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# Medical Advice from Lawyers: A Content Analysis of Advertising for Drug Injury Lawsuits

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This study examined the medical information contained in a sample of television ads soliciting consumers for lawsuits against drug and medical device manufactures. Almost all such ads involved drugs or devices that have not been recalled and remain on the market. These ads raise important public health questions because they may influence the prospective medical decisions of viewers.

The ads contained extensive descriptions of serious adverse events associated with the drugs or devices but almost uniformly failed to disclose information relating to the likelihood of such events. They also failed to effectively advise viewers to consult a doctor.

Results also identified a subset of ads that mimicked public service announcements, claiming to be a "medical alert" "consumer alert" or "FDA warning" at the start of the ad. Most such ads did not disclose the attorney source of the advertising until the final few seconds.

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#### **LINTRODUCTION**

This study focuses on television advertising for lawsuits relating to drugs and medical devices (hereinafter "drug injury advertising"). The purpose of the advertising is to recruit consumers for lawsuits against drug manufacturers. In particular, the ads seek to identify consumers that took a drug or used a medical device and subsequently experienced a particular medical problem that the drug manufacturer failed to disclose. The ads warn of the dangers associated with a particular drug or device. Ultimately, advertising attorneys hope that injured consumers will contact them for legal representation.

Drug injury lawsuits are typically brought as mass torts, consisting of thousands of individual claims against the manufacturer of a defective product. Unlike class actions, no single attorney or set of attorneys has a monopoly over representing plaintiffs in such claims. As a result, there is a lively market of lawyers competing over the airways for the attention of a limited number of injured consumers.

The business models of advertising attorneys vary. About half of the most prolific advertisers in this study appear to actively litigate at least some of the cases they receive. 4 Recoveries in such cases can be quite large in the aggregate. 5 For

<sup>&</sup>lt;sup>1</sup> Most drug injury lawsuits are pled as failure to warn claims. STEVEN GARBER, RAND INST. FOR CIVIL JUSTICE, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS, xiii (2013) (noting the "lion's share" of mass tort claims are brought as failure to warn cases). Some drug injury lawsuits involve manufacturing defects, as in the case of Fentanyl lawsuits discussed herein, involving a defect in a transdermal patch.

<sup>&</sup>lt;sup>2</sup> Id. at 24; see also Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 965 (1993) (explaining the structure of mass tort claims); Charles Silver & Geoffrey P. Miller, *The Quasi-Class Action Method of Managing Multi-District Litigations: Problems and a Proposal*, 63 VAND. L. REV. 107, 115 (2010) ("The largest [multidistrict litigations] encompass thousands of cases filed by legions of attorneys.").

<sup>&</sup>lt;sup>3</sup> In mass tort claims, judges select managerial attorneys. However, the "legion" of other lawyers representing the thousands of clients continue to participate. Their fees are reduced to reflect their client's share of the managing attorneys' fees, and judges sometimes set fee caps on the contingency fees of non-managerial attorneys. See GARBER, supra note 1, at 80.

<sup>&</sup>lt;sup>4</sup> This assertion is based on a docket search on Bloomberg Law for the firm's name and product liability cases. The search revealed any cases where that firm appeared on a case docket in federal court and certain state courts. A docket search on Bloomberg Law for product liability cases revealed that five of the

example, claims involving the birth control pill, Yaz, caused the manufacturer to set aside 1.5 billion dollars in reserve to settle claims.<sup>6</sup>

The other prolific advertisers in this study rarely, if ever, file drug injury lawsuits. It is possible that these advertisers are "settlement mills," meaning they settle large volumes of cases very quickly, without ever filing in court. Alternatively, their business model may be based primarily upon referrals. The disclaimers in some of these ads describe referring cases to associated attorneys. Although attorney ethics rules heavily regulate referral fees, they generally permit advertisers to recoup the cost of advertising. It is also possible that advertising attorneys base their business model on "maintain[ing] joint responsibility" for cases they refer.

This article is not about whether drug injury lawsuits, attorney advertising, or referral mills are good or bad. It is about the complex policy questions raised by advertising that disseminates important medical information to the public. This lucrative market operates with little to no regulation or scrutiny. The impact of such advertising on consumer medical decisions is unknown and demands further study.

Drug injury advertising is, in a sense, the functional opposite of direct-to-consumer pharmaceutical advertising. Whereas pharmaceutical advertising seeks to encourage viewers to take a drug, drug injury advertising may deter viewers from taking a drug by highlighting serious risks. The risks described in the advertisements are often relatively rare, affecting fewer than 1 in 100 or even 1 in 1000 consumers taking the drug. <sup>13</sup> Consequently, the vast majority of interested viewers are not the

ten most prolific advertisers listed in Table 5, *infra*, produced more than 100 results. The other five advertisers produced twenty or fewer results.

<sup>&</sup>lt;sup>5</sup> GARBER, *supra* note 1, at xv ("The potential cost of a mass tort to a drug company is in the billions of dollars.").

<sup>&</sup>lt;sup>6</sup> See Julie Beck, Bayer Designates \$1.5 Billion for Litigation over Yasmin and Yaz Contraceptives, INSIDE COUNS. (Mar. 4, 2013), http://www.insidecounsel.com/2013/03/04/bayer-designates-15-billion-for-litigation-over-ya.

<sup>&</sup>lt;sup>7</sup> See supra text accompanying note 4. Of these rare litigators, one firm produced no results, and two firms produced only two results on the Bloomberg docket search. It is possible, however, that these firms litigate in state courts excluded from Bloomberg's database.

<sup>&</sup>lt;sup>8</sup> See Nora Freeman Engstrom, Sunlight and Settlement Mills, 86 N.Y.U. L. REV. 805, 807 (2011) (discussing the rise and benefits of "settlement mills").

<sup>&</sup>lt;sup>9</sup> See Hensler & Peterson, supra note 2, at 1026 ("Many law firms that advertise [in the mass tort context] serve only as referring lawyers . . . ."); John Fabian Witt, Bureaucratic Legalism, American Style: Private Bureaucratic Legalism and the Governance of the Tort System, 56 DEPAUL L. REV. 261, 286 (2007) ("Many lawyers who advertise as personal injury specialists are little more than referral mills. They serve as intake officers for claims that they then farm out to specialized lawyers in return for a contingent referral fee. . . . [T]hey seem to thrive in an uncompetitive legal fees market that sometimes functions a little like a gold rush–locating and signing up clients is the key.").

No. 71<sup>st</sup> St., Suite 100, Scottsdale, AZ) is licensed to practice law only in Arizona, but associates with attorneys throughout the country. Principle responsibility for cases belongs to associate counsel although Robert Goldwater maintains joint responsibility. Not available in all states." The Goldwater Law Firm's website includes a section called "Co-Counsel Opportunities", which states that it is "one of the largest national advertising law firms in the United States and generate in excess of 10,000 new client inquiries per month. We co-counsel with experienced lawyers throughout the country and are always looking for new law firms to work with. In fact, most of our national advertising has been the direct result of other law firms approaching us with ideas on specific niche campaigns. If you would like to generate more tort cases for your law firm, please call attorney Bob Goldwater...." Co-Counsel Opportunities, GOLDWATER L. FIRM, P.C., http://www.bobgoldwater.com/Co\_Counsel\_Opportunities.aspx (last visited Mar. 25, 2015).

<sup>&</sup>lt;sup>11</sup> See MODEL RULES OF PROF'L CONDUCT R. 7.2(b)(1) (2011).

 $<sup>^{\</sup>rm 12}$  See GOLDWATER L. FIRM, supra note 10.

<sup>&</sup>lt;sup>13</sup> See BAYER, YAZ FULL PRESCRIBING INFORMATION 8 (2012), available at http://labeling.bayerhealthcare.com/html/products/pi/fhc/YAZ\_PI.pdf?WT.mc\_id=www.berlex.com.

injured consumers targeted by the advertisers, but uninjured consumers trying to decide whether to fill next month's prescription for the drug.

While considerable empirical research has been conducted on direct-to-consumer pharmaceutical advertising, <sup>14</sup> almost none has examined drug injury advertising. <sup>15</sup> Two small studies surveyed female urology patients about their opinions regarding transvaginal mesh, which is commonly featured in drug injury lawsuits. <sup>16</sup> In one study, patients that relied on television for their medical information were more likely to mistakenly believe that the mesh had been recalled. <sup>17</sup> In the other study, patients that learned about mesh through attorney ads expressed greater uncertainty about the safety of the product. <sup>18</sup>

The other limited research to date has been sponsored by partisan groups. <sup>19</sup> A 2003 Harris poll sponsored by the U.S. Chamber of Commerce found that 86% of consumers surveyed had seen drug injury advertising, and 21% had seen such advertisements about a drug they were taking. <sup>20</sup> Twenty-five percent of respondents reported that they would "immediately stop taking" a drug they had been prescribed if they saw it in a drug injury ad. <sup>21</sup> Similarly, a 2007 study sponsored by Eli Lilly and the nonprofit National Council for Community Behavioral Healthcare found that half of psychiatrists surveyed reported that patients had discontinued taking medication because of drug injury advertising. <sup>22</sup>

<sup>&</sup>lt;sup>14</sup> See generally Richard A. Hansen et al., Relationship of Pharmaceutical Promotion to Antidepressant Switching and Adherence: A Retrospective Cohort Study, 61 PSYCHIATRIC SERVICES 1232 (2010) (examining the effects of direct-to-consumer advertising for antidepressants); Daniel Hosken & Brett Wendling, Informing the Uninformed: How Drug Advertising Affects Check-up Visits, 31 INT'L J. INDUS. ORG. 181 (2013) (studying whether advertisements encourage consumers to seek treatment); Michael R. Law et al., Effect of Illicit Direct to Consumer Advertising on Use of Etanercept, Mometasone, and Tegaserod in Canada: Controlled Longitudinal Study, 337 BRIT. MED. J. 557 (2008) (examining how direct advertisement in the United States affects Canadian prescribing rates); Barbara Mintzes et al., Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Survey, 324 BRIT. MED. J. 278 (2002) (reviewing the relationship between direct-to-consumer marketing and patient pharmaceutical requests); Bennett Parnes et al., Lack of Impact of Direct-to-Consumer Advertising on the Physician-Patient Encounter in Primary Care: A SNOCAP Report, 7 ANNALS FAM. MED. 41 (2009) (considering the effects of direct-to-consumer advertisements on clinical encounters); Marta Wosinska, Direct-to-Consumer Advertising and Drug Therapy Compliance, 42 J. MARKETING RES. 323 (2005) (finding direct-to-consumer advertisements can increase compliance with a drug regimen).

<sup>15</sup> See generally Harris Interactive, Pharmaceutical Liability Study Report on Findings 39 (2003), available at https://www.uschamber.com/sites/default/files/legacy/press/rx\_pharmaceutical\_liability\_study\_report.pdf; David N. Juurlink et al., The Effect of Publication on Internet-Based Solicitation of Personal-Injury Litigants, 177 Can. Med. Assoc. J. 1369, 1369 (2007) (examining the relationship between the publication of major scientific studies and attorney solicitations on the internet); Michelle Koski et al., Patient Perception of Transvaginal Mesh and the Media, 84 J. Urology 575, 575 (2014); Judyth Pendell, The Adverse Side Effects of Pharmaceutical Litigation 1 (2003), available at https://www.mysciencework.com/publication/read/2199471/the-adverse-side-effects-of-pharmaceutical-litigation#page-null; Christopher F. Tenggardjaja et al., Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery, 85 J. Urology 326, 326 (2015).

<sup>&</sup>lt;sup>16</sup> See generally Koski, supra note 15; Tenggardjaja, supra note 15.

Tenggardjaja, *supra* note 15, at 328.

<sup>&</sup>lt;sup>18</sup> Koski, supra note 15, at 578.

<sup>&</sup>lt;sup>19</sup> HARRIS INTERACTIVE, *supra* note 15; PENDELL, supra note 15.

<sup>&</sup>lt;sup>20</sup> HARRIS INTERACTIVE, supra note 15, at 14.

 $<sup>^{21}</sup>$  Id

<sup>&</sup>lt;sup>22</sup> New Survey Shows Product Liability Litigation May Jeopardize Treatment Outcomes for People with Severe Mental Illnesses, ELI LILLY & Co. (June 13, 2007), https://investor.lilly.com/releasedetail.cfm?releaseid=248836.

Anecdotally, a law review article by Daniel Schaffzin describes reports of consumer harm from a doctor and a mass tort attorney. A recent *New York Times* profile of a mother making medical decisions for her son noted in passing that a drug injury ad had influenced her decision. Message boards and blogs on the internet include anecdotal self-reports of consumers responding in alarmist ways to mass tort advertising. While these anecdotal accounts and partisan research suggest the need for rigorous empirical research on the question, they are no substitute for such evidence.

This study provides context for policy discussions regarding the regulation of drug injury advertising. It analyzes content of drug injury advertising broadcast in Boston and Atlanta in 2009. An empirical snapshot of their content can inform the respects in which drug injury ads might influence consumer decisions, and how their content might be improved. This study also illustrates gaps in existing research that demand further study.

Drug injury advertising presents both public health opportunities and risks. It informs injured consumers of legal remedies, offers wider access to attorneys, and holds manufacturers accountable. <sup>26</sup> The advertisements also disseminate new information about medical risks from the FDA and medical journals. <sup>27</sup> Although the

<sup>&</sup>lt;sup>23</sup> 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, 343-46 (2013-2014).

<sup>&</sup>lt;sup>24</sup> Alan Schwarz, *One Drug or 2? Parents See Risk but Also Hope*, N.Y. TIMES (Nov. 14, 2014), http://www.nytimes.com/2014/11/15/us/one-drug-or-2-parents-see-risk-but-also-hope.html?\_r=0 ("Then she saw a television commercial in which class-action lawyers asked parents if their son had developed breasts while on the drug, a rare but disturbing side effect.").

<sup>&</sup>lt;sup>25</sup> See e.g., David Oliver, Bipolar Disorder Warning About Lawsuits and Attorneys, BIPOLAR CENT. (June 30, 2007, 7:32 AM), http://www.bipolarcentral.com/supporterblog/2007/06/bipolar-disorder-warning-about-lawsuits.html (describing mental illness blogger's conversation with acquaintance who stopped taking a drug after seeing a drug injury ad; comments to post included reports of similar behavior); Yaz & Gall Bladder Failure, MYFITNESSPAL (Sept. 10, 2009), http://www.myfitnesspal.com/topics/show/65554-yaz-gall-bladder-failure (describing one commenter's plan to consult her doctor about the risks, while another reported that she "stopped taking [the drug] the SECOND [she] heard that").

<sup>&</sup>lt;sup>26</sup> See Brief of the FTC as Amicus Curiae Supporting Arguments to Vacate Opinion 39 of the Committee on Attorney Advertising Appointed by the Supreme Court of New Jersey at 11, *In re* Petition for Review of Committee on Att'y Adver. Op. 39, No. 60,003 (F.T.C. May 8, 2007), 2007 WL 7947967, at \*4 [hereinafter Brief of the FTC] (citing empirical evidence that advertising for professional services is associated with lower prices and improved quality); Richard L. Abel, *The Real Tort Crisis—Too* Few *Claims*, 48 OHIO ST. L.J. 443, 448-57 (1987) (describing the social importance of tort claims, and the tendency of tort victims to avoid bringing claims); Nora Freeman Engstrom, *Attorney Advertising and the Contingency Fee Cost Paradox*, 65 STAN L. REV. 633, 665-66 (2013) (arguing that attorney advertising has not reduced the cost of legal services); Geoffrey C. Hazard, Jr. et al., *Why Lawyers Should be Allowed to Advertise: A Market Analysis of Legal Services*, 58 N.Y.U. L. REV. 1084, 1101 (1983) (arguing that advertising my be especially suitable for clams that benefit from economies of scale); Lyrissa Barnett Lidsky & Tera Jckowski Peterson, *Medium-Specific Regulation of Attorney Advertising: A Critique*, 18 U. FLA. J.L. & PUB. POL'Y 259, 263 (2007); Christopher M. Mensoian, Bates, *the Model Rules and Attorney Advertising*, 32 MCGEORGE L. REV. 77, 80 (2000) (describing a 1984 FTC study that found that competition in advertising reduced the price of legal services).

<sup>&</sup>lt;sup>27</sup> Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 634 (1985) (recounting testimony by an expert witness that attorney advertising is socially valuable in informing the public "of the potential health hazards associated with the Dalkon Shield"). An internet-based study of search result hits for websites soliciting plaintiffs for drug injury claims found that publication of a medical study highlight the risk of an adverse event was associated with "an immediate and sustained increase in [such] websites." Juurlink et al., *supra* note 15, at 1369. A marketing company specializing in mass tort advertising advises attorneys interested in pursuing a drug injury practice to monitor the FDA website and the *Journal of the American Medical Association* for potential adverse events that could form the basis of a

ads are not necessarily intended for uninjured viewers taking the drug,<sup>28</sup> the ads may nevertheless catch their attention.<sup>29</sup> As proponents of pharmaceutical advertising have argued, this additional information can motivate viewers to seek medical care, usefully inform medical decision-making, and improve interactions with physicians.<sup>30</sup> Paradoxically, they might even remind consumers to take their medication.<sup>31</sup>

At the same time, such advertising could also distort consumer medical decisions by causing them to misperceive drug-related risks.<sup>32</sup> Unlike consumers misled by pharmaceutical advertising,<sup>33</sup> those misled by drug injury advertising need not consult a doctor to make a medical decision based on the ad. They can simply stop taking the drug featured in the ad of their own accord.

Despite this potential to influence patient medical decisions, drug injury ads are not subject to the complex FDA regulations governing pharmaceutical ads.<sup>34</sup> Attorney

mass tort. See Risk vs. Reward: The Mass Tort Advertising Cycle, MCM SERVS. GRP. (Aug. 13, 2013, 3:13 PM), http://mcmservicesgroup.com/home/attorney-marketing-blog-mcm-services-group.

<sup>28</sup> A minority of states recognize a cause of action for "medical monitoring." This claim allows attorneys to sue on behalf of individuals never injured by the drug or device to recover the costs of medical monitoring through "diagnostic tests to facilitate the early detection of adverse health effects among exposed individuals." David M. Studdert et al., *Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public's Health?* 289 JAMA 889, 889 (2003). In that sense, uninjured plaintiffs could potentially form part of an advertiser's target audience. However, one advertising attorney that reviewed a draft of this study reported that uninjured plaintiffs are not the target audience in drug injury advertising because they are considered unprofitable.

<sup>29</sup> Schaffzin, *supra* note 23, at 325. Social science research suggests that individuals are more likely to pay attention to an advertisement when it is "personally relevant." David W. Stewart & Ingrid M. Martin, *Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical Research*, 13 J. PUB. POL'Y & MARKETING 1, 5 (1994) (synthesizing research on warnings). A consumer taking a drug featured in a drug injury would likely find it relevant to his or her health, even if the consumer not suffered an adverse event. Social science research also suggests that consumers pay more attention to warnings involving information that is not well known, which may be the case for adverse events associated with drugs and medical devices. *Id.* at 6.

<sup>30</sup> See Hosken & Wendling, supra note 14, at 182 (noting that direct-to-consumer pharmaceutical advertising is associated with an increase in likelihood that consumers visit the doctor); Ajit M. Menon et al., Consumers' Attention to the Brief Summary in Print Direct-to-Consumer Advertisements: Perceived Usefulness in Patient-Physician Discussions, 22 J. Pub. Pol.'y & MARKETING 181, 181 (2003) (summarizing policy arguments in favor of direct-to-consumer drug advertising); see also Hazard et al., supra note 26, at 1094 (arguing that attorney advertising spurs information seeking by consumers).

31 This is known in social science as the "mere exposure" effect, where repeated exposure to a product increases positive responses to that stimulus. Anthony Grimes & Philip J. Kitchen, *Researching Mere Exposure Effects to Advertising*, 49 INT'L J. MARKET RES. 191, 193 (2007). Even if the product appears in a negative context, repeated exposure to the product's name may nevertheless increase positive associations through the mere exposure effect.

Daniel Schaffzin argues that drug injury ads are also problematic because they erode trust between patients and physicians. Schaffzin, *supra* note 23, at 341. Similar trust-based arguments have been made in the context of requiring drug manufacturers to convey lengthy warnings to patients about the risks of a drug. *See* Lars Noah, *This is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 898 n.260 (2009)

(2009).

33 Joshua E. Perry et al., *Direct-to-Consumer Drug Advertisements and the Informed Patient: A Legal, Ethical, and Content Analysis*, 50 AM. BUS. L.J. 729, 730 (2013) ("In the case of direct-to-consumer (DTC) advertising of prescription drugs, the link between advertising exposure and purchase is often especially circuitous, in part because consumers . . . must first consult with a health-care provider, who then decides whether to prescribe the advertised product, an alternative treatment, or nothing at all.").

<sup>34</sup> I was able to identify no instances in which the FDA has weighed in on drug injury advertising or asserted that such ads are subject to drug advertising regulation. The FDA likely considers drug injury advertising outside of its jurisdiction. The legislation prohibiting "misbranded" drugs, from which the FDA derives its authority, presumes that the entities responsible for misbranding a drug are "the manufacturer, packer, or distributor [of]" prescription drugs. See 21 U.S.C. § 352(n) (2012) ("A drug or device shall be deemed to be misbranded . . . [i]n the case of any prescription drug distributed or offered for sale in any

advertising is theoretically subject to the jurisdiction of the FTC and state consumer protection law, but neither the FTC nor state attorneys general have a record of regulating drug injury ads.<sup>35</sup>

Attorney advertising is most commonly regulated through state attorney ethics rules prohibiting false or misleading attorney advertising. <sup>36</sup> However, as Fred Zacharias observed in a 2002 study of attorney *Yellow Pages* advertising, state bars have been reluctant to enforce ethics rules in the advertising context. <sup>37</sup> This appears equally true in the context of drug injury advertising. This research identified no ethics cases involving drug injury advertisements since the 1985 Supreme Court case, *Zauderer v. Office of Disciplinary Counsel.* <sup>38</sup>

Results of this study suggest that some drug injury ads could be considered misleading under state ethics rules. In particular, a subset of ads appeared to be public service announcements, by opening with the words "consumer alert," "medical alert," or "FDA warning." Most such ads also failed to disclose that the advertisement originated from an attorney until the very end. Such ads are misleading in two respects: (1) they suggest that the source of the advertising has a government, non-profit or public health affiliation or that the advertising attorney has authority to award compensation or administer claims; and (2) they suggest that the medical information presented was selected based on consumer needs, rather than a particular adverse medical event that forms the basis for a lawsuit.

State, unless the manufacturer, packer, or distributor thereof includes in all advertisements" various information required by the FDA, such as side effects.) (emphasis added); id. § 331. FDA regulations also suggest that their scope is limited to promotional advertising. 21 C.F.R. § 202.1(e)(1) (2014) ("All advertisements for any prescription drug...shall present a true statement of information in brief summary relating to side effects, contraindications... and effectiveness.") (emphasis added). Creative arguments could be made that the FDA has jurisdiction. Indeed, Lars Noah asserts that "[t]he FDA has shown tremendous creativity in construing the reach of its authority" in order to pursue extra-statutory goals. Lars Noah, The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures), 93 CORNELL L. REV. 901, 917 (2008).

35 The FTC's power over attorney advertising is somewhat uncertain. As one commentator described, "Congress neither expressly restricted nor expressly delegated to the FTC rulemaking authority over state laws or regulations." Tod H. Cohen, *Double Vision: The FTC, State Regulation, and Deciding What's Best for Consumers*, 59 GEO. WASH. L. REV. 1249, 1256 (1991). In any event, the FTC has not inserted itself into the regulation of attorney advertising beyond commenting on proposed attorney advertising rules that it deems overly restrictive. *See, e.g.*, Brief of the FTC, *supra* note 26. State consumer protection laws also protect consumers against false advertising. State attorneys general have sued drug manufacturers for misleading advertising. *See, e.g.*, Press Release, Fla. Office of the Att'y Gen., McCollum Announces \$8 Million Multi-State Settlement with Bayer (Jan. 23, 2007), http://web.law.columbia.edu/sites/default/files/microsites/attorneys-

general/files/McCollum%20Announces%208%20Million%20Dollar%20Multi-

State%20Settlement%20with%20Bayer\_0.pdf. I was, however, unable to find any examples of state attorneys general taking action against attorney advertisers for defective drug advertising.

<sup>37</sup> Fred C. Zacharias, What Lawyers Do When Nobody's Watching: Legal Advertising As a Case Study of the Impact of Underenforced Professional Rules, 87 IOWA L. REV. 971, 985-86 (2002).

<sup>38</sup> Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985). It is possible that state bars have taken action but that records of that action were not detectable on Westlaw. For example, state bars frequently negotiate with advertisers informally, especially in states that require attorneys to submit advertising to the state. Additionally, secrecy in disciplinary proceedings limits the availability of information on state bar practices. See Leslie C. Levin, The Case for Less Secrecy in Lawyer Discipline, 20 GEO. J. LEGAL ETHICS 1, 15-16 (2007); Deborah L. Rhode & Alice Woolley, Perspectives on Lawyer Regulation: An Agenda for Reform in the United States and Canada, 80 FORDHAM L. REV. 2761, 2767 (2012) (noting that most states do not disclose disciplinary complaints absent a subsequent finding of a violation or probable cause).

<sup>&</sup>lt;sup>36</sup> See infra Section IV(A).

Results also raise the question of whether the advertisements omit risk-related information that would be important to viewers currently taking the drug. Although the absence of such information does not necessarily qualify as misleading under state ethics rules, it may lead consumers to overestimate the likelihood of adverse events associated with a drug and ultimately distort their decision-making. This article argues that including some risk-related information would substantially enhance the positive public health impact of such ads, and mitigate potential harms.

Specifically, a basic understanding of a medical risk requires information about both the likelihood that harm will occur and the particular harm that will result. The ads in the sample devoted considerable time and text to describing the alarming and sometimes fatal adverse events associated with the drugs or devices at issue. However, none of the ads in the sample explained the likelihood of harm in quantitative terms. As a result, the repeated and emphasized presentation of adverse events could lead a reasonable consumer to assume that the adverse event is very likely or even inevitable.

Another critical component of medical risk information is what a patient can do to mitigate the risk of harm.<sup>39</sup> Given the complexity of medical decisions, it is not practicable for these advertisements to provide any concrete guidance in this regard, other than suggesting that viewers consult a doctor before making a medical decision. However, only 39% of advertisements ever advised viewers to consult a doctor before discontinuing their medication, and they did so via small written disclaimers competing with other content in much larger font sizes. The inconspicuous nature of these disclaimers almost certainly rendered them ineffective.

In some circumstances, relative risk information—meaning information about certain subpopulations disproportionately or exclusively affected by an adverse event—is central to understanding risk. For example, if a recall in a manufacturing defect case only applies to a single manufacturer, disclosing the name of the manufacturer would be important to viewers taking the drug. Likewise, if the risk of adverse events primarily affects viewers who have taken a drug on a long-term basis, disclosing that fact would be important to both viewers who have taken the drug on a long-term basis and those who have not. Information on affected populations can reduce the likelihood that viewers will rely on the otherwise incomplete medical information to their detriment.

Section II of this Article describes the methodology of the study, followed by the results in Section III. Section IV analyzes the extent to which the content observed in this study would be considered false and misleading under relevant law. Lastly, Section V provides some policy recommendations.

# II. METHODS

# A. SAMPLE

The data used in this study originated from media aggregator Kantar Media ("Kantar"). Kantar records cable television broadcasts in each Nielsen designated market area. 40 The sample consisted of digitized video for all advertising coded by

<sup>&</sup>lt;sup>39</sup> Isaac M. Lipkus, Numeric, Verbal, and Visual Formats of Conveying Health Risks: Suggested Best Practices and Future Recommendations, MED. DECISION MAKING 696, 698 (2007).

<sup>&</sup>lt;sup>40</sup> Nielsen divides the United States into 210 television market regions. *See DMA Regions*, Nielsen, http://www.nielsen.com/intl-campaigns/us/dma-maps.html (last visited Mar. 25, 2015) (defining "designated market area").

Kantar as "legal services" broadcast between June 15, 2009 and January 4, 2010 in the Boston and Atlanta media markets. <sup>41</sup> The sample was limited to advertising broadcast targeted to the Boston and Atlanta markets, as opposed to advertising broadcast nationally. <sup>42</sup> For that reason, few ads in the sample were broadcast in both Boston and Atlanta.

The dataset consisted of 234 unique attorney advertisements broadcast in Boston and 654 in Atlanta. Each of these ads was reviewed to determine whether it related to lawsuits involving drugs or medical devices. <sup>43</sup> Both over-the-counter and prescription drugs were included in the definition of "drug or medical device." The above-described review produced a subsample of 56 unique advertisements (hereinafter, the "subsample"), 10 of which were deemed duplicates of other advertisements within the subsample. <sup>44</sup>

The attorney ethics rules in Massachusetts and Georgia are typical of most states in that they do not require attorneys to file their advertising with the state bar for review. <sup>45</sup> Following the Model Rules of Professional Conduct, both Massachusetts and Georgia prohibit false or misleading advertising. <sup>46</sup>

# B. CONTENT ANALYSIS AND TRANSCRIPTION

Pairs of trained law students coded the subsample of drug injury ads using a coding instrument. The coding occurred in three successive rounds, with the trained

<sup>&</sup>lt;sup>41</sup> The Boston and Atlanta markets include the cities themselves and large portions of the surrounding geographic area, See NIELSEN, NIELSEN STATION INDEX: ZIP CODES BY DMA (2010) (on file with author). The Boston market also includes Manchester, New Hampshire. Id. Boston and Atlanta represent the seventh and eighth largest media markets in the country, respectively, as of 2009-2010. See NIELSEN, LOCAL (2009),UNIVERSE TELEVISION MARKET ESTIMATES 1. 1 available http://www.nielsen.com/content/dam/corporate/us/en/newswire/uploads/2009/08/2009-2010-dma-ranks.pdf. In 2009, the Atlanta designated media market encompassed an estimated 2.37 million homes and the Boston media market encompassed an estimated 2.41 million homes. Id. The two cities were selected on the basis of their geographic distance, on the assumption that they might support somewhat different advertising markets. The very largest media markets -New York, San Francisco and Los Angeles, for example, were ruled out to avoid a strong likelihood that the legal or media market were so large in those regions as to be idiosyncratic. See id.

Based on a dataset of national drug injury advertising for the same period, the volume of targeted advertising compares favorably to the volume of national network advertising, at 859 units, compared to 1,258 units. Over the same period, 6,460 additional units of drug injury advertising were broadcast over national cable, scattered throughout an array of channels with varying ratings. Relative pricing of network versus cable advertising within that dataset indicates that on average, a network ad costs more than twice the cost of a cable ad, which likely reflects average viewership. The targeted advertising in this sample would have been broadcast over local affiliates of national networks—for example, the local ABC or NBC station.

Ads relating to personal care products (e.g., denture cream) were excluded, as were ads relating to herbal supplements (e.g., the herbal supplement known as Hydroxycut).
 When content coding or transcriptions for two or more ads produced identical or substantially

<sup>&</sup>lt;sup>44</sup> When content coding or transcriptions for two or more ads produced identical or substantially identical results, the ads were played side by side for any observable differences. Where an ad appeared identical in all respects but the phone number, it was deemed a duplicate. I hypothesize that firms sometimes broadcast different phone numbers with the same ads to optimize their advertising strategy. The different phone numbers may be associated with different broadcast locations, times, or channels. A data-driven advertiser could then use the volume of calls associated with a single number to determine the yield associated with a particular advertising strategy.

<sup>&</sup>lt;sup>45</sup> A few states require attorneys to submit a copy of their advertisements to the state bar. *See, e.g.*, TEX. DISCIPLINARY RULES OF PROF'L CONDUCT R. 7.07 (2005).

<sup>&</sup>lt;sup>46</sup> See GA. RULES OF PROF'L CONDUCT R. 7.1 (2001); MASS. RULES OF PROF'L CONDUCT R.7.1 (1998). Unlike the ABA MODEL RULES OF PROFESSIONAL CONDUCT, Georgia's Rule 7.2 explicitly requires that attorneys disclose the identity and physical location of the sponsoring attorney, as well as the firms referral practices if a majority if cases will be referred. GA. RULES OF PROF'L CONDUCT R. 7.2 (2001).

students using a different instrument to identify different content in each round.<sup>47</sup> Two law students applied each of the three coding instruments to the ads.<sup>48</sup>

The instruments instructed coders to identify content relating to (1) adverse medical evidence; (2) the frequency of adverse medical events; (3) the benefits or use of the drug or device; (4) advice to consult a doctor before making medical decisions; and (5) the attorney or law firm sponsoring the ad. Definitions from the instruments are included in Table 1, below. Coders identified the time stamp(s) at which specified content first appeared in the ad, and the duration of that content. They also transcribed the audio and text of specified content.

TABLE 1. DEFINITIONS IN CODING INSTRUMENTS

TERM	DEFINITION	
Adverse events <sup>49</sup>	Side effects, adverse events or risks associated with the drug or medical device. Discussions of side effects, adverse events or risks would include, for example, a statement that a drug may cause heart disease. Another example might consist of an "important announcement," "warning" or "medical alert" that a drug has been associated with liver failure. Likewise, an assertion that the FDA has recalled a drug would also qualify.	
Frequency of adverse events	The frequency with which such adverse events occur (e.g. 1% chance, or 1 out of 100 patients experience the adverse effect).	
Benefits <sup>50</sup>	Benefits or use of the drug or medical device. This would include, for example, a statement that the drug or device treats a certain disease or symptom, or that it is administered in certain contexts, such as surgery.	
Consult a doctor	Viewers are advised to consult a doctor.	
Attorney identification	[Disclosure of] the source of the advertisement as an attorney or law firm (e.g. lists name of law firm, uses the word "attorney" or "lawsuit," or individual identifying him/herself as an attorney appears on screen).	

Coders were not informed of the purpose of the research.<sup>51</sup> They were instructed to code the ads independently. Each coder then met with his or her counterpart to

<sup>&</sup>lt;sup>47</sup> The coding instrument for the first round was focused primarily on whether and when the ad identified an attorney as the source of the ad. The second round was focused on content relating to medical information, such as adverse events, benefits, or advice to consult a doctor. The third round was focused on disclaimers relating to the geographic location and licensing status of the advertising attorney.

<sup>&</sup>lt;sup>48</sup> Different law students coded each round, with the exception of one student, who coded both the second and third rounds.

<sup>&</sup>lt;sup>49</sup> This definition is from the second coding instrument, the results of which are used for the analysis in this Article. A definition also appears in the first coding instrument and was refined for the second instrument to reduce inter-rater disagreement.

<sup>&</sup>lt;sup>50</sup> This definition is from the second coding instrument, the results of which are used for the analysis in this Article. A definition also appears in the first coding instrument and was refined for the second instrument to reduce inter-rater disagreement.

<sup>&</sup>lt;sup>51</sup> Following the independent coding, one coder was assigned a legal research project relating to attorney ethics and informed that the research was unrelated. During a debriefing discussion following the conclusion of the research project, the coder guessed that the purpose of the research related somehow to attorney ethics. Two of the other coders guessed that the project related to attorney ethics, one thought it was an assessment of the quality of the information in the ads, and another surmised that the study compared the processing of audio and visual information.

resolve inter-rater disagreement by reviewing the disputed portion of the relevant ad together. Their joint work product formed the basis of the analysis herein.

Table 2 summarizes the levels of inter-rater agreement for coding associated with the content defined above. Each type of content was coded for the timestamp at which the content was first discussed in the text or audio ("start time") and for the duration of such discussion, in seconds. The columns for observed agreement refer to the proportion of advertisements upon which the coders agreed. Coding differences of two seconds or less were deemed "agreement" for purposes of Table 2. The number of advertisements used to calculate inter-rater reliability exceeds the number of unique ads because the original sample included duplicates.

TABLE 2. INTER-RATER AGREEMENT

	Start Time		Duration		
	Kappa Statistic	Observed Agreement	Kappa Statistic	Observed Agreement	N <sup>52</sup>
Adverse events	0.31	0.93	0.18	0.20	56
Frequency of adverse events	*	1.00	*	1.00	56
Benefits	0.57	0.70	0.49	0.64	56
Consult a doctor	0.62	0.80	0.61	0.79	56
Attorney identification	0.76	0.82	0.75	0.78	55

As Table 2 illustrates, the coders identified no advertisements disclosing the frequency with which adverse events occur. Because they were in 100% agreement as to that variable, no Kappa statistic could be calculated. All variables except the duration of adverse events resulted in a reasonable level of observed agreement.

Inter-rater reliability in Table 2 was generally higher for the start time of content than for the duration because the start time only required coders to identify a single point in time. Conversely, estimates of duration were less reliable because they required the coders to estimate the start and end points of an audio and/or text discussion. Coding the duration of an advertisement's discussion of adverse events proved persistently complex for the coders, and ultimately unreliable.<sup>53</sup>

<sup>&</sup>lt;sup>52</sup> The "N" for attorney identification (55) is lower because the coders were unable to open one of the files during the first round of coding.

<sup>53</sup> Discussions of adverse events typically occurred for a large proportion of the ad but would start and stop intermittently. This led to the accumulation of short timing discrepancies when the discussion started and stopped. Adding to the complexity, coders were instructed to include any audio or text discussion of adverse effects in their "duration" calculation, but the audio and text frequently diverged. Were one coder to identify a short text discussion that the other coder overlooked, it produced noticeable differences in results. In reviewing the coders' independent transcriptions of the text and audio relating to adverse events, timing differences appeared primarily attributable to minor discrepancies in the inclusion or exclusion of conditional clauses such as "if your loved one has died while wearing the pain patch." The coders, however, generally captured the advertisement's core discussion of adverse events in their transcription.

Kantar identified the advertising firm for almost all ads. Where Kantar could not identify the source of the ad, the advertising firm could be ascertained through a very close review of the advertisement. Nevertheless, two unique ads, which jointly represented 7% of the ad volume, did not disclose the name of the advertising firm or attorneys.

# III. RESULTS

#### A. REPRESENTATION OF DRUG INJURY ADVERTISEMENTS

Tables 3 and 4, below, summarize the representation of drug injury ads among all attorney ads. Because national advertising was excluded from the sample, the tables do not accurately represent the likely proportion of drug injury advertising among all ads. A separate dataset from Kantar suggests that the bulk of drug injury advertising volume is broadcast nationally.<sup>54</sup>

TABLE 3. UNIQUE DRUG INJURY ADS AMONG ALL ATTORNEY ADS<sup>55</sup>

(Unique Ads)	Boston	Atlanta	Both	Total
Drug & medical device ads	30	13	3	46
All ads	214	636	18	850
Percentage representation	14%	2%	17%	5%

TABLE 4. DRUG INJURY AD VOLUME AMONG ALL LOCAL ATTORNEY ADS<sup>56</sup>

(Units of Advertising) <sup>57</sup>	Boston	Atlanta	Both	Total
Drug & medical device ads	649	389	82	1120
All ads	13,265	53,003	319	66,587
Percentage representation	5%	1%	26%	2%

<sup>&</sup>lt;sup>54</sup> Dataset on file with the author.

55 Table 3 may somewhat underestimate the number of unique ads relating to drugs and medical devices. Duplicate ads relating to drug and medical devices were identified as part of the in-depth content analysis described in this Article. See supra Part II(B). However, other attorney ads were not scrutinized for duplication for this research and instead relied on the unique identifiers Kantar associated with each ad. Therefore, the count for "all ads" likely includes some duplicates.

<sup>&</sup>lt;sup>56</sup> The over-representation of drug/device ads broadcast in both markets reflects the methodology by which duplicate advertising was identified. For drug/device ads, identical advertising in both markets was identified through (1) matching unique identifies originating from Kantar, or (2) identical or near identical content coding, followed by a side-by-side review of the ad. Due to practical constraints, all other attorney ads were only identified as jointly broadcast using the unique identifiers originating from Kantar. Therefore, the second row in Table 4 likely understates the volume of "All Ads" broadcast in both media markets.

<sup>&</sup>lt;sup>57</sup> Kantar uses "units" to refer to the volume of advertising—the number of ads multiplied by the number of times the ad each ad was broadcast.

As Table 3 illustrates, the subsample of drug and medical device ads is somewhat small. Because the dataset consisted of a six-month sample for only two local media markets, results are not necessarily generalizable to other media markets or for advertising more generally. The sample is also somewhat dated and therefore may not reflect recent developments in advertising.<sup>58</sup>

# B. SOURCE AND SUBJECT MATTER OF ADVERTISING

Drug injury advertising originated from a relatively small number of firms. Sixteen firms sponsored advertising in the subsample. The ten firms listed in Table 5 were responsible for more than 98% of the advertising volume. The majority of these advertisers were headquartered in states other than the state in which the advertising was broadcast. The three most prolific advertisers generated 70% of the advertising volume.

TABLE 5. TOP TEN MOST PROLIFIC ADVERTISERS

Firm	Ad Volume
Becker Law Office (KY)	38%
2. Ferrer Poirot & Wansbrough (TX)	17%
3. Mark E Salomone Attorney (MA)	15%
4. Kenneth S Nugent Attorney (GA)	7%
5. Goldwater Law Firm (AZ)	5%
6. Cohen & Malad (IN)	5%
7. Goldberg Attorneys PC (AL)	4%
8. Gary Martin Hays & Associates (GA)	3%
9. James E Rolshouse Attorney (MN)	3%
10. Bander & Bander Attorneys (MA)	2%

Figure 1 illustrates the volume of advertising associated with different drugs. The subsample included advertisements regarding 11 different types of drugs. <sup>59</sup> However, almost all of the advertising volume (87%) was focused on three drug types: Yaz/Yasmin/Ocella, Reglan, and Fentanyl. The combined advertising volume for all other drugs was substantially lower than the ad volume for each of these three drug types.

<sup>&</sup>lt;sup>58</sup> There have also been changes in the law relating to failure to warn claims since 2009. *See* Pliva v. Mensing, 131 S.Ct. 2567, 2578-80 (2011) (limiting "failure to warn" claims against generic drug manufacturers under state law).

<sup>&</sup>lt;sup>59</sup> Certain drugs were commonly featured together, such as Yaz, Yazmin & Ocella (birth control pills), or Advil, Ketek, Motrin and others (all allegedly associated with Stevens Johnson Syndrome). Each grouping of drugs was treated as a "type."

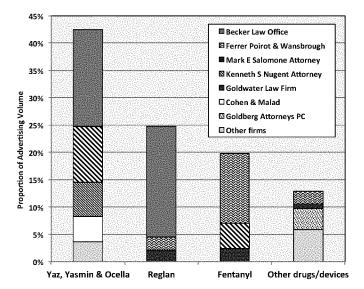


FIGURE 1. VOLUME OF ADVERTISING BY DRUG AND FIRM

No single firm had a monopoly on advertising for the high volume drugs. Indeed, eight different firms advertised for lawsuits involving Yaz. 60 As previously discussed, the multiplicity of firms advertising for litigation over each drug type reflects the procedural and substantive structure of drug injury claims.<sup>61</sup>

# C. MEDICAL INFORMATION IN THE ADVERTISING

All ads in the study sample discussed the adverse events associated with the drug/device in both the audio and on-screen text. By contrast, only about half (52%) of unique ads included some reference to the drug/device's benefits in either the audio or text. Only 39% of unique ads advised viewers to consult a doctor, and they did so only through on-screen text. None of the ads advised viewers to consult a doctor via the audio track.

Figure 2 illustrates the average number of words each unique ad devoted to three types of content: adverse events; the benefits or use of the drug/device; and advice to consult a doctor. 62

<sup>61</sup> See supra **p**. 2.

<sup>60</sup> Four of these firms are captured in the category "other firms."

<sup>&</sup>lt;sup>62</sup> Results for "benefits" and "consult a doctor" are skewed downward by the absence of such content in many of the ads. When averages were calculated based on the subset of ads containing some content in each category, the average word count for adverse events continues to dwarf other categories. The average words devoted to benefits among ads that discuss benefits is ten words of text, and twelve words of audio. Among ads that advise viewers to consult a doctor, an average of eleven words are devoted to that subject.

Spong 30

Adverse events

Benefits

Consult a doctor

FIGURE 2. AVERAGE WORDS BY TYPE OF MEDICAL CONTENT

These advertisements also spent much more time discussing adverse events than they spent describing benefits or advising viewers to consult a doctor, as illustrated in Figure 3. On average, the ads in the subsample lasted 28 seconds. Of these, the median ad devoted more than 20 seconds to discussing adverse events and 2 seconds to discussing benefits. The median ad did not advise viewers to consult a doctor.<sup>63</sup>

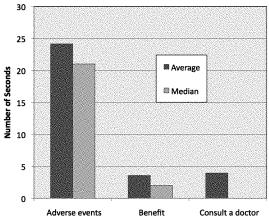


FIGURE 3. AVERAGE AND MEDIAN SECONDS DEVOTED TO MEDICAL TOPICS

The adverse events described in the advertisements were often presented in stark, alarming terms. Table 6 contains examples of some of the alarming text and audio that appeared at the start of each advertisement. Each row corresponds to a different advertisement. The advertisements typically began with words and phrases intended to capture viewers' attention, followed by lists of serious adverse events including death, heart attacks, and stroke.

<sup>&</sup>lt;sup>63</sup> Results displayed in Figure 8 include advertisements that did not reference drug benefits, or advise viewers to consult a doctor. The usefulness of Figure 8 is limited by the low inter-rater reliability for the calculated duration of adverse event discussions.

TABLE 6. TEXT AND AUDIO ABOUT ADVERSE EVENTS FROM START OF AD

Drug	Text	Audio
Yaz/ Yasmin/ Ocella	Attention Yaz, Yasmin, or Ocella users. Blood clots, pulmonary embolism, deep vein thrombosis, stroke, heart attack, gallbladder disease, you may have a claim for the harm caused.	If you have taken the popular birth control pills Yaz, Yasmin, or Ocella, and were hospitalized with blood clots, pulmonary embolisms, deep vein thrombosis, stroke, heart attack or gallbladder disease.
	Attention, important medical alert for birth control users including the product Yasmin, Yaz, and Ocella.	Attention, important medical alert for birth control users including the product Yasmin, Yaz, and Ocella.
Fentanyl	Warning: Consumer Alert. WARNINGS and RECALLS issued on pain killer patches containing Fentanyl.	The FDA has issued a second warning. After receiving continued reports of death.
	Attention. Pain Patch Warning. Certain Fentanyl pain patches have been recalled because of a defect that can case a fatal overdose. Pain Patch Warning. This is serious.	Attention. Certain fentanyl pain patches have been recalled because of a defect that can cause a fatal overdose. This is serious.
Reglan	Tardive Dyskensia Warning! Tardive Dyskenesia.	Tardive Dyskinesia is a disorder which causes involuntary tongue and facial movements.

Table 7, below, provides examples of content referring to the benefits or use of the drugs. <sup>64</sup> Discussions of a drug's function or benefits tended to be brief, and apparently served to help viewers identify whether they have taken the drug in the past. They did not counterbalance the prominent and stark descriptions of adverse events.

 $<sup>^{64}</sup>$  Because only half of advertisements made any reference to the benefits or use of the drug, the excerpts below do not correspond to the ads in Table 9.

TABLE 7. TEXT AND AUDIO REGARDING DRUG FUNCTION OR BENEFITS

Drug	Text	Audio
Yaz	None	Have you or a loved one taken the birth control pill Yaz or Yasmine?
Fentanyl	None	These patches are prescribed to treat chronic pain.
Reglan	Reglan treats acid reflux disease.	If you or a loved one was prescribed Reglan to treat acid reflux disease.

None of the ads explained the frequency with which individuals prescribed the drug or device experienced an adverse event. This prevented viewers from assessing the risk of the adverse events at issue. The frequency of adverse events would have been especially relevant to viewers taking Yaz, for whom the absolute risk of an adverse event was small.<sup>65</sup>

The advertisements also varied in terms of the information disclosed about relative risk 66—meaning, whether they disclosed which subgroups might be at a heightened risk of experiencing an adverse event. The coding instrument did not specifically instruct coders to identify content relating to relative risk. Statistical information in the ad, whether absolute or relative, would have been coded along with information about the frequency of adverse events. However, relative risk is periodically conveyed in non-quantitative terms, which the coders may have overlooked.

The incidental findings on disclosures about relative risk raise questions about how such risks are disclosed or omitted. For example, discussions of adverse events relating to the Fentanyl patch did not disclose the name of the manufacturer(s) associated with the recall, with the exception of two ads that showed a picture of the drug packaging bearing the manufacturer's name.<sup>67</sup> Such information would assist worried viewers in assessing their individual risk. Relative risk is also relevant in the case of Reglan, where the elderly, women, and diabetics are most at risk, and risk increases with prolonged use.<sup>68</sup> Interestingly, several Reglan ads advised that the message was "especially" for "children" and "elderly women," even though children are not among the subgroups the FDA identified.<sup>69</sup> One Reglan ad also alluded to the

<sup>&</sup>lt;sup>65</sup> The drug label for Yaz estimates the risk of blood clots associated with Yaz at 5-20 per 10,000 women taking the drug (compared with 5-13 per 10,000 for women taking other forms of oral contraceptives). See BAYER, supra note 13, at 8.

<sup>&</sup>lt;sup>66</sup> No such content was identified. The coders' transcriptions of content relating to adverse events and benefits revealed periodic references to information relating to relative risk, which are discussed herein. It is possible that relative risk was described qualitatively elsewhere in the ad and not detected by the coders. For that reason, discussions of relative risk factors is not discussed quantitatively.

<sup>&</sup>lt;sup>67</sup> Ads involving Fentanyl were subsequently reviewed by the author for information identifying the manufacturer of the recalled patch.

<sup>&</sup>lt;sup>68</sup> See ANI PHARM., REGLAN DRUG LABEL 8-9 (2011), available at http://www.accessdata.fda.gov/drugsatfda docs/label/2011/017854s058lbl.pdf

<sup>&</sup>lt;sup>69</sup> See id. The Reglan drug label provides: "It is not known if Reglan is safe and works in children." Id. at 14. The reference to children may reflect potential liability associated with off-label usage. See id.

risk associated with long-term use by referencing the drug's approval for "short term use only."  $^{70}$ 

# D. ADVICE TO CONSULT A DOCTOR

About 40% of unique ads and 56% of the ad volume included advice to consult a doctor before discontinuing medication. The warnings to consult a doctor appeared only in text; none occurred over the audio feed.<sup>71</sup>

Of those containing a disclaimer, the size, color and placement of information raise a question as to their effectiveness. As illustrated in Figures 4-7, the disclaimer tended to be in the smallest font on the screen. Screenshots of several such examples appear below.

FIGURE 4. SCREENSHOT OF REGLAN LAWSUIT



The FTC's "clear and conspicuous" standard for disclaimers in television advertising recommends that the information be presented in both audio and video portions of the ad to improve the consumer's processing of the information. See FTC, COMMISSION ENFORCEMENT POLICY STATEMENT IN REGARD TO CLEAR AND CONSPICUOUS DISCLOSURE IN TELEVISION ADVERTISING 1 (Oct. 21, 1970), available at http://www.ftc.gov/system/files/documents/public\_statements/288851/701021tvad-pr.pdf. The FTC's position is supported by social science research into knowledge, recall, and comprehension of information. See Mariea Grubbs Hoy & J. Craig Andrews, Adherence of Prime-Time Televised Advertising Disclosures to the "Clear and Conspicuous" Standard: 1990 Versus 2002, 23 J. Pub. Pol'y & Marketing 170, 172 (2004).

<sup>&</sup>lt;sup>70</sup> Id. at 4.

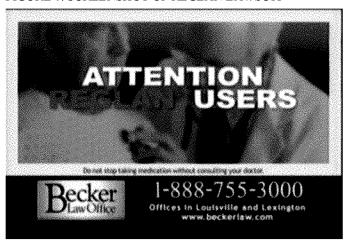
<sup>(2004).</sup>The FTC also recommends that the letters on the screen be "of 'sufficient size' so that it can be easily seen and read on all television sets, regardless of [screen size]." FTC, *supra* note 71, at 1.

# FIGURE 5. SCREENSHOT OF YAZ LAWSUIT

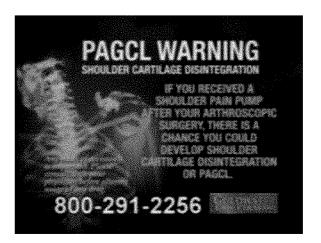
# ¥ Yasmin, Yaz and Ocella



# FIGURE 6. SCREENSHOT OF REGLAN LAWSUIT



## FIGURE 7. SCREENSHOT OF PAGCL LAWSUIT



Figures 4-7 are screenshots of ads containing a disclaimer to consult a doctor. Because the screenshots are small, with varying resolution, they may not accurately portray the actual legibility of the text. Nevertheless, the screenshots illustrate the small relative size of relevant disclaimers. In Figures 4 and 5, the disclaimer appears at the bottom, in the smallest font, within a much longer and unrelated disclaimer. The most visible disclaimer appears in Figure 6, but even that disclaimer is in the smallest font on the screen, competing with a picture and much larger text. The least legible disclaimer appears in Figure 7, in cursive, non-contrast font in front of a picture of a skeleton.<sup>73</sup>

# E. ADVERTISEMENTS FRAMED AS PUBLIC SERVICE ANNOUNCEMENTS

Eight of the unique ads, representing 20% of the ad volume, appear to be public service announcements. These ads were characterized by the phrases "FDA warning" "consumer alert" and/or "medical alert" at the outset of the ad (hereinafter "warning/alert ads"). <sup>74</sup>

Figures 8 and 9 are screenshots from the opening frame in two such advertisements. In Figure 8, the words "Warning: Consumer Alert!" occupies most of the screen. In Figure 9, the "important medical alert" is reinforced with a medical symbol in the background.

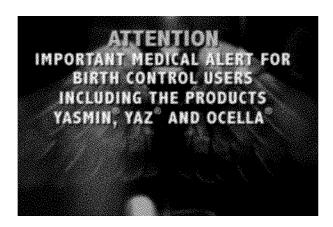
<sup>&</sup>lt;sup>73</sup> The relative importance of consulting a doctor is somewhat context specific. For example, the potential harm associated with the absence of advice to consult a doctor is limited in connection with this particular ad. The shoulder pain pump consists of a medical device delivering anesthetic post-surgery. Because the pump is a one-time treatment, it is unlikely that a patient would make decisions about the treatment without consulting a doctor.

<sup>&</sup>lt;sup>74</sup> Several ads used the word "warning" at the start, without reference to the FDA. If these ads did not also use the phrase "medical alert" or "consumer alert" at the start, they were not included in the "warning/alert" category, as they were less strongly associated with a failure to identify the attorney source of the ad early in the advertisement.

# FIGURE 8. SCREENSHOT OF FENTANYL ADVERTISEMENT



FIGURE 9. SCREENSHOT OF YASMIN, YAZ AND OCELLA ADVERTISEMENT



It is possible that the phraseology in these ads served to mimic local news broadcasts, which periodically contain segments about consumer information. By way of comparison, Figure 10 below consists of a screenshot of local news segments found on YouTube.

# FIGURE 10. CONSUMER ALERT NEWS SEGMENT FROM WENY TV NEWS<sup>75</sup>



Six of the warning/alert ads (representing 16% of the overall ad volume) did not disclose that the ad originated from an attorney within the first two seconds of the ad. These six ads disclosed their attorney source near the end of each ad—at the 20-second mark or later. The failure of the warning/alert ads to disclose their source at the outset sets them apart from most drug injury ads. Of the 36 unique ads that did not open with warning/alert language, 72% disclosed that the ad originated from an attorney within the first 2 seconds of the ad.

For example, one warning/alert ad involving Fentanyl devotes the first 18 seconds to the serious adverse effects associated with the drug. The ad opens with the text: "Warning: Consumer Alert" and "WARNINGS and RECALLS issued on pain killer patches containing fentanyl. SECOND WARNING FDA issues warnings in 2005 and 2007." "Millions of defective patches recalled!" The accompanying audio states, "The FDA has issued a second warning. After receiving continued reports of death, consumers have died after receiving continued reports of death." Briefly interspersed within the warnings about the "pain killer patch[es]" is a 2 second reference to the use of the drug ("These patches are prescribed to treat chronic pain."). The ad does not disclose that it originates from an attorney until the last five seconds, long after the viewers have already read or heard the words "death" and "killer" 8 times in the audio or text. The ad does not advise viewers to consult a doctor.

Figures 11 and 12 illustrate the aggregate differences in timing and sequencing of content between the warning/alert ads, and other drug injury ads. The x-axis depicts the number of seconds elapsed in the ad, ending at 30 seconds. The y-axis depicts the proportion of ads containing the specified content, among all ads containing content at that point in time.

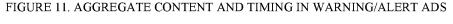
As Figure 11 illustrates, warning/alert ads all started with a discussion of the adverse events associated with the drug or device, lasting at least 10 seconds. Only one or two referenced an attorney within the first 3 seconds, and that percentage did not

<sup>&</sup>lt;sup>75</sup> Consumer Alert Segment (WENY TV News television broadcast Mar. 21, 2014), available at http://www.youtube.com/watch?v=Mi7wKrhPUr0 (describing a local fraud scheme).

<sup>&</sup>lt;sup>76</sup> Only a small number of ads extended past the thirty second mark. Data was analyzed in three second increments, which accounts for the jagged shape of the lines.

<sup>&</sup>lt;sup>77</sup> For example, the approximately 40% of ads that identify the attorney at the 23 second mark is calculated as a proportion of all ads at least 23 seconds long.

increase until the 20-second mark. These ads also did not advise viewers to consult a doctor, with the exception of one ad, which provides such advice only at the very end. Few such ads referenced the benefits of the drug/device, and those that did, did so only briefly.



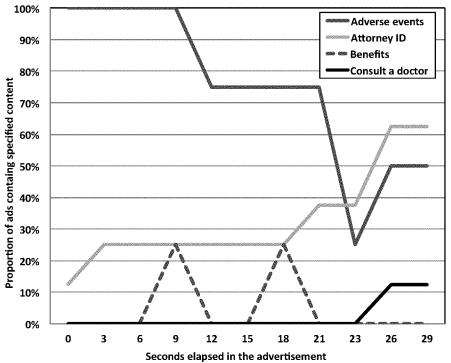


Figure 12 illustrates the timing and sequencing of content in all other drug injury ads. About 85% of them referenced the attorney source within the first five seconds, and most continued to refer to the attorney source throughout the advertisement. References to the benefits of the drug and advice to consult a doctor primarily occurred near the start of the ad. <sup>78</sup>

 $<sup>^{78}</sup>$  The competing information at the start of these ads could limit viewers' ability to process all of the information presented.

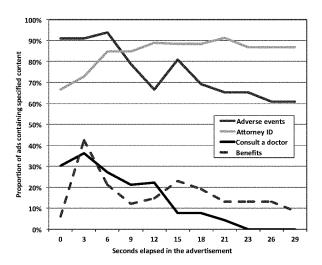
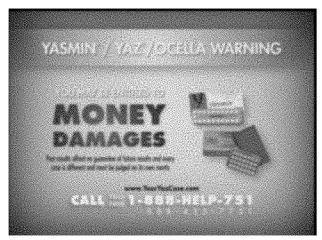


FIGURE 12. AGGREGATE CONTENT AND TIMING IN NON-WARNING/ALERT ADS

# F. FAILURE TO IDENTIFY ADVERTISING FIRM

Two unique ads did not disclose the identity of the advertising firm, which comprised 7% of the ad volume ("anonymous ads"). They disclosed only a web address at the end containing the name of the drug at issue. A screenshot of one such ad appears in Figure 13.





Four other unique ads in the subsample had the same uniform look and substantially similar content as the anonymous ads, although they identified different

sponsoring attorneys at the end. The uniformity of the ads suggested that they were mass produced by a third party entity, rather than commissioned by individual firms or attorneys.

A historical review of the websites revealed the names of the law firms associated with each in 2009.<sup>79</sup> Internet research also revealed the owner of the domain name at that time was a non-attorney marketing entity, which provides internet marketing, TV ads and call center services. One of the firms associated with the website confirmed that the marketing entity had produced the ad, and that several different law firms had been listed on the associated website over the years. The other law firm denied that the Yaz ad at issue failed to disclose the firm name.<sup>80</sup> The firm's denial suggests either that Kantar's copies of the ad were cut off prematurely<sup>81</sup> or that the firm was not informed of an abbreviated version of the ad ultimately broadcast.

# IV. DISCUSSION

Does the content described in the Results section comply with attorney ethics rules, and in particular, their prohibition on false or misleading advertising? Relatedly, would a state determination that certain content is false or misleading withstand First Amendment scrutiny? This section provides an overview of relevant jurisprudence, and then applies it to three types of content revealed in the Results section:

- (1) use of phrases such as "medical alert," "consumer alert," or "FDA warning" at the outset of the advertisement, without disclosing the attorney source until the end of the advertisement;
- (2) the failure to effectively disclose the attorney source; and
- (3) descriptions of the adverse events associated with the drug or device without disclosing the frequency of such adverse events, or advising viewers to consult a doctor before making medical decisions.

This section first explains how "false or misleading" advertising is defined under the First Amendment<sup>82</sup> and state ethics rules. It then examines whether some of the medical information and omissions in the ads might qualify as false or misleading.

#### A. DEFINING "FALSE OR MISLEADING" UNDER APPLICABLE LAW

All state ethics rules include a prohibition on false or misleading advertising, 83 defined under the Model Rules as advertising that "contains a material misrepresentation of fact or law, or omits a fact necessary to make the statement

<sup>&</sup>lt;sup>79</sup> Historical records of the Internet using the "Wayback Machine" provide only limited snapshots of the appearance of websites. The Internet Wayback Machine takes snapshots of webpages periodically. *See Internet Archive WaybackMachine*, INTERNET ARCHIVE, archive.org/web (last visited Mar. 25, 2015).

<sup>&</sup>lt;sup>80</sup> The firm provided a YouTube link to the ads that it claimed it ran during its Yaz campaign, which was 10 seconds longer than the ad in the Kantar dataset and identified the firm in the final 10 seconds.

<sup>81</sup> The Kantar dataset included three different copies of the ad at issue, none of which disclosed the name of the advertising firm. However, it is possible that the three copies originated from a single flawed file

<sup>82</sup> Considerable scholarly attention has been devoted to the history of Supreme Court jurisprudence on attorney advertising. See generally Terry Calvani et al., Attorney Advertising and Competition at the Bar, 41 VAND. L. REV. 761, 762-74 (1988); Jim Rossi & Mollie Weighner, Contemporary Studies Project: An Empirical Examination of the Iowa Bar's Approach to Regulating Lawyer Advertising, 77 IOWA L. REV. 179, 186-94 (1991). For the sake of brevity, the history is not recounted here.

<sup>83</sup> See Schaffzin, supra note 23, at 354.

considered as a whole not materially misleading." Laws in forty states follow, or closely resemble, the Model Rules. Those that depart from the rule tend to leave the definition of "false or misleading" intact, but furnish specific examples of content the state considers misleading. 66

State attorney advertising rules exist within the shadow of the First Amendment, which protects commercial speech.<sup>87</sup> but does not protect false or misleading speech.<sup>88</sup> As a practical matter, states cannot define "false or misleading" more broadly than under the First Amendment.<sup>89</sup> For that reason, the overview below focuses on First Amendment jurisprudence.

The Supreme Court has not rigidly defined speech that qualifies as false or misleading. Instead, the assessment of a false or misleading quality of content is complex and fact-specific. <sup>90</sup> A statement need not be factually inaccurate to be misleading. Rather, the Supreme Court considers the likely effect the content would have on a layperson and whether the ad omits information necessary to avoid a misunderstanding on the part of a layperson. For example, in *Zauderer*, the Supreme Court deemed the statement "[i]f there is no recovery, no legal fees are owed by our clients" factually accurate but misleading. <sup>91</sup> The statement was deceptive in suggesting

<sup>&</sup>lt;sup>84</sup> MODEL RULES OF PROF'L CONDUCT R. 7.1 (2011).

<sup>&</sup>lt;sup>85</sup> Forty states incorporate the language in the model rules, or very similar language. *See, e.g.*, Alaska Rules of Prof'l Conduct R. 7.1 (2009); Ark. Rules of Prof'l Conduct R. 7.1 (2014); Haw. Rules of Prof'l Conduct R. 7.1 (2013); Ky. Rules of Prof'l Conduct R. 7.1 (2013); Ky. Rules of Prof'l Conduct R. 3.130(7.15) (2009); Me. Rules of Prof'l Conduct R. 7.1 (2009); Md. Rules of Prof'l Conduct R. 7.1 (2015).

<sup>&</sup>lt;sup>86</sup> Many of these Model Rule states include additional examples of false or misleading advertising in their rule, such as statements "likely to create an unjustified expectation about results the lawyer can achieve" or that "compare the lawyer's services with other lawyer's services, unless the comparison can be factually substantiated." *See, e.g.*, KAN, RULES OF PROF'L CONDUCT R. 7.1(b)-(c) (2014); KY, RULES OF PROF'L CONDUCT R. 3.130(7.15)(b)-(c) (2009); LA, RULES OF PROF'L CONDUCT R. 7.1 (2014); MD, RULES OF PROF'L CONDUCT R. 7.1(b)-(c) (2015). Some states also depart from the Model Rules by defining "false or misleading" communications to include statements that cannot be substantiated or verified. *See e.g.*, D.C. RULES OF PROF'L CONDUCT R. 7.1 (2014); FLA, RULES OF PROF'L CONDUCT R. 4-7.2(c) (2014); IOWA RULES OF PROF'L CONDUCT R. 32:7.1 (2014); OHIO RULES OF PROF'L CONDUCT R. 7.1 (2014).

<sup>&</sup>lt;sup>87</sup> See Bates v. State Bar of Ariz., 433 U.S. 350, 363 (1977); see also Daniel Backer, Note, Choice of Law in Online Legal Ethics: Changing a Vague Standard for Attorney Advertising on the Internet, 70 FORDHAM L. REV. 2409, 2415 (2002); Daniel Callendar, Attorney Advertising and the Use of Dramatization in Television Advertisements, 9 UCLA ENT. L. REV. 89, 92-95 (2001).

<sup>&</sup>lt;sup>88</sup> See Bates, 433 U.S. at 383; see also Fla. Bar v. Went For It, Inc., 515 U.S. 618, 623-24 (1995); In re R.M.J., 455 U.S. 191, 201 (1982); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980); William G. Hyland Jr., Attorney Advertising and the Decline of the Legal Profession, 35 J. LEGAL PROF. 339, 358 (2011) ("[T]he Bates decision established two principles regarding lawyer advertising: first, the informational function of lawyer advertising is entitled to First Amendment protection. Second, states have the power to protect the public from harmful commercial speech, such as false or misleading advertising.").

<sup>&</sup>lt;sup>89</sup> Were a state to define "false or misleading" more broadly, then speech prohibited by the bar but protected under the First Amendment would be subject to the *Central Hudson* test, which has historically proved difficult for state bars to overcome. *See*, *e.g.*, Peel v. Att'y Registration & Disciplinary Comm'n of Ill., 496 U.S. 91, 115-16 (1990) (holding state prohibition on advertising references to certifications or specializations unconstitutional); Shapero v. Ky. Bar Ass'n, 486 U.S. 466, 479 (1988) (holding state prohibition on targeted direct mail advertising unconstitutional); *In re R.M.J.*, 455 U.S. at 201 (holding rule restricting advertising to ten categories of information unconstitutional).

<sup>&</sup>lt;sup>90</sup> Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 645 (1985) ("[D]istinguishing deceptive from nondeceptive advertising in virtually any field of commerce may require resolution of exceedingly complex and technical factual issues and the consideration of nice questions of semantics.").

<sup>&</sup>lt;sup>91</sup> *Id*. at 652.

that clients would not incur any out-of-pocket costs. 92 To avoid being misled, the layperson would have to understand the technical meaning of "fees" and the distinction between "fees" and "costs." The Supreme Court doubted that a layperson would have such background knowledge, and deemed the deceptive quality of the statement "self-evident."

The Supreme Court has also opined that context can alter whether a statement qualifies as false or misleading. In Peel, the Supreme Court observed that the statement that an attorney has been "certified" would not be misleading if the certifying entity applied rigorous certification standards. 95 It would however be misleading if the certifying agency accepts applicants indiscriminately or provides the certification to anyone willing to pay a price. 96 A statement in an advertisement can also be misleading by implication—for example, a fictional vignette where an insurance representative decides to settle a case after learning that the advertising attorney represents the plaintiff.<sup>97</sup> Although the advertisement did not overtly state that insurance representatives base settlement decisions on a plaintiff's choice of attorney, it implied as much. 98 A federal court deemed the implied message of the vignette misleading and outside the protection of the First Amendment.<sup>99</sup>

Following the Supreme Court, state ethics boards have examined both express and implied claims for a deceptive purpose. 100 State bars have deemed advertising misleading where it suggests that the advertisement originated from or is affiliated with a government entity or non-profit, through labels such as "Legal Helpline," "Injury Helpline," <sup>101</sup> "Public Service," <sup>102</sup> and "Workers Compensation Relief Center." Likewise, New Jersey deemed an attorney referral service that offered a

<sup>&</sup>lt;sup>92</sup> Id.

<sup>93</sup> *Id*.

<sup>&</sup>lt;sup>94</sup> See id. Where the misleading quality of the advertisement is not apparent, the Supreme Court expects some evidence of actual harm to support arguments that the advertisement is potentially misleading. See Peel, 496 U.S. at 101-04 (noting the absence of any evidence of actual harm where Supreme Court was unpersuaded by state's argument as to the potentially misleading nature of a statement); see also Ibanez v. Fla. Dept. of Bus. & Prof l Regulation, Bd. of Accountancy, 512 U.S. 136, 145 (1994) (finding state must proffer some evidence of deception, or more than the "possibility of deception in hypothetical cases"); Mason v. Fla. Bar, 208 F.3d 952, 957 (11th Cir. 2000) (finding "common sense" arguments insufficient to justify disclaimer requirement absent empirical evidence that public was misled).

95 Peel, 496 U.S. at 102.

<sup>&</sup>lt;sup>96</sup> For example, in *Peel*, the Supreme Court observed the question of whether or not a certification is misleading depends in part on the methodology used to certify the attorney. An identical statement about a certification could be non-misleading where the certifying agency imposes rigorous requirements, but misleading if the certifying agency accepts applicants indiscriminately or for anyone willing to pay a price.

<sup>97</sup> See Farrin v. Thigpen, 173 F. Supp. 2d 427, 437 (M.D.N.C. 2001).

<sup>98</sup> See id.

<sup>100</sup> See Kraft, Inc. v. FTC, 970 F.2d 311, 314 (7th Cir. 1992) (interpreting Zauderer to mean that implied claims can also be the basis of false or misleading speech outside the protection of the First Amendment).

<sup>101</sup> S.C. Bar Ethics Advisory Comm., Ethics Advisory Op. 13-05 (2013), 2013 WL 7196338, at \*1 (cautioning lawyers against using phrases such as "Legal Helpline" or "Injury Hotline" because they misleadingly suggest an affiliation with the state bar, a charity or the government).

Onn. Bar Assoc. Comm. on Prof'l Ethics, Informal Op. No. 01-03 (2001), 2001 WL 694581, at \*3 (characterizing referral service that described itself as "A Free Public Service" as misleading because it "could create a misleading perception on the part of the lay reader that ABC . . . [is a] nonprofit referral service[]").

State Bar of Cal. Standing Comm. on Prof'l Responsibility & Conduct, Formal Op. 2004-167 (2004), 2004 WL 3079032, at \*2 (deeming practice as misleading because it suggested that the firm itself

"free evaluation" misleading because it suggested that it matched attorneys to consumers based on their legal needs, rather than exclusive arrangements with advertising attorneys. 104

Under First Amendment jurisprudence<sup>105</sup> and the Model Rules,<sup>106</sup> a disclaimer may or may not cure an otherwise deceptive statement. In *Farrin v. Thigpen*, a federal court upheld a state court determination that a fictional vignette was misleading, notwithstanding a disclaimer stating "no specific results implied." The Court reasoned "[i]t would defeat the purpose of Rule 7.1 and other advertising regulations if the advertiser could employ deceptive and misleading methods so long as the ad included a disclaimer of what was portrayed." State bars characterize the practice of contradicting an overtly misleading statement through a disclaimer as having a "yes and no" quality that further confuses consumers. First Amendment jurisprudence also takes into account whether the disclaimer is effectively communicated through font, color and duration of appearance. <sup>110</sup>

State bar determinations that content violates its prohibition on false and misleading content can be challenged under the First Amendment. In such cases, courts will review the state bar's determination on a de novo basis to assess whether it is false and misleading under First Amendment jurisprudence. States must either persuade the court that the misleading quality of the advertisement is self-evident, States and Theorem 12 of the advertisement is self-evident, States and Theorem 22 of the advertisement is self-evident, States and Theorem 23 of the advertisement is self-evident, States and Theorem 24 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and Theorem 25 of the advertisement is self-evident, States and St

was an official government office, or that it awarded benefits rather than offering legal representation in seeking benefits).

<sup>&</sup>lt;sup>104</sup> N.J. Supreme Court Advisory Comm. on Att'y Adver., Internet Adver., Misleading Content, & Impermissible Referral Servs., Op. No. 43 5 (2011), available at 2011 WL 2691355.

<sup>&</sup>lt;sup>105</sup> See Farrin v. Thigpen, 173 F. Supp. 2d 427, 445 (M.D.N.C. 2001).

<sup>&</sup>lt;sup>106</sup> See MODEL RULES OF PROF'L CONDUCT R. 7.1 cmt. 3 (1983); see also N.C. State Bar, Adver. for Legal Emp't in Non-Practicing Areas, 2010 Formal Ethics Op. 6 (2011), 2011 WL 665760, at \*2 ("Previous ethics opinions have determined that an appropriate disclaimer may cure an otherwise misleading advertisement.").

<sup>107</sup> Farrin, 173 F. Supp. 2d at 445.

<sup>108</sup> Id

<sup>&</sup>lt;sup>109</sup> Pa. Bar Assoc. Comm. on Legal Ethics & Prof'l Responsibility, Informal Op. No. 93-124 (1993), 1993 WL 851228, at \*2 (citation omitted) (concluding that firm name containing the names of unaffiliated lawyers was not cured by accompanying disclaimer stating "individual practitioners, not a partnership"); *see also* N.J. Op. No. 43, *supra* note 104, at 9-10 (warning advertiser not to undermine a disclosure about the attorney selection process with contradictory statements, like telling users their zip code is needed because "the law varies from state to state" or requesting financial information in order to suggest that such information is used to select a suitable attorney).

<sup>&</sup>lt;sup>110</sup> See Farrin, 173 F. Supp. 2d at 445-46.

<sup>111</sup> The legal standard is more stringent when the attorney challenges a prophylactic rule that bars certain categories of content as inherently misleading or deceptive. Such prophylactic rules must withstand intermediate scrutiny under the First Amendment, as outlined in *Central Hudson*. Cent. Hudson Gas & Elec. Corp. v. Hub. Serv. Comm'n, 447 U.S. 557, 564 (1980); *see also* Fla. Bar v. Went For It, Inc., 515 U.S. 618, 624 (1995). Such rules rarely survive intermediate scrutiny. *See, e.g.*, Peel v. Att'y Registration & Disciplinary Comm'n of Ill., 496 U.S. 91, 115 (1990) (finding state prohibition on advertising references to certifications or specializations unconstitutional); Shapero v. Ky. Bar Ass'n, 486 U.S. 466, 479 (1988) (holding state prohibition on targeted direct mail advertising unconstitutional); *In re* R.M.J., 455 U.S. 191, 201 (1982) (finding rule restricting advertising to ten categories of information unconstitutional).

<sup>112</sup> See Peel, 496 U.S. at 108 ("Whether the inherent character of a statement places it beyond the protection of the First Amendment is a question of law over which Members of this Court should exercise *de novo* review."); see also Ibanez v. Fla. Dept. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 145 (1994) (finding that attorney successfully argued that a CPA designation in commercial communications was not misleading).

<sup>&</sup>lt;sup>113</sup> See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 653 (1985); see also Kraft, Inc. v. FTC, 970 F.2d 311, 321 (7th Cir. 1992) ("Zauderer teaches that consumer surveys are not compelled by the first amendment when the alleged deception although implied, is conspicuous.").

provide some evidence that consumers were actually mislead or harmed. 114

# B. ADVERTISEMENTS FRAMED AS PUBLIC SERVICE ANNOUNCEMENTS

Drug injury advertisements that masquerade as public service announcements would likely be considered misleading under state ethics rules.

Like a demand letter formatted as a summons, or an infomercial disguised as a news program, an advertisement mimicking the format of a public service announcement misleads the viewer about the purpose of the communication. An advertisement framed as a "consumer alert" or a "warning" suggests that its purpose is to inform or to warn, rather than to solicit business. Although the deception is less overt than the Florida advertising stating that it was "not an advertisement," <sup>120</sup> it nevertheless seeks to mislead. It suggests that the medical information provided is based on the viewer's medical interests, rather than whatever adverse event happens to form the basis of the advertiser's lawsuit of choice. <sup>121</sup> It also obscures the pecuniary

<sup>114</sup> See Ibanez, 512 U.S. at 145.

ABA Comm. on Prof'l Ethics & Grievances, Formal Op. 178 (1938).

<sup>116</sup> See Fla. Bar v. Doe, 634 So.2d 160, 161 (Fla. 1994).

<sup>117</sup> Id. at 162-63.

<sup>118</sup> Id. at 161.

<sup>119</sup> FTC, FREQUENTLY ASKED QUESTIONS: A GUIDE FOR SMALL BUSINESS, GENERAL ADVERTISING POLICIES (2008), available at 1998 WL 207800, at \*10; see also Press Release, FTC, FTC Seeks to Halt 10 Operators of Fake New Sites form Making Deceptive Claims About Acai Berry Weight Loss Products (Apr. 19, 2011), available at http://www.ftc.gov/news-events/press-releases/2011/04/ftc-seeks-halt-10-operators-fake-news-sites-making-deceptive (describing restraining orders filed in federal court to enjoin "fake news websites" that promoted acai berry weight-loss products).

<sup>120</sup> See Doe, 634 So.2d at 161.

<sup>121</sup> In this respect, the deception is structurally similar to a bankruptcy referral website that the New Jersey State Bar deemed misleading. The website "offer[ed] to connect visitors . . . with a bankruptcy attorney" by asking them to fill out information about their situation, including their zip code. See N.J. Op. No. 43, supra note 104, at 1. Unbeknownst to users, the website simply matched users to an attorney based on whichever law firm had paid for the exclusive right to receive referrals in that zip code. See id. The New Jersey State Bar deemed the use of the phrase "free evaluation" misleading, because it "connotes a nuanced, fact-specific consideration of the User's financial condition," rather than referral based on a paid arrangement. Id. at 10. Just as the New Jersey website might mislead a visitor to assume that the attorney produced is a curated match for his or her particular circumstances, a viewer of a "consumer alert" might mistakenly assume that the medical information presented represents a dire risk upon which they should base their decision-making.

<sup>&</sup>lt;sup>121</sup> In this respect, the deception is structurally similar to a bankruptcy referral website that the New Jersey State Bar deemed misleading. The website "offer[ed] to connect visitors . . . with a bankruptcy attorney" by asking them to fill out information about their situation, including their zip code. *See* N.J. Op.

motive behind the advertisement, <sup>122</sup> which would cue viewers to consider the information with greater skepticism.

The warning/alert language may also be misleading in that it suggests a non-profit or governmental affiliation. Like cases involving phrases such as "Legal Helpline," "Free Public Service" "123 or "Workers' Compensation Relief Center," 124 framing the advertisement as a "warning" suggests that it originates from a public health or other governmental authority. Ads that start by reciting FDA warnings are especially misleading in this regard because they suggest that the advertisement originates from the FDA. 125

All of the warning/alert ads eventually disclose that they originated from an attorney, and do so in prominent fashion. A strong argument could be made that consumers cannot be misled once it is later revealed that the ad originates from a law firm. On the other hand, including the firm's name at the end of the ad may not actually cure the misimpression. Like references to a "helpline" or "relief center," consumers may mistakenly assume that the law firm has been designated to administer claims for injured parties and award relief.

Alternatively, they might conclude that the advertisement consists of some sort of public service announcement sponsored by a law firm, and fail to scrutinize the adequacy of the medical information conveyed. Tellingly, when confronted with infomercials that pose as news or other independent programming, the FTC demands a clear disclaimer at the start of the advertisement stating "THE PROGRAM YOU ARE WATCHING IS A PAID ADVERTISEMENT FOR [NAME OF PRODUCT]." Such a disclaimer discloses the pecuniary motive of the advertiser up front, rather than after a viewer may have already reacted to the medical information.

From a social science standpoint, delayed disclosure of the source of the advertisement could lead viewers to be insufficiently skeptical of the medical information conveved at the start of the ad. Under the "persuasion knowledge model,"

No. 43, *supra* note 104, at 1. Unbeknownst to users, the website simply matched users to an attorney based on whichever law firm had paid for the exclusive right to receive referrals in that zip code. *See id.* The New Jersey State Bar deemed the use of the phrase "free evaluation" misleading, because it "connotes a nuanced, fact-specific consideration of the User's financial condition," rather than referral based on a paid arrangement. *Id.* at 10. Just as the New Jersey website might mislead a visitor to assume that the attorney produced is a curated match for his or her particular circumstances, a viewer of a "consumer alert" might mistakenly assume that the medical information presented represents a dire risk upon which they should base their decision-making.

<sup>&</sup>lt;sup>122</sup> See Conn. Bar Assoc. Comm. on Prof'l Ethics, Informal Op. No. 01-03 (2001), 2001 WL 694581, at \*3 (describing referral service as a "public service" misleading because it obscures the advertiser's "concealed financial interest").
<sup>123</sup> Id.

<sup>&</sup>lt;sup>124</sup> See State Bar of Cal. Standing Comm. on Prof'l Responsibility & Conduct, Formal Op. 2004-167 (2004), 2004 WL 3079032, at \*2.

<sup>&</sup>lt;sup>125</sup> Citing an FDA warning as authority for statements in an advertisement is not necessarily misleading where the purpose of the advertisement is otherwise apparent. In fact, Daniel Schaffzin argues that drug injury attorneys should be more transparent about the sources of their medical information by citing them in their advertisements. *See* Schaffzin, *supra* note 23, at 340.

<sup>126</sup> See FTC, FREQUENTLY ASKED QUESTIONS, supra note 119, at \*10. The Supreme Court has opined that state bars can require attorneys to correct potentially misleading advertising through a disclosure identifying the content as an advertisement. See Shapero v. Ky. Bar Ass'n, 486 U.S. 466, 477 (1988) (citing Bates v. State Bar of Ariz., 433 U.S. 350, 384 (1977); In re R.M.J., 455 U.S. 191, 206 n.20 (1982)); see also Terrence C. Mead, Writing the Law of Lawyer Advertising, 23 ARIZ. St. L.J. 191, 210 (1991) ("The Supreme Court, in various dicta discussing less restrictive alternatives to tested prohibitions, has suggested that lawyer advertising be labeled as such.").

consumers possess sophisticated marketing knowledge that allows them to disengage with a marketing message, draw inferences, or discount the information presented.<sup>12</sup> However, they must recognize a message as a "persuasive attempt" in order to activate this knowledge. 128 Upon recognizing the persuasive attempt, consumers experience a change of meaning that alters how they interpret the information presented. 129 When an ad appears to be a public service announcement and does not disclose its attorney source until the end, consumers may not experience that "change of meaning" until that time. 130 They will have already processed the medical information in the ad without applying their marketing-related skepticism. 131

To survive a First Amendment challenge to a state bar determination that such content is false or misleading, the state would need to persuade a court that such language is inherently misleading or that consumers have actually been misled. 132 Calling an advertisement a "consumer alert" or "medical alert" has an inherently misleading quality, because such labels are superfluous to the advertiser's message to prospective plaintiffs. Viewers already injured by a drug need not be "warned" or "alerted" of a potential injury. They have already suffered the injury. The sole purpose, therefore, of including such language is to deceive viewers as to the purpose of the message and the motives of the advertiser. That most warning/alert ads do not disclose the attorney source of the ad until the end of the advertising further supports the inference that the purpose of the warning/alert language is deceptive.

## C. FAILURE TO IDENTIFY THE ADVERTISING ATTORNEY

A failure to disclose the attorney source of the advertising violates Model Rule 7.2(c), which requires that the sponsoring firm or attorney be disclosed. 133 As previously noted, it is possible that the 7% of ads in the Kantar sample without such information represents a flaw in the data and that the ads were inadvertently cut off prematurely.

The factual dispute about whether the ads at issue contained identifying information raises a larger question about the extent to which attorneys control the content ultimately broadcast. Attorneys are making greater use of the sophisticated, data-driven marketing services available to other businesses.<sup>134</sup> These services can drastically reduce the cost of advertising to individual attorneys through economies of scale. A non-attorney third party marketing service can develop the content and distribute the ad. A small firm or solo practitioner can pay to have its name inserted into a pre-produced ad, or to have a website listed in the ad display the firm name. Indeed, existing technology already permits a television ad to refer to a website, which redirects the consumer to an attorney in that consumer's geographic location.<sup>135</sup> The

<sup>127</sup> See Elizabeth Cowley & Chris Barron, When Product Placement Goes Wrong: The Effects of Program Liking and Placement Prominence, 37 J. ADVERTISING 89, 90 (2008).

<sup>&</sup>lt;sup>128</sup> See id.

<sup>129</sup> *Id.* 

<sup>&</sup>lt;sup>130</sup> *Id.* at 91.

The extent to which this principle applies to drug injury advertising is unknown. It is also possible that repeated exposure to attorney advertising allows consumers to immediately identify all attorney advertising and apply this "change of meaning" at the start of the ad.

See supra note 94 and accompanying text.

<sup>&</sup>lt;sup>133</sup> See MODEL RULES OF PROF'L CONDUCT R. 7.2(c) (2011).

<sup>&</sup>lt;sup>134</sup> See, e.g., RELION GRP., http://www.reliongroup.com (last visited Mar. 25, 2015).

<sup>135</sup> See e.g., Change Content Depending on Visitor IP Address, GEOLIFY, http://geolify.com/displaycontent-on-website-based-on-visitor-ip/ (last visited Mar. 25, 2015). A variation of this business structure is

consumer would never know that the particular attorney did not exclusively sponsor the television ad or even that the website was not exclusively owned by the attorney.

Marketing companies make advertising accessible for smaller firms and solo practitioners that might otherwise be priced out of the advertising market. This trend could provide public benefits in the form of increased access to attorney representation. It might also bolster local advertising markets, allowing injured plaintiffs to choose a local attorney rather than a national firm advertising from another state. Innovative marketing models that reduce the cost of advertising may also boost the overall volume of advertising. Specialized marketing services also offer the potential for efficient production of very high quality advertising, reflecting best practices regarding consumer information.

At the same time, the presence of non-attorney marketing entities makes advertising more complex to regulate because such entities are beyond the reach of ethics boards. For example, the Relion Group is now a frequent source of attorney advertising. <sup>136</sup> The identities of law firms sponsoring Relion's advertising, if any, are not at all obvious from Relion's website or from Relion's YouTube ads. <sup>137</sup> Consequently, it would be challenging for state bars to enforce attorney advertising rules should the advertisements fail to comply with ethics rules. <sup>138</sup>

# D. OMISSION OF RISK INFORMATION

The ads in the sample almost uniformly focused exclusively on one type of medical information: the adverse medical events associated with the drug/device at issue. The adverse events are often described in very stark terms as fatal, life threatening or disfiguring. In doing so, the ads omit other relevant risk-related information that may be important to uninjured consumers watching the ad.

Consumers may, however, be inferring the other risk-related information from the ad and drawing problematic conclusions from those inferences. For example, without information on risk frequency, the stark, repeated and unqualified discussion of adverse events may lead viewers to believe that the adverse event is much more

described in a New Jersey advisory opinion. Although it did not involve television ads, visitors to an apparent attorney-client matching service for bankruptcy claims were told to enter information about their claim, including their zip code. In fact the website was a form of advertising, which simply matched the visitor to whichever attorney paid for exclusive rights to that zip code. See N.J. Op. No. 43, supra note 104, at 9-10; see also discussion supra note 109.

<sup>136</sup> See RELION GRP., supra note 134.

<sup>137</sup> A disclaimer at the conclusion of a Relion YouTube ad states "Relion Group is an advertising group that represents lawyers jointly advertising their services; it is not a law firm or a lawyer referral service." *See* Relion Group, *Xarelto Lawsuit*, YOUTUBE (Jan. 21, 2015), https://www.youtube.com/watch?v=W6CfVXChqao.

<sup>&</sup>lt;sup>138</sup> The involvement of non-attorney marketing entities raises questions about permissible attorney referral arrangements and unauthorized practice of law rules, which are beyond the scope of this study.

Lipkus, supra note 39, at 696.

likely than it actually is. 140 The absence of relative risk information may lead viewers in certain subgroups to believe they are at high risk of an adverse event, when in fact they face little to no risk of such an event. For example, when an ad involving a Fentanyl patch recall fails to disclosure the manufacturer of the recalled patch, a viewer using a patch from a different manufacturer may mistakenly believe that he or she is at high risk when in fact the viewer faces no such risk. The failure to advise viewers to consult a doctor may exacerbate the harm resulting from other omissions, such that viewers may assume there is no need to consult a doctor about discontinuing the drug if the risk of adverse events is as dire and likely as the ads suggest.

Model Rule 7.2 deems false or misleading any advertising that "omits a fact necessary to make the statement considered as a whole not materially misleading."<sup>141</sup> While the argument above supports a theoretical case that such an omission is false and misleading under the Model Rules, there is currently insufficient evidence to support such a conclusion under First Amendment jurisprudence.

The 1985 Supreme Court decision in Zauderer stands for the proposition that the misleading quality of a statement must be "self-evident" to withstand First Amendment scrutiny absent evidence that consumers were actually misled or harmed. 142 That case involved a drug injury ad about the Dalkon Shield medical device. 143 Although the Court concluded that a statement about fees was patently misleading, it assumed, based on a state bar stipulation, that the medical statements in the ad were accurate and informative. 144 Those medical statements were reasonably similar to current drug injury ads, in that they described the adverse events associated with the Dalkon Shield. 145 While the factual and regulatory context surrounding the Dalkon Shield are arguably quite different, <sup>146</sup> it would be hard to argue that the current omission of risk information is self-evident if the Supreme Court previously considered similar omissions unobjectionable.

Where the misleading quality of a statement is not self-evident, the bar would need to produce evidence that consumers were actually misled or harmed by the ad to withstand First Amendment scrutiny. 147 As previously discussed, empirical evidence of harm is thin, and has been associated with drug injury advertising generally, rather than specific misrepresentations or omissions in the ads. 148

<sup>140</sup> Social science research suggests that warnings in general "may create the impression that a product is more dangerous than it is in reality or may be more dangerous than an alternative that does not contain a warning." Stewart & Martin, supra note 29, at 3.

<sup>&</sup>lt;sup>141</sup> MODEL RULES OF PROF'L CONDUCT R. 7.2 (2011).

<sup>&</sup>lt;sup>142</sup> Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 652 (1985).

143 See id. at 626.

<sup>144</sup> See id. at 633, 639-40.

<sup>145</sup> The relevant medical statement is visible at the very start of the text of the ad and reads, "The Dalkon Shield Interuterine Device is alleged to have cause serious pelvic infections resulting in hospitalizations, tubal damage, infertility, and hysterectomies." See id. at 631.

<sup>&</sup>lt;sup>16</sup> At the time the device was introduced to the market, it was not subject to FDA authority and was never reviewed for safety or effectiveness. See Andrea Tone, Devices and Desires 277 (2001). The device was recalled several years prior to the ad's dissemination. See Zauderer, 471 U.S. at 630. Even if viewers of the ad inferred that the Dalkon Shield was very dangerous, it is not at all clear that such a risk inference would have been exaggerated. It caused 18 deaths and over 200,000 other adverse events. See TONE, supra, at 279. These factual distinctions would be relevant to a First Amendment analysis, as the Supreme Court has previously emphasized the central importance of context in evaluating whether a statement is false or misleading. See Peel v. Att'y Registration & Disciplinary Comm'n of Ill., 496 U.S. 91, 114 (1990).

<sup>&</sup>lt;sup>147</sup> See Peel, 496 U.S. at 101.

 $<sup>^{148}</sup>$  See supra pp. 2-3.

Moreover, a disciplinary approach to the omission of risk information—even if successful—may not produce much, if any improvement in the content of risk information. Because disciplinary rules represent a floor rather than a ceiling on attorney conduct, they cannot compel more than minimal corrective practices. A punitive approach sacrifices a norms-based approach. A norms-based approach would identify and encourage best practices in attorney advertising, where consumers are effectively informed in a way that promotes medical decision-making. As Lynn Mather argues, "professionalism in practice does not reside in each lone individual lawyer, but in the social community in which each lawyer practices." Mobilizing the plaintiff's bar to examine and address the issue may ultimately be more effective in changing advertising practices.

## V. RECOMMENDATIONS

#### A. STATE BAR APPROACHES

State ethics boards and other regulatory agencies have not grappled with the complexities of medical information in attorney advertising in any detectable way. This research did not uncover any examples of a state bar, state attorney general, private party or company bringing a claim against these advertisers for ethical breaches or consumer harm associated with the ads in recent decades. 153

In many respects, their inaction is understandable. As Fred Zacharias observed in a 2002 article documenting widespread non-compliance with ethical rules in *Yellow Pages* ads, <sup>154</sup> state bars face resource constraints that force them to choose the types of ethical violations they prosecute. <sup>155</sup> Chastened by adverse Supreme Court rulings in decades past, state bars may be leery of any action that might give rise to expensive First Amendment litigation. <sup>156</sup>

An absence of robust evidence about the effect of drug injury ads on consumers also complicates state bar action. State bars typically act based on complaints by

<sup>&</sup>lt;sup>149</sup> Lynn Mather, What Do Clients Want? What Do Lawyers Do?, 52 EMORY L.J. 1065, 1068 (2003).

<sup>150</sup> See id. at 1084.

<sup>151</sup> *Id.* at 1085.

<sup>&</sup>lt;sup>152</sup> See generally Zacharias, supra note 37.

<sup>153</sup> The FTC may be disinclined to act based on its previously stated preference for state agencies regulate any advertising within their jurisdiction. "How does the FTC decide what cases to bring? . . . FTC jurisdiction. Although the FTC has jurisdiction over ads for most products and services . . . [t]he FTC concentrates on national advertising and refers local matters to state, county or city agencies. . . . State or local consumer protection agencies or private groups such as the Better Business Bureau (BBB) often are in a better position to resolve disputes involving local businesses or local advertising." FTC, FREQUENTLY ASKED QUESTIONS, *supra* note 126, at \*2. Advertisers bring informal claims against other advertisers through the Advertising Self-Regulatory Council's National Advertising Division. A review of NAD Case Reports dating back to 1997 did not reveal any cases reports involving attorney advertisers. *See Case Reports*, ADVERTISING SELF-REG. COUNCIL, http://case-report.bbb.org/search/search.aspx?doctype=1&casetype=1 (last visited Mar. 25, 2015).

<sup>&</sup>lt;sup>154</sup> Fred Zacharias found that more than 30% of the 857 *Yellow Pages* advertisements he reviewed did not comply with California's detailed ethics rules regarding advertising. *See* Zacharias, *supra* note 37, at 985-86. He also found fewer than ten cases of attorney discipline in California that directly addressed advertising violations over a thirteen year period, which he found comparable to discipline rates in five other jurisdictions. *Id.* at 987-88. As a result, Zacharias concluded that state bars "seem to have made a conscious decision not to enforce advertising rules stringently." *Id.* at 996.

<sup>155</sup> Id. at 997-98.

 $<sup>^{156}</sup>$  Id. at 996, 1004 (noting a heightened level of awareness about the constitutionality of rules, and that state bars may prefer to spend their enforcement dollars on "less controversial violations").

aggrieved clients or competitors.<sup>157</sup> Here, competitors do not seem to be harmed by the misleading advertising. Indeed, advertisers may believe that noncompliance by competitors provides cover for their own questionable practices. Likewise, while aggrieved former clients might be motivated to complain about a former attorney, clients of the advertisers are not harmed by this advertising. Instead, it is non-client consumers, who may not be motivated to complain, or may not identify state bars as an avenue for complaints.<sup>158</sup>

State bars may find themselves in a difficult political position to the extent that they are perceived to be siding with pharmaceutical companies. Mass tort attorneys, who view their mission as consumer protection, bristle at the suggestion that their advertising poses public health risks. <sup>159</sup> Given their personal experience helping thousands of injured consumers, it seems unimaginable that their efforts to inform consumers of their legal rights would pose unintended harms. <sup>160</sup> Yet, the service that such ads play to injured consumers does not exclude the possibility of harm to viewers grappling with medical information never intended for them. An adverse event that affects 1% of consumers taking a drug will reach 99 uninjured viewers for every injured viewer.

Ultimately, drug injury advertising may be more similar to pharmaceutical advertising than drug injury advertisers care to admit. Pharmaceutical advertising helps to educate consumers that may benefit from a drug, just as it harms those needlessly prescribed the drug or insufficiently warned of its risks. <sup>161</sup> For that very reason, the FDA heavily regulates such advertising. <sup>162</sup> Drug injury advertising likewise demands careful study and scrutiny.

State bars could play several potentially useful roles in the factually complex realm of medical information in drug injury advertising. One might be floor-setting: addressing the most egregious practices of the day through advisory opinions, and ultimately disciplining those who fail to comply. <sup>163</sup> For example, state bars might

<sup>157</sup> Id. at 1002.

<sup>&</sup>lt;sup>158</sup> Advertising attorneys insist that they have received no complaints from consumers, and focus on the thousands of injured consumers they have helped.

<sup>&</sup>lt;sup>159</sup> References to the arguments from advertising lawyers are based on email correspondence and telephone discussions with advertising attorneys and drug injury litigators that were provided a draft of this study and an opportunity to respond or comment. At least one advertising firm requested anonymity. I therefore have not specifically identified the individual firms and attorneys.

<sup>&</sup>lt;sup>160</sup> One advertising attorney even described a client who continued taking the prescribed medication even after experiencing an adverse event.

<sup>161</sup> Ray Moynihan & David Henry, *The Fight Against Disease Mongering: Generating Knowledge for Action*, 3 PLoS Med. 425, 425 (2006) (describing the problem of disease mongering: "[T]he selling of sickness [by pharmaceutical companies] that widens the boundaries of illness and grows the markets for those who sell and deliver treatments"). Drug injury advertisements also have interesting parallels to "disease-mongering" pharmaceutical sponsored ads that promote a particular disease, without mentioning the specific drug at issue. Depending on the circumstances, such ads are subject to considerably less FDA oversight than direct-to-consumer pharmaceutical advertising. Barbara Mintzes, *Disease Mongering in Drug Promotion: Do Governments Have a Regulatory Role?*, 3 PLOS Med. 461, 461 (2006) (noting that the FDA has no authority over "disease awareness" advertisements unless they are "perceptually similar" to the branded ads, or the advertiser manufactures the only drug in its class).

<sup>&</sup>lt;sup>162</sup> See supra note 34 (discussing statutes and regulations governing drug advertisements).

<sup>&</sup>lt;sup>163</sup> State bars might be tempted to enact a prophylactic rule barring the appearance of certain types of content, such as the words "medical alert" at the start of an advertisement. Regardless of the efficacy of such a prohibition, prophylactic rules are subject to much more stringent constitutional scrutiny. For a prophylactic rule to survive First Amendment scrutiny, the state must demonstrate a "substantial governmental interest justifying the restriction" and "demonstrate that the restriction vindicates that interest through the least restrictive available means." Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 627 (1985). This standard is very demanding by design—the Supreme Court

opine that preceding or simultaneous disclosure of the firm's name or the fact that it is an advertisement would cure the misleading quality of phrases such as "medical alert" or "consumer alert."

State bars can also play a useful role by investing in identifying best practices based on medical expertise and empirical research about the provision of risk information, and disseminating the results to relevant advertisers. Thirdly, state bars might usefully serve as a convener for discussions among relevant constituents—such as mass tort attorneys, pharmaceutical companies, doctors and social scientists—on practical approaches for conveying medical information within the constraints of the advertising medium.

Best practices are unknown in the context of drug injury ads. However, drawing from social science research on best practices in risk communication, a potential framework for presenting additional risk information is described below.

## B. PROVIDING ADDITIONAL INFORMATION ABOUT RISK

What additional information might advertisers provide to mitigate the potential harm to consumers or even enhance their medical decision-making? The question is an empirical one that has not yet been applied to drug injury advertising. It is also context specific, as the particular risks posed by each drug vary. Any answer to the question must necessarily contend with the limited time and viewer attention available within a short television ad, and the ad's primary purpose to inform injured plaintiffs of the availability of a remedy and legal representation. Lipkus's white paper on best practices in risk communication offers a few options for conveying the most important risk-related information in a compact way. <sup>164</sup>

Central to an informed understanding of the risk posed by a drug is the likelihood of an adverse event. This information may be unknown or difficult to convey for some drugs. Absolute risk information for Reglan in particular would be difficult to convey because the likelihood of acquiring a movement disorder associated with the drug accumulates over time. In other cases, absolute risk is straightforward. For Yaz, the product label discloses an absolute risk of a blood clot to be in the range of 5-13 women out of 10,000. While this risk is higher than that posed by other oral contraceptives, Isa providing the quantitative risk information may promote a more measured and deliberative reaction by consumers.

Attorney advertising about fentanyl pain patches offers a contrasting case in risk disclosure. In 2008 and 2009, three fentanyl pain patch manufacturers issued recalls in connection with potentially fatal manufacturing defects. <sup>169</sup> The absolute risk of dying

<sup>165</sup> *Id.* at 697 ("Most recent conceptualizations of risk view risk as a combined function, often multiplicative, of the probability of loss and consequence of loss . . . .").

168 In the case of Yaz, for example, some studies have shown they do not present an elevated risk of blood clots compared to other forms of birth control, while others suggest that they double or triple the risk. *Id.* at 6.

expressly prefers for state bars to make individualized determinations regarding false and misleading advertisements. *Id.* at 649.

See Lipkus, supra note 39, at 707-09.

<sup>&</sup>lt;sup>166</sup> See Stewart & Martin, supra note 29, at 1 (noting that "long-term hazard information is difficult to quantify meaningfully").

See BAYER, supra note 13, at 8 fig.2.

Id. at 6.
 169 See Actavis Inc. Issues a Voluntary Recall of 18 Lots of Fentanyl Transdermal System 25 mcg/h,

 FDA (Oct. 21, 2010), http://www.fda.gov/Safety/Recalls/ucm230498.htm; Fentanyl Transdermal System Patch Recall, FDA (Aug. 8, 2008),

from a defective pain patch would probably not be a foremost concern for an uninjured consumer in possession of such a patch. Instead, consumers would almost certainly want to know the manufacturer of the defective patch, to enable them to identify whether they possessed a defective patch. In other words, the identity of the patch manufacturer is a form of relative risk information. However, none of the fentanyl advertisements disclosed the name of the manufacturers subject to a recall, with the exception of two ads that showed a picture of the drug packaging containing the manufacturer's name. <sup>170</sup> Disclosing the names of the manufacturers would have only required adding a sentence or less to the ads, but would have substantially improved the quality of the medical information in the ad.

Reglan offers another useful case study. Long-term use of the drug was associated with tardive dyskinesia, a disorder that caused involuntary body movement. Although the FDA warned against prescribing the drug for longer than 12 weeks, an FDA-commissioned study revealed that 13% of patients prescribed the drug received treatment for more than 90 days. A substantial portion of patients prescribed Reglan may have been prescribed the drug improperly. Drug injury ads for Reglan patients who have developed tardive dyskinesia therefore could serve an important public health function by alerting patients of the risk associated with long-term use.

At least one Reglan ad hinted at the cumulative nature of the risk, stating that the FDA only approved the drug for short-term use. <sup>173</sup> Had the ad, and others like it, communicated the relative risk more clearly— by noting that the disorder has been associated with long-term use or use for longer than 12 weeks—it could have helped high-risk but uninjured patients to consult their doctors and switch to another medication.

The final prong of Lipkus's taxonomy of risk information involves the pros and cons of preventative actions necessary to control/avert the harm. <sup>174</sup> The obvious inference from drug injury ads is that discontinuing the drug is the best way to avert potential harm. Such a conclusion neglects the health costs of discontinuing the drug. Because some consumers might benefit from discontinuing, while others may not, advertisers are poorly positioned to advise as to preventative actions. Satisfying the fourth prong of risk communication would therefore consist of effectively advising viewers that they should talk to their doctor before making any medical decisions.

Several reasonable objections could be made to the argument that advertisers should provide additional risk information. These objections are addressed below.

# Providing more medical information could confuse consumers about the purpose of the advertising.

It is possible that providing additional medical risk information would further obscure the purpose of the advertising and make it appear more similar to a public

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm1267 27.htm; *Pricara Recalls 25 mcg/hr Duragesic (Fentanyl Transdermal System) CII Pain Patches*, FDA (Feb. 12, 2008), http://www.fda.gov/safety/recalls/archiverecalls/2008/ucm112374.htm.

<sup>&</sup>lt;sup>170</sup> See supra note 66 (regarding methodological limitations as it related to the identification and coding of relative risk information).

<sup>&</sup>lt;sup>171</sup> See ANI PHARM., supra note 68, at 1.

<sup>172</sup> FDA, CTR. FOR DRUG EVALUATION & RESEARCH, MEMORANDUM: METOCLOPRAMIDE: DRUG USE DATA REVIEW 1 (2005), available at http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4167B1 02 11-FDA-Tab11-Review.pdf.

<sup>&</sup>lt;sup>173</sup> See ANI PHARM., supra note 68, at 1 (concerning discussion of relative risks in Reglan ads).

<sup>&</sup>lt;sup>174</sup> See Lipkus, supra note 39, at 695.

service announcement. The further an advertisement deviates from a clear message of solicitation, the harder it is for consumers to consider advertisers' pecuniary motives.

This concern might favor a different approach to disclosure, such as a very prominent disclaimer at the start of the ad to the effect that it is a "paid advertisement." Indeed, given the lack of empirical research on consumer reactions to this particular genre of advertising, this article does not argue that disclosing additional risk information is the only way to correct potential consumer confusion. Alternate approaches to disclosure, which may prove equally effective or may be more appealing to advertisers, are described in greater detail below.

To mitigate the potential risk of consumer confusion as to the advertiser's purpose, it would be important for advertisers to disclose their attorney source early in the commercial, to avoid warning/alert language, and to clearly advise consumers to consult a doctor before making medical decisions.

## Consumers won't understand statistics.

Recent social science research suggests that consumers understand statistical information presented in percentage form. <sup>175</sup> An FDA-sponsored study presented consumers with a simple table containing risk information about a drug. <sup>176</sup> For example, the table stated that 0.8% of people taking a drug experience a blood clot. <sup>177</sup> The large majority of participants in the study correctly answered questions about the statistical information in the table. <sup>178</sup>

Similarly, Lipkus proposed conveying risk in numerical form (such as a 5% chance or a 5 in 100 chance) rather than in qualitative terms such as "likely" or "unlikely." Lipkus argued that numbers are more precise and therefore lead to more accurate perceptions of risk. Consumers prefer numerical information when making important health decisions. Lipkus also cautioned against describing increases in risk in terms of multipliers ("if you are a smoker, your chance of getting a disease is 10 times higher than that of a nonsmoker") because it leads consumers to overestimate the increase in risk. 182

Although some of the risk-related information described above would be communicated as statistics, information about the relative risk need not be. Disclosing the circumstances in which a risk would or would not apply (such as the identity of the recalled drug manufacturer), does not require statistical information.

# Attorneys do not and should not provide medical information.

Advertising attorneys strenuously objected to the characterization that they are providing medical information and asserted that their advertisements are not intended for uninjured viewers. <sup>183</sup> Regardless of their intentions or their intended audience, the

<sup>&</sup>lt;sup>175</sup> See Lisa M. Schwartz et al., The Drug Facts Box: Providing Consumers with Simple Tabular Data on Drug Benefit and Harm, 27 MED. DECISION MAKING 655, 659 (2007).

<sup>176</sup> Id. at 655, 659.

<sup>&</sup>lt;sup>177</sup> *Id.* at 659. For the statistical information about the blood clot, 89% later identified the proportion of patients taking the drug that would experience a blood clot.

See Lipkus, supra note 39, at 701.

<sup>&</sup>lt;sup>180</sup> Id. at 699; see also Michael D. Slater et al., Developing and Assessing Alcohol Warning Content: Responses to Quantitative Information and Behavioral Recommendations in Warnings with Television Beer Advertisements, 17 J. Pub. Pol'y & Marketing 48, 55 (1998) (finding that quantitative information in a warning was "recalled substantially better than nonquantitative").

<sup>&</sup>lt;sup>181</sup> See Lipkus, supra note 39, at 699.

<sup>&</sup>lt;sup>182</sup> *Id.* at 701.

<sup>&</sup>lt;sup>183</sup> See *supra* note 159 regarding the source(s) of this information.

fact remains that the ads reach a wide swath of the public for whom the medical information is relevant.

This study did not reveal any examples of drug injury advertising that did not contain some form of medical information. Describing the adverse events associated with the drugs and devices is a necessary component of the advertising, as it identifies the harm that forms the basis of a drug injury claim. In such a context, it would therefore be prudent to consider how best to convey that information to both injured and uninjured consumers.

A related objection may be that attorneys lack the expertise to present additional risk-related information. However, attorneys bringing these lawsuits need to have a detailed knowledge of the medical risks at issue to litigate them. <sup>184</sup> The lawsuits themselves, and the related advertising, are often prompted by scientific studies or FDA warning or relabeling notices that include additional information about absolute and relative risk. <sup>185</sup> These sources could be reliably used for relevant medical content. <sup>186</sup> Where risk information is unknown, subject to considerable uncertainty or lengthy to convey, it would not be reasonable to expect advertisers to include such information.

# Attorney advertisers should not be expected to provide statistical information if the FDA does not require it of pharmaceutical advertisers.

FDA regulations do not require that direct-to-consumer drug advertisements describe the frequency of adverse events. <sup>187</sup> Instead, they require advertisers to provide a "fair balance" between benefit and risk information. <sup>188</sup>

As discussed in greater detail below, attorney advertisers certainly could follow an FDA-like approach to addressing consumer risk perceptions and include additional information about drug benefits. Given the relative paucity of benefit-related information in existing ads, altering their content to provide a "fair balance" would represent a substantial change.

By contrast, a risk-disclosure approach may be less intrusive and disruptive of the existing content in the ads. It takes only one sentence to explain that blood clots are estimated to affect between 5 and 13 women out of every 10,000 women taking Yaz. Further, disclosing the manufacturer of a recalled drug requires even fewer words. Some of the Reglan ads already vaguely referenced relative risks, such that doing so with greater precision would not substantially alter the overall content of the ad. For that reason, a risk-disclosure approach may be preferable to attorney advertisers over other potential approaches.

<sup>&</sup>lt;sup>184</sup> To the extent the attorneys responsible for the advertising are not those litigating the mass tort claims, the advertisers can consult the counsel to whom they refer their cases for additional factual context.

<sup>&</sup>lt;sup>185</sup> See Juurlink et al., supra note 15, at 1369-70 (finding that Internet hits for websites soliciting plaintiffs for lawsuits increased substantially following online publication of study identifying new risk associated with a drug).

<sup>&</sup>lt;sup>186</sup> For example, the revised Yaz labeling includes extensive statistical information about absolute and relative risk. *See* BAYER, *supra* note 13, at 6-8.

<sup>&</sup>lt;sup>187</sup> See 21 C.F.R. § 202.1(e)(1) (2014).

<sup>&</sup>lt;sup>188</sup> *Id.* § 202.1(e)(5)(ii).

# Additional disclaimers won't help the consumer and would burden the advertiser.

One advertising attorney observed that it is difficult to convey their intended message within a thirty-second ad in a way that consumers will understand. He argued that attorney advertising is already replete with disclaimers and that including additional information will further obscure the core message to consumers.

To the extent state bars recommend including additional medical information, they should consider compromising as to other disclaimers. For example, the ads in the sample often contained lengthy disclosures about the states in which their attorneys were licensed to practice law, presumably in order to address unauthorized practice of law rules. Many also included disclaimers about the likelihood that a case would be referred. The policy considerations associated with referrals and unauthorized practice of law are beyond the scope of this article. Nevertheless, it would be important for state bars to consider the overall burden of all disclaimers and advertising regulation in crafting a proposed approach.

Second, the risk information described here would likely be of questionable utility if it were to appear as a disclaimer at the bottom of a screen in small, illegible text. Although state bars may demand that a disclaimer be effective for otherwise misleading content, they cannot necessarily require that it be incorporated in the main audio or text of an ad, where it would be more likely to be understood by consumers. <sup>190</sup> A far better outcome would involve mass tort attorneys adopting best practices to convey high quality information in a streamlined way that does not encumber their overall message.

## C. OTHER DISCLOSURE-BASED APPROACHES

Alternative approaches to providing medical information may ultimately prove equally or more effective at helping uninjured consumers make medical decisions.

One such alternative could involve very prominent disclosures at the start of an advertisement about its purpose. The methodology for this study did not specifically code for disclaimers that the content is an "advertisement." However, at least a few of the ads included disclaimers near the end in small, capitalized text as part of a longer disclaimer. By contrast, a very prominent disclaimer at the very start of the ad, to the effect of "The following information is a paid advertisement from the law firms of []" or "This is paid attorney advertising for lawsuits against [manufacturer] involving [drug]" might prove effective. The standard FTC infomercial disclaimer in processing the information provided. To the extent consumers are more skeptical of all information in the advertising, they may be less likely to trust and therefore act upon

<sup>&</sup>lt;sup>189</sup> See *supra* note 159 regarding the source(s) of this information.

<sup>&</sup>lt;sup>190</sup> See, e.g., Pub. Citizen, Inc. v. La. Att'y Disciplinary Bd., 632 F.3d 212, 228 (5th Cir. 2011) (deeming minimum font size and duration requirements for disclaimers unduly burdensome under the First Amendment absent empirical evidence that they effectively prevented consumer deception).

<sup>&</sup>lt;sup>191</sup> The coding instrument did, however, include instructions to identify any content referencing attorneys, law firms, or lawsuits. *See infra* Table 3.

<sup>&</sup>lt;sup>192</sup> See infra Figures 10-11.

<sup>&</sup>lt;sup>193</sup> See Advertising FAQ's: A Guide for Small Business, FTC, http://www.ftc.gov/tips-advice/business-center/advertising-faqs-guide-small-business (last visited Mar. 25, 2015).

the medical information. A more skeptical consumer may be also be more likely to seek out other sources of information before making any decisions.

Another alternative could be for advertisers to provide additional information about a drug's benefits. Commentator Daniel Schaffzin advocated such an approach in proposing that FDA-like rules be applied to drug injury advertising. <sup>194</sup> In particular, the FDA requires that pharmaceutical advertisements discuss a drug's side effects in the same "scope, depth or detail" as its benefits. <sup>195</sup> An FDA-like approach to drug injury ads would require that manufacturers devote similar discussion to a drug's benefits as to the risks of an adverse event.

Research by social scientist Paul Slovic reveals a relationship between emotions and risk perceptions, which he calls the "affect heuristic." Slovic's research suggests that when people have negative feelings about a subject, they consequently view it as both high risk and low benefit. Conversely, positive feelings are associated with perceptions that a subject is low risk and high benefit. Slovic observes that providing additional information about a subject's benefits would increase positive feelings towards that subject, and consequently reduce perceptions that the subject is risky. Therefore, providing additional information about the benefits of a drug could serve to counteract consumer overestimation of risk.

Addressing consumer misperceptions through benefit information may nevertheless prove to be a blunt instrument. The risks associated with the drugs and devices at issue vary considerably. Devoting equal time to discussing both benefits and risks would likely reduce consumer perceptions of risk to an equal degree for all drugs. Likewise, using the affect heuristic to reduce risk perceptions would fail to address differences in relative risk. A viewer with an old prescription for a recalled fentanyl patch would have good cause to worry. That viewer would not be well-served by providing benefit information rather than information to identify whether that viewer's patch was recalled.

As previously noted, a "fair balance" approach may also prove burdensome to advertisers. Unduly burdensome disclaimer requirements are inconsistent with the First Amendment where they effectively rule out the ability of attorneys to convey their message. <sup>200</sup> Attorneys are ultimately selling a service to injured plaintiffs. Information about the drug is to some extent incidental, even as it currently occupies a large portion of the airtime and poses a potential public health risk. Requiring

<sup>&</sup>lt;sup>194</sup>The FDA regulation applicable to direct to consumer pharmaceutical drug advertising requires that manufacturers present a "fair balance" between discussions of a drug's effectiveness and discussions of its side effects and contraindications. *See* 21 C.F.R. § 202.1(5)(ii) (2014); Schaffzin, *supra* note 23, at 369-70.

<sup>&</sup>lt;sup>195</sup> The reverse application in this context would be that a discussion of adverse events should not be in greater depth than the benefits.

<sup>&</sup>lt;sup>196</sup> Paul Slovic, What's Fear Got To Do with It? It's Affect We Need to Worry About, 69 Mo. L. Rev. 971, 972 (2004).

<sup>&</sup>lt;sup>197</sup> Id. at 976.

<sup>198</sup> *Id.* 

<sup>199</sup> Id. at 977 ("This process, which we have called 'the affect heuristic' . . . suggests that, if a general affective view guides perceptions of risk and benefit, providing information about benefit should change perception of risk and vice-versa . . . . For example, information stating that benefit is high for a technology such as nuclear power would lead to more positive overall affect which would, in turn, decrease perceived risk . . . .").

risk . . . . ").

200 See Ibanez v. Fla. Dept. of Bus. & Prof'l Regulation, Bd. of Accountancy, 512 U.S. 136, 146 (1994) (noting that absent evidence of harm, a disclaimer was unjustified where it effectively rules out the advertiser's ability to convey otherwise non-misleading message); Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985) ("[U]njustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected speech.").

advertisers to reallocate a substantial portion of their airtime to an incidental aspect of their message could be potentially burdensome. Substantial attention to a drug's benefits may also further confuse viewers as to the purpose of the advertisement.

# VI. CONCLUSION

Drug injury advertising relating to drugs and medical devices has the potential to harm as well as improve public health. Its impact on consumers remains largely unknown. State bars have an important role to play in addressing misleading advertising practices, and identifying best practices for advertisers.