Drug Lawsuit Advertisements and the Importance of Physician Consultation Prior to Voluntary Medication Withdrawal or Transition

The Journal of Clinical Pharmacology
2022, 62(12) 1468–1471

DOI: 10.1002/jcph.2136

Kenneth T. Moore, MA, MS, FAHA, Sudhakar M. Pai, PhD, FCP, Mark Rogge, PhD, FCP
On behalf of the ACCP Public Policy Committee

Keywords

drug lawsuit advertisement, medication transition, medication withdrawal, physician consultation, position statement

The American College of Clinical Pharmacology (ACCP) strongly endorses greater patient awareness and education concerning the potential for inaccurate and misleading statements made in advertisements supporting drug lawsuit recruitment campaigns. When appropriate, health professionals should discuss these campaigns with their patients to ensure that a medically and scientifically balanced understanding of the risks and benefits of their current care is provided prior to stopping or transitioning to alternative treatments without the health care provider's knowledge. The ACCP also strongly recommends that all plaintiff recruitment advertising, regardless of modality, for pharmaceutical lawsuits should include a prominent warning that patients should first consult with a physician before discontinuing any prescribed medication to ensure that a safe withdrawal or transition of the product occurs, when warranted.

The ability to take legal action in support of patients inadvertently injured from taking a pharmacological product or implantation of a device is an important part of our judicial system. However, along with this right is a need for properly balanced methods and messaging when actions are taken to recruit potential plaintiffs. The current realm of methods employed ranges from television advertisements and social media platforms to directly contacting individuals via email and phone. While some of these modalities are appropriately used, others are not. Messaging can often be aggressive and confusing in nature, with inaccurate, incomplete, and/or unbalanced statements about the products in question.[1–4] As such, the nature of this messaging has raised concerns regarding patient safety when decisions to abruptly stop the medication are made without first consulting a medical professional.[2–4]

In an ever-advancing technologically based global society, direct-to-consumer (DTC) advertising is both a powerful and necessary tool for communication. As such, those using these modalities must also adopt the responsibility of communicating information accurately and should consider the tone, content, language, imagery, and audience being addressed. This is especially important when communicating medical and scientific data that may entail a level of complexity that is not generally understood by those consuming the product. Over the past several years, there have been many examples of drug liability DTC ad campaigns in support of mass tort litigation that have been found to be either deceptive, confusing, or alarming, along with presenting a misrepresentation of and/or leading to a misinterpretation of the known scientific and medical information.[5–7] Concerningly, the subsequent actions taken by some patients based on these campaigns (ie, abruptly stopping the drug in question without prior consultation with their primary health care practitioner) have led to occurrences of severe adverse reactions, permanent disability, and even death.[8]

Examples of this consequence were reported in a 2016 case report by Burton and Peacock, in which the authors documented a series of severe medical

Janssen Pharmaceuticals Inc., Medical Affairs, Titusville, New Jersey, USA

Submitted for publication 1 August 2022; accepted 2 August 2022.

Corresponding Author:
Kenneth Todd Moore, MA, MS, FAHA, ACCP Public Policy Committee, PO Box 1758, Ashburn, VA 20146
Email: info@ACCP1.org

events that were reported to MedWatch, the Food and Drug Administration's (FDA) Safety Information, and Adverse Event Reporting System (FAERS), following the start of a DTC drug liability campaign with the Factor Xa inhibitor rivaroxaban (XARELTO), a new class of anticoagulant.[9] A primary concern of this particular campaign was the lack of scientific and medical balance while inciting immediate fear for those prescribed the therapy in question. This case report describes 28 severe adverse events that occurred in patients after abruptly discontinuing rivaroxaban upon viewing the legal recruitment commercials.[9] This abrupt termination of prescribed treatment, without proper consultation or transition to another anticoagulant, likely led to subsequent events that included 20 cases of stroke (1 of which led to patient death), 3 cases of deep vein thrombosis, 3 cases of transient ischemic attack, and 2 cases of pulmonary embolism (1 of which led to patient death).[9]

Another known example followed in 2019, when the FDA responded to a request sent a year earlier from Congressman Andy Harris, MD, US House of Representatives.[10,11] Dr Harris requested that the agency perform a search of the same reporting system (eg, FAERS) for patients who discontinued either their antidiabetic, antidepressants, or anticoagulant medications after viewing legal product liability advertisements.[10] This report identified 213 adverse medical events from 37 different states, in which patients viewed an advertisement and then discontinued their medication.[11] Of the 213 adverse events reported, 44 (≈21%) were identified as being related to discontinuations upon viewing a legal advertisement, 14 of which included a narrative identifying "bad drug ads" as the specific advertisement that prompted their discontinuation of the medication.[11] Another 155 (≈73%) were described as patients discontinuing their medication after viewing an advertisement, but the specific type of advertisement was not identified. Finally, 58 (≈27%) described an adverse event that occurred after discontinuation of the prescribed medication.[11] Although the ACCP recognizes the limitations of the FAERS platform for collecting and reporting these types of events, the supportive literature, legal testimonies, and recent federal response validate these serious concerns.[12–15]

While on the surface this method of plaintiff recruitment through commercial advertisement is similar to pharmaceutical DTC advertisements, there is a major difference in how they are regulated. Pharmaceutical DTC campaigns have oversight by the FDA and the Office of Prescription Drug Promotion to ensure that drug advertisements are accurate and display fair and balanced claims before being made publicly available.[16] Drug liability DTC ads are self-regulated and are guided by attorney ethics rules and the individual state bars.[5] Unfortunately, unlike the Office of Prescription Drug Promotion, the state bars do not routinely monitor drug liability DTC ads prior to their being made publicly available.[5] The fact that many of these ads are less than transparent regarding who is sponsoring the messaging (eg, a law firm, a "lead generator," or the FDA) further complicates the state's ability to easily investigate any claims, if made.[5] Additionally, the First Amendment places an outer limit on restrictions states can impose on attorney advertising, as it is protected commercial speech.[5] Only if the advertisement is considered (1) "inherently misleading" or (2) "experience has proved that in fact such advertising is subject to abuse" can the individual state bar associations intervene.[5] In addition, the above-mentioned criteria would require some supportive proof that consumers have been harmed, which until recently has been difficult to obtain.[5]

From a federal standpoint, the Federal Trade Commission (FTC) may intervene if significant evidence is found that lawyer advertisements are unfair and deceptive or can potentially cause public harm. After the case reports published by Burton and Peacock; results from the FDA-FAERS analysis requested by Congressman Andy Harris, MD, US House of Representatives; and a public survey conducted by Public Opinion Strategies for the US Chamber Institute for Legal Reform, the FTC did take some action.[9,10,17] On September 24, 2019, the FTC announced that it had sent warning letters to 7 legal practitioners and lead generators. These formal letters expressed concerns that some television advertisements that solicit clients for personal injury lawsuits against pharmaceutical companies "may be deceptive or unfair in violation of the FTC Act."[18–24] The letters also indicate that their ads "may misrepresent" the risks associated with the treatment and could leave consumers with the false impressions that (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits or (2) the ads constitute public "medical alerts" or have been approved by the FDA.[18–24]

Whereas the ACCP recognizes that these ads do bring awareness to potentially negative drug side effects and can act as a check and balance to pharmaceutical drug development and marketing, they *should not* be misconstrued as public service announcements; many patients misinterpret them as such because of the manner in which the advertisements are produced. Due to the potential for patient harm, secondary to confusing, deceptive, unfair, and/or medically and scientifically unbalanced statements made in these recruitment campaigns, improved patient awareness and education is needed to stress the importance of consulting with a physician before taking any actions to discontinue

their current treatment regimen. Although the health care professional plays a significant role in educating patients regarding these ads to ensure that a medically and scientifically balanced understanding of the risks and benefits of care is provided before stopping or transitioning to alternative treatments, sponsors of these ads should also partner in this endeavor.

American College of Clinical Pharmacology Call to Action

The ACCP strongly recommends greater patient awareness and education concerning the potential for inaccurate and misleading statements made in advertisements supporting drug lawsuit recruitment campaigns. When appropriate, health professionals should discuss these campaigns with their patients to ensure a medically and scientifically balanced understanding of the risks and benefits of their current care is provided before stopping or transitioning to alternative treatments. The ACCP also strongly recommends that all plaintiff recruitment advertising, regardless of modality, for pharmaceutical lawsuits should include a prominent warning that patients should first consult a physician before discontinuing any prescribed medication to ensure that the safe withdrawal or transition of the product occurs, when clinically warranted.

Conflicts of Interest

K.T.M., an employee and shareholder of Janssen Pharmaceuticals, declares no conflicts of interest.

Disclaimer

The opinions expressed in this article are those of the authors on behalf of the American College of Clinical Pharmacology and should not be interpreted as the position of the entities or institutions at which the authors are employed.

ACCP Public Policy Committee

Mark Rogge, PhD, FCP; Sudhakar M. Pai, PhD, FCP; JeanMichel Gries, PharmD, PhD; Michael J. Fossler Jr, PharmD, PhD, FCP; Bruce Gaynes, OD, PharmD; Douglas Greene, PhD, FCP; Manoj Jadhav, PhD, FCP; Parag Kumar, PharmD; Kenneth T. Moore, MA, MS, FAHA; Joanna C. Masters, PharmD; Ahmed A. Othman, PhD, FCP; Lorraine Rusch, PhD, FCP; Ahmed Hamed Salem, PhD, FCP; and Islam Younis, PhD, MSc.

REFERENCES

1. Rickard LA. How lawyers scare people out of taking their meds. *The Washington Post*. 2016. https://www.washingtonpost.com/opinions/2016/08/05/8c821c32-5295-11e6-88eb-7dda4e2f2aec_story.html. Accessed June 2, 2022.
2. Bad for Your Health, Lawsuit Advertising Implications and Solutions. U.S. Chamber, Institute for Legal Reform, An Affiliate of the U.S. Chamber of Commerce. (OCTOBER 24, 2017). Prepared for the U.S. Chamber Institute for Legal Reform by Cary Silverman, Shook, Hardy & Bacon L.L.P. https://instituteforlegalreform.com/research/bad-for-your-healthlawsuit-advertising-implications-and-solutions/. Accessed June 2, 2022.
3. Gilliam FR, Peschin S. Drug lawsuit ads are scaring seniors to death. *STAT*. 2019. https://www.statnews.com/2019/05/13/drug-lawsuit-ads-scaring-seniors/#:~:text=Attorneys%20spend%20millions%20of,threatening%20problems%20like%20blood%20clots. Accessed June 2, 2022.
4. Habte S. Curb Attorney TV Ads, Drug Makers and Doctors Urge Congress. 2017. https://news.bloomberglaw.com/pharma-and-life-sciences/curb-attorney-tv-ads-drug-makers-and-doctors-urge-congress. Accessed June 2, 2022.
5. Examining Ethical Responsibilities Regarding Attorney Advertising: Held by the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice. 2017. (Testimony of Elizabeth C. Tippett, Assistant Professor, University of Oregon School of Law). https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=106162. Accessed June 2, 2022.
6. Healy EY. Does Trial Lawyer Advertising Pose a Growing Risk to Public Health? The Doctor's Advocate | Second Quarter 2019 Government Relations Report. https://www.thedoctors.com/the-doctors-advocate/second-quarter-2019/does-trial-lawyer-advertising-pose-a-growing-risk-to-public-health/. Accessed June 2, 2022.
7. McConnell S. The risks of plaintiff lawyer DTC advertising. *Drug & Device Law*. 2015. https://www.druganddevicelawblog.com/2015/11/the-risks-of-plaintiff-lawyer-dtc.html. Accessed June 2, 2022.
8. King J, Tippett E. Drug injury advertising. *Yale J Health Policy Law Ethics*. 2020. https://openyls.law.yale.edu/handle/20.500.13051/5953. Accessed June 2, 2022.
9. Burton P, Peacock WF. A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising. *HeartRhythm Case Rep*. 2016;2(3):248-249.
10. Congress of the United States, House of Representatives: Letter of Request from Andy Harris M.D., Congressman, First District, Maryland to Scott Gottlieb, M.D., Commissioner, U.S. Food and Drug Administration. Request for the FDA to perform a renewed query of its FAERS database for reports of adverse events related to patients discontinuing prescribed medications after viewing legal advertisements. 2018. https://www.agingresearch.org/app/uploads/2019/05/Harris-Medwatch-ltr-2.pdf. Accessed June 2, 2022.
11. U.S. Food and Drug Administration. Response to Andy Harris M.D., House of Representatives, 2018 Request for Information: MedWatch Report of patients discontinuing their anticoagulants, antidepressants, and antidiabetic therapies after viewing a legal advertisement. 2019. Response from Maren McBride, Legislative Director for Appropriations. https://www.agingresearch.org/app/uploads/2019/05/2019-0206-Harris-Letter.pdf. Accessed June 2, 2022.
12. Examining Ethical Responsibilities Regarding Attorney Advertising: Held by the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice. 2017. (Testimony of Shawn H. Fleming, MD – Section Chief, Vascular Surgery, Novant Health Vascular Specialists). https://docs.house.gov/meetings/JU/JU10/20170623/106162/HHRG-115-JU10-Wstate-FlemingS-20170623.pdf. Accessed June 3, 2022.
13. Tippett E. Medical advice from lawyers: a content analysis of advertising for drug injury lawsuits. *Am J Law Med*. 2015;41(1):7-48.

14. Galgay C, Herling-Mintz DJ. FTC identifies concerns with plaintiff's lawyers advertisements concerning risks associated with pharmaceutical drugs. *Natl Law Rev*. 2019;IX(269). https://www.natlawreview.com/article/ftc-identifies-concerns-plaintiff-s-lawyers-advertisements-concerning-risks. Accessed June 3, 2022.
15. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program. Accessed June 2, 2022.
16. OPDP Regulatory Information. *US Food and Drug Administration*. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-regulatory-information?source=govdelivery. Accessed June 2, 2022.
17. Bill McInturff and Lori Weigel/Public Opinion Strategies to The Institute for Legal Reform, June 13, 2017, Re: Key findings from survey research regarding implications of trial lawyer advertising targeting prescription medicines. https://instituteforlegalreform.com/wp-content/uploads/media/2017_ILR_Rx_Drug_Survey_Key_Findings_D1c.pdf. Accessed June 6, 2022.
18. Engle MK. Associate Director, United States of America Federal Trade Commission to Mr. Ravi Jaiswal, President and Chief Executive Officer, MCM Services Group LLC. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
19. Engle MK. Associate Director, United States of America Federal Trade Commission to Mr. Bill Tilley, Chief Executive Officer, Amicus Legal Group, LLC. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
20. Engle MK. Associate Director, United States of America Federal Trade Commission to Brian Ketterer, Esq, Managing Partner, Ketterer Browne & Anderson. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
21. Engle MK. Associate Director, United States of America Federal Trade Commission to Mr. Travis Marble, Managing Director, Lucy Business Services, LLC. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
22. Engle MK. Associate Director, United States of America Federal Trade Commission to David Matthews, Esq. Matthews and Associates. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
23. Engle MK. Associate Director, United States of America Federal Trade Commission to Adam Pulaski, Esq. Pulaski Law Firm PLLC. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.
24. Engle MK. Associate Director, United States of America Federal Trade Commission to Ricky A. LeBlanc, Esq. Managing Partner, Sokolove Law, LLC. 2019. https://www.ftc.gov/system/files/documents/foia_requests/warning_letters_regarding_prescription_drug_lawsuit_tv_ads.pdf. Accessed June 6, 2022.