests to lawsuit ads.
- In most cases, stopping the medication, reducing dosage, or switching from a medication that was working led to relapse or hospitalization. In some cases, it resulted in suicide attempts.

The U.S. Food & Drug Administration has indicated that healthcare professionals filed 61 reports of patients stopping their prescribed anticoagulant after viewing a lawsuit advertisement though December 31, 2016. These reports included six deaths: three following a stroke, one following a cardiac arrest, one following a pulmonary embolism, and one stemming from an unreported cause. Other patients who stopped their medication as a result of a lawsuit ad experienced a range of adverse events, the most common of which was a stroke.

Recent medical literature has also revealed:

- Lawsuit ads make scientifically unsupported claims about the risk of taking certain antidepressants during pregnancy.
- Television ads recruiting women to serve as plaintiffs in lawsuits against manufacturers of pelvic mesh devices have misled women who seek treatment for pelvic organ prolapse or stress urinary incontinence to believe the FDA has recalled the devices.

Many doctors have shared personal encounters with patients who stopped taking their medications without consultation as a result of a lawsuit ad. These physicians express deep concern that the ads bombard their patients with exaggerated and untrustworthy medical information, damage the trust they have developed with patients, place their patients' health at risk, and, in some cases, have led to tragic consequences.

Recognizing the danger and prevalence of "fearmongering" lawsuit ads, the American Medical Association (AMA) has called upon legislators and regulators to require attorney commercials to have appropriate warnings that patients should not discontinue medications without seeking the advice of their physician.

The Mass Tort Litigation Underbelly

Recent litigation has exposed the types of practices that plaintiffs' law firms and others use to generate as many lawsuits as possible, as quickly as possible. Lawsuit advertising is an essential element of this process. The goal is to overwhelm a company with claims and pressure it to enter a global settlement of all cases, regardless of their merit.

- A lawsuit filed by a former chief business development officer of a law firm specializing in mass tort litigation described a "business model" by which the firm borrows money to buy as many television ads as possible, waits for "real lawyers" to establish liability "against somebody for something," and then pressures defendants to "settle the cases for whatever they can get."
- A Texas lawyer who handles medical device litigation filed a lawsuit after he received a robocall soliciting him to be a plaintiff in the very litigation in which he had a lead role. "Sadly, there are attorneys and law firms that ignore ethical rules and barratry laws and use any means necessary in the mad dash to grab as many clients as possible," his complaint observed.
- Patient affidavits submitted to courts in pelvic mesh litigation document cold calls soliciting them to file lawsuits. Callers misrepresent their affiliation, are located in foreign call centers, and appear to possess patients' confidential medical information.
- A federal judge handling litigation against one mesh product manufacturer recently recognized that many of the cases were fueled by "an onslaught of lawyer television solicitations" and "probably should never have been brought in the first place."
- Saturation of lawsuit ads in the St. Louis market claiming that talcum powder causes ovarian cancer has led some to question whether these commercials are intended to solicit claims or whether their true purpose is to scare the public and influence the jury pool as trials approach.

"Despite concern expressed by healthcare professionals, patients, and the AMA that drug and medical device lawsuit advertising is misleading the public, there is no oversight."

Lack of Oversight

Despite concern expressed by healthcare professionals, patients, and the AMA that drug and medical device lawsuit advertising is misleading the public, there is no oversight.

- The FDA closely monitors prescription drug advertising, viewing it as important to ensure that manufacturer ads do not overstate the effectiveness of a drug or understate its risks. The FDA does not, however, monitor information disseminated in lawsuit ads that understates (or does not recognize at all) the benefits of a drug and overstates its risks.
- Federal Trade Commission (FTC) policy and precedent prohibit many of the misleading practices employed in lawsuit ads in other contexts. When lawyers

engage in such practices, however, the FTC traditionally defers to state bars and attorney disciplinary authorities.

- There is little likelihood of effective self-regulation by the bar.
    - State ethics rules focus on whether attorney ads are likely to mislead potential clients *about the terms of a lawyer's services*. State bars and disciplinary authorities rarely enforce such rules and, when they do, are not likely to focus on the broader impact of misleading information conveyed in such ads on public health. Even if they act, these groups cannot reach non-lawyer entities that often sponsor such ads.
    - In response to a recent inquiry from the Chairman of the House Judiciary Committee, the ABA took the position that state ethics rules provide sufficient authority for the bar to address misleading attorney ads. Although virtually all complaints about lawyer ads are made by other lawyers, the ABA and state bars mistakenly view the lack of complaints they receive from doctors, patients, and the general public about drug lawsuit ads as indicating there is no need for action.

Recommendations

The FTC, FDA, and states each have a role to play in addressing misleading information about prescription drugs and medical devices contained in lawsuit ads.

- The FTC, in coordination with the FDA, should declare common misleading lawsuit advertising practices unfair or deceptive under the FTC Act. While the FTC can bring actions in individual cases, promulgating a rule that specifically defines prohibited practices and required disclosures would provide clear guidance for law firms, attorneys, and marketing companies that engage in lead generation.
- Congress should empower the FDA to monitor information about drugs and medical devices disseminated in lawsuit ads. When information is brought to the FDA's attention showing that exaggerated or unsupported claims conveyed in lawsuit ads have adversely affected public health, the FDA should send a warning letter to the sponsor, urging it to discontinue the ad or change it so that it is no longer misleading. If a sponsor does not comply, then the FDA might refer the matter to the FTC for consideration of civil penalties and to state bar authorities for potential disciplinary action. The FDA might also provide a mechanism for healthcare providers, patients, and the public to bring lawsuit ads of concern to the agency's attention.
- State legislatures and attorneys general can find that the types of misleading lawsuit advertising practices discussed above violate their state unfair and deceptive trade practices acts. States can also amend their health privacy laws to prohibit use of private health information to solicit individuals for lawsuits. State bars and disciplinary authorities are the only entities with the power to suspend or disbar attorneys who repeatedly engage in unethical lawsuit advertising or solicitation practices.

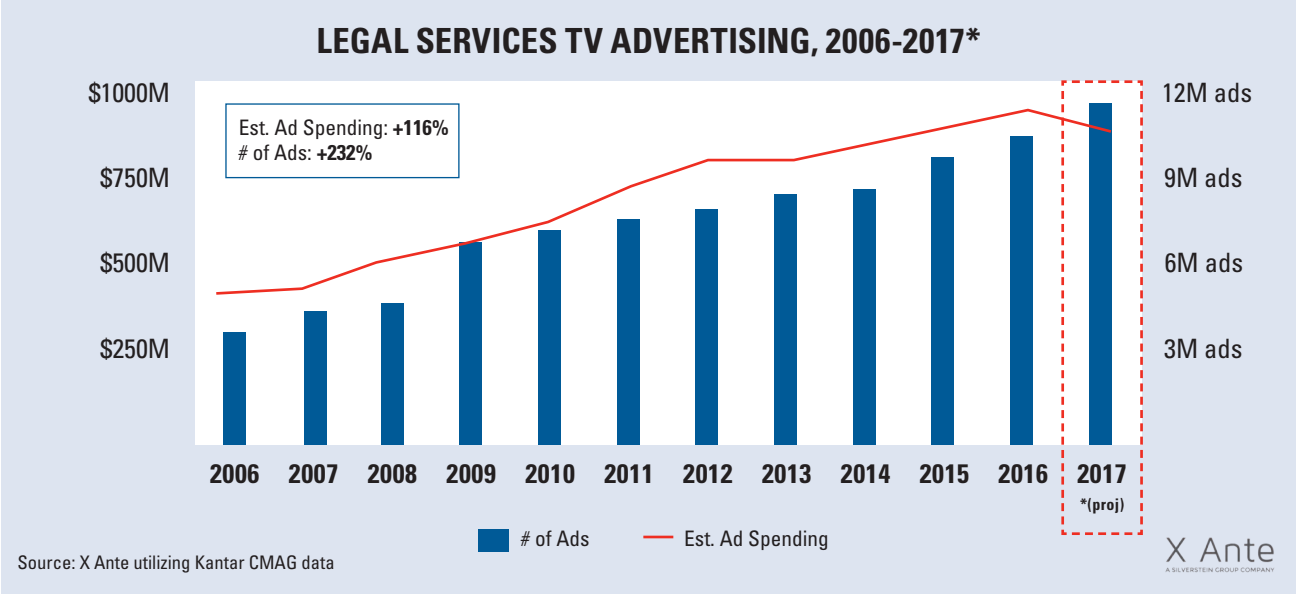
The Mass Tort Litigation Machine

In the absence of a public health crisis or massive recall, how does the number of lawsuits claiming that a drug, medical device, or other product is defective quickly go from a handful to thousands of cases? The answer is "lead generation," a system by which law firms and marketing operations spend millions of dollars on television advertising and use websites, social media, call centers, and even cold calls to generate lawsuits.

The Rise of Lawsuit Advertising

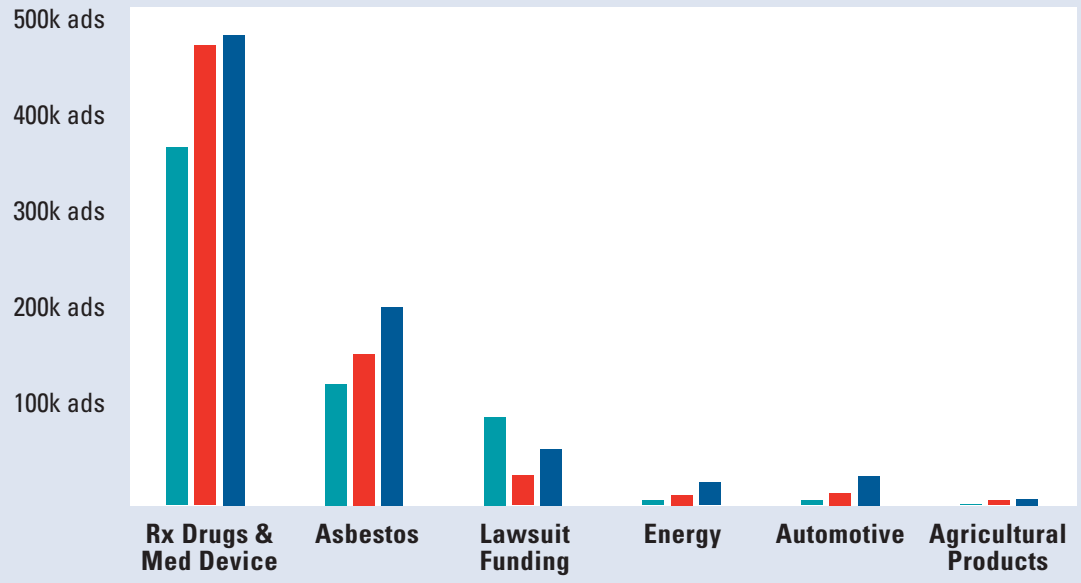
The number of television commercials seeking clients for lawsuits has more than tripled over the last decade. It is projected that law firms and others sponsoring the ads will spend nearly $1 billion running ads in 2017—116% more than they did in 2006, even as inflation remained under two percent.[1]

Commercials targeting drugs and medical devices make up the largest portion of all legal service advertising on television. The number of these ads increased from 365,000 in 2015 to a projected 467,000 in 2017—a 28% increase—at an estimated cost of $143 million.



Source: X Ante utilizing Kantar CMAG data

TOP LEGAL SERVICES TV ADVERTISING CATEGORIES, 2015-2017
NUMBER OF ADS



Source: X Ante utilizing Kantar CMAG data

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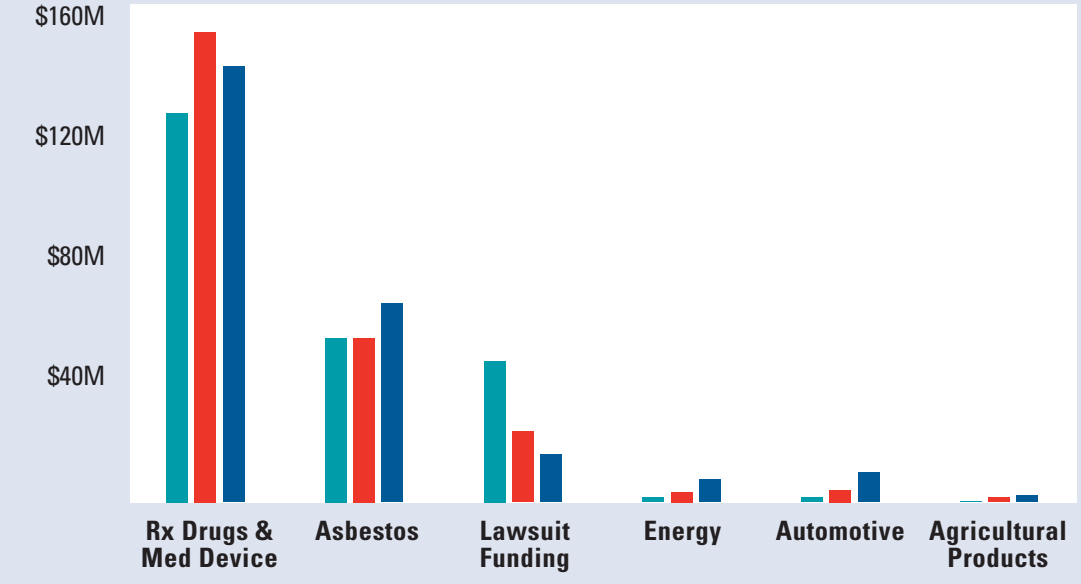
TOP LEGAL SERVICES TV ADVERTISING CATEGORIES, 2015-2017
AD SPENDING



Source: X Ante utilizing Kantar CMAG data

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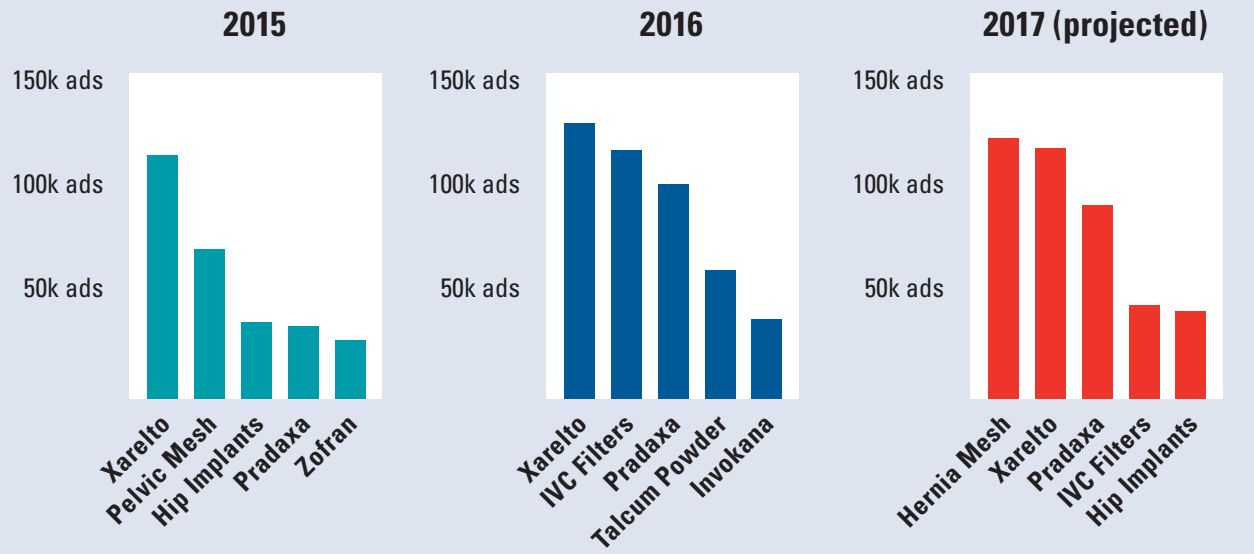
SHIFTING TARGETS

Lawsuit advertising targeting a particular prescription drug, medical device, or other product may suddenly surge and can just as quickly disappear. Ad spending is usually not tied to a recall or withdrawal of a drug or device, or the development of firm scientific evidence indicating a problem. Rather, the public is often inundated with lawsuit ads after the FDA and manufacturer make a minor change to the labeling of a drug to reflect continuous monitoring of risks, the release of preliminary study results suggesting the possibility of an association between a product and an adverse event, or a plaintiff's verdict or report of a settlement.

For example, a "Medical Alert" sponsored by "1-800-BAD-DRUG" in 2015 told viewers that taking Zofran during pregnancy can lead to birth defects including heart defects, cleft lip, and cleft palate (See Figure 1, page 11).[2] Zofran, an anti-nausea drug approved for use during chemotherapy, is also often prescribed by doctors to help pregnant women who develop severe nausea and vomiting that can pose a risk

> *"Ad spending is usually not tied to a recall or withdrawal of a drug or device, or the development of firm scientific evidence indicating a problem."*

TOP DRUGS & MEDICAL DEVICES IN MASS TORT TV ADS
NUMBERS OF ADS



Source: X Ante utilizing Kantar CMAG data

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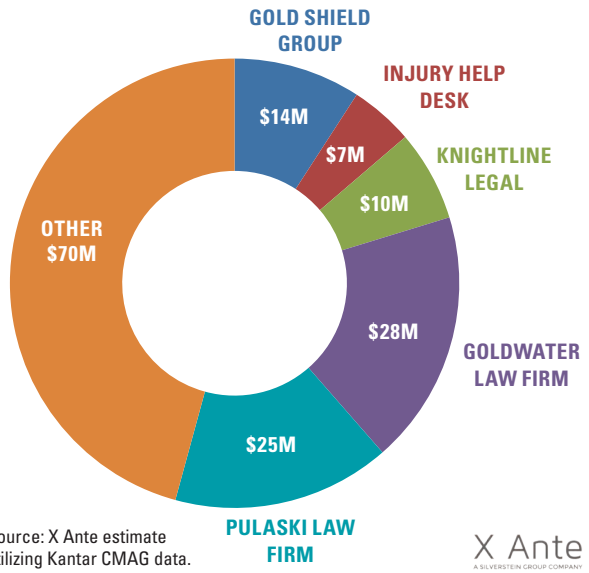
to the health of the mother and fetus. The "BAD-DRUG" ad was not alone. Twenty-five law firms sponsored over 1,300 ads targeting Zofran in February 2015 at a cost of approximately $2 million, according to the mass tort advertising tracking firm X Ante.[3] Zofran was one of the top ten most targeted drugs, with nearly 30,000 ads run between January 2015 and June 2016,[4] peaking in March 2015 with 7,800 ads that month alone. In the midst of this lawsuit advertising surge, however, the FDA found insufficient scientific evidence to support such claims.[5] Ads targeting the drug then plunged before evaporating almost completely.[6] A scientific study finding no connection between Zofran and birth defects published in 2016 confirmed that these ads unnecessarily scared pregnant women away from taking medication for severe nausea.[7]

WHO PLACES THE ADS?

A few law firms and non-attorney marketing companies (also known as "lead generators") are responsible for most lawsuit advertising. In fact, just five entities sponsored about half of all lawsuit ads targeting drugs and medical devices on television in 2016. Similarly, five entities accounted for half of all spending on these ads that year.

> *"[J]ust five entities sponsored about half of all lawsuit ads targeting drugs and medical devices on television in 2016."*

DRUG & MEDICAL DEVICE LAWSUIT AD SPONSORS BY SPENDING, 2016



Source: X Ante estimate utilizing Kantar CMAG data.

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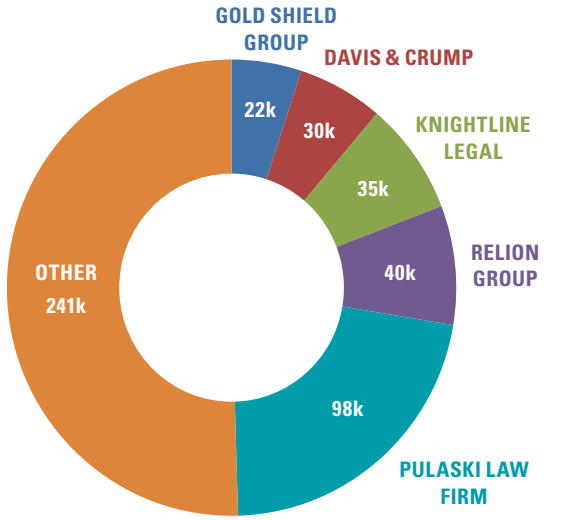
DRUG & MEDICAL DEVICE LAWSUIT AD SPONSORS BY NUMBER OF ADS, 2016



Source: X Ante estimate utilizing Kantar CMAG data.

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A study by University of Oregon Law School Professor Elizabeth Tippett shows that advertising seeking clients for drug and medical device lawsuits in major media markets follows a similar pattern. She found

that the three most prolific advertisers in the Atlanta and Boston markets ran seventy percent of the ads.[8] Ten firms were responsible for ninety-eight percent of the advertising volume.[9] She found that only about half of the most prolific advertisers for drug lawsuits actually litigate at least some of the cases they receive.[10] The other half of the entities running ads rarely, if ever, file lawsuits.[11] Rather, they concentrate on finding potentially viable claims, then refer them to law firms to be filed and litigated or settled.

Anatomy of a Lawsuit TV Ad

Television advertisements for mass tort claims follow a familiar script that is intended to alarm the public.[12] They typically air during the day or late at night, reaching people who are elderly, disabled, ill, or out of work.[13]

TACTIC 1: MEDICAL ALERT

The typical lawsuit advertisement opens in a manner intended to both get the viewer's attention and misleadingly suggest that it will provide impartial health information. Many are framed as public service announcements.[14] Ads open with the words "medical alert" or "consumer alert," suggesting affiliation with a public health or government entity. (See Figure 1.)

TACTIC 2: DIRE CONSEQUENCES

After grabbing the viewer's attention, lawsuit ads authoritatively inform the audience that they or a loved one may have been injured by a drug or medical device. They then convey the most alarming adverse events associated with the product, such as heart attack, stroke, uncontrollable bleeding, coma, or death. (See Figures 2 and 3.)

Figure 1: Lawsuit ads often begin disguised as a "medical alert," such as this ad targeting the anti-nausea medication Zofran.

Figure 2: Lawsuit ads warn patients of dire consequences of taking a medication that is approved by the FDA and prescribed by a doctor.

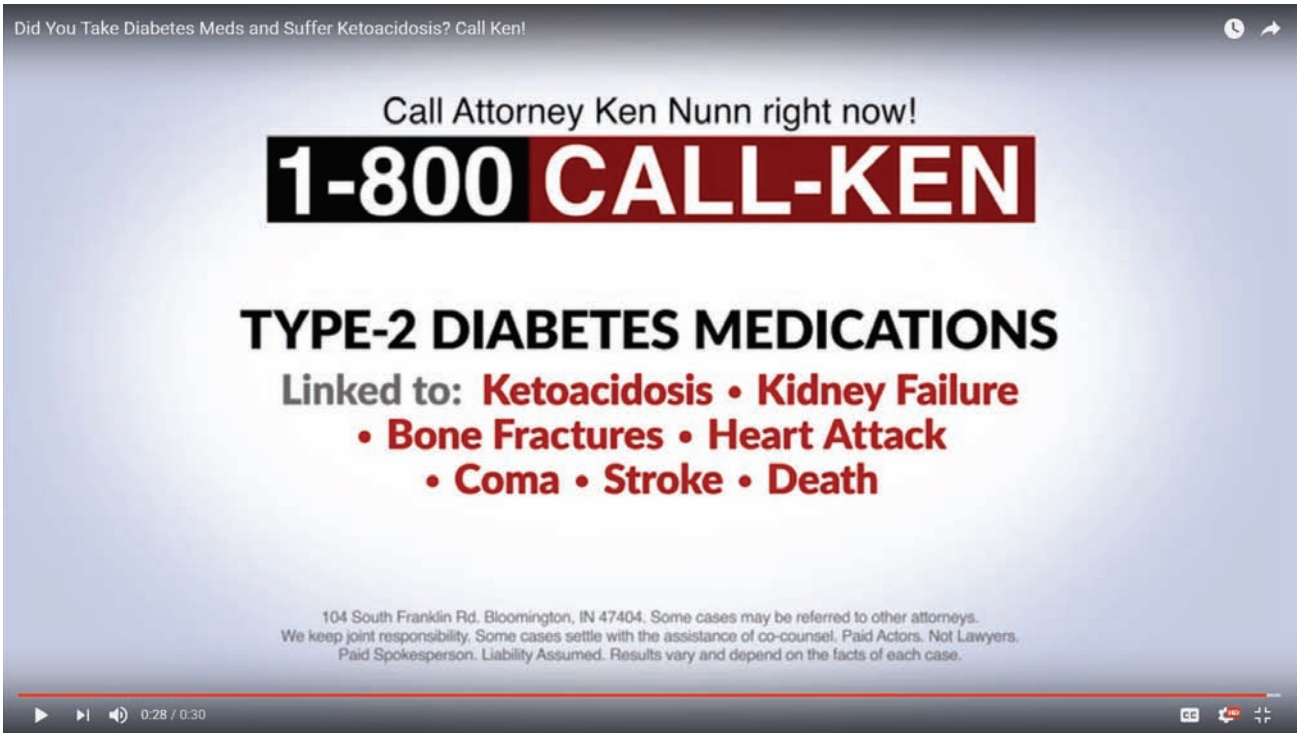


Figure 3: A lawsuit ad targeting commonly prescribed blood thinning drugs may scare patients into stopping their medication without speaking with their doctor, placing them at risk of a stroke or death.

The ads sometimes make a passing reference to a drug's benefits, but such mentions are only intended to help users identify whether they have taken the drug. Professor Tippett found that lawsuit ads targeting prescription drugs spent an average of twenty seconds discussing adverse events and just two seconds mentioning benefits.[15] These fleeting mentions of a drug's function or benefits "did not counterbalance the prominent and stark descriptions of adverse events," she found.[16]

Even when scientific evidence suggests that some patients may experience side effects or complications from a drug or medical device, lawsuit ads do not discuss the actual level of risk. Without such information, viewers cannot compare the potentially life-saving or significantly life-improving benefits that the medication or device offers to what may be relatively infinitesimal risks. None of the ads in Professor Tippett's study provided consumers with information on the frequency or likelihood of a listed adverse effect.[17] This practice, she recognized, can lead the public to assume an adverse event "is very likely or even inevitable" when it is extremely rare.[18] For example, a patient viewing the commercial will not know that while a blood thinning drug presents a 0.0009 annual fatal bleeding risk, the medication significantly reduces a 4.8% (roughly 1 in 20) chance that he or she will suffer a debilitating stroke within the year.[19]

Individuals who rely on prescribed drugs to control diabetes (Figure 2), reduce the risk of a stroke (Figure 3), and treat severe depression (Figure 4), for example, may be frightened away from taking their medications. As law professor Daniel Schaffzin of the University of Memphis has

Figure 4: Small print following TV ad reveals the sponsoring law firm refers cases to attorneys throughout the country for principal responsibility.

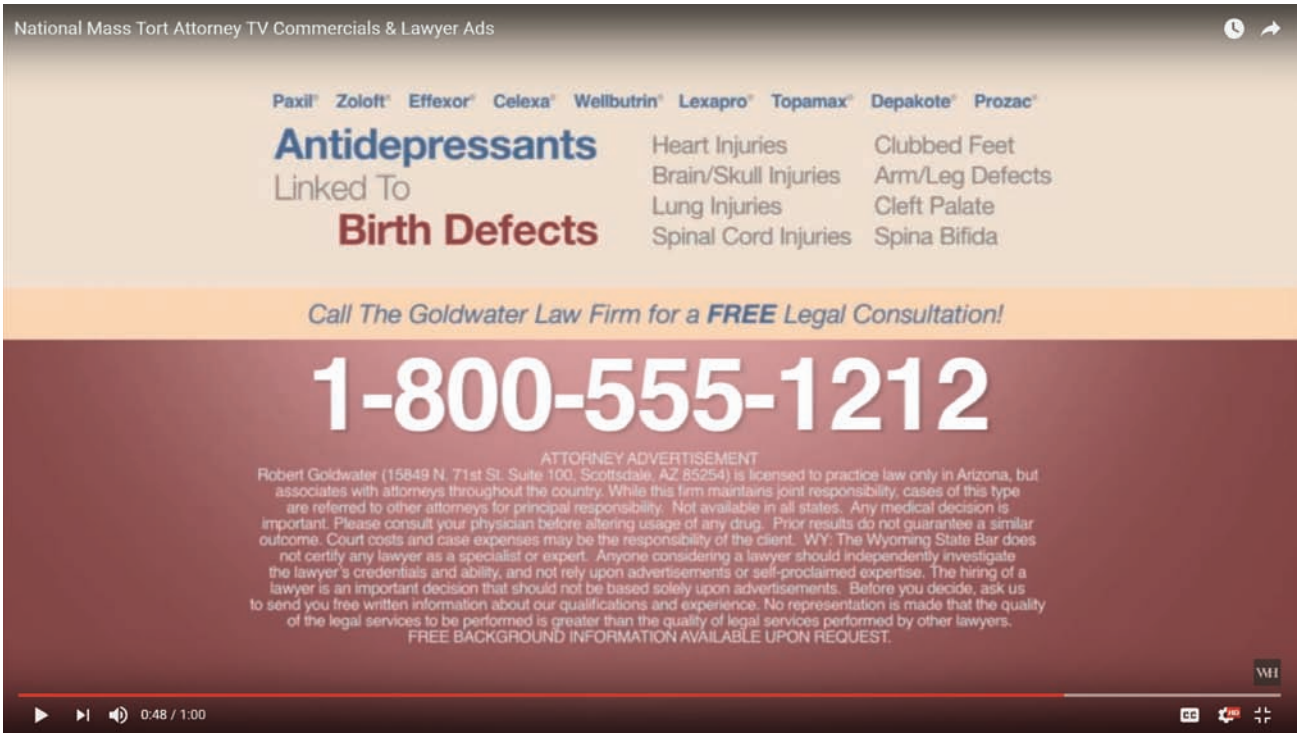
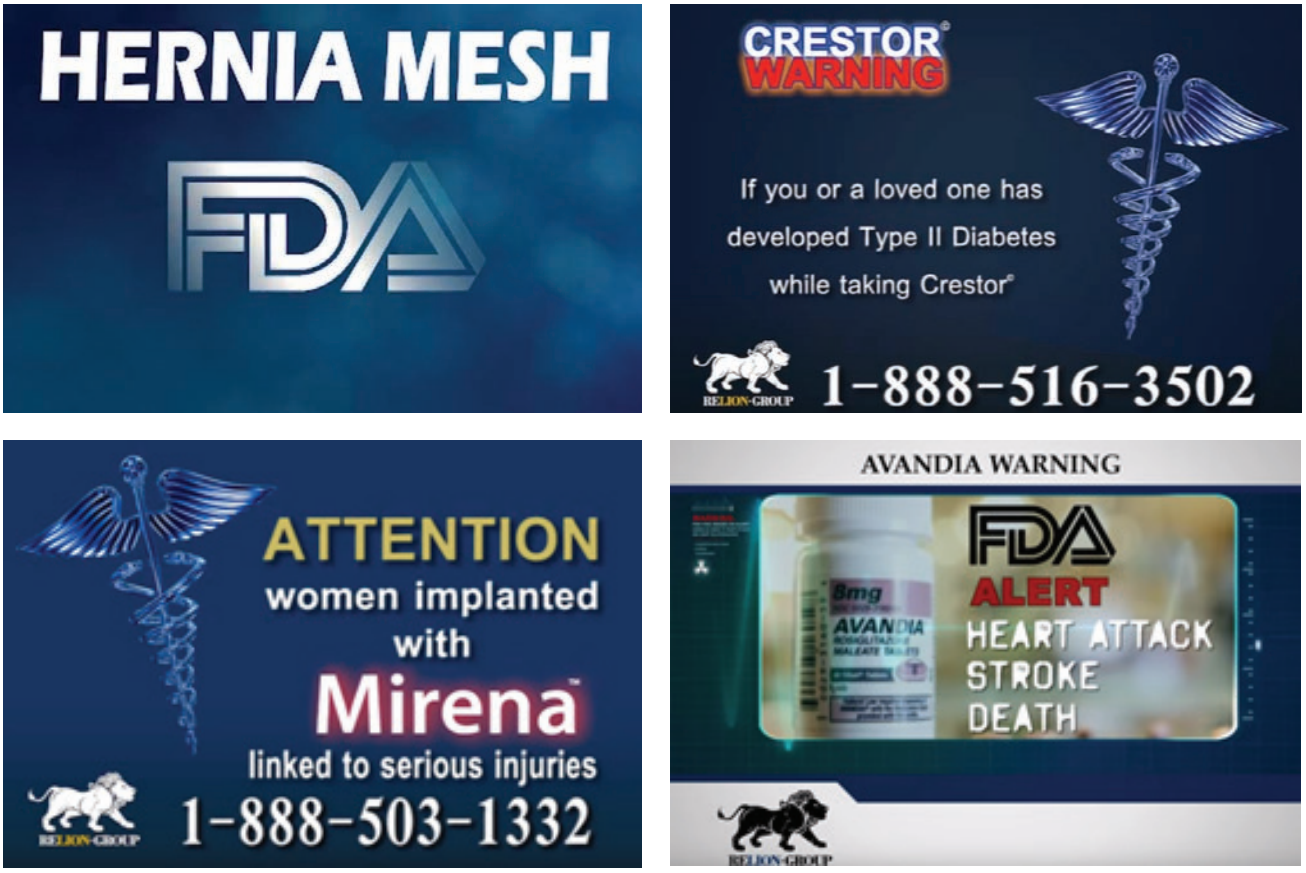


Figure 5: The Relion Group is among lawsuit advertising sponsors that incorporate the FDA logo and medical symbols into commercials. The fine print reveals that the Relion Group is "an advertising group that represents lawyers jointly advertising their services" and that it is "not a law firm or a lawyer referral service."



observed, "the impact of the authoritative—but unqualified—message of the lawyer [is that] . . . the consumer, already generally more susceptible by virtue of age or medical condition, loses confidence in, or simply stops taking, a medication prescribed by his or her physician."[20]

TACTIC 3: REINFORCEMENT OF PUBLIC HEALTH MESSAGE

Some ads display the FDA logo and use the language "FDA Alert," which could lead reasonable viewers to believe that the ad is sponsored or endorsed by the government agency (Figure 5). Ads often incorporate medical symbols in the background, further suggesting they are providing health, not legal, information. Some ads indicate that a product is a "bad drug," which could lead the public to believe that an FDA-approved drug will harm them simply because a small percentage of people may have an adverse reaction or after a questionable study suggests an association between the drug and an illness or condition.

TACTIC 4: URGENCY

Much like an infomercial for a watch or blender, lawsuit ads typically urge viewers to "call right now!" (Figure 2).[21] Some ads also tell viewers that they may be "entitled to substantial compensation."

TACTIC 5: ILLEGIBLE FINE PRINT

Some lawsuit advertisements bury information that could shape how viewers evaluate its content. For example, some ads fail to disclose that they are affiliated with a law firm until the very end.[22] At that point, those who pause the television broadcast, find their glasses, and stand close to the TV will read in the fine print that the law firm sponsoring the ad will not actually handle the case, but will refer it to another attorney (Figure 4), or that the entity behind the ad is not a law firm at all, but a marketing company that pledges to connect callers with law firms.

Most lawsuit ads targeting prescription drugs do not warn viewers that they should not stop taking a prescribed medication without consulting a doctor, and the few that do place such language in fine print. Just thirty-nine percent of lawsuit ads in Professor Tippett's study advised viewers to consult a doctor before discontinuing their medication. Those that did provide a written disclaimer did so in small font. None of the ads suggested that patients consult their doctor in the audio track. Professor Schaffzin provides a typical example: A lawsuit ad targeting the cholesterol drug Zocor flashed the words "Never stop taking any medication without consulting your doctor" in tiny, white print, but were drowned out by "Zocor Alert: You May be Entitled to Compensation" in large, red font.[23]

Misleading Medical Information on the Internet

When people have questions about illnesses and treatment options, they may turn to the internet for information. Viewers of lawsuit ads on television also may seek more information from an advertised website or internet search. While scientific information from reputable sources is often available online, medical professionals have observed that credible websites can easily get buried among lawsuit ads in internet search results.[24]

> *"While scientific information from reputable sources is often available online, medical professionals have observed that credible websites can easily get buried among lawsuit ads in internet search results."*

Tracking the number of searches related to a drug's or medical device's side effects or possible legal action can prove to be an effective proxy for the efficacy of widespread television advertising. That is, as the number of TV ads trumpeting the risks associated with a drug and urging viewers to contact an attorney increase, the number of searches related to that drug's name plus "side effect," "lawyer," or "lawsuit" also increases.

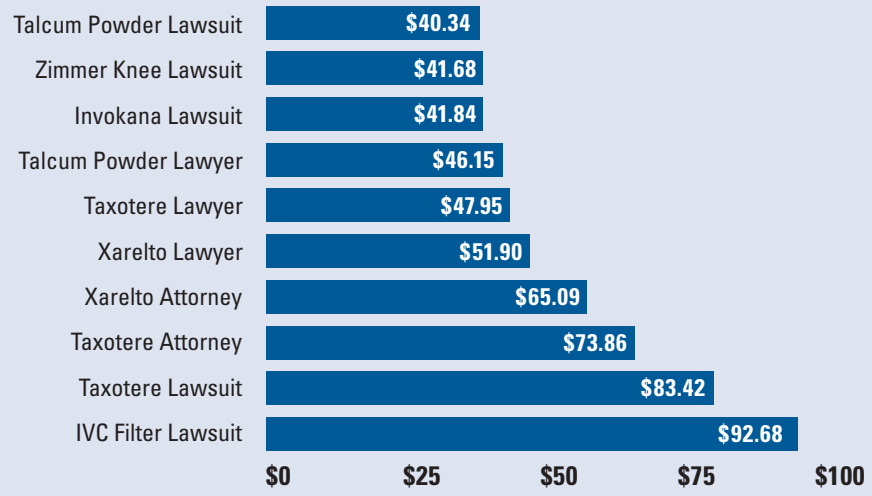
Those seeking to identify potential claims online devise strategies to ensure that their websites are among the top results that appear when people seek more information online about a product's side effects or litigation. Plaintiffs' law firms and others soliciting claims will bid up the price they are willing to pay for each click on an ad to ensure that their website is among the top paid search results when online users seek side effect or litigation information. For example, in July 2017, online advertisers were willing to pay nearly $100 for each click on a highly placed ad appearing among the search results for Google searches for "IVC Filter Lawsuit."

In addition to dominating the top paid ad results, plaintiffs' law firms and other mass tort online advertisers design their websites so that they are among the top non-paid or "organic" search results shown. X Ante's analysis finds that websites soliciting legal claims are often the majority of what appear on the first two pages of results for searches related to a product's side effects and litigation.

Many websites sponsored by law firms and companies that are in the business of identifying potential plaintiffs disguise themselves as providing objective scientific information on drugs, medical devices, or other products. Others provide "informational resources about drugs and defective devices" and "lawsuit

MOST EXPENSIVE DRUG & MEDICAL DEVICE LITIGATION GOOGLE ADS

AVERAGE COST-PER-CLICK PRICE, JULY 2017



Source: X Ante utilizing Google Keyword Planner

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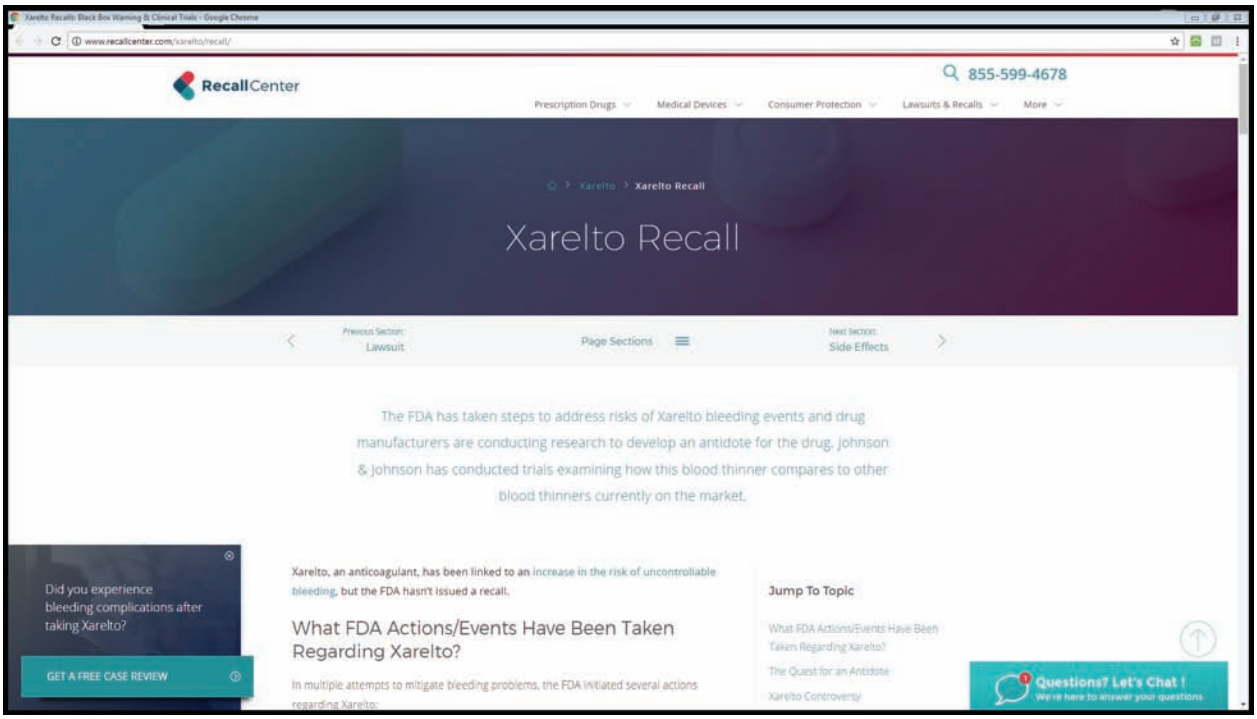
information" side-by-side.[25] Websites such as medrecallnews.com, recallcenter.com, baddrugrecalllawyer.com, 1800baddrug.com, and baddrugrecall.com may lead the public to believe that the FDA has recalled a drug or medical device when, in fact, it has not and thousands of patients continue to benefit from it.

For example, recallcenter.com includes a menu option for information on a "Xarelto Recall" and an entire page with a large headline, "Xarelto Recall," discussing FDA actions related to the blood thinner (Figure 6). That page acknowledges in its text that "Xarelto, an anticoagulant, has been linked to an increase in the risk of uncontrollable bleeding, but the FDA hasn't issued a recall."[26] While the website details FDA actions pertaining to Xarelto, it fails to mention a critical FDA-approved warning: "Do not stop taking XARELTO without talking to the doctor who prescribes it for you. Stopping XARELTO increases your risk of having a stroke."[27] For viewers to learn that "RecallCenter" is sponsored by a plaintiffs' law firm, Weitz & Luxenberg P.C., they must scroll through several pages of text to the fine print at the bottom of the webpage. Alternatively, a reader could find this information by selecting "More" from the top menu bar, then "About Us," which indicates the law firm's sponsorship of the website in a page that emphasizes the healthcare backgrounds of fifteen editors who contribute to the website.[28]

Another website, www.medrecallnews.com, includes information on drugs that doctors continue to prescribe and that the FDA has never recalled, including the antidiabetic medication Actos, the antidepressant Zoloft,

Figure 6: Screenshot of web page entitled "Xarelto Recall" on a plaintiffs' law firm-run website called "RecallCenter," that is no longer online. The FDA has not recalled the blood thinner.



and the migraine prevention and seizure medicine Topamax.[29] The site portrays itself as "educating consumers on the potential dangers of certain medications, FDA 'Black Box' Warnings, FDA recalls, faulty medical devices, and other health issues" and explicitly states (in small print at the bottom of the "About Us" page) that "MedRecall News is not a law firm or lawyer referral service and is not associated with pharmaceutical companies or the FDA."[30] Yet, the website provides a toll free number for a "Free Consultation"[31] and to "learn more about your legal rights."[32] Nowhere on the website does it disclose the identity of the sponsor beyond indicating a location in Norristown, Pennsylvania.[33] Further research reveals that the website is one of several run by a non-lawyer lead generator, Jesse Levine, whose troubling past and questionable operation is detailed in a *Bloomberg* exposé.[34]

Some websites include professionally produced lawsuit commercials that may have aired on television. Many prompt viewers with popup messages asking whether they would like to "live chat" over the internet.

Use of Social Media to Identify Potential Clients

Law firms and lead generators are not content to wait for potential clients to contact them as a result of a TV ad or internet search. They actively track down people who might have used a prescription drug or medical device through social media.

Through use of demographic data from the U.S. Centers for Disease Control and Prevention (CDC) and other sources, as well as marketing tools available on Facebook, lead generators can identify people most likely to be exposed to a particular drug or medical treatment.[35] One lead generator candidly revealed, for example, that personal injury lawyers will pay as much as $3,000 for each name of a woman who may have had a mesh implant (and his company, casting a wide net, had identified about 10,000 such women through Facebook).[36]

Facebook has emerged as a particularly potent platform for mass tort advertisers because it allows those seeking claims to precisely target potential clients based on the demographic and geographic information it is able to provide. Advertisers can pay for

> *"Many websites sponsored by law firms and companies that are in the business of identifying potential plaintiffs disguise themselves as providing objective scientific information on drugs, medical devices, or other products."*

their solicitation to appear unobtrusively in a user's "News Feed" alongside updates from friends, family, and others in their network. For example, an advertiser seeking claims related to Zofran and alleged birth defect risk could place ads in the news feed of women over the age of 18 with young children.

Furthermore, plaintiffs' law firms and other mass tort marketers can inexpensively set up Facebook pages for all manner of litigation, complete with photos and embedded videos to promote their message. These pages—many of which provide little, if any indication of being sponsored by a law firm—can become an online hub for information about a product and its side effects, thereby attracting users with similar concerns to "like" posts and post their comments. This online "community" becomes a rich resource of potential clients for those law firms sponsoring the sites.

Other social media outlets have also become attractive platforms for mass tort advertisers. "Tweets" sent out by law firms and others on Twitter about potential side effects or litigation can be read widely and "retweeted" among a vast network—particularly by journalists who rely on the service for news leads.

YouTube allows advertisers to establish their own "channels" where they may place video of their television ads and other commentary about potential litigation for a fraction of the cost of TV advertising. These YouTube videos can be linked and posted across all of a firm's online platforms. YouTube is also the second most popular search engine after Google. A robust presence on the site allows those soliciting claims to capture the attention of online users interested in more information about a particular drug, medical device or other product.

"YouTube allows advertisers to establish their own 'channels' where they may place video of their television ads and other commentary about potential litigation for a fraction of the cost of TV advertising."

Adverse Public Health Implications of Misleading Lawsuit Advertisements

Doctors express concern that lawsuit ads mislead the public to believe that FDA-approved medications will harm them, even when the agency has found that a drug's benefits exceed its potential risks. A recent survey of patients and scientific research confirm that, after viewing frightening lawsuit ads, many Americans stop taking their prescribed medication without consulting a doctor. Others may decide not to seek treatment that could improve, or even save, their lives. This public health concern is not hypothetical. Doctors have submitted reports to the FDA documenting harm resulting from lawsuit ads scaring patients off their medications.

Lawsuit advertising does far more than generate claims. While the commercials that air on television may target people who have experienced injuries, most viewers are the general public, including people who are considering seeking treatment and patients who are deciding whether to continue to take prescribed medication.[37] Surveys of patients and healthcare professionals, FDA reports, medical literature and academic research, and the firsthand experience of doctors all point to a consistent, troubling conclusion: the public's bombardment with information that is scientifically unsupported or significantly exaggerates the risks of drugs or medical devices poses its own public health risk. Observers express concern that such advertising with its half-truths, nondisclosures, and profit-driven motives threatens the doctor-patient dialogue and places vulnerable consumers potentially "at even greater risk than that being hyped by the legal advertising at issue."[38]

Surveys of Patients and Doctors Find Lawsuit Ads Scare Patients Away From Taking FDA-Approved Medications

2017 PUBLIC AND PATIENT SURVEY

Nearly three quarters of Americans (72%) have seen ads run by law firms about prescription drugs in the past year, according to a May 2017 poll commissioned by the U.S. Chamber Institute for Legal Reform. The poll, conducted by one of the nation's leading public opinion research firms, included an online survey of 1,335 adults, 500 of whom were currently taking, or had taken, one or more of twelve prescription drugs frequently targeted in lawsuits.[39] Patients rely on these medications to treat diabetes, high cholesterol, kidney disease, acid reflux, depression and anxiety, to reduce the risk of stroke and blood clots, and to prevent pregnancy, among other conditions. Four out of five respondents taking one of the targeted medications recalled seeing a lawsuit ad.

Respondents were asked how they would react to an advertisement by a law firm indicating lawsuits against the manufacturer of a prescription drug they were taking (Table 1). Four out of five respondents (84%) said that they would be concerned if a medication prescribed by their doctor was the subject of an advertisement by a law firm. Nearly half of all respondents (46%) and one third of those currently taking one of the targeted drugs (29%) said they would definitely or probably stop taking the medication immediately after seeing such an ad. Fifty-eight percent said they would definitely or probably reduce the amount of medication to below the prescribed amount. Respondents indicated they were nearly as likely to seek more information through searching the internet as they were to call their doctor.

"Nearly half of all respondents (46%) and one third of those currently taking one of the targeted drugs (29%) said they would definitely or probably stop taking the medication immediately after seeing such an ad."

TABLE 1: RESPONDENT REACTION TO HYPOTHETICAL LAWSUIT AD

How concerned would you be if you were taking a medication, prescribed by your doctor, and saw an advertisement by a law firm indicating they were suing the manufacturer over the medication you were taking?

	Very Concerned	Concerned	Not Very Concerned	Not Concerned at All
All Respondents	51%	33%	11%	5%
Using Medication	44%	42%	11%	3%

Suppose you were taking a medication, prescribed by your doctor, and saw an advertisement by a law firm indicating they were suing the manufacturer of the medication you were taking over that particular medication. Please indicate whether you would do each of the following:

		Definitely Yes	Probably Yes	Probably No	Definitely No
Talk to your doctor about it at your next visit	All Respondents	54%	34%	8%	4%
	Using Medication	59%	31%	6%	4%
Call your doctor	All Respondents	44%	33%	18%	5%
	Using Medication	42%	28%	24%	6%
Google the lawsuit mentioned in the advertisement	All Respondents	38%	36%	18%	8%
	Using Medication	34%	34%	22%	10%
Stop taking the medication immediately	All Respondents	15%	31%	43%	11%
	Using Medication	9%	20%	49%	22%
Call the law firm mentioned in the advertisement	All Respondents	11%	22%	47%	20%
	Using Medication	7%	18%	48%	27%
Reduce the amount of medication you take to be less than what your physician prescribed	All Respondents	1%	8%	60%	31%
	Using Medication	2%	7%	52%	39%

Respondents who indicated that they or a member of their household had taken a prescription drug that is frequently targeted in litigation were then shown a video clip of a lawsuit ad for that drug (Table 2). Unlike the prior series of questions, these questions were not hypothetical. They assessed how people who had actually taken a drug would respond to a commercial that had aired on television.

After viewing the lawsuit ad, one in four respondents taking a prescribed drug indicated that he or she would definitely or probably stop taking that medication immediately. In addition, nearly sixty percent of respondents taking a targeted medication indicated that they would reduce the amount of medication below what their physicians prescribed due to concern created by the advertisement. When they were asked how they believed others being treated by the drug would respond to such an ad, more than eighty percent agreed that some people might stop taking their medication after seeing it.

Most of these respondents agreed that the government should regulate information about medications in lawsuit advertisements. Only one in five respondents viewed such regulation as unnecessary.

TABLE 2: PATIENT REACTION TO AN ACTUAL LAWSUIT AD TARGETING A DRUG THAT THEY OR A HOUSEHOLD MEMBER HAD TAKEN

How effective was this ad in raising concerns about this particular medicine?

Very Effective	Somewhat Effective	Not Very Effective	Not Effective At All
29%	50%	16%	5%

How concerned are you about that medicine having seen that?

Very Concerned	Concerned	Not Very Concerned	Not Concerned At All
17%	39%	31%	13%

Some people have indicated they might make some changes based on having seen that ad while others have not. So again suppose you were taking that medication for your condition, prescribed by your doctor, and please indicate whether you would do each of the following:

	Definitely Yes	Probably Yes	Probably No	Definitely No
Talk to your doctor about it at your next visit	50%	33%	9%	8%
Call your doctor	36%	23%	28%	13%
Google the lawsuit mentioned in the advertisement	24%	29%	28%	19%
Stop taking the medication immediately	8%	18%	39%	35%
Call the law firm mentioned in the advertisement	8%	14%	39%	39%
Reduce the amount of medication you take to be less than what your physician prescribed	17%	41%	32%	10%

Indicate whether you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with each statement:

	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree
Some people might stop taking their medication after seeing this ad.	32%	49%	13%	4%	2%
This ad helps people by alerting them to potential medical side effects.	22%	42%	24%	7%	5%
This ad exaggerates the dangers because lawyers are interested in making more money on the lawsuit.	23%	36%	28%	10%	3%
This type of information about medications in ads like this should be regulated by the government.	23%	30%	28%	8%	11%

2007 PSYCHIATRIST SURVEY

A survey of psychiatrists who treat patients with schizophrenia and bipolar disorder yielded similar results.

Treating patients with these conditions and having them regularly take their medication is particularly challenging due to side effects, an unwillingness to accept a diagnosis of illness, the cost of medication, and lack of support. That challenge is magnified when patients and their families are inundated with alarmist lawsuit advertisements overemphasizing the risks of antipsychotic drugs.

The poll, commissioned by the National Council for Community Behavioral Healthcare and Eli Lilly and Company, surveyed over 400 psychiatrists in 2007. It found:

- Nearly all (97%) of the surveyed psychiatrists had patients who stopped taking medication or reduced their dosage. More than half of the psychiatrists believed that patients took these actions due to lawsuit ads.
    - Ninety-three percent of these psychiatrists had one or more patients make medication changes without consulting them first, and most of these psychiatrists (94%) reported patient relapse as a result of discontinuing medication. Relapses resulted in symptom reoccurrence (93%), hospitalization (75%), loss of an important relationship (40%), and suicide attempts (26%).
- Nearly all (97%) of surveyed psychiatrists received requests from patients to stop or switch their medication. Of these psychiatrists, fifty-nine percent felt patients made these requests based on concerns triggered by lawsuit ads.
- Most of these psychiatrists (93%) felt their patients were responding to treatment.
    - Over two thirds (71%) of patients who were responding to their medication, but switched, experienced a relapse along with the consequences indicated above.
- Half of surveyed psychiatrists reported that patient caregivers requested a medication switch or stop due to concerns triggered by lawsuit ads.

More than half of the surveyed psychiatrists reported frustration and concern that product liability cases involving antipsychotic medicines interfered with patient treatment and led them to change their prescribing practices.[40]

EARLIER DATA ARE CONSISTENT

An earlier study of physicians, pharmacists, and patients commissioned by the U.S. Chamber Institute for Legal Reform in July 2003 returned results consistent with the 2007 and 2017 studies. Among other findings, nearly one third of surveyed doctors reported that their patients refused to take a drug prescribed to them because of litigation.[41]

The poll sparked an op-ed by Dr. Louis W. Sullivan, the founding dean and former president of Morehouse School of Medicine and a former secretary of the U.S. Department of Health and Human Services. In a *Chicago Tribune* column, Dr. Sullivan expressed concern that advertising campaigns designed to recruit plaintiffs for lawsuits stemming from rare side effects "may be creating a new health care crisis"—leading patients to stop taking their medications and discouraging companies from developing new drugs.[42]

Recent Medical Literature

STROKES AND DEATHS LINKED TO XARELTO LAWSUIT AD SPIKE

Lawsuit advertising on television, radio, and print media targeting Xarelto skyrocketed in mid-2014. In a dire tone, these ads repeatedly told viewers that the drug could cause "uncontrolled bleeding or even death." Spending on these ads spiked from $8,000 in June 2014 to $1.2 million the following month, paying for about 1,800 television spots.[43] The ad buys occurred soon after a settlement of lawsuits against the maker of Pradaxa, another blood thinner.[44]

In light of the surge of these lawsuit ads, researchers explored whether the advertising itself had resulted in patient harm. Their conclusion: "Legal advertising concerning XARELTO (rivaroxaban) has resulted in some patients stopping XARELTO therapy and experiencing clinical events, such as stroke."[45]

When a healthcare professional observes or suspects that a person experienced an adverse event while taking a drug or using a medical device, he or she may report it through "Medwatch," the FDA's Safety Information and Adverse Event Reporting System.[46] The FDA received reports indicating that 31 patients who were prescribed Xarelto discontinued taking the medication after viewing a negative lawsuit ad and experienced a serious injury or death as a result.[47] These injuries and deaths occurred between September 2014 and December 2015, soon after the lawsuit advertising explosion began.

In seventy-five percent of these cases, patients experienced a stroke or a mini-stroke. Two patients were paralyzed. A 45-year-old man receiving Xarelto for treatment of deep vein thrombosis died of a pulmonary embolism after he stopped taking the medication. A woman who

> *"[A]dvertising campaigns designed to recruit plaintiffs for lawsuits stemming from rare side effects 'may be creating a new health care crisis'—leading patients to stop taking their medications and discouraging companies from developing new drugs."*

> *"The FDA reports included six deaths: three following a stroke, one following a cardiac arrest, one following a pulmonary embolism, and one stemming from an unreported cause."*

had been prescribed Xarelto for stroke prevention died of a massive stroke. "It is clear that some patients are intimidated enough by the ongoing legal campaign to stop their anticoagulant, and thus suffer an adverse event," the authors of the case study observed.[48]

According to the FDA, injuries and deaths associated with these lawsuit ads continue to rise. The FDA indicated in response to a subsequent Congressional inquiry that through December 31, 2016, doctors submitted 61 reports indicating patients had discontinued or decreased their use of Xarelto or Pradaxa after viewing a lawsuit ad.[49] These reports, some of which involved multiple patients, indicated that patients had suffered a wide range of adverse events, the most common of which was a stroke.

The FDA reports included six deaths: three following a stroke, one following a cardiac arrest, one following a pulmonary embolism, and one stemming from an unreported cause. Other patients who stopped their medication after viewing a television ad, many of which referred to their medication as a "bad drug," experienced transient ischemical attack (TIA), deep vein thrombosis (DVT) of the arm, intracardiac thrombus, and cerebral and foot thrombosis.

While harming patients, these lawsuit ads have achieved the results sought by plaintiffs' lawyers. Over roughly three years, the ads have generated over 19,000 claims in federal court targeting Xarelto.[50] The first three juries to consider these lawsuits, however, found that the blood thinner's manufacturers adequately warned doctors of its risks and properly instructed them on how to use it safely, returning defense verdicts.[51]

LAWSUIT ADS CONVEY INACCURATE INFORMATION REGARDING USE OF CERTAIN DRUGS DURING PREGNANCY

Obtaining information about the safety of using medications during pregnancy can be challenging for both clinicians and pregnant women, leading many women to turn to the internet, among other sources. A team of researchers affiliated with the CDC identified over 300 videos on YouTube that discussed the safety of using a class of medications during pregnancy.[52] Law firms were behind two out of every three of these videos, while government agencies, academic sources, and physicians each constituted less than 10% of the video sources.[53]

Most videos addressed antidepressants, particularly selective serotonin reuptake inhibitors (SSRIs) such as sertraline (Zoloft) and paroxetine (Paxil).[54] Some videos also targeted serotonin and norepinephrine reuptake inhibitors (SNRIs), such as

venlafaxine (Effexor).[55] Videos claimed that using the medication during pregnancy could result in specific birth defects (56%), persistent pulmonary hypertension of the newborn (26%), non-specific birth defects (18%), and behavioral or developmental disabilities (11%).[56]

The researchers compared the safety of the medication suggested in each video to the magnitude of risk rating listed in the Teratogen Information System (TERIS), a subscription database that rates both a specific drug's teratogenic risk (risk to the development of the embryo or fetus) and the quality of the data on risk of use in pregnancy.[57]

They found that while eighty-eight percent of YouTube videos addressing antidepressants identified the medications as unsafe for use in pregnancy, the TERIS ratings for those drugs ranged from "unlikely" to "minimal" teratogenic risk for SSRIs and an "undetermined" risk for SNRIs.[58] Videos also suggested that other types of medications were unsafe for use during pregnancy, such as acetaminophen (Tylenol), which TERIS ranked as having "minimal" risk.[59]

CDC researchers concluded that the video content they reviewed "does not adequately reflect what is known about the medication's teratogenic risk."[60] They cautioned, "[P]eople seeking information about the safety of medications in pregnancy from YouTube videos should be mindful of the information source when drawing conclusions about the teratogenic risk of specific medications and consider the video content with caution."[61] To counteract such misinformation, the authors recommended that "credible sources," such as the FDA, CDC, and physicians disseminate "factual, reliable content" through YouTube and encouraged women to discuss treatment questions with their doctors.[62]

"CDC researchers concluded that the video content they reviewed 'does not adequately reflect what is known about the medication's teratogenic risk.'"

AS A RESULT OF LAWSUIT ADS, PATIENTS MAY MISTAKENLY BELIEVE THAT THE FDA HAS RECALLED MEDICAL DEVICES

Advertisements seeking clients for cases against manufacturers of transvaginal mesh may be discouraging women from seeking treatment for pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These are common conditions that develop after childbirth or with age and, if untreated, can significantly affect a woman's quality of life. Surgeons have addressed these conditions through implanting various mesh products. For many patients, the implant improves their quality of life. Some patients, however, experience complications, and the FDA has informed the public of these risks.[63] The devices continue to have FDA approval and many patients continue to benefit from their use. Nevertheless, plaintiffs' lawyers have run a deluge of advertisements urging

anyone who has experienced complications to contact a lawyer. Although there are several types of mesh procedures, and each carries its own risks and benefits, these litigation ads target the devices with a broad brush.

A team of experts in female pelvic health set out to examine whether the television advertising recruiting individuals for lawsuits against mesh device manufacturers had led patients to mistakenly believe that the FDA had ordered a recall. They found that more than half of new patients (52%) that went to a specialty urology clinic to seek treatment for POP or SUI mistakenly believed there was a recall.[64]

Nearly seventy percent of the patients surveyed listed television as a source of information about mesh use in surgery, while only sixteen percent listed a doctor as a source of information.[65] Patients who relied on television as a source of medical information were three times more likely than others to believe there was a recall.[66] The authors attributed this misinformation to "the numerous litigation ads that are seen on television."[67] They also expressed concern that the misinformation could "erode physician-patient trust" and result in confusion, fear, and uncertainty when a doctor suggests mesh as an option for treatment after the patient has viewed lawsuit ads.[68]

> *"Efforts by the FDA and medical societies to provide balanced information on the internet have been 'hijacked' by lawsuit ads that dominate web search results."*

An editorial comment to the study noted that a limitation of the study is that it does not account for "significantly more biased information available on the internet."[69] The author of the comment, Dr. Gopal H. Badiani, observed that "[d]edicated sites posing as news . . . gleefully present all litigation information as well as testimonies from experts against the mesh."[70] Efforts by the FDA and medical societies to provide balanced information on the internet have been "hijacked" by lawsuit ads that dominate web search results, Dr. Badiani noted.[71]

Doctors Share Personal Accounts of the Troubling Effects of Misleading Lawsuit Ads

Below is a sample of what individual doctors, whose practices span a wide range of areas, have written about how lawsuit advertising has harmed their patients and their ability to effectively provide medical care.[72]

DR. ILANA KUTINSKY
Director of Atrial Fibrillation Services
William Beaumont Hospital
Troy, Michigan

[A]n elderly patient of mine who was independent and quite active, refused

anticoagulation for her atrial fibrillation for some time in fear of potential bleeding complications. After several years of office visits and long discussions and education, I built a successful enough relationship with this patient and she agreed to initiate appropriate anticoagulation therapy. . . . Three years later she presented to the hospital with a massive stroke. I was confused and went to speak with her family, concerned that her treatment had failed. They informed me that two weeks prior she had received a flyer in the mail that warned her that her medication could cause massive internal bleeding and death. She didn't want to die and so she stopped her medication. She didn't want to 'bother' me and decided to wait until her next appointment to discuss her decision. She was unaware there was any danger to her stopping her medication. She was unable to communicate with me when I saw her and subsequently fell into a coma and died. . . . She was under my care for nearly 8 years and after finally convincing her to take an anticoagulant so she would be protected from a stroke, she stopped the medication after receiving a flyer from a solicitous attorney that likely has no medical background at all. . . .

Patients are dying because they are afraid to take the medications prescribed for them due to the fear brought on by these negative and one-sided campaigns.[73]

DR. W. FRANK PEACOCK
Professor, Emergency Medicine
Associate Chair and Research Director
Baylor College of Medicine
Houston, Texas

[M]y patient, being 66 years old, female, with a history of high blood pressure and diabetes, has a 4.8% (~1 in 20) risk of having a stroke within the next year that would leave her debilitated, unable to speak, wearing diapers in a nursing home for the rest of her markedly shortened life, vs. taking a pill every day with a risk of a fatal bleed from anticoagulation of 0.0009 per year. To summarize, this patient had a 4.8 annual stroke risk, vs. 0.0009 annual fatal bleeding risk. In medicine, we call this a "no-brainer" and pick the lower of the risks.

So I went to the patient's bedside to have what I thought would be a relatively straightforward conversation. Usually this is a 5 minute exchange about what atrial fibrillation is, and what would be the recommended treatment. I answer some questions, write a prescription, move on to the next patient.

That is not how it went. I went to the bedside and told my patient that her test showed she had atrial fibrillation. But instead of her asking me the expected question of "What is Atrial Fibrillation", she said "I know". So if she had atrial fibrillation, the obvious next question for me was "What anticoagulant are you taking?" She couldn't answer me, as she broke down in tears. . . .

Wednesday, 4 days before coming to my ER she had felt tired, and weak, and had a fluttering feeling in her chest. She went to her physician who did an electrocardiogram and diagnosed atrial fibrillation. He found the same results as I had, that of a controlled heart rate in a patient with a very high risk of having a massive debilitating stroke. He spent 30 minutes teaching her about atrial fibrillation, the risks, the benefits, the treatment options. Answered her questions, then gave her a prescription for rivaroxaban and discharged her home.

On Wednesday afternoon my patient filled the prescription, went home, and took rivaroxaban. All was well until Thursday evening, when while watching television she saw the first 1-800-Bad-Drug commercial that implied that rivaroxaban was a dangerous drug. Having already taken it, as instructed, with dinner, she did not know what to do. She called her doctor, but got an answering service. She called the lawyer firm, who was glad to take her information, but offered no advice. She did not sleep that night.

Friday came and she again called her doctor, but he didn't have an appointment available until the following week. She called the 1-800-Bad-Drug ad number again, but got no instructions. What to do? Petrified with fear, she did not take her anticoagulant that night.

On Saturday morning, in my ER, I spent an hour talking with this patient. This was an extremely educated, intelligent woman who absolutely felt abused by our system. Her physician of many years, prescribing a drug to save her life, and lawyers coming into her house by the way of her television to destroy the doctor [patient] relationship, and prompt her to engage in behavior that could prove fatal.

My patient left my ER about mid-day. She took her rivaroxaban before she left. Nobody will know what would have happened had she waited to take her anticoagulant. Would she be dead from a massive stroke, or in a nursing home at this very minute? What if it had been a different patient that just listened to the TV and didn't come to my ER?[74]

DR. SHAWN H. FLEMING
Section Chief, Vascular Surgery
Novant Health Vascular Specialists
Winston-Salem, North Carolina

Not long ago, I encountered a patient in my surgical practice who was simultaneously under the care of another doctor in a different health system for an unrelated medical condition—a pulmonary embolism. . . . During our discussion, the patient told me he was not taking his anticoagulation medication, nor would he ever. He specifically cited a commercial he had seen as the reason for not following his doctor's advice. Even though I wasn't the physician treating his pulmonary embolism, I attempted to educate the patient on the importance of taking his medications—

and, specifically, the risk of not taking the anticoagulant given his recent diagnosis. Several weeks later, I learned that the patient had passed away and that the cause of death was determined to be recurrent pulmonary embolism.

While this is the only case that I am aware of that resulted in loss of life, over the past several years I have encountered many patients who are concerned, confused and even hostile when prescribed these medications. This occurs on a regular basis.

It is my opinion that tone and content of these advertisements imply a qualitative judgment of these medications that are in contradiction to the best known medical facts and current medical practice recommendations. . . .

[P]atients perceive these advertisements as medical advice that is often in direct contradiction to the advice of their physicians. The level of fear that this has generated is, in my opinion, unwarranted and in fact dangerous to my patients and certainly many other patients across our country. . . .

[C]reators of these commercials should be held to the same standards as physicians and drug companies.[75]

DR. EVAN S. LEVINE
Cardiologist and Clinical Assistant Professor of Medicine at Montefiore Medical Center – Albert Einstein College of Medicine
New York, New York

I recently had an encounter with a patient who watched, in shock, a television ad portraying this new drug as problematic and dangerous. He sat in my waiting room anxiously waiting to see me. He was concerned that I had prescribed a medication, to prevent a stroke, as a result of his irregular rhythm, that could cause him to hemorrhage to death. "It's all over the TV," he told me. "I saw it on the commercials. Pradaxa is causing people to bleed to death and I stopped it. I don't think I should be taking a drug that can make you bleed like that. People are suing too."

He had mistakenly placed himself at risk of a stroke by stopping the drug . . . .

Since many patients with atrial fibrillation are elderly and perhaps more easily persuaded by these slick ads, such ads represent a kind of public health risk. It took me an entire visit to educate him, again, about the risks and benefits of Pradaxa compared to Coumadin, and after our visit the patient decided to continue his Pradaxa. Lucky for him he did not have a stroke during the few weeks he was not anticoagulated with Pradaxa.[76]

DR. ANTHONY PEARSON
Clinical Cardiologist
St. Louis, Missouri

One of my patients called the office today concerned about a medication she was taking because she was "seeing about 4-5 commercials a day about how bad Xarelto is."

She is the latest of many of my patients who have been inundated with ads like these which state in very strident tones that a drug is bad and that if "you or a loved one has had a serious bleeding problem" contact 1-800-BAD DRUG and see if you are eligible for compensation.

These drugs are not bad and the only reason these advertisements are being played is that tort lawyers sense an opportunity to make money.[77]

American Medical Association Urges Action

In 2016, the American Medical Association (AMA) joined the growing chorus of doctors expressing concern. The AMA found that "rampant" television commercials presenting an unbalanced, one-sided view of prescription drugs had led patients to jeopardize their health by stopping medications without speaking with a doctor.[78] At its annual meeting, the organization's policymaking body, the House of Delegates, passed a resolution taking issue with "fearmongering" lawsuit ads.[79] These ads, the AMA found, are "dangerous to the public at large" because the ads typically emphasize lethal potential side effects or complications without informing the viewers of the benefits of the medication, the degree of risk, or that the FDA has and continues to approve the medication.[80]

The AMA's House of Delegates voted to advocate for a requirement that any attorney commercial that might lead a patient to discontinue taking a needed medication include a warning that patients should not do so without first talking with their physician.[81]

Following the vote, the AMA notified all state and national medical specialty societies of its interest in working with them to advocate for such a requirement and develop model state legislation that is consistent with the resolution.[82]

American Medical Association

House of Delegates Resolution 208 (A-16)
adopted as amended

Whereas, Television commercials that seek plaintiffs regarding new medications are rampant on late-night television; and

Whereas, The public has little knowledge regarding the new medication; and

Whereas, Often potential complications are spoken about them in an alarming way; and

Whereas, It is often the first time the public learns about potential complications regarding a new medication or potential side effects; and

Whereas, As a result of these ads, some patients have endangered themselves by stopping prescribed medications without speaking to a physician; and

Whereas, These commercials did not present a fair and balanced view of the product, but emphasize only potential side effects; and

Whereas, Only the lethal side effects are described, not the benefit of the medication and the side effect explained is often a known complication and the product has been evaluated by the FDA and received FDA approval; and

Whereas, Neither the incidence of the side effect not the degree of risk is explained to the viewer; and

Whereas, These publicities are "fearmongering" and dangerous to the public at-large because they do not present a clear picture regarding the product; therefore be it

RESOLVED, That our American Medical Association advocate for a requirement that attorney advertising which may cause patients to discontinue medically necessary medications have appropriate and conspicuous warnings that patients should not discontinue medications without seeking the advice of their physician.[83]

A Peek Into the Mass Tort Litigation Underbelly

Lawsuit advertising is part of a process known as lead generation. Millions of dollars are spent on advertising and other practices to generate as many claims as possible, as quickly as possible. Viewers are directed to call centers that process their information, then refer or sell the claims of those who meet minimum criteria to others. Some firms are even going beyond relying on advertising and directly contacting people through robocalls and cold calls, urging them to agree to file a claim. Whether a claim has merit is secondary. The end goal is to overwhelm a company with claims and pressure it to enter a global settlement. Recent litigation has exposed how this process works.

The Business Model

In 2015, Houston-based law firm AkinMears spent the most money on television advertising to recruit mass tort claims of any firm that year, over $25 million, according to Kantar Media data.[84] That year, the former chief business development officer of the firm sued his former employer alleging it owed him commissions for money he raised to finance the operation.[85] In the process, Amir Shenaq exposed, as he called it, the firm's "business model."[86]

Shenaq describes AkinMears as a small firm that relies on television advertisements to obtain clients in mass tort litigation targeting drugs such as Viagra, Zofran, Xarelto, Lipitor, and Risperdal, several medical devices, as well as asbestos claims. The complaint indicates that the firm had purchased over 2,000 television ads in just the 30 days preceding his filing the complaint.[87]

The complaint describes how AkinMears operates—information that the firm initially attempted to hide from public view.[88]

SHENAQ V. AKIN COMPLAINT

"AkinMears is not run like a traditional plaintiff's law office, and the firm's lawyers do not do the types of things that regular trial lawyers do. Things like meet their clients, get to know their clients, file pleadings/motions, attend depositions, or, heaven forbid, try a lawsuit. AkinMears leaves the heavy legal lifting to others.

Rather, the Firm is in the business of purchasing generic television spots, running a call center with script-reading 1-800 operators, signing up clients and bundling claims, and then sending them en masse to other lawyers who will hopefully settle them. Despite the fact that AkinMears' lawyers do not have to dirty their hands with the mundane chores that come with actually practicing law, the Firm nonetheless charges a robust 40% contingency fee for its efforts (which is then divided in some fashion among the various participants in its ever-shifting syndicate). Indeed, it would be impossible for the Firm to represent clients in the manner in which the verb is generally understood. It would be impossible because AkinMears handles tens of thousands of claims and, according to the Firm's website, *has a grand total of five (5) attorneys*.

In actuality, AkinMears is nothing more than a glorified claims processing center, where the numbers are huge, the clients commodities, and the paydays, when they come, stratospheric."[89]

Shenaq describes AkinMears' "business model" as a six-step process:

"(i) borrow as much money as possible;

(ii) buy as many television ads and/or faceless clients as possible;

(iii) wait on real lawyers somewhere to establish liability against somebody for something;

(iv) use those faceless clients to borrow even more money or buy even more cases;

(v) hire attorneys to settle the cases for whatever they can get;

(vi) take a plump 40% of the settlement from the thousands and thousands of people its lawyers never met or had any interest in meeting; and

(vii) lather, rinse, and repeat. . . ."[90]

Shenaq alleged that the firm fired him to avoid paying him $4.2 million in commissions after he raised nearly $100 million in capital for its operations.[91] The litigation settled in April 2016.[92]

> *"[S]adly, there are attorneys and law firms that ignore ethical rules and barratry laws and use any means necessary in the mad dash to grab as many clients as they can."*

From Lawsuit Ads to Direct Solicitation

A MASSIVE ROBOCALL CAMPAIGN: IVC FILTER LITIGATION

IVC (inferior vena cava) filters were the second most targeted drug or medical device in lawsuit television advertising between January 2015 and June 2016, running nearly 100,000 ads.[93] According to a lawsuit filed by a Texas plaintiffs' lawyer involved in the litigation, some law firms are not only sponsoring ads; they have also used robocalls to find clients.

IVC filters are small devices that are implanted into the inferior vena cava, the largest vein in the body, to help people recover from injuries by preventing potentially fatal lung clots. They have been used for decades but sometimes result in complications for patients. There are about 5,000 IVC lawsuits pending against two manufacturers in federal multidistrict litigation.[94] These lawsuits generally allege that certain IVC filters failed, causing the device to fracture or move, causing injury.

In July 2016, John "Scotty" MacLean received a call from the "IVC Claims Center."[95] An automated voice asked if he or anyone he knew had been harmed by an IVC filter. MacLean played along, entering a response to speak with a live person about his "potential claim," and eventually learning the identity of the lawyer and firm that had sponsored the call.[96] Then, in November 2016, he sued in federal court.

In the midst of this race to bring as many lawsuits as possible, MacLean's complaint alleges that two law firms, Arentz Law Group and The Johnson Law Group, "initiated a massive robocall campaign indiscriminately contacting Texans all over the state with unsolicited automatic telephone calls."[97] The complaint observes that while many law firms legally and ethically pursue mass tort litigation, "sadly, there are attorneys and law firms that ignore ethical rules and barratry laws and use any means necessary in the mad dash to grab as many clients as they can."[98] MacLean's lawsuit also names as defendants the marketing company that obtained the phone numbers and initiated the calls on behalf of the law firms, and the company hired to screen potential clients.[99]

Barratry laws place restrictions on how lawyers can solicit clients. These state laws are intended to protect the public from harassment. The Texas law applicable to MacLean's case subjects attorneys who, with the intent to obtain economic benefit, solicit employment either in person or by phone, to civil liability and criminal penalties.[100] Under that law, McLean sought

an award of $10,000 in civil penalties for each and every unsolicited call made in violation of state law for each class member, plus attorneys' fees and injunctive relief.

The defendant law firms responded with a counterattack, claiming MacLean committed fraud by repeatedly providing false information to them for the purpose of bringing a lawsuit against them. The firms also brought claims against him for interference with prospective economic advantage and interference with prospective mass tort clients. A federal district court dismissed the counterclaims against MacLean, finding the firms had presented "nothing more than conclusory allegations, which are not sufficient to state a plausible claim for relief."[101]

Days later, the district court denied the law firm defendants' motion to dismiss MacLean's complaint. The court, however, also found that MacLean had failed to timely file a motion for class certification. As a result, the court permitted the lawsuit to move forward on an individual basis only and not on behalf of everyone who received robocalls soliciting them for a lawsuit.[102]

In July 2017, the court further whittled down the lawsuit when it found MacLean could not sue under the state's barratry law because he never became a "client" of the law firms that solicited him, as the statute requires.[103] The court also granted summary judgment for the Arentz Law Group, which the court found had not participated in the calling practice.[104]

Other claims continue to move forward. MacLean argues that the law firms have refused repeated discovery requests for documents that would show the nature of the relationship between the law firms and the marketing companies retained to solicit potential IVC clients.[105] The case is scheduled for a jury trial in December 2017.[106]

COLD CALLING: PELVIC MESH LITIGATION

Litigation against manufacturers of pelvic mesh has exploded. According to the latest statistics available, over 100,000 lawsuits have been filed in federal courts against six manufacturers.[107] This occurred even as the FDA continues to approve these devices and surgeons continue to implant them for treatment of stress urinary incontinence. What then has led so many women to file lawsuits? Some of the defendants, backed by affidavits from women, say many of the lawsuits are a result of inappropriate and illegal solicitation practices combined with misleading attorney advertising.

> *"Each woman indicated that callers misrepresented their identities, knew details of their private medical history, promised them money if they would agree to submit a claim, and appeared to be affiliated with a foreign call center."*

In January 2015, Johnson & Johnson and Ethicon filed a bombshell motion in the federal pelvic mesh litigation that was innocuously titled "Motion to Revise Case Management Procedures and for Discovery Related to Plaintiff Solicitation."[108] The motion indicated that upset women had contacted the companies after they received unsolicited phone calls asking them to join a lawsuit.

The motion was backed by the affidavits of six women and a transcript of an audio recording of one of the calls. Each woman indicated that callers misrepresented their identities, knew details of their private medical history, promised them money if they would agree to submit a claim, and appeared to be affiliated with a foreign call center.

Here is an excerpt of the recording between a caller and a woman who is a registered nurse in Indiana:

> SOLICITOR: "I know, [Name] you never had done this surgery, but if you are interested to receive 30 up to 40 thousand dollars, you just have to tell my compensation officer that I had a bladder sling surgery and after that I had a complication."
>
> RESPONSE: "I know, but –"
>
> SOLICITOR: "So I will tell my –"
>
> RESPONSE: "That would be lying though."
>
> SOLICITOR: "I do understand, but you have to tell a lie if you want to get the 30 up to 40 thousand dollars."
>
> RESPONSE: "No."
>
> SOLICITOR: "No one will give you 30, 40 thousand dollars like that. You have to tell a lie for that."
>
> RESPONSE: "Right, but that's illegal."
>
> SOLICITOR: "Can you do this?"
>
> RESPONSE: "No, I will not do that."
>
> SOLICITOR: "Can you?"
>
> RESPONSE: "That is ridiculous, that is illegal."
>
> SOLICITOR: "Okay, [NAME] bye-bye."[109]

An affidavit filed by a Florida woman similarly indicated that she received numerous calls from people claiming to be with "American Medical Services" urging her to sign up for a legal settlement of $30,000 to $40,000 for bladder sling surgery. The callers, she noted, all spoke with an Indian accent and there were telemarketing noises in the background. They somehow knew the woman had gallbladder surgery many years earlier and mentioned it during the call. "When I tell them I have never had mesh, they say 'that's ok, wouldn't you like $30,000?" Her affidavit logged 15 calls she received in July 2014.[110]

When another Florida woman, a nurse, received near weekly calls, the caller ID sometimes indicated they were from the "Medical Compensation Department" or the "Federal Medical Department." One caller falsely claimed that he worked for Johnson & Johnson. Another said she was calling from the "Family Health Care Department." According to the affidavit, the callers spoke

with a "thick foreign accent" and sounded as if they were calling from a call center. When she asked to talk with a supervisor, her calls were disconnected.[111]

A Virginia woman who had an Ethicon pelvic mesh device implanted, but did not experience complications, submitted an affidavit indicating she received over 50 phone calls in just one month asking her to sign up for a lawsuit. Callers indicated that they knew she had been implanted with a mesh device. In response, the woman indicated that she contacted her hospital's privacy officer and sought help from the Better Business Bureau.[112]

Likewise, a California woman received unsolicited calls in which callers indicated that they knew she had surgery and received a mesh implant. A caller, who had a foreign accent, indicated he was with "U.S. Healthworks." According to the affidavit, that caller insisted that she join a "class action lawsuit." When she repeatedly told the caller that she did not need follow-up surgery, had no pain or discomfort, and had no problem with the implant, he would end the conversation, only to call again. She documented 38 calls over a three-month period.[113]

Incredibly, even the spouse of one of the attorneys representing the manufacturers in the mesh litigation received two calls claiming they had information showing she had undergone bladder sling surgery or mesh implant surgery and indicating "you don't have to do anything" to receive compensation.[114]

In their motion, the manufacturers expressed concern that the MDL could be inflated by baseless and fraudulent lawsuits resulting from this practice. The presence of these lawsuits on the docket, the companies observed, jeopardizes the ability of women with non-fraudulent claims to have their day in court. They noted that the flood of baseless suits and their mixing with potentially valid claims would be used by plaintiffs' lawyers "as a hammer to force settlement without ever having to demonstrate the merit of their claims." In light of the "mounting evidence that fraud is being perpetrated in the pelvic mesh litigation," the companies asked the court to allow them to require plaintiffs' lawyers in all pending cases to answer a series of questions intended to cull the docket of fraudulent claims. One month later, however, Johnson & Johnson, with the court's permission, withdrew its motion.[115]

American Medical Systems (AMS), another defendant in the pelvic mesh suits, picked up where Johnson & Johnson left off. In March 2016, AMS subpoenaed the Texas law firm AkinMears, a group of four small law firms that had transferred thousands of mesh cases to AkinMears, and a Florida-based legal marketing business called "Law Firm Headquarters." The subpoenas sought information on how Law Firm HQ acquired the claims, transferred them to small firms with one or two lawyers, which, in turn transferred them to AkinMears. Law Firm HQ contracted with 75 call centers in countries such as Mexico, India, and the Philippines, from which it purchases leads for lawsuits.[116] Its co-owner, Michael Chhabra, has acknowledged that some of these call centers engaged in the types of improper tactics documented in the Johnson & Johnson motion.[117]

> *"AMS submitted to the court affidavits from three women who stated that they repeatedly received cold calls from foreign call centers pressuring them to agree that they had complications from mesh implants, when they had no such problems."*

AMS charges that Law Firm HQ and the small affiliated firms to which it transferred cases "are at the center of an illicit enterprise,"[118] summarizing its evidence as showing:

> [M]esh patients are being solicited by cold callers armed with confidential medical information who employ distortion, exaggeration, and outright untruth to pressure these women to sign retention letters. Once signed up, the cases are bundled and sent by the [companies seeking to quash the subpoenas] to other law firms, and the plaintiffs are funneled to faraway surgeons they've never met for revision surgeries their own doctors never recommended (and, in some cases, recommended against). The surgeons are paid inflated cash fees (and substantial "bonuses" for each explant)—up to ten times the norm—by "funding companies" that insist that the plaintiffs avoid using insurance and then place exorbitant liens on the plaintiffs' recoveries. By all appearances, a pyramid of businessmen, doctors and lawyers is orchestrating the exploitation of unsophisticated medical and legal consumers and seeking to perpetrate a fraud on AMS and the Court.[119]

In an attempt to require a response to its subpoenas, AMS submitted to the court affidavits from three women who stated that they repeatedly received cold calls from foreign call centers pressuring them to agree that they had complications from mesh implants, when they had no such problems. AMS also included statements from six women who were convinced by callers to have a mesh implant removed by a doctor who worked with those involved in the litigation. According to the women's deposition testimony, some of these callers told them that their mesh implants had been recalled, when the FDA had taken no such action.[120] Others were also told (falsely) that only a few doctors perform such surgeries.[121]

AMS alleges that Law Firm HQ and the related firms have resisted responding to the subpoenas. After a hearing in August 2016, the court ordered Michael Chhabra and others to appear for depositions at which AMS could explore who called each plaintiff, what that person told the plaintiff about a product being recalled or defective, and how the surgery was arranged and funded.[122] After those depositions confirmed the existence of more evidence that would support AMS's concerns, AMS requested that the court allow it to serve subpoenas

requiring production of materials such as the "SalesForce" database that logged each contact with a lawsuit lead and recordings of calls with plaintiffs.[123] As of the publication of this paper, that motion remains pending.

The End Goal: Mass Settlement

Lawsuit advertising has increased as a result of the business model employed by plaintiffs' law firms that bring pharmaceutical and medical device litigation. Lawyers are in a race to file as many claims as possible to gain a strategic advantage in litigation and pressure manufacturers to settle.

Plaintiffs' lawyers who specialize in mass tort litigation understand that generating thousands of claims can overwhelm a company, making it impossible to closely scrutinize whether each individual lawsuit has merit. A surge of lawsuits is also likely to make headlines, damaging the reputation of the company, its brand, and its products. As a result, manufacturers that face thousands of lawsuits sometimes settle the claims en masse to avoid lengthy, expensive litigation and bad press, and to move on.

In September 2016, a federal judge observed the use of these practices in mesh device litigation, threatened plaintiffs' attorneys with sanctions, and declared "enough is enough."[124]

That litigation involves Mentor Worldwide's ObTape vaginal sling products. The lawsuits began with a few cases alleging that after the product was implanted, it would begin to deteriorate, harming the patient. After the cases were placed in multidistrict litigation in the U.S. District Court for the Middle District of Georgia before Judge Clay D. Land in 2008, the docket grew to more than 850 cases.[125]

Expressing frustration with the amount of time he had spent dismissing cases that clearly lacked merit and "probably should never have been brought in the first place," Judge Land put the plaintiffs' lawyers "on notice": he would consider imposing sanctions when dismissing cases in the future.[126] In some cases, he observed, the plaintiff's counsel had not identified an expert witness or other evidence indicating that the device had caused the client's injury. Other cases were clearly barred by the statute of limitations. In some instances, he noted the plaintiffs' lawyers "threw in the towel and did not even bother to respond," when the defendant sought to dismiss the case through filing a motion for summary judgment.[127] Judge Land warned the plaintiffs' lawyers that they should closely look at their remaining cases and voluntarily dismiss claims where they did not have admissible evidence that the product had injured a client or where they did not file

"Plaintiffs' lawyers who specialize in mass tort litigation understand that generating thousands of claims can overwhelm a company, making it impossible to closely scrutinize whether each individual lawsuit has merit."

> *"Judge Land found that the ObTape litigation 'explosion appears to have been fueled, at least in part, by an onslaught of lawyer television solicitations.'"*

the lawsuit until many years after a client's medical treatment.[128]

Judge Land could have ended his scolding there, but he did something uncommon: he appended an "Obiter Dictum," which is Latin for "something said in passing" and indicates a comment that is not necessary to the court's opinion. He used the three-page missive to offer his views on how lawyers were abusing the federal multidistrict litigation system.

Judge Land found that the ObTape litigation "explosion appears to have been fueled, at least in part, by an onslaught of lawyer television solicitations."[129] While consolidating these and other cases before a single federal judge may, in some cases, lead to more efficient resolution of litigation, the process has "unintended consequences," he observed.[130] Judge Land expressed concern that the MDL process has "produced incentives for the filing of cases that otherwise would not be filed if they had to stand on their own merit as a stand-alone action."[131]

Judge Land ended his order by providing advice for his colleagues who handle mass tort dockets, suggesting that they "weed out non-meritorious cases early, efficiently, and justly" and with the "robust use" of the federal rule authorizing judges to sanction frivolous claims.[132] Soon after issuing this order, Judge Land requested that the Judicial Panel on Multidistrict Litigation stop transferring ObTape actions to his MDL docket, finding "the benefit of accepting new cases is marginal."[133]

Are Lawsuit Ads Scaring the Public to Taint the Jury Pool?

While lawsuit ads are often intended to generate as many plaintiffs as possible in order to pressure a company to settle all claims, some question whether the TV commercials scare the public with an ulterior motive: to poison the local jury pool before a trial.

In recent years, plaintiffs' lawyers have asserted that use of baby powder, which contains talc, has caused women to develop ovarian cancer. The FDA has not found that scientific evidence demonstrates such a link.[134] While the FDA has not recalled, restricted, or required a warning on products containing talc, plaintiffs' lawyers have filed more than 3,000 lawsuits nationwide against Johnson & Johnson.

The St. Louis area had the most television commercials asserting that talc can cause ovarian cancer in 2016. In one particular month that year, plaintiffs' lawyers ran 830 of these ads on St. Louis TV stations.[135]

While plaintiffs' lawyers have filed about one third of these cases in St. Louis, most of their clients are from outside Missouri.[136]

That raises the question: are the TV ads in the St. Louis market ineffective in identifying clients or could the ads serve another purpose?

That is the issue Johnson & Johnson raised in a motion filed in the St. Louis Circuit Court in July 2016, when it requested that the court transfer a talc case to a court at least 100 miles from St. Louis.[137] The company argued that the "barrage of highly inflammatory commercials" in the St. Louis area made it impossible for the company to receive a fair trial in the city. Its motion was supported by affidavits showing:

- More television ads asserting talc causes ovarian cancer aired in the St. Louis area than any other media market in the year preceding the motion according to an X Ante analysis.
- A quarter of talc lawsuit ads nationwide were broadcast solely in St. Louis, even though the city represents just over one percent of the national television audience.
- Some ads explicitly told viewers (who were potential jurors) that "Johnson & Johnson's Baby Powder is linked to ovarian cancer" and that "J&J failed to inform women of the potential risk for years." This ad ran about four times a day in St. Louis in one particular month. Another widely shown ad told viewers that "the American Cancer Society has found a link between the use of talcum powder and the development of ovarian cancer." (In fact, the organization's website indicates that the findings of studies "have been mixed, with some studies reporting a slightly increased risk and some reporting no increase" and that the types of studies that found a slight increase use a method that "can be biased.")[138]
- A survey found that nearly sixty-two percent of potential jurors in St. Louis had seen such commercials. On average, potential jurors recalled viewing nine commercials.
- The number of ads in St. Louis that included mentions of jury awards in talc cases was substantially higher than ads that aired elsewhere.
- About seven in ten prospective jurors surveyed who recalled being exposed to a commercial linking talcum powder to ovarian cancer indicated that they perceived the products as harmful after watching the ad. Most reported that the lawsuit ad was important in shaping their opinion.

"About seven in ten prospective jurors surveyed who recalled being exposed to a commercial linking talcum powder to ovarian cancer indicated that they perceived the products as harmful after watching the ad."

- Local ads placed less emphasis on urging viewers to call a lawyer than ads that aired nationally.[139]

Given these findings, Johnson & Johnson argued that the pervasive local talc lawsuit advertisements had saturated the jury pool and that these ads were more focused on inflaming potential jurors than attracting clients.[140] Nevertheless, the court allowed the case to go to trial in St. Louis. It resulted in a $70 million verdict in October 2016.[141] That verdict was preceded by blockbuster awards of $72 million in February and $55 million in May 2016, and was followed by a $110 million award in May 2017—all in St. Louis—while one case there ended in a defense verdict.[142] In contrast, in the midst of the St. Louis verdicts, a state court judge in New Jersey dismissed two talc lawsuits against Johnson & Johnson even before they reached trial, finding the claims were not backed by credible scientific evidence.[143]

Warning: Lawsuit Ads Lack Oversight

The FDA closely regulates information about drugs disseminated by manufacturers on television, the internet, and print for accuracy and balance. The Federal Trade Commission and state regulators intervene when a business engages in deceptive advertising, but rarely consider the marketing practices of law firms. Bar associations have rules and issue ethics opinions governing some aspects of lawyer advertising, but do not actively monitor lawyer ads and rarely enforce existing rules. As a result, despite the public health implications of exaggerating the risks of medical treatment, lawsuit advertising practices lack significant oversight.

Traditionally, the legal profession frowned upon lawyer advertising. Soliciting employment through advertisements was considered undignified and unprofessional. Rules of professional conduct placed significant restrictions on their use. In fact, the American Bar Association generally prohibited all attorney advertising in its 1908 Canons of Professional Ethics and 1969 Code of Professional Responsibility.

The blanket ban unraveled in 1977 when the U.S. Supreme Court invalidated an Arizona disciplinary rule that prohibited lawyers from advertising their services on television or radio, or in print. The First Amendment's protection of commercial speech, the Court found, does not allow rules that prohibit lawyers from *truthfully* advertising the availability and terms of routine legal services.[144] The Court reaffirmed, however, that "[a]dvertising that is false, deceptive, or misleading of course is subject to restraint."[145] The following year, in upholding an Ohio rule that prohibited lawyers from soliciting people in person or by phone when they are injured or distressed, the Court found that preventing "aspects of solicitation that induce fraud, undue influence, intimidation, overreaching and other forms of vexatious conduct" overrides a lawyer's interest in advertising his or her services.[146]

In a subsequent ruling outside the lawyer advertising context, the Supreme Court articulated a four-part analysis, known as the *Central Hudson* test, for evaluating the constitutionality of restrictions on commercial speech that continues to be applied today: (1) the expression is

protected by the First Amendment because it concerns lawful activity and is not misleading; (2) the asserted government interest is substantial; (3) the regulation directly advances the governmental interests; and (4) the regulation is not more extensive than necessary to serve that interest.[147] The Supreme Court has applied this test to find that attorney advertising, even if factually accurate, can mislead the public. For example, the Court has found that a state could discipline a lawyer who ran a newspaper ad soliciting clients for lawsuits against the manufacturer of the Dalkon Shield Interuterine Device (IUD) that stated "If there is no recovery, no legal fees are owed by our clients," without disclosing that they might still be liable for significant litigation costs.[148]

These rulings demonstrate that it is fully consistent with the First Amendment for government agencies or state bars to regulate the type of misleading lawyer advertising practices employed in mass tort advertising. As this report shows, a growing body of evidence indicates that some lawsuit ads lead viewers to believe they are public health alerts or affiliated with government agencies, overstate the risks of medical treatment, lead patients to believe a drug or device was recalled when it is still widely prescribed, and have led to injuries as a result of viewers stopping their medication without consulting a doctor. There is a substantial government interest in adopting safeguards to protect public health.[149] Nevertheless, while mass tort lawyers have engaged in an anything-goes "mad dash" to sign up as many clients as possible,[150] officials have remained on the sidelines.

The FDA Closely Monitors Prescription Drug Information Disseminated by Manufacturers but Ignores Similar Information Disseminated in Lawsuit Ads

The FDA closely monitors prescription drug information disseminated by manufacturers, but it does not consider the accuracy of drug information spread by plaintiffs' lawyers and others through television ads, websites, and social media. As this report shows, however, when lawsuit ads contain exaggerated or unscientifically supported claims, or do not warn patients to speak with their doctor before discontinuing a medication, public health suffers.

> *"[I]t is fully consistent with the First Amendment for government agencies or state bars to regulate the type of misleading lawyer advertising practices employed in mass tort advertising."*

REGULATION OF DRUG INFORMATION DISSEMINATED BY MANUFACTURERS

The FDA regulates the accuracy of drug information disseminated by manufacturers, whether to healthcare professionals or directly to the public. The agency could use its expertise to take a similar approach with respect to information on drugs contained in lawsuit ads.

The FDA's power to prohibit misbranding stems from the Food, Drug & Cosmetic Act. The Act provides that a prescription drug is misbranded if its labeling or advertising is misleading.[151] Generally, the FDA requires a manufacturer's marketing of a drug to be consistent with approved product labeling. Claims about the safety and effectiveness of a drug must be supported by substantial evidence. Prescription drug advertising must present a "fair balance" between effectiveness of the drug and its potential side effects. FDA regulations prohibit drug marketing that selectively presents favorable research or studies, uses headlines or graphics in a way that is misleading, presents quotes out of context, claims one drug is safer than another without substantial evidence, or otherwise omits or minimizes risk information or overstates the effectiveness of a drug.[152]

The FDA provides manufacturers with an opportunity to submit promotional materials to the agency for advisory comment prior to disseminating or publishing them.[153] Congress has also authorized the FDA to "require the submission of any television advertisement for a drug . . . not later than 45 days before dissemination of the television advertisement" and to recommend changes necessary to "protect the consumer good and well-being" or make the advertisement "consistent with prescribing information."[154]

> *"When it comes to prescription drug information disseminated to the public by manufacturers, the FDA takes an active role to ensure the public receives accurate, scientifically-supported information."*

When it comes to prescription drug information disseminated to the public by manufacturers, the FDA takes an active role to ensure the public receives accurate, scientifically-supported information. The Office of Prescription Drug Promotion (OPDP), which is part of the FDA's Center for Drug Evaluation and Research (CDER), monitors marketing activities and takes action when necessary.

- The FDA estimates that OPDP will receive 98,000 submissions of promotional materials from manufacturers in FY 2017,[155] approximately 8,000 submissions each month.
- OPDP employs about 30 reviewers, who specialize in specific drug categories.[156]
- OPDP issues enforcement letters asking companies to stop marketing activities that could create a misleading impression about the safety or effectiveness of a drug. These take the form of notice of

violation letters (or "untitled letters") for minor violations and warning letters for more serious violations. OPDP issued 11 enforcement letters in 2016 (eight untitled letters and three warning letters).[157] These letters raised concern with television ads, webpages, and YouTube videos—the same media through which plaintiffs' law firms disseminate information.

- If the sponsor of an ad does not adequately respond to a warning letter, then the FDA may work with the Department of Justice to obtain an injunction and can also withdraw approval of the product and seek substantial civil penalties.[158]

- OPDP's "Bad Ad" program encourages healthcare professionals to report drug advertising that may mislead patients to the FDA.[159] OPDP also receives concerns about drug advertising from consumers and competitors.[160]

NO FDA OVERSIGHT OF SIMILAR DRUG INFORMATION DISSEMINATED BY LAWYERS AND LEAD GENERATORS

While information the public receives from manufacturers about prescription drugs is carefully monitored by the FDA, the public is subject to a barrage of unregulated and often misleading ads on television and the internet about prescription drugs sponsored by plaintiffs' lawyers and lead generating firms.

Many of the public health concerns that the FDA and critics express with respect to direct-to-consumer (DTC) advertisements by manufacturers apply equally to plaintiffs' lawyer advertising. While the goal (attract clients) and source (plaintiffs' lawyers and lead generators) of the advertisements are different, both types of ads convey health information about the risks and benefits of drugs. In fact, OPDP describes its mission as "[t]o protect public health by ensuring that prescription drug *information* is truthful, balanced, and accurately communicated" (emphasis added).[161] This mission would appear to apply to information about prescription drugs conveyed to the public regardless of its source or purpose.

- While DTC advertisements may be criticized as overemphasizing benefits and not sufficiently discussing risks, lawsuit ads may significantly overstate risks while conveying none of the benefits of the drug.

- Whereas DTC ads may suggest that a drug provides a more effective treatment option than others without sufficiently solid scientific backing, lawsuit ads may make unsupported assertions that one drug presents greater risks than other available drugs.

- Both DTC ads and lawsuit ads may make claims based on scientific studies that are "inadequate in design, scope, or conduct to furnish significant support for such information or conclusions."[162] As examples in this report show, lawsuit ads may use headlines or graphics, or selectively present research, in a way that is misleading—actions that would subject a manufacturer to FDA scrutiny.[163]

There is also a critical safeguard with respect to pharmaceutical advertising that is not present with respect to lawsuit ads. Individuals who view commercials for prescription drugs must speak with their

doctor about whether the drug would help them and its potential risks. The doctor must find the drug would benefit the patient and write a prescription before a patient can obtain the product. Viewers of lawsuit ads, however, may stop taking their medication immediately without consulting their doctor.

The FDA recently indicated that while it can regulate pharmaceutical advertisements under its authority to prevent misbranding, it views lawsuit ads as beyond the agency's reach. Advertisements for legal services "are not advertising for the drug itself issued by a manufacturer or other party responsible for marketing the drug" and the FDA therefore cannot ensure such advertising is truthful, balanced, and not misleading, the FDA responded to a Congressional inquiry in June 2017.[164]

In light of this position, policymakers should ask: If it is important to stop pharmaceutical advertising that *overstates* the effectiveness of a drug or *understates* its risks, then why is it not equally damaging to public health and safety for lawsuit advertisements to *understate* (or not recognize at all) the effectiveness of a drug or *overstate* its risks?

The FTC's Hands-Off Approach to Lawyer Advertising

The FTC is empowered to regulate attorney advertising and professes to have a "longstanding interest in the effects on consumers and competition of the regulation of attorney advertising and solicitation."[165] The FTC, however, has generally taken a hands-off approach to lawyer advertising practices, deferring to state bars.

The Federal Trade Commission Act gives the FTC broad authority to regulate "unfair or deceptive acts or practices" including misleading advertisements.[166] The FTC considers an advertisement "unfair" if it causes or is likely to cause substantial consumer injury which a consumer could not reasonably avoid, and it is not outweighed by the benefit to consumers.[167] An ad is deceptive when it is likely to mislead reasonable consumers and affect the consumer's conduct with regard to a product or service.[168]

The FTC has taken positions on the advertising of products and services that would appear to apply equally to the types of attorney advertising practices discussed in this report.

"*If it is important to stop pharmaceutical advertising that* overstates *the effectiveness of a drug or* understates *its risks, then why is it not equally damaging to public health and safety for lawsuit advertisements to* understate *(or not recognize at all) the effectiveness of a drug or* overstate *its risks?*"

> *"The FTC, however, has generally taken a hands-off approach to lawyer advertising practices, deferring to state bars."*

For example:

- The FTC recognizes that infomercials that mimic the format of news reports, talk shows, or other independent programming can be deceptive. The FTC has required companies to clearly disclose that "THE PROGRAM YOU ARE WATCHING IS A PAID ADVERTISEMENT FOR [NAME OF PRODUCT]" at the beginning of an infomercial and before the ad provides information to purchase the product or service.[169]
- The FTC has taken action when advertisements are presented as public service announcements or suggest a government affiliation.[170]
- The FTC has challenged as deceptive websites that purport to be an objective resource for scientific information, but are selling a product.[171]
- Advertisements that make health or safety claims must be supported by "competent and reliable scientific evidence."[172]
- Products and services advertised on the internet must include clear and conspicuous disclosures when needed to prevent the ad from being unfair or deceptive.[173]

Some lawsuit ads targeting drugs and medical devices employ these very practices. As a nonprofit research organization concerned about elderly patients observed, under the FTC's truth-in-advertising rules, an ad calling blood thinners "bad drugs" is "deceptive on its face."[174] Statements about these drugs being linked to dangerous bleeding omit material information—the few people who experience such side effects compared to its benefit to many people in preventing strokes—rendering the ads deceptive.[175] Yet, the FTC has not acted, for two possible reasons.

First, the FTC may be reluctant to take action on lawsuit advertising targeting drugs or devices because it views the FDA as having primary responsibility in this area. The FTC and FDA have a longstanding arrangement regarding the regulation of advertisements for products in which they share jurisdiction. A Memorandum of Understanding (MOU) between the agencies provides that the FDA has primary responsibility for regulating the truth or falsity of advertising of prescription drugs, while the FTC has primary responsibility for regulating the truth or falsity of advertisements for over-the-counter drugs and medical devices (as well as foods, dietary supplements, and cosmetics).[176] This MOU, however, envisions joint planning and coordination so that the public benefits from the expertise of each agency. Moreover, the MOU does not address attorney advertising, leaving the FTC with full discretion to act.

Second, the FTC has deferred to state bars to regulate attorney advertising. The agency has generally limited its involvement to occasionally submitting comments to state bars and judicial committees when they consider adopting or amending rules regulating lawyer advertising. The American Bar Association (ABA) website has compiled 17 such FTC comments since 1989, only one of which was submitted in the past decade.[177] The FTC's most recent comment regarding proposed regulation of lawyer advertising opposed pre-screening of ads by a review committee of Tennessee's Board of Professional Responsibility (and warned that the screening committee would be subject to federal antitrust laws).[178] In rare cases in which the FTC has expressed a position on attorney advertising, it has done so to *oppose* restrictions because it views constraints on advertising as leading to less competition between law firms for clients.[179]

The Legal Profession is Unlikely to Act

While policymakers and regulators may look to state bars and judiciaries to respond to misleading lawsuit advertising practices, the public cannot solely rely on these bodies for oversight. Attorney ethics rules are not likely to provide an effective safeguard against misleading medical information contained in lawyer ads for several reasons.

ETHICS RULES ADDRESS MISLEADING COMMUNICATIONS ABOUT LEGAL SERVICES, NOT MISLEADING MEDICAL INFORMATION

State bars and disciplinary authorities can take steps to rein in misleading attorney advertising practices, but their efforts will understandably concentrate on whether lawsuit ads mislead potential clients, not the general public.

Rules of professional conduct generally prohibit a lawyer from making a "false or misleading communication *about the lawyer or the lawyer's services*."[180] For example, specific rules focus on how attorneys can tout results obtained for former clients without overpromising and creating unjustified expectations,[181] whether an attorney can market himself or herself as a specialist in a certain area of law,[182] and the conditions under which lawyers can directly contact injured people.[183]

Some state attorney ethics rules can address deceptive practices employed in lawsuit ads targeting prescription drugs and medical devices, but they are limited and insufficient to respond to the range of public health concerns involved. For example, ethics rules generally require lawyer ads to be labeled "advertising material" and to reveal referral arrangements.[184] Some states require other disclaimers.[185] In mass tort advertising, these disclaimers are often hidden in the fine print at the conclusion of a television commercial. Occasionally,

> *A recent survey of fifty-one lawyer regulation offices found that only seventeen percent of jurisdictions actively monitor lawyer advertisements.*

state bars have issued ethics opinions that find attorney advertisements presented as public service announcements or "helplines" are misleading, which provides limited, but supportive, precedent for addressing an aspect of mass tort lawsuit ads.[186]

ETHICS RULES ARE ENFORCED BASED ON COMPLAINTS FILED BY CLIENTS AND COMPETITORS, NOT THE PUBLIC

When state bars or disciplinary authorities take action with respect to lawyer advertising practices, it is usually prompted by a complaint filed by a lawyer who is competing for clients.[187] Other complaints typically result from how a person was treated as a client, such as an attorney's lack of communication or improper fees.

Most individuals who are misled by lawsuit advertising targeting drugs or medical devices are unlikely to file a complaint with a state bar. They are not clients of the law firm sponsoring the ad. They are people concerned about their illness or health condition, not legal representation. They have not suffered an injury from a drug or medical device, but, after viewing lawsuit ads, they are concerned about the safety of their medication or treatment. Viewers of these ads have no reason to believe the information is false or that they have been misled. Even in the unlikely case that a concerned viewer of a lawyer ad considers taking action, he or she faces challenges in identifying the lawyer or law firm behind the ad and determining how to file an ethics complaint. And busy doctors who are concerned about the impact these ads have on their patients are more likely to contact their medical association or the FDA than track down the appropriate judicial authority.[188]

Unless a complaint is filed, a state bar or disciplinary authority is unlikely to take any action when lawyer ads raise public health concerns. A recent survey of fifty-one lawyer regulation offices found that only seventeen percent of jurisdictions actively monitor lawyer advertisements.[189] Eighty-six percent of respondents indicated that formal complaints regarding false or misleading attorney advertisements "rarely" or "never" result in disciplinary sanctions.[190]

Professor Elizabeth Tippett's research uncovered no instance of a state bar bringing an action against an advertiser for ethical breaches or consumer harm associated with lawyer ads in recent decades.[191] They may be reluctant to take action that will face significant resistance from a segment of their own membership and may result in an expensive legal challenge.[192]

THE BAR CANNOT REACH ADVERTISING BY NON-LAWYER LEAD GENERATORS

Even if spurred to act, any regulation by a state bar or judiciary cannot reach non-lawyer advertisers. Lead generation and other marketing firms commonly develop and sponsor advertisements to recruit plaintiffs in mass tort litigation, then bundle and sell the information of potential plaintiffs to law firms. Several of the top advertisers, such as the Relion Group and Knightline Legal, describe themselves as legal networks consisting of a group of participating attorneys. The website medicalrecallnews.com proclaims it is "not a law firm or lawyer referral service."[193] As Professor Tippett has observed, it is unclear what individual attorney's license is at stake should a state bar or disciplinary authority decide to take action with respect to a false or misleading ad funded and disseminated in this manner or through a complex referral arrangement.[194]

"Even if spurred to act, any regulation by a state bar or judiciary cannot reach non-lawyer advertisers."

THE BAR IS MOVING TOWARD LESS OVERSIGHT OF ATTORNEY ADVERTISING

Bar associations are moving toward allowing broader lawsuit advertising. The legal profession is in the process of eliminating constraints on lawyer advertising practices that are viewed as outdated. Changes proposed by the Association of Professional Responsibility Lawyers (APRL) to the American Bar Association's model rules of professional conduct governing attorney advertising do not address the troubling practices employed to generate pharmaceutical and medical device mass tort litigation. Rather, the proposed rule changes would permit solicitations of clients through "organized information campaigns" that would include television, internet, and other forms of electronic communications and explicitly permit lawyers to use legal fees to pay for online group advertising services.[195] Some bar leaders have expressed concern that these changes, if adopted, would open the door to fee sharing between lawyers and non-lawyer lead generation firms.[196]

A Recent Congressional Inquiry

The ABA recently confirmed that it will not take any action to address the types of misleading lawsuit advertising practices identified in this report in its response to an inquiry from House Judiciary Committee Chairman Bob Goodlatte.

In March 2017, Chairman Goodlatte sent letters to the ABA and the bar associations of all fifty states and the District of Columbia urging them to curb lawyer advertisements that are "designed to frighten patients," are misleadingly presented as medical alerts, and that suggest certain prescription drugs are inherently dangerous. Consistent with the AMA's resolution (see p. 32), Chairman Goodlatte urged the ABA to self-regulate by "adopting common sense reforms that require all lawsuit advertising to contain a clear and conspicuous admonition to patients not to discontinue medication without consulting their physician."[197] Letters sent to state bar leaders requested similar action.[198]

The initial response to Chairman Goodlatte's letters confirms that such self-regulation is unlikely. The ABA referred the Chairman to its ongoing process to update the ABA's legal advertising rules (which does not address the issue), noted the benefits of lawyer advertisements that alert people that they may be entitled to compensation from harm caused by prescribed medications, and defensively cited First Amendment protection of lawyer ads as commercial speech. Its position is that state ethics rules already prohibit lawyer advertising that is false or misleading, giving disciplinary authorities the ability to respond if a complaint is filed about a specific ad. The ABA also drew an untenable distinction between a lawsuit ad that is "false, misleading, or deceptive," which violates disciplinary rules, and an ad that has "harmful consequences to some members of the public who may misunderstand ads and decide on their own to discontinue a course of treatment," which apparently is permissible.[199]

State bars similarly responded to Chairman Goodlatte's inquiry by indicating that they had received few if any complaints of lawyer misconduct regarding these types of commercials, suggesting they would not take action.[200]

Chairman Goodlatte also sent inquiries to mass tort lead generation firms, such as the the Relion Group. These letters asked the firms to respond to a series of questions about how much they annually spend on lawsuit advertising targeting drugs and medical devices and whether their ads warn patients not to discontinue medication without consulting with a doctor, as well as their use of call centers, relationships with law firms, and storage and transfer medical information.[201] There is no indication as to whether these groups have responded.

In June 2017, the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice continued its engagement in this area with an oversight hearing examining ethical responsibilities regarding attorney advertising. Two physicians testified at the hearing. Dr. Shawn Fleming and Dr. Ilana Kutinsky conveyed heart-wrenching personal accounts of how lawsuit advertising had harmed their patients.[202] Law professor Elizabeth Tippett identified misleading advertising practices often present in such ads and pleaded for greater oversight.[203] Nonprofit organizations representing nurses[204] and caregivers,[205] those providing support services to cardiovascular patients[206] and women living with atrial fibrillation,[207] and groups advocating for scientific research on aging and health[208] each submitted statements indicating their concern that legal advertising is frightening patients from taking their medications.

In response, a legal ethics lawyer, Lynda Shely, testified that state bars have sufficient authority to discipline attorneys who engage in false or misleading advertising. While acknowledging that "virtually all" complaints about lawyer advertising come from other lawyers, not the public, she suggested the lack of complaints about drug lawsuit ads indicates no need for additional regulations or disclaimers.[209]

Recommendations

Under its existing legal authority and precedent in other contexts, the FTC can and should prohibit common misleading practices employed in lawsuit ads targeting prescription drugs and medical devices. Congress should also empower the FDA to intervene when unsupported, misleading, or false information disseminated in lawsuit ads results in injuries or jeopardizes public health. States also have an important role to play in stopping deceptive advertising practices, protecting private health information, and disciplining attorneys who violate ethical rules.

If the ABA's response to Congressman Goodlatte's inquiry is indicative of how state bars and attorney disciplinary authorities address concerns raised by misleading lawsuit advertising practices, then others charged with safeguarding consumers and protecting public health will need to act. The FTC, FDA, and states each have a role to play in protecting the public that fits their expertise and legal authority.

The FTC Should Prohibit Lawsuit Advertising Practices that are Clearly Deceptive

The FTC, in coordination with the FDA, should adopt regulations that declare common, misleading lawsuit advertising practices unfair or deceptive under the FTC Act. At minimum, the following practices should be deemed unfair or deceptive:

- Presenting a lawsuit advertisement as a "medical alert" or "health alert," or using a similar term.
- Displaying the logo of the FDA or any other government agency in a lawsuit ad.
- Using the word "recall" in a television advertisement, website address, or internet content advertising legal services when the product at issue has not been subject to a recall by a government agency.
- Failing to clearly inform the viewer of the identity of the sponsor of the advertisement, whether that entity is a law firm, and whether the sponsor will handle the litigation.

The FTC should also find that sponsors of lawsuit advertisements engage in an unfair or deceptive practice when an ad does not include needed disclosures, such as:

- Stating at the outset: "This is an advertisement for legal services. It is not affiliated with any government agency."
- Absent a recall, indicating that the drug or medical device targeted in the ad remains approved by the FDA, the purposes for which it is approved, and that healthcare providers may prescribe the product to treat other conditions.[210]
- In ads targeting prescription drugs, warning viewers: "Do not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death."

Television ads should make these disclosures orally as well as in legible print. Websites should prominently display the disclosures on the landing page.

These steps are firmly within the FTC's existing legal authority to regulate unfair and deceptive advertising. As discussed earlier, such measures are consistent with how the FTC has treated advertisements for other goods and services.

The Commission can immediately develop a regulation for notice and comment specifying that these acts or practices are unfair or deceptive acts.[211] While the FTC could also take action through its adjudicatory powers to respond to a specific ad, adopting a rule would provide clear requirements for law firms and marketing companies that sponsor attorney advertisements.

Once the Commission adopts such a regulation, it can issue cease-and-desist orders to those that run advertisements that violate the rule. Anyone who violates a cease-and-desist order or violates the rule "with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule" is subject to civil penalties.[212]

If the FTC does not exercise its existing authority to prohibit these types of misleading lawsuit advertising practices, then Congress can enact legislation prohibiting such practices and directing the FTC exercise oversight and enforcement in this area.

Congress Should Extend FDA Oversight of Drug Information Disseminated to the Public to Lawsuit Advertisements

Congress should provide the FDA with authority to protect public health by monitoring lawsuit ads for misleading, scientifically unsupported, or false information about FDA-approved drugs or medical devices.[213] The FDA should also routinely monitor its adverse event reporting system for incidents reported by healthcare professionals in which patients were injured as a result of stopping a prescribed medication after viewing lawsuit ads.

The FDA is well suited to take on this role, given its experience in evaluating, approving, and monitoring prescription drugs and medical devices that are the subject of the advertisements. The FDA can also draw from its extensive experience in scrutinizing advertising and other information disseminated by manufacturers of these products and taking action when there is a concern.

After the FDA finds that an ad is likely to mislead consumers, it could issue a warning letter urging the sponsor to discontinue the ad within a certain number of days or take other action, much as it does when it has concerns with regard to the marketing of prescription drugs.[214] If the ad sponsor does not take appropriate action within an established time period, then Congress might provide the FDA with independent authority either to seek an injunction and civil penalties, or for the FDA to refer the ad to the FTC for action as a deceptive act or practice and bring its finding to the attention of the appropriate state attorney disciplinary body.

Legislation should authorize the FDA to develop regulations implementing the new law. Much like the requirements placed on information disseminated by manufacturers, the regulation could generally require claims made in lawsuit ads to have scientific support. The regulation might also specifically prohibit lawsuit ads from:

- Overstating the risks of a drug by failing to include available information about the rates of adverse events indicated in the advertisement.[215]
- Making misleading claims about FDA action with respect to a drug or use studies, literature, or quotations that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim.
- Presenting risk information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions.
- Presenting information from a study in a way that implies a study represents larger or more general experience with the product than it actually does.

Upon finding a violation, the regulation might provide that the FDA would issue a warning letter:

- Identifying the misleading, scientifically unsupported, or false information contained in the advertisement;
- Instructing the disseminating party to cease and desist from further dissemination of the untrue, unsupported, or misleading information;
- Suggesting changes necessary to render the advertisement not untrue, unsupported, or misleading; and
- Notifying the disseminating party that failure to take the requested action may lead to civil penalties, or referral of the matter to the FTC or state disciplinary authorities.

In addition, the FDA should consider developing a user-friendly mechanism for patients, healthcare providers, and the general public to bring problematic lawsuit advertisements to the attention of the FDA.

The States Should Play an Important Role

Any new federal law or regulations should fully preserve the authority of states to regulate attorney advertising and solicitation practices.

Every state has adopted an unfair and deceptive trade practices law, sometimes referred to as a mini-FTC Act. State legislatures and attorneys general can define the same types of practices indicated for FTC action above as deceptive practices under the state's existing consumer protection law.

In addition, state legislators should amend their health privacy laws to specifically prohibit use of a person's private health information to solicit individuals for lawsuits or disclosure of such information to another person or entity for solicitation purposes. State attorneys general should investigate cold-calling practices where it appears that a caller has obtained information about a person's medical condition or treatment. Consistent with existing health privacy laws, use, sale, or transfer of private health information for financial gain should be subject to criminal and civil penalties.

State bars also have an important role. They should discipline attorneys who engage in egregious practices or repeatedly sponsor misleading ads. They can also investigate and take disciplinary action when attorneys engage in unethical and illegal solicitation practices. State bars can also contribute by playing a "floor-setting" role, prohibiting common misleading practices, such as presenting ads as "medical alerts" or burying the identity of the sponsoring attorney or law firm.[216]

Endnotes

1 X Ante data based on doubling of January through June 2017 data.

2 Zofran Birth Defects Warning 1-800-BAD-DRUG Ad, at https://www.youtube.com/watch?v=nfG6d3bIrQs (uploaded June 22, 2015) (last visited Oct. 5, 2017).

3 *See* X Ante, Zofran Ad Surge Signals Heightened Litigation Interest, Insights (blog), Mar. 31, 2015.

4 *See* Jessica Karmasek, AMA: Lawyer Ads Alarming Prescription Drug Users, Jeopardizing Health Care, Legal NewsLine, July 26, 2016.

5 *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 data).

6 According to data provided by X Ante, in October 2015 plaintiffs' lawyers ran only 416 ads targeting Zofran. One year after the high point, in March 2016, only 126 ads ran.

7 *See* Marlena S. Fejzo et al., 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).

8 *See* Elizabeth Tippett, Medical Advice From Lawyers: A Content Analysis of Advertising for Drug Injury Lawsuits, 41 Am. J. L. & Med. 7, 18 (2015) (studying data for legal service advertising broadcast between June 15, 2009 and January 4, 2010).

9 *Id.*

10 *Id.* at 2.

11 *Id.* at 3.

12 *See* Daniel M. Schaffzin, Warning: Lawyer Advertising May be Hazardous to Your Health! A Call to Fairly Balance Solicitation of Clients in Pharmaceutical Litigation, 8 Charleston L. Rev. 319, 334-37 (2014).

13 *See id.* at 336-37.

14 An empirical study of the content of lawsuit advertising conducted by University of Oregon Law School Professor Elizabeth Tippett found that about 20% of lawsuit ads in her sample were framed as public service announcements. Tippett, 41 Am. J. L. & Med. at 11 (examining content of drug lawsuit ads in Atlanta and Boston that aired in 2009).

15 *Id.* at 20.

16 *Id.* at 22.

17 *See id.* at 23.

18 *Id.* at 14.

19 *See* Statement of Dr. W. Frank Peacock, MD, FACEP, FACC, Professor, Emergency Medicine, Associate Chair and Research Director, Baylor College of Medicine, Houston, Texas, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017, at 1.

20 *See* Schaffzin, 8 Charleston L. Rev. at 325.

21 *See also* Goldwater Law Firm, YouTube Channel, at https://www.youtube.com/user/GoldwaterLawFirm/videos (last visited Oct. 5, 2017).

22 These were a small but significant percentage of the ads in Professor Tippett's sample (16%). *See* Tippett, 41 Am. J. L. & Med. at 13-14, 19-28.

23 Schaffzin, 8 Charleston L. Rev. at 339 n.76.

24 *See, e.g.,* Christopher F. Tenggardjaja et al., Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery, 85 Urology 326, 332-33 (2015) (Editorial Comment of Dr. Gopal H. Badiani discussed *infra* at 64). Law firms pay top dollar for their websites to appear near the top of search results when users enter keywords that could indicate a potential client. *See* Ken Goldstein & Dhavan V. Shah, Trial Lawyer Marketing Broadcast, Search and Social Strategies at 11-13 (U.S. Chamber Inst. for Legal Reform, Oct. 2015). Some marketing firms specialize in helping lawyers seeking mass tort leads to obtain high search rankings. *See, e.g.,* Consultwebs: Helping Law Firms & Clients Connect, Pay-Per-Click Advertising for Lawyers (PPC), at https://www.consultwebs.com/law-firm-web-marketing/ppc/ (last visited Oct. 5, 2017).

25 *See, e.g.,* Drugwatch, at https://www.drugwatch.com/ (last visited Oct. 5, 2017).

26 *See* RecallCenter, XareltoRecall, at http://www.recallcenter.com/xarelto/recall/ (last visited Oct. 5, 2017).

27 *See* FDA, Medication Guide, Xarelto® (2011, as revised May 2016).

28 *See* RecallCenter, About Us, Disclaimer, at http://www.recallcenter.com/about-us/ (last visited Oct. 5, 2017).

29 *See* MedRecallNews, Recalls + Warnings, at https://www.medrecallnews.com/recalls-warnings/ (last visited Oct. 5, 2017). The manufacturer of Topomax voluntarily recalled two lots of the drug in in April 2011 due to an uncharacteristic odor, not a general health concern. *See* FDA, Ortho-McNeil Neurologics Voluntarily Recalls Two Lots of TOPAMAX®, Apr. 14, 2011.

30 MedRecallNews, About Us, at https://www.medrecallnews.com/about-us/ (last visited Oct. 5, 2017).

31 *Id.*

32 MedRecallNews, Actos, at https://www.medrecallnews.com/actos/ (last visited Oct. 5, 2017).

33 MedRecallNews, About Us, at https://www.medrecallnews.com/about-us/ (last visited Oct. 5, 2017).

34 *See* Paul M. Barrett, Need Victims for Your Mass Lawsuit? Call Jesse Levine, Bloomberg, Dec. 12, 2013; *see also* MedRecallNews, Press Release, Jesse Levine, Tireless Consumer Advocate and Founder of MedRecallNews, Offers Consultative Assistance to Wronged Consumers, PRNewswire, Oct. 7, 2013. The press release indicates:

> At a phone consultation, an assessment is made of the client's medical history and eligibility to file a compensation claim for all the damage that has been done as a result of the medical mistake. He will then recommend you to a lawyer who will fight for compensation on your behalf. There is never a *front fee* charged by MedRecallNews or the recommended lawyer.

Id. (emphasis added). Thus, the website appears to refer callers to lawyers in exchange for some form of compensation.

35 Doni Bloomfield & Shannon Pettypiece, How Law Firms Use Facebook and Other Data to Track Down Medical Victims, Bloomberg, May 27, 2015.

36 *See id.* (interview with Tim Burd, whom the authors describe as a "digital bounty hunter").

37 *See* Tippett, 41 Am. J. L. & Med. at 4 ("[T]he vast majority of interested viewers are not the injured consumers targeted by the advertisers, but uninjured consumers trying to decide whether to fill next month's prescription for the drug.").

38 *See* Schaffzin, 8 Charleston L. Rev. at 341.

39 These drugs included Actos, Avandia, Crestor, Granuflo, Nexium, Paxil, Pradaxa, Prozac, Testosterone, Xarelto, Yaz/Yasmon/Ocella, and Zoloft or the generic versions of these drugs.

40 *See* National Council for Community Behavioral Healthcare, Press Release, New Survey Shows Product Liability Litigation May Jeopardize Treatment Outcomes for People with Severe Mental Illness, June 13, 2007.

41 *See* Judyth Pendell, The Adverse Side Effects of Pharmaceutical Litigation (AEI-Brookings Joint Center for Regulatory Studies Sept. 2003) (discussing Pharmaceutical Liability Study Report on Findings, Harris Interactive, July 2003). The study was based on interviews with 250 physicians, 251 pharmacists, and 301 patients diagnosed with at least one of eight specified medical conditions.

42 *See* Louis W. Sullivan, When Patients Take Medical Advice from Lawyers, Chic. Trib., Sept. 7, 2003.

43 *See* Ed Silverman, The Clot Thickens: Lawyers Boost Spending to Solicit Xarelto Lawsuits, Wall St. J. (blog), Aug. 29, 2014; *see also* The Silverstein Group, Xarelto Debuts as Top Ad Target, Mass Tort Ad Watch, Aug. 28, 2014.

44 *See* Katie Thomas, $650 Million to Settle Blood Thinner Lawsuits, N.Y. Times, May 28, 2014.

45 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).

46 *See* FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, at https://www.fda.gov/safety/medwatch/.

47 Burton & Peacock, *supra*, at 248.

48 *Id.* at 249. Critics may point out that the physicians who conducted the review of case reports are affiliated with the manufacturer of Xarelto, Janssen Pharmaceuticals Inc. Ordinary doctors concerned about harm to their patients, however, submitted the reports to the FDA.

49 *See* Letter from Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, U.S. Food and Drug Admin. to The Hon. Andy Harris, M.D., U.S. House of Representatives (undated 2017).

50 *See* U.S. Judicial Panel on Multidistrict Litig., MDL Statistics Report - Distribution of Pending MDL Dockets by District, Sept. 15, 2017.

51 *See* Dave Simpson, Jury Hands J&J, Bayer Win In 3rd Xarelto Bellwether, Law360, Aug. 18, 2017.

52 *See* Craig Hansen et al., Assessment of YouTube Videos as Source of Information on Medication Use in Pregnancy, 25 Pharmacoepidemiology & Drug Safety 35 (2015).

53 *Id.* at 39.

54 *Id.* at 38.

55 *Id.*

56 *Id.*

57 *Id.* at 37.

58 *Id.*

59 *Id.*

60 *Id.* at 39.

61 *Id.* at 39-40.

62 *Id.* at 43.

63 *See* FDA, Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse (July 2011).

64 Christopher F. Tenggardjaja et al., Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery, 85 Urology 326, 327 (2015).

65 *Id.*

66 *Id.* at 328.

67 *Id.* at 330.

68 *Id.*

69 *Id.* at 331.

70 *Id.* at 331-32.

71 *Id.* at 332. *Cf.* Michelle E. Koski et al., Patient Perception of Transvaginal Mesh and the Media, 84 Urology 575, 575-80 (2014) (finding that although some lawsuit ads "use inflammatory language and imaging" and others "contain information that is false or misleading," most patients who did not seek treatment for POP or SUI remained uncertain of the safety of treatment with mesh, rather than viewing mesh as unsafe, and recommending that clinicians be aware of the impact of these advertisements on patient opinion and counsel patients with unbiased and scientifically accurate information).

72 For additional examples of doctors who have expressed concern with the impact of lawsuit ads on their patients, *see* Christine Canterbury, Don't Let a Lawyer be Your Doctor, Houston Chron., July 10, 2016; J. Michael Orms, MD, Guest Post: Lawyer Ads are Fiction, Not Fact, SickofLawsuits.org, Mar. 10, 2015.

73 Statement of Ilana Kutinsky, Director of Atrial Fibrillation Services, William Beaumont Hospital, Troy, Michigan Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

74 Statement of Dr. W. Frank Peacock, MD, FACEP, FACC, Professor, Emergency Medicine, Associate Chair and Research Director, Baylor College of Medicine, Houston, Texas, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

75 Testimony of Shawn H. Fleming, MD, Novant Health Vascular Specialists, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

76 Evan Levine, M.D., Your Medication Can Kill You; Call Your Lawyer, Leftist Rev., May 12, 2012.

77 Dr. Anthony Pearson, Why Does the TV Tell Me Xarelto is a Bad Drug?, The Skeptical Cardiologist (blog), Dec. 4, 2014, at https://theskepticalcardiologist.com/2014/12/04/why-does-the-tv-tell-me-xarelto-is-a-bad-drug/.

78 *See* Am. Med. Ass'n, Resolution 208 (A-16) (received Apr. 25, 2016).

79 *Id.*

80 *Id.*

81 *Id.*

82 *See* Am. Med. Ass'n, Status Implementation of Resolutions and Report Recommendations AMA House of Delegates Annual Meeting - June 8-15, 2016, at 13 (Oct. 27, 2016).

83 *See* Am. Med. Ass'n, Attorney Ads on Drug Side Effects, Policy H-105.985 (2016).

84 *See* Ken Goldstein & Dhavan V. Shah, Trial Lawyer Marketing: Broadcast, Search and Social Strategies at 7 (U.S. Chamber Inst. for Legal Reform, Oct. 2015).

85 *See* Plaintiff's Original Petition and Request for Disclosure, *Shenaq v. Akin*, No. 2015-57942, at 29 (D. Ct., Harris County, Tex. filed Sept. 29, 2015) [hereinafter *Shenaq* Complaint].

86 *Id.* at 29.

87 *Id.* at 2-3.

88 *See* Defendant AkinMears G.P.'s Verified Emergency Motion for Temporary Sealing Order and Motion to Seal a Court Record, *Shenaq v. Akin*, No. 2015-57942 (D. Ct., Harris County, Tex. filed Oct. 1, 2015) (asserting that Shenaq's petition "discloses confidential, proprietary, and trade-secret information

concerning AkinMears' financing, business model, and business transactions"). The court granted an agreed-upon temporary order to seal the document. The firm withdrew that request after the media published some of the allegations in Shenaq's petition, declaring that "the damage . . . has already been done." *See* Defendant's Notice of Withdrawal of Motion to Seal A Court Record and Passing Oral Hearing, *Shenaq v. Akin*, No. 2015-57942 (D. Ct., Harris County, Tex. filed Nov. 2, 2015).

89 *Shenaq* Complaint at 3-4.

90 *Id.* at 29.

91 *Id.* at 22-23.

92 *See* Notice of Nonsuit with Prejudice to Defendants Truett Akin IV, Michelle Mears, and AkinMears, G.P., *Shenaq v. Akin*, No. 2015-57942 (D. Ct., Harris County, Tex. filed Apr. 4, 2016) (granted Apr. 11, 2016). Shenaq has since started his own business, offering his services to other law firms that are interested in raising capital to finance mass tort litigation. *See* David Yates, Fired AkinMears Fund Officer Settles $4M Suit, Starts His Own Firm, SE Tex. Record, Mar. 7, 2016.

93 *See* Jessica Karmasek, AMA: Lawyer Ads Alarming Prescription Drug Users, Jeopardizing Health Care, Legal NewsLine, July 26, 2016.

94 *See* U.S. Judicial Panel on Multidistrict Litigation, MDL Statistics Report – Distribution of Pending MDL Dockets by District (Sept. 15, 2017).

95 Plaintiff's First Amended Class Action Complaint, *MacLean v. Arentz Law Group*, No. 4:16-cv-797, at 4 (N.D. Tex. filed Nov. 9, 2016).

96 *Id.* at 4-5; *see also* Alison Frankel, Client Solicitation 101: Don't Robocall the Guy Running the Mass Tort, Reuters, Aug. 30, 2016.

97 *Id.*

98 Plaintiff's First Amended Class Action Complaint, *MacLean v. Arentz Law Group*, No. 4:16-cv-797, at 4 (N.D. Tex. filed Nov. 9, 2016).

99 *See id.*

100 *See* Tex. Gov't Code § 82.065(c); Tex. Penal Code § 38.12(a)(2).

101 *See* Memorandum Opinion and Order, *MacLean v. Arentz Law Group*, No. 4:16-cv-797, at 5 (N.D. Tex. Nov. 30, 2016) (Dkt. 33).

102 Order, *MacLean v. Arentz Law Group*, No. 4:16-cv-797, at 1-2 (N.D. Tex. Dec. 9, 2016) (Dkt. 33).

103 Memorandum Opinion & Order, *MacLean v. Arentz Law Group*, No. 4:16-cv-797, at 7 (N.D. Tex. July 27, 2017) (Dkt. 67).

104 *Id.* at 8.

105 *See* Plaintiff's Response to Defendants' Motion to Reconsider, *MacLean v. Arentz Law Group*, No. 4:16-cv-797 (N.D. Tex. Filed Aug. 18, 2017) (Dkt. 69).

106 Order Setting Schedule and Providing Special Pretrial Instructions, *MacLean v. Arentz Law Group*, No. 4:16-cv-797 (N.D. Tex. Nov. 15, 2016) (Dkt. 29). The court entered a default judgment against the telemarketer, Berken Media, LLC on March 3, 2017 and against Digital Brand Group, Inc. on June 16, 2017. On April 12, 2017, the court denied the plaintiff's motion to file an amended complaint that would have added two law firms as defendants, which shared the same principal shareholder as the Arentz Law Group.

107 *See* Judicial Panel on Multidistrict Litigation, MDL Statistics Report – Distribution of Pending MDL Dockets by District (Sept. 15, 2017). Just under half of these lawsuits remain pending. *See id.*

108 *See* Johnson & Johnson's and Ethicon's Motion to Revise Case Management Procedures and for Discovery Related to Plaintiff Solicitation, *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-MD-02327, MDL 2327 (S.D. W. Va. filed Jan. 14, 2015).

109 *See* Johnson & Johnson's and Ethicon's Memorandum in Support of Motion to

Revise Case Management Procedures and for Discovery Related to Plaintiff Solicitation, Affidavit A, Attachment 5, at 3-4, *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-MD-02327, MDL 2327 (S.D. W. Va. filed Jan. 14, 2015).

110 *Id.* Affidavit B.

111 *Id.* Affidavit D.

112 *Id.* Affidavit E.

113 *Id.* Affidavit F.

114 *Id.* Affidavit C.

115 *See* Johnson & Johnson's and Ethicon's Motion to Withdraw Motion, *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.,* No. 2:12-MD-02327, MDL 2327 (S.D. W. Va. granted Feb. 11, 2016).

116 *See* Alison Frankel, Medical Device Defendant Probes Origin of Mesh Claims, Reuters, Mar. 10, 2016.

117 *Id.*

118 AMS's Memorandum of Law in Opposition to Motion to Quash Subpoenas Issued by American Medical Systems, Inc., and for a Protective Order, *In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02325 (S.D. W. Va. filed May 12, 2016) (Dkt. 2294).

119 *Id.* at 2.

120 *See id.* at 8.

121 *Id.* at 5.

122 *See* Motion for Defendant American Medical Systems, Inc. for Leave to Serve Document Subpoenas on Non-Parties Michael Chhabra, Vincent Chhabra, Mitch Hammer, David Hammer, Key Legal Services, LLC, Biz Data Solutions, LLC and Law Firm Headquarters, LLC, *In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02325, 8/30/16 Hearing Transcript, Ex. B at 7:7-22 (S.D. W. Va. filed Apr. 13, 2017) (Dkt. 3847).

123 *Id.* at 5-8, Ex. A; *see also* Omnibus Reply in Support of Motion of Defendant Am. Med. Sys., Inc. for Leave to Serve Document Subpoenas on Non-Parties Michael Chhabra, Vincent Chhabra, Mitch Hammer, David Hammer, Key Legal Services, LLC, Biz Data Solutions, LLC and Law Firm Headquarters, LLC , *In re: Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02325, (S.D. W. Va. filed May 31, 2017) (Dkt. 4235).

124 Order, *In re Mentor Corp. ObTape Transobutator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004, at 1-2 (M.D. Ga. Sept. 7, 2016).

125 About half of the cases settled; others were dismissed voluntarily by the parties or by the court. *See id.* at 3 n.2. Three cases were selected for bellwether trials. The first resulted in a defense verdict, the second settled before trial, and the third resulted in a $4.4 million verdict, which the trial court reduced to $2.2 million. *See* Brandon Lowrey, Judge Defends Jury But Carves $2M from Mesh Verdict, Law360, Oct. 20, 2016).

126 Order, *In re Mentor Corp. ObTape Transobutator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004, at 1-2 (M.D. Ga. Sept. 7, 2016).

127 *Id.*

128 *Id.* at 2.

129 *Id.* at 3 n.2.

130 *Id.* at 2-3.

131 *Id.* at 3.

132 *Id.* at 5.

133 Order, *In re Mentor Corp. Obtape Transobutator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004, at 1-2 (M.D. Ga. Oct. 18, 2016).

134 *See* FDA, Talc, at https://www.fda.gov/cosmetics/productsingredients/ingredients/ucm293184.htm (last updated Mar. 19, 2014).

135 *See* Mary Gray, Op-ed, Lawyers' TV Ads Can be Hazardous to Our Health, St. Louis Post-Dispatch, Nov. 11, 2016.

136 *See* Margaret Cronin Fisk & Tim Bross, J&J Loses $110 Million Verdict over Talc Cancer-Link Claim, Bloomberg, May 4, 2017.

137 *See* Defendants' Motion to Change Venue for the Upcoming September Trial, *Hogans v. Johnson & Johnson*, No. 1422-CC09012-01 (Mo. Cir. Ct., City of St. Louis, filed July 26, 2016).

138 Am. Cancer Society, Talcum Powder and Cancer, at https://www.cancer.org/cancer/cancer-causes/talcum-powder-and-cancer.html (last revised May 3, 2016).

139 Defendants' Motion to Change Venue, *supra*, at 1-9.

140 *See id.* at 16-17.

141 *See* Nassim Benchaabane, St. Louis Jury Awards $70 Million to Woman Claiming Baby Powder Products Contributed to her Cancer, St. Louis Post-Dispatch, Oct. 28, 2016.

142 *See* Daniel Siegal, J&J Hit With $110M Verdict In Latest Mo. Talc Cancer Trial, Law360, May 4, 2017.

143 *See Carl v. Johnson & Johnson*, No. ATL-L-6546-14 (N.J. Super. Ct., Atlantic County, Sept. 2, 2016); *see also* Jef Feeley, J&J Wins Dismissal of Two New Jersey Talc Cancer Lawsuits, Bloomberg, Sept. 2, 2016.

144 *See Bates v. State Bar of Arizona*, 433 U.S. 350, 384 (1977).

145 *Id.* at 383.

146 *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 464-65 (1978).

147 *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.,* 447 U.S. 557, 566 (1980).

148 *See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 650 (1985). The Court also held that the bar could not maintain a blanket prohibition on the use of pictures or illustrations in attorney advertisements, finding the attorney could not be disciplined for including an accurate representation of the Dalkon Shield in the ad that had no features likely to deceive, mislead, or confuse the reader. *See id.* at 647-49.

149 Even where lawyer solicitation practices are not misleading, the Supreme Court has found that narrowly tailored restrictions are permissible where there is a substantial interest in protecting the public from intrusive attorney solicitation practices. *See Florida 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).

150 Schaffzin, 8 Charleston L. Rev. at 368.

151 21 U.S.C. § 321(n).

152 *See generally* 21 C.F.R. § 202.1(e)(5)-(7).

153 21 C.F.R. § 202.1(j)(4).

154 21 U.S.C. § 353c(a), (b).

155 U.S. Dep't of Health and Human Servs., Fiscal Year 2017: Food and Drug Admin., Justification of Estimates for Appropriations Committees 82 (2016).

156 *See* FDA, Keeping Drug Advertising Honest and Balanced (June 2013) (interview with Thomas Abrams, Director of OPDP).

157 *See* FDA, OPDP, Warning Letters 2015 (last visited Oct. 5, 2015).

158 *See* 21 U.S.C. § 333(g) (authorizing civil penalties of up to $250,000 for the first violation and up to $500,000 for each subsequent violation in a three-year period for disseminating or causing another party to disseminate a false or misleading direct-to-consumer advertisement).

159 *See* FDA, OPDP, Truthful Prescription Drug Advertising and Promotion (last updated July 11, 2017).

160 *See, e.g.,* FDA, Bad Ad Program 2010-2011 Year End Report (reporting that in its first year, the program received 328 reports of untruthful

or misleading promotion, including 188 submitted by healthcare professionals, 116 by consumers, and 24 by representatives of the pharmaceutical industry).

161 FDA, The Office of Prescription Drug Promotion (OPDP) (last updated Aug. 5, 2015) (emphasis added).

162 21 C.F.R. § 202.1(e)(7).

163 *See* 21 C.F.R. § 202.1(6)(iv), (xviii).

164 *See* Letter from Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, U.S. Food and Drug Admin. to The Hon. Andy Harris, M.D., U.S. House of Representatives (undated 2017).

165 *See* FTC, Letter Regarding Proposed Amendments to the Tennessee Rules of Professional Conduct Relating to Attorney Advertising (Jan. 24, 2013) [hereinafter FTC Tennessee Comment].

166 15 U.S.C. § 45(a)(1). Federal law also specifically prohibits dissemination of any false advertisement. *See* 15 U.S.C. §52.

167 *See generally* FTC, Policy Statement on Unfairness (1980).

168 *See generally* FTC, Policy Statement on Deception (1983).

169 *See* FTC, Enforcement Policy Statement on Deceptively Formatted Advertisements at 4-6 (2015) (citing cases).

170 *Id.* at 5-6, 15-16 (citing cases).

171 *See id.* at 5.

172 *See, e.g.,* POM Wonderful LLC, 155 F.T.C. 56, 193 (2013), *aff'd in part*, 777 F.3d 478, 504-05 (D.C. Cir. 2015); Telebrands Corp., 140 F.T.C. 278, 347 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); Novartis Corp., 127 F.T.C. 580, 725 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000).

173 *See generally* FTC, com Disclosures: How to Make Effective Disclosures in Digital Advertising (2013).

174 Statement of Susan Peschin, MHS, President and CEO, Alliance for Aging Research, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017, at 2.

175 *Id.*

176 *See* Memorandum of Understanding Between The Federal Trade Commission and The Food and Drug Administration, MOU 225-71-8003 (1971).

177 *See* Am. Bar Ass'n, FTC Letters Regarding Lawyer Advertising (last visited Oct. 5, 2017).

178 *See* FTC Tennessee Comment, *supra.*

179 *See, e.g.,* Brief of the Federal Trade Commission as Amicus Curiae Supporting Arguments to Vacate Opinion 39 of the Committee on Attorney Advertising Appointed by the Supreme Court of New Jersey, In the Matter of the Petition for Review of Committee on Attorney Advertising, No. 60,003 (N.J. filed May 8, 2007) (opposing regulation prohibiting attorneys from advertising their inclusion in lists rating and ranking lawyers such as "Super Lawyers" and "The Best Lawyers in America").

180 *See* Am. Bar Ass'n, Model Rules of Professional Conduct, Rule 7.1 (emphasis added).

181 *See id.* Rule 7.1 cmt. 3.

182 *See id.* Rule 7.4

183 *See id.* Rule 7.3.

184 *See id.* Rule 7.2(b)(4).

185 *See* Schaffzin, 8 Charleston L. Rev. at 355-56 (providing examples of state-specific disclaimers required in attorney advertising).

186 *See* Tippett, 41 Am. J. L. & Med. at 33 (citing S.C. Bar Ethics Advisory Comm., Ethics Advisory Op. 13-05, 2013 WL 7196338, at *1 (2013); Conn. Bar Assoc. Comm. on Prof'l Ethics, Informal Op. No. 01-03, 2001 WL 694581, at *3 (2001)); *see also Fla. Bar v. Doe,*

634 So.2d 160, 161 (Fla. 1994) (upholding disciplinary decision against an attorney who published an ad labeled as a "public service announcement").

187 *See* Andrew Strickler, ABA Attorney Ad Rule Revamp Picks Up Steam, Law360, Feb. 16, 2017 (reporting that the organization supporting changes to ABA rules governing lawyer advertising presented data showing the "vast majority of complaints about attorney ads come from other lawyers, not misled clients").

188 *See, e.g.,* Statement of Dr. W. Frank Peacock, MD, FACEP, FACC, Professor, Emergency Medicine, Associate Chair and Research Director, Baylor College of Medicine, Houston, Texas, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017 (indicating that he contacted the American College of Emergency Physicians to share his concern about lawsuit ads that suggested the blood thinner rivaroxaban was a "bad drug").

189 *See* Ass'n of Professional Responsibility Lawyers, 2015 Report of the Regulation of Lawyer Advertising Committee 28 (June 22, 2015).

190 *Id.*

191 Tippett, 41 Am. J. L. & Med. at 40.

192 *See id.* at 40-41.

193 MedRecallNews, About Us, at https://www.medrecallnews.com/about-us/ (last visited Oct. 5, 2017).

194 *See* Testimony of Elizabeth C. Tippett, Assistant Professor, University of Oregon School of Law, Before the Hearing "Examining Ethical Responsibilities Regarding Attorney Advertising," House Judiciary Committee Subcommittee on the Constitution and Civil Justice, June 23, 2017, at 16.

195 *See* APRL Proposed Amendments to ABA Model Rule of Professional Conduct 7.1, 7.2, 7.3, 7.4, and 7.5 (Sept. 29, 2016) (proposed change to Rule 7.1).

196 *See* Thomas H. Prol, President, New Jersey State Bar Association, Comment submitted to American Bar Association Standing Committee on Ethics and Professional Responsibility, Proposed Amendment to Model Rules of Professional Conduct Rules 7.1 – 7.5, Feb. 27, 2017.

197 *See* Letter from Bob Goodlatte, Chairman, House Judiciary Comm. to Linda A. Klein, President, Am. Bar Ass'n, Mar. 7, 2017.

198 *See, e.g.,* Letter from Bob Goodlatte, Chairman, House Judiciary Comm. to Edward L. Davis, Bar Counsel, Virginia State Bar, Mar. 7, 2017.

199 *See* Letter from Linda A. Klein, President, Am. Bar Ass'n to Bob Goodlatte, Chairman, House Judiciary Comm., Mar. 23, 2017. Likewise, the attorney spearheading the proposal to change the ABA's lawyer advertising rules commented that only lawyers complain about lawyer advertising and indicated that she was unaware of situations in which an ad led a person to stop taking their medication. *See* Joan C. Rogers, Limit Plaintiffs' Attorney Drug Ads, Goodlatte Says, Bloomberg BNA, Mar. 23, 2017 (quoting Lynda C. Shely, speaking in her personal capacity).

200 Chairman Bob Goodlatte, Opening Statement, Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

201 *See* Letter from Bob Goodlatte, Chairman, House Judiciary Comm. to The Relion Group Legal Network, Mar. 7, 2017.

202 Statement of Ilana Kutinsky, Director of Atrial Fibrillation Services, William Beaumont Hospital, Troy, Michigan Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017; Testimony of Shawn H. Fleming, MD, Novant Health Vascular Specialists, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining

Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

203 *See* Testimony of Elizabeth C. Tippett, Assistant Professor, University of Oregon School of Law, Before the Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," House Judiciary Committee Subcommittee on the Constitution and Civil Justice, June 23, 2017, at 5-11.

204 *See* Statement of Mary Ann Champagne et al. on Behalf of the Preventative Cardiovascular Nurses Association Advocacy Committee Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

205 *See* Letter from John Schall, Chief Executive Officer, Caregiving Action Network, to the Hon. Bob Goodlatte and the Hon. Steve King, House Committee on the Judiciary, re: Hearing on Examining Responsibilities Regarding Attorney Advertising (undated 2017).

206 *See* Statement of Andrea Baer, Director of Patient Advocacy, Mended Hearts, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

207 *See* Statement of Mellanie True Hills, CEO, StopAfid/American Foundation for Women's Health, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 22, 2017.

208 *See* Statement of Susan Peschin, *supra.*

209 *See* Written Statement of Lynda C. Shely, Esq., The Shely Firm, PC, Before the Committee on the Judiciary, Subcommittee on the Constitution, U.S. House of Representatives, Hearing on "Examining Ethical Responsibilities Regarding Attorney Advertising," June 23, 2017.

210 *See, e.g.,* Statement of Susan Peschin, *supra*, at 1 (recommending that lawsuit ads include a disclosure "remind[ing] patients that the drugs are approved by the FDA and that doctors prescribe these medications because of the overwhelming health benefits from these drugs").

211 *See* 15 U.S.C. § 57a(a)(1)(B).

212 *See* 15 U.S.C. § 45(m)(1). The maximum civil penalty, which is adjusted annually for inflation, is $40,654 for each violation in 2017. *See* FTC, Adjustments to Civil Penalty Amounts, 82 Fed. Reg. 8,135, 8,136 (Jan. 24, 2017). In determining the amount of the civil penalty, a court would take into account "the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require." 15 U.S.C. § 45(m)(1)(C).

213 Since, under existing law, the FDA responds to misleading or unsupported information in advertisements through its authority to prohibit misbranding of regulated products, additional authority may be needed for the agency to monitor drug information disseminated by others that could mislead the public.

214 The FDA's role in monitoring ads by law firms, attorneys, marketing firms, and other non-lawyer advertisers might be narrower than its supervision of information disseminated by manufacturers of FDA-approved products. Congress could limit FDA action to situations in which the FDA has received evidence that, as a result of misleading or unsupported claims in a lawsuit ad, patients stopped taking their medication or declined to receive treatment, or where the FDA has otherwise found a serious threat to public health.

215 *See* Tippett, 41 Am. J. L. & Med. at 42-46 (arguing for a risk-disclosure approach and considering how it might work in practice); *see also* Statement of Susan Peschin, *supra,* at 3 (recommending the FTC require lawsuit ads to "state the use of the medication . . . and the factual info regarding rates of adverse events").

216 *See* Tippett, 41 Am. J. L. & Med. at 41-42.

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