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PRO TE: SOLUTIO™

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FUNDING LITIGATION AND TREATMENT:

Leveling the Playing Field or Exploiting the Little Guy?

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The Spring 2016 issue of Pro Te Solutio deals head-on with issues that are driving litigation in this modern era. And as it is with many issues, there are two sides to every story.

The first topic we wrangle involves the heart (or soul?) of mass tort practice: massive-scale funding of litigation. In "Funding Litigation and Treatment: Leveling the playing field or exploiting the little guy?", we look at both sides of the issue. Does the real-world practice of funding litigation rightly serve the greater good, by assisting individuals who might never realistically be able to prosecute a case—or does the process, instead, taint the entire system with unethical outside influences that drive up the cost of litigation—and in turn making reasonable settlements out of reach? This article grapples with the two sides of this coin, and addresses the lack of regulation in this arena.

Our second article also looks at a topic that can send a shiver up our clients' spines (and ours). The very term "off-label marketing" evokes thoughts of whistleblower suits, class actions, and product liability claims. But not so fast: in "Off-Label Use: Protected Commercial Speech or Misbranding?", we consider both the downsides and potentially protected aspects of this topic.

Another admittedly distasteful topic (at least to our readers!) involves attorney advertising. We're not talking support of the local PBS station by well-intentioned, long-standing law firms. Nope. We are looking square in the eye of those frequent advertisements leading with "Have YOU been injured by [name the product]? You may be entitled to compensation!" In "Plaintiff Attorney Advertising: Protected or Prosecutable?", we evaluate the permissible angles of plaintiff advertising, with a discussion about what recourse—if any—may be had against false attorney advertising in the mass tort context.

The final article in this edition, "New and Noteworthy", discusses West Virginia's switch to the other side of the learned intermediary doctrine "story" across the United States: thanks to recent state legislative action, West Virginia has abandoned its previous minority position and, at last, has joined the majority of states recognizing this doctrine, holding that a manufacturer's duty to warn runs to the informed intermediary (healthcare provider), not directly to the patient.

We hope that these articles are both informative and thought-provoking.

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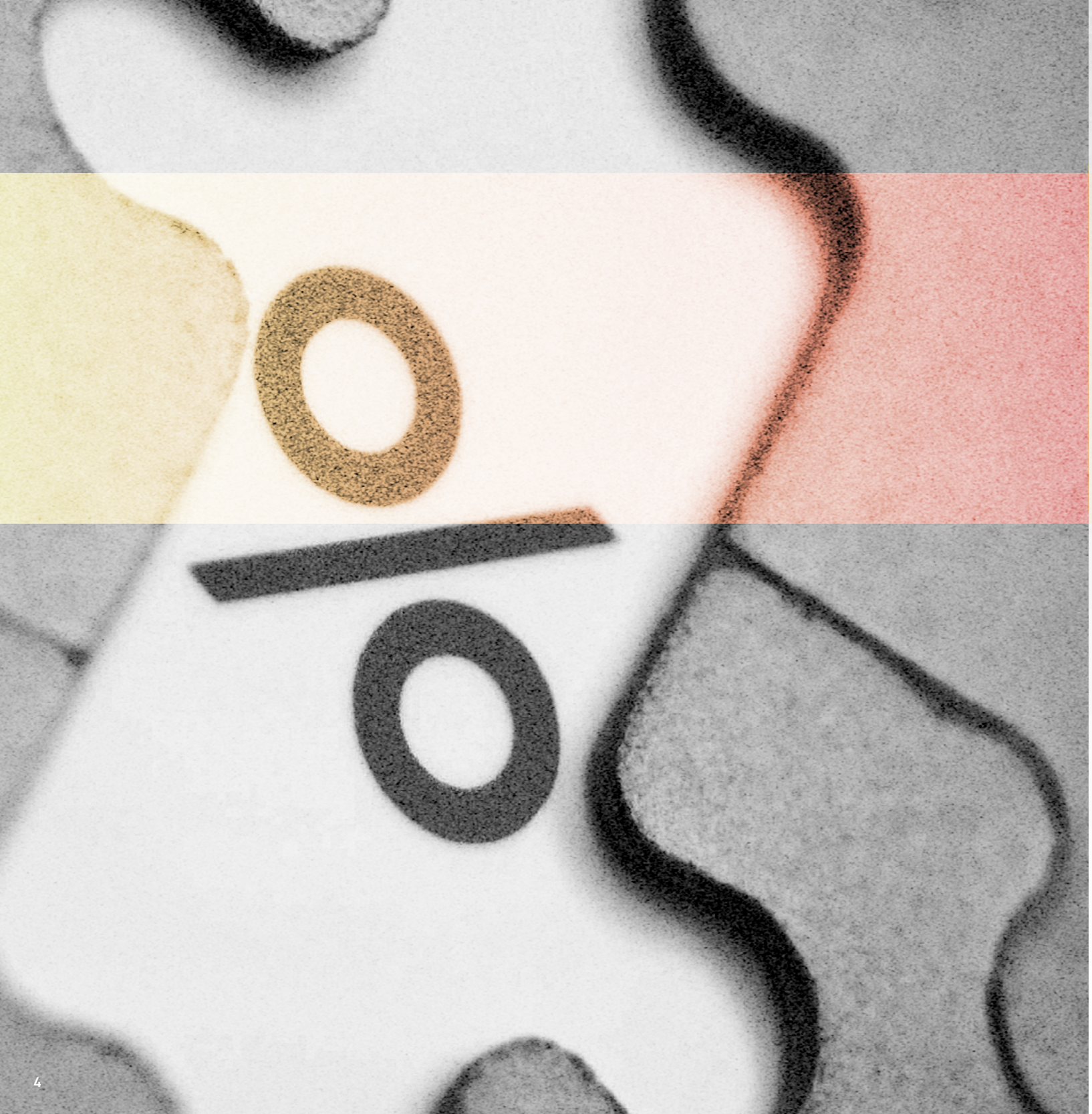


FUNDING LITIGATION AND TREATMENT

LEVELING THE PLAYING FIELD OR EXPLOITING THE LITTLE GUY?

Is litigation funding a creative way to help "the little guy" or the resurrection of a practice that even the Athenians deemed impolitic?[1] In an environment where many posit that access to the courts can be at least somewhat dependent on a person's financial viability, does outside financing of litigation level the playing field between the Davids and the Goliaths? Some say yes; some say no. And each side says so vehemently. Those in favor argue that an infusion of funds helps the smaller players pursue more complex, long-term, high-stakes lawsuits. Those opposed maintain that the practice proliferates unmeritorious claims and that reasonable settlements for valid suits would occur more quickly if the stakes were not escalated by monied meddlers with no "skin in the game" other than the bottom dollar (or "first dollars"). Adding to concerns is the fact that there is very little – read: no – regulation over this type of investing. And there is disagreement over whether plaintiffs should have to disclose that they have "investors," who those investors are, what has been told to the investors about the claim, and the amount and contingencies of the investment. While much remains unclear about how this practice will evolve, everyone seems to agree that it will continue to grow.

WHAT IS IT?

Third party litigation funding is the practice of an otherwise disinterested investor providing financing to litigants in exchange for a percentage of a successful outcome – whether a jury verdict or a favorable settlement.[2] These agreements typically are non-recourse, meaning the investor takes nothing if the plaintiff loses. To justify the shouldering of this risk, some funding contracts call for quite high interest rates.

A new offshoot of litigation funding is treatment or surgical funding. Under this scenario, a plaintiff contractually allows her treating surgeon to discount his bill and sell it to a medical lender, which then places a lien – not just for the discounted note but the entire cost of care – against any legal reward.[3] In particular circumstances, liens "can spiral to as much as 10 times what health insurers would pay for the same procedures."[4] Some medical funders also offer "concierge" services, such as cash advances, hotel rooms for recovery after the funded surgery, and travel arrangements – also available at high interest rates.[5]

THE GOOD, THE BAD AND THE UGLY

A. THE ALLEGED GOOD

As noted above, the demarcation lines are pretty starkly drawn. For those in favor, the first "virtue" of litigation finance is that it "can help the powerless avail themselves of our civil justice system."[6] Proponents make the unremarkable point that "litigation is expensive," and that funding provides access to the courts for those unable to afford it.[7] But is that not the point of contingency fees?

Such funding can go beyond access to the courts, however, and stretch to include living costs[8] or operating costs for a business. And any recovery is held hostage until repayment of the loan *and* the interest. The service also can morph into funding for either uninsured surgeries, deductibles, or surgeries performed by out-of-network doctors.[9] The advantage trumpeted for this controversial practice is akin to that for litigation finance – it helps the vulnerable, economically disadvantaged person have access to that which he formerly could not. In this circumstance, the argument is that it facilitates surgery or other treatment by "top doctors."[10]

Another outcome lauded by advocates is that it helps manage risk – either in a commercial setting [11] or perhaps mass tort. Who, they ask, is better able to handle the uncertainty associated with high litigation costs juxtaposed against a high and likely – but not guaranteed – return? The single company who has this promising claim but perhaps little free excess capital to expend on lawyers? (Again, the question of the purpose of contingency fees arises.) Or … a litigation finance company/hedge fund? The enthusiasts champion the latter because diversification is protection: "the risk of holding an entire portfolio of litigation claims is lower than the risk of holding a single claim, just like the risk of holding a portfolio of stocks is lower than the risk of holding a single stock."[12] Defenders also suggest that a business that monetizes its claim frees itself and its money to stick with – as Michael Corleone said, albeit in a different context – "strictly business."[13]

Lastly, some supporters claim "litigation finance might actually *reduce* the time and cost of litigation." [14] The idea as espoused is two-fold and, actually, self-contradictory. First, they theorize that defendants will settle more quickly when they realize that a plaintiff is backed by outside funds and able to hold his own in a discovery war of attrition. But such conjecture requires the acknowledgement that "litigation finance might prolong the litigation by allowing for robust discovery."[15] The latter outcome is quickly embraced, however, by noting that "there's nothing wrong with that – the record should be properly developed before the parties decide how to resolve the case." [16]

For those in favor, the first "virtue" of litigation finance is that it "can help the powerless avail themselves of our civil justice system.

B. THE BAD

You know things have gone awry when Spider-Man enters the fray. But yes, even Spidey has gotten caught in "the web of litigation finance."[17] Elliott Management Corp., a hedge-fund giant, helped bankroll a lawsuit by Stan Lee Media Inc. against Walt Disney Co. over profits made from comic book characters such as Spider-Man. But this investment went belly-up when a federal judge dismissed the lawsuit.[18] So does the plight of our hero, who in the movies lives hand to mouth as Peter Parker, epitomize equal access to justice for the little guy? Or was this a bad investment from the start and a lawsuit that never should have been brought?

Some business groups, the U.S. Chamber of Commerce and U.S. Chamber Institute for Legal Reform (ILR) chief among them, say "the practice gives outside undue influence over cases and drives up the cost of litigation."[19] According to the ILR, there is no question but that "[l]itigation financing is a sophisticated scheme for gambling on litigation, and its impact on American companies is unambiguous: more lawsuits, more litigation uncertainty, higher settlement payoffs to satisfy cash-hungry funders, and in some instances, even corruption."[20]

Opposers also note that litigation funders might have conflicting interests. For instance, a funder typically has as part of the agreement that he takes "first dollars."[21] This means that he recoups his investment (and generally some percentage on anything above his investment) first before any trickle down of funds to the actual plaintiff or plaintiff's lawyer. If the prospects of the case have dimmed with time and a settlement offer is made that would allow the financier to break even and also perhaps have a little cushion, he might push for resolution despite the fact that the plaintiff takes little to nothing. The flip side of that same bad coin is that "a litigation financier may set a threshold amount for a settlement, which may force the litigation into later stages in the hope of obtaining a larger damage award at trial or through settlement."[22]

And while proponents of the practice argue, as noted above, that a plaintiff company can focus on its business as opposed to the litigation with the help of outside litigation finance, what of the defendant company? Opponents say it is exactly the opposite as litigation costs increase and "companies may be diverted from investing their own capital in the economic markets and may not be able to invest their own capital into research and development."[23] Those increased costs, as we all know, get passed down. Perhaps litigation truly *is* expensive.

You know things have gone awry when Spider-Man enters the fray. But yes, even Spidey has gotten caught in "the web of litigation finance."

C. AND THE UGLY

While there are many issues left for discussion, including the legal and ethical implications of funding practices, the role of mass advertising, and how the existence and particulars of these agreements might be discovered[24] (all of which, teaser, might be addressed in a later issue), the question here is a pretty simple one: Is litigation funding and surgical funding good for the little guy?

To recap, the person typically predisposed to enter a financing agreement is someone who needs or *thinks he needs* additional money – whether it's our hero Peter Parker living hand to mouth or a small company going up against a much larger company. The "little guy" already is at a disadvantage and, as critics note, some funders gouge plaintiffs by charging sky high interest rates that leave a paltry amount, if anything, for the plaintiff while ensuring returns sometimes as high as 200% for finance companies.[25] Additionally, with that kind of return for investment, even in the light of the risk involved, it is difficult to see how proponents argue with a straight face that the practice will not engender more litigation.

Other potential pitfalls include the very real risk that Plaintiff counsel's independent professional judgment might be affected. In fact, while sounding somewhat ominous but without providing much actual guidance, the ABA warns that "attorneys must approach transactions involving alternative litigation finance with care."[26] Conflicts of interest, which are anathema, could abound. They might even unwittingly adhere to defense counsel or judges who would not know it unless the existence and identity of any funder is revealed at the outset.

Perhaps most troubling are the pitfalls attendant to litigation financing's younger brother, surgical funding. Consider the incentives for surgical treatment in this scenario: (1) the plaintiff need not pay for the surgery or claim it on insurance because it is funded by outsiders, (2) the plaintiff has access to a surgeon now billed as a "top doctor," (3) the doctor might have his own separate agreement with the funder that financially incentivizes him to perform more surgeries, and (4) the value of the plaintiff's damages increases with each surgery or subsequent treatment. The potential problems are manifest. First, a plaintiff could be encouraged to have unnecessary treatment because it increases the value of his claim, but costs him nothing … at the time. Or a plaintiff who truly does need treatment could be forced into signing an unconscionable agreement where he essentially signs away his potential legal recovery. Lastly, a defendant could face artificially inflated damages claims where a funder seeks upwards of 10 times the cost of treatment. It is little wonder that the Consumer Financial Protection Board has been called upon to examine the practices of the medical funding industry.[27]

THE CONCLUSION

One last consideration is this: what effect does financing have on the profession itself? Is it a good thing for our profession or our society in general to allow outsiders to profit on legal disputes? Methinks maybe not. As one author aptly put it:

> *Over the last century, many have come to see lawsuits as a means of expression, a political weapon and a powerful deterrent against those who might do wrong. And yet creating lawsuits is not the same as creating something like the [Volkswagen] Bug. Litigation is a zero-sum industry – every dollar in damages taken home by the winner, minus fees, must be wrung out of the loser. Litigation also helps shape legal precedent, defining the terms under which civil justice may be sought. It's hard to imagine how billions in outside capital won't wind up changing the justice system. The only question is how.* [28]

And how much. At whose peril. ■

[1] Schwartz, *Should you be allowed to invest in a lawsuit?*, New York Times Magazine (Oct. 22, 2015) (noting "members of Athenian political clubs would back each other in lawsuits against their rivals" until the practice was banned by Emperor Anastasius).

[2] General Thurbert Baker, *Paying to Play: inside the Ethics and Implications of Third Party litigation Funding*, 23 Widener L.J. 230 (2014); see also Bjornlund and Hanofee, *How Third-Party litigation Financing May be Affecting Your Practice*, For The Defense 18 (July 2015).

[3] Frankel and Dye, *U.S. business groups call for probe of medical funding industry*, Reuters (Aug. 26, 2015).

[4] *Id.*

[5] Frankel and Dye, *Special Report: Investors profit by funding surgery for desperate women patients*, Reuters (Aug. 18, 2015).

[6] Lat, *6 Virtues of Litigation Finance*, Above the Law (Nov. 24, 2015).

[7] *Id.*

[8] *Id.*

[9] Frankel and Dye, *Hip implant maker claims surgical funder inflated patients' bills*, Reuters (Sept. 28, 2015).

[10] *See supra* Reuters, *Special Report.*

[11] *See supra* Above the Law, *Virtues.*

[12] *Id.*; see also Barrett, *Hedge Fund Betting on Lawsuits is Spreading*, Bloomberg Business (Mar. 18, 2015). In personal injury litigation, however, law firms large enough to handle mass torts typically already have a diversified inventory – thus diluting this argument in this setting.

[13] *Supra* Above the Law, *Virtues.*

[14] *Id.* (emphasis in original).

[15] *Id.*

[16] *Id.*

[17] Copeland, *Litigation Finance is a Tangled Web: Just Ask Spider-Man*, MoneyBeat Wall Street Journal (Mar. 24, 2014).

[18] *Id.*

[19] *Id.*; see also Lat, *5 Ethical Issues with Litigation Finance*, Above the Law (Dec. 2, 2015).

[20] *Supra* Above the Law, *5 Ethical issues* (quoting ILR President Lisa A. Rickard).

[21] *Id.*

[22] *See supra* For the Defense.

[23] *Id.*

[24] Even Congress is interested in the details of this practice. News Releases (Aug. 27, 2015) (noting Senators Chuck Grassley and John Cornyn sent letters of inquiry to three of the largest commercial litigation financing firms) (http://ww2.cfo.com/legal/2015/08/gop-senators-seek-details-litigation-finance/) (last accessed Feb. 5, 2016).

[25] *Supra* For the Defense; *supra* Above the Law (*5 Ethical Issues*).

[26] Am. Bar Ass'n Comm'n on Ethics 20/20, Informational Report to the House of Delegates, *White Paper on Alternative Litigation Finance* (Feb. 2012) (a 39-page single-spaced novella with no less than 163 footnotes).

[27] *Supra* Reuters, *U.S. business groups call for probe of medical funding industry.*

[28] Schwartz, *Should you Be Allowed to Invest in a Lawsuit?*, New York Times Magazine (Oct. 22, 2015).

By Kari L. Sutherland

OFF-LABEL USE:

PROTECTED COMMERCIAL SPEECH OR MISBRANDING?

For years, the Food and Drug Administration has recognized that there is a prevalence of off-label use of drugs approved by FDA for specific indications, there is clinical relevance and value from such off-label use, and there is a large amount of information about both on- and off-label uses of such drugs available even with a limited ability by manufacturers to disseminate this information. This recognition requires a balancing by FDA between enforcing the Food, Drug, and Cosmetic Act's regulations prohibiting promotion of off-label use and permitting dissemination of off-label information to healthcare professionals for use in treating their patients. Key to this balancing act is FDA's position that any off-label discussions by manufacturers constitutes "misbranding" and are in violation of FDCA. Recent success by manufacturers establishing that disclosure of truthful and non-misleading information about off-label use of their products is protected commercial speech has thrown the FDA's balance out of whack. While currently limited in scope, such challenges may change the FDA's enforcement actions to focus more on false and misleading content in such off-label discussions and less on a presumption of "misbranding" based solely on the fact of off-label discussions.

I. FDCA AND MARKETING OF DRUGS

The FDCA and its amendments create the statutory requirement for drugs to be approved for safety and effectiveness for their intended uses before being introduced into commerce.[1,2] The FDA has long maintained that manufacturers must market and promote products consistent with the FDA-approved labeling, and therefore off-label use means "misbranded" under the FDCA[3]. In addition to FDA's own enforcement activities, the Department of Justice, in conjunction with the FDA, have in recent years actively pursued enforcement of misbranding provisions against drug manufacturers by claiming that off-label promotion by manufacturers has generated increased requests for reimbursement of healthcare claims in violation of the False Claims Act[4]. With the punitive consequence of exclusion from participation in federal healthcare programs, these misbranding claims have resulted in numerous significant settlements with manufacturers, such as Pfizer in 2009 ($2.3 billion),[5] Abbott Laboratories, Inc. in 2012 ($1.5 billion),[6] and GlaxoSmithKline LLC in 2012 ($3 billion),[7] among others.

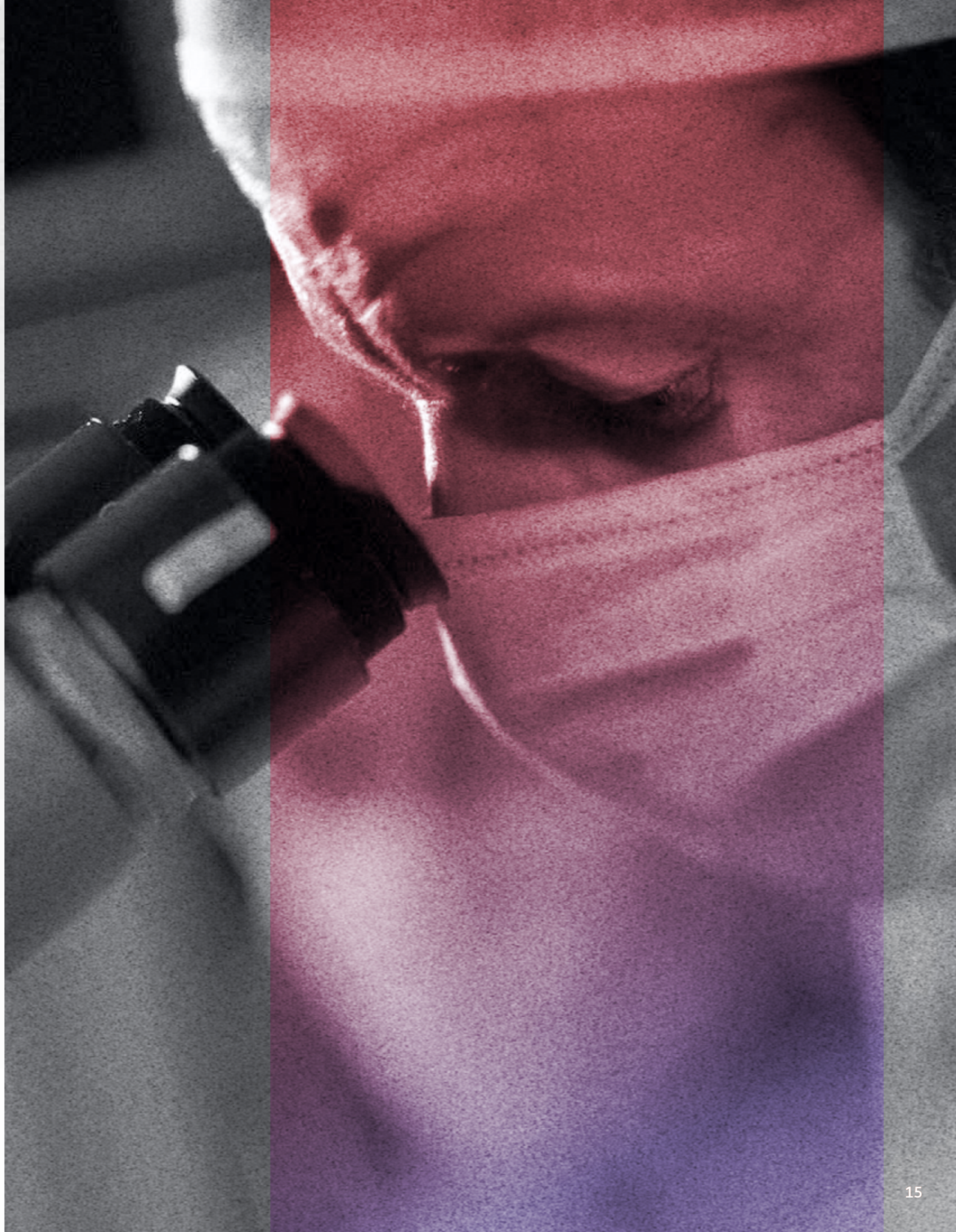
II. FDA GUIDANCE ON DISSEMINATION OF OFF-LABEL INFORMATION

The FDA recognizes that off-label uses by healthcare professionals may be important to support public health regardless of their approved indications. In fact, off-label use may be supported in published medical literature and journals and may even constitute the medically recognized standard of care.[8] In order to restrict the expansion of off-label use, FDA issued guidance permitting some limited dissemination of materials related to off-label uses.

A 2009 FDA guidance document describes the process permitting manufacturers to disseminate medical or scientific publications about off-label uses of their products.[9] That draft guidance was replaced in February 2014 to specify revised requirements and limitations on when such published materials can be distributed. To avoid misbranding, such materials must: be created by independent experts; contain scientifically sound evaluations; not be false or misleading; not be written by or influenced by a manufacturer; be provided in unabridged form; be distributed separately from promotional information or material; be distributed with FDA-approved labeling; be distributed with a bibliography of publications describing the clinical studies about the off–label use; and be distributed with a prominent statement that the use discussed has not been approved by FDA, including any known risks or safety concerns related to the off-label use.[10]

In addition to the *proactive* dissemination of content to physicians and healthcare entities described above, FDA issued a 2011 draft guidance allowing the *reactive* dissemination of information in response to unsolicited requests for off-label information. Pursuant to such draft guidance, manufacturers may respond to unsolicited requests for information about off-label uses of their products. The responses must be truthful, balanced, and non-misleading, non-promotional, scientific or medical information; limited to the specific request; delivered to the specific individual who requested the information; delivered by medical or scientific personnel independent from the sales and marketing departments; and include any FDA-required labeling.[11]

The FDA has long maintained that manufacturers must market and promote products consistent with the FDA-approved labeling, and therefore off-label use means "misbranded" under the FDCA.



III. RECENT CHALLENGES ON FIRST AMENDMENT GROUNDS

While the existing FDA guidance provides a mechanism for sharing off-label information, the restrictions in such guidance have frustrated the ability to make the information available in a timely and concise manner. Some manufacturers, emboldened by recent court rulings, have pursued constitutional challenges to these restrictions based on first amendment protected speech grounds. In a December 2012 decision, the Second Circuit, in *United States v. Caronia*,[12] vacated the conviction of a pharmaceutical sales representative for conspiring to promote a drug for off-label use. Caronia argued that his sales pitch, using truthful and non-misleading information, is protected speech under the First Amendment. The court agreed, and because there is no specific prohibition against off-label promotion,[13] held that the government cannot "prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."[14]

On May 7, 2015, Amarin Pharmaceuticals went on offense, filing a complaint to permit it to share truthful and non-misleading off-label information about its FDA-approved product, Vascepa®, under the First Amendment. Amarin originally sought approval to market Vascepa for treatment of persistently high triglyceride levels. The FDA declined that approval, and Amarin used alternative measures (including special protocol assessments and a separate clinical trial) to extrapolate the clinical safety and effectiveness of the drug for the intended treatment. But, based on the results from three unrelated clinical trials for unrelated cardiovascular products that had found no impact on cardiovascular risk, FDA concluded that these results raised substantial scientific issues about the results of Amarin's clinical trial. FDA also added in its letter to Amarin that the drug would be deemed misbranded if Amarin promoted Vascepa for reduction of triglyceride levels in persons with persistently high triglyceride levels.

Amarin responded by filing a complaint seeking protection that would enable it to make truthful, non-misleading statements about Vascepa consistent with its clinical trial results.[15] Amarin's complaint further alleged that the prescription of Vascepa by physicians is lawful, and the limitation by FDA severely restricts medical professionals' access to information from the source most knowledgeable about the drug.[16] The court granted preliminary relief to Amarin, finding that Amarin could engage in truthful and non-misleading speech promoting the off-label use of Vascepa and, under *Caronia*, such speech may not be the basis of a prosecution for misbranding.

Relying upon the success of *Caronia* and *Amarin*, in September, 2015, Pacira Pharmaceuticals filed a complaint seeking declaratory and injunctive relief that FDA's restrictions on Pacira's truthful and non-misleading speech harmed Pacira's commercial interests and ability to advance public health.[17] In October 2011, the FDA approved Exparel® for post-surgical pain management based on a demonstration of safety and effectiveness in two clinical trials for soft tissue and hard tissue applications. In September 2014, FDA issued a warning letter to Pacira demanding that it stop providing instructions that imply Exparel is approved for use in procedures other than the two specific applications from the clinical trials. Pacira responded to FDA, outlining its disagreement that the materials violated the FDCA. In July 2015, FDA issued a closing letter regarding Pacira's warning letter, concluding that Pacira's speech was violative of the FDCA which led to the filing of the complaint.

The parties then entered a settlement agreement on December 14, 2015, resulting in a mutual release of claims, a withdrawal of the warning letter with an FDA letter of explanation, a revision of the product labeling and instructions, and a confirmation by FDA that the drug was approved for broad use across various applications, not just for the two procedures originally tested. While the settlement did not respond to the rights of Pacira to discuss off-label uses, it did expressly preserve Pacira's ability to assert constitutional rights related to its Exparel marketing efforts.

In March 2016, Amarin and FDA settled their dispute, and FDA acknowledged (by accepting the court's determination) that Amarin's proposed statements were truthful and non-misleading. Amarin agreed to assure its communications remained truthful, and FDA agreed to preview up to two proposed communications by Amarin and to provide Amarin with any concerns FDA may have with the communications. The parties agreed to an established dispute resolution process prior to requesting judicial resolution.

While the existing FDA guidance provides a mechanism for sharing off-label information, the restrictions in such guidance have frustrated the ability to make the information available in a timely and concise manner.

IV. FUTURE IMPACT OF *CARONIA, AMARIN* AND *PACIRA*

The results in *Caronia, Amarin* and *Pacira* undoubtedly support a manufacturer's dissemination of truthful and non-misleading information on the risks and benefits of the off-label use of its products and provide potential defenses to enforcement actions by FDA and the DOJ. The FDA's recent acknowledgement and recognition of Amarin's rights to promote off-label use through truthful and non-misleading speech may illustrate a shift in the FDA's enforcement of manufacturer's promotional activities. However, before manufacturers move forward with wholesale promotion of off-label uses of their products based on these recent decisions, it is worthwhile to consider the limitations and specifics of these decisions.

A manufacturer should have a process to vet and script in advance the statements it intends to make about a drug's off-label use to assure that its communications remain truthful and non-misleading.

First, as observed by the court in *Amarin* and agreed to by Amarin in its settlement, a manufacturer should have a process to vet and script in advance the statements it intends to make about a drug's off-label use to assure that its communications remain truthful and non-misleading. These decisions will not protect manufacturers from speech that is false or misleading. Also, manufacturers must remain diligent in reviewing content to be disseminated and ensure that appropriate training is provided to the representatives engaged in discussions about their products, whether sales, marketing or other specialties, to make sure they do not "misbrand" their products. This is emphasized by the FDA's public statements since *Caronia* that it does not view these decisions as significantly affecting its enforcement of the misbranding provisions of the FDCA,[18] even though it will likely cause FDA to be more prudent in its enforcement activities.

Second, the decisions do not protect manufacturers if the government uses the off-label speech as evidence in cases under the False Claims Act, although it will make it more difficult to prove that the lawful, truthful and non-misleading speech caused the submission of a non-reimbursable claim.

Third, while the *Caronia* decision applies to government prosecution of manufacturers generally in the promotion of lawful, off-label use of an approved drug, it is worth noting that FDA elected not to seek a petition for *certiorari*, thus leaving the decision somewhat limited. While the settlement in *Pacira* did serve to preserve Pacira's first amendment rights, the resolution of the matter did not turn as much on the constitutional rights issue as it did on permitting Pacira to rely upon the broad indication issued by FDA in its original approval and preventing the FDA from seeking to limit the approved indications of products without following its own regulations and due process.

These decisions provide some additional latitude to manufacturers to discuss truthful and non-misleading information about their products, but they should not be viewed as providing broad protection to promote off-label uses as constitutionally protected free speech. Manufacturers remain obligated to maintain a review process for any information or material communicated to their customers. ■

1 US Food Drug & Cosmetic Act, 21 USC 351 (1938)

2 Public L. No 87-781, 76 Stat. 780 (1962)

3 21 USC 331(a)

4 31 U.S.C. 3729, *et seq.*

5 Press Release, US Department of Justice, *Justice Department Announces Largest Health Care Fraud Settlement in Its History, Pfizer to Pay $2.3 Billion for Fraudulent Marketing (September 2, 2009) available at http://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history*

6 Press Release, Department of Justice, *Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-Label Promotion of Depakote* (May 7, 2012), available at http://www.justice.gov/opa/pr/2012/May/12-civ-585.html.

7 Press Release, Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), available at http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

8 USFDA, Draft Guidance, *Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan 2009), at 2.*

9 *Id.*

10 USFDA, Revised Draft Guidance, *Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices (February 2014).*

11 USFDA, Draft Guidance, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (December 2011).

12 703 F.3d. 149 (2d Cir. 2012)

13 *Id*, at 160.

14 *Id*, at 169.

15 *Amarin Pharma, Inc. v USFDA, 15 Civ. 3588 (S.D.N.Y 2015.), at 26.*

16 *Id.*

17 *Pacira Pharmaceuticals, Inc. v. USFDA, 15 Civ. 7055 (S.D.N.Y. 2015)*

18 PharmaExec.com, *Tom Abrams: Caronia Won't Stop Off-Label Enforcement (January 2013), available at: http://www.pharmexec.com/tom-abrams-caronia-wont-stop-label-enforcement.*

By David W. Ohlwein

PLAINTIFF ATTORNEY ADVERTISING:

PROTECTED OR PROSECUTABLE?

The barrage of plaintiff-attorney advertisements soliciting plaintiffs for drug and device litigation may spawn calls by executives, board members, and other company decision-makers to find out what can be done to stop them. Although certain categories of advertising are constitutionally protected as "free speech," developing precedent shows that attorney advertising may be susceptible to legal challenges under the Lanham Act. These claims have not been tested in court, but they present a legitimate possibility for manufacturers to mount an offensive attack against certain advertisements. This article provides an overview of the constitutional protections afforded attorney advertising in the United States, followed by an overview of new precedent under the Lanham Act and how it may be applied to combat certain advertising.

CONSTITUTIONAL PROTECTIONS FOR ATTORNEY ADVERTISING

Attorney advertising in the United States is well established as constitutionally-protected commercial speech. In March 1975—when many state bar associations prohibited any form of attorney advertising—two lawyers in Arizona defied their state bar association's regulation prohibiting any form of attorney advertising and placed a newspaper ad that read: "DO YOU NEED A LAWYER? LEGAL SERVICES AT VERY

REASONABLE FEES."[1] When the Arizona State Bar suspended the lawyers for placing the ad, they challenged the disciplinary rule, paving the way for lawyer advertising to become protected free speech under the First Amendment.

The case, *Bates v. State Bar of Arizona,* reached the Supreme Court, which found outright bans on advertising like that imposed by the Arizona state bar to be unconstitutional.[2] The Court specifically rejected the premise that advertising eroded "true professionalism" in the legal field, and determined instead that it was protected commercial speech.[3] *Bates* was the end of absolute bans on attorney advertising.

It didn't take long for attorney advertising to develop into a vehicle for mass torts, starting in the 1980s with an attorney's advertisement in 36 Ohio newspapers soliciting women who used the Dalkon Shield Intrauterine Device.[4] This advertisement contained a drawing of the device, asked the question "DID YOU USE THIS IUD?" and claimed that the device was "alleged to have caused serious pelvic infections resulting in hospitalizations, tubal damage, infertility, and hysterectomies."[5] The ad offered legal representation, noting that "[i]f there is no recovery, no legal fees are owed by our clients."[6] The Ohio Office of Disciplinary Counsel found such advertising was not sufficiently "dignified" or limited in scope to permissible information under its rules prohibiting illustrations and self-recommendation.[7] It also found the ad violated a rule requiring that contingency-fee rates should disclose whether the percentages were computed before or after costs and expenses.[8] The Supreme Court held that—except with regard to the misleading contingency fee statement—the advertisement's statements and illustration regarding the IUD were not false or misleading and were entitled to First Amendment protection.[9]

REGULATORY RESTRICTIONS ON ATTORNEY ADVERTISING

The American Bar Association's Model Rules of Professional Conduct ("Model Rules") serve as a standard for state bar associations, and each of the 50 states and the District of Columbia have adopted some variation of the Model Rules.[10] The initial ethics rules, published in 1908, sought to compile a collection of norms for all attorney conduct.[11] Solicitation by advertisement was deemed "unprofessional" and all forms of "self-laudation" were "intolerable," "defy[ing] the traditions and lower[ing] the tone of our high calling."[12] Indeed, the best advertisement was "the establishment of a well-merited reputation for professional capacity and fidelity to trust."[13]

The ABA Model Rules published in 1983—after *Bates*—permitted attorney advertising through various publication modes, including television.[14] The 1983 Model Rules also put specific limits on lawyers' direct solicitation of prospective clients and on lawyers' statements about certification fields of practice,[15] but several Supreme Court rulings striking down state rules similar to the Model Rules spurred amendments.[16] Further amendments resulted in the key prohibition on attorney advertising being limited to a showing that it is false or misleading speech.[17] Under the Model Rules, an advertisement is "false or misleading if it contains a material misrepresentation of fact or law, or omits a fact necessary to make the statement considered as a whole not materially misleading."[18] The result from the dilution of restrictions on advertising in the Model Rules following *Bates* is that most attorney advertising soliciting drug or device plaintiffs is permitted by state bar associations.

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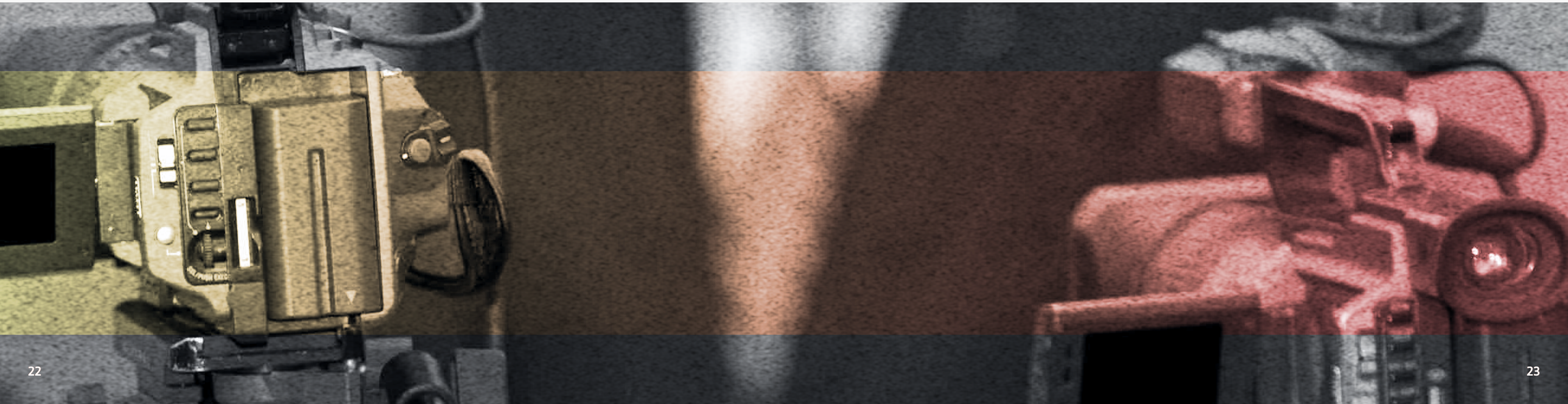

CHALLENGING FALSE OR MISLEADING ADVERTISING

Given the unlikelihood that state bar associations will pursue enforcement actions against attorney advertising, challenges by manufacturers must instead be made under common-law theories such as defamation and business torts or statutory claims under the Lanham Act. These claims focus not on statements about the lawyer or the lawyer's services, but on the content of the advertising that relates to a company's products and the impact of the advertisement on those products.

The most straightforward example of advertising that is "false or misleading" and susceptible to challenge is an ad that is obviously false. For example, an ad that claims a drug or medical device has been recalled by the FDA when in fact it has not is false and subject to immediate challenge. Such ads are usually addressed through cease-and-desist letters without the need for litigation.

Other examples of obvious falsity include misstatements about the product itself. For example, in 2011, Zimmer, Inc. sued Pulaski & Middleman, LLC—infamous for its "1-800-BAD-DRUG" ads—for "making false, misleading and defamatory statements about Zimmer and [its] NexGen® Knee System" in television advertisements.[19] Zimmer alleged that the Pulaski Firm's ad was false or misleading by saying: "Reports show the ZIMMER NEXGEN KNEE IMPLANT MAY HAVE A FAILURE RATE OF 9%."[20] Zimmer sued for defamation, tortious interference with business relationships, false advertising under the Lanham Act, product disparagement, and several trademark theories.[21] The parties reached a confidential settlement, summarized by Zimmer in a public statement that the law firms "retracted the misleading claims in their advertisements" and that the firms would run corrective statements on their respective websites for six months. Zimmer's statement also indicated that the law firms either paid a monetary settlement, issued a retraction, or did both.[22] Pulaski & Middleman's statement on its website admitted that it had "determined that the sources we previously relied upon to make claims about the Zimmer NexGen Knee System do not support the statements or implication" in the ads.[23]

While the Zimmer example is informative when an attorney advertisement obviously misstates factual information about a product, the more difficult question arises when an advertisement is not *per se* false, but is arguably misleading. Although claims for defamation and business torts remain options, recent precedent under the Lanham Act suggests that drug and medical-device manufacturers may have a better avenue to combat false or misleading advertising.

LANHAM ACT DEVELOPMENTS AND CHALLENGES TO ATTORNEY ADVERTISING

The Lanham Act provides a federal cause of action akin to unfair competition claims. The Act's provision regarding false advertising states:

> (1) any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any . . . false or misleading representation of fact which—
>
> > (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of . . . another person's goods services or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."[24]

Traditionally, a false-advertising claim under the Lanham Act arises when "one competito[r] directly injur[es] another by making false statements about his own goods [or the competitor's goods] thus inducing customers to switch."[25] This underscores that any Lanham Act false-advertising claim must be framed around economics—the manufacturer is losing business on the drug or device because of the defendant law firm's false advertising about that drug or device.

STANDING

The initial hurdle under the Lanham Act is standing to sue. Federal courts are prohibited from hearing cases in which the plaintiff has not "suffered or been imminently threatened with a concrete and particularized 'injury in fact'" that is traceable to the defendant's action.[26] In 2014 the Supreme Court, in *Lexmark International, Inc. v. Static Control Components, Inc.*, resolved a split in the Circuit Courts of Appeal as to the proper test for standing under the Lanham Act.[27]

Before *Lexmark*, a widely used limitation on Lanham Act claims was the "direct-competitor test," which required a plaintiff be in direct competition with the defendant in order to have standing. Under this test, a pharmaceutical or device manufacturer would not have standing to sue a law firm which would not be in competition with it. *Lexmark* rejected this approach, concluding that "a rule categorically prohibiting all suits by noncompetitors would read too much into the Act's reference to 'unfair competition.'"[28] The Court noted that when the Lanham Act was adopted, noncompetitors could sue one another under the common-law tort of unfair competition. Thus, it would be "a mistake to infer that because the Lanham Act treats false advertising as a form of unfair competition, it can protect *only* the false-advertiser's direct competitors."[29]

The *Lexmark* Court determined that where a federal statute—like the Lanham Act—creates a cause of action, the plaintiff must fall within the "zone of interests" of that statute to have standing. To be "within the zone of interests in a suit for false advertising under [the Lanham Act], a plaintiff must allege an injury to a commercial interest in reputation or sales."[30] Plaintiffs must also show that their injuries are proximately caused by violation of the statute. Therefore, a manufacturer would have to show "economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff."[31]

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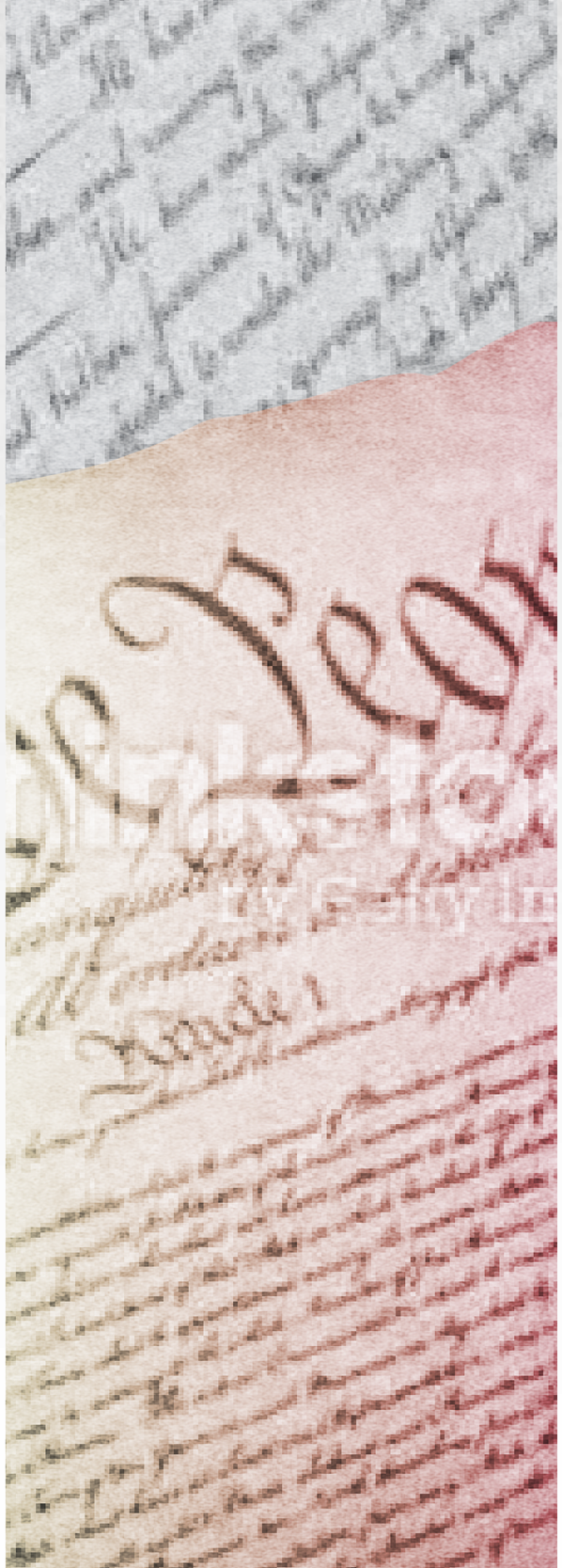

ELEMENTS OF A CLAIM

Assuming that the Supreme Court's ruling in *Lexmark* gives pharmaceutical and medical-device manufacturers *standing* to pursue a Lanham Act claim, they must still prove the elements of the claim itself. Generally, a plaintiff must prove "(1) the defendant has made false or misleading statements of fact concerning his own product or another's; (2) the statement actually or tends to deceive a substantial portion of the intended audience; (3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions; (4) the advertisements were introduced into interstate commerce; and (5) there is some causal link between the challenged statements and harm to the plaintiff."[32]

First and foremost, the focus of the claim must be that losses are suffered because a *false* statement influenced a consumer's *purchasing decision*. The fact that the advertisements result in an increase in litigation is not relevant to any claim under the Lanham Act.

An actionable statement in an advertisement "must be based upon a statement of fact, not of opinion,"[33] and a plaintiff must show that the advertisement "is literally false or that it is true yet misleading or confusing."[34] If a statement is literally false, the plaintiff need not show actual deception of consumers; if a statement is literally true yet misleading, the plaintiff must show that consumers' decisions to purchase were actually influenced.[35] Thus, the word "bad" next to "drug" in "1-800-BAD-DRUG" would be evaluated in context to determine whether it misleads consumers. Some courts apply a presumption of damages where the deception was willful, but this presumption only applies "to cases of comparative advertising where the plaintiff's product was specifically targeted."[36] Therefore, a pharmaceutical manufacturer suing a noncompetitor law firm would likely have to present "evidence of the public's reaction through consumer surveys,"[37] showing "that a significant portion of the consumer population was deceived."[38] These proof requirements are not easily satisfied, and consumer surveys that satisfy the Lanham Act's requirements are both expensive and time consuming..

LIMITS

A pharmaceutical or device manufacturer will face two hurdles in bringing this type of Lanham Act claim. First, it must prove its standing to bring the claim—that it comes within the zone of interests of the statute. Although the Supreme Court's 2014 decision in *Lexmark* indicates that noncompetitors may bring claims under the Act, lower courts have not yet considered the standing of noncompetitors who are in different industries altogether. Second, pharmaceutical and device manufacturers must prove all of the elements of the Lanham Act claim itself, including deception of consumers and actual reliance.

The First Amendment's protection of commercial speech allows plaintiff law firms to solicit clients through advertisements that are not false or misleading...

CONCLUSION

The First Amendment's protection of commercial speech allows plaintiff law firms to solicit clients through advertisements that are not false or misleading, and states' rules of professional responsibility generally only prohibit false or misleading statements by an attorney. The Lanham Act and other common-law defamation causes of action may be available, but their proof requirements are strenuous. While the Supreme Court's *Lexmark* decision suggests that Lanham Act claims may be available against plaintiff law firms, those claims have not been tested. And, even if lower courts apply *Lexmark* to permit Lanham Act claims by manufacturers against plaintiff-firms, drug and device manufacturers still face an uphill battle in combating all but patently false advertisements. ■

[1] *Bates v. State Bar of Ariz.*, 433 U.S. 350, 385 (1977).

[2] *Id.* at 383.

[3] *Id.* at 368. As "commercial speech," attorney advertising became subject to a four part test for evaluating whether regulations limiting such speech are constitutional: (1) is the speech lawful and not misleading; (2) is the government interest in regulating the speech substantial; (3) does the regulation actually advance the government interest; and (4) if the interest could be achieved by a more limited restriction on commercial speech, the limitation fails.

[4] *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 630 (1985).

[5] *Id.* at 631.

[6] *Id.*

[7] *Id.* at 632.

[8] *Id.*

[9] *Id.* at 641.

[10] *See Chronological List of States Adopting Model Rules*, ABA, http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/chrono_list_state_adopting_model_rules.html.

[11] Colin Croft, *Reconceptualizing American Legal Professionalism: A Proposal for Deliberative Moral Community*, 67 N.Y.U. L. REV. 1256, 1306 (1992).

[12] FINAL REPORT OF THE COMMITTEE ON CODE OF PROFESSIONAL ETHICS, Canon 27, *available at* http://www.americanbar.org/content/dam/aba/migrated/2011_build/professional_responsibility/1908_canons_ethics.authcheckdam.pdf.

[13] *Id.*

[14] Model R. Prof. Conduct 7.2 (1983).

[15] Model R. Prof. Conduct 7.3, 7.4 (1983).

[16] See *Shapero v. Ky. State Bar*, 486 U.S. 466 (1988) (striking down Kentucky's rule regarding direct contact with prospective clients that was identical to the model rule); *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91 (1990) (holding that states may not impose restrictions that burden a lawyer's truthful statement that he or she is a specialist, certified by an organization).

[17] Model R. Prof. Conduct 7.1.

[18] *Id.*

[19] Complaint ¶¶ 53–58, *Zimmer, Inc. v. Kresch/Oliver PLLC et al.*, No. 11CV00063, 2011 WL 767056 (N.D. Ind. Feb. 26, 2011); *see also* Erin Fuchs, *Knee Device Maker Sues Plaintiffs Firm Over Ads*, LAW360, http://www.law360.com/articles/284095/knee-device-maker-sues-plaintiffs-firm-over-ads (Nov. 7, 2011).

[20] Complaint, *supra* note 30, ¶ 54.

[21] *See id.* ¶ 70–104.

[22] *Correcting the Record: Zimmer's Lawsuit*, ZIMMERFACTS, http://zimmerfacts.com/background/index.html (last visited Jan. 29, 2016).

[23] Alex Nussbaum & David Voreacos, *Artificial-Knee Suits Targeting Zimmer Haunt Lawyers*, BLOOMBERGBUSINESS, http://www.bloomberg.com/news/articles/2011-08-09/artificial-knee-suits-targeting-zimmer-haunt-lawyers-correct- (Aug. 9, 2011).

[24] Lanham Act § 43(a), 60 Stat. 441, codified at 15 U.S.C. § 1125(a).

[25] *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1393 (2014) (internal quotation marks and citations omitted).

[26] *Id.* at 1386 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

[27] 134 S. Ct. 1377.

[28] *Id.* at 1392 (citing 11 U.S.C. § 1127).

[29] *Id.* at 1392.

[30] *Id.* at 1390.

[31] *Id.* at 1391.

[32] *Fed. Exp. Corp. v. United Parcel Serv., Inc.*, 765 F. Supp. 2d 1011, 1016–17 (W.D. Tenn. 2010) (quoting *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery*, 185 F.3d 606, 613 (6th Cir. 1999).

[33] *Am. Council of Certified Podiatric Physicians & Surgeons*, 185 F.3d at 614.

[34] *Id.*

[35] *Id.*

[36] *Balance Dynamics Corp. v. Schmitt Indus., Inc.*, 204 F.3d 683, 694 (6th Cir. 2000) (citing *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329 (8th Cir. 1997)).

[37] *Id.* at 616.

[38] *Id.*

By Kyle R. Cummins

By Eric E. Hudson

NEW AND NOTEWORTHY

LEARNED INTERMEDIARY

As many of you may know, West Virginia has *finally* decided to jump onto the learned intermediary band wagon. From eliminating the learned intermediary rule completely in *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007), to adopting the learned intermediary rule with the passage of W. Va. Code §55-7-30 (effective May 17, 2016), West Virginia can count itself among the clear majority of jurisdictions now. Perhaps this sea change will permanently remove West Virginia from the (far from coveted) number-one spot on the Drug and Device Law's blog post - *The Best and Worst of 2007: The Worst* – a dubious distinction which it earned with its *Karl* decision.

West Virginia's new statute is significant because it adopts the learned intermediary rule as it is seen in the Third Restatement of Torts, but *without any exceptions*. W. Va. Code §55-7-30:

> Adequate pharmaceutical warnings; limiting civil liability for manufacturers or sellers who provide warning to a learned intermediary.
>
> (a) A manufacturer or seller of a prescription drug or device may not be held liable in a product liability action for a claim based upon inadequate warning or instruction unless the claimant proves, among other elements, that:
>
> (1) The manufacturer or seller of a prescription drug or medical device acted unreasonably in failing to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; and
>
> (2) Failure to provide reasonable instructions or warnings was a proximate cause of harm.
>
> (b) It is the intention of the Legislature in enacting this section to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or devices.

Nonconformists to the learned intermediary rule are even more distinctly the "exception to the rule" now.

CONTINUED ON NEXT PAGE

Nonconformists to the learned intermediary rule are even more distinctly the "exception to the rule" now.

LEARNED INTERMEDIARY - CONT.

And contrary to the forecasts at the time, the "DTC advertising" exception to the learned intermediary rule in *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999) ("when direct warnings to consumers are mandatory, the learned intermediary doctrine ... drops out of the calculus"), and the ruling in *Karl*, were not harbingers of an anti-learned intermediary rule movement. In fact, despite their attempts, plaintiffs have been unsuccessful in pushing expansion of *Perez* and *Karl:* "not a single state's high court (or any other court, for that matter) has followed *Karl* down the path to perdition. And now *Karl* itself is history." *Renaissance of the Learned Intermediary Rule*, http://www.druganddevicelaw.blogspot.com (March 3, 2016). And "every state now has pro-learned intermediary precedent." Id.

It is almost as if the *Karl* decision launched a movement to avoid its ramifications, resulting in adoption or reaffirmance of the learned intermediary rule, because "recent precedent uniformly refutes" the proposition that the rule is obsolete or archaic. *See Id.*

The Drug and Device Law's blog has provided an excellent summary of the law in this area, and we encourage our readers to take a look. (http://www.druganddevicelaw.blogspot.com; http://druganddevicelaw.blogspot.com/search?q=renaissance). ■

It is almost as if the *Karl* decision launched a movement to avoid its ramifications, resulting in adoption or reaffirmance to the learned intermediary rule...

By Ashley J. Markham

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