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# GIVING PERSONAL INJURY ATTORNEYS WHO RUN MISLEADING DRUG ADS A DOSE OF THEIR OWN MEDICINE

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*Like direct-to-consumer advertising of prescription drugs undertaken by pharmaceutical companies, client-seeking advertising sponsored by lawyers that highlights the dangers of such products may pose health risks to patients. Unlike the drug industry, whose advertising the federal government subjects to various restrictions, personal injury attorneys face essentially no oversight regarding campaigns that target therapeutic products. Lawyers enjoy no greater rights, however, when engaging in such commercial speech, so the U.S. Constitution would not stand in the way of crafting a sensible response. Nonetheless, because state bar authorities do not seem up to the task of doing so, and tort claims for either negligent misrepresentation or product disparagement would encounter serious obstacles as well, this Article recommends that the federal agency with the greatest stake in the matter—notwithstanding its conceded lack of regulatory jurisdiction over these speakers—take the lead in trying to define what types of attorney drug advertising cross the line. Only then might state officials and courts get the message that some client-seeking advertisements might well mislead patients in ways that threaten their health.*

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## I. INTRODUCTION

A couple of years ago, the *Washington Post* ran an op-ed piece with the provocative title “How Lawyers Scare People out of Taking Meds.”<sup>1</sup> The author, an executive vice president of the U.S. Chamber of Commerce, highlighted client-seeking advertisements related to the anticoagulant drug Xarelto<sup>®</sup> (rivaroxaban): “According to a recent report, at least 30 people suffered serious medical problems—such as strokes, heart attacks and pulmonary embolisms—because they stopped taking Xarelto without their doctors’ approval after seeing the commercial. Two of those patients died . . . . Two others were paralyzed.”<sup>2</sup> Although some readers undoubtedly would discount this opinion piece as simply another hatchet job by members of the business community against personal injury lawyers, might the possibility of such adverse outcomes merit serious consideration? The American Medical Association (“AMA”) has expressed its misgivings,<sup>3</sup> while the American Bar Association (“ABA”) has defended the

1. Lisa A. Rickard, Opinion, *How Lawyers Scare People out of Taking Meds*, WASH. POST, Aug. 7, 2016, at B3 (warning that such ads can “scare patients to death” and cause “panic”).

2. *Id.*; see also *id.* (“Ads like this often include extensive descriptions of serious adverse reactions, with little context about how common these side effects are. They routinely mimic public-service announcements, claiming to be a ‘medical alert’ or an ‘FDA warning.’ Most don’t disclose that the ad is for lawyers until the final few seconds.”); *id.* (“[L]eft unregulated, the ads are their own ‘public health risk,’ says Albert Einstein College of Medicine cardiologist Evan Levine. In a 2012 article, Levine profiled a patient who put himself at risk for a stroke after he stopped his blood-thinning medication [Pradaxa<sup>®</sup>] because of lawsuit commercials.”); *infra* note 40 (discussing the Xarelto study).

3. See Mary Gray, Opinion, *Lawyers’ TV Ads Can Be Hazardous to Our Health*, ST. LOUIS POST-DISPATCH, Nov. 11, 2016, at A17 (“Last month the American Medical Association passed a resolution calling for personal injury ads to include warnings that patients should not discontinue medications without seeking the advice of their physician. According to a statement by the AMA, ‘The onslaught of attorney ads has the potential to frighten patients . . . .’”).

practice,<sup>4</sup> even though the organized bar historically frowned upon all forms of attorney advertising.<sup>5</sup>

Part II of this Article considers the extent of the problem, describing aspects of client-seeking drug ads that may mislead patients and frighten some into discontinuing prescribed treatments. Insofar as prescription noncompliance may endanger patients' health, Part III canvasses a range of possible responses. Although state bar authorities offer a natural avenue for guarding against problematic drug advertisements sponsored by lawyers, such a solution encounters a variety of obstacles. Alternatively, victims of such advertising might look to the courts for relief, with either injured patients asserting negligent misrepresentation claims or manufacturers alleging product disparagement. Ultimately, this Article recommends that the U.S. Food and Drug Administration ("FDA") take the lead in defining the general sorts of ads that it finds most threatening to the public health, which then might help to trigger productive activity in state agencies and the courts.

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4. See *Health Industry Pushes Scrutiny of Lawsuit Advertisements*, CONG. Q. NEWS, July 6, 2017 ("Each state already prohibits legal advertising that is false or misleading—and the ABA says the [drug] lawsuit ads are neither. . . . ABA President Linda Klein said the bar's priority is 'ensuring that individuals who are injured or killed each year by taking prescribed medications, or their survivors, are able to obtain information about their legal rights and engage counsel to seek redress.'"); see also *id.* (contrasting this stance with the AMA's, and reporting that the chair of the House Judiciary Committee had sent a letter of concern to state bar authorities and recently held a hearing on the issue but did not anticipate proposing any legislation). A survey released by the U.S. Chamber of Commerce on the eve of the congressional hearing had found that "[o]ne in four Americans taking certain prescribed medicines say they would stop taking them immediately—without consulting their doctor—after seeing ads promoting lawsuits against the drugs' manufacturers." *Survey: Rx Drug Lawsuit Ads Could Scare Millions out of Taking Their Medications*, BUS. WIRE (June 22, 2017), <http://www.businesswire.com/news/home/20170622005703/en/Survey-Rx-Drug-Lawsuit-Ads-Scare-Millions>.

5. See *Bates v. State Bar of Ariz.*, 433 U.S. 350, 371 (1977); William E. Hornsby, Jr., *Ad Rules Infinitum: The Need for Alternatives to State-Based Ethics Governing Legal Services Marketing*, 36 U. RICH. L. REV. 49, 55–57 (2002); *id.* at 59 ("Lawyers had been taught for nearly seventy years that lawyer advertising was wrong.")

## II. DELINEATING THE SCOPE OF THE PROBLEM

Manufacturers of prescription drugs have broadcast direct-to-consumer advertising (“DTCA”) for more than two decades.<sup>6</sup> Although routinely subject to criticism,<sup>7</sup> this channel for promoting pharmaceuticals shows no signs of shrinking.<sup>8</sup> It did not take long for personal injury attorneys to follow suit,<sup>9</sup> prompted in large part by a string of high-profile drug withdrawals in the late 1990s.<sup>10</sup> Occasionally, academic commentators made passing references to the fact that plaintiffs’ lawyers embraced DTCA in an effort to reach persons possibly harmed by therapeutic products.<sup>11</sup>

One of my favorites aired during the summer of 2008, from a series of ads run by the firm Ferrer Poirot & Wansbrough on various cable channels, was styled as a “Medical Alert!” and did not focus on any particular drug

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6. See Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673, 674–78 (2007) (examining initial trends in this category after the FDA allowed television ads in 1997); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 141 (1997) (“1997 represented a watershed for pharmaceutical company promotions of prescription drugs directed to lay consumers. . . . [F]ifteen years earlier, these same companies engaged in essentially no [such] advertising . . .”).

7. See, e.g., Dominick L. Frosch et al., *A Decade of Controversy: Balancing Policy with Evidence in the Regulation of Prescription Drug Advertising*, 100 AM. J. PUB. HEALTH 24 (2010); see also Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 894–905 (2009) (summarizing these issues in connection with the debate over recognizing a DTCA exception to the learned intermediary doctrine in tort).

8. See Joanne Kaufman, *Think You’re Seeing More Drug Ads on TV? Well, You Are*, N.Y. TIMES, Dec. 25, 2017, at B4 (reporting that spending on TV drug ads had more than doubled over the last four years); John Russell, *FDA: Ads Carry Risk of Excessive Warnings; Agency Examines Side Effects of Too Much Information*, CHI. TRIB., Sept. 6, 2015, at D1 (reporting that companies spent \$4.5 billion advertising prescription drugs directly to consumers in 2014); see also Notice, *Consumer-Directed Promotion of Regulated Medical Products*; Public Hearing, 70 Fed. Reg. 54,054, 54,055–59 (Sept. 13, 2005) (summarizing milestones in the FDA’s supervision of the practice and some of the special regulatory issues that it presents).

9. See Michael Freedman, *New Techniques in Ambulance Chasing*, FORBES, Nov. 12, 2001, at 56; see also Mary Flood, *Drug Doubts Put Lawyers in Motion*, HOUS. CHRON., June 10, 2007, at Bus. 1 (reporting that plaintiffs’ attorneys use newspaper and television ads and “case-soliciting Web sites that already look like a pharmacy’s inventory, except that the drugs listed are alleged to cause harm,” adding that one firm’s phone number is “1-800-BAD-DRUG”); Joseph P. Fried, *Specialty Lawyers Gear up for Suits over Two Medications*, N.Y. TIMES, July 30, 2000, § 1, at 28 (“The advertising for clients who may have been hurt by Rezulin or Propulsid vividly illustrates how an aggressive segment of the legal profession sets the stage for mass-tort actions . . .”).

10. See Alastair J.J. Wood, Editorial, *The Safety of New Medicines: The Importance of Asking the Right Questions*, 281 JAMA 1753, 1753 (1999) (“[A] staggering 19.8 million patients (almost 10% of the US population) were estimated to have been exposed to these 5 drugs before their removal.”); Naomi Aoki, *A Question of Speed and Safety*, BOS. GLOBE, Nov. 28, 2001, at G1 (noting “the growing number of drugs that have been recalled in the past three years—nearly a dozen implicated in more than 1,000 deaths”).

11. See LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 567 (2d ed. 2007) (“What if plaintiffs’ lawyers and consumer activists had whipped up public hysteria about supposed risks with a product . . . ? What if such hysteria caused people to forego the use of valuable therapeutic agents . . . ?”); Lars Noah, *Platitudes About “Product Stewardship” in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. & TECH. L. REV. 359, 377 (2009) (“[P]laintiffs’ lawyers do their share of tacky (and potentially hazardous) direct advertising to users of such products, . . . [with] exaggerated risk information appearing in ads trolling for clients.”); Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 166 & n.204 (2005); Chen-Sen Wu, *Distributive Justice in Pharmaceutical Torts: Justice Where Justice Is Due?*, LAW & CONTEMP. PROBS., Fall 2006, at 207, 223–24.

but instead a class of serious side effects (Stevens Johnson syndrome or toxic epidermal necrolysis) allegedly associated with two dozen (mostly still marketed, and many OTC) pharmaceutical products.<sup>12</sup>

Notwithstanding its growing prevalence,<sup>13</sup> this practice has attracted little sustained attention.<sup>14</sup>

#### A. *The Extent and Nature of Lawyer Drug Advertising*

In 2015, Elizabeth Tippet published a scholarly article that sought to document the nature of drug-related promotional campaigns by personal injury lawyers. She selected cable television commercials that aired during the second half of 2009 in two major metropolitan markets, which left her with a sample of forty-six different spots for closer scrutiny.<sup>15</sup> The “results” section of her article featured numerous graphs and charts, and it also reproduced several screen shots from these ads.<sup>16</sup> Professor Tippet properly identified various limitations of her

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12. Noah, *supra* note 7, at 895 n.242 (“One of the firm’s latest TV spots (focusing on the risk of diabetes associated with the atypical antipsychotic drug Seroquel®) helpfully tells prospective clients not to discontinue treatment without first checking with their doctors.”).

13. See Rickard, *supra* note 1, at B3 (“In 2015, lawyers spent \$128 million to air 365,000 ads . . . seek[ing] plaintiffs for lawsuits against drug and medical-device manufactures. In the first six months of [2016], that number jumped to \$85 million, or about 14 percent of all lawyer advertising dollars, according to X Ante, which tracks mass tort litigation advertising.”). For a collection of recent client-seeking ads (not limited to pharmaceutical litigation, though searchable by particular products), see *Legal Services TV Commercials*, iSPOT.TV, <https://www.ispot.tv/browse/Y.L.0/business-and-legal/legal-services?view-all=true> (last visited Jan. 12, 2019).

14. To date, only a pair of scholarly articles have focused on the issue (both documenting, though from different vantage points, the nature of such advertising before recommending that state licensing boards address the problem). See Daniel M. Schaffzin, *Warning: Lawyer Advertising May Be Hazardous to Your Health! A Call to Fairly Balance Solicitation of Clients in Pharmaceutical Litigation*, 8 CHARLESTON L. REV. 319 (2013); Elizabeth Tippet, *Medical Advice from Lawyers: A Content Analysis of Advertising for Drug Injury Lawsuits*, 41 AM. J.L. & MED. 7 (2015). This Article will give sustained attention to their findings and recommendations as a prelude to suggesting a different tack.

15. See Tippet, *supra* note 14, at 14–15 (covering Atlanta and Boston from June 15, 2009 until January 4, 2010, but excluding any nationally broadcast advertisements). Further limiting the generalizability of her results, this group of forty-six ads related to only a handful of products subject to active tort litigation at that particular time. See *id.* at 19 (“The subsample included advertisements regarding 11 different types of drugs. However, almost all of the advertising volume (87%) was focused on three drug types: Yaz/Yasmin/Ocella, Reglan, and Fentanyl.” (footnote omitted)). A study of client-seeking drug advertising can hardly capture the full range of issues when it focuses only on a class of oral contraceptives containing drospirenone, an antiemetic used for gastrointestinal reflux, and a transdermal patch containing a powerful opioid analgesic subject to a partial recall for manufacturing defects. Cf. *id.* at 23, 42–43 (discussing some of the peculiar issues associated with each of these three product types). For a similar review of industry campaigns, which seemed to capture a more representative sample, see Dominick L. Frosch et al., *Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising*, 5 ANNALS FAM. MED. 6, 8 (2007).

16. See Tippet, *supra* note 14, at 18–31.

survey,<sup>17</sup> but she nonetheless extracted seemingly precise findings from this rather modest exercise.<sup>18</sup>

For instance, Professor Tippet found that just 39% of the advertisements that she reviewed had “advised viewers to consult a doctor, and they did so only through on-screen text.”<sup>19</sup> This apparent failing featured repeatedly in her later discussion,<sup>20</sup> but there may be less to it than first meets the eye. In later discussing an ad for a pain medication pump implanted after shoulder surgery, she conceded that a “first ask your physician” statement might have less importance in relation to certain therapeutic products but in that case simply because the device “is a one-time treatment.”<sup>21</sup> Unlike other implanted pumps, however, patients exercised no control over its use, which means that premature discontinuation would have necessitated a surgical explantation procedure. Moreover, Tippet included lawyer ads for over-the-counter (“OTC”) drugs,<sup>22</sup> which would have made a reminder to check with a doctor seemingly even less apt.<sup>23</sup> I do not mean to question the potential value of including such disclaimers where appropriate, but it strikes me as somewhat misleading to conclude from this small and varied sample that the majority of client-seeking ads have failed to do so.

Even if her study does not allow drawing any firm conclusions about the frequency of arguably misleading elements in lawyer drug ads, Professor Tippet offered other important findings: routine failures to explain the low probability of experiencing a frightening side effect,<sup>24</sup> almost no discussion of countervailing benefits,<sup>25</sup> and insufficient disclosures of the commercial interests underlying

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17. *See id.* at 18 (“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.”); *id.* at 19 (“[T]he subsample . . . 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.”).

18. *See id.* at 11 (“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.”).

19. *Id.* at 20; *see also id.* at 14 (“The inconspicuous nature of these disclaimers almost certainly rendered them ineffective.”); *id.* at 24 (elaborating).

20. *See, e.g., id.* at 39 (“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.”); *id.* at 43 (same).

21. *See id.* at 26 n.73; *see also id.* (“The relative importance of consulting a doctor is somewhat context specific.”).

22. *See id.* at 15; *id.* at 19 n.59 (grouping together OTC analgesics such as Advil<sup>®</sup> and Motrin<sup>®</sup>).

23. *Cf.* Noah, *supra* note 7, at 887 n.201 (“In some instances, physicians may even ‘prescribe’ OTC products.”); *id.* at 896 & n.249 (elaborating). *See generally* Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359 (2006).

24. *See* Tippet, *supra* note 14, at 17, 23; *id.* at 14 (“[N]one 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.”); *see also id.* at 21 (“The adverse events described in the advertisements were often presented in stark, alarming terms. . . . 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.”).

25. *See id.* at 20 (“[O]nly about half (52%) of unique ads included some reference to the drug/device’s benefits in either the audio or text.”); *id.* at 21 (“[T]he median ad devoted more than 20 seconds to discussing adverse events and 2 seconds to discussing benefits.”); *id.* at 22 (“Discussions of a drug’s function or benefits

the TV spot.<sup>26</sup> In addition, even though sponsoring attorneys sought to reach patients already adversely affected by a product,<sup>27</sup> Tippett usefully emphasized that, by virtue of the typically low probability of an adverse event, most viewers likely to take an interest when exposed to such ads would not have suffered the reported side effects.<sup>28</sup> She speculated that these uninjured patients could suffer harm if they relied on the broadcast messages when making decisions about continued use of a prescribed course of treatment.<sup>29</sup>

### B. *Endangering the Health of Frightened Viewers*

In 2014, Daniel Schaffzin published a scholarly article that paid greater attention to the potential adverse consequences of drug advertising by lawyers. First, though, he offered a handful of illustrations of such client-seeking efforts,<sup>30</sup> generalizing as follows:

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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.”)

26. *See id.* at 28 (finding that six of the ads failed to disclose until the end that they had originated from a lawyer); *id.* at 30–31 (noting that two other ads apparently failed to provide even such a belated disclosure, which would render them “anonymous”); *id.* at 26 (finding that 20% of the ads “appear to be public service announcements”); *id.* at 27 (“It is possible that the phraseology in these ads served to mimic local news broadcasts . . .”); *see also id.* at 28 (discussing at some length a fentanyl ad that “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” and “does not advise viewers to consult a doctor”).

27. *See id.* at 44 (“Advertising attorneys strenuously objected . . . and asserted that their advertisements are not intended for uninjured viewers.”); *see also id.* at 41 (“Mass tort attorneys, who view their mission as consumer protection, bristle at the suggestion that their advertising poses public health risks.”); *cf. id.* at 12 n.28 (noting the limited prospect of asserting “medical monitoring” claims on behalf of persons exposed but not yet injured). Later in her article, Tippett argued that ads masquerading as public services announcements (PSAs) are “inherently misleading” in part for the following reason: “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.” *Id.* at 37. This strikes me as somewhat unfair insofar as injured viewers may not have made the connection to their use of the identified product. Conversely, personal injury lawyers may want to reach nonusers as well because those viewers may end up serving as jurors.

28. *See id.* at 9–10 (“[T]he vast majority of interested viewers are not the injured consumers targeted by the advertisers, but uninjured consumers trying to decide whether to fill next month’s prescription for the drug.”); *id.* at 11–12 (“Although the ads are not necessarily intended for uninjured viewers taking the drug, the ads may nevertheless catch their attention.” (footnote omitted)); *id.* at 41 (“An adverse event that affects 1% of consumers taking a drug will reach 99 uninjured viewers for every injured viewer.”); *id.* at 44–45 (“[T]he fact remains that the ads reach a wide swath of the public for whom the medical information is relevant.”); *see also id.* at 8 (“[T]here is a lively market of lawyers competing over the airways for the attention of a limited number of injured consumers.”).

29. *See id.* at 9 (“[D]rug injury advertising may deter viewers from taking a drug by highlighting serious risks.”); *id.* at 12 (“Unlike consumers misled by pharmaceutical advertising, those misled by [overly alarming] 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.” (footnote omitted)); *id.* at 14 (suggesting that such ads “may lead consumers to overestimate the likelihood of adverse events associated with a drug and ultimately distort their decision-making”); *id.* at 35 n.121 (“[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.”).

30. *See Schaffzin, supra* note 14, at 334–41; *id.* at 335 (providing examples of “repetitive television commercials that utilize intimidating images, harsh phrases, and urgent tones that encourage the viewer to consider potential claims arising from ingestion of a drug product”); *see also id.* at 330 (“[I]t is common for lawyers to

[T]he marketing tactics they employ often toe the line between merely sensational and objectively misleading or confusing. In their thirty-second television spots and website headlines, lawyers authoritatively offer mere pieces of a bigger story, making broad claims about negative data, serious side effects, and adverse government action, without providing a proper context against which to weigh those claims. Although they are almost without exception not medically trained, legal advertisers seldom advise the target consumer to stay on the drug until they are able to talk to a doctor. . . . [They] regularly attempt to bury identifying or affiliation information in their promotional materials, designing materials to masquerade as unbiased news stories or purely informational resources devoted to patient support.<sup>31</sup>

Thus, Schaffzin's qualitative assessment generally aligned with the more detailed findings from the small survey that Professor Tippett published the following year.

Unlike Tippett, he then elaborated on the danger that uninjured but alarmed viewers might discontinue using their prescribed medications.<sup>32</sup> Professor Schaffzin summarized a pair of surveys, though both sponsored by entities with interests opposed to the personal injury bar. In 2003, the U.S. Chamber of Commerce's Institute for Legal Reform commissioned such a study, which found that one-quarter of the patients interviewed said that they would immediately stop taking a drug if they saw a client-seeking advertisement about it.<sup>33</sup> In 2007, the pharmaceutical giant Eli Lilly underwrote a survey of psychiatrists about non-compliance with prescriptions for antipsychotic drugs, which found that half of the respondents blamed client-seeking ads for their patients' frequent decisions to discontinue or reduce the prescribed dose.<sup>34</sup> Largely on the strength of these

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begin advertising for possible lawsuits within hours of a report that a marketed drug product has come to be associated with significant consumer injury or negative data.”).

31. *Id.* at 339–40 (footnotes omitted); *see also id.* at 340 n.77 (“Although most legal advertisements offer no source or reference information, those that do tend to bury the presentation of that information.”). Others have echoed such impressions. *See* Michelle Elaine Koski et al., *Patient Perception of Transvaginal Mesh and the Media*, 84 *UROLOGY* 575, 575 (2014) (“Advertisements are being widely used to recruit plaintiffs for mesh litigation. Some advertisements use inflammatory language and imag[es], whereas others contain information that is false or misleading.”).

32. *See* Schaffzin, *supra* note 14, at 342–46. At times, however, Schaffzin seemed equally concerned that patients actually injured by drugs might get duped. *See id.* at 341 (“[T]he messaging frequently omits any information about the prospect of referral or only does so in the fine print.”); *cf. id.* at 335 (“[T]he commercial outreach efforts [personal injury lawyers] are undertaking present significant risks of misleading and confusing the already vulnerable consumers they are attempting to recruit.”). He noted that relatively less sophisticated patients often get targeted. *See id.* at 336 (“To further seize on this vulnerable audience, drug lawyers place their ads to run during the day and late at night, when they are more likely to reach individuals who are low-income, out of work, infirmed, and elderly.” (footnote omitted)).

33. *See id.* at 342–43 (sample size was 301); *see also id.* at 328 n.29 (explaining the goals of the sponsoring organization); Tippett, *supra* note 14, at 10 (“The other limited research to date has been sponsored by partisan groups.”). *See generally* Alyssa Katz, *The Chamber in the Chambers: The Making of a Big-Business Judicial Money Machine*, 67 *DEPAUL L. REV.* 319 (2018). Another such survey released by this organization in 2017 generated similar results. *See supra* note 4.

34. *See* Schaffzin, *supra* note 14, at 343 (sample size was 402); *see also* John Russell, *Mailing Aims to Reassure Psychiatrists; Eli Lilly Hires Firm to Soothe Legal Concerns*, *INDIANAPOLIS STAR*, Dec. 8, 2007, available at 2007 WLNR 27738929 (discussing this survey). Eli Lilly manufactures the blockbuster drug Zyprexa®



two fairly small studies (eliciting, in turn, nothing more concrete than the intentions or suspicions of those interviewed), Schaffzin concluded that the “survey data offer support for the broad premise that histrionic ads for pharmaceutical litigation can pose risks to patient safety.”<sup>35</sup>

In addition, he discussed at length one cardiologist’s blog post about a patient who had discontinued taking his prescribed anticoagulant (Pradaxa<sup>®</sup>) after watching a client-seeking ad.<sup>36</sup> A powerful anecdote but little more than that.<sup>37</sup> Schaffzin made no effort to relate this possibility to the research literature about the causes and consequences of patient noncompliance, though he did speculate that frightening messages about therapeutic products also might undermine a patient’s confidence in the prescribing physician.<sup>38</sup> A small study published in 2016, which got highlighted in the *Washington Post* piece discussed at the outset,<sup>39</sup> offered stronger evidence that attorney ads could cause discontinuation of prescribed medications in ways that endangered patient health.<sup>40</sup>

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(olanzapine). See Jeff Swiatek, *Eli Lilly Acts to Counter Law Firms’ Ads Seeking Participants in Drug Suit*, INDIANAPOLIS STAR, Oct. 14, 2004, available at 2004 WLNR 12369143 (reporting that the company had asked personal injury lawyers to “tone down” their ads and had sent letters to physicians in an effort to reassure them about continued use of this atypical antipsychotic).

35. Schaffzin, *supra* note 14, at 344.

36. See *id.* at 344–45 (quoting Evan Levine, *Your Medication Can Kill You: Call Your Lawyer!*, LEFTIST REV., May 19, 2012); see also *id.* at 345–46 (quoting a prominent personal injury attorney expressing similar concerns).

37. See *id.* at 342 (conceding the anecdotal nature of the evidence); cf. *id.* at 368 (crediting “the growing body of anecdotal evidence showing the adverse patient impact caused by advertising for pharmaceutical litigation”). In contrast, Professor Tippet largely dismissed this evidence as unhelpful. See Tippet, *supra* note 14, at 11 (“While these anecdotal accounts and partisan research suggest the need for rigorous empirical research on the question, they are no substitute for such evidence.”); *id.* at 48 (concluding that the “impact on consumers remains largely unknown”). Then again, one also could dismiss her small sample as representing little more than a string of anecdotes, which hardly justifies the effort to derive apparently precise conclusions about the nature of these ads. Cf. Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 93 n.13 (2014) (offering an “unapologetically qualitative survey” about agency behavior as an alternative to the “seemingly tone-deaf empirical assessment” of others).

38. See Schaffzin, *supra* note 14, at 368 (fearing that a worried viewer “may also now have broader doubts about the discretion of her doctor, who decided to prescribe a ‘dangerous’ medication to her in the first place”); see also Noah, *supra* note 6, at 157 (“[W]arnings that contradict information supplied by the physician will undermine the patient’s trust in the physician’s judgment.”). If that happened, then serious conditions might go entirely untreated for extended periods of time.

39. See *supra* note 2 and accompanying text.

40. See Paul Burton & W. Frank Peacock, *A MedWatch Review of Reported Events in Patients Who Discontinued Rivaroxaban (XARELTO) Therapy in Response to Legal Advertising*, 2 HEARTRHYTHM CASE REP. 248, 248–49 (2016) (discussing thirty-one reports received by the FDA from health care professionals about patients who suffered serious injuries, including numerous strokes and two deaths, after abruptly stopping the prescribed use of this anticoagulant allegedly because of watching client-seeking advertisements that discussed the drug). The authors properly disclosed their close linkages with Janssen Pharmaceuticals (a unit of Johnson & Johnson), which sells Xarelto, see *id.* at 248, and they conceded numerous limitations to their review, including an inability to verify the information supplied in these case reports, see *id.* at 248–49; see also Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 402 (2002) (explaining that “one can understand the publication of [such] case reports as hypothesis-generating rather than hypothesis-testing”).

Wholly apart from the impact of such client-seeking efforts, nonadherence to prescribed medications represents a serious public health problem.<sup>41</sup> Not surprisingly, patients' concerns about side effects often explain such failures to follow their doctors' orders.<sup>42</sup> Insofar as client-seeking ads emphasize the most worrisome potential risks associated with prescription drugs and perhaps exaggerate their likelihood, they may well contribute to patterns of nonadherence.<sup>43</sup> Alternatively, ads might cause imagined side effects, triggering what amounts to a negative placebo response.<sup>44</sup> If patients cease using drugs prescribed to treat serious conditions, then their health may suffer, as evidently happened in the case of Xarelto.<sup>45</sup> Even if patients do not need to continue using a particular drug, quitting cold turkey and without physician supervision can pose dangers.<sup>46</sup>

41. See Lars Osterberg & Terrence Blaschke, *Adherence to Medication*, 353 NEW ENG. J. MED. 487, 488 (2005) ("Poor adherence to medication regimens accounts for substantial worsening of disease, death, and increased health care costs [including approximately \$100 billion annually for hospital admissions] in the United States."); Meera Viswanathan et al., *Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States: A Systematic Review*, 157 ANNALS INTERNAL MED. 785, 785 (2012) (summarizing the scope and serious consequences of prescription nonadherence); Andrew Pollack, *Drug Makers Nag Patients to Stay the Course*, N.Y. TIMES, Mar. 11, 2006, at C1 ("[M]any studies show[] that failure to take medicines as prescribed can cause patients to develop more serious and costly complications later.").

42. See Steven E. Nissen, Editorial, *Statin Denial: An Internet-Driven Cult with Deadly Consequences*, 167 ANNALS INTERNAL MED. 281, 281 (2017) (bemoaning the negative consequences of misinformation circulating about adverse effects associated with highly effective cholesterol-lowering drugs); Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. TIMES, Apr. 18, 2017, at D7 (calling "fear of side effects a common deterrent to adherence"); Amy Dockser Marcus, *The Real Drug Problem: Forgetting to Take Them*, WALL ST. J., Oct. 21, 2003, at D1 ("[T]he major reason [for nonadherence] appears to be a fear of side effects.").

43. See Beth Musgrave, *Tort Advertisements Worry Some Health Advocates*, SUN HERALD (Biloxi, Miss.), Mar. 21, 2004, at A1, available at 2004 WLNR 19186564 ("Mental health advocates want Mississippi television stations to quit airing an advertisement [related to the antipsychotic drugs Risperdal and Zyprexa] that has prompted some mentally ill patients to stop taking their medications."); cf. Noah, *supra* note 6, at 170 (explaining that "providing information that contradicts the physicians' advice to the patient or unnecessarily alarms the patient" may cause "noncompliance with the prescribed therapy"); Noah, *supra* note 7, at 898 n.260 ("Extensive warnings conveyed directly by pharmaceutical manufacturers might make patients . . . discontinue necessary drug therapies because of undue anxiety about the reported side effects that the physician felt did not deserve mention or emphasis in a particular case . . .").

44. Cf. Arthur J. Barsky et al., *Nonspecific Medication Side Effects and the Nocebo Phenomenon*, 287 JAMA 622, 624 (2002) ("Patients who expect distressing side effects before taking a medication are more likely to develop them.").

45. See *supra* note 40 and accompanying text; see also Flood, *supra* note 9, at 1 (reporting that the manufacturer of the diabetes drug Avandia<sup>®</sup> expressed concern that "lawyer ads could frighten patients into discontinuing their medicine, which could endanger their health"). By comparison with some of the client-seeking ads for Xarelto, the manufacturer's DTCA included the following statement (among a litany of other risk information): "Like all blood thinners, don't stop taking Xarelto without talking to your doctor as this may increase your risk of a blood clot or stroke." *Xarelto TV Commercial, 'High Risk' Featuring Jerry West*, iSPOT.TV, [https://www.ispot.tv/ad/ARh\\_/xarelto-high-risk-of-stroke-featuring-jerry-west](https://www.ispot.tv/ad/ARh_/xarelto-high-risk-of-stroke-featuring-jerry-west) (0:43-0:49) (last visited Jan. 12, 2019).

46. See Ranit Mishori, *Prescribing Drugs Is Good. So Is Deprescribing*, WASH. POST, Jan. 31, 2017, at E1 ("Deprescribing is its own process, requiring extreme caution and a certain skill on the part of the physician. . . . [M]any medications (for example, anti-depression medications, some high blood pressure drugs and steroids) need to be stopped gradually because stopping abruptly can be dangerous."); see also Benedict Carey & Robert Gebeloff, *The Murky Perils of Quitting Antidepressants After Years of Use*, N.Y. TIMES, Apr. 8, 2018, at A1 (discussing the difficulties that some patients encounter when trying to taper off long-term use of antidepressants).

Lastly, attorney advertising may adversely impact the prescribing decisions of physicians. Already unduly influenced by advertising (though of the type designed to promote rather than discourage use), health care professionals may overreact when presented with risk information about pharmaceuticals,<sup>47</sup> and having it delivered by lawyers might make it seem even more worrisome.<sup>48</sup> For a variety of reasons, then, client-seeking campaigns undertaken by personal injury attorneys that relate to therapeutic products may pose genuine public health concerns.

### III. ASSESSING POSSIBLE RESPONSES

Although Professors Tippet and Schaffzin ably described, in turn, the nature and possible consequences of drug-related advertising by lawyers, they had rather less to offer by way of useful prescriptions for addressing this problem. Both of them favored a response by state disciplinary authorities, even while recognizing the practical and constitutional obstacles confronted by such bodies.<sup>49</sup> Neither one of these commentators, however, discussed the possibility of tort recoveries for persons harmed by such advertising;<sup>50</sup> whether framed as negligent misrepresentation (and perhaps emotional distress) claims brought on behalf of patients or product disparagement claims asserted by the sellers of targeted products, such private policing of the airwaves also would confront some practical and constitutional constraints. After evaluating these distinctive options for responding to broadcasts of misleading risk information about therapeutic

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47. See LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 813 (4th ed. 2017) (“There is a danger that physicians may alter their prescribing decisions in response to warnings about trivial drug risks . . . . Even if physicians are not misled . . . , they may nonetheless avoid using perfectly safe and effective therapeutic agents for fear of malpractice liability if they disregard a warning.”); Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 455–56 (2002); see also *id.* at 431–33 (discussing the excessive influence of promotional messages on prescribing behavior); Brady Dennis, *Antidepressant Warnings May Have Backfired*, WASH. POST, June 19, 2014, at A4 (reporting that publicity over the risk of suicidality dramatically reduced prescribing rates and increased the number of suicides from untreated depression).

48. See Wu, *supra* note 11, at 225 (“Physicians wary of legal problems might avoid giving a potentially litigation prone drug . . . .”); *id.* at 225 n.93 (“The 2003 Harris Poll found that forty-three percent of physicians did not prescribe what they regarded as a clinically indicated drug due to worries that the medication might become embroiled in litigation.”); see also Rita Rubin, *IUDs Rarely Used Because of Doctors’ Perceptions, Study Says*, USA TODAY, Jan. 31, 2002, at 11D (“16% of respondents agreed that providing IUDs [intrauterine devices for contraception] would open them up to lawsuits.”).

49. See Schaffzin, *supra* note 14, at 346–53, 371 (discussing only the constitutional obstacles); Tippet, *supra* note 14, at 31–41 (discussing both the constitutional and practical obstacles); *id.* at 13 (finding “no ethics cases involving drug injury advertisements”); see also *id.* at 38 (adding that “non-attorney marketing entities . . . are beyond the reach of ethics boards”). See generally Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 186 (2004) (“[S]tate boards have done a notoriously poor job of monitoring and disciplining their own.”); *id.* at 186–87 n.161 (citing scholars who “have lodged [such] complaints against the supervision of lawyers by state boards”).

50. Cf. Schaffzin, *supra* note 14, at 371–72 (concluding with a joke from a blog post that imagined a new type of ad seeking victims of lawyer ads that had caused the dangerous discontinuation of prescribed drug regimens); Tippet, *supra* note 14, at 40 (offering nothing other than a passing reference to the absence of any examples of a “private party or company bringing a claim against these advertisers for ethical breaches or consumer harm associated with the ads”).

products, this Part suggests that a federal regulatory response may facilitate both public and private enforcement efforts.

*A. State Regulation Subject to First Amendment Strictures*

In response to the problems that he had identified with this category of advertising, Professor Schaffzin summarized his recommended modifications of state ethics codes as follows:

[L]awyers soliciting pharmaceutical litigants should make a series of clear and prominent disclosures regarding the nature of the commercial speech as advertising; should refer the consumer to neutral, third-party sources from which more information can be obtained; and should offer clear instruction to consult with a physician before making any decisions regarding the use of the subject medication after seeing the advertisement.<sup>51</sup>

In later elaborating on his proposals, he added a requirement for explaining the referral process.<sup>52</sup> Of these four recommended changes to state ethical codes, two have nothing to do with the particular concerns associated with drug advertising by attorneys. Although more clearly disclosing that the spot represents an “advertisement” may help to reduce patient alarm,<sup>53</sup> existing state rules of ethics already require doing so,<sup>54</sup> making this instead a problem of inadequate enforcement.<sup>55</sup>

The ABA’s *Model Rules of Professional Conduct* include other recommended guidance about advertising by attorneys. Rule 7.1 provides as follows: “A lawyer shall not make a false or misleading communication about the lawyer or the lawyer’s services. A communication is false or misleading if it contains a material misrepresentation of fact or law, or omits a fact necessary to make the

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51. Schaffzin, *supra* note 14, at 326; *see also id.* at 370–71 (elaborating).

52. *See id.* at 370; *cf.* Tippet, *supra* note 14, at 46 (discussing the referral issue only in the sense that this and other types of already required disclosures would make it difficult to demand the inclusion of additional information). Subsection III.C.1 of this Article more fully addresses their recommendations that relate particularly to drug advertising by lawyers.

53. *See* Tippet, *supra* note 14, at 46–47; *cf.* *Leoni v. State Bar*, 704 P.2d 183, 194 (Cal. 1985) (“This massive advertising campaign [by a pair of bankruptcy lawyers] which seemed to personalize letters to individuals named as defendants in pending [debt collection] lawsuits was almost certain to cause panic and to mislead the recipients.”); *id.* (“A ‘clear’ indication to laypersons that a message concerns availability for professional employment is required and the rule could easily be satisfied by a statement such as ‘This is an advertisement.’”).

54. *See* Schaffzin, *supra* note 14, at 354 (discussing Model Rule 7.3(c), which requires a disclosure that it represents “Advertising Material,” including the use of such a statement at both the outset and conclusion of any non-print ad); *id.* at 356 n.159 (elaborating on this requirement by quoting the relevant rules in Kentucky and New York); *id.* at 356 (“[M]any states have incorporated into ethical rules language requiring that all mandated disclosures be displayed with a prominence at least equivalent to the information about the legal services being advertised.”); Tippet, *supra* note 14, at 37; *see also id.* at 35–36 (elaborating on enforcement actions against ads that mimic public service announcements).

55. *See generally* 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, 988 (2002) (“[E]nforcing advertising rules is not a priority anywhere in the United States.”); *id.* at 994–95 (“[M]ost jurisdictions share California’s tendency to overlook violations of the rules.”).

statement considered as a whole not materially misleading.”<sup>56</sup> Rule 7.2 makes clear that “a lawyer may advertise services through written, recorded or electronic communication, including public media,” so long as any “communication made pursuant to this rule shall include the name and office address of at least one lawyer or law firm responsible for its content.”<sup>57</sup> Every jurisdiction in the United States has adopted some version of these provisions.<sup>58</sup>

Professor Tippett offered a detailed analysis of possible charges that some client-seeking TV drug ads violate the existing prohibitions against “false or misleading” claims,<sup>59</sup> but she repeatedly neglected to mention the qualifier that such claims relate to “the lawyer or the lawyer’s services.”<sup>60</sup> Even if a state disciplinary authority could establish that distorted representations about the risks of a highlighted drug product tended to deceive viewers, that would hardly make the advertisement misleading as to the nature of the promoted legal services. As Tippett correctly recognized, it seems unlikely that state boards would bother paying attention to this category of attorney advertising,<sup>61</sup> and, contrary to her analysis, proscriptions against misleading ads as currently framed would have essentially no application in this particular setting. Let us, therefore, imagine that a state has decided to promulgate a novel rule to guard against the adverse public health consequences of lawyers exaggerating the risks associated with still-marketed prescription drugs. Because any effort at an outright

56. MODEL RULES OF PROF’L CONDUCT r. 7.1 (AM. BAR ASS’N 2016) [hereinafter MODEL RULES]. The accompanying comments nowhere suggest any intent to prohibit advertisements that might be false or misleading as to any matter collateral to the nature of the lawyer or the legal services. For a catalog of some types of advertising that attract the attention of disciplinary authorities, see Rodney A. Smolla, *Lawyer Advertising and the Dignity of the Profession*, 59 ARK. L. REV. 437, 445–50, 454 n.55, 457–61 (2006); Nat Stern, *Commercial Speech, “Irrational” Clients, and the Persistence of Bans on Subjective Lawyer Advertising*, 2009 BYU L. REV. 1221, 1261–76 (criticizing common objections to self-laudatory and comparative ads).

57. MODEL RULES, *supra* note 56, r. 7.2(a)&(c).

58. See Schaffzin, *supra* note 14, at 354–56, 356 n.154; Tippett, *supra* note 14, at 32; cf. Hornsby, *supra* note 5, at 50 (“While many states have adopted portions of the Model Rules governing the communications of legal services, no two states have identical ethics provisions in this area.”); *id.* at 61–77 (elaborating).

59. See Tippett, *supra* note 14, at 13–14, 35–39; *id.* at 13 (“[S]ome drug injury ads could be considered misleading under state ethics rules.”). Elsewhere she made brief mention of state attorneys general acting under broader authority to regulate unfair and deceptive business practices, see *id.* at 13 & n.35; *id.* at 40, and they probably could take issue with misleading lawyer ads that had not run afoul of the relevant ethical codes, but her focus remained squarely on the potential role played by state bar authorities, see *id.* at 48 (concluding that “[s]tate bars have an important role to play in addressing misleading advertising practices”); see also Zacharias, *supra* note 55, at 1002 (“Advertising rules are unusual in their fairly distinct commands, their transparency (i.e., the ability of the bar to identify violations), and the unlikelihood that any institution other than the state bar will address violations.”); cf. Shelley D. Gatlin, Note, *Attorney Liability Under Deceptive Trade Practices Acts*, 15 REV. LITIG. 397, 404–08 (1996) (discussing the possible application of broader state consumer protection laws).

60. See Tippett, *supra* note 14, at 15 & n.46; *id.* at 31 (“All state ethics rules include a prohibition on false or misleading advertising . . .”); *id.* at 39.

61. See *id.* at 40–41 (“State bars typically act based on complaints by aggrieved clients or competitors. Here, [prospective clients and attorney] competitors do not seem to be harmed by the misleading 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.”); *id.* (mentioning other factors such as constrained resources, fears of expensive constitutional litigation, and seeking to avoid any perception of taking the side of the pharmaceutical industry); see also Zacharias, *supra* note 55, at 1003–04 (offering similar explanations for the routine underenforcement of all lawyer advertising rules). Indeed, as noted at the outset, the ABA recently defended this category of advertising. See *supra* note 4 and accompanying text.

prohibition of such ads would encounter stiff political resistance as well as serious constitutional problems, this rule aligns with proposals that call for additional disclosures.

Since the mid-1970s, the U.S. Supreme Court has recognized that advertising enjoys some of the First Amendment's guarantees for freedom of expression.<sup>62</sup> Promotional efforts by attorneys have become a staple of the "commercial speech" case law,<sup>63</sup> and personal injury lawyers in particular took full advantage of their new-found constitutional rights.<sup>64</sup> In 1977, in striking down a blanket prohibition on attorney price advertising in newspapers, Justice Blackmun wrote that:

[S]ignificant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. And commercial speech serves to inform the public of the availability, nature, and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system.<sup>65</sup>

The opinion cautioned, however, that "the special problems of advertising on the electronic broadcast media will warrant special consideration."<sup>66</sup> The next year, the Court upheld a prohibition on in-person attorney solicitation as a safeguard

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62. See Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 35–65 (2011); *id.* at 67–68 (summarizing); Amanda Shanor, *The New Lochner*, 2016 WIS. L. REV. 133 (complaining that the more protective commercial speech doctrine represents a triumph for deregulation).

63. See Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 630 (1990) ("Lawyer advertising, initially an area covered by mainstream commercial speech jurisprudence, became the subject of so many cases that it developed into its own distinct area of common law. . . . [T]he law of attorney advertising has grown to such an extent that it has been able to seal itself off from its roots in first amendment theory . . .").

64. See Nora Freeman Engstrom, *Legal Access and Attorney Advertising*, 19 AM. U. J. GENDER SOC. POL'Y & L. 1083, 1089 (2011) ("In the decades following the *Bates* decision, advertisements for legal services—and particularly personal injury legal services, which now make up the bulk of television attorney advertising—have proliferated."); Victor Li, *Ad It up: 40 Years After Bates, Legal Advertising Blows Past \$1 Billion and Goes Viral*, A.B.A. J., Apr. 2017, at 34, 36 (reporting estimates that more than \$900 million would get spent this year just for television campaigns, and adding that "the ad-buy rush is being fueled by personal injury and mass tort lawyers").

65. *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977) (citation omitted); *cf. id.* at 383 ("[L]eeway for untruthful or misleading expression that has been allowed in other contexts has little force in the commercial arena."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 773 n.25 (1976) (suggesting that advertising about variable professional services might pose greater dangers of deceptiveness than advertising about standardized products).

66. *Bates*, 433 U.S. at 384; see also Nora Freeman Engstrom, *Run-of-the-Mill Justice*, 22 GEO. J. LEGAL ETHICS 1485, 1545–46 (2009) (discussing some impacts of the *Bates* decision); *id.* at 1524 ("Television advertising for legal services disproportionately attracts the unsophisticated and the uneducated."). Nonetheless, forty years later the high Court still has not confronted a case involving broadcast lawyer advertising.

against coercion,<sup>67</sup> but it struck down a disciplinary action based on written solicitation of clients.<sup>68</sup>

In 1985, in *Zauderer v. Office of Disciplinary Counsel*,<sup>69</sup> the Court upheld a requirement that attorneys fully disclose fee information in print advertisements.<sup>70</sup> It accepted as plausible the fear that average consumers of legal services would not, when reading an advertisement about a contingency fee arrangement, understand that they might owe court costs even if their lawsuit failed,<sup>71</sup> and it demanded only that the state regulation be “reasonably related” to the asserted governmental interest.<sup>72</sup> Separately, however, the Court held it improper to reprimand Mr. Zauderer for using a nondeceptive illustration and offering services regarding a specific legal problem in local newspaper ads.<sup>73</sup> In fact, the lawyer had drawn attention to problems with the Dalkon Shield, an intrauterine device (“IUD”) subject at that time to only limited supervision by the FDA and already

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67. See *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 457 (1978) (“Unlike a public advertisement, which simply provides information and leaves the recipient free to act upon it or not, in-person solicitation may exert pressure and often demands an immediate response, without providing an opportunity for comparison or reflection.”); see also *Edenfield v. Fane*, 507 U.S. 761, 776 (1993) (“The ban on attorney solicitation in *Ohralik* was prophylactic in the sense that it prohibited conduct conducive to fraud or overreaching at the outset, rather than punishing the misconduct after it occurred.”); *id.* at 778 (O’Connor, J., dissenting) (“States have the broader authority to prohibit commercial speech that, albeit not directly harmful to the listener, is inconsistent with the speaker’s membership in a learned profession and therefore damaging to the profession and society at large.”).

68. See *In re Primus*, 436 U.S. 412, 439 (1978) (involving solicitation of clients in order to pursue public interest litigation); see also *Shapero v. Ky. Bar Ass’n*, 486 U.S. 466, 475 (1988) (contrasting written and personal solicitation).

69. 471 U.S. 626 (1985).

70. See *id.* at 650–53.

71. See *id.* at 652–53.

72. See *id.* at 651; *id.* at 651–52 n.14 (“Although we have subjected outright prohibitions on speech to such [a strict ‘least restrictive means’] analysis, all our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech.”); see also *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249–53 (2010) (upholding requirement that bankruptcy attorneys include disclosures in advertisements); *Peel v. Att’y Registration & Disciplinary Comm’n*, 496 U.S. 91, 109 (1990) (plurality) (noting the “presumption favoring disclosure over concealment”); *In re R.M.J.*, 455 U.S. 191, 203 (1982) (“prefer[ring] a requirement of disclaimers or explanation”); *cf. id.* at 200 n.11 (“If experience with particular price advertising indicates that the public is in fact misled or that disclaimers are insufficient to prevent deception, then the matter would come to the Court in an entirely different posture.”). The Court recognized, however, that “unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.” *Zauderer*, 471 U.S. at 651. See generally Note, *Repackaging Zauderer*, 130 HARV. L. REV. 972 (2017) (discussing disagreement among recent lower court decisions applying the Court’s seemingly more lenient standard of scrutiny for disclosure requirements, though primarily in contexts other than lawyer advertising).

73. See *Zauderer*, 471 U.S. at 641–49; *id.* at 642 (emphasizing the fact that the attorney had engaged in print advertising); *id.* at 642–43, 645 n.12 (rejecting a separate state interest to discourage stirring up litigation); *id.* at 649 (“Given the possibility of policing the use of illustrations in advertisements on a case-by-case basis, the prophylactic approach taken by Ohio cannot stand . . . .”); see also *Ibanez v. Fla. Dep’t of Bus. & Prof’l Reg.*, 512 U.S. 136, 141–43, 149 (1994) (overturning a Board of Accountancy order censuring one of its members for including in her law firm’s advertising references to her credentials as a certified public accountant (CPA) and certified financial planner (CFP)); *id.* at 143–48 (emphasizing that the state had failed to present evidence that anyone had been misled by the petitioner’s truthful representation of her credentials); *id.* at 144 (“[A]s long as Ibanez holds an active CPA license from the Board we cannot imagine how consumers can be misled by her truthful representation to that effect.”).

withdrawn from the market for causing a number of serious injuries.<sup>74</sup> The Court noted that “[t]he advertisement’s information and advice concerning the Dalkon Shield were . . . neither false nor deceptive: in fact, they were entirely accurate,”<sup>75</sup> though the remainder of this paragraph in the majority opinion recounted truthful statements related to that mass tort litigation as opposed to aspects of the device itself or the appropriate medical management of recipients.<sup>76</sup>

A decade after *Zauderer*, the Supreme Court upheld a ban on targeted direct mail solicitation of victims within thirty days of an accident or disaster.<sup>77</sup> The sharply divided decision turned largely on conflicting assessments of the evidence offered in support of the asserted link between ends and means. The Florida Bar had submitted a lengthy summary of its two-year study of lawyer advertising and solicitation containing both statistical and anecdotal data to demonstrate that the public viewed direct-mail solicitation of accident victims and their families as intrusive and reflecting poorly on the legal profession.<sup>78</sup> Aside from questioning the significance of these asserted interests, the dissenting members of the Court took particular issue with the majority’s acceptance of the Bar’s study as evidence of any link to the forbidden types of advertising.<sup>79</sup> The majority concluded, however, that the limited prohibition “targets a concrete, nonspeculative harm.”<sup>80</sup>

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74. See *Zauderer*, 471 U.S. at 630 n.2; *id.* at 631 (explaining that, according to the ad, the Dalkon Shield allegedly “caused serious pelvic infections resulting in hospitalizations, tubal damage, infertility, and hysterectomies,” as well as “unplanned pregnancies ending in abortions, miscarriages, septic abortions, tubal or ectopic pregnancies, and full-term deliveries”).

75. *Id.* at 639; see also *id.* at 633–34 (“The complaint did not allege that the Dalkon Shield advertisement was false or deceptive in any respect other than its omission of information relating to the contingent-fee arrangement . . .”); *id.* at 647 (explaining that “the illustration for which appellant was disciplined is an accurate representation of the Dalkon Shield and has no features that are likely to deceive, mislead, or confuse the reader”); *id.* at 634 (adding that Mr. Zauderer had submitted expert testimony to the disciplinary board that his “advertising in particular was socially valuable in that it served to inform members of the public of . . . the potential health hazards associated with the Dalkon Shield”).

76. See *id.* at 639–41; see also *id.* at 645 (“[A]ppellant’s statements regarding Dalkon Shield litigation were in fact easily verifiable and completely accurate.”). In contrast, some commentators misunderstood that product’s regulatory status. See, e.g., Tippet, *supra* note 14, at 39 n.146 (“At the time the device was introduced to the market [in 1970], it was not subject to FDA authority . . .”). Although licensing requirements only came later, the agency had secured regulatory jurisdiction over medical devices in 1938, which made its prohibitions against adulteration and misbranding fully applicable to IUDs. See *United States v. An Article of Drug Bactoidisk*, 394 U.S. 784, 797–98 (1969).

77. See *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 635 (1995) (concluding that the rule was sufficiently “narrow both in scope and in duration”).

78. See *id.* at 626–28.

79. See *id.* at 640 (Kennedy, J., dissenting) (“This document includes no actual surveys, few indications of sample size or selection procedures, no explanations of methodology, and no discussion of excluded results.”); *id.* at 641 (“Our cases require something more than a few pages of self-serving and unsupported statements by the State to demonstrate that a regulation directly and materially advances the elimination of a real harm when the State seeks to suppress truthful and nondeceptive speech.”).

80. *Id.* at 629; see also *id.* at 628, 632, 635 (emphasizing that no effort had been made to refute the Bar’s study). Given the interests and evidence endorsed by the majority, a comparable prohibition on client-seeking television ads in the immediate aftermath of an accident or disaster should also pass muster. Cf. Schaffzin, *supra* note 14, at 333 (“[D]oes the lawyer’s drive to be ‘first to air’ with commercials preclude a full and complete investigation of the negative study data or new warnings giving rise to the purported claims being shopped?”).



Where does that leave our hypothesized amendments to state ethics codes? The limited “record” assembled by Schaffzin might not even pass muster under the fairly forgiving approach taken by the Court in 1995.<sup>81</sup> More seriously, and notwithstanding the confident conclusions of commentators who have recommended disclosure requirements,<sup>82</sup> the limited mission of state bar authorities would make even fairly modest restrictions on drug advertising by lawyers vulnerable constitutionally.<sup>83</sup> After all, they have no delegated role or expertise in protecting the public health. Separately, one of the expressed rationales for reduced constitutional protection of commercial speech—namely, an advertiser’s supposedly greater capacity to verify the accuracy of representations made about its products or services<sup>84</sup>—would have no real application in this context. In short, state bar authorities might face daunting challenges if they decided to tackle potentially misleading drug ads broadcast by attorneys, which makes it unlikely that they would even bother trying to do so.

### B. Tort Litigation Brought by Patients or Manufacturers

Whether or not state officials take action against client-seeking advertising by lawyers that might trigger patient noncompliance with prescribed courses of treatment, private parties have potential avenues for recourse in the courts. First, patients suffering injuries after discontinuing use of prescription drugs featured in such ads might assert negligent misrepresentation claims, and even those patients who did not rely to their detriment but came to fear that they would experience a worrisome adverse effect might have claims for the negligent infliction of emotional distress. Second, sellers of therapeutic agents negatively portrayed in client-seeking ads could pursue claims for product disparagement. Various difficulties would, of course, attend any efforts to use litigation in this manner, but the threat of private lawsuits might persuade personal injury attorneys to exercise greater care in how they broadcast negative portrayals of targeted pharmaceuticals.

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81. Cf. Schaffzin, *supra* note 14, at 368–69 & n.225 (confidently asserting otherwise). Even with Tippet’s more detailed study about the nature (though not the effects) of such advertising, *see supra* Section II.A, coupled with still more recent evidence of dangerous discontinuance, *see supra* note 40 and accompanying text, the link to harmful outcomes remains uncertain, *see* Tippet, *supra* note 14, at 9 (“The impact of such advertising on consumer medical decisions is unknown and demands further study.”); *id.* at 38–39 (concluding that the available evidence of feared effects would fail to justify restrictions that could pass muster under the First Amendment).

82. *See* Schaffzin, *supra* note 14, at 371; *cf.* Tippet, *supra* note 14, at 46 & n.190, 47 & n.200 (recognizing that “unduly burdensome” disclaimer requirements would pose constitutional problems).

83. Cf. *Hampton v. Mow Sun Wong*, 426 U.S. 88, 105, 115 (1976) (“[T]he interests which the petitioners have put forth as supporting the Commission regulation . . . are not matters which are properly the business of the Commission.”); Lars Noah, *When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?*, 85 GEO. WASH. L. REV. 1462, 1481 n.75 (2017) (elaborating).

84. *See* *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976); *cf.* Kozinski & Banner, *supra* note 63, at 635–37 (explaining the weaknesses of this rationale).

### 1. *Negligent Misrepresentation and Emotional Distress Claims*

Liability may attach to persons who communicate inaccurate information that other parties foreseeably rely upon and endanger themselves.<sup>85</sup> Product sellers must guard against making even innocent misrepresentations,<sup>86</sup> while in other contexts only negligent and intentional misstatements (*i.e.*, fraud) become actionable.<sup>87</sup> Whatever the standard for imposing this sort of liability, misleading “half-truths” would encounter the same scrutiny as outright fabrications.<sup>88</sup> Normally, of course, the express or implied falsehoods that trigger litigation involve failures to disclose unflattering information,<sup>89</sup> but nothing prevents lodging misrepresentation claims for providing excessively negative information insofar as the source of such communications could foresee reliance by listeners that leads to harmful outcomes.

For a rare case premised on communicating excessively negative information, consider *Bailey v. Huggins Diagnostic & Rehabilitation Center, Inc.*<sup>90</sup> Diane Bailey alleged that, in authoring a book and doing interviews for a local television program, Dr. Hal Huggins had exaggerated the risks associated with mercury in dental amalgam.<sup>91</sup> After viewing his statements, she arranged for a different dentist to remove the amalgam used in her prior dental work and

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85. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 311 (Ct. App. 2008) (explaining that anyone who “authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information”); RESTATEMENT (SECOND) OF TORTS § 311 (AM. LAW INST. 1965); see also *Gutter v. Dow Jones, Inc.*, 490 N.E.2d 898, 900 (Ohio 1986) (recognizing, in the course of rejecting such a claim, that “a growing number of courts have demonstrated a willingness to extend liability for negligent misrepresentation in special cases”); Lars Noah, *Medical Education and Malpractice: What’s the Connection?*, 15 HEALTH MATRIX 149, 159–60 (2005) (noting a growing judicial willingness to allow third parties to assert negligent misrepresentation and related tort claims).

86. See, e.g., *Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 433 (Tex. 1974) (allowing a claim to proceed against the seller of a prescription analgesic drug for misrepresenting it as non-addictive); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 9 (AM. LAW INST. 1998); Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor’s Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 674–75, 684–95 (2010) (criticizing the expansive use of misrepresentation claims against brand-name drug manufacturers for injuries caused by generic versions sold by other companies); Gary Massey, Jr., Comment, *Interpreting the Restatement of Torts Section 402B After the Changes to Section 402A*, 28 CUMB. L. REV. 177, 213 (1998) (Section “402B will remain relatively unchanged in the new Restatement and will retain its strict liability principles. With the contraction of 402A . . . , plaintiffs are likely to find 402B far more attractive than they have in the past.”).

87. See *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 522–24 (Ct. App. 1969) (agreeing that the purchaser of an allegedly defective pair of shoes reasonably had relied on *Good Housekeeping* magazine’s seal of approval, an endorsement representing that the defendant had made a reasonable examination of the product).

88. See *Barden v. HarperCollins Publishers, Inc.*, 863 F. Supp. 41, 43 (D. Mass. 1994); *Randi W. v. Muroc Joint Unified Sch. Dist.*, 929 P.2d 582, 591–93 (Cal. 1997).

89. See, e.g., *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 820–23 (N.D. Ohio 2004) (rejecting misrepresentation claims against manufacturers of a prescription weight-loss drug); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) (labeling had incorrectly implied to a physician that an antibiotic solution was safe to use continuously as an irrigant during surgery); see also Alissa J. Strong, “*But He Told Me It Was Safe!*”: *The Expanding Tort of Negligent Misrepresentation*, 40 U. MEM. L. REV. 105 (2009) (discussing the historical development of this doctrine, especially its more recent use in connection with employment references, and criticizing its expansive reach).

90. 952 P.2d 768 (Colo. App. 1997).

91. See *id.* at 770–71.

replace it with a substitute.<sup>92</sup> Reversing judgment for the plaintiff,<sup>93</sup> a Colorado appellate court rejected the negligent misrepresentation claim on two separate grounds. First, it held that Ms. Bailey could not establish detrimental reliance: Dr. Huggins had qualified his statements by noting that others disagreed with his views and, before she could act on his advice, another professional would have to concur.<sup>94</sup> Second, the court concluded that Dr. Huggins owed her no duty in any event because the First Amendment reflected a policy against sanctioning speech in such circumstances.<sup>95</sup>

Both of the court's conclusions seem mildly disingenuous given the facts of the case. The dentist who worked on Ms. Bailey was an associate of Dr. Huggins in the latter's practice group,<sup>96</sup> which undermines the assumption that he made an independent judgment about the advisability of removing her dental amalgam. Moreover, Ms. Bailey did not simply happen to pick up and read Dr. Huggin's book or catch his interviews when broadcast on TV; instead, Dr. Huggins' clinic had supplied both of these to her, which ultimately convinced her to come in for this unnecessary work.<sup>97</sup> Putting these factual quibbles aside, the court never suggested that the negligent misrepresentation theory applied only to unduly favorable claims. Moreover, its analysis of the detrimental reliance factor seemingly would allow for a different judgment in cases where patients foreseeably might act on exaggerated risk information without any involvement of a health care professional.

The duty limitation also seems less apt in connection with client-seeking ads by lawyers. Dental amalgam has attracted the attention of activists,<sup>98</sup> and no one questions their constitutional right to whip up hysteria about this health scare *du jour*.<sup>99</sup> Similarly, medical professionals have every right to lend their voices

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92. See *id.* at 771.

93. See *id.* at 774. Her treating dentist and the clinic that employed both of the individual defendants had not appealed the separate malpractice judgment for the plaintiff. See *id.* at 769.

94. See *id.* at 772–73 (discussing the reliance issue as an aspect of foreseeability in deciding whether to recognize a duty).

95. See *id.* at 773.

96. See *id.* at 769.

97. See *id.* at 770 (“[T]hese materials are made available to prospective patients at the Center.”); *cf. id.* at 771–72 (explaining that she had procured these materials only indirectly and, therefore, “plaintiff’s status with respect to the materials is not significantly different from the status of other members of the public who may have read Huggins’ book or viewed the television program”). Perhaps the plaintiff made a tactical blunder in asserting only a vicarious and not also a direct liability claim for negligent misrepresentation against the dental clinic.

98. See *id.* at 769–70; see also *Moms Against Mercury v. FDA*, 483 F.3d 824, 826–28 (D.C. Cir. 2007) (dismissing for lack of subject matter jurisdiction a petition to review the agency’s failure to take action on a form of dental amalgam because a device classification process remained pending); *Consumer Cause, Inc. v. SmileCare*, 110 Cal. Rptr. 2d 627, 639–45 (Ct. App. 2001) (reversing summary judgment granted to providers of dental care on claims brought by consumer activists alleging violations of the state’s right-to-know law); Linda Shrieves, *Ban Dental Mercury, Foes Again Urge FDA*, ORLANDO SENTINEL, May 6, 2011, at A1.

99. See Noah, *supra* note 62, at 90 (“Obviously, the government could not prevent the advocacy groups from disseminating their message—core First Amendment principles would prohibit efforts to stifle such debate no matter how wrong-headed and potentially detrimental to the public health.”); see also Thomas M. Burton, *Medical Flap: Anti-Depression Drug of Eli Lilly Loses Sales After Attack by Sect*, WALL ST. J., Apr. 19, 1991,

to such debates, even if they take an unorthodox position in siding with the activists.<sup>100</sup> If, however, they do so in an effort to drive more business to their practice, then the reduced protections for commercial speech should allow for greater official scrutiny of false or misleading claims that cause injury when relied upon.<sup>101</sup> In short, the Colorado court's invocation of the First Amendment exaggerated the constitutional issues at stake in this tort litigation.

Nonetheless, the potentially expansive reach of misrepresentation claims has made courts hesitate when these lawsuits name certain types of defendants. For instance, authors of books, scholarly articles, or news stories that disseminate potentially hazardous misinformation often get additional protection from the prospect of tort liability thanks to concerns derived from—though not necessarily dictated by—constitutional safeguards for free speech.<sup>102</sup> Typically, lawyers only face misrepresentation lawsuits for false statements made in connection with representing a client and allegedly injuring that person, an adversary in litigation, or a third party affected by a transaction.<sup>103</sup> Nonetheless, if patients take seriously exaggerated claims made about therapeutic products in client-

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at A1 (describing publicity campaigns attacking psychotropic drugs mounted by the Church of Scientology, adding that “severely depressed patients were frightened enough by one Scientology official’s remarks on television to stop taking the medication [Prozac<sup>®</sup>], only to deteriorate rapidly”).

100. See *Kids Against Pollution v. Cal. Dental Ass’n*, 134 Cal. Rptr. 2d 373, 378–79, 388–90 (Ct. App. 2003) (dismissing misrepresentation claims against professional association for, among other things, threatening to discipline dentists who questioned the safety of amalgam), *vacated*, 143 P.3d 655 (Cal. 2006). In an earlier era, similar questions arose when professional organizations bad mouthed (pun intended) dentists and physicians who questioned fluoridation of municipal water supplies. See *Mick v. Am. Dental Ass’n*, 139 A.2d 570 (N.J. Super. Ct. App. Div. 1958) (affirming dismissal of a defamation claim); *Exner v. Am. Med. Ass’n*, 529 P.2d 863 (Wash. Ct. App. 1974) (same).

101. See Lars Noah, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books*, 77 OR. L. REV. 1195, 1218–28 (1998); Avi Salzman, *Dentist Wins a Round on Mercury Warnings*, N.Y. TIMES, July 24, 2005, § 14, at 4 (reporting that a Connecticut dentist opposed to the use of dental amalgam settled with the state’s department of public health after it had objected to an editorial that he authored on the subject, restricting the statements that he could make about the issue only when done in connection with advertising his services); see also Noah, *supra* note 47, at 464–65 (discussing the potential tort liability of entities that supply inaccurate information about therapeutic products even though they played no role in the production or distribution of those products).

102. See, e.g., *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 325–28 (S.D.N.Y. 2006) (dismissing negligent misrepresentation and other claims against the source of diet books, products, and a website that recommended consumption primarily of high-fat and high-protein foods, concluding that the information qualified as fully protected noncommercial speech), *aff’d*, 279 F. App’x 40, 41–42 (2d Cir. 2008); *Smith v. Linn*, 563 A.2d 123, 124–27 (Pa. Super. Ct. 1989) (rejecting negligent misrepresentation and strict products liability claims brought on behalf of the reader of a diet book who died of complications associated with the diet), *aff’d*, 587 A.2d 309 (Pa. 1991); cf. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 19 cmt. d (AM. LAW INST. 1998) (emphasizing the intangible nature of information-laden products such as books and suggesting, instead, the use of negligent misrepresentation claims in such cases).

103. See Douglas R. Richmond, *Fraud and Misrepresentation Claims Against Lawyers*, 16 NEV. L.J. 57, 103–05 (2015) (summarizing). In fact, negligent misrepresentation claims against lawyers typically invoke the somewhat narrower doctrine governing misstatements that threaten economic as opposed to physical harms. See RESTATEMENT (SECOND) OF TORTS § 552 (AM. LAW INST. 1977); cf. *Renn v. Provident Tr. Co.*, 29 Pa. D. & C. 689, 693 (Ct. Com. Pl. 1937) (“[O]ne engaged in the business of giving information in one kind of matters is not liable for information given in regard to another matter. So, a lawyer may incur liability if, in the transaction of his business, he gives wrong information concerning a legal matter, but he would not be liable if . . . he undertakes to advise someone as to the proper treatment for typhoid fever.”).

seeking ads and suffer injuries after discontinuing a prescribed course of treatment, then courts could well entertain negligent misrepresentation claims against the attorneys responsible for distributing such misinformation.<sup>104</sup>

Even if a patient does not suffer injury from discontinuing a prescribed course of treatment, attorney advertising that exaggerated the risks posed by therapeutic products might trigger emotional distress in listeners. For instance, previous users of a prescription drug might come to fear that their prior exposure might at some point trigger a dreaded disease.<sup>105</sup> Similarly, the recipient of an implanted medical device might become preoccupied with the prospect of suffering a life-threatening malfunction. If well-founded, of course, then such fears might prompt productive responses: greater vigilance and routine screening, which some courts treat as presently compensable,<sup>106</sup> or device explantation.<sup>107</sup>

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104. Cf. *In re* Factor VIII or IX Concentrate Blood Prod. Litig., 25 F. Supp. 2d 837, 845–46, 848 (N.D. Ill. 1998) (allowing misrepresentation claims to proceed against the National Hemophilia Foundation for publishing some allegedly inaccurate information about blood factor concentrates intended for distribution to patients, rejecting First Amendment defense). Comparative negligence should serve as little or no defense to such claims. Noncompliance with physician instructions may provide an affirmative defense in medical malpractice actions. See Kurtis A. Kemper, Annotation, *Contributory Negligence or Comparative Negligence Based on Failure of Patient to Follow Instructions as Defense in Action Against Physician or Surgeon for Medical Malpractice*, 84 A.L.R.5th 619 (2000 & Supp. 2017); *id.* § 5 (discussing cases that involved patient failures to use prescribed medications). Noncompliance should not, however, limit or defeat claims premised on actions by other parties that foreseeably induced such behavior by patients.

105. See, e.g., *In re* Rezulin Prod. Liab. Litig., 361 F. Supp. 2d 268, 276–79 (S.D.N.Y. 2005) (rejecting such claims in connection with a withdrawn drug for diabetes); *Wetherill v. Univ. of Chi.*, 565 F. Supp. 1553, 1559–60 (N.D. Ill. 1983) (allowing emotional distress claims for women exposed to diethylstilbesterol (DES) *in utero*, which increased their risk of developing cancer); *Payton v. Abbott Labs.*, 437 N.E.2d 171, 173–74, 181 (Mass. 1982) (requiring proof of physical harm as a prerequisite for such DES claims); see also *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 812 (Cal. 1993) (“If and when negative data are discovered and made public, . . . one can expect numerous lawsuits to be filed by patients who currently have no physical injury or illness but who nonetheless fear the risk of adverse effects from the [prescription] drugs they used.”). In asbestos cases, the U.S. Supreme Court has rejected such “cancerphobia” claims. See *Metro-North Commuter RR v. Buckley*, 521 U.S. 424, 432–38 (1997); cf. *Norfolk & W. Ry. v. Ayers*, 538 U.S. 135, 148–59 (2003) (allowing recovery for fear of cancer where plaintiffs had already developed a precancerous condition).

106. See David M. Studdert et al., *Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public's Health?*, 289 JAMA 889 (2003); see also *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 856–59 (Ky. 2002) (recognizing this trend, but declining to join it in a fenfluramine case); *Sinclair v. Merck & Co.*, 948 A.2d 587, 594–96 (N.J. 2008) (same, in a Vioxx® case); Tamara J. Dodge, Comment, *Raging Hormones?: The Legal Obstacles and Policy Ramifications to Allowing Medical Monitoring Remedies in Hormone Replacement Therapy Suits*, 21 WIS. WOMEN'S L.J. 263 (2006); Allan L. Schwartz, Annotation, *Recovery of Damages for Expense of Medical Monitoring to Detect or Prevent Future Disease or Condition*, 17 A.L.R.5th 327 (1994 & Supp. 2017).

107. See, e.g., *Larsen v. Pacemaker Sys., Inc.*, 837 P.2d 1273, 1287 (Haw. 1992) (allowing recovery for damages associated with surgery to replace a faulty pacemaker). Where defects require explantation in only limited circumstances, plaintiffs may request medical monitoring costs. See *In re* Telectronics Pacing Sys., Inc., 172 F.R.D. 271, 276–78, 284–87 (S.D. Ohio 1997), *rev'd on other grounds*, 221 F.3d 870 (6th Cir. 2000); see also *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005) (holding that plaintiff had standing to pursue a class action lawsuit for medical monitoring expenses on behalf of cardiac bypass patients who received an allegedly defective aortic connector and faced an increased risk of injury). If, however, explantation is not medically indicated but undertaken at the patient's insistence, courts have rejected such claims. See, e.g., *O'Brien v. Medtronic, Inc.*, 439 N.W.2d 151 (Wis. Ct. App. 1989).

If, however, the actual risks do not justify these sorts of follow-up medical interventions, then the unfounded fears will simply cause mental anguish, and courts have treated these as noncompensable.<sup>108</sup>

When a different party communicates information that overstates the dangers associated with an exposure, courts might regard this behavior as providing a basis for allowing a negligent infliction of emotional distress. Perhaps the closest parallel involves health care providers incorrectly informing patients that they had tested positive for the human immunodeficiency virus (“HIV”).<sup>109</sup> Courts occasionally also allow awards for mental anguish in legal malpractice cases.<sup>110</sup> Even in the absence of such professional relationships, courts may allow distress claims based on some “undertaking” by a defendant that foreseeably threatens emotional tranquility when performed negligently,<sup>111</sup> such as the delivery of messages that incorrectly advise family members of a person’s death.<sup>112</sup> Nonetheless, when such information gets broadcast more widely, courts become hesitant to extend tort liability. Thus, the negligent publication of an obituary may not entitle the purportedly deceased individual or close relatives to recover for their emotional harms.<sup>113</sup> Similarly, a court rejected distress claims where a hospital had notified hundreds of patients that the tortious conduct of a former employee may have exposed them to infectious diseases.<sup>114</sup> In short, physical harms

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108. See, e.g., *Angus v. Shiley Inc.*, 989 F.2d 142, 147–48 (3d Cir. 1993) (potentially defective heart valve); *Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 44–45 (D.N.J. 1993) (collecting cases); *Pfizer, Inc. v. Farsian*, 682 So. 2d 405, 407–08 (Ala. 1996), *conformed to certified question*, 97 F.3d 508 (11th Cir. 1996); see also *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33, 35 (M.D. Pa.) (emphasizing that “plaintiffs’ emotional distress is related to the contents of a television show and not from a defective prosthetic valve”), *affirmed*, 902 F.2d 1558 (3d Cir. 1989); cf. *Khan v. Shiley Inc.*, 266 Cal. Rptr. 106, 112 (Ct. App. 1990) (allowing such a claim only upon a showing of fraud). See generally Lars Noah, *Comfortably Numb: Medicalizing (and Mitigating) Pain-and-Suffering Damages*, 42 U. MICH. J.L. REFORM 431, 437–39 (2009) (discussing negligent infliction of emotional distress claims).

109. See, e.g., *Baker v. Dorfman*, 239 F.3d 415, 421–22 (2d Cir. 2000) (analogizing such claims to long recognized liability for incorrectly advising someone that a family member has died); *Chizmar v. Mackie*, 896 P.2d 196, 205, 206 n.9 (Alaska 1995); *Hedgepeth v. Whitman Walker Clinic*, 22 A.3d 789, 792, 812–20 (D.C. 2011); *Bramer v. Dotson*, 437 S.E.2d 773, 774–75 (W. Va. 1993); cf. *Molein v. Kaiser Found. Hosps.*, 616 P.2d 813, 817, 821 (Cal. 1980) (allowing the husband of a patient misdiagnosed with syphilis to pursue claims for his serious emotional distress against the health care providers for their alleged negligence in examining his wife).

110. See *Miranda v. Said*, 836 N.W.2d 8, 25–33 (Iowa 2013) (surveying the case law and commentary in the course of allowing such damages); cf. *Vincent v. DeVries*, 72 A.3d 886, 894 (Vt. 2013) (“The vast majority of jurisdictions do not allow recovery of emotional distress damages in legal malpractice cases . . .”).

111. See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 47(b) (AM. LAW INST. 2012); see also Dan B. Dobbs, *Undertakings and Special Relationships in Claims for Negligent Infliction of Emotional Distress*, 50 ARIZ. L. REV. 49, 53–59, 63 (2008) (focusing on undertakings that extend out from existing special relationships).

112. See, e.g., *Johnson v. State*, 334 N.E.2d 590, 591–93 (N.Y. 1975) (allowing a distress claim where a hospital had misinformed the plaintiff’s aunt that her mother had died); see also *Hoard v. Shawnee Mission Med. Ctr.*, 662 P.2d 1214, 1220 (Kan. 1983) (“A minority of jurisdictions have also recognized an exception to the rule for emotional harm resulting from the negligent transmission of a death message by a telegraph company.”).

113. See *Decker v. Princeton Packet, Inc.*, 561 A.2d 1122, 1127–30 (N.J. 1989); *Rubinstein v. N.Y. Post Corp.*, 488 N.Y.S.2d 331, 333–35 (Sup. Ct. 1985). These decisions, however, involved claims brought against only the publishers of the inaccurate obituaries rather than the sources that had supplied the misinformation.

114. See *Jane W. v. President & Dirs. of Georgetown Coll.*, 863 A.2d 821, 828 (D.C. 2004); *id.* at 823–24 (elaborating on the decision to send—and the contents of—the hospital’s letter). The court had, however, only applied the zone of danger test, and the plaintiffs had not objected to the defendant’s decision to send the letter

suffered by users of prescription drugs flowing from detrimental reliance on misleading lawyer advertisements probably stand on much firmer ground than any emotional harms allegedly arising from the possible anxiety induced by such communications.

## 2. *Product Disparagement and Related Claims*

Whether or not injured patients tried to pursue negligent misrepresentation claims, another class of plaintiffs might attempt to combat misleading drug ads run by lawyers. Companies that sell therapeutic products have an obvious interest at stake when promotional campaigns offer negative portrayals of their wares, but they would have to make use of disparagement or defamation theories rather than pursuing misrepresentation claims.<sup>115</sup> In its most basic form, a product disparagement (a.k.a., injurious falsehood or trade libel) claim requires proof that the defendant published a false statement of fact about the quality of the plaintiff's product that caused pecuniary losses because customers declined to purchase it any longer.<sup>116</sup> Of course, even if they stood little chance of success in the end, manufacturers might find themselves tempted to press such claims simply in an effort to discourage persons from sharing bad reviews.<sup>117</sup>

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(instead, they unsuccessfully sought to use the letter as evidence that the conduct of the defendant's employee had in fact put them in some danger).

115. *Demuth Development Corp. v. Merck & Co.*, 432 F. Supp. 990 (E.D.N.Y. 1977), helps to illustrate some of the differences. A major pharmaceutical company that produced a widely used compendium of chemicals had included arguably exaggerated toxicity information about the disinfecting agent triethylene glycol, which the plaintiff used in a vaporizer designed for sterilizing the air in hospitals and similar settings. *See id.* at 991–92 (adding that plaintiff alleged that it lost substantial business as a result). Because the defendant's publication had made absolutely no reference to the plaintiff or its particular product, the court dismissed a disparagement claim. *See id.* at 991. Then, because it found that the defendant owed no duty to the plaintiff to ensure the accuracy of information appearing in the compendium even though foreseeably relied upon by institutional customers of the plaintiff, the court granted summary judgment against separate claims for negligent and intentional misrepresentation. *See id.* at 993–95; *see also id.* at 993 (“[E]ven if we assume that Merck was under a duty to its readers to provide such information with care, how does that help plaintiff? Plaintiff does not and could not claim it relied to its detriment on misinformation published by Merck.”); *id.* at 994 (worrying also that a contrary holding might have a “manifestly chilling effect upon the right to disseminate knowledge”).

116. *See Sys. Operations, Inc. v. Sci. Games Dev. Corp.*, 555 F.2d 1131, 1139–44 (3d Cir. 1977); *Teilhafer Mfg. Co. v. Unarco Materials Storage*, 791 P.2d 1164, 1166–68 (Colo. App. 1989) (affirming judgment for over \$1.7 million on a product disparagement claim where a competitor disseminated a false report about the strength of the plaintiff's industrial storage rack); RESTATEMENT (SECOND) OF TORTS §§ 623A, 626, 629 (AM. LAW INST. 1977); *see also id.* § 646A (recognizing certain limited privileges to disparage); *cf.* *Diapulse Corp. of Am. v. Birtcher Corp.*, 362 F.2d 736, 738–39, 743–44 (2d Cir. 1966) (affirming a judgment for plaintiffs in a libel action against a competitor that had characterized their atypical and pricier diathermy machine as a quack device in promotional mailings); *GN Danavox, Inc. v. Starkey Labs., Inc.*, 476 N.W.2d 172, 176–78 (Minn. Ct. App. 1991) (affirming a sizeable defamation judgment for a hearing aid manufacturer based on a flyer distributed to customers by its competitor falsely implying that the plaintiff was going out of business); *Harwood Pharmacal Co. v. Nat'l Broad. Co.*, 174 N.E.2d 602, 602–04 (N.Y. 1961) (deciding that broadcast statement about the addictive character of a sleep aid also defamed its manufacturer).

117. *See* Nicolas Bagley et al., *Scientific Trials—In the Laboratories, Not the Courts*, 178 JAMA INTERNAL MED. 7, 7 (2018) (“When lawsuits target scientists, it does not matter that plaintiffs almost never win. It does not even matter if the case goes to trial. The goal is to intimidate.”); John O'Dell, *Bruising Tests Await Consumer Reports in Court*, L.A. TIMES, Sept. 19, 1999, at A1 (“The magazine's lawyers also maintain . . . that the auto makers are trying to bludgeon *Consumer Reports* into silence with crippling legal bills.”); Andrew Pollack, *No*

For example, in *Vascular Solutions, Inc. v. Marine Polymer Technologies, Inc.*,<sup>118</sup> the federal courts resolved litigation between rivals in the market for specialized bandages used by physicians after cardiac catheterization and similar procedures. In the 1990s, the FDA had authorized Marine Polymer Technologies (“MPT”) to market a medical patch constructed of thin fibers derived from single-celled organisms known as diatoms; several years later, the agency allowed the introduction of a competing product (called “D-Stat Dry”) from Vascular Solutions, Inc. (“VSI”), with warnings to alert physicians that exposure to the bovine thrombin used in this patch might cause patients to produce antibodies and experience certain bleeding complications.<sup>119</sup> Faced with a threat to its market share, MPT issued a marketing bulletin with talking points for use by its sales force when calling on catheterization laboratories and other purchasers.<sup>120</sup> Although based on a then-recently published scientific article, the court agreed that MPT’s bulletin misrepresented the findings of this study, as it had discussed the adverse effects of a less pure form of bovine thrombin and primarily when used in the course of major surgeries.<sup>121</sup> On VSI’s claim for product disparagement, the jury returned a verdict for \$4.5 million, the trial judge also enjoined any further use of these false statements by MPT,<sup>122</sup> and the federal appellate court affirmed the judgment though only after ordering a remittitur of the damage award to \$2.7 million.<sup>123</sup>

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*Clear Winner in Decision in Isuzu vs. Consumer Reports*, N.Y. TIMES, Apr. 8, 2000, at C3 (“The lawsuit was closely watched because a verdict against Consumers Union could have had a chilling effect on the publication of negative reviews. Some . . . had called the lawsuit an attempt to intimidate . . .”); see also Sean D. Lee, Note, “I Hate My Doctor”: Reputation, Defamation, and Physician-Review Websites, 23 HEALTH MATRIX 573, 575 (2013) (“Many doctors who are angry about these websites are increasingly suing or threatening to sue patients over their online reviews.”); *id.* at 583 (calling such litigation “virtually useless for managing doctors’ online reputations”); Dante Ramos, Editorial, *Are You Ready to Be Rated?*, BOS. GLOBE, Nov. 30, 2014, at K5 (“In recent years, small-business owners have sued for defamation over reviews on Yelp and the site Angie’s List. Aggrieved doctors have tried to unmask anonymous reviewers on physician-review sites.”). Relatedly, targets of litigation have deployed different methods when trying to retaliate against what they regarded as irresponsible plaintiffs’ attorneys. See Nora Freeman Engstrom, *Retaliatory RICO and the Puzzle of Fraudulent Claiming*, 115 MICH. L. REV. 639, 643–44, 669–74, 691–706 (2017); *id.* at 669 (“[C]orporate entities are now harnessing civil RICO, the tool they once despised . . . , as a bludgeon against those who initiate suits.”).

118. 590 F.3d 56 (1st Cir. 2009) (per curiam).

119. See *id.* at 57–58.

120. See *id.* at 58–59. For a vaguely comparable lawsuit (though not involving direct competitors), see Joe Carlson, *Abbott Legal Fight Intensifies*, STAR TRIB. (Minn.), May 13, 2017, at 1D (reporting that a manufacturer of cardiac-assist devices filed such a claim against a consulting company for publicizing an alleged cybersecurity vulnerability).

121. See *Vascular Solutions*, 590 F.3d at 60 (“The most inflammatory of the five statements, and the most glaringly unsupported, are the two that associated D-Stat Dry with specific and serious outcomes in percentages that would be remarkable for a relatively straightforward medical task—to stop bleeding at a modest-size doctor-created incision.”); *id.* at 61 (“The[se] statements were recklessly false . . . : their assertion of high percentage risks of lurid complications would have alarmed any doctor considering D-Stat Dry.”); see also *id.* at 58 (noting that “VSI had sold more than one million D-Stat Dry patches, without reports of severe bleeding or blood clots resulting from proper use of the device”).

122. See *id.* at 59; see also *id.* at 61 (noting that MPT had not separately objected on appeal to this injunction).

123. The panel in the appellate court split three ways on the compensatory damage award. See *id.* at 64 (explaining that the remittitur reflected a compromise between the two judges joining in the per curiam opinion of the court); *id.* at 64–72 (Lipez, dissenting in part) (discussing VSI’s failure to either satisfy the requirement to



When rivals attack the products of a competitor in this fashion, they may face claims beyond simply product disparagement.<sup>124</sup> For instance, federal law creates a private right of action for misleading promotional efforts, and, insofar as it broadly covers any commercial advertising, this provision might even encompass client-seeking drug ads by lawyers. In one case brought under the Lanham Act,<sup>125</sup> where a seller of filters used in ventilators and oxygen concentrators had sent an “ALERT” to institutional customers of a competitor about supposed flaws in the latter’s product, an appellate court affirmed an award of \$1.6 million though the jury had rejected a separate product disparagement claim.<sup>126</sup> In addition, several states have enacted legislation to create a private right of action against anyone who improperly questions the safety of certain agricultural goods,<sup>127</sup> but these would have no application to advertising campaigns by attorneys targeting prescription drugs.

Product disparagement requires that plaintiffs prove more elements than necessary to make out a traditional negligence claim or even the intentional tort of defamation.<sup>128</sup> For instance, the common law typically demands some sort of

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prove specific lost sales or properly invoke the “widespread dissemination” exception, and preferring to order a new trial on damages).

124. See Paul T. Hayden, *A Goodly Apple Rotten at the Heart: Commercial Disparagement in Comparative Advertising as Common-Law Tortious Unfair Competition*, 76 IOWA L. REV. 67, 76–82, 97–98 (1990) (discussing the history of claims for disparagement of quality).

125. 15 U.S.C. § 1125(a)(1) (2018); see also *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 138–40 (2014) (holding that the adversarial parties need not be direct competitors). See generally Arlen W. Langvardt, *Section 43(a), Commercial Falsehood, and the First Amendment: A Proposed Framework*, 78 MINN. L. REV. 309, 319–42 (1993) (comparing what amount to strict liability claims brought under this provision with more burdensome defamation and injurious falsehood claims asserted under the common law and constrained by free speech principles).

126. See *Porous Media Corp. v. Pall Corp.*, 173 F.3d 1109, 1113–15, 1120–22 (8th Cir. 1999). Lanham Act claims involving comparative advertising of FDA-regulated products arise with some frequency. See, e.g., *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 65–73 (2d Cir. 2016) (home pregnancy test kits); *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 513–14 (8th Cir. 1996) (prescription antihypertensives); *Johnson & Johnson \* Merck Consumer Pharms. Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 297–99 (2d Cir. 1992) (affirming trial judge’s rejection of claim alleging that the defendant had falsely implied that its competitors’ OTC antacid products contained a harmful ingredient).

127. These statutes usually apply to persons who knowingly make scientifically unfounded claims about the safety of perishable agricultural commodities. See *Engler v. Winfrey*, 201 F.3d 680, 687–89 (5th Cir. 2000) (holding that comments about the risk of “mad cow” disease among U.S. beef cattle broadcast on *The Oprah Winfrey Show* had not violated the Texas statute); Sara Lunsford Kohen, *What Ever Happened to Veggie Libel?: Why Plaintiffs Are Not Using Agricultural Product Disparagement Statutes*, 16 DRAKE J. AGRIC. L. 261, 280–92 (2011) (discussing the constitutional infirmities of such statutes); Melody Petersen, *Farmers’ Right to Sue Grows, Raising Debate on Food Safety*, N.Y. TIMES, June 1, 1999, at A1 (counting more than a dozen states, and discussing some of the consequences of these laws); *ABC Settles Lawsuit over “Pink Slime”*; *Beef Products Inc. Accused Network of Misleading Consumers About Product Added to Ground Beef*, L.A. TIMES, June 29, 2017, at C2 (discussing a high-profile lawsuit brought under South Dakota’s law). It seems entirely unlikely that the legislature of any state would consider mounting a similar effort to facilitate the bringing of disparagement claims by pharmaceutical manufacturers against local lawyers.

128. See *Hurlbut v. Gulf Atl. Life Ins. Co.*, 749 S.W.2d 762, 766 (Tex. 1987) (“More stringent requirements have always been imposed on the ‘plaintiff seeking to recover for injurious falsehood in three important respects—falsity of the statement, fault of the defendant and proof of damage.’” (citation omitted)).

a showing of malice,<sup>129</sup> and, as contrasted with certain categories of defamation, courts impose stringent requirements for proof of pecuniary damages in these cases.<sup>130</sup> Like its defamation cousin, however, even literally true but incomplete statements may qualify as false when they imply an unfounded conclusion about the quality of a product.<sup>131</sup>

Whether or not free speech principles might further limit the availability of damages for product disparagement,<sup>132</sup> claims against attorneys exaggerating the dangers posed by still-marketed prescription drugs should not founder on First Amendment concerns. Although sometimes framed as public services announcements (“PSAs”), client-seeking ads represent commercial speech entitled to reduced constitutional protection.<sup>133</sup> Disparagement claims lodged against sponsors of such campaigns would not resemble lawsuits sometimes brought against research scientists publishing worrisome findings about therapeutic agents or

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129. See *HipSaver, Inc. v. Kiel*, 984 N.E.2d 755, 762–63, 767–69 (Mass. 2013); see also *Modern Prods., Inc. v. Schwartz*, 734 F. Supp. 362, 363–64 (E.D. Wis. 1990) (granting summary judgment to defendants—the physician author and the publisher of a book about hazardous foods that included an image of the plaintiff’s health food product on the jacket—on product disparagement but not on defamation claims because only the former theory required proof of actual malice where the plaintiff did not qualify as a public figure).

130. See, e.g., *Amerinet, Inc. v. Xerox Corp.*, 972 F.2d 1483, 1502–04 (8th Cir. 1992); *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 75 F. Supp. 2d 235, 239–41 (S.D.N.Y. 1999), *aff’d*, 314 F.3d 48, 59–61 (2d Cir. 2002); *Drug Res. Corp. v. Curtis Publ’g Co.*, 166 N.E.2d 319, 322 (N.Y. 1960) (diet pills); see also *Morton Grove Pharm., Inc. v. Nat’l Pediculosis Ass’n*, 494 F. Supp. 2d 934, 942–43 (N.D. Ill. 2007) (allowing defamation and trade disparagement claims asserted by the manufacturer of a prescription lice treatment to proceed against a non-profit group that questioned its safety).

131. See *Metabolife Int’l, Inc. v. Wornick*, 264 F.3d 832, 848–49 (9th Cir. 2001); see also *Brown & Williamson Tobacco Corp. v. Jacobson*, 827 F.2d 1119, 1133, 1137 (7th Cir. 1987) (crediting as evidence of falsity and actual malice the distortion of an FTC report in a news broadcast); *Charles Atlas, Ltd. v. Time-Life Books, Inc.*, 570 F. Supp. 150, 152–53 (S.D.N.Y. 1983) (holding that a book’s alleged misstatements about the dangers of plaintiff’s exercise program were reasonably susceptible of a defamatory meaning); *M & W Gear Co. v. AW Dynamometer, Inc.*, 424 N.E.2d 356, 364 (Ill. App. Ct. 1981) (affirming conclusion that the defendant’s advertisements misleadingly suggested that competing farm equipment manufactured by the plaintiff posed an explosion and other risks).

132. See *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 492 & n.8, 513–14 (1984) (assuming without deciding that the actual malice standard used when public figures sue for defamation, coupled with the obligation of independent examination on appeal, should be applied in a product disparagement suit by a manufacturer of loudspeakers against the publisher of *Consumer Reports*); *Vascular Solutions, Inc. v. Marine Polymer Techs., Inc.*, 590 F.3d 56, 59 (1st Cir. 2009) (per curiam) (explaining that this question remains open); *Dairy Stores, Inc. v. Sentinel Publ’g Co.*, 516 A.2d 220, 224–37 (N.J. 1986) (discussing these questions in connection with a news story about the source of bottled water sold by the plaintiff).

133. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637 & n.7 (1985); cf. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66–68 (1983) (treating pamphlets that promoted the use of condoms as commercial speech even though they included discussions of “important public issues” such as sexually transmitted diseases and family planning); *Porous Media Corp. v. Pall Corp.*, 173 F.3d 1109, 1121 (8th Cir. 1999) (“Whatever nobler concerns may have driven Pall to inform the market of the public health dangers allegedly posed by Porous’s non-hydrophobic filter, ‘commercial speech’ need not originate *solely* from economic motives.”).

other products,<sup>134</sup> consumer activists eager to overhype the latest scare,<sup>135</sup> news organizations that disseminate such unflattering information to a wider audience,<sup>136</sup> or authors and publishers of books and magazines offering advice to consumers.<sup>137</sup> Instead, personal injury attorneys may disparage products in the course of proposing a transaction, though related to the professional services that they offer rather than any sale of products that they mention in their spots. Moreover, unlike broadside attacks against an undifferentiated class of products,<sup>138</sup> these client-seeking ads identify particular agents by name and specify alleged

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134. See, e.g., *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 494–98 (2d Cir. 2013) (affirming the dismissal of various claims against the authors of a study published in the *Journal of Perinatology* about the comparative efficacy of different surfactants, which concluded that premature infants given plaintiff's product experienced a higher mortality rate); *Melaleuca, Inc. v. Clark*, 78 Cal. Rptr. 2d 627, 630–31, 638–40 (Ct. App. 1998) (reversing, because of an erroneous jury instruction on the actual malice standard, a judgment rendered against a research scientist who claimed in a series of books to find traces of benzene in various natural products sold by the plaintiff and linking serious diseases to such exposures); *HipSaver, Inc. v. Kiel*, 984 N.E.2d 755, 762–75 (Mass. 2013) (affirming summary judgment in favor of a research physician against a disparagement claim based on a study that he published in *JAMA* finding no efficacy in the use of devices of the same general sort as sold by the plaintiff); see also *Tobinick v. Novella*, 848 F.3d 935, 945–47, 950–52 (11th Cir. 2017) (affirming dismissal of various claims brought by a practicing physician against a physician blogger who criticized the plaintiff's off-label use of a drug product as dangerous).

135. See, e.g., *Auvil v. CBS "60 Minutes"*, 800 F. Supp. 941, 944–45 (E.D. Wash. 1992) (granting summary judgment on disparagement claims brought against the Natural Resources Defense Council and a public relations firm that this environmental group had hired to promote its report about the carcinogenicity of commonly used agricultural chemicals including Alar® (daminozide), a growth regulator); see also Sarah Lyall, *The "McLibel" Verdict; Her Majesty's Court Has Ruled; McDonald's Burgers Are Not Poison*, N.Y. TIMES, June 22, 1997, § 4, at 7 (describing the English trial judge's mixed decision in high-profile litigation brought by the fast-food chain against consumer activists).

136. See, e.g., *Auvil v. CBS "60 Minutes"*, 67 F.3d 816, 821–23 (9th Cir. 1995) (affirming summary judgment on product disparagement claims that apple growers brought against the broadcaster of a news story questioning the safety of Alar because extrapolation from animal data did not make those statements false); see also *Unelko Corp. v. Rooney*, 912 F.2d 1049, 1055–58 (9th Cir. 1990) (affirming summary judgment for the defendants on defamation and product disparagement claims after Andy Rooney made a crack on CBS's "60 Minutes" program that Rain-X "didn't work" for him); cf. *Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 845–50 (9th Cir. 2001) (reversing dismissal of trade libel and related claims based on an investigative report broadcast by a local TV station about the dangers of the plaintiff's herbal supplement containing ma huang, a natural form of the stimulant ephedrine).

137. See, e.g., *Cranberg v. Consumers Union of U.S., Inc.*, 756 F.2d 382, 389–90 (5th Cir. 1985) (affirming judgment for the defendant on a disparagement claim asserted by the inventor of a specialized fireplace grate upset about a less than glowing review in *Consumer Reports* magazine); see also O'Dell, *supra* note 117, at A1 ("The magazine's stature is such that only nine other companies have ever dared sue it and risk a consumer backlash. Consumers Union won all nine cases."); cf. *Suzuki Motor Corp. v. Consumers Union of U.S., Inc.*, 330 F.3d 1110, 1117–23 (9th Cir. 2003) (Kozinski, J., dissenting from denial of petition for en banc rehearing) (lam-basting the panel's decision to allow a product disparagement claim to proceed based on a fully explained negative review published in *Consumer Reports* magazine that focused on the heightened rollover risk of the plaintiff's sports utility vehicle (SUV)); *id.* at 1115 (noting the many lawsuits brought by "disgruntled CU [Consumers Union] reviewees seeking revenge through the courts"); *Isuzu Motors Ltd. v. Consumers Union of U.S., Inc.*, 66 F. Supp. 2d 1117, 1124–26 (C.D. Cal. 1999) (denying a motion for summary judgment filed by the defendant because a reasonable jury could find actual malice in publication of a *Consumer Reports* story on the rollover risk posed by a different manufacturer's SUV).

138. See *Demuth Dev. Corp. v. Merck & Co.*, 432 F. Supp. 990, 991 (E.D.N.Y. 1977); *HipSaver*, 984 N.E.2d at 765–67; cf. *Auvil*, 800 F. Supp. at 933–36 (holding that a news broadcast about the dangers of the chemical Alar may have disparaged all apples and apple products as a class, *aff'd on other grounds*, 67 F.3d 816, 819 n.4 (9th Cir. 1995)).

side effects.<sup>139</sup> Lastly, personal injury attorneys plainly know (or should know) the meaning of the regulatory information that they disseminate and the burdens of establishing causation at trial,<sup>140</sup> which should make it somewhat easier to prove actual malice in the event that they have overstated or otherwise mischaracterized a product's risks.

*C. Federal Guidance to Promote Such Public or Private Efforts*

If state disciplinary authorities would find it difficult to tackle client-seeking campaigns that target prescription drugs in arguably misleading ways, and if tort claims against personal injury attorneys who run such ads represent something of a long-shot, then responses to this problem may have to come from elsewhere. Lawyers who engage in drug-related advertising do not contemplate any sale of a product, which explains why the FDA would enjoy no jurisdiction over them.<sup>141</sup> This has not stopped some commentators from suggesting that Congress delegate such authority to the agency.<sup>142</sup> The FDA, like other federal agencies, has some power to supervise the conduct of attorneys appearing before it.<sup>143</sup> Nonetheless, Congress surely would not extend the FDA's reach to supervise aspects of practice by lawyers involved in tort litigation.<sup>144</sup> The agency could, however, offer influential guidance about potentially misleading attorney advertisements concerning the therapeutic products that it regulates.

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139. For one peculiar recent incident involving charges by a television celebrity that attracted substantial attention, see David Bauder, *Roseanne Blames Ambien for Tweet; Drug Maker Replies; Sanofi Says "Racism Is Not a Known Side Effect" in Social Media Post*, TORONTO STAR, May 31, 2018, at A4.

140. See Tippet, *supra* note 14, at 45 ("[A]ttorneys bringing these lawsuits need to have a detailed knowledge of the medical risks at issue to litigate them."). The same could be said of persons offering commentary on this subject. See, e.g., *supra* note 76 (noting Tippet's misconception about the regulation of the Dalkon Shield); *infra* notes 146–51 and accompanying text (chastising Schaffzin for misunderstanding the FDA's drug advertising restrictions).

141. See Noah, *supra* note 62, at 55; Tippet, *supra* note 14, at 12 n.34 ("The FDA likely considers drug injury advertising outside of its jurisdiction."); *id.* at 47 ("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."); cf. *United States v. Evers*, 643 F.2d 1043, 1053 & n.16 (5th Cir. 1981) (same for physicians who do nothing more than advertise about using drugs in ways that the agency finds objectionable).

142. See, e.g., Rickard, *supra* note 1, at B3 ("[R]eforms could be achieved by empowering the FDA's Office of Prescription Drug Promotion to review lawyer ads, just as it does drugmaker ads. As these ads proliferate, those responsible for protecting the public's health and safety should make sure trial lawyers aren't held to a lower standard than those who advertise the products over which they're suing.")

143. See Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 52 (1995); see also Food and Drug Administration Amendments Act, Pub. L. No. 110-85, § 914, 121 Stat. 823, 953 (2007) (codified at 21 U.S.C. § 355(q)(1)(H)-(I) (2018)) (imposing a certification requirement on certain petitions filed before the agency).

144. Cf. *Leis v. Flynt*, 439 U.S. 438, 442 (1979) (per curiam) ("Since the founding of the Republic, the licensing and regulation of lawyers has been left exclusively to the States . . ."); Noah, *supra* note 49, at 165–71, 192 (explaining the strong tradition of congressional noninterference in professional medical and legal practice).

### 1. *Moving Beyond Undifferentiated Disclosure Proposals*

Professor Schaffzin's pair of suggestions that had related specifically to drug advertising by attorneys—namely, disclosures directing viewers to a reliable source for more details and reminding them to consult with a physician before discontinuing use<sup>145</sup>—claimed to borrow heavily from the FDA's requirements for DTCA,<sup>146</sup> but they did so in ways that do not in fact follow the agency's guidance. Demanding that advertisers provide links to further information differs from the FDA's "brief summary" requirement and allowance for "adequate provision" of this summary in the case of non-print advertising:<sup>147</sup> approved labeling represents the official and complete document about a product's risks and benefits, while an announcement of new risk information (whether from the FDA or some other source) would tell only half of the story even if it does a better job of describing the seriousness and certainty of the risk than possible in a short TV spot. Moreover, adequately cross referencing such a summary would not satisfy obligations of "fair balance" in the advertisement itself or relieve drug manufacturers of the need to provide a "major statement" of risks.<sup>148</sup>

Schaffzin's core recommendation, a reminder to see a physician before discontinuing use,<sup>149</sup> has essentially nothing to do with the FDA's approach to DTCA. Demanding "fair balance" instead would necessitate reminding viewers of a particular drug's helpful attributes, but it seems entirely implausible to expect that personal injury lawyers would waste time touting the benefits of products that they want to attack.<sup>150</sup> Moreover, the FDA specifically rejected a suggestion that DTCA use a boilerplate disclaimer about first checking with a doctor

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145. See Schaffzin, *supra* note 14, at 370.

146. See *id.* at 359 (calling for "similar restrictions as a means of mitigating the public health risk posed by direct solicitation of clients in pharmaceutical litigation"); see also *id.* at 359–68 (elaborating on the FDA's rules and guidance governing DTCA); *id.* at 369 ("At the heart of the requirements governing pharmaceutical DTC advertising is the expectation that promotional messaging will be fairly balanced in its reporting of the drug product's risk-benefit profile.").

147. See 21 C.F.R. § 202.1(e)(1) (2018); Notice, Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43,197, 43,198 (Aug. 9, 1999); see also Notice, Revised Draft Guidance for Industry, Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs, 80 Fed. Reg. 46,990 (Aug. 6, 2015); Noah, *supra* note 6, at 148–49.

148. See 21 U.S.C. § 352(n) (2018); 21 C.F.R. § 202.1(e)(3), (5)(ii), (6)–(7); see also Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner, 75 Fed. Reg. 15,376 (proposed Mar. 29, 2010) (to be codified at 21 C.F.R. pt. 202).

149. See Schaffzin, *supra* note 14, at 372 ("In order to protect the public, those advertisements must be fairly balanced so as to remind the consumer that no decisions about use of a medication should be made without first consulting a healthcare professional.").

150. See Tippet, *supra* note 14, at 45 ("[A]ttorney 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."); *id.* at 47 ("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."); *id.* at 47–48 (dismissing this approach as unduly burdensome).

in lieu of communicating more detailed risk information.<sup>151</sup> Yet Schaffzin urged precisely that approach for client-seeking ads. In short, the suggested parallels to existing rules and guidance for advertising to consumers do not help to make the case for the fixes that he offered.

Professor Tippett made only passing reference to the FDA's requirements for DTCA,<sup>152</sup> preferring instead to draw on the insights of communications theory.<sup>153</sup> Nonetheless, her basic suggestions largely aligned with Schaffzin's recommendations: she called on lawyers to (1) avoid running ads that masquerade as public service announcements by making plain at the outset the commercial nature of the television spot;<sup>154</sup> (2) provide clearer information about the typically low probability of serious adverse events;<sup>155</sup> (3) give more attention to the benefits of continued use;<sup>156</sup> and (4) include prominent reminders—not just in small font text—to consult with a physician.<sup>157</sup> Tippett did not, however, imagine that state disciplinary authorities would legislate such requirements or use their enforcement powers under existing rules to do so on a case-by-case basis; rather, she urged bar groups to help develop “best practices” for lawyers to consider when they engage in such advertising.<sup>158</sup> Indeed, Tippett worried about overly aggressive regulatory responses; she suggested that drug advertising by lawyers

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151. See Notice, Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24,316 (May 14, 1996) (“Such disclosures, however, are susceptible to habituation or ‘wear-out,’ which results in the viewer quickly learning to ignore the message, thus lowering its effectiveness. In addition, such messages may not be perceived as risk messages at all, but instead interpreted as reassurances.”); see also Noah, *supra* note 6, at 153 (reproducing one version of the suggested disclaimer); Yumiko Ono, *Fine Print in Drug Ads Sparks a Debate*, WALL ST. J., Apr. 1, 1997, at B1 (“One powerful ad-industry coalition is pushing for a bare-bones one-sentence warning that would cover all drugs. Its suggestion: ‘Prescription drugs are potent medications and should not be taken without specific instructions from your physician or other health-care professional.’”). Recently, the FDA proposed truncating the major statement of risks in broadcast DTCA to include only the most serious hazards so long as it appended the following statement: “This is not a full list of risks and side effects. Talk to your health care provider and read the patient labeling for more information.” See Request for Information and Comments, Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements, 82 Fed. Reg. 39,598, 39,599 (Aug. 21, 2017).

152. See Tippett, *supra* note 14, at 47 & n.194. She explained that the FDA does not require a description of adverse event frequency, see *id.* at 45, but that may have more to do with not wanting drug sponsors to underplay risks.

153. See *id.* at 42 (“drawing from social science research on best practices in risk communication”); *id.* at 36–37 (discussing the “persuasion knowledge model”).

154. See *id.* at 44, 46–47; *id.* at 36 (“[D]elayed disclosure of the source of the advertisement could lead viewers to be insufficiently skeptical of the medical information conveyed at the start of the ad.”).

155. See *id.* at 42 (“[P]roviding the quantitative risk information may promote a more measured and deliberative reaction by consumers.”); *id.* at 44.

156. See *id.* at 47–48 (explaining that “providing additional information about the benefits of a drug could serve to counteract consumer overestimation of risk,” but also recognizing that this could “prove to be a blunt instrument” as well as unduly burdensome).

157. See *id.* at 43, 44.

158. See *id.* at 40, 42; *id.* at 46 (“A far better outcome [than mandated disclaimers] would involve mass tort attorneys adopting best practices to convey high quality information in a streamlined way that does not encumber their overall message.”). Pollyanna strikes again!

may have a silver lining by drawing patients' attention to important new information.<sup>159</sup> Professor Tippet made no effort, however, to tease out the very different triggers that might prompt such television campaigns, and she neglected to recognize that client-seeking ads sometimes propagate information that may conflict with the FDA's position on the relative safety and effectiveness of an approved therapeutic product, which would present far more serious concerns about lawyers disseminating false and misleading claims.

Instead of such undifferentiated (and aspirational) approaches, it would make more sense to recognize gradations among the situations likely to attract client-seeking ads, borrowing FDA guidance relevant to these more subtle parallels. After all, attorneys have not limited their campaigns to potentially life-threatening consequences associated with arguably trivial drug products.<sup>160</sup> In 2016, for instance, TV spots started airing to draw attention to new warnings that linked the oncology agent Taxotere<sup>®</sup> (docetaxel) to permanent hair loss (alopecia).<sup>161</sup> Although generally posing less immediate hazards from cessation, other valuable therapeutic agents (*e.g.*, antibiotics, treatments for diabetes and cholesterol-lowering statins) have also gotten attacked in client-seeking campaigns.<sup>162</sup> As the value of the targeted products increases and the basis for claiming a risk of injury becomes weaker, the government could pursue more aggressive efforts to prevent such commercial messages without much fear that doing so might run afoul of the First Amendment.<sup>163</sup>

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159. See *id.* at 14 ("This article argues that including some risk-related information would substantially enhance the positive public health impact of such ads, and mitigate potential harms."); see also *id.* at 12 ("[T]his additional information can motivate viewers to seek medical care, usefully inform medical decision-making, and improve interactions with physicians. Paradoxically, they might even remind consumers to take their medication." (footnote omitted)); *id.* at 48 ("Drug injury advertising relating to drugs and medical devices has the potential to harm as well as improve public health.").

160. Cf. Noah, *supra* note 62, at 90 ("For the most part, . . . the products subject to these sorts of advertisements do not fill any critical therapeutic need or serve any public health function.").

161. See, *e.g.*, Davis & Crump, *Taxotere & Permanent Hair Loss, TV Spot*, YOUTUBE (Apr. 15, 2016), <https://www.youtube.com/watch?v=fmHZ5pbXX8E>; see also Onder Law Firm, *Tasigna Legal Helpline* (July 6, 2018), <https://www.ispot.tv/ad/w4IH/onder-law-firm-tasigna-legal-helpline> (explaining that Canadian authorities have linked the leukemia drug Tasigna<sup>®</sup> (nilotinib) to a risk of developing atherosclerosis).

162. See David N. Juurlink et al., Research Letter, *The Effect of Publication on Internet-Based Solicitation of Personal-Injury Litigants*, 177 CAN. MED. ASS'N J. 1369, 1370 (2007) ("We found that the publication of a study concerning the adverse drug events associated with gatifloxacin [the antibiotic Tequin<sup>®</sup>] led to a rapid, dramatic and sustained increase in Internet-based solicitation for litigants for personal-injury claims."); Noah, *supra* note 62, at 90 n.237 ("For example, one recent ad campaign run by an Orlando plaintiffs' lawyer alarmingly noted that the diabetes drug Avandia<sup>®</sup> (rosiglitazone maleate) may cause heart attack and stroke . . ."); Louis W. Sullivan, Opinion, *When Patients Take Medical Advice from Lawyers*, CHI. TRIB., Sept. 7, 2003, at 9 ("According to media reports, the advertising campaign designed to recruit Baycol plaintiffs may have persuaded patients to stop taking this and similar heart-attack-preventing 'statins.'").

163. For instance, what if personal injury attorneys directed their advertisements to the parents of children inoculated with the measles, mumps, and rubella (MMR) vaccine who mysteriously happened to develop autism shortly afterwards?

Although the hypothesized link, which in fact originated with a physician who had received financial support from plaintiffs' lawyers, has been completely discredited, vocal advocacy groups continue to insist that the MMR vaccine and the preservative thimerosal may cause autism. . . . If, however, plaintiffs' lawyers propagated the same message in client-seeking advertisements, then commercial speech doctrine presumably would allow the government somewhat greater leeway to restrict the dissemination of such (mis)information.

The Appendix appearing at the end of this Article attempts to illustrate a method for triaging the problem. It considers the strength of the safety signal by differentiating among several possible triggering events, and it sorts products according to their relative therapeutic value or the dangers that patients might encounter if they suddenly discontinued use. Along that latter dimension, therapeutic agents might have high, moderate, or low value, though even less valuable products might be tricky to “deprescribe” safely.<sup>164</sup> Although difficulties often arise in making such comparative judgments,<sup>165</sup> the FDA has various mechanisms in place for identifying relatively more valuable products, which it does most clearly at the time of initial licensure.<sup>166</sup>

The Appendix offers a larger number of gradations along the other dimension—namely, the strength of the safety signal—in recognition of the fact that several different events might trigger client-seeking ads. The FDA can select from a variety of steps in response to new risk information, ranging from relatively informal letters that identify suspected infractions (whether related to good manufacturing practices, advertising campaigns, or some other regulatory matter) and seek to encourage companies to undertake voluntary corrections, to demands that manufacturers strengthen the risk information in previously approved product labeling and, at the extreme, license withdrawal and perhaps recalls of

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Noah, *supra* note 62, at 90–91 (footnotes omitted).

164. See *supra* note 46 and accompanying text (discussing issues in deprescribing). Thus, even if some would regard antidepressants as offering only moderate therapeutic value, failures to wean patients off of them gradually and under medical supervision can endanger health. See Matthew Gabriel & Verinder Sharma, *Antidepressant Discontinuation Syndrome*, 189 CAN. MED. ASS’N J. E747 (2017); Alexia Elejalde-Ruiz, *Don’t Quit Cold Turkey; Reducing Your Reliance on Antidepressants Requires Patience and a Doctor’s Involvement*, CHI. TRIB., Aug. 29, 2010, at 22; Melissa Healy, *Go off Drugs, Lose Control?*, L.A. TIMES, Feb. 25, 2008, at F1. Indeed, when it announced stronger warnings for selective serotonin reuptake inhibitors (SSRIs), the FDA offered the following advice: “People currently prescribed antidepressant medications should not stop taking them. Those who have concerns should notify their healthcare providers.” Ralph F. Hall, *The Risk of Risk Reduction: Can Postmarket Surveillance Pose More Risk Than Benefit?*, 62 FOOD & DRUG L.J. 473, 487 (2007).

165. See Noah, *supra* note 7, at 863–66, 899 & n.264; *id.* at 865 (“[A]re powerful analgesics properly dismissed as merely “lifestyle” drugs? Contraceptives sometimes get trivialized in this fashion.”); *id.* at 866 (“In the final analysis, all drugs are, to one degree or another, lifestyle drugs.”). The World Health Organization (WHO) maintains a list of “essential medicines,” <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited Jan. 12, 2019).

166. See Notice, Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics, 79 Fed. Reg. 31,117 (May 30, 2014) (issuing final guidance on the agency’s various expedited programs for agents intended to treat serious conditions for which no available therapies exist); Mary K. Olson, *Are Novel Drugs More Risky for Patients than Less Novel Drugs?*, 23 J. HEALTH ECON. 1135, 1138 & n.2 (2004); Stephanie M. Lee, *FDA Speeds up Approval of Drug Breakthroughs*, S.F. CHRON., Aug. 4, 2014, at A1 (“To qualify [for the new ‘breakthrough therapy designation’], the company must show evidence suggesting that a drug could be much better at treating serious or life-threatening conditions than existing therapies.”); see also Noah, *supra* note 11, at 381 (“[N]ot all prescription drugs offer equally high utility. . . . [T]he agency will tolerate substantial risks for drugs that may save lives, while products that treat simple conditions or offer only symptomatic relief will not get approved unless fairly benign.” (footnote omitted)). Manufacturers of medical devices face an explicit three-tiered classification system, though one that reflects degrees of riskiness more so than therapeutic value. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77 (1996). A drug’s relative importance also may factor into efforts at managing supply shortages. See 21 C.F.R. § 314.81(b)(3)(iii)(a)(1) (2018); Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 747, 759 (2003).



already distributed inventory.<sup>167</sup> Although the most dramatic regulatory steps would seem to justify the most aggressive forms of attorney advertising, precisely because the FDA may want to scare patients into immediately discontinuing use, some license withdrawals may have little to do with genuine safety concerns,<sup>168</sup> and even those that do may expressly allow for continued use by existing patients.<sup>169</sup>

Short of withdrawing a prescription drug, the FDA has several less draconian options for addressing newly discovered risks: require relabeling with stronger warnings or clearer directions for use,<sup>170</sup> use other avenues to educate physicians and patients,<sup>171</sup> or perhaps impose restrictions on distribution and use.<sup>172</sup> (Conversely, when follow-up research fails to confirm a suspected link,

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167. See Noah, *supra* note 37, at 122–34 (discussing the range of regulatory options available to the FDA).

168. See Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 170 & n.19 (2015); see also Hall, *supra* note 164, at 476 (“It is important to remember that ‘recalls’ can occur in the absence of any safety issue.”). The agency maintains a list of drugs withdrawn on safety grounds. See 21 C.F.R. § 216 (2018); see also Diane K. Wysowski & Lynette Swartz, *Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969–2002*, 165 ARCHIVES INTERNAL MED. 1363 (2005) (finding safety-related withdrawals of more than seventy-five drugs, though that represents only approximately 1% of all those marketed since the FDA first imposed postmarket reporting requirements).

169. See, e.g., Denise Grady, *Serious Danger of Blood Clots Halts Sale of Leukemia Drug*, N.Y. TIMES, Nov. 1, 2013, at B4 (reporting that the FDA ordered, with limited exceptions, the withdrawal of Iclusig® (ponatinib) less than a year after approval); see also Noah, *supra* note 7, at 857 (“Occasionally after drug withdrawal, the FDA permits continued use by an even more narrowly defined class of patients.”); Andrew Pollack, *After Brief Halt, F.D.A. Allows Sales of Drug for Cancer to Resume*, N.Y. TIMES, Dec. 21, 2013, at B3 (“It is rare but not unprecedented for the F.D.A. to lift restrictions on use of a drug. Lotronex, a medicine for irritable bowel syndrome, and Tysabri, for multiple sclerosis, were returned to the market in 2002 and 2006. Both had been withdrawn because of potentially lethal side effects and both had strong support from patients.”).

170. See, e.g., Duff Wilson, *F.D.A. Puts New Limits on Cholesterol Drug*, N.Y. TIMES, June 9, 2011, at B2 (reporting labeling revisions for Zocor® and other drugs containing simvastatin to recommend against use of the highest approved dose in new patients because of the risk of myopathy); Abigail Zuger, *Caution: That Dose May Be Too High*, N.Y. TIMES, Sept. 17, 2002, at F1; *Cipro Side Effects May Outweigh Benefit*, SAN DIEGO UNION TRIB., May 14, 2016, at A4 (“The FDA issued previous warnings about [fluoroquinolone antibiotics] in 2008 and 2013, but didn’t go so far as to advise doctors to restrict their use.”); see also Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 326–32 (1994) (explaining that risk labeling for prescription drugs uses a hierarchy of categories based on degrees of severity and substantiation).

171. See, e.g., Jennifer C. Dooren, *FDA Warns of Possibly Lethal Drug Combination*, WALL ST. J., July 20, 2006, at D3; Denise Grady, *F.D.A. Discourages Procedure in Uterine Surgery*, N.Y. TIMES, Apr. 18, 2014, at A13 (reporting that, rather than banning morcellators, the agency “‘discourages’ doctors from using them in hysterectomies or fibroid surgery”); Francesca L. Kritz, *Why All the Drug Alerts? Step-up Signals FDA Bid for Renewed Trust*, WASH. POST, Feb. 26, 2008, at F1 (“[T]he agency has begun issuing three new types of advisories: an ‘early communication’ that indicates a recently reported problem with a drug; a ‘public health advisory’ that advises consumers to speak with their doctors because a drug may pose a serious risk; and a Q&A for physicians to help them answer patient questions.”).

172. See, e.g., Gardiner Harris, *F.D.A. Imposes Tougher Rules for Acne Drug*, N.Y. TIMES, Aug. 13, 2005, at A1 (“[I]nstead [of withdrawing effective drugs], the agency has begun fashioning restricted distribution programs . . . to ensure that health professionals follow its guidelines.”); Gardiner Harris, *F.D.A. to Restrict a Diabetes Drug, Citing Heart Risk*, N.Y. TIMES, Sept. 24, 2010, at A1 (Avandia®); see also Noah, *supra* note 37, at 134–37 (discussing the evolution in the agency’s authority to impose distribution restrictions).

the agency may remove previously imposed warning requirements and distribution restrictions.<sup>173</sup>) Labeling revisions run the gamut from contraindications,<sup>174</sup> and “black box” warnings,<sup>175</sup> to plain warnings,<sup>176</sup> and still milder precautionary statements.<sup>177</sup>

The risk information included in the labeling provided to health professionals does not, however, necessarily appear in any materials intended for distribution to patients. Indeed, the FDA has at times intentionally downplayed hazards communicated directly to patients precisely because of fears that laypersons may misunderstand and overreact to such information in potentially counterproductive ways.<sup>178</sup> It even has issued a regulation providing that the FDA “will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential.”<sup>179</sup>

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173. See, e.g., Linda A. Johnson, *Study: Chantix, Zyban Produce No Suicide Risk*, ORLANDO SENTINEL, Apr. 27, 2016, at A11; Karen Kaplan, *FDA Lifts Drug’s Safety Limits; The Diabetes Medication Avandia Does Not Cause an Unusual Heart Risk After All, Regulators Say in a Sharp Reversal*, L.A. TIMES, Nov. 26, 2013, at AA1; see also James Yeh et al., *Ethical and Practical Considerations in Removing Black Box Warnings from Drug Labels*, 39 DRUG SAFETY 709 (2016).

174. See Noah, *supra* note 47, at 437, 461 & n.397 (explaining that these amount to directions that physicians never use a product in particular circumstances). The agency may decide to narrow the range of approved uses if new adverse event information renders the risk-benefit ratio for just some of multiple indications unfavorable. See, e.g., *Kuhn v. Sandoz Pharm. Corp.*, 14 P.3d 1170, 1174–75 (Kan. 2000) (summarizing FDA negotiations with the manufacturer of Parlodel® that led to the removal from the originally approved labeling of the indication for the suppression of lactation).

175. See, e.g., Laurie McGinley, *FDA Requires New Warnings on Dangers of Mixing Drugs*, WASH. POST, Sept. 1, 2016, at A12 (reporting that the agency mandated black box warnings for numerous opioids and benzodiazepines to emphasize the serious risks associated with concomitant use); see also Cassie Frank et al., *Era of Faster FDA Drug Approval Has Also Seen Increased Black-Box Warnings and Market Withdrawals*, 33 HEALTH AFF. 1453, 1456 (2014) (finding 32 withdrawals and 114 added boxed warnings in a survey of 748 new chemical entities approved from 1975 to 2009).

176. See, e.g., Thomas M. Burton & Ron Winslow, *FDA Warns on Statin Drugs: Labels on Popular Cholesterol Medicines Must Cite Risk of Diabetes, Memory Loss*, WALL ST. J., Feb. 29, 2012, at A3.

177. See, e.g., Thomas M. Burton, *FDA to Require Diabetes Warning on Class of Schizophrenia Drugs*, WALL ST. J., Sept. 18, 2003, at D3 (reporting that revised labeling urged physicians to watch for suspected but not yet confirmed side effects); Marc Kaufman, *Impotence Drugs Will Get Blindness Warning*, WASH. POST, July 9, 2005, at A6 (same).

178. See, e.g., *Henley v. FDA*, 77 F.3d 616, 620–21 (2d Cir. 1996) (rejecting a challenge to the agency’s decision to remove animal carcinogenicity disclosures from the patient labeling for oral contraceptives); see also Noah, *supra* note 62, at 91 n.244 (noting that the agency sometimes “prevents drug manufacturers from including truthful but unduly alarming risk information in patient labeling for therapeutically valuable products”); Julie Bell, *“Black Box” Leaves Patients in the Dark*, BALT. SUN, June 30, 2003, at 7A (discussing “a debate over whether the warnings—printed on package inserts given to doctors and pharmacists but not to patients—help ensure that risky drugs are safely used”); cf. Gina Kolata, *Osteoporosis Drugs Shunned for Fear of Rare Side Effects*, N.Y. TIMES, June 2, 2016, at A1 (reporting that patients had overreacted to warnings passed along by their physicians).

179. 21 C.F.R. § 7.50 (2018); see also *Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibilities*, 43 Fed. Reg. 26,202, 26,217 (June 16, 1978) (offering “recall of defective heart valves” as an illustration of when it might invoke this proviso); Francesca Lunzer Kritz, *Recalls: Who Knew?*, WASH. POST, Oct. 22, 2002, at F1 (reporting that patients often do not receive notifications of drug recalls).

The weakness of some safety signals should make them largely ineligible as triggers for client-seeking drug ads. In 2007, Congress ordered the FDA to post information about approved pharmaceuticals undergoing review because of adverse event reports.<sup>180</sup> Such disclosures must, however, take care to avoid overreactions that may cause more harm than good.<sup>181</sup> Lawyers should not use preliminary information of this sort as the basis for undertaking an alarmist advertising campaign. Similarly, although researchers may announce their latest findings with some fanfare at a conference prior to publication in the pages of a scientific journal,<sup>182</sup> the FDA typically awaits confirmatory evidence before taking regulatory action.<sup>183</sup> Even worse, expert witnesses may testify in litigation and persuade juries of alleged hazards with a therapeutic agent without ever subjecting their claims to peer review, which occasionally prompts the agency to announce that it finds no merit to the charges.<sup>184</sup> Notwithstanding the possibility (or reality) of success in the courtroom, using TV ads to share such unfounded fears with patients would represent the height of irresponsibility.<sup>185</sup>

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180. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 915, 121 Stat. 823, 958 (codified at 21 U.S.C. § 355(r)(3) (2018)) (requiring that the agency maintain a web site to post preliminary safety information in advance of potential labeling revisions).

181. See David Brown, *FDA to List Drugs Being Investigated: Complaints Will Be Posted Quarterly*, WASH. POST, Sept. 6, 2008, at A2 (“FDA officials said they realize that the new policy . . . may unintentionally alarm some patients.”); see also Noah, *supra* note 170, at 385–88, 396–97 (discussing these issues in relation to warnings for consumer goods).

182. See Lawrence K. Altman, *Promises of Miracles: News Releases Go Where Journals Fear to Tread*, N.Y. TIMES, Jan. 10, 1995, at C3 (“Sometimes scientists . . . say things in releases that they would never dream of saying in a scientific paper, where evidence is demanded to support a claim.”); see also Ray Moynihan et al., *Coverage by the News Media of the Benefits and Risks of Medications*, 342 NEW ENG. J. MED. 1645, 1647–49 (2000) (finding distorted reporting of such announcements by the media); Lars Noah, *Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decisionmaking*, 59 U. PITT. L. REV. 677, 708 (1998) (“[E]ditors of scientific journals pursue scoops, and they increasingly use embargoed press releases to inform the national media about the publication of important new research in the latest issue of their journal.”).

183. See, e.g., Molly Selvin, *Hormone Suits Face Hurdle as Drugs Keep FDA Backing*, L.A. TIMES, Nov. 7, 2005, at C1; Rob Stein, *Antibiotics May Raise Risk for Breast Cancer*, WASH. POST, Feb. 17, 2004, at A1 (“There could be other explanations for the association, and much more research is needed before scientists understand what the surprising results mean, [experts] said.”); see also Mitchell Levine et al., *Users’ Guides to the Medical Literature: IV. How to Use an Article About Harm*, 271 JAMA 1615, 1617 (1994); Noah, *supra* note 47, at 395–416 (elaborating on some of the limitations in the medical literature); Noah, *supra* note 182, at 683 (discussing the “hazard of premature responses to incomplete information”); *id.* at 717 (“[S]erious questions about the effectiveness of the editorial peer review process should caution against too ready a dependence on the output of scientific journals in protecting the public health and welfare.”); J. Venulet et al., *How Good Are Articles on Adverse Drug Reactions?*, 284 BRIT. MED. J. 252, 254 (1982) (“It is striking that while so much importance is placed on published articles the quality of so many is so poor.”).

184. See, e.g., *Determination That Bendectin Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness*, 64 Fed. Reg. 43,190 (Aug. 9, 1999); Lars Noah, *Civil Jury Nullification*, 86 IOWA L. REV. 1601, 1656–57 (2001) (summarizing the history of the Bendectin litigation).

185. See Gray, *supra* note 3, at A17 (criticizing the fact that “personal injury lawyers have spent almost \$10 million to run nearly 19,000 talcum powder litigation commercials on national and local television networks over the past year”); see also Michael Hiltzik, *Is Junk Science Going to Sway Jurors?*, L.A. TIMES, July 13, 2017, at C1. Although it would represent no great loss if frightened consumers needlessly discontinued using personal care products containing talc, fomenting hysteria among former users that they may develop an often fatal form of cancer hardly seems defensible.

## 2. *Urging a Public Health Agency to Get the Ball Rolling*

Insofar as state disciplinary authorities are unable or unwilling to take the lead in guarding against the potential health hazards associated with misleading advertising by lawyers about therapeutic products, or can only design fairly clumsy (one-size-fits-all) responses, the federal agency with the greatest stake and expertise in the issue should exercise some leadership on the subject. Indeed, while the FDA has not yet shown any apparent inclination to join this debate,<sup>186</sup> surely the matter has not escaped its notice, and it would not represent the first time that the agency injected itself into a controversy of this sort. Moreover, to the extent that the available evidence offers only limited support for regulatory responses by state disciplinary officials, any insights offered by this respected public health entity might tip the balance in the face of constitutional objections.<sup>187</sup>

A quarter of a century ago, the FDA approved the new animal drug Posilac<sup>®</sup> (recombinant bovine somatotropin (“rbST”)).<sup>188</sup> Because it could detect no difference between milk from cows administered rbST and other milk, the FDA declined to require any special disclosure statement in labeling.<sup>189</sup> A couple of months later, and just as a congressional moratorium on the sale of rbST came to an end, the FDA published in the *Federal Register* an “Interim Guidance on

186. See Tippet, *supra* note 14, at 12 n.34 (“identify[ing] no instances in which the FDA has weighed in on drug injury advertising”).

187. See, e.g., Int’l Dairy Foods Ass’n v. Boggs, 622 F.3d 628, 642 (6th Cir. 2010) (“Although the FDA’s Interim Guidance [on claims about the nonuse of a genetically engineered hormone in milk production] and the consumer comments relied on by the State constitute weak evidence of deception, they at least demonstrate that the risk of deception in this case is not speculative.”); cf. Pharm. Mfrs. Ass’n v. FDA, 484 F. Supp. 1179, 1192 (D. Del.) (“[T]he [FDA] Commissioner was called upon to forecast possible patient reaction to the labeling information. This was a matter with respect to which the agency had had some relevant prior experience. . . . [T]he Commissioner was entitled to make a forecast without supporting clinical data or expert opinion.”), *aff’d*, 634 F.2d 106, 108 (3d Cir. 1980) (per curiam); Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 902, 920 n.102, 922 & n.117 (2008) (conceding that the FDA does not get as much judicial deference as it once did); Noah, *supra* note 62, at 35 (“The FDA has had an enviable record of success in the courts because judges have shown tremendous deference to the agency’s expertise in implementing its public health mission, but recently it has fared less well when challenged on First Amendment grounds.” (footnote omitted)).

188. See Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946, 59,947 (Nov. 12, 1993) (codified at 21 C.F.R. § 522.2112 (2018)); see also Kurt Eichenwald, *Redesigning Nature: Hard Lessons Learned; Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES, Jan. 25, 2001, at A1 (calling Monsanto’s decision to develop rbST “a major strategic blunder,” at least when viewed from a public relations standpoint). See generally Lars Noah, *Managing Biotechnology’s [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, ¶¶ 26–44 (2006) (discussing the FDA’s initial responses to agricultural applications of genetic engineering).

189. See *Stauber v. Shalala*, 895 F. Supp. 1178, 1185–86 (W.D. Wis. 1995); see also *id.* at 1192–93 (rejecting a challenge to the FDA’s decision against mandating rbST disclosure in labeling). For a more recent version of this sort of a controversy, see Lars Noah, *Whatever Happened to the “Frankenfish”? The FDA’s Foot-Dragging on Transgenic Salmon*, 65 ME. L. REV. 605 (2013). Although the FDA finally approved the genetically modified salmon, see Andrew Pollack, *Genetically Engineered Salmon Declared Ready for U.S. Plates*, N.Y. TIMES, Nov. 20, 2015, at A1, Congress passed an appropriations rider one month later calling for the FDA to issue guidance for disclosure in labeling, see Consolidated Appropriations Act, 2016, Pub. L. No. 114–113, Div. A, § 761, 129 Stat. 2242, 2285 (2015), which has derailed commercialization, see Jenna Gallegos, *Regulations Slow GMO Salmon Sales in U.S., but Canadians Are Eating Tons*, WASH. POST, Aug. 6, 2017, at A6.

the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin.”<sup>190</sup> The agency explained that “[s]everal States and industry and consumer representatives have asked FDA to provide guidance on the labeling of milk and milk products from [untreated] cows.”<sup>191</sup> Although it referenced a pair of broad provisions in the applicable federal statute,<sup>192</sup> the agency emphasized that it “view[ed] this document primarily as guidance to the States as they consider the proper regulation of rbST labeling claims.”<sup>193</sup> After all, the FDA exercises no authority over the advertising of foods,<sup>194</sup> and its power to regulate labeling only applies to products that move in interstate commerce.<sup>195</sup>

The interim guidance explained that consumers could misunderstand unadorned statements about the nonuse of rbST:

Because of the presence of natural bST in milk, no milk is “bST-free,” and a “bST-free” labeling statement would be false. Also, FDA is concerned that the term “rbST free” may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as “from cows not treated with rbST” or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.<sup>196</sup>

The agency suggested ways of providing such “proper context” in labeling or advertising: “For example, accompanying the statement ‘from cows not treated

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190. 59 Fed. Reg. 6279 (Feb. 10, 1994).

191. *Id.* at 6280.

192. *See id.* (discussing sections 201(n) and 403(a) of the federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. §§ 321(n), 343(a) (2018)); *see also id.* (“The guidance presented here reflects FDA’s interpretation of the [federal] act and may be relevant to States’ interpretation of their own similar statutes.”).

193. *Id.*; *see also id.* (“Given the traditional role of the States in overseeing milk production, the agency intends to rely primarily on the enforcement activities of the interested States to ensure that rbST labeling claims are truthful and not misleading. The agency is available to provide assistance to the States.”).

194. *See* 15 U.S.C. § 52(a) (2018) (granting the FTC jurisdiction over the advertising of food); Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388, 28,388–89 (June 1, 1994); *see also* Kraft, Inc. v. FTC, 970 F.2d 311, 322–27 (7th Cir. 1992) (sustaining an order against a manufacturer of processed cheese slices for misrepresenting in an advertising campaign the amount of calcium contained in its product). Among federal agencies, only the FTC (with its authority over false and misleading advertising) is thought to have any role to play in regulating promotional activities by lawyers; given its antitrust focus, however, the Commission tends instead to push back against anticompetitive state restrictions. *See* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 646 n.13 (1985) (citing an FTC report on the subject); Tippet, *supra* note 14, at 13 n.35 (“The FTC’s power over attorney advertising is somewhat uncertain. . . . 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.”); *id.* at 40 n.153 (noting the agency’s “disinclination to act”); *see also* Am. Med. Ass’n v. FTC, 638 F.2d 443, 449–53 (2d Cir. 1980) (affirming a Commission order invalidating the AMA’s ethics rules against physician advertising), *aff’d by an equally divided court*, 455 U.S. 676 (1982).

195. *See* 21 U.S.C. § 331(a)–(c), (k) (2018); Kordel v. United States, 335 U.S. 345, 347–51 (1948).

196. Interim Guidance, 59 Fed. Reg. at 6280.

with rbST' with the statement that 'No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows' would put the claim in proper context."<sup>197</sup> It also emphasized the need to substantiate such claims, pointing out that no tests of milk existed to detect the use of rbST and that supplies of milk from different dairy farms often get commingled.<sup>198</sup> The agency offered fairly detailed suggestions for suitable recordkeeping requirements and the creation of third-party certification programs to facilitate the substantiation of "rbST-free" claims.<sup>199</sup>

As an "interim guidance," the FDA's announcement had no binding effect.<sup>200</sup> Although this early encounter with the issue would influence the agency's subsequent responses to broader questions about the labeling of genetically modified organisms ("GMOs") in food,<sup>201</sup> the interim guidance never got finalized. Nonetheless, this document unmistakably played a role in both public and private law responses to the use of "rbST-free" or comparable claims for dairy products from untreated cows.<sup>202</sup> One state's agricultural department took

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197. *Id.*; see also *id.* ("Proper context could also be achieved by conveying the firm's reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST . . .").

198. See *id.*; see also Patricia Callahan & Scott Kilman, *Some Ingredients Are Genetically Modified, Despite Labels' Claims*, WALL ST. J., Apr. 5, 2001, at A1 (reporting that commingling has impacted sellers of other food products that make "non-GMO" claims); William Neuman, *Biotech-Free, Mostly*, N.Y. TIMES, Aug. 29, 2009, at B1 ("At harvest and afterward, biotech and nonbiotech crops and their byproducts are often handled with the same farm equipment, trucks and so on."); Stephanie Strom, *Seeking Food Ingredients That Aren't Gene-Altered*, N.Y. TIMES, May 27, 2013, at B1.

199. See Interim Guidance, 59 Fed. Reg. at 6280; see also *id.* (hastening to add that "[t]he physical handling and recordkeeping provisions of such a program would be necessary not because of any safety concerns about milk from treated cows but to ensure that the labeling of the milk is not false or misleading").

200. See *id.* ("This document does not bind FDA or any State, and it does not create or confer any rights, privileges, benefits, or immunities for or on any persons. Furthermore, this document reflects FDA's current views on this matter. FDA may reconsider its position at a later date . . ."). On this agency's penchant for using such nonbinding pronouncements, see Noah, *supra* note 37, at 103, 113–22; *id.* at 120–21 ("Over the last quarter of a century, for instance, the agency has relied exclusively on guidance documents to address the various issues that have arisen with genetically engineered (GE) plants, animals, and appropriate labeling of food products derived from these sources." (footnotes omitted)).

201. In 2001, the FDA issued guidelines for the voluntary labeling of GM or non-GM foods. See Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001). In contrast to its 1994 interim guidance on "rbST-free" claims, this draft guidance addressed itself to sellers rather than to state officials, focused just on labeling rather than also advertising, explained primarily why it decided against mandating disclosure, and offered more questions than answers about absence claims, though what little it did say about these paralleled its more detailed guidance on "rbST-free" statements. See *id.* at 4840 ("[T]hese terms would be misleading if they imply that the food is superior because the food is not bioengineered."); *id.* at 4841 (discussing options available to food processors for substantiating absence claims); see also Lars Noah, *Genetic Modification and Food Irradiation: Are Those Strictly on a Need-to-Know Basis?*, 118 PENN. ST. L. REV. 759 (2014) (elaborating on the FDA's policy, and contrasting it with disclosure requirements that it imposed on the use of a different food production technology). In 2015, the FDA finalized this document without making any fundamental modifications. See Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants, 80 Fed. Reg. 73,194 (Nov. 24, 2015); see also Stephanie Strom, *F.D.A. Takes Issue with the Term "Non-G.M.O."*, N.Y. TIMES, Nov. 21, 2015, at B1.

202. See Robert Steyer, *Label Rule on BST Unpopular: FDA Makes It Tough to Prove a Negative*, ST. LOUIS POST-DISPATCH, Feb. 13, 1994, at 1E (reporting that the National Association of State Departments of Agriculture opposed voluntary labeling, adding that Illinois and Missouri would not allow such claims); see also Andrew Martin, *Fighting on a Battlefield the Size of a Milk Label*, N.Y. TIMES, Mar. 9, 2008, at BU7 (discussing

the hint and prohibited the use of such absence claims,<sup>203</sup> though it reversed course a short time later.<sup>204</sup> Ohio's Department of Agriculture adopted similar restrictions, which a federal court largely invalidated on constitutional grounds.<sup>205</sup>

The FDA's interim guidance spurred legislative activity as well. A few states considered proposals consistent with the agency's recommendations,<sup>206</sup> and Alaska ultimately adopted such a law.<sup>207</sup> In contrast, Vermont thumbed its nose at the FDA's position by mandating the disclosure of rbST use,<sup>208</sup> but this effort got derailed by the ensuing First Amendment litigation, which included references to the agency's interim guidance.<sup>209</sup> Thereafter, the Vermont legislature instead decided to require a disclosure statement to accompany any nonuse

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the continued debate over rbST and new proposals in more than half a dozen states to restrict the growing use of absence labeling claims).

203. See Tom Avril, *Hormone Labeling of Pa. Milk to End; It Can Unfairly Imply Injecting Cows Isn't Safe, Officials Say*, PHILA. INQUIRER, Dec. 23, 2007, at A1 (reporting that the state agriculture department had adopted the policy, adding that "Monsanto has lobbied for similar changes in other states, so far unsuccessfully").

204. See Peter Smith, "Hormone-Free" Milk Spurs Labeling Debate, CHRISTIAN SCI. MONITOR, Apr. 21, 2008, at 13 ("Pennsylvania . . . essentially banned labeling claims in October 2007, but rescinded the ban after considerable consumer backlash."); see also *id.* (reporting that Monsanto had unsuccessfully petitioned the FTC on the matter).

205. See Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 635–44 (6th Cir. 2010) (holding that a prohibition on "rbST-free" labeling violated the First Amendment, while sustaining a disclaimer requirement except insofar as it had to appear immediately after the text of the claim rather than using an asterisk); *id.* at 632–33 (quoting at length from the FDA's interim guidance); see also Beth Berselli, *Settlement Reached in Hormone Labeling Case: Ben and Jerry's, States Agree Food Makers Can Indicate Absence of Added Product*, WASH. POST, Aug. 15, 1997, at A22 (reporting that, after a constitutional challenge to such a prohibition in Illinois, the state agreed to allow qualified rbST absence claims accompanied by a disclaimer, adding that similar rules existed at the time in Hawaii, Nevada and Oklahoma).

206. See Smith, *supra* note 204, at 13 ("Ohio, Missouri, Kansas, Indiana, and Michigan all have pending legislation or rule changes that would limit labeling claims about hormones."); see also Rachel Melcer, *Lawmakers Consider Bill to Restrict Labels on Milk Containers*, ST. LOUIS POST-DISPATCH, Apr. 17, 2008, at B1 (discussing a legislative proposal in Missouri, and adding that retailers often included the FDA's recommended statement without sufficient prominence).

207. See ALASKA STAT. § 17.20.013(a) (2017) (requiring that the following statement accompany claims about nonuse: "No significant difference has been shown between milk derived from rBST treated and non-rBST treated cows.>").

208. See VT. STAT. ANN. tit. 6, § 2754(c) (Michie 1995); cf. Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 21 & n.77 (noting that a couple of states had imposed brief moratoria on sales).

209. See Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 248–49, 252 (D. Vt. 1995) (quoting the guidance), *rev'd*, 92 F.3d 67, 74 (2d Cir. 1996) (deciding that the plaintiffs should have been granted a preliminary injunction). A couple of decades later, Vermont became the first state to mandate disclosure of the use of GMOs in food products. See Stephanie Strom, *G.M.O.s in Food? Now Vermonters Will Know, and So May You*, N.Y. TIMES, July 2, 2016, at B3; see also Noah, *supra* note 201, at 765 & n.30 (discussing other state initiatives). In 2016, however, Congress preempted state requirements and directed the U.S. Department of Agriculture (rather than the FDA) to develop rules. See National Bioengineered Food Disclosure Standard, Pub. L. No. 114–216, 130 Stat. 834 (2016) (to be codified at 7 U.S.C. §§ 1639–1639j, 6524); National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,871 (Dec. 21, 2018) (to be codified at 7 C.F.R. pt. 66); Amy Harmon, *What Will G.M.O. Labels Tell Consumers?*, N.Y. TIMES, May 13, 2018, at A19 ("Food makers would be given a choice of three disclosure methods: spelling out the information, as in 'contains a bioengineered food ingredient'; using a standard icon (the agency proposed several evoking sun and smiles); or affixing a QR code that directs consumers to a website with more information.").

claims.<sup>210</sup> Lastly, the FDA's interim guidance has played a role in private litigation brought by suppliers and users of rbST.<sup>211</sup>

As revealed by the announced policy on "rbST-free" claims, the FDA can use its bully pulpit to address public health issues that it cannot control directly. This expert agency's expressed views may influence state officials, whether they reside in the legislative, executive, or judicial branches of government.<sup>212</sup> The time has come for a similar federal initiative to combat misleading attorney advertising about still-marketed therapeutic products. Although the FDA has at times in the past shown solicitude for the personal injury bar,<sup>213</sup> and it may even appreciate having drug safety alerts propagated in this manner (free of charge), the agency surely must recognize that some client-seeking efforts have gone too far and may imperil the health of patients prescribed drugs that it regulates.

#### IV. CONCLUSION

Client-seeking advertising that targets prescription drugs may pose health risks to patients. Unlike DTCA, which the FDA has subject to various restrictions, personal injury attorneys face essentially no oversight with regard to

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210. See VT. STAT. ANN. tit. 6, § 2762(3) (2017) (requiring the use of a disclaimer such as "the U.S. Food and Drug Administration has not found a significant difference to exist between milk derived from rbST-treated and non-rbST-treated cows").

211. See *Eli Lilly & Co. v. Arla Foods Inc.*, No. 17-C-703, 2017 WL 4570547, at \*1, \*8 (E.D. Wis. June 15, 2017) (granting a preliminary injunction in favor of the sellers of Posilac on their Lanham Act and related claims against an ad campaign by the sellers of rbST-free dairy products, citing the FDA's interim guidance and its latest scientific review), *order amended*, 2017 WL 5244681 (E.D. Wis. July 18, 2017); *id.* at \*9 (finding the use of "a very small FDA disclaimer at the bottom of the commercial" insufficient); Rick Barrett, *Lawsuit Says Dairy Ads Portray Bovine Growth Hormone rbST as a Six-Eyed Monster*, MILWAUKEE J. SENTINEL, June 7, 2017, available at 2017 WLNR 17490635 (elaborating on this litigation); Andrew Pollack, *Which Cows Do You Trust?*, N.Y. TIMES, Oct. 7, 2006, at C1 ("A few years ago Monsanto sued Oakhurst Dairy in Maine, saying its labeling of milk as coming from cows not treated with the hormone was misleading. The dairy added a sentence to the effect that the F.D.A. had found no significant difference between the milk from treated and untreated cows."); see also Stephen J. Hedges, *Monsanto Having a Cow in Milk Label Dispute: "Hormone Free" Tag Unfair, Company Says*, CHI. TRIB., Apr. 15, 2007, at A1 (reporting that the supplier of Posilac had alerted the FDA and the FTC to more than a dozen sellers making allegedly misleading absence claims).

212. It certainly has a better chance of success than the seemingly ineffectual effort by the chair of the U.S. House Judiciary Committee when he mailed letters expressing such concerns to every state's bar authorities in March 2017. See *supra* note 4. The U.S. Drug Enforcement Administration (DEA) engaged in vaguely similar tactics—issuing a policy statement and sending threatening letters to state medical boards—when it sought to undermine state initiatives authorizing the use of marijuana for medical purposes. See Office of National Drug Control Policy Administration, Notice, Response to Arizona Proposition 200 and California Proposition 215, 62 Fed. Reg. 6164, 6164 (Feb. 11, 1997) (announcing that the Departments of Justice and "Health and Human Services (HHS) will send a letter to national, state, and local practitioner associations and licensing boards which states unequivocally that DEA will seek to revoke the DEA registrations of physicians who recommend or prescribe Schedule I controlled substances" and which explains that HHS can "exclude specified individuals or entities from participation in the Medicare and Medicaid programs"); see also Noah, *supra* note 49, at 150–51, 179–84 (explaining that it did this again in response to state efforts to allow physician-assisted suicide, though in both cases courts later decided that the DEA had exceeded the bounds of its jurisdiction).

213. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2154 & n.30 (2000); see also *id.* at 2158 ("[P]ublic health agencies may not mind having the tort system serve as a 'safety valve' for deflecting adverse publicity from themselves when hazards with a product subsequently come to light.").



the particular hazards associated with such campaigns. Lawyers enjoy no greater rights, however, than does the drug industry when engaging in such commercial speech, so the Constitution does not stand in the way of crafting a sensible response. Nonetheless, because state bar authorities do not seem up to the task of doing so, and tort litigation would encounter serious obstacles as well, this Article has recommended that the federal agency with the greatest stake in the matter—notwithstanding its conceded lack of regulatory jurisdiction over the speakers—take the lead in trying to define what types of attorney drug advertising cross the line. Only then might state officials and courts get the message that some client-seeking advertisements might well mislead patients in a way that threatens their health.

## APPENDIX: MATRIX OF MISLEADINGNESS

|   |                             | <u>THERAPEUTIC VALUE (OR HAZARD IN DEPRESCRIBING)</u> |                 |            |
|---|-----------------------------|---|-----------------|------------|
|   |                             | <u>High</u>   | <u>Moderate</u> | <u>Low</u> |
| <u>TRIGGERING EVENT</u> (based on new safety information) | Withdrawal (or recall)      | ?   | √               | √          |
|   | Relabeling:                 |   |                 |            |
|   | • Contraindication          | ?   | √               | √          |
|   | • Black box warning         | ?   | ?               | √          |
|   | • Warning statement         | X   | ?               | √          |
|   | • Precaution (or ADE)       | X   | ?               | ?          |
|   | FDA issues a warning letter | X   | ?               | ?          |
|   | FDA posts prelim. concern   | X   | X               | ?          |
|   | New research announced      | X   | X               | ?          |
|   | Unfounded fears             | X   | X               | X          |

Key: √ = presumptively permissible (with basic disclosures)  
 ? = potentially misleading (requires contextual review)  
 X = presumptively impermissible