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Congress of the United States
House of Representatives
Washington, DC 20515

October 15, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Delivered by email to: legislation@fda.hhs.gov

Dear Dr. Gottlieb,

In December 2016, I requested from your predecessor, Dr. Robert Califf, a summary of MEDWATCH reports received by the Food & Drug Administration ("FDA") concerning patients forgoing their prescribed anticoagulant medications, including rivaroxaban, dabigatran, apixaban, and edoxaban, after viewing a legal advertisement (i.e., television, online, or other advertisement placed by a law firm or other company that is not the medication's manufacturer or marketer).[1] My request came in the wake of a paper published in *Heart Rhythm Case Reports*[2] outlining several serious cases of patients discontinuing anticoagulant therapy after viewing legal advertisements, in addition to the American Medical Association's contemporaneous admonition of some legal advertising practices as "fearmongering."[3]

Anna Abram, FDA Deputy Commissioner for Policy, Planning, Legislation and Analysis, responded to my request in early 2017 with a letter outlining the results of an FDA Adverse Event Reporting System ("FAERS") query conducted by the Center for Drug Evaluation and Research's pharmacovigilance group.[4] The query results were shocking and greatly distressing. As you will see from a review of that correspondence (attached), the FAERS query unveiled twenty-two instances in which patients viewed "legal" advertisements before discontinuing Pradaxa (dabigatran) or Xarelto (rivaroxaban). These advertisement-induced discontinuations lead to various serious medical events, including strokes, transient ischemic attacks, deep vein thrombosis of the arm, intracardiac thrombus, and cerebral and foot thrombosis. Another thirteen patients reported discontinuing their prescribed anticoagulant therapy after viewing an advertisement that used the term "bad drug." Most disturbingly, the FAERS query produced documentation of at least five deaths related to patients stopping their prescribed medications after viewing a legal advertisement.

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[1] Letter from The Hon. Andy Harris, M.D., U.S. House of Representatives to Food & Drug Administration Commissioner Robert M. Califf, M.D. (Dec. 2, 2016)(*Attached*).
[2] Paul Burton and W. Frank Peacock, *A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising*, 2 Heart Rhythm Case Reps. 248-249 (May 2016).
[3] American Medical Association House of Delegates Resolution 208: A-16 (April 2016)(*Attached*).
[4] Letter from Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, U.S. Food and Drug Admin. to The Hon. Andy Harris, M.D., U.S. House of Representatives (undated 2017)(*Attached*).

Since late 2016, when my office received those initial FAERS query results, much more information on the negative impacts of false and misleading lawsuit advertising practices on public health have come to light. In June 2017, the U.S. House Judiciary Committee held a hearing entitled, *Examining Ethical Responsibilities Regarding Attorney Advertising*[5], featuring two practicing physicians who recounted their firsthand experiences with "the impact of reckless attorney advertising on patient safety."[6] One poll submitted into the record at the June 2017 hearing stated that "[o]ne-in-four people who see an actual trial lawyer ad regarding a medicine they currently take say they would immediately stop taking the medicine without consulting their doctor."[7] The aforementioned polling data is backed by empirical evidence proffered in a forthcoming *Yale Journal of Health Policy, Law, and Ethics* article by Professors Jesse King and Elizabeth Tippett. King and Tippett's article notes that some drug lawsuit advertisements do indeed mislead consumers, and when framed as health warnings, can cause patients to "reduce their reported likelihood of filling or refilling a prescription for the [advertised] drug...."[8]

Groups like the AARP have also recently taken notice of the serious implications of these practices. In March 2018, the AARP's Fraud Watch Network issued an alert entitled "Don't let Lawsuit Ads Put You at Risk," warning its members to be on the lookout for lawsuit ads that use terms like "medical alert," "consumer alert," "recall," or "FDA warning," and to always consult a doctor prior to discontinuing a prescribed medication.

In light of these many developments, and given that is has been nearly two years since my last request, I write to ask that the FDA perform a renewed query of its FAERS database for reports of adverse events related to patients discontinuing prescribed medications after viewing legal advertisements. Specifically, I request that you provide this office with the following:

- A summary of MEDWATCH reports received by FDA concerning patients who stopped taking an anticoagulant medication, including but not limited to: apixaban, dabigatran, edoxaban, enoxaparin, fondaparinux, or rivaroxaban, as prescribed, after viewing legal advertisements (i.e., television, online, or other advertisement placed by a law firm or other company that is not the medication's manufacturer or marketer). Please use the terms in the attached spreadsheet to inform your search.

- A summary of MEDWATCH reports received by FDA concerning patients who stopped taking an antidepressant medication, including but not limited to: citalopram, desvenlafaxine, escitalopram, fluoxetine, paroxetine, sertraline, or venlafaxine, as

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[5] Examining Ethical Responsibilities Regarding Attorney Advertising: Hearings Before the Subcomm. on the Constitution and Civil Justice of the House Comm. on the Judiciary, 115th Cong. (2017).
[6] Examining Ethical Responsibilities Regarding Attorney Advertising: Hearings Before the Subcomm. on the Constitution and Civil Justice of the House Comm. on the Judiciary, 115th Cong. 2 (2017) (statement of Ilana Kutinsky, DO, FACC Director of Atrial Fibrillation Services, William Beaumont Hospital, Troy, Michigan); *See also* Statement of Shawn H. Fleming, MD Section Chief, Vascular Surgery, Novant Health Vascular Specialists.
[7] Memorandum from Bill McInturff and Lori Weigel, Public Opinion Strategies, to the Institute for Legal Reform (June 13, 2017) (on file with the Institute for Legal Reform).
[8] Jesse King and Elizabeth Tippet, *Drug Injury Advertising*, Yale Journal of Health Policy, Law, and Ethics (forthcoming July 25, 2018).

prescribed, after viewing legal advertisements (i.e., television, online, or other advertisement placed by a law firm or other company that is not the medication's manufacturer or marketer). Please use the terms in the attached spreadsheet to inform your search.

- A summary of MEDWATCH reports received by FDA concerning patients who stopped taking an antidiabetic medication, including but not limited to: canagliflozin, dapagliflozin, or empagliflozin, as prescribed, after viewing legal advertisements (i.e., television, online, or other advertisement placed by a law firm or other company that is not the medication's manufacturer or marketer). Please use the terms in the attached spreadsheet to inform your search.

- A list of patients' home states coinciding with reports found in the above requested FAERS queries and the total number of coinciding reports from each of those states.

Thank you for your continued attention to this important issue concerning patient safety. I am confident that these queries will produce data necessary to helping us better understand the significant public health impacts of false and misleading drug lawsuit advertising practices and will lead to the development of safeguards to prevent future injuries and deaths. I look forward to your reply and hope to be able to review it by November 15. Please direct your response to John Dutton in my office at john.dutton@mail.house.gov.

Sincerely,

Andy Harris, M.D.
Member of Congress