IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

Wheeling Division

STEVEN M. RECHT, ALESHA BAILEY, and STEPHEN P. NEW, Plaintiffs, v. 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.	)	Case No. 5:20-cv-00090 (JPB)

BRIEF OF AMICUS CURIAE CHAMBER OF COMMERCE OF THE UNITIED STATES OF AMERICA IN SUPPORT OF DEFENDANTS

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June 2, 2020

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STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases that raise issues of concern to the nation's business community.

The Chamber has a particular interest in this case due to the work of its Institute for Legal Reform ("ILR"), which champions legal-reform initiatives that promote economic growth and opportunity. In 2017, ILR issued a report documenting the substantial public health threat posed by lawyers' advertisements presenting misleading information about prescription drugs and medical devices. *See* U.S. Chamber Inst. for Legal Reform, *Bad for Your Health: Lawsuit Advertising, Implications and Solutions* (Oct. 2017) ("*Bad for Your Health*").[1] The law Plaintiffs challenge directly responds to this serious public health threat.

INTRODUCTION

States have always regulated lawyer advertising, even banning it for most of the last century. It was not until 1977 that the Supreme Court announced lawyer advertising is commercial speech protected by the First Amendment. Under that framework, many regulations—including those at issue here—are entirely lawful. States have broad authority to prohibit false, deceptive, and misleading statements in lawyers' advertisements. *See Zauderer v.*

[1] https://www.instituteforlegalreform.com/research/bad-for-your-health-lawsuit-advertising-implications-solutions.

Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 638 (1985) (collecting cases). They may also mandate statements "as long as [those] disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651.

West Virginia's Prevention of Deceptive Lawsuit Advertising and Solicitation Practices Regarding the Use of Medications Act ("the Act") is facially constitutional under the *Zauderer* framework. The Act targets specific aspects of lawyers' advertisements that several studies conclude are inherently likely to mislead and confuse viewers and that doctors have confirmed do, in fact, deceive patients into believing the ads are unbiased medical advice. A chorus of organizations—the American Medical Association, the AARP, and the Federal Trade Commission ("FTC")—have condemned these misleading ads.

Plaintiffs essentially concede that they *want* viewers to mistake their advertisements for medical advice and not what they actually are: recruitment tools for lawsuits. They argue repeatedly that legal advertisements are fairly—and often—perceived as unbiased sources of medical information. *See, e.g.*, Plaintiffs' Mem. in Supp. of Prelim. Inj. ("PI Mem."), Dkt. No. 11-1, at 8 ("Health problems place a premium on assuring that the people receive truthful and accurate information about their conditions. . . . . Lawyer advertising provides one way to convey that information."); *id.* at 15 (legal advertisements "provide important information about drugs and devices"); *id.* at 24 (medical "information in the legal advertisement particularly serves consumers well"). And they oppose the Act *precisely* because it distinguishes such ads from actual medical advice. *Id.* at 27 (contending that the Act's "purpose to prevent the suggestion that the 'advertisement is offering professional advice . . . rather than legal services' makes no sense"). These are all reasons that support upholding the Act, not striking it down.

The Court should refuse the preliminary injunction.

BACKGROUND

A. Inherently misleading medical drug and device litigation advertisements

Advertisements seeking plaintiffs for medical drug and device litigation bombard television viewers with increasing frequency. *Bad for Your Health* at 6. Often airing at times calculated to reach elderly viewers, these advertisements seek to enlist plaintiffs for mass tort lawsuits. *See* Daniel M. Schaffzin, *Warning: Lawyer Advertising May Be Hazardous To Your Health! A Call To Fairly Balance Solicitation Of Clients In Pharmaceutical Litigation*, 8 Charleston L. Rev. 319, 336 (2013). While not all such advertisements are inherently deceptive, those that are misleading often have one or more of the following characteristics.

First, the advertisements open with an "alert" or "warning" that mimics a public service announcement, suggesting it will convey impartial medical information. *Bad for Your Health* at 10. University of Oregon law professor Elizabeth Tippett concluded that 20% of lawsuit ads opened this way. *See* Elizabeth Tippett, *Medical Advice from Lawyers: A Content Analysis of Advertising for Drug Injury Lawsuits*, 41 Am. J. L. & Med. 7, 18 (2015) (examining ads in Atlanta and Boston in 2009). The FTC warns that "sensational warnings or alerts . . . may initially mislead consumers into thinking they are watching a government-sanctioned medical alert or public service announcement." Press Release, FTC, FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits (Sep. 24, 2019) ("FTC Press Release").[2]

Second, the advertisements display without context the logo of the U.S. Food and Drug Administration ("FDA") or other government entities, suggesting that those agencies and the medical community sponsor or endorse the message. *Bad for Your Health* at 13.

[2] https://www.ftc.gov/news-events/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.

Third, the advertisements misrepresent the scientific research, overstating remote risks and glossing over (or omitting) the product's benefits. *See Bad for Your Health* at 10–12; FTC Press Release, *supra*, at 1 (explaining that ads "may misrepresent the risks associated with certain pharmaceuticals"). As one doctor explained, one drug-lawsuit advertisement persuaded a highly educated patient to consider abandoning a blood thinning medication because of a 0.0009 annual fatal bleeding risk, even though the drug had a high likelihood of preventing a debilitating stroke. *Bad for Your Health* at 12, 28–29 (testimony of Dr. W. Frank Peacock, MD).

Fourth, these ads fail to caution viewers not to discontinue a prescription without consulting the doctor who prescribed the medication, upending a system of medically informed judgment designed to protect patients. *See* FTC Press Release, *supra*, at 1. When the advertisements do include a warning, the message appears in fine print, overshadowed by larger messages about the product's adverse effects. *See* Schaffzin, *supra*, at 339 n.76.

Fifth, the advertisements disclose the sponsoring law firm or lead generator only in fine print, usually near the end of the message, preventing viewers from accurately assessing the advertisement's content from the outset. *See Bad for Your Health* at 14.

Sixth, the advertisements imply that medical devices or drugs have been taken off the market or lost FDA approval when, in fact, they have not. Numerous ads prominently use the word "recall," even though the drugs or devices are still being prescribed. *See* FTC Press Release, *supra*, at 1 (noting that ads "could leave consumers with the false impression that their physician-prescribed medication has been recalled"); *Bad for Your Health* at 15–16. One peer-reviewed study found that over half of new patients at a specialty urology clinic believed that government agencies or manufacturers had recalled mesh products used to treat female pelvic disorders, when no such recall had occurred. Christopher F. Tenggardjaja et al., *Evaluation of*

Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery, 85 Urology 326, 327 (2015). A statistical analysis of the results suggested a strong association between that misperception and television as a source of information. *Id.*

B. Evidence that medical drug and device litigation ads mislead and deceive

Several sources confirm that these lawyer ads can and do deceive viewers—with tragic effects. Surveys uniformly find that a significant percentage of respondents would stop taking prescribed medications after viewing drug litigation advertisements. And physician reports show that, in fact, these ads have driven patients to discontinue drug treatments against medical advice.

1. Consumer and physician surveys

In 2017, ILR commissioned a consumer-survey firm, Public Opinion Strategies, to study consumer perceptions of drug and device litigation advertisements. *See Bad for Your Health* at 20. It uncovered these concerning results:

- 72% of respondents had viewed a drug litigation ad on television in the past year.
- 84% said they would be concerned if a medication prescribed by their doctor was targeted by a law firm's advertisement.
- 46% said that they would definitely or probably stop taking a prescribed medication directly after viewing an advertisement.

See Bad for Your Health at 20–22. A subset of 500 respondents who were taking or had previously taken a targeted drug were shown a lawsuit ad for that drug. *Id.* at 21. Afterwards, 26% said they would definitely or probably stop taking the drug immediately, and 58% said they would definitely or probably reduce the amount they take below prescribed levels. *Id.*

An independent survey conducted by academic researchers in 2018 revealed similar results. *See* Jesse King & Elizabeth Tippett, *Drug Injury Advertising*, 18 Yale J. Health Pol'y L.

& Ethics 114 (2019).[3] That study found "clear evidence that deceptive drug injury advertisements are likely to be misidentified" as public service announcements and that the ads "increase the perceived risks associated with the medications they feature." *Id.* at 146–47; *see also* National Council for Community Behavioral Healthcare, *New Survey Shows Product Liability Litigation May Jeopardize Treatment Outcomes for People with Severe Mental Illness* (June 13, 2007) (finding that 97% of the responding psychologists treated patients who had stopped taking their medication—and that more than half of those surveyed held litigation advertisements responsible for patient defiance) (Eli Lilly provided financial support).

2. Data on physician reports to the FDA

Physician reports to the FDA confirm these studies. The FDA's "Medwatch" database collects voluntary reports by healthcare professionals about adverse drug-related events. *See* FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program.[4] Though the database captures only voluntary reports, FDA searches reveal scores of cases where patients unilaterally discontinue a medical treatment as a result of lawyer advertising.

For example, following a 2016 congressional inquiry, a search focusing on anticoagulant medications retrieved sixty reports noting that a patient had discontinued the medication after viewing a drug-litigation advertisement. Letter from Anna K. Abram, Deputy Commissioner, FDA, to Hon. Andy Harris, M.D., U.S. House of Representatives, at 1–2 (undated 2017) (attached as Exhibit A). Physicians documented several instances of cardiovascular harm after patients discontinued treatment following a viewing—including six deaths. *Id.*

[3] https://digitalcommons.law.yale.edu/yjhple/vol18/iss2/3.

[4] https://www.fda.gov/safety/medwatch/.

In a broader search two years later, again prompted by congressional concern, the FDA "identified 213 reports in which a patient viewed an advertisement and then discontinued" a course of medication. Letter from Maren McBride, FDA, to Hon. Andy Harris, M.D., U.S. House of Representatives, at 1 (Feb. 6, 2019) (attached as Exhibit B). Approximately 27% of those reports "described an adverse event after medication discontinuation." *Id.*

C. West Virginia's response to misleading litigation advertisements

Private groups, the federal government, and several states all have taken steps responding to the significant recent evidence. Both the American Medical Association and the AARP have condemned drug and device litigation advertisements. *Bad for Your Health* at 3–4, 31–32. In June 2017, the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice held a hearing examining these types of lawyer advertisements. *Id.* at 53. The FTC sent warning letters to seven legal practitioners and lead generators, encouraging "clear and prominent audio and visual disclosures stating that consumers should not stop taking their medications without first consulting their doctors." FTC Press Release, *supra*, at 1. And both Tennessee and Texas enacted laws targeting misleading tactics in lawyer advertisements in 2019. *See* Tennessee Code § 47-18-3002; Texas Gov't Code § 81.151, *et. seq.*

West Virginia joined its sister states and passed the challenged Act earlier this year, targeting the specific advertising tactics discussed above. First, the Act requires several disclosures making the ad's sponsorship clear. West Virginia Code § 47-28-3(a)(1), (5), (6). Second, the Act prohibits a legal advertisement that, among other things:

- Presents a legal advertisement as a "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;

- Displays the logo of a federal or state government agency in a manner that suggests affiliation with the sponsorship of that agency;
- Uses the word "recall" when referring to a product that has not been recalled by a government agency or through an agreement between a manufacturer and government agency.

Id. § 47-28-3(a)(2), (3), (4). The Act also requires the following statements in certain legal advertisements:

- "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."
- Disclosure 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. § 47-28-3(b).

ARGUMENT

I. The Act is facially constitutional.

A. States may prohibit or mandate certain statements in lawyer advertising.

Limits on advertising are familiar in the legal profession. The prevailing view for much of the 20th century "was that advertising by lawyers was a form of solicitation of legal business, equally to be condemned with 'ambulance chasing' and other forms of direct or personal solicitation." Robert F. Boden, *Five Years After* Bates*: Lawyer Advertising in Legal and Ethical Perspective*, 65 Marq. L. Rev. 547, 550 (1982). Echoing the British legal tradition's belief that "law [was] a form of public service," disapproval of lawyer advertising in the United States "evolved into an aspect of the ethics of the profession." *Bates v. State Bar of Arizona*, 433 U.S. 350, 371 (1977). The American Bar Association adopted "a flat prohibition against advertising and solicitation" in 1908 and again embraced comprehensive prohibitions in its 1969 *Code of Professional Responsibility*. Boden, *supra*, at 549, 551–52. Consistent with this, states condemned lawyer advertising entirely for years. *See In re R.M.J.*, 455 U.S. 191, 193 (1982).

This status quo changed abruptly in 1977. In *Bates*, the Supreme Court recognized for the first time that lawyer advertising is commercial speech and held that "advertising by attorneys may not be subjected to blanket suppression." 433 U.S. at 379, 383. The Court determined that Arizona could not prohibit a "truthful" newspaper advertisement "concerning the availability and terms of routine legal services." *Id.* at 385.

Bates was a "radical departure from old and accepted norms," Boden, *supra*, at 554, which the Court soon emphasized "was a narrow" decision, *In re R.M.J.*, 455 U.S. at 200. Five years later, the Court reiterated that "advertising by lawyers still could be regulated" and that *Bates* left untouched the states' ability to regulate "[f]alse, deceptive, or misleading" lawyer advertisements. *Id.* Lawyer advertising "poses special risks of deception" due to "[t]he public's comparative lack of knowledge, the limited ability of [lawyers] to police themselves, and the absence of any standardization in the 'product.'" *Id.* at 202; *see also Bates*, 433 U.S. at 383.

By 1985, it was "well settled" that states remained "free to prevent the dissemination of . . . false, deceptive, or misleading" lawyer ads. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 638 (1985). Not all regulations of such ads are subject to the balancing test for commercial speech announced in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980). *First*, states have broad authority to prohibit statements in lawyer advertising that are "inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive." *In re R.M.J.*, 455 U.S. at 202; *see also Zauderer*, 471 U.S. at 641. That sort of "[m]isleading advertising may be prohibited entirely." *In re R.M.J.*, 455 U.S. at 203. *Second*, states may mandate certain statements "as long as [those] disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 651.

B. The Act prohibits deceptive and inherently misleading statements in lawyer ads.

1. The Act's several prohibitions fall well within the state's authority to bar statements that are "inherently likely to deceive" or have been proven to do so. *In re R.M.J.*, 455 U.S. at 202. The prohibitions are not broad "prophylactic rules" that make no attempt to distinguish between "deceptive and nondeceptive legal advertising." *Zauderer*, 471 U.S. at 644. Each of the three prohibitions is targeted specifically at "a particular form or method of advertising" that is defined as misleading or that "has in fact been deceptive." *In re R.M.J.*, 455 U.S. at 202.

The first prohibition prevents disguising an offer for legal services as instead "offering professional, medical, or government agency advice about pharmaceuticals or medical devices." W. Va. Code § 47-28-3(a)(2). It bars certain phrases that "[p]resent[] a legal advertisement" as something it is not—a public service announcement or health alert. *Id.* That is textbook deception for which there is ample real-world concern. As the FTC has explained, "sensational warnings or alerts . . . may initially mislead consumers into thinking they are watching a government-sanctioned medical alert or public service announcement." FTC Press Release, *supra*, at 1; *see also* King & Tippett, *supra*, at 146–47 (finding "clear evidence that deceptive drug injury advertisements are likely to be misidentified" as public service announcements).

The second prohibition disallows using "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). By its terms, this prohibition applies only to inherently misleading and actually deceptive uses of government logos. Even Plaintiffs do not argue that it would *ever* be truthful to suggest that private legal advertisements have "the sponsorship" of a government agency.

The third prohibition bars misleading use of the word "recall." W. Va. Code § 47-28-3(a)(4). Although Plaintiffs complain about the prohibition's sweep, they do not contest that it legitimately bans some inherently false and misleading uses of the word "recall." Nor do they

dispute that this prohibition rests on sound data. As discussed above, one study found that over half of new patients at a specialty urology clinic mistakenly believed government agencies or manufacturers had recalled mesh products and that nearly 70% received information on the topic from the television. Tenggardjaja et al., *supra*, at 327; *see also* FTC Press Release, *supra*, at 1 (noting that many drug and device litigation ads "could leave consumers with the false impression that their physician-prescribed medication has been recalled").

2. Plaintiffs' challenges to these prohibitions fail because they facially attack the law but complain only about particular applications—and even those complaints are dubious. They ask this Court to "[d]eclare that the Act is invalid and unenforceable in its entirety." Compl., Dkt. No. 1, at 31. Yet even in the First Amendment context, facial challenges are disfavored because they "often rest on speculation," "run contrary to the fundamental principle of judicial restraint," and "threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450–51 (2008).

As to the first and second prohibitions, Plaintiffs primarily raise vagueness concerns about various hypothetical situations. PI Mem. 26–30. But the Supreme Court has made clear that "speculation about possible vagueness in hypothetical situations not before the Court will not support a facial attack on a statute when it is surely valid 'in the vast majority of its intended applications.'" *Hill v. Colorado*, 530 U.S. 703, 733 (2000) (citing *United States v. Raines*, 362 U.S. 17, 23 (1960)). And Plaintiffs have not shown unconstitutional vagueness in their few hypotheticals, much less in the vast majority of applications. As the Supreme Court has said, "because we are 'condemned to the use of words, we can never expect mathematical certainty from our language.'" *Id.* (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 110–11 (1972)).

Even in Plaintiffs' most imaginative hypotheticals, it is "clear what the [law] as a whole prohibits." *Id.* (internal quotations omitted). For example, there is little doubt that merely "displaying a letter sent by the FDA on its letterhead" would *not* violate the prohibition on using an agency logo in a way that suggests agency sponsorship of the ad. PI Mem. 29.

As to the third prohibition, Plaintiffs attempt to sidestep the limitations on facial challenges by appealing to the overbreadth doctrine. PI Mem. 25–26. But the Supreme Court has held that "the overbreadth doctrine does not apply to commercial speech." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); *accord United Seniors Ass'n, Inc. v. Soc. Sec. Admin.*, 423 F.3d 397, 407 (4th Cir. 2005). Indeed, the Court has specifically found lawyer advertising to be "a context where [the overbreadth doctrine] is not necessary to further its intended objective," since such ads seem unlikely to be "crushed by overbroad regulation." *Bates*, 433 U.S. at 381. Here, Plaintiffs have many other ways to describe a "recall" without using that word—*e.g.*, the product has been withdrawn, called back, or taken off the market—to which they will undoubtedly turn if the Act goes into effect.

In any event, Plaintiffs' arguments illustrate the dangers of weighing hypotheticals not before a court. It is hardly clear that, as Plaintiffs speculate, the law bars the use of "recall" in cases of voluntary action. *See* PI Mem. 20–26. At least with respect to FDA-regulated products, on which Plaintiffs focus, there are *no* recalls that do not involve government participation. Every "recall," including so-called voluntary ones, is subject to ongoing FDA oversight. *See* 21 C.F.R. § 7.40(a) ("setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall"). Those voluntary recalls may be "through an agreement between a manufacturer and government agency," W. Va. Code § 47-28-3(a)(4), and thus may lawfully be described as a "recall" in a legal ad.

Finally, Plaintiffs also rely heavily on *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), but that case has no application here. The state in *Sorrell* "nowhere contend[ed] that [the regulated activity was] false or misleading within the meaning of this Court's First Amendment precedents." *Id.* at 579. That case did not change or speak to the *Zauderer* framework for assessing regulations aimed at deceitful and misleading tactics in legal advertisements.

C. The Act mandates uncontroversial disclosures reasonably related to West Virginia's interest in preventing consumer deception.

The state may mandate disclosures in legal ads to correct a "self-evident" possibility of deception. In *Zauderer*, the Supreme Court considered a legal advertisement promoting a contingency fee arrangement that failed to disclose a client's potential liability for "costs." *Id.* at 633. Ohio's requirement that the ad disclose the distinction between "fees" and "costs" "easily passe[d] muster" because, "to laymen not aware of the meaning of these terms of art," the advertisement would falsely suggest a "no-lose proposition." *Id.* at 652. As the chance of deception was "self-evident," the court "[did] not require the State to 'conduct a survey of the . . . public before it [may] determine that the [advertisement] had a tendency to mislead.'" *Id.* at 652–53 (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391–392 (1965)).

More recently, the Court has said that disclosures must convey "purely factual and uncontroversial information," cannot be "unjustified or unduly burdensome," and must seek "to remedy a harm that is potentially real not purely hypothetical." *Nat'l Inst. of Family & Life Advocates v. Becerra ("NIFLA")*, 138 S. Ct. 2361, 2372, 2377 (2018) (citing *Zauderer*, 471 U.S. at 651). The Court refused to apply *Zauderer* to disclosures about abortion because they were "anything but [] 'uncontroversial.'" *Id.* at 2372. Separately, the Court struck down a disclosure law that was justified by "purely hypothetical" reasons and that required the speaker to post the

notice in "as many as 13 different languages" and "call attention to the notice, instead of its own message, by some method such as larger text or contrasting type or color." *Id.* at 2377–78.

The Act's mandatory disclosures meet all of these requirements. To begin with, they seek to prevent deception that is nonhypothetical, "self-evident," and verified by substantial evidence. The need for the first disclosure requirement—that advertisers caution viewers to consult their doctors—is confirmed by survey data and actual physician accounts of patients unilaterally discontinuing a course of medical treatment after viewing a legal advertisement. *See* Exs. 1 and 2; FTC Press Release, *supra*, at 1. And as to the second requirement—that advertisers disclose that a medication or device remains approved by the FDA—the disclosure addresses the self-evident and documented concern that an ad raising questions about a drug or medical device could mislead a viewer into thinking the FDA has recalled the product. *See* Tenggardjaja et al., *supra*, at 327; *see also* FTC Press Release, *supra*, at 1.

Moreover, the disclosures here fall in the heartland of *Zauderer*. They address the same content—lawyer advertising—and are purely factual and uncontroversial. It is neither controversial nor "medical advice" to remind a viewer to consult with the medical professional on whose authority and instruction a treatment was assigned in the first place. PI Mem. 27. It is common sense. Likewise, disclosing that a drug or device remains approved by the FDA, when that is the truth, is not controversial either. Even if there are questions surrounding whether that approval will or should continue, PI Mem. 37–38, the required disclosure takes no position on *future* approval. And finally, unlike in *NIFLA*, these disclosures do not burden the speaker by effectively requiring it to "call attention to the notice, instead of its own message."[5]

[5] Beyond their alleged burden, Plaintiffs do not contest the disclosures regarding the advertiser's identity and nature of the advertisement. W. Va. Code § 47-28-3(a)(1), (5), (6).

II. The Equal Protection Clause does not require heightened scrutiny.

Invoking the Equal Protection Clause, Plaintiffs attempt to circumvent the Supreme Court's commercial speech jurisprudence. But courts have uniformly rejected such an end-around. *See, e.g.*, *Chambers v. Stengel*, 256 F.3d 397, 401 (6th Cir. 2001) ("[E]qual protection claims involving commercial speech also are subject to the same level of review."); *Anderson v. Treadwell*, 294 F.3d 453, 465 (2d Cir. 2002) (same); *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1278 (9th Cir. 2017) (same). Plaintiffs turn again to *Sorrell, see* PI Mem. 40–41, but *Sorrell* did not consider an equal protection challenge or suggest that the Equal Protection Clause is a backdoor to heightened scrutiny unavailable under the First Amendment.

III. The Act is severable.

To the extent this Court disagrees that the Act's provisions all survive constitutional scrutiny, the Act is severable, and any preliminary injunction should be limited accordingly. West Virginia Code § 2-2-10(cc) provides that "the provisions of every section, article or chapter of this code, whether enacted before or subsequent to the effective date of this subdivision, are severable." This provision, which Plaintiffs fail even to acknowledge, has been applied consistently by the West Virginia Supreme Court of Appeals to statutes that lack any contrary indication on severability, as here. *See State ex rel. Loughry v. Tennant*, 732 S.E.2d 507, 519 (W. Va. 2012) (applying 2-2-10(cc) to remove unconstitutional portion of statute); *Women's Health Ctr. of W. Virginia, Inc. v. Panepinto*, 446 S.E.2d 658, 667 (W. Va. 1993) (same). This Court need not—and may not—undertake its own assessment as to whether the Legislature intended each provision to stand alone, as Plaintiffs baselessly invite the Court to do.

CONCLUSION

Because the Act is constitutional, the Court should deny Plaintiffs' motion for a preliminary injunction.

Respectfully submitted,

By: /s/ Elbert Lin

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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2020, I electronically filed this brief with the Clerk of this Court by using the CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

/s/ Elbert Lin
Elbert Lin

EXHIBIT A

FDA U.S. FOOD & DRUG ADMINISTRATION

The Honorable Andy Harris
U.S. House of Representatives
Washington, DC 20515

Dear Representative Harris:

Thank you for your letter dated December 2, 2016, to the U.S. Food and Drug Administration (FDA) regarding MEDWATCH reports of patients discontinuing their anticoagulant therapy after exposure to legal advertising.

The FDA's MEDWATCH program collects adverse event reports for drugs and biologics. These reports are housed within FDA Adverse Event Reporting System (FAERS). Reporting of adverse events and medication errors by healthcare professionals and consumers is generally voluntary in the United States. FDA receives some adverse event and medication error reports directly from healthcare professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others). Healthcare professionals and consumers may also report adverse events and/or medication errors to the products' manufacturers. If a manufacturer receives an adverse event report, they are required to send the report to the FDA. The reports received directly and those received from manufacturers are entered into FAERS, where they are then reviewed by FDA for safety concerns that may be related to a marketed product.

In response to your letter, FDA's pharmacovigilance group, part of the FDA's Center for Drug Evaluation and Research (CDER), conducted a query of the FAERS database through December 31, 2016, to identify reports of interest. The query identified 61 reports in which a patient, or multiple patients per report, indicated they viewed an advertisement and then discontinued (60) or decreased (1) the dose of a novel oral anticoagulant (NOAC).

Twenty-two of the 61 reports mentioned that the patient viewed a "legal" advertisement before discontinuing Pradaxa (dabigatran) or Xarelto (rivaroxaban). No other NOACs were associated with these 22 reports. These 22 reports are summarized further below.

Pradaxa (dabigatran) (3 reports)

- All three reports describe patients who discontinued Pradaxa and subsequently had a stroke. One of these patients died two weeks after discontinuing Pradaxa following a cardiac arrest.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Xarelto (rivaroxaban) (19 reports)

- Three reports referencing individual patients did not mention any subsequent adverse events.
- Two reports referenced more than one patient. One of these reports referred to "multiple" patients and did not report any subsequent adverse event. The other report referred to three patients with subsequent stroke.
- Two reports indicated that patients died after discontinuing Xarelto. One patient died following stroke and the other report did not mention any specific adverse event leading up to death.
- The 12 remaining reports referenced individual patients and noted the following adverse events: stroke (8), transient ischemic attack (TIA) (1), deep vein thrombosis (DVT) of the arm (1), intracardiac thrombus (1), cerebral and foot thrombosis (1).

The source of the advertisement for the remaining 39 of 61 reports is unclear. For example, 13 of these 39 reports included mention of the term "bad drug" advertisement and 26 reports included mention of nonspecific terms such as "television ads" or "commercials". Among these 39 reports, three patients died after discontinuing Xarelto (rivaroxaban). One patient died following pulmonary embolism and 2 patients died following strokes.

Your letter also requested an assessment of the authority of FDA to regulate the legal advertisements, specifically mentioning FDA-approved drugs, with which you are concerned. Pursuant to section 502(n) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), (21 USC 352(n)) and FDA regulations at 21 CFR Part 202, a prescription drug marketed in the United States is misbranded unless advertisements issued by the "manufacturer, packer, or distributor thereof" meet specific requirements, including that they contain accurate information about the drug, addressing both risks and benefits, and that the advertising is truthful, balanced, and not misleading. The legal advertisements you refer to are disseminated by lawyers seeking clients for legal services, and are not advertising for the drug itself issued by a manufacturer or other party responsible for marketing the drug within the scope of section 502(n), FD&C Act.

Thank you, again, for contacting us concerning this matter.

Sincerely,

Anna K. Abram

Anna K. Abram
Deputy Commissioner for Policy, Planning,
Legislation, and Analysis

EXHIBIT B

FDA U.S. FOOD & DRUG ADMINISTRATION

The Honorable Andy Harris, M.D.
House of Representatives
1533 Longworth House Office Building
Washington, DC 20515

FEB 06 2019

Dear Congressman Harris:

Thank you for your letter dated October 15, 2018, to the U.S. Food and Drug Admininistration (FDA) regarding MedWatch reports of patients discontinuing their anticoagulants, antidepressants, and antidiabetic therapies after viewing a legal advertisement.

In your letter, you requested that the Agency pull various types of MedWatch summary reports in the FDA Adverse Event Reporting System (FAERS) database that FDA received concerning patients who discontinued their anticoagulants, antidepressants, and antidiabetic products after viewing a legal advertisement.

In performing the searches you requested, FDA identified 213 reports in which a patient viewed an advertisement and then discontinued their antidiabetic, antidepressant, or anticoagulant medication.

- Approximately 21% (44/213) of all reports described patients viewing a legal advertisement and then discontinuing their medication.
- 14 report narratives mentioned "Bad drug ads" as the advertisement that prompted medication discontinuation.
- In 73% (155/213) of the reports that described medication discontinuation after viewing an advertisement, we were unable to determine the specific type of advertisement.
- Approximately 27% (58/213) of all reports described an adverse event after medication discontinuation.
- Reports of medication discontinuation after viewing an advertisement were submitted from 37 different states.

Furthermore, attached you will find specifc details of the queries the Agency performed to ensure you have a full understanding of the methodology of reviewing the MedWatch reports and our findings. An explanation of the limitations of this review is also included in Appendix A.

Thank you for contacting us concerning this matter. Please let us know if you have further questions.

Sincerely,

Maren McBride
Legislative Director for Appropriations

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ATTACHMENT 1.

METHODS AND MATERIALS

The FAERS search criteria is described in **Table 1**.

Table 1. FAERS Search Strategy*

Date of search	October 22, 2018
Time period of search	All reports through September 30, 2018
Products	Anticoagulants, antidepressants, antidiabetic agents†
Country	United States
Other Search Criteria‡	Narrative search: ("adverti" [OR] "tv" [OR] "televis" [OR] "commercial" [OR] "publicity" [OR] "bad drug") [AND] ("discontin" [OR] "not taking" [OR] "stop" [OR] "quit")

* See **Appendix B** for a description of the FAERS database.
† See **Appendix C** for all product active ingredients.
‡ Text strings were case insensitive.

Identification of reports was an iterative process that required multiple preliminary searches. In response to your first inquiry in 2016, the Division of Pharmacovigilance (DPV) conducted preliminary searches in the FAERS database using the list of terms provided in your inquiry. We excluded several terms from the current search because these yielded a large number of reports unrelated to medication discontinuation following viewing legal advertisements. For example:

- Lawyer/attorney: a disproportionate number of litigation reports have been submitted to FDA that are unrelated to medication discontinuation because of a legal advertisement
- Radio: non-specific because of the frequency of references to unrelated terms such as radiographs, radiology, and estradiol
- Ad: non-specific because "ad" is a common component of words such as addition
- Contact/call: non-specific and non-informative in identifying related reports to the topic of the search

Because expanded search capabilities using logic and Boolean terms are not available in FAERS Business Intelligence Solution (FBIS), DPV searched the FAERS using Empirica Signal 7.3. Partial words were used in the narrative search to allow for variation of the words by reporters (e.g., misspelling, plural forms).

In our final search for the first inquiry in 2016, we included an additional term, "bad drug," because many reports contain this specific descriptor when referring to the viewed drug advertisements. We applied the query identified in Empirica Signal as having the highest utility to the FAERS data retrieved from FBIS for validation. Statistical Analysis System (SAS) software was used to apply the narrative criteria to the data retrieved from FBIS (SAS Institute Inc., version 9.4, Cary, NC).

For the current inquiry, our strategy for retrieving reports followed the same rationale, with one modification: we focused our search on identification of "drug discontinuation" instead of "drug

discontinuation *or* dose tapering." This decision was made after consideration of the volume of reports retrieved and reviewed for the first inquiry, the subsequent low yield of a single report of decreased dose, and the large volume of reports retrieved across all anticoagulants, antidiabetic agents, and antidepressants for the present inquiry.

Below is a summary of all reports describing discontinuation of an anticoagulant, antidiabetic, or antidepressant agent after viewing an advertisement through September 30, 2018. This includes reports of Novel Oral Anticoagulant (NOAC) discontinuation identified from the 2016 inquiry.

REPORT SELECTION CRITERIA

We included FAERS reports if:

- Patient was taking an anticoagulant, antidepressant, or antidiabetic product AND
- Patient reportedly discontinued therapy after viewing an advertisement

We characterized reports meeting the above criteria by product, patient demographics, advertisement type, advertisement medium, adverse events reported following drug discontinuation if any, reporter state, reporter qualification (i.e., consumer, healthcare provider, lawyer), and FDA initial received date.

We classified the advertisement type into three categories based on the description in the narrative:

- "Legal" advertisements clearly described a lawyer or law firm advertisement or appeared to be advertisements that advise consumers to contact a law firm for help
- "Bad drug" advertisements described "Bad drug ads" in the report narrative. These ads appear to be public service announcements describing side effects of a product. The source of the advertisement was unclear (e.g., lawyers, law firm, advocacy group).
- "Unspecified" advertisements did not provide enough information to classify the advertisement (e.g., "I saw an advertisement on TV and decided to discontinue the drug X.")

RESULTS

The FAERS search retrieved 2,865 reports. After applying the report selection criteria listed above, we identified 213 reports where patients presumably saw an advertisement that prompted medication discontinuation. **Table 2** summarizes the descriptive characteristics. **Appendix D** lists the FAERS report numbers, FAERS version numbers, and Manufacturer Control numbers for the 213 reports. Note that all of these characteristics are based solely upon the information provided by the reporter to FDA; FDA has not independently verified its accuracy.

Table 2. Descriptive Characteristics of FAERS Reports of Antidiabetic, Antidepressant, and Anticoagulant Discontinuation after Viewing an Advertisement, Received by FDA Through September 30, 2018 (n=213 reports)

	Antidiabetics (n=108)	**Antidepressants[¶] (n=36)**	**Anticoagulants* (n=69)**
Age (years)[†]	n=68	n=21	n=29
Mean	62	54	81
Median	62	55	81
Range	44-86	14-91	76-90
Sex			
Male	45	8	31
Female	59	28	27
Not reported	4	-	11
Discontinued medication	Canagliflozin (21) Canagliflozin/metformin (1) Dapagliflozin (2) Empagliflozin (1) Exenatide (4) Glimepiride/rosiglitazone (2) Insulin glargine (1) Liraglutide (4) Metformin/rosiglitazone(4) Metformin/sitagliptin (1) Pioglitazone (4) Rosiglitazone(39) Saxagliptin (1) Sitagliptin (21) Troglitazone[§] (2)	Aripiprazole (9) Brexpiprazole (1) Duloxetine (16) Lurasidone (2) Olanzapine (1) Paroxetine (1) Quetiapine (5) Risperidone (1)	Apixaban (4) Rivaroxaban (57) Dabigatran (8)
Reporter qualification			
Heath care professional	36	4	50
Consumer	48	25	19
Lawyer[‖]	23	1	-
Not reported	1	6	-
Advertisement type			
Legal	17	2	25
Bad drug	2	-	12
Unspecified	89	34	32
Advertisement medium			
TV	66	34	41
Other[∞]	2	-	1
Unknown[€]	40	2	27
Reported subsequent adverse event	n=6 Hyperglycemia (3) Elevated A1c (2) Weight gain (1)	n=6 Headache (2) Hospitalization (1) Suicide (1) Depression (1) Withdrawal Symptoms (1)	n=46 Stroke[‡] (32) Transient Ischemic Attack (2) Thromboembolism[‡,£] (11) Unspecified[¥] (1)
Year report initially received by FDA	1997 (1) 1998 (1) 2001 (1) 2003 (1) 2004 (2)	2001 (1) 2004 (1) 2006 (1) 2007 (1) 2010 (4)	2012 (4) 2013 (2) 2014 (8) 2015 (33) 2016 (13)

	2007 (3) 2008 (4) 2009 (10) 2010 (4) 2011 (8) 2012 (18) 2013 (13) 2014 (11) 2015 (10) 2016 (10) 2017 (3) 2018 (8)	2011 (2) 2012 (3) 2013 (1) 2014 (2) 2015 (10) 2016 (4) 2017 (4) 2018 (2)	2017 (6) 2018 (3)

*Includes NOAC discontinuation reports previously identified in the prior 2016 Congressional request
† Refers to the number of reports in which the specific demographic data were provided; balance of the total had incomplete data
§ Troglitazone was withdrawn from the US market in 2000
‖ Among the 23 lawyer reports for the antidiabetics, there were multiple firms, lawyers, and states represented.
∞Includes all other advertisement medium (e.g., print, radio)
€ Unknown refers to reports where the advertisement medium was not specified
‡ Includes six death reports after either a stroke or thromboembolism
£Thromboembolic events include pulmonary embolism, deep vein thrombosis, splenic infarct, and "clots"
¥ Report of death but adverse event was not specified
¶List includes atypical antipsychotics with indications for major depressive disorder or depressive episodes associated with bipolar disorder.

Table 3. A List of Reporters' Home States for Reports of Antidiabetic, Antidepressant, and Anticoagulant Discontinuation after Viewing an Advertisement, Received by FDA Through September 30, 2018 (n=179*) (as reported, not verified by FDA)

	Antidiabetics (n=89)	**Antidepressants (n=29)**	**Anticoagulants† (n=61)**	**Total number of reports by state**
Reporter State	AK (1) AL (4) AR (2) AZ (1) CA (7) CT (3) FL (6) GA (3) IL (2) IN (3) KY (2) LA (3) MA (1) MD (3) MI (2) MO (3) MS (2) NC (3) NM (2) NY (9) OH (5) PA (5) TN (3)	CA (4) GA (1) KY (1) MA (2) MI (3) MN (1) MO (1) NC (1) NE (1) NJ (2) NM (1) NV (1) NY (2) OH (1) PA (1) SC (1) TX (4) VA (1)	CA (1) CO (2) CT (5) DE (3) FL (10) GA (3) IL (1) IN (1) KS (1) KY (2) LA (4) MA (2) MD (1) MI (3) MO (2) MS (1) NC (2) NE (1) NV (1) NY (3) OH (2) OK (1) RI (1)	AK (1) AL (4) AR (2) AZ (1) CA (12) CO (2) CT (8) DE (3) FL (16) GA (7) IL (3) IN (4) KS (1) KY (5) LA (7) MA (5) MD (4) MI (8) MN (1) MO (6) MS (3) NC (6) NE (2)

	Antidiabetics (n=89)	Antidepressants (n=29)	Anticoagulants† (n=61)	Total number of reports by state
	TX (9) UT (1) VA (4)		TX (5) VA (2) WA (1)	NJ (2) NM (3) NV (2) NY (14) OH (8) OK (1) PA (6) RI (1) SC (1) TN (3) TX (18) UT (1) VA (7) WA (1)
*The reporter's state was not reported in 34 of 213 reports † These reports include NOAC discontinuation reports previously identified in the prior Congressional request				

APPENDIX A. LIMITATIONS

We did not have sufficient information to confirm the adverse events reported following drug discontinuation were related directly to the discontinuation (i.e., the event may have been related to underlying disease or other etiologies). Additional limitations of our assessment are consistent with those of spontaneously reported data and include underreporting, variable reporting quality, selective or delayed reporting, and the lack of event adjudication. Most reports did not provide sufficient information to determine if the advertisement the patient viewed was a legal advertisement (i.e., advertisements that advise consumers to contact a law firm for help) or an advertisement promoting the drug.

Identification of FAERS reports describing drug discontinuation following a legal advertisement requires a manual assessment of each report's narrative by specialized safety staff. Because the FDA has received over 1 million adverse event reports for the drug products requested, we used a search strategy that considered the feasibility of review in addition to specificity of terms. It is possible that there are additional relevant reports in FAERS; however, the number is likely small given the low yield from using the search terms that were determined to be more specific (i.e., we were able to determine a legal advertisement preceded a discontinuation in fewer than 2% of the 2,865 reports manually reviewed).

APPENDIX B. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and biologic products. The informatic structure of the database adheres to the international safety reporting

guidance issued by the International Conference on Harmonisation. Adverse events are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary (FPD).

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be shown, and reports often do not contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

APPENDIX C. PRODUCT ACTIVE INGREDIENTS EVALUATED

Anticoagulants

Apixaban
Argatroban
Bivalirudin
Dabigatran
Dabigatran Etexilate
Dabigatran Etexilate Mesylate
Dalteparin
Dalteparin Sodium
Dextrose\Heparin
Dextrose\Heparin Sodium
Edoxaban Tosylate
Enoxaparin
Enoxaparin Sodium
Enoxaparin\Enoxaparin Sodium
Fondaparinux
Fondaparinux Sodium
Heparin Calcium
Heparin Sodium
Heparin Sodium\Sodium Chloride
Rivaroxaban
Warfarin
Warfarin Potassium
Warfarin Sodium

Antidepressants*

Agomelatine	Levomilnacipran Hydrochloride
Amitriptyline Hydrochloride	Fluoxetine Hydrochloride
Amitriptyline	Fluoxetine Hydrochloride\Olanzapine
Amitriptyline Hydrochloride\Chlordiazepoxide	Fluvoxamine
Amitriptyline Hydrochloride\Perphenazine	Fluvoxamine Maleate
Amitriptyline\Chlordiazepoxide	Imipramine
Amitriptyline\Perphenazine	Imipramine Hydrochloride
Amitriptylinoxide	Imipramine Pamoate
Amoxapine	Isocarboxazid

Clomipramine Hydrochloride	Levomilnacipran
Bupropion Hydrobromide	Sertraline Hydrochloride
Mirtazapine	Mianserin Hydrochloride
Nortriptyline Hydrochloride	Milnacipran
Vortioxetine Hydrobromide	Moclobemide
Bupropion Hydrochloride	Phenelzine Sulfate
Bupropion	Nefazodone
Citalopram Hydrobromide	Nefazodone Hydrochloride
Choline\Citalopram Hydrobromide	Norfluoxetine
Choline\Fluoxetine Hydrochloride	Nortriptyline
Escitalopram Oxalate	Opipramol
Citalopram Hydrochloride	Tranylcypromine Sulfate
Clomipramine	Paroxetine
Duloxetine Hydrochloride	Paroxetine Hydrochloride
Desipramine	Paroxetine Mesylate
Desipramine Hydrochloride	Phenelzine
Desvenlafaxine	Protriptyline
Desvenlafaxine Succinate	Protriptyline Hydrochloride
Trazodone Hydrochloride	Trimipramine Maleate
Doxepin	Tranylcypromine
Doxepin Hydrochloride	Trimipramine
Duloxetine	Vilazodone Hydrochloride
Reboxetine Mesylate	Vilazodone
Venlafaxine Hydrochloride	Viloxazine Hydrochloride
Selegiline	Vortioxetine
Olanzapine	Aripiprazole
Quetiapine	Quetiapine Fumarate

*List includes atypical antipsychotics with indications for major depressive disorder or depressive episodes associated with bipolar disorder.

Antidiabetic Products

Acarbose	Miglitol
Acetohexamide	Insulin Beef/Pork
Metformin Hydrochloride\Pioglitazone Hydrochloride	Insulin Pork\Insulin Purified Pork
Pioglitazone Hydrochloride	Insulin Beef
Insulin Human	Insulin Degludec
Lixisenatide	Insulin Degludec\Liraglutide
Insulin Lispro	Insulin Detemir
Metformin Hydrochloride	Insulin Glargine\Lixisenatide
Albiglutide	Insulin Nos
Aleglitazar	Ipragliflozin L-Proline
Alogliptin	Metformin Hydrochloride\Sitagliptin Phosphate
Alogliptin Benzoate\Metformin Hydrochloride	Sitagliptin Phosphate
Alogliptin Benzoate\Pioglitazone Hydrochloride	Linagliptin\Metformin Hydrochloride
Alogliptin Benzoate	Simvastatin\Sitagliptin Phosphate
Glimepiride	Metformin Hydrochloride\Saxagliptin Hydrochloride
Aminoglutethimide	Linagliptin
Insulin Glulisine	Liraglutide
Metformin Hydrochloride\Rosiglitazone Maleate	Phenformin
Glimepiride\Rosiglitazone Maleate	Metformin Hydrochloride\Saxagliptin
Rosiglitazone Maleate	Metformin Hydrochloride\Sitagliptin
Insulin Glargine	Metformin Hydrochloride\Vildagliptin
Buformin	Metformin\Nateglinide

Exenatide	Metformin\Sitagliptin
Canagliflozin	Metformin\Sitagliptin Phosphate
Canagliflozin\Metformin Hydrochloride	Metformin\Vildagliptin
Chlorpropamide	Mitiglinide
Clikstar	Nateglinide
Bromocriptine Mesylate	Omarigliptin
Dapagliflozin	Saxagliptin Hydrochloride
Dapagliflozin Propanediol	Tolbutamide
Dapagliflozin Propanediol\Metformin Hydrochloride	Tolbutamide Sodium
Phenformin Hydrochloride	Semaglutide
Glyburide	Pioglitazone
Diazoxide	Pramlintide Acetate
Glimepiride\Pioglitazone Hydrochloride	Metformin Hydrochloride\Repaglinide
Dulaglutide	Repaglinide
Empagliflozin	Dapagliflozin\Saxagliptin Hydrochloride
Empagliflozin\Linagliptin	Troglitazone
Empagliflozin\Metformin Hydrochloride	Rosiglitazone
Ertugliflozin	Insulin Aspart\Insulin Degludec
Insulin Aspart	Saxagliptin
Gliclazide	Ertugliflozin Pidolate\Metformin Hydrochloride
Glimepiride\Metformin	Sitagliptin
Glimepiride\Metformin\Voglibose	Ertugliflozin Pidolate
Glipizide	Ertugliflozin Pidolate\Sitagliptin Phosphate
Glipizide\Metformin Hydrochloride	Tofogliflozin
Glucagon Hydrochloride	Tolazamide
Glucagon	Vildagliptin
Glyburide\Metformin Hydrochloride	Voglibose
Glyburide\Metformin	

APPENDIX D. FAERS REPORT NUMBERS, FAERS VERSION NUMBERS, AND MANUFACTURER CONTROL NUMBERS

FAERS Report Number	FAERS Version Number	Manufacturer Control Number
3736010	1	Direct Report
4198147	1	US_0408104756
6031769	1	2006UW06965
6417804	2	US-ASTRAZENECA-2006UW27841
7285663	1	US-ELI_LILLY_AND_COMPANY-US201002003274
7548233	1	Direct Report
7591624	1	US-ASTRAZENECA-2007UW06152
7596548	1	US-ASTRAZENECA-2010SE12191
8292643	1	Direct Report
8391447	1	Direct Report
8525578	1	US-ELI_LILLY_AND_COMPANY-US201204002971
8612099	1	Direct Report
8737713	1	Direct Report
9355224	1	Direct Report
10438411	1	US-BRISTOL-MYERS SQUIBB COMPANY-20561585
10440114	1	US-BRISTOL-MYERS SQUIBB COMPANY-19413897
10724546	1	US-ROXANE LABORATORIES, INC.-2015-RO-00088RO
10932533	3	US-JNJFOC-20141117048
11217726	1	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-039970

11471156	2	US-ELI_LILLY_AND_COMPANY-US201201006154
11482290	2	US-ELI_LILLY_AND_COMPANY-US201204001760
11482915	2	US-ELI_LILLY_AND_COMPANY-US201201005763
11482946	1	US-ELI_LILLY_AND_COMPANY-US201203006763
11484972	1	US-ELI_LILLY_AND_COMPANY-US201209002142
11484997	1	US-ELI_LILLY_AND_COMPANY-US201209002314
11526390	1	US-ELI_LILLY_AND_COMPANY-US201308007727
11913338	1	Direct Report
12173859	1	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-018740
12345530	1	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-034813
12825612	1	Direct Report
13137892	3	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-004249
13236437	2	US-ELI_LILLY_AND_COMPANY-US201607008851
14068474	1	Direct Report
14272932	1	US-OTSUKA-2017_000941
14367487	1	Direct Report
14542611	1	US-OTSUKA-DJ201402892
12213379	1	Direct Report
12276324	2	US-JNJFOC-20160413109
12469243	1	US-JNJFOC-20160611604
12710873	1	US-JNJFOC-20160701093
12790435	1	US-ASTRAZENECA-2008BM13590
12806264	1	Direct Report
12895834	1	US-JNJFOC-20160919613
12895910	1	US-JNJFOC-20161018872
12895936	2	US-JNJFOC-20160825941
13126045	2	US-NOVOPROD-526549
13396469	2	US-JNJFOC-20170320626
14259180	1	US-JNJFOC-20171137763
14401939	2	US-JNJFOC-20180112851
14411195	1	US-JNJFOC-20171209155
14676965	1	US-JNJFOC-20180317158
14787166	1	US-JNJFOC-20180344964
14824272	1	US-JNJFOC-20180415523
14903393	1	US-SA-2017SA140425
14905167	1	US-SA-2017SA226282
15363996	1	US-JNJFOC-20180839992
14328553	1	US-JNJFOC-20171223814
14916889	2	US-JNJFOC-20180512844
15254679	1	US-SA-2018SA197774
15274154	6	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2018-BI-04
3001064	3	001-0991-971226
3149837	2	001-0991-981893
3721643	3	2001020550-1
3948334	1	Direct Report
4174518	1	US-GLAXOSMITHKLINE-A0443057A
4174816	2	US-GLAXOSMITHKLINE-A0508206A
6323481	2	A0653178A
6367744	3	A0665821A
6463939	1	A0652185A
6708365	1	A0657632A
6708416	1	A0664903A
6834587	6	A0759186A

6867956	1	Direct Report
6959027	6	A0776641A
7009935	3	A0788113A
7022010	3	A0790450A
7023297	5	A0790820A
7036155	3	A0766619A
7060629	1	A0738269A
7068945	2	A0799508A
7071852	2	A0790458A
7138378	2	A0810009A
7138385	2	A0810019A
7453422	2	US-ELI_LILLY_AND_COMPANY-US201007000469
7542276	1	TPA2010A04259
7572725	1	A0878677A
7701908	3	A0898494A
7798772	1	US-BRISTOL-MYERS SQUIBB COMPANY-15512379
7906483	1	A0849012A
8096459	1	US-GLAXOSMITHKLINE-A0839780A
8115200	1	US-GLAXOSMITHKLINE-A0875011A
8172751	2	US-GLAXOSMITHKLINE-A0881162A
8226136	4	US-GLAXOSMITHKLINE-A0915676A
8276628	1	US-GLAXOSMITHKLINE-A0884665A
8276649	2	US-GLAXOSMITHKLINE-A0931090A
8319549	2	US-GLAXOSMITHKLINE-A0934674A
8329164	2	US-GLAXOSMITHKLINE-A0834452A
8342041	1	US-GLAXOSMITHKLINE-B0730664A
8389723	4	US-GLAXOSMITHKLINE-A0913489A
8422842	1	US-GLAXOSMITHKLINE-A0849012A
8578487	1	US-MERCK-1204USA01641
8603183	2	US-GLAXOSMITHKLINE-A0875872A
8628693	4	US-009507513-1204USA03840
8669083	2	US-009507513-1207USA001432
8694600	1	US-GLAXOSMITHKLINE-A0790237A
8718136	3	TPA2012A04831
8770067	3	US-009507513-1201USA03652
8843013	2	US-GLAXOSMITHKLINE-A0775980A
8917650	1	US-MERCK-1211USA006797
8932157	1	US-MERCK-1211USA011429
8952270	3	US-MERCK-1212USA000767
8973141	3	US-009507513-1212USA006360
9024483	1	US-009507513-1301USA006113
9179585	1	US-GLAXOSMITHKLINE-A0815636A
9208106	1	US-009507513-1304USA000794
9226388	1	US-009507513-1304USA003455
9270914	1	US-009507513-1305USA000575
9276335	1	US-GLAXOSMITHKLINE-A0757551A
9284558	4	US-009507513-1305USA003539
9303704	1	US-GLAXOSMITHKLINE-A0783333A
9400887	3	US-GLAXOSMITHKLINE-A1033009A
9414335	1	US-GLAXOSMITHKLINE-A0837513A
9692710	1	Direct Report
9711215	1	US-BRISTOL-MYERS SQUIBB COMPANY-18738260
9711370	2	US-BRISTOL-MYERS SQUIBB COMPANY-19217124

9722365	2	US-009507513-1311USA010382
9889829	3	US-009507513-1402USA004622
9901824	2	US-GLAXOSMITHKLINE-A1036071A
9924102	1	US-009507513-1402USA011448
9993649	1	US-009507513-1403USA002546
10025170	5	US-MERCK-1403USA009219
10385391	2	US-GLAXOSMITHKLINE-A0745296A
10396602	2	US-GLAXOSMITHKLINE-A0719198A
10483712	1	US-009507513-1409USA014646
10607903	2	US-BRISTOL-MYERS SQUIBB COMPANY-21459953
10630591	1	Direct Report
10651676	1	US-009507513-1412USA005621
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11056904	3	US-JNJFOC-20150312002
11105649	1	US-009507513-1505USA002254
11282694	1	US-JNJFOC-20150708845
11330488	2	US-ASTRAZENECA-2015SE72777
11343992	1	US-JNJFOC-20150723003
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11408168	1	US-NOVOPROD-440226
11757804	2	US-JNJFOC-20151115711
12127663	1	US-APOTEX-2015AP015388
13149457	2	US-JNJFOC-20170121089
13341774	1	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-015047
13598486	1	US-JNJFOC-20170526534
13729666	1	US-JNJFOC-20170324930
13730853	6	US-JNJFOC-20170611527
11187200	1	US-JNJFOC-20150423971
11755434	1	US-JNJFOC-20151116924
12204585	2	US-JNJFOC-20160318682
10593492	1	US-JNJFOC-20141108462
11187588	1	US-JNJFOC-20150509080
11187491	2	US-JNJFOC-20150507305
11280888	1	US-JNJFOC-20150415479
11341055	2	US-JNJFOC-20150800157
9566607	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-29995BP
10955674	1	US-JNJFOC-20150311014
13016055	2	US-JNJFOC-20161115394
10305941	1	
10993284	2	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-019096
11058813	1	US-JNJFOC-20150416037
11062028	1	US-JNJFOC-20150418417
11086002	2	US-JNJFOC-20150414999
11496747	2	US-JNJFOC-20150809730
11539703	1	US-JNJFOC-20150913870
11705668	1	US-JNJFOC-20151103205
11834644	1	US-JNJFOC-20151202517
12659652	2	US-JNJFOC-20160810948
8812704	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-23284BP
11085415	2	US-JNJFOC-20150318032
11340978	1	US-JNJFOC-20150719847
8546638	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-09708BP

10892124	2	US-JNJFOC-20150217754
11033532	2	US-JNJFOC-20150217748
8783247	5	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BP-22419BP
11040472	2	US-JNJFOC-20141101271
11132093	1	US-JNJFOC-20150511236
12085001	2	US-JNJFOC-20160211583
11130833	1	US-JNJFOC-20150510497
12344646	1	US-JNJFOC-20160408775
10962280	1	US-JNJFOC-20150319289
11721546	1	US-JNJFOC-20150926767
12130647	2	US-JNJFOC-20160118912
12924398	2	US-JNJFOC-20161105136
9027746	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2013-BI-01034BP
10276971	1	
11280456	1	US-JNJFOC-20150519088
10026037	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-11494BP
11130816	1	US-JNJFOC-20150511383
11268573	1	US-JNJFOC-20150705153
11086143	2	US-JNJFOC-20150409895
12516417	1	US-JNJFOC-20160511307
12733128	2	US-JNJFOC-20160816773
11052156	1	US-JNJFOC-20150413672
12319086	2	US-JNJFOC-20160425330
10615875	3	US-JNJFOC-20141115825
10386783	8	US-JNJFOC-20140807384
8945760	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2012-BI-01856BP
9943111	1	US-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2014-BI-08358BP
10843740	1	US-JNJFOC-20150210309
11280968	2	US-JNJFOC-20150710673
12273189	2	US-JNJFOC-20160411987
10551607	2	US-JNJFOC-20141016788
12344243	1	US-JNJFOC-20160324756
11084626	2	US-JNJFOC-20150311015
11096743	1	US-JNJFOC-20150500389
12651710	1	US-JNJFOC-20160807695