UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA
AT WHEELING

STEVEN M. RECHT, ALESHA BAILEY, and STEPHEN P. NEW;

Plaintiffs,

v. **CASE NO. 5:20-CV-90 (BAILEY)**

JIM JUSTICE, in his Official Capacity as Governor of West Virginia; and PATRICK MORRISSEY, in his Official Capacity as Attorney General of West Virginia,

Defendants.

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND INCORPORATED MEMORANDUM OF LAW

COME NOW Plaintiffs, by and through Counsel, and for their Memorandum of Law in support of their Motion for Preliminary Injunction, state as follows:

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Both West Virginia and the United States currently struggle in the midst of a life-threatening pandemic and a continuing opioid crisis. While neither is likely a permanent condition, they remain emblematic of challenges ahead. Health problems place a premium on assuring that the people receive truthful and accurate information about their conditions, the drugs and medical devices available to treat them, and their legal rights when injured by those treatments, so that they can make informed judgments about their care and about their remedies when treatments go wrong.

Lawyer advertising provides one way to convey that information – and is protected speech under the First Amendment. The "First Amendment protect[s] the dissemination of truthful and nonmisleading commercial messages about lawful products and services." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 496 (1996). A form of the test applicable to commercial speech is utilized when attorney advertising is at issue. Government authority to limit or regulate lawyer advertising that is not false or deceptive must advance "a substantial governmental interest, and only through means that directly advance that interest." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) (citing *Cent. Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557, 566 (1980))[1]. In the advertising statute at issue here, which is aimed at regulating some lawyer advertising, no substantial government interest exists sufficient to justify the Act's restrictions and requirements.

[1] The *Central Hudson* test for evaluating unconstitutional restrictions on commercial speech covers the same ground: (1) whether the expression concerns lawful activity and is not be misleading; (2) whether the asserted governmental interest is substantial; (3) whether the regulation directly advances the governmental interest asserted, and (4) whether it is not more extensive than is necessary to serve that interest. 447 U.S. at 566.

The so-called Prevention of Deceptive Lawsuit Advertising and Solicitation Practices Regarding the Use of Medications Act (the Act), codified at W. Va. Code § 47-28-1 *et seq.*, was signed into law on March 25, 2020 by Defendant Governor Jim Justice. The Act becomes effective ninety days after passage, which would be June 5, 2020. The Act plainly violates the protection the First Amendment affords commercial speech.

The Act is a welter of confusion, prohibitions on truthful and non-deceptive speech, vague *and* overbroad obligations, and blatantly unconstitutional requirements. As the Supreme Court said about a different state statute placing restrictions on pharmaceutical marketing, "[b]oth on its face and in its practical operation, [the Act] imposes a burden based on the content of speech and the identity of the speaker" unconstitutionally. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). Here, the Act is aimed solely at a form of legal advertising concerning drugs and medical devices, even though its title and definitional section appears to limit the Act to medication issues.

The Act defines the legal advertising it regulates inconsistently with its substantive provisions. By definition and in its title, the Act limits the advertising it covers to "solicitation[s] for cases involving legal services regarding the use of medications," while the Act's actual restrictions and requirements apply to any "legal advertisement soliciting clients for legal services in connection with a prescription drug or medical device." *Compare, e.g.*, W. Va. Code §47-28-2(1), *with* W. Va. Code §47-28-3(b)(1). Among its irrational provisions is one that requires a legal advertisement concerning a defective medical device to carry a disclaimer stating: "Do not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death." *Id.* The required disclaimer must be carried even if the medical device does not require or involve any type of medication.

The Act also forbids advertisements from using the word "recall," W. Va. Code §47-28-3(a)(4), even if the manufacturer has voluntarily recalled the drug or device and even if the Food & Drug Administration (FDA) has requested a recall because it regards the product as dangerous, thereby prohibiting truthful non-deceptive statements about a recall request or an actual recall that is underway.

While these examples merely hint at a vast number of problems with the Act, it plainly prohibits truthful and non-deceptive information about drugs and medical devices to be conveyed to potential legal clients – while burdening those communications with compelled disclosures unrelated to legal services. These types of burdens on protected commercial speech cannot be reconciled with either the First or Fourteenth Amendments.

The Act's prohibitions and disclosure requirements have no substantial justification, which is the State's burden to prove, fail the narrowly tailored requirement, prohibit the communication of truthful, non-deceptive information, put forth mandates that are both vague and overbroad, unreasonably burden protected commercial speech in unjustifiable ways, and discriminates among both the content and its speaker, depriving listeners of their First Amendment right to receive the message. For these reasons, the statute is unconstitutional.

II. THE ACT.

On March 25, 2020, Defendant Governor Jim Justice approved the Act, codified at W. Va. Code § 47-28-1 *et seq.* The Act becomes effective ninety days after passage, which would be June 5, 2020. The Act purports to place requirements and prohibitions on legal advertising that informs potential clients, like Plaintiff Alesha Bailey, of potential legal recourse for injuries suffered as a result of defective prescription drugs or defective medical devices.

The Act regulates permissible types of "legal advertisement," which it defines as "a solicitation for legal services regarding the use of medications through television, radio, newspaper or other periodical, outdoor display, or other written, electronic, or recorded communications wherein the advertisement solicits clients or potential clients for legal services." W. Va. Code § 47-28-2(1). The definition appears to cover all forms of communication.

The Act further defines "solicit" to be "an offer to provide legal services regarding the use of medications by written, recorded, or electronic communication or by in-person, telephone, or real-time electronic contact." W. Va. Code § 47-28-2(4).

The Act then prohibits certain conduct with respect to legal advertisements and requires several disclosures. Violations are deemed unfair or deceptive acts or practices, *id*. at §47-28-3, and thus subject to an enforcement action brought by the Attorney General under West Virginia's Consumer Credit and Protection Act. *See* W. Va. Code § 46A–7–104.

A. Prohibited Speech.

The Act prohibits the use of several specific words or images. Among these, the Act places a categorical prohibition against the use of the word "recall" in a "legal advertisement" in connection with a product unless the recall was ordered by a government agency or was the product of an agreement between the manufacturer and a government agency. *Id*. at §47-28-3(a)(4). It further prohibits legal advertisements from using the phrases "'consumer medical alert', 'health alert', 'consumer alert', 'public service health announcement', or substantially similar phrase suggesting to a reasonable recipient that the advertisement is offering professional, medical, or government agency advice about pharmaceuticals or medical devices rather than legal services." *Id*. at §47-28-3(a)(2).

The Act further prohibits a "legal advertisement" from "display[ing] the logo of a federal or state government agency in a manner that suggests affiliation with the sponsorship of that agency. *Id*. at §47-28-3(a)(3).

B. Mandatory Disclaimers.

In addition, the Act requires a number of disclaimers for all "legal advertisements." Whether written or oral, the solicitation must include in clear and conspicuous presentation:

1. "[t]his is a paid advertisement for legal services," *id*. at §47-28-3(a)(1);
2. the sponsor of the legal advertisement, *id*. at §47-28-3(a)(5);
3. "the identity of the attorney or law firm that will represent clients, or how potential clients or cases will be referred to attorneys or law firms that will represent clients if the sponsor of the legal advertisement may not represent persons responding to the advertisement," *id*. at §47-28-3(a)(6);
4. the words, "[d]o not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death," regardless of whether the "legal advertisement solicits clients for legal services in connection with a prescription drug or medical device approved by the U.S. Food and Drug Administration," *id*. at §47-28-3(b)(1); and,
5. a disclaimer that "the subject of the legal advertisement remains approved by the U.S. Food and Drug Administration, unless the product has been recalled or withdrawn," *id*. at §47-28-3(b)(1).

III. THE PARTIES

Plaintiff Steven M. Recht is a licensed West Virginia lawyer who practices from the Recht Law Offices, 3405 Main St, Weirton, WV 26062, the locality where he grew up. He is active in West Virginia's legal associations, including service as a member of the board of governors of the West Virginia Association for Justice and as immediate past president of the Hancock County Bar Association. His legal practice includes representing plaintiffs injured by dangerous drugs and defective medical devices.

Plaintiff Recht has used advertising to inform the public about his practice and their rights. He maintains a website for his law firm (https://www.rechtlaw.com/). The website covers various areas of law that are part of his legal practice, including those subject to the Act's restrictions and requirements, and informs viewers that "[s]ome prescription drugs that have been shown to present particular danger" and "[s]ome of the defective medical devices at the center of lawsuits." *See* https://www.rechtlaw.com/personal-injury-lawyers/product-liability/#drugs. These statements would appear to run afoul of the requirements of the Act without further disclaimers, if not enjoined.

Plaintiff Recht believes that some of his potential clients in West Virginia will receive television advertising from law firms located in Pittsburgh that will not be subject to the restrictions and requirements of the Act and are likely to find that advertising unencumbered by prohibitions

or disclaimers imposed by the Act to be more informative and therefore the law firms sponsoring those advertisements more attractive to handle viewers' cases.

Plaintiff Recht is uncertain of his rights as to what the Act defines as legal advertisements in light of the Act's prohibitions and requirements.

Plaintiff Alesha Bailey, of Welch, McDowell County, West Virginia, is a consumer of legal services who started taking the drug, Invokana, around November 2018 for Type 2 Diabetes. Soon thereafter, she began feeling dizzy and suffered a fall. She reported a slew of unusual symptoms to her doctor, although no explanation was discovered for the sudden turn in her health. When she discovered a spot on her genital area that proceeded to get worse, she went to the Welch Community Hospital emergency room. Doctors there had her transported by ambulance to Raleigh General Hospital, where she was diagnosed with gangrene and underwent surgery to drain the abscess.

Despite the surgical care she received, Plaintiff Bailey went into septic shock, underwent three additional surgeries to drain the infection, and received around-the-clock antibiotics. Ms. Bailey also suffered kidney failure, which required dialysis. Plaintiff Bailey has no memory of the procedures performed on her while she was in septic shock.

After her stay at Raleigh General Hospital, Plaintiff Bailey stopped taking Invokana. In May 2019, Ms. Bailey's sister, Denise Bailey Iofalla, who serves as Secretary to Judge Randolph J. Murkensky of the Circuit Court of McDowell County, West Virginia, was watching television when she saw a legal advertisement about the adverse effects some people have when taking

Invokana and mentioned genital gangrene as one of those effects. Ms. Iofalla then got in touch with attorney Stephen P. New about making a claim about Invokana.

Plaintiff Bailey believes she would not have realized the full connection between her Invokana therapy and her illness, nor pursued her legal rights without that legal advertisement. She believes legal advertisements, like those run by Plaintiff New, provide important information about drugs and devices, which she values and pays attention to. Plaintiff Bailey is uncertain about whether she will be able to continue to receive information as useful as that which tipped her sister off about Invokana and about other drugs and medical devices if the prohibitions and burdens imposed by the Act go into effect.

Plaintiff Stephen P. New, a life-long West Virginia resident, is licensed to practice law in West Virginia and is the principal in the law firm of Stephen P. New, L.C., d/b/a New, Taylor and Associates, with offices at 114 Main Street, Beckley, WV 25801. He has advertised his practice in several mediums, including digital marketing and social media marketing, including Twitter and Facebook. He also operates a website for his law firm (https://newtaylorlaw.com/), which the Act treats as a legal advertisement. The length and required prominence of the disclaimers required by the Act appear to foreclose entirely advertising in some of those media.

In October 2018, he began marketing his practice to consumers of legal services whose children were affected by the opioid epidemic throughout West Virginia and other states. In February 2019, Plaintiff New and his firm engaged in a statewide television marketing campaign to raise awareness of the opioid epidemic and the legal rights of infant children who have been diagnosed with Neonatal Abstinence Syndrome (NAS), as well as the rights of their parents or guardians. Thereafter, Plaintiff New and his law firm commenced a television advertising

campaign, along with a digital marketing campaign throughout the United States, as part of a team of lawyers representing NAS-addicted children.

Plaintiff New's marketing to consumers through legal advertisements, particularly those affected by the opioid crisis in West Virginia, continues through present. He also plans to continue advertising in the future. Plaintiff New's advertisements have not previously included the disclaimers required by the Act.

On his website, Plaintiff New indicates he handles cases involving defective drugs and medical devices and informs viewers that he provides information for "Opioid Claims for Addicted Babies" and "Zantac® Claims in Beckley, WV." After FDA testing discovered carcinogens in Zantac® and the generic version of it, ranitidine, the FDA requested that all manufacturers of the prescription and over-the-counter versions of the drug be withdrawn from the market. U.S. FDA, "FDA Requests Removal of All Ranitidine Products (Zantac) from the Market" news release, https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market. Manufacturers have now voluntarily recalled the drug. *See* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (compiling FDA announcements of voluntary recalls). Under the terms of the Act, if not enjoined, advertising concerning Zantac® could not use the word "recall," and would have to tell viewers to keep using Zantac® until they consult a doctor and that Zantac® remains approved by the FDA, despite the recall now in effect and FDA's own "alerts," another term the advertising could not use under the Act.

Plaintiff New continues to want to advertise his legal services and maintain his website, but the Act purports to impose unconstitutional conditions upon that advertising, and Plaintiff New

is uncertain about his rights in light of the enactment and imminent implementation of W. Va. Code § 47-28-1 *et seq*.

Defendants have the authority to enforce the Act. Defendant Jim Justice is Governor of West Virginia. The West Virginia Constitution vests the State's "chief executive power" in its governor, who is charged with "tak[ing] care that the laws be faithfully executed." W. VA. Const. art. VII, § 5. Under this affirmative requirement of the Constitution, the Governor must, consistent with his oath of office, utilize all the power at his command to require the execution of the valid laws, which the Legislature has passed. *State ex rel. W. Virginia Bd. of Ed. v. Miller*, 153 W. Va. 414, 420, 168 S.E.2d 820, 824 (1969). In short, he is the chief executive of West Virginia and charged with carrying out the State's laws.

Defendant Patrick Morrissey is attorney general of West Virginia and serves as the State's chief legal officer. *See State ex rel. Discover Fin. Servs., Inc. v. Nibert*, 231 W. Va. 227, 244, 744 S.E.2d 625, 642 (2013). In that capacity, he is responsible for investigating and prosecuting violations of state law, as well as, commencing legal actions on behalf of the State. The Act explicitly assigns him authority to enforce the statutory provisions at issue in this case by commencing actions against violators under the West Virginia's Consumer Credit and Protection Act. *See* W. Va. Code § 46A–7–104.

IV. INJUNCTIVE RELIEF IS WARRANTED.

A well-established test governs eligibility for preliminary injunctive relief. The movant must demonstrate: (1) likelihood of success on the merits, (2) likelihood of irreparable harm, (3) the balance of hardships tips in favor, and (4) the injunction is in the public interest. *Metro. Reg'l Info. Sys., Inc. v. Am. Home Realty Network, Inc*., 722 F.3d 591, 595 (4th Cir. 2013) (citation omitted). This action fully qualifies for injunctive relief because it satisfies all four elements.

First, as further explained below, Plaintiffs are likely to succeed on the merits because the Act violates the First and Fourteenth Amendment. Second, in First Amendment cases, the first and second elements merge, because "irreparable harm is 'inseparably linked' to the likelihood of success on the merits of plaintiff's First Amendment claim." *WV Ass'n of Club Owners & Fraternal Servs., Inc. v. Musgrave*, 553 F.3d 292, 298 (4th Cir. 2009). Moreover, the "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Third, the balance of hardships plainly tip in Plaintiffs' favor. The prohibitions and burdens placed on speakers and listeners for legal advertisements by the Act would alter the status quo that has existed without significant problem for decades, ever since legal advertising was recognized as protected speech in 1977. Moreover, "a state is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction." *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 191 (4th Cir. 2013) (citation omitted).

Finally, the injunction is plainly in the public interest because "upholding constitutional rights surely serves the public interest." *Id.*

Because the constitutionality of the Act provides the basis for all four elements of injunctive relief, this brief will focus on that issue.

A. There Is a Likelihood that the Statute's Prohibitions Violate the First Amendment.

1. The First Amendment protects legal advertising.

The First Amendment protects truthful, non-deceptive lawyer advertising from censorship. *Bates v. State Bar of Arizona*, 433 U.S. 350, 383 (1977); s*ee also Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 472 (1988). It affords protection to a wide "variety of forms of lawyer advertising

embodying a wide range of content," and "an attorney's First Amendment right to advertise necessarily includes the right to tailor the content of the ad to persons with specific legal problems." *Ficker v. Curran*, 119 F.3d 1150, 1151-52 (4th Cir. 1997) .

Advertising discharges a constitutionally protected "informational function." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563 (1980). Solicitation of clients through advertising, as a form of "[c]ommercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information." *Id*. at 561-62. Undue advertising restrictions reduce[] the information available for consumer decisions and thereby defeat[] the purpose of the First Amendment." *Id*. at 567.

Legal advertising, like all commercial speech, "serves individual and societal interests in assuring informed and reliable decisionmaking." *Bates*, 433 U.S. at 364. It "may often carry information of import to significant issues of the day" and "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." *Id*.

The right infringed, then, is not just the right of the speaker to communicate, but the right of consumers and the general public to receive the information. *See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976) ("If there is right to advertise, there is a reciprocal right to receive the advertising.").

The First Amendment's commercial speech protections extend not only to the prevention of prior restraints, but also "unwarranted governmental regulation." *Cent. Hudson*, 447 U.S. at 561 (citation omitted). When the State attempts to regulate truthful, non-deceptive lawyer advertising, it "must assert a substantial interest to be achieved by restrictions on commercial

speech," and "the regulatory technique must be in proportion to that interest." *Id.* In other words, "[t]he limitation on expression must be designed carefully to achieve the State's goal." *Id. See also In re R.M.J.*, 455 U.S. at 203 ("Although the potential for deception and confusion is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.").

2. The Act fails to comport with these requirements.

a. The prohibition on the use of the word "recall" except in limited circumstances unconstitutionally censors truthful information.

The Act prohibits the use of the term "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." W. Va. Code § 47-28-3(a)(4). Yet, the vast majority of recalls occur without a government agency order or an agreement between the agency and the manufacturer. As the earlier discussion of Zantac® demonstrates, the FDA usually requests a withdrawal of a drug found too dangerous to be on the market despite an earlier approval, and the recall that usually follows is voluntary on the part of the manufacturer. *See* pp. 13-14 *infra*.

The FDA defines a "recall" as a "voluntary action taken by a company at any time to remove a defective drug product from the market." FDA, Drug Recalls, available at https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls. *See also* 21 C.F.R. § 7.40(a) ("Recall is a voluntary action that takes place because manufacturers and distributors carry out *their responsibility* to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.") (emphasis added). The FDA further states that "[d]rug recalls may be conducted on a company's own initiative or by FDA request." FDA, FDA's Role in Drug Recalls, available at https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls. Neither of those situations satisfies the Act's requirements for saying the word "recall."

Voluntarily recalls, with no government participation, are also the norm for medical devices. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 n.5 (2008) ("Significant defects in cardiac pacemakers have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972.") (quoting H.R. Rep. No. 94–853, at 8 (1976)). In fact, there have been "massive recalls of defibrillators, pace-makers, heart valves, hip and knee prostheses, and heart pumps--all of which have exacted a serious toll on the patients who face the daunting prospect of removal-and-replacement surgeries." David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 Cornell L. Rev. 981, 996-97 (2008) (footnotes omitted).

While the Secretary of the Department of Health and Human Services has authority to issue a recall, subject to a hearing, 21 U.S.C. § 360h(e) & 21 U.S.C. § 360bbb-8d(a)(1), and has delegated it to the FDA,[2] that "authority is rarely invoked, if at all." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996).[3] *See also* Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 Ind. L.J. 623, 668 (2007) ("an FDA initiated 'recall' of an approved treatment or device is extremely rare"). In fact, a "request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations." 21 C.F.R. § 7.40(a). Compliance with FDA recall requests, however, remains voluntary.

Plainly, when a manufacturer initiates a voluntary recall, it is still a recall. *See* 21 CFR § 7.46(a). In those circumstances, the manufacturer must communicate with "directly affected

[2] *See* FDA, Investigations Operations Manual 2020, at ch. 2.2, available at https://www.fda.gov/media/113432/download.

[3] One scholar examined that question in 2005 and found that "the FDA has never exercised its power to recall a defective medical device, although it has used the threat of a recall to force device manufacturers to withdraw defective devices from the market." David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95, 129 (2005).

accounts" in a written document with the words "conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]." 21 CFR § 7.49(b). Even so, a recall initiated at the request of the FDA is not a government agency order or an agreement between the agency and the manufacturer within the meaning of the Act.

Based on these judicially noticeable facts,[4] the Act prohibits the use of the word "recall" when a legal advertisement accurately and truthfully indicates that a drug or device has been recalled by the manufacturer, even though the manufacturer itself is required by federal law to label its communication about withdrawing a drug from the market a "recall."

The censorship of the word "recall" in the Act also prohibits a legal advertisement from advocating that the manufacturer should be forced to recall a drug or device that is dangerous due to the high number of injuries or lawsuits it has engendered. Advocacy of this type, concerning issues of health and safety, is political speech and the essence of First Amendment expression, *McIntyre v. Ohio Elections Comm'n*, 514 U.S. 334, 347 (1995), entitled to its greatest protection. *See Mills v. Alabama*, 384 U.S. 214, 218-19 (1966) ("a major purpose of [the First] Amendment was to protect the free discussion of governmental affairs.").

Still, a legal advertisement that accurately informs consumers that a drug or device was recalled, even if the recall is the unilateral action of the manufacturer, is factually "true and verifiable," *Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 100 (1990), and cannot mislead or deceive a recipient of that information. Nor can a legal advertisement that accurately states that the FDA has requested the manufacturer recall the product, even when no recall subsequently occurs. Thus, the Act violates the First Amendment when it forbids an

[4] A "court may properly take judicial notice of 'matters of public record' and other information that, under Federal Rule of Evidence 201, constitute 'adjudicative facts.'" *Goldfarb v. Mayor & City Council of Baltimore*, 791 F.3d 500, 508 (4th Cir. 2015).

advertisement seeking to help those injured as a result of taking Zantac® that the drug has been recalled.

It undermines the First Amendment "principle that disclosure of truthful, relevant information is more likely to make a positive contribution to decisionmaking than is concealment of such information." *Id*. at 108 (citation omitted).

The Act further violates the First Amendment by prohibiting use of "recall" where the advertisement accurately relates that the FDA requested a recall of the product, the manufacturer refused to recall it, and the U.S. Justice Department then sued and obtained a court order that the product be withdrawn. That very procedure of relying on a Justice Department lawsuit is how the government requires a product to be withdrawn. *See* U.S. Dep't of Justice, Monograph, Office of Consumer Litigation 2-3 (2011), available at https://www.justice.gov/sites/default/files/civil/legacy/2011/09/06/CPB_Monograph.pdf. *See also, e.g., United States v. Medtronic, Inc.*, Civil No. 015-cv-2168 (D. Mn., filed Apr. 27, 2015), available at https://www.justice.gov/file/414351/download (lawsuit seeking withdrawal of medical device from market).

The ensuing court order from such a lawsuit does not qualify as one of the government agency exceptions contained in the Act that permit the use of the word "recall." *See Hubbard v. United States*, 514 U.S. 695, 699 (1995) ("[i]n ordinary parlance, ... courts are not described as 'departments' or 'agencies' of the Government."). *See also* W. Va. Code § 55-17-2 (defining "Government agency" as an entity "within the executive branch of state government.").

Although, at some point, a withdrawn prescription drug will no longer be on the market for consumers to purchase, a withdrawn medical device may be implanted in an individual and subsequent surgery to remove it may prove too dangerous to undertake. *See, e.g., Eghnayem v.*

Bos. Sci. Corp., 873 F.3d 1304, 1320 (11th Cir. 2017) (describing a transvaginal mesh that was "very difficult, if not impossible, to remove"). When the implanted medical device is more dangerous to remove than to leave in the body, the information in the legal advertisement particularly serves consumers well. Yet the prohibition on the word "recall" when that is what happened would deny that nondeceptive and truthful information from being circulated – only by those who might seek to represent a person facing that dilemma – even when, for example – a medical provider might state the same information to attract patients whose continuing difficulty with the device might be eased through medication. The First Amendment also condemns that type of content discrimination. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2230 (2015) (stating that restrictions based on the identity of the speaker demands strict scrutiny and is inherently and impermissibly content-based).

The First Amendment prohibits the type of censorship that the ban on the word "recall" entails. Even when a statement is "potentially misleading to some consumers, that potential does not satisfy the State's heavy burden of justifying a categorical prohibition against the dissemination of accurate factual information to the public." *Peel*, 496 U.S. at 109 (citation omitted). That some unscrupulous lawyer might misrepresent a recall situation simply requires the bar to police those statements. However, there is no authority to "completely ban statements that are not actually or inherently misleading." *Id*. at 110. The "'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech," including burdens on commercial speech. *Sorrell v. IMS Health Inc*., 564 U.S. 552, 577 (2011) (citation omitted).

Even when misleading, "States may not place an absolute prohibition on certain types of potentially misleading information, …, if the information also may be presented in a way that is not deceptive." *In re R. M. J.*, 455 U.S. 191, 203 (1982). Moreover, because "bans against truthful,

nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996). The Act at issue here adopts that same misguided form of paternalism that the Supreme Court has repeatedly condemned. *See id*.

b. The prohibition on the word "recall" is also unconstitutionally overbroad.

The prohibition on the use of the word "recall," even when accurate, also implicates the Overbreadth Doctrine. It is well-established that the "First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Id*. at 503 (opinion of Stevens, J.) (cited with approval by *Sorrell*, 564 U.S. at 577). The Act does precisely that by restricting the use of the word "recall" to only those instances where the government is part of the recall effort (excluding those accomplished through court order).

The First Amendment's Overbreadth Doctrine is premised on the idea that "the First Amendment needs breathing space and that statutes attempting to restrict or burden the exercise of First Amendment rights must be narrowly drawn and represent a considered legislative judgment that a particular mode of expression has to give way to other compelling needs of society." *Broadrick v. Oklahoma*, 413 U.S. 601, 611-12 (1973). Thus, a statute is invalid and abhorrent to the First Amendment when "a substantial number of its applications are unconstitutional, judged in relation to the statute's plainly legitimate sweep." *United States v. Stevens*, 559 U.S. 460, 473 (2010) (citation omitted).

The Supreme Court utilizes a two-step analysis to determine whether a law is unconstitutionally overboard. First, it asks what the scope of the prohibition or burden is, and, then,

it determines whether the law restricts or burdens a substantial amount of protected expression. *United States v. Williams*, 553 U.S. 285, 292-97 (2008).

Here, the prohibition on the use of the word "recall" is comprehensive outside of instances where the recall was effectuated by a government agency or an agreement between a manufacturer and a government agency. W. Va. Code § 47-28-3(a)(4). Second, the FDA itself describes recalls as a voluntary action by the manufacturer. 21 C.F.R. § 7.40(a). On the rare occasions when the FDA believes a recall is necessary for the safety of patients and its suggestion to a manufacturer is denied, the FDA's authority is so circumscribed that it usually must ask the Department of Justice, which makes its own independent evaluation of the situation, to initiate an action to obtain a court order withdrawing the product from the market. *See* U.S. Dep't of Justice, Monograph, *supra* at 2-3 (2011).

As the foregoing establishes, the prohibition on the use of "recall" does not cover just the necessary substantial number of applications where its use is truthful and not misleading, but the vast majority of instances where drugs or medical devices are recalled. It must be struck as unconstitutionally overbroad.

c. The Act's vague restriction on the use of consumer alerts in legal advertising also violates the First Amendment.

The Act further prohibits legal advertisements from using the phrases "'consumer medical alert', 'health alert', 'consumer alert', 'public service health announcement', or substantially similar phrase suggesting to a reasonable recipient that the advertisement is offering professional, medical, or government agency advice about pharmaceuticals or medical devices rather than legal services." W. Va. Code § §47-28-3(a)(2). The State bears the burden of justifying the prohibition by showing the "possibility of misleading some consumers with such communications is so

substantial that it outweighs the cost of providing other consumers with relevant information." *Peel*, 496 U.S. at 106 (1990). The State cannot carry that burden.

The prohibition is also constitutionally problematic on three additional grounds. First, its purpose to prevent the suggestion that the "advertisement is offering professional advice . . . rather than legal services" makes no sense and confirms that it discriminates against speakers who offer legal services, rather than other professional or medical services, a form of content discrimination. *See Reed*, 135 S. Ct. at 2230. Legal services are a form of professional advice, and the advertisements seek to provide legal advice to viewers who choose to become clients. The prohibition reclassifies legal advice as something other than professional advice, which conflicts with the entire professional licensing structure that exists in West Virginia for those who offer legal services in West Virginia. *See Comm. on Legal Ethics of W. Virginia State Bar v. Blair*, 174 W. Va. 494, 496, 327 S.E.2d 671, 673 (1984).

Moreover, if the Act's disclaimer that asks viewers not to stop taking their medication without seeking their doctor's advice is valid, then the Act actually imposes an obligation upon the legal services provider to provide *medical advice*, an issue discussed later. The irrational explanation for the prohibition, that offering private legal services might appear to be an offer of other professional or governmental services, recalls the Supreme Court's analysis of a Vermont law that restricted the sale, disclosure, and use of certain pharmacy records for marketing purposes. In striking the statute down, the Court explained that a "more coherent policy" would not have targeted "a narrow class of disfavored speakers," *Sorrell*, 564 U.S. at 573, just as the Act does here. Moreover, the Act separately requires a conspicuous disclaimer that makes clear that the advertisement is for legal services and thus cannot be for other services. W. Va. Code §47-28-3(a)(1).

West Virginia law permits a wide variety of marketers to use the prohibited form of "consumer alert;" only lawyers representing clients with potential cases involving drugs or medical devices are prohibited from doing so, a clear form of content discrimination under *Reed*. That means, the pharmaceutical companies themselves, credit card companies, makers of devices that alert a service when a person falls, and even medical-malpractice lawyers may use the prohibited language; only advertising drug and medical device lawyers suffer this proscription. In fact, others are free to report accurately, as in the case of Zantac®, that the FDA has issued an alert about its recall – but not those who engage in legal advertising about drugs and devices.

Second, the prohibition on the use of "consumer alert" illogically denies that those who might be clients of a lawyer are not consumers, who might need to be alerted to their legal rights. The government may not reserve the term "consumer" for only some consumers of legal businesses. That constitutes content discrimination.

Third, there is an inherent vagueness to the prohibition on any "substantially similar phrase." Does the word "attention," as was used in advertising by Plaintiff New, violate the prohibition? Would a letter addressed to "consumers of medical devices?" Would a "consumer alert from the XYZ law firm?" The uncertainty of what is prohibited and what is not constitutes a separate First Amendment violation. Laws that are vague in their terms "may trap the innocent by not providing fair warning." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (footnote omitted). They are susceptible to enforcement "on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application." *Id*. (footnote omitted). And, they inhibit the exercise of First Amendment freedoms by causing "citizens to 'steer far wider of the unlawful zone' . . . than if the boundaries of the forbidden areas were clearly marked." *Id*. (footnote omitted).

The prohibition on various types of attention-getting language, the vagueness of the proscription, and the lack of a sufficient rationale that both permits its scope and justifies the prohibition render it a First Amendment violation.

d. The Act's prohibition on the display of a government logo also suffers from unconstitutional vagueness.

The Act further prohibits a "legal advertisement" from "display[ing] the logo of a federal or state government agency in a manner that suggests affiliation with the sponsorship of that agency." W. Va. Code §47-28-3(a)(3). While West Virginia can prohibit the false representation that a lawyer is acting on behalf of a government agency, it is not clear how displaying the logo of an agency might impermissibly suggest that affiliation. Would displaying a letter sent by the FDA on its letterhead requesting the manufacturer recall a drug or device to indicate that the product's safety has come under serious question violate the provision? Would the display of a slew of FDA warning letters run afoul of the prohibition? Would the logo of the U.S. Department of Justice be prohibited if it was used to convey that the United States has sued in federal court to take the product off the market?

The uncertainty about the logo prohibition would likely force a prudent lawyer to "steer far wider" than a constitutionally compliant consumer-protection measure would entail, as condemned in *Grayned*, 408 U.S. at 108, and also undermine a consumer's right to receive information, as anticipated in *Peel*, 496 U.S. at 110 (advertising "facilitates the consumer's access to legal services and thus better serves the administration of justice."). It is a given that "disclosure of truthful, relevant information is more likely to make a positive contribution to decisionmaking than is concealment of such information." *Id*. at 108 (citations omitted).

While the Act does not prevent legal advertisements from stating, in writing or though spoken words, that the government has raised serious questions about the safety of a drug or device,

it appears to prohibit the display of a government agency logo as a visual in support of the same purpose. Pictorial displays in "advertisements serve[] important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985). For that reason, pictures receive the same "First Amendment protections afforded verbal commercial speech." *Id*. The Act's prohibition on the use of government logos fails to provide with sufficient precision the permissible and impermissible use of the logos as to provide the fair notice that the First Amendment requires to potential speakers and their listeners. *See Grayned*, 408 U.S. at 108 (requiring laws to provide "explicit standards"); *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997) (discussing the "the precision that the First Amendment requires when a statute regulates the content of speech."). The non-affiliation purpose of the logo ban can be accomplished by more narrow means.

B. There Is a Likelihood that the Statute's Required Disclaimers Violate the First Amendment.

The Act requires five separate disclosures that are guaranteed to take up a considerable amount of space in a typical 30-second television advertisement. While certain types of consumer warnings or disclosures may be mandated without offending the First Amendment, a "disclosure requirement cannot be 'unjustified or unduly burdensome.'" *Nat'l Inst. Of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (quoting *Zauderer*, 471 U.S. at 626). The burden is on the State to prove that the harm it seeks to remedy is "potentially real not purely hypothetical" and "extend[s] 'no broader than reasonably necessary,'" to avoid the "risk [of] 'chilling' protected speech." *Id*. (citations omitted).

Like the disclosure invalidated in *Becerra*, the Act "imposes government-scripted, speaker-based disclosure requirement[s] that [are] wholly disconnected from [West Virginia's]

informational interest." *Id*. The State cannot meet its burden with respect to most of the Act's disclosure requirements.

1. The requirement to warn viewers not to stop taking medication cannot be justified and is unduly burdensome.

The Act requires a:

> legal advertisement soliciting clients for legal services in connection with a prescription drug or medical device approved by the U.S. Food and Drug Administration shall include the following warning: "Do not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death."

W. Va. Code §47-28-3(b)(1).[5]

As the provision makes plain, the requirement applies to a solicitation for legal services in connection with an FDA-approved *medical device*. Medical devices rarely require the recipient to take medication. As the FDA itself tells consumers, "[m]edical implants are devices or tissues that are placed inside or on the surface of the body," and "many implants are prosthetics, intended to replace missing body parts." U.S. Food & Drug Admin., "Implants and Prosthetics," https://www.fda.gov/medical-devices/products-and-medical-procedures/implants-and-prosthetics. Still other implants "monitor body functions, or provide support to organs and tissues." *Id*. For example, one common medical device is an artificial hip, which is used to replace a diseased

[5] In conflict with this disclosure requirement, the Act defines a "legal advertisement" as a solicitation of clients "for legal services regarding the use of medications," and *not for medical devices*. W. Va. Code §47-28-2(1). The disclosure requirement thus contradicts the Act's definitional section by including within its scope legal advertisements in connection with a medical device. Generally, "[s]tatutory definitions control the meaning of statutory words." *Lawson v. Suwannee Fruit & S.S. Co*., 336 U.S. 198, 201 (1949). *See also Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) ("When a statute includes an explicit definition, we must follow that definition."). Certainly, if the West Virginia legislature wanted to cover advertising involving legal services for medical devices, it could easily have included medical devices in the definition – and the Act's title. *See Burgess v. United States*, 553 U.S. 124, 130 (2008). Yet, the substantive provision at issue here plainly seeks to cover medical devices and does so irrationally because an advertisement about devices does not necessarily implicate medication.

hip. The failure of metal-on-metal designs resulted in "metallic ion debris (cobalt and chromium) within the periprosthetic space," causing the body to "have a significant inflammatory response to metal debris that can lead to periprosthetic bone and/or tissue necrosis, resulting in the need for revision surgery." *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *1 (N.D. Tex. July 18, 2014).

The Act requires a legal advertisement solely about a problematic medical device that does not involve the administration of any drug on an ongoing basis to carry a warning about discontinuing prescribed medication under the Act. There is no legitimate, let alone substantial, government interest that justifies compelling promotional materials for legal services relating to medical devices to add these 27 words conspicuously. In addition, an advertisement that concerns medical devices without this mandated disclosure is not "inherently misleading." *See, e.g.*, *Zauderer*, 471 U.S. at 639-41 (holding that a legal advertisement that informed readers that a particular medical device had "spawned an impressive number of lawsuits" was not "inherently misleading" and, indeed, was "entirely accurate").

Plainly, this disclosure requirement, as applied to advertisements about medical devices, is broader than necessary to prevent the concern that animated the Legislature. *See Peel*, 496 U.S. at 107 ("In this case, as in those, we conclude that the particular state rule restricting lawyers' advertising is broader than reasonably necessary to prevent the perceived evil.") (internal quotation marks and citation omitted). Thus, the Act impermissibly burdens speech that in no way addresses the Legislature's concern and, for that reason, must be invalidated. *See Cent. Hudson*, 447 U.S. at 570 ("To the extent that the Commission's order suppresses speech that in no way impairs the State's interest in energy conservation, the Commission's order violates the First and Fourteenth Amendments and must be invalidated.").

Even with respect to advertising that concerns prescription drugs, the mandated warning cannot be justified. First, the Act requires the disclaimer to be attached to an offer of legal services, not medical services or advice. A legal advertisement that indicates a particular drug has been associated with adverse effects in some people or that it has "spawned an impressive number of lawsuits," as in *Zauderer*, 471 U.S. at 640, does not convey a message that suggests the drug should be abandoned. Moreover, it unjustifiably requires the Legislature's precise disclosure language regardless of what the legal advertisement actually says or even potentially implicates. *Cf*. *Becerra*, 138 S. Ct. at 2377.

In *Becerra*, the Supreme Court recognized that the required notice that family planning clinics without a medical doctor post a notice to that effect was "not an informed-consent requirement or any other regulation of professional conduct." *Id*. at 2373. It had no relationship to any type of medical procedure and therefore burdened a wholly different activity. *Id*. Here, the same can be said as to both counts. The disclosure is not a regulation of professional conduct. The Act specifically disclaims that it is. W. Va. Code §47-28-5 ("This article does not limit or otherwise affect the authority of the judiciary or the Lawyer Disciplinary Board to regulate the practice of law, enforce the West Virginia Rules of Professional 2 Conduct, or discipline persons admitted to the bar."). Plus, it burdens the offer of legal services that are utterly and completely unrelated to the treatment of disease or injury.

Zauderer permitted disclosure requirements only when "reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651. Because the legal advertisements are directed to consumers of legal services, the connection to the concern about continuing to take medication unless contraindicated by a doctor is simply not implicated. And, unlike in-person solicitations that "encourage speedy and perhaps uninformed decisionmaking, legal

advertisements of the type regulated here provide "an opportunity for comparison or reflection" that enables the listener to consider what was said more carefully and take responsibility for any decision going forward. *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 457 (1978).

Moreover, the presumed rationale behind the requirement is a fear that some impressionistic individuals might hear an advertisement about adverse effects or lawsuits and take it upon themselves to stop taking medication. In its first lawyer advertising case, the Supreme Court rejected that argument because it "assumes that the public is not sophisticated enough to realize the limitations of advertising, and … rests on an underestimation of the public." *Bates*, 433 U.S. at 374-75. Instead of compelling others to speak words they do not choose, West Virginia could inform patients about the importance of seeking medical advice before discontinuing medications "without burdening a speaker with unwanted speech." *Becerra*, 138 S. Ct. at 2376 (quoting *Riley v. Nat'l Fed. of the Blind*, 487 U.S. 781, 800 (1988)). Even anticipation of a "tepid response" does not prove that the State's own "advertising campaign is not a sufficient alternative." *Id*. The State simply "cannot co-opt" the speech of another speaker "to deliver its message for it." *Id*.

Instead, the courts regularly insist that government use its own opportunities to speak to encourage different behavior, such through the "launch a public awareness campaign" when concerned that residents will forego medical treatment or "produce a document or website." *Centro Tepeyac*, 722 F.3d at 190 (4th Cir. 2013). *See also id*. at 199 (stating that the government "could speak with its own voice" by "undertak[ing] public education campaigns … or, more generally, promoting consultations with physicians"); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (suggesting "educational campaigns focused on the problems").

Second, where the drug is deemed dangerous by federal authorities, the requirement sends a potentially fatal mixed message. According to one study, more than 10 percent of FDA-approved drugs between 1975 and 1999 were either required to bear a black box warning, which indicates a severe safety risk, or were withdrawn from the market entirely. Daniel Kazhdan, *Other Developments in Intellectual Property: Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 Berkeley Tech. L.J. 893, 904 (2012) (citing a 2002 study published in the Journal of the American Medical Association (JAMA)). Adverse drug reactions are "common, overlooked, expensive, serious, and under-reported." Michael Fotis and William Budris, "Clinical Analysis of Adverse Drug Reactions," in Arthur J. Atkinson, Jr., ed., Principles of Clinical Pharmacology 455 (3d ed. 2013). They account for "somewhere between the fourth and sixth most common cause of death in the United States." *Id*.

In fact, little has changed since JAMA concluded that "clinical trials and routine regulatory oversight as currently practiced often fail to uncover important adverse effects for widely marketed products." Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 311 (2007). For example, the drug Zinbryta was approved on May 27, 2016 to treat adults with relapsing forms of multiple sclerosis. FDA News Release, FDA Approves Zinbryta to Treat Multiple Sclerosis, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm504000.htm. On March 2, 2018, its manufacturers announced its voluntary withdrawal from the global market because of concerns that the drug's risks outweighed any benefits. FDA, FDA Working with Manufacturers to Withdraw Zinbryta from the Market in the United States, https://www.fda.gov/Drugs/DrugSafety/ucm600999.htm.

Lawsuits play a critical role in drug and medical device safety. The FDA, with its limited resources, is dependent upon the manufacturers to tell them what clinical trials have shown. The manufacturers are not always forthcoming, meaning that drug approvals are granted on incomplete information. Discovery made possible through litigation can unearth internal concerns expressed by the manufacturers' doctors and scientists that were not disclosed to the FDA. *See* Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308 (2007), available at https://jamanetwork.com/journals/jama/article-abstract/205083. *See also* Alex Berenson, *For Merck, the Vioxx Paper Trail Won't Go Away*, N.Y. Times, Aug. 21, 2005, at 3, available at https://www.nytimes.com/2005/08/21/business/for-merck-vioxx-paper-trail-wont-go-away.html (reporting that documents placed in evidence proved that Merck's scientists were concerned about Vioxx's cardiovascular risks as early as 1997, two years before the drug went on sale).

FDA approval is not tantamount to a determination that a drug or device is safe. For example, Guidant Corporation manufactured an implanted defibrillator that was used to treat a common genetic disease that results in erratic heartbeats. Nearly 30,000 of the units were sold, a number after Guidant became aware of a design flaw and redesigned their product. When approved by the FDA, the agency was unaware of the defect. Yet, the defibrillator failed dozens of times, caused at least two deaths, and triggered heart attacks. Only then did the FDA ask and Guidant voluntarily recalled the model. Vladeck, 33 Pepp. L. Rev. at 96.

The medical advice required by this disclaimer, then, is not uniformly accurate and demonstrates a misapprehension of the FDA approval process and its meaning that makes it unjustifiable – and unconstitutional.

2. The requirement to tell listeners that the drug or device remains approved by the FDA, unless withdrawn or recalled is similarly constitutionally flawed.

Like the admonition about continuing medication until a doctor advises differently, the reminder that the drug or device is still FDA approved is neither a regulation of professional conduct" or necessary factual information that clarifies an offer of legal services. *See Becerra*, 138 S. Ct. at 2373. The requirement is imposed irrespective of the actual content the advertisement, which likely does not convey any contrary impression, and which, if important to the State, can be conveyed through its own public awareness campaign. *See Centro Tepeyac*, 722 F.3d at 199.

Moreover, the message, which is only deemed unnecessary if the product has been recalled[6] or withdrawn, continues the Act's misunderstanding of the FDA's regulatory responsibilities and process. It would require the message if the FDA has sent warning letters that show the manufacturing facilities do not meet FDA standards to that the product put out is deemed adulterated. *See, e.g.*, FDA Warning Letter 320-20-14 from Francis Godwin, Director, FDA Office of Manufacturing Quality, to Mr. Philippe Agostini, Executive Chairman, CGA Limited (Dec. 19, 2019), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cga-limited-589028-12192019 (indicating a failure to test samples for purity, strength, and quality and a failure to conform each batch of the drug to final specifications).

It would require such a message even if the FDA has requested a recall and the manufacturer has refused to initiate one. It would require the message, even if the FDA has asked the Justice Department to commence an action to obtain a court order withdrawing the product from the market. It would continue to require that message even if it comes to light, as in the case

[6] It is not clear whether the use of "recall" in this disclaimer is limited to government-initiated or part of a government agreement with the manufacturer, as the Act otherwise treats it.

of Vioxx, that internal company documents have revealed the product's lack of safety that were never disclosed to the FDA.

And it would continue to require that message concerning opioids, which are still on the market, even though the Centers for Disease Control says that 68 percent of the 70,000 annual deaths from drug overdoses involved prescription or illicit opioids, Centers for Disease Control and Prevention, CDC's Response to the Opioid Overdose Epidemic, https://www.cdc.gov/opioids/index.html, and some 1,900 states, cities, counties, and other local government entities have brought suit to seek "compensation for the cost of public services needed to address the consequences of addicted communities." Morgan A. McCollum, *Local Government Plaintiffs and the Opioid Multi-District Litigation,* 94 N.Y.U. L. Rev. 938, 938 (2019). In fact, Defendant Morrissey, on behalf of West Virginia, has sued opioid manufacturers Johnson & Johnson and Teva Pharmaceuticals USA for misrepresenting the risks associated with their product. Associated Press, "West Virginia AG sues opioid makers, says they hid risks," Aug. 23, 2019, https://apnews.com/e060fef7d4ad4248a22355e459ae3be0.

The *Zauderer* test for mandatory disclosures requires, *inter alia*, that it be "'uncontroversial information' appropriate to prevent deception in the regulated party's commercial speech." *Am. Meat Inst. v. U.S. Dep't of Agric*., 760 F.3d 18, 21 (D.C. Cir. 2014). In a substantial number of instances, the statement would not be uncontroversial.

In sum, there cannot be any substantial government interest accomplished through narrow tailoring to justify this disclaimer and assure compliance with First Amendment requirements. Indeed, the required disclaimer has more potential to mislead than to inform.

3. The cumulative effect of the required disclaimers run afoul of requirement that disclaimers cannot be unjustified or unduly burdensome.

Becerra confirms that mandatory disclaimers cannot be unjustified or unduly burdensome. 138 S. Ct. at 2377. In addition to the lack of justification explicated in prior sections of this brief, the cumulative impact of the Act's disclaimers are unduly burdensome. The Act makes clear that all communications soliciting clients for legal services in whatever format made must include the disclaimers. *See* W. Va. Code §§ 47-28-2, 47-28-3.

For a lawyer like Plaintiff New, who advertises on Twitter, the disclaimers dominate the message. Twitter messages have a maximum of 280 characters. Twitter, How to Tweet, https://help.twitter.com/en/using-twitter/how-to-tweet. Not including the Act's disclaimers requiring the identity of the legal advertisement's sponsor and the identity of the lawyer or law firm that would represent a client responding to the advertisement, the Act requires approximately 294 characters in disclaimers.[7] It effectively prohibits advertising on Twitter because the required characters by themselves are longer than a Twitter message and leave no room for the advertisers message. The same is true for digital marketing, like that utilized by Plaintiff New, which utilizes other forms of social media that also embrace limited words or visual timing. Saying the words of the disclaimers, again without identifying the sponsor of the advertisement or the lawyer or law firm that would represent clients, takes approximately 20 seconds. A typical legal advertisement on television is 30 seconds long. David Ciccarelli, "What is the Most Effective Length for a TV Commercial?," Voices.com Blog (May 7, 2020),

[7] "This is a paid advertisement for legal services;" "Do not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death;" and, "drug remains approved by the U.S. Food and Drug Administration." W. Va. Code §47-28-3.

https://www.voices.com/blog/effective_length_for_tv_commercials/. Thus, the disclaimers would obliterate the message intended by a legal advertisement of the usual and most effective length.

The unduly burdensome standard operates to prevent disclosures so extensive that it discourages constitutionally protected speech, *see Ibanez v. Florida Dep't of Bus. and Prof. Reg.*, 512 U.S. 136, 146-47 (1994), or where it operates to "chill[ ] protected commercial speech." *Zauderer*, 471 U.S. at 651. In one recent case applying these principles, the district court held that an injunction should issue where the disclaimer requirements "are so long and cumbersome" that they leave little or no room for the advertiser's message. *Yes on Prop B v. City & Cty. of San Francisco*, No. 20-CV-00630-CRB, 2020 WL 836748, at *3 (N.D. Cal. Feb. 20, 2020). Without adopting a hard-and-fast rule, that court held that a 40-percent threshold of disclaimer to overall advertisement plainly violated the First Amendment. *Id*. In *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 916 F.3d 749, 757 (9th Cir. 2019), the Ninth Circuit held that occupying 20% of an advertisement "is not justified and is unduly burdensome when balanced against its likely burden on protected speech," rejecting evidence as "unpersuasive" that the 20% size represented the "best practices for health and safety warnings."

Similarly, no justification can explain the outsized extent to which legal advertisements must carry the government's message unrelated to the provision of legal services.

C. There is a Likelihood that the Act's Requirements Violate the Fourteenth Amendment.

The Fourteenth Amendment's Equal Protection Clause guarantees that similarly situated persons are treated similarly. *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985). Because the Act "impose[s] a specific, content-based burden on protected expression[, …] heightened judicial scrutiny is warranted." *Sorrell*, 564 U.S. at 565. On the other hand, content-neutral commercial speech regulations are "those that are *justified* without reference to

the content of the regulated speech" *Id*. at 566 (quoting *Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 48 (1986) (emphasis in orig.)).

The heightened scrutiny imposes the burden on the State "to justify its content-based law as consistent with the First Amendment" by showing "at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Id*. at 571–72. *See also Carey v. Brown*, 447 U.S. 455, 461-62 (1980) (government regulation that discriminates among speech-related activities must "be finely tailored to serve substantial state interests, and the justifications offered for any distinctions it draws must be carefully scrutinized.").

The Act unquestionably regulates speech based on its content: advertising for or by a lawyer concerning drugs or devices. Just as "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment, and requires "heightened judicial scrutiny," *Sorrell*, 564 U.S. at 557, speech in aid of legal marketing on drugs and devices also warrants heightened scrutiny. The Act "burdens disfavored speech by disfavored speakers," and may only be regarded as impermissibly content-based. *Id*. at 564. The applicable scrutiny applies not only to the Act's prohibitions, but also content-based burdens such as disclaimers. *Id*. at 566.

When intertwined with the commands of the Equal Protection Clause, "statutes affecting First Amendment interests [must] be narrowly tailored to their legitimate objectives," and cannot discriminate against the point of view, however controversial, of one speaker as opposed to another. *Police Dep't of City of Chicago v. Mosley*, 408 U.S. 92, 101, 96 (1972).

The Act plainly singles out some speakers about defective drugs and medical devices for regulatory treatment, while leaving others unregulated. It further discriminates as a result of the

burdens it places on some forms of communication by the length of its mandatory disclaimers, effectively banning those means of communications, as explained earlier with reference to Twitter, social media, and 30-second television advertising. It cannot satisfy either the substantial-justification requirement, nor the narrow-tailoring obligation. It constitutes an equal-protection violation.

V. THE ACT IS NON-SEVERABLE.

When a statute is deemed unconstitutional, courts will sometimes sever the unconstitutional portions of the law from those portions that are either unchallenged or determined to be without constitutional flaw. The "well established" "standard for determining severability" holds that "[u]nless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as a law." *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987). Yet, here, if the unconstitutional requirements are excised, what remains cannot serve as a "fully operative" law, *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010), capable of "functioning independently." *Alaska Airlines*, 480 U.S. at 685. Because the Act would not fulfill the purpose declared in its title, prevention of deceptive lawsuit advertising and solicitation practices regarding medications (or even medical devices), the remaining shards of the Act cannot stand alone. These would be the identification of the sponsor of the advertisement, the lawyer or law firm who would represent a plaintiff, and privacy provisions that duplicate the existing law under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), which ensures the privacy of a person's medical records by designating it as "protected health information" and prohibits its disclosure unless authorized

by the individual whose information is being transmitted. *See United States v. Elliott*, 676 F. Supp. 2d 431, 436-37 (D. Md. 2009). Nothing in the Act goes beyond what HIPAA already requires.

For these reasons, the Act is non-severable.

VI. CONCLUSION.

For the foregoing reasons, the Act should be preliminarily enjoined. Through its outright censorship of certain words and images, even if truthful and not misleading, and through its required disclaimers, even if inapplicable, unjustifiable, or unduly burdensome, Plaintiffs are likely to succeed on the merits of this constitutional challenge, are likely to suffer irreparable harm by the impairment of the communicative activities they have, are and will continue to undertake or receive, only they, and not the State, will suffer any hardship from implementation of the Act, and the vindication of First and Fourteenth Amendment constitutional guarantees makes the requested injunction unquestionably in the public interest. The preliminary injunction should issue.

Respectfully submitted,

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