UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Chairman

November 17, 2020

The Honorable Greg Walden
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Representative Walden:

Thank you for your November 2, 2020 letter to the Federal Trade Commission ("FTC" or "Commission") about attorney television advertisements that solicit potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs (hereafter "lawsuit advertisements"). We appreciate your concerns that certain lawsuit advertisements could present a serious threat to public health and safety. Advertising plays a critical role in our economy. It is one of the primary ways that people find out about available goods and services. Attorney advertising, in particular, may alert people who have been injured that they be may be entitled to compensation. However, to be useful, advertising must not be misleading.

As you know, the Commission acts in the interests of consumers to prevent deceptive or unfair acts or practices in or affecting commerce, pursuant to Section 5 of the FTC Act.[1] An act or practice is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, likely to affect a consumer's conduct or decision with regard to a product or service.[2] An act or practice is unfair if it causes or is likely to cause substantial consumer injury that consumers cannot reasonably avoid, and that is not outweighed by benefits to consumers or competition.[3] When an advertisement is targeted to a specific audience, such as the elderly or terminally ill, the Commission determines the ad's effect on a reasonable member of that group.[4] The important criterion is the net impression the ad is likely to make on that group.[5]

As you note, in September 2019, staff sent warning letters to seven legal practitioners and lead generators about lawsuit advertisements.[6] We address your follow-up questions, below.

1. **Please provide an update as it relates to the warning letters that the FTC sent last year to the seven legal practitioners and lead generators running potentially unlawful ads. Has the FTC taken any additional actions? If yes, please identify**

---

[1] 15 U.S.C. § 45.
[2] *See Federal Trade Commission Policy Statement on Deception ("Deception Policy Statement"), appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984).
[3] 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).
[4] *Deception Policy Statement*, *supra* note 2.
[5] *Pfizer, Inc*., 81 F.T.C. 23, 58 (1972).
[6] FTC Press Release, *FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits* (Sept. 24, 2019), www.ftc.gov/news-events/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits.

what actions have been taken. If not, please explain why no additional actions have been taken.

Yes. FTC staff followed up with all seven of the warning letter recipients, and each recipient committed orally or in writing to heed staff's concerns for future lawsuit advertisements. Staff also opened a formal investigation into Relion Group, Inc.'s lawsuit advertisements about the prescription drug Valsartan. Staff closed the investigation based on several factors. Relion discontinued the ads at issue prior to being contacted by the FTC. With respect to any future drug lawsuit advertising, Relion committed to incorporate clear and conspicuous, audiovisual disclosures; specify the scope of any recalls; avoid suggesting the ads are medical alerts or government-sanctioned messages; and not overstate the risks of taking prescription medication.[7]

2. **Do lawsuit advertisements that make claims that are not based on competent and reliable scientific evidence violate the FTC Act? If yes, please explain why. If not, please explain why not.**

Whether it violates the FTC Act for lawsuit advertisements to make claims that are not based on competent and reliable scientific evidence depends on the claim. A lawsuit advertisement might convey any number of claims about a particular drug or class of drugs—*e.g.*, the drug is not efficacious for the indicated condition, the drug has dangerous side effects, the drug is adulterated, scientific evidence shows that the drug is ineffective or dangerous, or consumers should reduce or eliminate their use of the drug.

If the claim is an "establishment claim"—*i.e.*, the ad refers to the specific amount, type, or strength of scientific support for the drug's efficacy or safety, then the advertiser must possess at least the level of support that they claim to have. For example, a representation that "a clinical study proves" that a drug does not deliver a particular health benefit or has adverse side effects will generally be interpreted as asserting that scientific or clinical studies prove the claims. In such cases, the advertiser must possess the level of proof sufficient to satisfy the relevant scientific community of the claim's truth.

For claims about a drug's safety or efficacy, advertisers must have a reasonable basis for those claims before disseminating an ad. A number of factors determine the appropriate amount and type of substantiation required,[8] but typically claims about the efficacy or safety of a drug requires "competent and reliable scientific evidence."[9]

---

[7] *See Closing Letter to Relion Group, Inc.* (July 8, 2020), www.ftc.gov/system/files/documents/closing_letters/nid/1923253relionclosingletter.pdf.

[8] *See FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation. These factors are known as the *Pfizer* factors, after the 1972 case in which they were first enunciated. *Pfizer, Inc.*, *supra* note 5.

[9] *See POM Wonderful LLC*, 777 F.3d 478, 495-97 (D.C. Cir. 2015), *cert. denied*, No. 15-525, 2016 U.S. LEXIS 2991 (May 2, 2016) (affirming Commission's competent and reliable scientific evidence standard for disease-related claims about food products).

3. **Do lawsuit advertisements that include the FDA logo, when the FDA is not involved in the advertisement or related to the underlying action, violate the FTC Act? If yes, please explain why. If not, please explain why not.**

   It might violate the FTC Act for lawsuit advertisements to include the FDA logo when the FDA has not been involved in the advertisement or the underlying action. Depending on the FDA's logo's placement and the ad's other audiovisual elements, reasonable consumers might interpret a lawsuit advertisement with the FDA logo as a government-sanctioned medical alert or public service announcement. Consumers might take away the misleading claim that the FDA has sponsored the ad or endorsed its messages. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[10]

4. **Do lawsuit advertisements that include the text or phrase "FDA Warning," when the FDA is not involved in the advertisement or related to the underlying action, violate the FTC Act? If yes, please explain why. If not, please explain why not.**

   It might violate the FTC Act for lawsuit advertisements to use language like "FDA Warning" when the FDA has not been involved in the advertisement or the underlying action. Consistent with the response to Question 3, above, a lawsuit advertisement that references an FDA warning might, depending on the ad's other audiovisual elements, deceptively state or imply that the FDA sponsors the ad or a particular message therein, when that is not the case.

5. **Do lawsuit advertisements that include the text or phrase "medical alert" or "drug alert" violate the FTC Act? If yes, please explain why. If not, please explain why not.**

Whether it violates the FTC Act for lawsuit advertisements to include language like "medical alert" or "drug alert" depends upon the advertisement's net impression. If the use of "alert" language, combined with the ad's other audiovisual elements, conveys the message that taking a particular drug or class of drugs poses substantial health risks or that the risks of taking these medications outweigh their benefits, then the advertiser must possess competent and reliable scientific evidence to support such claims. Further, if the lawsuit advertisement induces or is likely to induce viewers to discontinue their medications, then the ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician. Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

---

[10] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

6. **Does the FTC have the tools it needs to bring enforcement actions against plaintiff lawyers, legal practitioners, lead generators, or any other individual or organization responsible for deceptive lawsuit marketing and advertising practices? If no, please provide any recommendations for additional tools you may need, such as the request you recently made regarding your 13(b) authority.**

   Sections 5 and 12 of the FTC Act provide a sufficient legal basis to challenge deceptive lawsuit advertising.

7. **Does the FTC conduct any kind of outreach, such as lectures or workshops, to interest groups who represent the plaintiff bar, such as the American Association of Justice, so that such parties are aware of FTC guidelines, concerns over certain lawsuit marketing and advertising practices, and the enforcement tools available to protect vulnerable Americans? If not, does the FTC plan to conduct such outreach in the future?**

   The FTC does not conduct the specific outreach activities described in the question. However, staff from the Bureau of Consumer Protection routinely give speeches and appear on panels at industry-attended events that highlight the Commission's false advertising enforcement priorities and actions. Moreover, publicizing warning letters and investigation closing letters educates industry and the Bar about the Commission's concerns and provides insight into how staff analyzes lawsuit advertisements for potential false or deceptive claims. Members of staff also make themselves available to outside counsel who have questions about the FTC Act's application to lawsuit advertisements.

8. **West Virginia, Texas, and Tennessee all have enacted laws that address deceptive lawsuit marketing and advertising practices within their respective states.[11] Has the FTC reviewed such state laws and, if so, do you have any recommendation as to whether Congress should consider similar laws at the federal level?**

   The laws against deceptive lawsuit advertising in West Virginia, Texas, and Tennessee target the same concerns about lawsuit advertising raised in Commission staff's warning letters. For example, those state laws prohibit legal advertising from: (1) using phrases like "consumer medical alert," "health alert," "consumer alert," or "public service health announcement" to the extent they suggest an offer of professional, medical, or government agency advice about pharmaceuticals or medical devices rather than legal services; (2) displaying the logo of a federal or state government agency in a manner that suggests affiliation with the sponsorship of that agency; (3) using the word "recall" when referring to a product that has not been recalled by a government agency or through an agreement between a manufacturer and government agency; (4) failing to identify the sponsor of the legal advertisement; and (5) failing to identify the attorney or law firm that will represent clients, or how potential clients or cases will be referred to attorneys or law

[11] W. VA. CODE § 47-28-3 (2020), *available at* https://code.wvlegislature.gov/47-28-3/; TENN. CODE. ANN. §§ 47-18-5602-5605, *available at* https://legiscan.com/TN/text/SB0352/id/1998216; TEX. GOV'T CODE §§ 81.151-154, *available at* https://texas.public.law/statutes/tex._gov't_code_section_81.152.

firms that will represent clients if the sponsor of the legal advertisement may not represent persons responding to the advertisement.

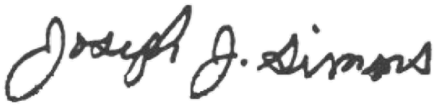
The Commission consistently has taken the position that, while unfair or deceptive advertising should be prohibited, consumers do not benefit from the imposition of overly-broad restrictions that prevent the communication of truthful and non-misleading information that some consumers value. The requirements and restrictions in the aforementioned laws, however, appear narrowly tailored to prevent deception and not unnecessarily restrictive of truthful and non-misleading information about either potential harms from FDA-approved medication or available legal remedies for such harms. The prohibitions against "alert" language, government logos, and references to product recalls apply only when ads employ those elements in a deceptive manner. To this extent, the laws codify prohibitions already subsumed by the general prohibition against false advertising in the FTC Act and similar state laws.

While FTC staff has reviewed these state laws, the FTC has not taken a position on federal legislation on this topic.

The Commission shares your concerns about the importance of protecting consumers from misleading health-related information, including deceptive lawsuit advertisements. Staff will remain vigilant for lawsuit advertisements that make false or deceptive claims about the efficacy or safety of drugs that reasonably could lead to consumer harm. Among other things, staff will continue to consult and share information with their FDA counterparts. Staff will address concerning lawsuit advertisements through, as appropriate, law enforcement, warning letters, guidance, and consumer and business education materials.

If you or your staff have additional questions or comments, please do not hesitate to have your staff call Jeanne Bumpus, the Director of our Office of Congressional Relations, at (202) 326-2195.

Sincerely,



Joseph J. Simons
Chairman