

**Statement for the Congressional Record
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**United States House of Representatives
Judiciary Committee
Subcommittee on the Constitution and Civil Justice
Hearing on “Examining Ethical Responsibilities Regarding Attorney Advertising”
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Chairman Goodlatte, Ranking Member Conyers, Subcommittee Chairman King, Ranking Member Cohen, and Distinguished Members of the Committee.

It is an honor and a privilege to submit a statement for the record on behalf of the Alliance for Aging Research on “Examining Ethical Responsibilities Regarding Attorney Advertising.”

I am Susan Peschin, President and CEO at the Alliance for Aging Research. The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. We believe that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term.

I first want to thank Chairman Goodlatte for his leadership in encouraging the American Bar Association (ABA) to self-regulate and amend its Model Rules of Professional Conduct to contain common sense reforms that require all legal advertising to “contain a clear and conspicuous admonition to patients not to discontinue medication without consulting their physician. They should also remind patients that the drugs are approved by the FDA and that doctors prescribe these medications because of the overwhelming health benefits from these drugs.”

The Alliance has been concerned with the “1-800-BAD-DRUG” advertisements since 2015, when the advertisements targeting oral anticoagulants—used to reduce stroke risk in patients with atrial fibrillation—first came to our attention.

Atrial fibrillation (AFib) is the most common form of cardiac arrhythmia, affecting about 1 in 25 adults age 60 or older, and 1 in 10 adults age 80 or older.ⁱ Those living with AFib are at an increased risk of stroke—stroke risk in AFib patients is 5 times greater than in those without the disease.ⁱⁱ And AFib-related strokes are quite serious—according to the National Stroke Association, 70% of AFib patients who suffer a stroke will die.ⁱⁱⁱ Additionally, the condition is associated with an approximate doubling of the risk of all-cause mortality^{iv} and is a contributory cause of death for more than 137,000 Americans each year.^v

AFib has also proven to be a major economic burden for the United States. At least \$6.65 billion in health care costs are attributable to the condition each year, an estimate that may in fact be extremely low.^{vi} One study estimates that Medicare pays \$15.7 billion per year to treat newly

diagnosed AFib patients.^{vii} As our nation ages, those costs are going to skyrocket and the American Heart Association estimates the annual healthcare expenditures related to all types of stroke can be expected to increase to \$140 billion by 2030.^{viii}

To reduce stroke risk, patients with AFib are often treated with an anticoagulant, which are highly effective at reducing stroke risk by as much as 80% in AFib patients.^{ix} Anticoagulants do increase the risk of bleeding— from minor bleeding to fatal hemorrhage—but experts are generally united in the opinion that the net benefit of ischemic stroke prevention through anticoagulation supersedes bleeding risk concerns for most AFib patients.^x

Despite the fact that oral anticoagulation is highly effective at reducing stroke risk, elderly patients are often not anticoagulated, owing in part to under-appreciation of the stroke risk associated with AFib, the tendency of some health care professionals to prioritize bleeding risk over stroke prophylaxis, and concern over falls and bleeding risk.^{xi}

In October 2014, the Alliance convened a symposium with representatives from federal agencies including the Food and Drug Administration (FDA), Veteran’s Administration, National Heart, Lung, and Blood Institute, National Institute of Neurological Disorders and Stroke, and the National Institute on Aging; patient advocacy groups; and medical professional societies to discuss those factors leading to undertreatment of older AFib patients, and to identify gaps in current clinical practice, education, research, and policy. Symposium participants concluded that an integrated, national effort is needed to promote adoption of best practices, develop alternate reimbursement models, expand patient and caregiver education on stroke risk and treatment, leverage existing initiatives, and address gaps in research on stroke and bleeding in AFib.^{xii}

Such an integrated effort is necessary because the public health impact of under-anticoagulation is severe. AFib patients who discontinue the use of their anticoagulation revert to their original stroke risk.^{xiii} We are concerned about the 1-800-BAD-DRUG advertising because it has caused patients to discontinue their potentially life-saving oral anticoagulant without consulting with a healthcare professional. **Adverse event data show that this discontinuation has directly led to serious medical events, including stroke and death^{xiv}; and future advertising of this nature will undoubtedly lead to more.**

Deceptive Advertising

We believe that one problem with the 1-800-BAD-DRUG ads is that they are deceptive under the FTCs’ truth-in-advertising rules. First, calling the hotline “bad drug” and referring to a “dangerous blood thinner drug,” or “blood thinner warning” gives the impression that the drug being featured is dangerous for the consumer. This is deceptive on its face.

Second, the statement in the ads about the drugs being linked to dangerous bleeding while true, are deceptive because they omit “material” information. That omitted information is the number of people on anticoagulants that have a serious bleed—which is very low—and the benefits of anticoagulation—which is high. An October 2015 piece from Dr. Ellis Unger, Director of the Office of Drug Evaluation in the Office of New Drugs at the FDA, emphasized the fact that

anticoagulation for stroke prevention in AFib almost always outweighs the potential bleeding risk: <http://www.fda.gov/Drugs/NewsEvents/ucm467203.htm>.

A reasonable consumer could conclude from the wording and visuals used in the 1-800-BAD-DRUG advertisements that anticoagulants are dangerous drugs that cause serious harm and even death, and that they have no benefits. The failure to include the information mentioned above is likely to leave the consumer with a misimpression about anticoagulants.

While the firms are soliciting AFib patients who experienced bleeding events, the number of people who experience serious bleeds with this class of drugs is statistically very low, while the risk of debilitating stroke from NOT taking them is quite high—and that information is nowhere in the ad. The tone and style of the advertisements are reminiscent of asbestos and thalidomide—very high profile cases of consumer harm from recalled products. It would be reasonable for the viewer to conclude that their medically prescribed anticoagulant is similarly a drug now found to be too dangerous to take, when in fact it is statistically very likely to save their lives. These advertising tactics are designed to solicit clients who have experienced a serious bleeding event, yet the messaging is, in practice, creating a second group of patients who have suffered harm.

We believe these ads fall within the regulatory authority of the FTC and would like to see them publicly request that ads like these should express, in written and oral form, that patients should NEVER go off prescribed medications without speaking with their healthcare provider. They should also request that the ads should state the use of the medication (in this case, for stroke prevention in people with AFib), and the factual info regarding rates of adverse events. Any ads that fail to follow these requirements should be enjoined from future airings.

Violation of ABA Model Rules of Professional Conduct

In her March 23, 2017 response to Chairman Goodlatte’s letter that references the American Medical Association resolution on this issue and requests that the ABA self-regulate this advertising; ABA President Linda Klein states that “The ABA, of course, does not sanction misleading or untruthful advertising—by lawyers, doctors, pharmaceutical companies, or anyone else. The issue raised by the AMA [resolution] appears to be not the misleading nature of advertisements, but the harmful consequences to some members of the public who may misunderstand ads and decide on their own to discontinue a course of treatment.”

Ms. Klein’s rationale is professionally convenient but ethically inconsistent: when a potential plaintiff suffers injury by a medical product he or she is a victim, but when a consumer suffers injury from an attorney advertisement he or she “misunderstand ads and decide on their own to discontinue course of treatment.” Are both groups victims or are both groups uninformed, reckless consumers? Ms. Klein and the ABA cannot have their cake and eat it too.

We share Ms. Klein and the ABA’s “interest in 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 if supported by the law and the facts in each case.” We do not take issue in any way with the practice of personal injury

law. However, we hope that Ms. Klein and the ABA also share our interest in ensuring that individuals are not injured by misleading advertising that leaves them under the impression that their life-saving, FDA approved drugs, are instead dangerous drugs that they should stop taking immediately.

Our interest in protecting consumers from these advertisements is supported by ABA Model Rule 7.1 *Communication Concerning a Lawyer's Services*, which states that “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 statement considered as a whole not materially misleading.”^{xv} Lawyers in violation of this Model Rule are subject to discipline.

A misleading communication conveys a factually incorrect idea or impression, and, as a result, leads the person receiving that communication in the wrong direction. The adverse event data reported in the [May 2016 Heart Rhythm Case Reports](#) journal prove that viewers are getting the wrong impression and going off their medications—suffering actual harm. While the language of the ABA Model Rule is not clear on whether the communication must be *deliberately* misleading, this is clearly deliberate. The advertisements are created with the express purpose of leading viewers to believe that these are dangerous drugs that people shouldn't take. It doesn't take much imagination to see that if the ads work, patients on the drugs will want to get off them quickly. Ironically, the patient victims who go off their medication as a result of these advertisements do not suffer bleeding events but strokes and deaths, which are arguably worse. I would imagine that Ms. Klein would want to do everything in her association's power to ensure that ABA member marketing practices are not causing personal injuries to occur.

While we believe the BAD-DRUG ads are misleading, the *Central Hudson Standard* that is currently used to determine if a lawyer advertisement can be regulated does not require the ad to be misleading. In fact, according to the [Association of Professional Responsibility Lawyers' \(APRL\) June 2015 report](#) cited by Ms. Klein, it must first be shown to be expressly protected by the First Amendment and *not be* misleading. It must then be shown that the government interest is substantial, that the regulation directly advances the governmental interests, and that the regulation is not more extensive than is necessary to serve that interest. We believe that the interest of preventing serious medical harm and death is substantial, that the disclaimers outlined above would help prevent this harm, and that the regulation would not be more extensive than necessary since advertisements would still be able to recruit patients harmed by the drugs.

Conclusion: Next Steps in Protecting Patient Lives

The Alliance for Aging Research agrees with Chairman Goodlatte that the ABA should, ideally, amend its own Model Rules of Professional Conduct to effectively self-regulate these advertisements. However, it is also clear that government regulation is clearly supported by the standard embraced by APRL and the ABA, should the ABA fail to take the necessary steps to protect patient lives.

We call on the ABA and this subcommittee to ensure that all future television advertisements on BAD-DRUGs include the outlined disclaimers—in legible print and verbally communicated.

Visual acuity diminishes with age, and vision impairment impacts nearly 3 million older adults. Written disclaimers on legal advertisements are often hard to read for people with healthy vision, so such disclaimers should be mandated to be presented in at least a 12-point font. Written disclaimers can also be ignored—especially since 90% of the TV viewing public admit to doing other things while watching advertisements^{xvi}. Oral disclaimers reinforce the content and help ensure that they are seen and/or heard by viewers. The Alliance for Aging Research would welcome the opportunity to work with the ABA and this subcommittee on parameters for medical product disclaimer language.

Thank you to the subcommittee for holding today’s hearing, and to Judiciary Committee Chairman Goodlatte for his leadership on this issue. We appreciate the opportunity to share our views on this important issue for older adult health and well-being.

ⁱ Go, AS, EM Hylek, KA Phillips, et al. 2001. Prevalence of Diagnosed Atrial Fibrillation in Adults: National implications for rhythm management and stroke prevention: The Anticoagulation & Risk Factors in Atrial Fibrillation (ATRIA) study. *JAMA* 285(18).

ⁱⁱ Dulli, DA, H Stanko, RL Levine. 2003. Atrial Fibrillation is Associated with Severe Acute Ischemic Stroke. *Neuroepidemiology* 22:118-23.

ⁱⁱⁱ National Stroke Association. 2015. Atrial Fibrillation and Stroke Fact Sheet. Available at http://www.stroke.org/sites/default/files/resources/Fact%20Sheet_Afib%20and%20Stroke.pdf.

^{iv} Benjamin, EJ, PA Wolf, RP D’Agostino, et al. 1998. Impact of Atrial Fibrillation on the Risk of Death: The Framingham Heart Study. *Circ* 98(10):946-52.

^v Benjamin, E, M Blaha, S Chiuve, et al. 2017. Heart Disease and Stroke Statistics—2017 Update, *Circ* 135.

^{vi} Coyne, KS, C Paramore, S Grandy, et al. 2006. Assessing the Direct Costs of Treating Nonvalvular Atrial Fibrillation in the United States. *Value Health* 9(5):348-56.

^{vii} Sullivan, E, E Eisenhart, A Heer, et al. 2009. *Medicare and Atrial Fibrillation: Consequences in cost and care*. Washington, DC: Avalere Health.

^{viii} Heidenrich, PA, JG Trogdon, OA Khavjou, et al. 2011. Forecasting the Future of Cardiovascular Disease in the United States: A policy statement from the American Heart Association. *Circ*; published on-line DOI: 10.1161/CIR.0b013e31820a55f5.

^{ix} Piccini & Fonarow. 2016. Preventing Stroke in Patients with Atrial Fibrillation—A steep climb away from achieving peak performance. *JAMA Cardiol* 1(1)-63-4.

^x<http://www.agingresearch.org/backend/app/webroot/files/Publication/42/AFib%20Expert%20Consensus%20Statement.pdf>

^{xi} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3501369/>

^{xii}http://www.agingresearch.org/backend/app/webroot/files/Publication/126/Call%20to%20Action%20Managing%20Elderly%20AFib%20Patients_FINAL.pdf

^{xiii} <http://www.medscape.com/viewarticle/763128>

^{xiv} Burton, P., et al. 2016. A Medwatch review of reported events in patients who discontinued rivaroxaban (XARELTO) therapy in response to legal advertising *HeartRhythm Case Reports*, Volume 2, Issue 3, 248 – 249. Available open access at: [http://www.heartrhythmcasereports.com/article/S2214-0271\(16\)00014-2/fulltext](http://www.heartrhythmcasereports.com/article/S2214-0271(16)00014-2/fulltext)

^{xv}https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_7_1_communication_concerning_a_lawyer_s_services.html

^{xvi} 2017 Deloitte Digital Democracy Survey, 11th Edition