

# 09-5006-CR

---

IN THE  
UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

---

UNITED STATES OF AMERICA

*Appellee,*

v.

ALFRED CARONIA

*Defendant-Appellant.*

---

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK,  
JUDGE ERIC N. VITALIANO

---

**AMICUS CURIAE BRIEF OF WASHINGTON LEGAL FOUNDATION  
IN SUPPORT OF APPELLANT ALFRED CARONIA AND REVERSAL**

---

Of Counsel:

Daniel J. Popeo  
Richard A. Samp  
Washington Legal Foundation  
2009 Massachusetts Avenue, N.W.  
Washington, D.C. 20036  
(202) 588-0302

Michael A. Carvin  
Eric E. Murphy  
JONES DAY  
51 Louisiana Avenue, N.W.  
Washington, D.C. 20001-2113  
(202) 879-3939  
macarvin@jonesday.com  
eemurphy@jonesday.com

*Attorneys for Amicus Curiae  
Washington Legal Foundation*

---

## **CORPORATE DISCLOSURE STATEMENT**

Amicus Curiae Washington Legal Foundation submits the following in compliance with Federal Rule of Appellate Procedure 26.1:

Washington Legal Foundation has no parent corporation and no company owns more than 10% of its stock.

**TABLE OF CONTENTS**

	<b>PAGE</b>
CORPORATE DISCLOSURE STATEMENT .....	i
TABLE OF CONTENTS.....	ii
TABLE OF AUTHORITIES .....	iii
STATEMENT OF INTEREST.....	1
REGULATORY REGIME .....	1
ARGUMENT .....	5
I. CARONIA’S CONVICTION IS BASED ON A SPEECH BAN UNSUPPORTED BY ANY SUFFICIENT INTEREST.....	5
II. CARONIA’S CONVICTION CANNOT SURVIVE THE FIRST AMENDMENT’S COMMERCIAL-SPEECH TEST.....	9
A. The Restriction Here Is Not About Unlawful Conduct.....	10
1. The Government cannot avoid the First Amendment by characterizing its speech ban as a conduct ban.....	12
2. The Government here penalized speech .....	15
B. The Banned Speech Is Not Misleading .....	16
C. The Government’s Speech Ban Is Not Narrowly Tailored To Serve Any Substantial Interest.....	22
CONCLUSION .....	31
CERTIFICATE OF COMPLIANCE	
CERTIFICATE OF SERVICE	

## TABLE OF AUTHORITIES

### Cases

<i>Alexander v. Cahill</i> , 598 F.3d 79 (2d Cir. 2010) .....	16, 22, 26
<i>Board of Trustees of Leland Stanford Jr. University v. Sullivan</i> , 773 F. Supp. 472 (D.D.C. 1991).....	8
<i>Board of Trustees of State University of New York v. Fox</i> , 492 U.S. 469 (1989).....	21, 29
<i>Bolger v. Youngs Drug Products Corp.</i> , 463 U.S. 60 (1983).....	14
<i>Buckman Co. v. Plaintiffs’ Legal Committee</i> , 531 U.S. 341 (2001).....	17
<i>Central Hudson Gas &amp; Electric Corp. v. Public Service Commission of New York</i> , 447 U.S. 557 (1980).....	9-11, 16, 24
<i>Citizens United v. FEC</i> , 130 S. Ct. 876 (2010).....	6-7, 20
<i>City of Cincinnati v. Discovery Network, Inc.</i> , 507 U.S. 410 (1993).....	6, 18
<i>Edenfield v. Fane</i> , 507 U.S. 761 (1993).....	23
<i>First National Bank of Boston v. Bellotti</i> , 435 U.S. 765 (1978).....	7
<i>44 Liquormart, Inc. v. Rhode Island</i> , 517 U.S. 484 (1996).....	25
<i>Greater New Orleans Broadcasting Association, Inc. v. United States</i> , 527 U.S. 173 (1999).....	6, 18-20, 23

**TABLE OF AUTHORITIES**  
**Cases**

*Griffin v. United States*,  
502 U.S. 46 (1991).....22

*Ibanez v. Florida Department of Business & Professional Regulation,  
Bd. of Accountancy*, 512 U.S. 136 (1994) .....23

*In re R.M.J.*,  
455 U.S. 191 (1982).....26

*Linmark Associates, Inc. v. Township of Willingboro*,  
431 U.S. 85 (1977).....18

*Lorillard Tobacco Co. v. Reilly*,  
533 U.S. 525 (2001).....11

*Pearson v. Shalala*,  
164 F.3d 650 (D.C. Cir. 1999).....26

*Peel v. Attorney Registration and Disciplinary Commission of Illinois*,  
496 U.S. 91 (1990).....26

*Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations*,  
413 U.S. 376 (1973).....10

*Rubin v. Coors Brewing Co.*,  
514 U.S. 476 (1995)..... 6, 14, 18-19, 23

*Shapero v. Kentucky Bar Association*,  
486 U.S. 466 (1988).....26

*Thompson v. Western States Medical Center*,  
535 U.S. 357 (2002)..... 9-10, 12-13, 21, 23-24, 26-28

*United States v. Caputo*,  
288 F. Supp. 2d 912 (N.D. Ill. 2003),  
*aff'd in part, vacated in part*, 517 F.3d 935 (7th Cir. 2008) ..... 26-27

## TABLE OF AUTHORITIES

### Cases

<i>United States v. Caputo</i> , 517 F.3d 935 (7th Cir. 2008) .....	11-12, 26
<i>United States v. Caronia</i> , 576 F. Supp. 2d 385 (E.D.N.Y. 2008) .....	3, 7, 11, 25
<i>Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.</i> , 425 U.S. 748 (1976) .....	14, 21
<i>Washington Legal Foundation v. Friedman</i> , 13 F. Supp. 2d 51 (D.D.C. 1998), appeal dismissed, 202 F.3d 331 (D.C. Cir. 2000) .....	11, 15, 20, 24-25
<i>Whitaker v. Thompson</i> , 353 F.3d 947 (D.C. Cir. 2004) .....	13
<i>Wisconsin v. Mitchell</i> , 508 U.S. 476 (1993) .....	10, 16
<i>Wyeth v. Levine</i> , 129 S. Ct. 1187 (2009) .....	20

### Statutes

Ala. Code § 27-1-10.1(a) .....	18
Ala. Code § 27-1-10.1(c) .....	18
N.J. Stat. Ann. § 26:1A-36.9(c) .....	18
Federal Food, Drug & Cosmetic Act	
21 U.S.C. § 301-397 .....	1
21 U.S.C. § 352 .....	3
21 U.S.C. § 352(a) .....	22
21 U.S.C. § 352(f)(1) .....	3
21 U.S.C. § 355(a) .....	1-2, 13
21 U.S.C. § 355(b)(1)(F) .....	1
21 U.S.C. § 396 .....	2

## TABLE OF AUTHORITIES

### Statutes

42 U.S.C. § 1395w-102(e) .....	18, 28
42 U.S.C. § 1396r-8(k)(6).....	18, 28-29
21 C.F.R. 202.1(e)(4) .....	2

### Other

FDA, <i>Legal Status of Approved Labeling of Prescription Drugs; Prescribing for Uses Unapproved by the FDA</i> , 37 Fed. Reg. 16503 (Aug. 15, 1972).....	2, 15
FDA, <i>Request for Comments About the Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices</i> , 59 Fed. Reg. 59820 (Nov. 18, 1994) .....	6, 20
FDA, <i>Final Guidance on Industry-Supported Scientific and Educational Activities</i> , 62 Fed. Reg. 64074 (Dec. 3, 1974).....	2, 15
FDA, <i>Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices</i> , 63 Fed. Reg. 64556 (Nov. 20, 1998).....	17
FDA, <i>Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools</i> , 74 Fed. Reg. 48083 (Sept. 21, 2009).....	15
FDA, <i>Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs § III</i> (Jan. 2009) .....	2-3, 11, 17
GAO, <i>FDA’s Oversight of the Promotion of Drugs for Off-Label Uses 2</i> (July 2008) .....	17
J. H. Beales III, <i>New Uses for Old Drugs</i> , printed in <i>Competitive Strategies in the Pharmaceutical Industry</i> (Robert B. Helms ed., 1996).....	28

## TABLE OF AUTHORITIES

### Other

James M. Beck & Elizabeth D. Azari, <i>FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions</i> , 53 Food & Drug L.J. 71 (1998).....	17
<i>More Information for Better Patient Care: Hearing of the Senate Committee on Labor and Human Resources</i> , 104th Cong. 81 (1996).....	20
<i>The Health Consequences of Smoking; Nicotine Addition; A Report of the Surgeon General</i> (1988) .....	10

## STATEMENT OF INTEREST

Washington Legal Foundation (“WLF”) is a public interest center with members in all 50 states. It seeks to defend the rights of individuals against excessive government regulation. WLF’s members include physicians who seek to receive truthful information about lawful “off-label” uses of FDA-approved drugs, and patients who want their doctors to have such information. Alfred Caronia’s conviction, if allowed to stand, will chill the availability of this information for WLF’s members, in violation of the First Amendment.<sup>1</sup>

## REGULATORY REGIME

The Federal Food, Drug & Cosmetic Act (“the Act”) regulates the manufacture and distribution of drugs. *See* 21 U.S.C. §§ 301-397. Under the Act, a manufacturer cannot distribute a “new drug” unless it first files an application with, and obtains approval from, the FDA. *Id.* § 355(a). The manufacturer must include with its application “the labeling proposed to be used for such drug.” *Id.* § 355(b)(1)(F).

Once the FDA approves a drug, it permits physicians to prescribe the drug (and their patients to use it) for *any* purpose. In other words, a physician can prescribe the drug not simply for the uses identified in its approved labeling, but

---

<sup>1</sup> Caronia’s counsel did not author this brief and, other than WLF and its counsel, no other person or entity financially contributed to the brief. The parties have consented to the brief’s filing, so leave of court is unnecessary.

also for other uses that the physician believes appropriate. Since the Act does not regulate the practice of medicine, *see* 21 U.S.C. § 396, the FDA has interpreted it not to reach these “off-label uses.” The FDA has instead indicated that a “physician may . . . vary the conditions of use from those approved in the package insert, without informing or obtaining [its] approval.” FDA, *Legal Status of Approved Labeling of Prescription Drugs; Prescribing for Uses Unapproved by the FDA*, 37 Fed. Reg. 16503, 16503 (Aug. 15, 1972).

At the same time, the FDA broadly restricts a manufacturer’s ability to make these lawful off-label uses known to physicians. In fact, the FDA “has consistently prohibited the promotion of . . . unapproved uses of approved products,” but only by manufacturers. FDA, *Final Guidance on Industry-Supported Scientific and Educational Activities*, 62 Fed. Reg. 64074, 64081 (Dec. 3, 1997). As such, manufacturer advertisements cannot “recommend or suggest any use that is not in the [drug’s] labeling.” 21 C.F.R. § 202.1(e)(4).

No *statutory* provision, however, prohibits manufacturers from promoting off-label uses. Instead, the FDA has created this speech ban in two distinct ways. First, the FDA has at times treated an approved drug promoted for off-label uses as a “new drug” within the meaning of 21 U.S.C. § 355(a), the distribution of which is unlawful without FDA approval. *See* FDA, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference*

*Publications on Unapproved New Uses of Approved Drugs* § III (Jan. 2009)

(hereinafter “*Good Reprint Practices*”). In this case, however, the Government has made no allegation that Xyrem was an unapproved new drug.

Second, the FDA has greatly expanded the Act’s prohibition against the “misbranding” of a drug. 21 U.S.C. § 352. Specifically, the Act states that a drug is “misbranded,” and therefore unlawful, if its labeling lacks “adequate directions for use.” *Id.* § 352(f)(1). The FDA converts this statutory requirement for “adequate directions” into a prohibition against manufacturers promoting off-label uses by *conclusively presuming* that a drug’s directions are inadequate for all off-label uses, no matter what the directions actually indicate or whether they are actually ill-designed for the recommended off-label use. *See Good Reprint Practices* § III (“An approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include ‘adequate directions for use.’”); *United States v. Caronia*, 576 F. Supp. 2d 385, 392 (E.D.N.Y. 2008) (“It is well established that . . . the promotion of a drug for an off-label use by the manufacturer . . . is prohibited regardless of what directions the manufacturer . . . may give for that use.”). The FDA thus prohibits speech promoting an off-label use even if the directions for that use are just as adequate as they are for the approved use.

This case illustrates its practice. Here, the jury found that Caronia had conspired to introduce a “misbranded” drug into interstate commerce. But the Government presented no evidence that the drug’s directions were inadequate on such subjects as Xyrem’s dosage or administration for the promoted off-label uses. Instead, the United States argued that Xyrem’s directions were inadequate as a matter of law because Caronia had “marketed Xyrem for medical indications that were not approved by the FDA.” Trial Tr. 906; *see also* Trial Tr. 40 (Government’s opening statement noting that the terms “off-label, misbranding, [and] unapproved use[]” “[a]ll . . . mean the same thing”). The Government also presented no evidence over whether Xyrem could effectively treat the promoted off-label conditions.

The Court accepted the Government’s argument, so its jury charge noted that “a misbranded drug may be shown by a promotion of the drug by a distributor for an intended use different from the use for which the drug was approved,” no matter what the directions indicated. *Id.* at 920. The jury was further instructed that a “manufacturer, its agents, representatives and employees, [were] not permitted to promote uses for a drug that have not been cleared by the [FDA].” *Id.* at 921. Consequently, the jury had to conclude that the directions were inadequate as a matter of law—and that the drug was misbranded—if it found that Caronia promoted off-label uses.

In sum, two points are clear from this regulatory regime. First, the FDA permits physicians to advise their patients to use approved medications for any off-label use that physicians find medically appropriate. Second, the FDA prohibits manufacturers from encouraging doctors to engage in such off-label prescriptions and advice. This regulatory regime—which allows doctors to recommend that patients use Xyrem for off-label uses but prohibits manufacturers from encouraging those recommendations—cannot survive First Amendment scrutiny.

## **ARGUMENT**

### **I. CARONIA’S CONVICTION IS BASED ON A SPEECH BAN UNSUPPORTED BY ANY SUFFICIENT INTEREST.**

The jury charge here required the jury to convict Caronia of conspiring with Dr. Peter Gleason to illegally “misbrand” Xyrem, a prescription drug, based on nothing more than Dr. Gleason’s promotion of Xyrem’s off-label uses. Specifically, Dr. Gleason was criminally prohibited from suggesting that physicians recommend that patients use Xyrem for “excessive daytime sleepiness” or any condition other than cataplexy, the approved use. But it was perfectly permissible for Dr. Gleason to make such suggestions, as he did, prior to being paid by the manufacturer, or for anyone else besides the manufacturer’s agents to engage in precisely that speech, in medical journals or elsewhere. Indeed, it was permissible for Dr. Gleason to engage in precisely such speech after he became the manufacturer’s “agent” if it was said “in response to unsolicited requests for

scientific information from healthcare professionals.” FDA, *Request for Comments about the Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices*, 59 Fed. Reg. 59820, 59823 (Nov. 18, 1994). It was also permissible for all doctors to recommend that patients use Xyrem for excessive daytime sleepiness and for Dr. Gleason to make such recommendations to his patients.

In short, although the Government allows doctors to advise patients to use Xyrem for excessive daytime sleepiness (or to prescribe it for that condition), it seeks to criminalize speech encouraging doctors to engage in such advice (or conduct) if, and only if, the speech is done by an agent of Xyrem’s manufacturer. Needless to say, “decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment.” *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 194 (1999) (“*GNOBA*”). This is so for two obvious reasons.

First, if the Government has not prohibited speech in some circumstances, this is nearly dispositive evidence that the speech is not harmful, or at least not sufficiently harmful to justify government regulation. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488-89 (1995); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 426-28 (1993). Second, allowing speech by certain speakers but not others constitutes forbidden speaker-based discrimination. *See Citizens United v.*

*FEC*, 130 S. Ct. 876, 898-99 (2010) (The First Amendment “[p]rohibit[s] . . . restrictions distinguishing among different speakers, allowing speech by some but not others.”); *First Nat. Bank of Boston v. Bellotti*, 435 U.S. 765, 784 (1978) (“In the realm of protected speech, the legislature is constitutionally disqualified from dictating the subjects about which persons may speak and the speakers who may address a public issue.”). Where, as here, the Government’s commercial-speech regulatory regime authorizes Speaker A to say “X,” it is virtually impossible to prove that it has a substantial interest in precluding Speaker B from engaging in the same speech.

Moreover, the regime here is particularly indefensible because, bizarrely, the Government allows physicians to tell unsophisticated patients that they should use Xyrem for “excessive daytime sleepiness,” but does not allow Dr. Gleason to make the same suggestion to the sophisticated medical professionals doing the prescribing. As the district court correctly found, physicians “are familiar with the FDA-approval process and able to independently evaluate the validity of [manufacturer] claims.” *Caronia*, 576 F. Supp. 2d at 397 (internal quotation marks omitted). Yet the Government perversely shields the sophisticated medical community from speech recommending Xyrem’s efficacy for off-label uses, but provides no similar paternalistic protection to the unsophisticated patients when their physicians make such recommendations.

If the Government’s regulatory regime correctly perceives no cognizable danger in doctors prescribing drugs for unapproved uses—because physicians can be trusted to intelligently fulfill their fiduciary duty to not prescribe dangerous or ineffective drugs—there can be no cognizable evil in providing those physicians with information from the manufacturer concerning those off-label uses. The only consequence of this manufacturer-to-doctor speech ban is that physicians receive less information about the drug’s efficacy for off-label uses. Even assuming the FDA could justify such paternalistic deprivation of truthful information under the First Amendment in any circumstances (*but see supra* at 23-25), the FDA itself recognizes that such information is not harmful because that information is permitted when the physician makes an “unsolicited request” for it.

Finally, since the prohibition here concerns speech between well-informed medical professionals about important scientific information affecting public health, it is at the core of the First Amendment and government restrictions are particularly disfavored. *See Bd. of Trs. of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (“It is equally settled . . . though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.”).

In any event, the conviction here, and the FDA regulations underlying it, manifestly violate the protections afforded even normal, purely commercial

speech. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

## **II. CARONIA'S CONVICTION CANNOT SURVIVE THE FIRST AMENDMENT'S COMMERCIAL-SPEECH TEST.**

Under the *Central Hudson* test, the Government may only proscribe commercial speech in two ways. First, it may prohibit commercial speech that promotes unlawful activity or that inherently misleads its audience. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002). Second, it may regulate such speech if it can prove that it has a substantial interest; that “the [restriction] [on speech] directly advances the governmental interest asserted”; and that the restriction “is not more extensive than is necessary to serve that interest.” *Id.* (internal quotation marks omitted). The FDA’s restrictions here cannot satisfy either standard.

Likely for that reason, the Government argued below that its regulatory regime did not implicate the First Amendment at all. Specifically, it asserted that the regime made certain conduct unlawful and used speech only as evidence of intent to engage in that conduct. (R.53 at 8-9.) But its argument fails. First, *Western States* clarifies that the Government cannot use speech as a proxy for unlawful conduct. Second, even if the Government could validly make its distinction between prohibiting speech and using speech only as evidence of intent

to engage in unlawful conduct, it has not done so here. Rather, the Government targets speech itself.

**A. The Restriction Here Is Not About Unlawful Conduct.**

Under *Central Hudson*, courts “ask as a threshold matter whether the commercial speech concerns unlawful activity . . . .” *W. States*, 535 U.S. at 367. If so, it may be banned. Since prostitution is illegal, for example, an individual “constitutionally [can] be forbidden to publish a want ad . . . soliciting prostitutes.” *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 388 (1973). More relevant here, if the Government prohibits certain drugs, such as marijuana, from being used, it may prohibit speech promoting their use. Moreover, since the Government can directly outlaw speech promoting unlawful activity, it can obviously take the less intrusive step of using the defendant’s speech as evidence of intent to engage in the unlawful conduct. *See Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993).

On the other hand, if the Government does not make the drug unlawful, it cannot ban speech on this basis. Thus, although the Government views cigarettes as addictive drugs analogous to marijuana, *see The Health Consequences of Smoking; Nicotine Addiction; A Report of the Surgeon General* (1988), its decision to not make them illegal means it cannot outlaw their promotion under *Central Hudson*’s threshold test, but must show any speech restrictions are narrowly

tailored to a substantial government interest. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001).

Consequently, the Government's power to prohibit the promotion of unlawful conduct has no relevance here. As the district court correctly found, Dr. Gleason's "promotion of off-label uses" to physicians "does not promote unlawful activity." *Caronia*, 576 F. Supp. 2d at 397. Indeed, the Government itself concedes that "[o]nce a drug or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling." *Good Reprint Practices* § III.

Since there is nothing unlawful about prescribing Xyrem for off-label uses, the speech recommending that physicians engage in that lawful activity is not within *Central Hudson*'s threshold test. "[O]nly at such time as off-label prescriptions are proscribed by law could the FDA legitimately claim that speech [about those prescriptions] addresses 'illegal activities.'" *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). As the Seventh Circuit noted:

If it is lawful to sell a product . . . , the [Supreme] Court held, it must be lawful to inform consumers that the product is available to buy. Consumers themselves must decide what to do; the Constitution forecloses an enforced ignorance based on a paternalistic view that informed consumers will make mistakes.

*United States v. Caputo*, 517 F.3d 935, 938-39 (7th Cir. 2008).

**1. The Government cannot avoid the First Amendment by characterizing its speech ban as a conduct ban.**

The Government argued below that its regulatory scheme made *conduct* unlawful and that it used speech only as *evidence of intent* to engage in that conduct. But that argument is squarely foreclosed by *Western States*. There, Congress chose not to deem “compounded drugs” unapproved and unlawful. (Compounding is the “process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.” *W. States*, 535 U.S. at 360-61.) At the same time, the law stated that a compounded drug would become an *unapproved* “new drug” if a pharmacist “advertise[d] or promote[d]” the drug. *Id.* at 365. Thus, the statute did not directly prohibit advertising; it simply used such speech to determine whether the drug was approved and legal or unapproved and illegal. To defend this scheme, the FDA made a similar argument to the one it made below, namely, that it used speech only as “a fair proxy for *actual or intended*” use of the compounded drug. *Id.* at 371 (emphasis added).

Under the circular theory advanced by the Government below, the use of speech in *Western States* was not a speech ban, because speech is simply used to render conduct (the sale of a drug) unlawful or as evidence to show that the

compounding pharmacist intended to sell a drug that was unapproved. Under this convoluted thesis, the Government can evade the Constitution’s speech protections simply by characterizing the statute as prohibiting the *conduct* of selling “*advertised* compounded drugs,” such that the regulation of advertisements is simply permissible regulation of unlawful conduct or evidence of unlawful intent.

That semantic gamesmanship is so transparently frivolous, however, that, unlike here, the Government in *Western States* did not even “*argue* that the prohibited advertisements would be about unlawful activity . . . .” *Id.* at 368 (emphasis added). Rather, it conceded that its regime restricted speech, *id.* at 366, asserting instead that its speech ban was narrowly tailored to a substantial government interest. And *Western States*’ invalidation of the scheme there as an improper speech restriction establishes that the First Amendment governs laws that use speech as the *determining factor* over whether conduct is unlawful just as fully as a direct prohibition on speech.<sup>2</sup> Using a defendant’s promotion as the *test* for

---

<sup>2</sup> As the Government noted below, the D.C. Circuit has permitted the FDA to look at a manufacturer’s speech to show that it intended to market an *unapproved, illegal* “new drug.” *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004). That is irrelevant here because, as described above, Xyrem is an *approved, legal* drug (indeed, the Government made no claim that Xyrem was an unlawful “new drug” under 21 U.S.C. § 355(a)). And, unlike here and in *Western States*, there was no indication in *Whitaker* that the Government used speech as the determining factor to distinguish lawful from unlawful conduct. In any event, in light of *Western States*’ holding, even if *Whitaker* supported the conduct/intent distinction advocated by the Government, it could not be followed under that binding Supreme Court precedent.

whether a compounded drug is approved or unapproved, or using the defendant's promotion here as the *test* for whether the sale of Xyrem is approved (because the manufacturer intends that it be prescribed for on-label use) or unapproved (because the manufacturer intends that it be prescribed for off-label use), is constitutionally indistinguishable from directly outlawing advertising of compounded drugs or off-label uses.

The contrary theory advanced by the Government below would effectively eviscerate all commercial-speech protections. Unconstitutional commercial speech restrictions would be rendered valid by recharacterizing them in the way the Government seeks to do here. For example, the Government could simply recharacterize a speech ban on the alcohol content of beer, *Rubin*, 514 U.S. at 483, as a ban on the "conduct" of selling "beer displaying alcohol content." It could recharacterize a ban on price advertising for drugs, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976), as a prohibition on the "conduct" of selling "price-advertised drugs." Or it could prohibit the "conduct" of selling condoms if the manufacturer's "intended use" was the prevention of "venereal disease," and then use the manufacturer's promotional pamphlets on venereal disease as *evidence* that the manufacturer intended to sell condoms for this illegal use. *But see Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 75 (1983). And, of course, since the Government cannot transform such

speech regulation into “unlawful conduct” regulation, it cannot use speech as evidence of intent to engage in that “unlawful conduct.”

## **2. The Government here penalized speech.**

Even if there were a cognizable distinction between banning speech and using it as the touchstone for illegal conduct, this would not help the Government here because Caronia’s conviction was directly based on engaging in certain speech. The Government advocated, and the district court accepted, using speech as the basis for the criminal conviction. As described above, the Government’s interpretation of the Act has transformed the “adequate directions for use” requirement into a pure speech ban. It considers a drug to be “misbranded as a matter of law if it is promoted by the manufacturer for an off-label use,” regardless of whether the “directions” are just as “adequate” for the off-label uses.<sup>3</sup>

*Friedman*, 13 F. Supp. 2d at 66. In short, promotion equals misbranding.

Here, the United States told the jury that the illegal “act of misbranding of a drug . . . occurs when [Caronia] marketed and promoted Xyrem for [unapproved]

---

<sup>3</sup> See FDA, *Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools*, 74 Fed. Reg. 48083, 48087 (Sept. 21, 2009) (“Under the act, companies are prohibited from promoting approved . . . drugs . . . for unapproved uses.”); 62 Fed. Reg. at 64081 (The FDA “has consistently prohibited the promotion of . . . unapproved uses of approved products.”); 37 Fed. Reg. at 16504 (“[W]here a manufacturer or his representative . . . does anything that directly or indirectly suggests to the physician . . . that an approved drug may properly be used for unapproved uses, that action [*i.e.*, expression] constitutes a direct violation of the Act and is punishable accordingly.”).

uses.” Trial Tr. 43. Accordingly, when defining “misbranding” for the jury, the court explained that “[t]he manufacturer, its agents, representatives and employees, [were] not permitted to *promote* uses for a drug that have not been cleared by the [FDA].” *Id.* at 921 (emphasis added). There was no evidence that the directions on Xyrem’s label were inadequate when used for “excessive daytime sleepiness” or other off-label uses. The jury thus had to find that the off-label “promotion of the drug” itself violated the misbranding statute. *Id.* at 920.

Thus, even assuming the distinction were ever relevant in this context, the Government cannot rely on the principle that “[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.” *Mitchell*, 508 U.S. at 489. *Mitchell* obviously cannot apply where, as here, speech is not simply *evidence* of the crime, but the crime *itself*.

**B. The Banned Speech Is Not Misleading.**

For the reasons already described, it is clear that promotion of off-label uses is not “inherently false, disceptive, or misleading” under *Central Hudson*. *Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010). To the contrary, off-label uses are a widely accepted, government-subsidized, and beneficial means of providing safe and effective drugs.

Off-label uses are “generally accepted.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 (2001). “For example, a 2006 study found that more than 20 percent of prescriptions written for 100 of the 500 most commonly used prescription drugs, and 60 prescription drugs chosen by random selection, in the United States were for off-label use.” Government Accountability Office, *FDA’s Oversight of the Promotion of Drugs for Off-Label Uses 2* (July 2008).

Moreover, off-label uses often represent the proper standard of care. *Good Reprint Practices* § III. “Examples of medical conditions whose standard treatments involve or have involved extensive off-label use include cancer, heart and circulatory disease, AIDS, kidney diseases requiring dialysis, osteoporosis, spinal fusion surgery, and various uncommon diseases.” James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 80 (1998).

The FDA itself confirms that public health benefits from the “dissemination of objective, balanced, and accurate information on important unapproved uses of approved products.” FDA, *Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices*, 63 Fed. Reg. 64556, 64579 (Nov. 20, 1998). Indeed, the Government *subsidizes* off-label uses, because the Medicare program and many states routinely require reimbursement for them. *See*

42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6); Ala. Code § 27-1-10.1(a), (c); N.J. Stat. Ann. § 26:1A-36.9(c).

1. Since the Government permits physicians to recommend that patients use drugs for off-label purposes, it cannot possibly show that such information is misleading, or that its speech ban furthers any substantial interest related to protecting consumers from unsafe or ineffective drugs. The Supreme Court has repeatedly made clear that barring speech only in certain contexts or by certain speakers fatally undermines any assertion that the speech is harmful or that restricting the speech is reasonably tailored to a substantial government interest. Such “exceptions and inconsistencies,” *Rubin*, 514 U.S. at 489, show that the Government does not view the speech as harmful, that the regulation is not narrowly tailored to resolve the alleged problem, and that the regulation is unlikely to “cure” the problem because the harmful message may be delivered through other means. *See GNOBA*, 527 U.S. at 195; *Rubin*, 514 U.S. at 476; *Discovery Network*, 507 U.S. at 424 (while *complete ban* on newsracks might be justified as furthering safety and aesthetic concerns, *exemption* for noncommercial newspapers made it an impermissible “selective ban” on commercial publications); *Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85, 93-94 (1977) (ordinance banning “for sale” signs is not “genuinely concerned” with “manner of the speech,” because “township has not prohibited all lawn signs . . . in order to

promote aesthetic values”). Indeed, the Supreme Court has frequently emphasized that the prohibition against such *inconsistent* commercial-speech regulation is “critical.” *GNOBA*, 527 U.S. at 188.

Thus, in *Rubin*, the Court found that the prohibition on disclosing the alcohol content of beer on *labels* could not “materially advance” the concededly substantial interest in “preventing brewers from competing on the basis of alcohol strength” because the Government did not completely ban such disclosures in *advertising* (but allowed it if state law so required). 514 U.S. at 488. Similarly, a ban on casino advertising was invalid because certain speakers—casinos on Indian lands—were allowed to so advertise and “selecting among speakers conveying virtually identical messages” was impermissible “in commercial speech cases.” *GNOBA*, 527 U.S. at 194. Accordingly, even if federal schemes create exceptions because they do not want to inject themselves into the regulatory ambit of separate sovereigns—the states in *Rubin* and the Indian reservations in *GNOBA*—allowing exemptions for certain media or by certain speakers invalidates the ban.

The FDA’s off-label speech restriction suffers from both flaws. The FDA’s speech regime permits speech encouraging off-label uses in certain contexts (doctors speaking to patients) but not others (manufacturers speaking to doctors), which is at least as indefensible as banning alcohol content information on labels but allowing it in advertising. *Rubin*, 514 U.S. at 488. Even more problematically,

it discriminates among speakers by prohibiting manufacturers from engaging in unsolicited speech about off-label uses, while allowing all others to do so. *See Friedman*, 13 F. Supp. 2d at 67 (“The FDA has a categorically different view on whether [speech about off-label uses is] ‘inherently misleading’ when anyone other than the drug manufacturers is responsible for [it].”) Such speaker-based discrimination is precisely what invalidated the restriction in *GNOBA* and, as a general matter, is at odds with important First Amendment principles. *See Citizens United*, 130 S. Ct. at 898-99.

Moreover, the FDA’s selective speech restrictions are irrational. First, it makes no sense to allow physicians, but not manufacturers, to encourage off-label uses because manufacturers have far more information about a drug’s efficacy than practicing doctors. Obviously, “manufacturers have superior access to information about their drugs,” *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009), as their “[s]cientific departments . . . generally maintain a large body of information on [them].” 59 Fed. Reg. at 59823. Accordingly, manufacturers “happen to be in the best position to share information with the physician community at the earliest possible time, when it may really make a difference in treatment options.” *More Information for Better Patient Care: Hearing of the Senate Comm. on Labor and Human Resources*, 104th Cong. 81 (1996) (statement of Dr. Gregory H. Reaman, Director, Medical Specialty Services, Children’s National Medical Center).

Second, as noted, since the manufacturers' intended audience is sophisticated medical practitioners, while physicians are speaking to uninformed patients, it makes no sense to ban the former speech but not the latter.

Moreover, contrary to the Government's belief, manufacturers cannot be singled out for this discriminatory speech restriction simply because they hope to profit from the speech, any more than the pharmacists' advertising could be restricted in *Western States* simply because they profited from providing compounded drugs. It is black-letter law that the First Amendment protects paid speech to the same extent as unpaid speech. *See Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989) ("Some of our most valued forms of fully protected speech are uttered for a profit."); *Va. Citizens*, 425 U.S. 761 ("[S]peech does not lose its First Amendment protection because money is spent to project it, as a paid advertisement of one form or another" or because it "is 'sold' for profit.").

2. Moreover, there is *no* evidence in *this* case that the speech about Xyrem was misleading either because it was ineffective for the promoted off-label uses or because the "directions" for the approved use were somehow "inadequate" for the off-label uses. To the contrary, the FDA *approved* Xyrem for one of those off-label uses—excessive daytime sleepiness—within *days* of Gleason's discussions. Trial Tr. 57. Nor did the Government hint that the directions that

were adequate for the approved use were inappropriate for any off-label use. More generally, the Government did not suggest that defendant's claims were "false or misleading in any particular," although the statute prohibits such statements. 21 U.S.C. § 352(a). Indeed, the Government withdrew its original charge that Caronia engaged in fraudulent conduct. *Compare* R.28, Superseding Indictment at 10, *with* R.74, Superseding Information at 4-5.

Instead, the United States argued that Caronia's off-label promotion *automatically* "cross[ed] the line from [the] right way to the wrong way." Trial Tr. 38. Thus, the jury charge never instructed the jury that it had to find any false or misleading statements. *Id.* at 904-928. Nor did the general verdict require such speech. R.103, Jury Verdict at 1-2. The Court must therefore conclude that Caronia was convicted only for truthful, non-misleading speech. *See Griffin v. United States*, 502 U.S. 46, 53 (1991) ("[W]here a provision of the Constitution forbids conviction on a particular ground, the constitutional guarantee is violated by a general verdict that may have rested on that ground.").

**C. The Government's Speech Ban Is Not Narrowly Tailored To Serve Any Substantial Interest.**

Where, as here, commercial speech is not about unlawful activity or inherently misleading, *Alexander*, 598 F.3d at 89, the Government faces a daunting burden in seeking to suppress such speech. Specifically, courts need to evaluate the "entire regulatory scheme" to determine whether the Government has met its

“burden” of proving that the restriction “directly and materially advances” a “substantial” interest and does so in a way that “is not more extensive than necessary to serve that interest.” *GNOBA*, 527 U.S. at 183, 188, 192; *see also W. States*, 535 U.S. at 371 (“[I]f the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”). The Government “must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). This evidentiary burden is not satisfied by “unsupported assertions,” *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation, Bd. of Accountancy*, 512 U.S. 136, 149, (1994), or “anecdotal evidence and educated guesses,” *Rubin*, 514 U.S. at 490.

The Government cannot sustain its burden here. This is because, as the Supreme Court has repeatedly noted, it is difficult to even conceive of any interest in depriving people of truthful speech that is not improperly based on the paternalistic notion—at war with the First Amendment’s protection of the marketplace of ideas—that the Government can suppress speech in order to “protect” the citizenry from too much information. As *Western States* put it, because “bans against truthful, non-misleading commercial speech usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth . . . , 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.” 535 U.S. at 375 (internal quotation marks omitted). Consequently, it will be extraordinarily difficult for the Government to prove or even explain why it is necessary to preclude physicians and patients from receiving truthful, non-misleading information about a legal drug.

Thus far, the Government has not even attempted any such explanation. In the district court, it did not identify any specific interest for its treatment of truthful, off-label promotion as “illegal misbranding.” That fact alone invalidates Caronia’s conviction because the Government must “identify specifically ‘a substantial interest to be achieved.’” *W. States*, 535 U.S. at 374 (quoting *Central Hudson*, 447 U.S. at 564).

Nonetheless, in other cases, the United States has asserted two potential interests: “1) ensuring that physicians receive accurate and unbiased information so that they may make informed prescription choices, and, 2) providing manufacturers with ample incentive to get previously unapproved uses on label.” *Friedman*, 13 F. Supp. 2d at 69.

1. The FDA’s first potential interest—ensuring that physicians receive complete information—is facially inadequate. Again, “[i]f there is one fixed principle in the commercial speech arena, it is that ‘a State’s paternalistic assumption that the public will use truthful, non-misleading information unwisely

cannot justify a decision to suppress it.” *Friedman*, 13 F. Supp. 2d at 69-70 (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996) (plurality opinion)). And this paternalistic assumption is particularly counterintuitive and offensive when applied to *doctors*. As the district court found, physicians “are familiar with the FDA-approval process and able to independently evaluate the validity of [manufacturer] claims”—a finding the Government did not attempt to disprove. *Caronia*, 576 F. Supp. 2d at 397.

Indeed, if the Government believes doctors are incapable of processing information about off-label uses, its regulatory scheme is manifestly irrational. If doctors are unable to intelligently assess information about a drug’s efficacy for unapproved uses, they are plainly incapable of prescribing such uses or advising their patients about them. Since the regulatory regime allows doctors to engage in such recommendations, the Government must believe they are capable of intelligently processing such information. Consequently, the *only* effect of the FDA’s speech ban is to deprive doctors of valuable information they need to make *better* decisions about the drugs they are prescribing.

At an absolute minimum, whatever concerns the Government has about doctors being too gullible to intelligently evaluate manufacturer claims, any such concerns would necessarily be cured by a requirement that the manufacturer make appropriate disclaimers. The Supreme Court has “repeatedly point[ed] to

disclaimers as constitutionally preferable to outright suppression.” *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999) (citing *Peel v. Attorney Registration and Disciplinary Comm’n of Ill.*, 496 U.S. 91, 110 (1990); *In re R.M.J.*, 455 U.S. 191, 206 (1982); *Shapero v. Ky. Bar Ass’n*, 486 U.S. 466, 478 (1988)). Thus, *Pearson* flatly rejected the FDA’s argument that “the commercial speech doctrine does not embody a preference for disclosure over outright suppression.” 164 F.3d at 657. This Court, too, has overturned blanket bans where “[n]othing in the record suggest[ed] that . . . disclaimers would have been ineffective.” *Alexander*, 598 F.3d at 96. Since the Government has not proven that disclaimers could not “cure” its unidentified paternalistic concerns, the FDA’s suppression-first regime violates the First Amendment.

2. The next potential government interest—providing incentives to submit approved drugs to the FDA for new uses—is a legitimate one. But, as in *Western States*, the means of accomplishing that goal—regulating speech—is not narrowly tailored because that interest could be achieved by restricting either conduct or far less speech than the current blanket ban. Specifically, the Government might legitimately be concerned that “[m]anufacturers, knowing that they could promote off-label uses, would have an incentive only to seek FDA approval for uses that would be approved easily” and then promote other potential uses. *United States v. Caputo*, 288 F. Supp. 2d 912, 921 (N.D. Ill. 2003), *aff’d in*

*part, vacated in part* 517 F.3d 935 (7th Cir. 2008). The FDA’s blanket speech ban might well deter such activity, but it does so in a way that is unconstitutionally overbroad because the same interest can be served by “not restricting speech” at all or by “restricting less speech.” *W. States*, 535 U.S. at 371.

In *Western States*, as here, the Government prohibited advertising compounded drugs because such advertising would increase the market for those drugs and thus create a “loophole that would allow unregulated drug manufacturing to occur under the guise of pharmacy compounding.” *Id.* (internal quotation marks omitted). But *Western States* nonetheless rejected this regulatory interest because “[s]everal non-speech-related means of drawing the line between compounding and large-scale manufacturing might be possible.” *Id.* at 372.

Identical analysis applies here. The most obvious conduct restriction would be to just outlaw all off-label uses. If the Government thinks this regulation would be too sweeping because FDA approval delays effective drugs from reaching the market, *that* decision undermines any interest in regulating speech about off-label uses. First, it means that the Government cannot have a substantial interest in subjecting *all* off-label uses to FDA approval, so its speech restriction on *all* such uses, by definition, is not a “necessary as opposed to merely convenient means of achieving its interest.” *Id.* at 373. Moreover, as noted, if it is optimal to not preclude all off-label uses, restricting speech about those off-label uses is

*counterproductive* for patients because it limits doctors’ access to accurate information about a drug’s efficacy and safety—the worst of all worlds. As in *Western States*, if the Government cannot justify regulating off-label uses, it cannot justify regulating speech about the off-label uses.

Perhaps more important, short of this outright ban on off-label uses, the Government could have chosen countless “non-speech-related means of” providing manufacturers with an incentive to go through the FDA-approval process. *Id.* at 372. To name just a few, the Government could “cap[] the amount” of the drug that a manufacturer could sell for off-label uses. *Id.* Or it could adopt a “limitation on the percentage of [a drug’s] total sales that [off-label uses] may represent.” *Id.* At a minimum, it could narrow the circumstances under which Medicare would provide reimbursement for off-label uses. *See* 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6). And since official drug compendia often identify standard off-label uses well in advance of FDA approval, *see* J.H. Beales III, *New Uses for Old Drugs*, in *Competitive Strategies in the Pharmaceutical Industry* (Robert B. Helms ed., 1996), it could require manufacturers to initiate the approval process once off-label uses have made it into official compendia. Just as in *Western States*, “[t]he Government has not offered any reason why these possibilities, alone or in combination, would be insufficient to prevent [manufacturer opportunism] on such a scale as to undermine the new drug approval process.” 535 U.S. at 373.

In any event, even if the Government had to resort to a speech restriction, its ban does not reasonably fit with its asserted interest. Most notably, the United States broadly criminalizes promotional speech even for off-label uses that are *already* proceeding through the FDA approval process. Here, as noted, Xyrem’s manufacturer had begun to seek approval to use Xyrem for excessive daytime sleepiness and fibromyalgia at the time Gleason mentioned those off-label uses, and shortly thereafter the FDA approved it for the former. *See* Trial Tr. 57, 618.

The FDA ban on speech about uses that are *already* going through the approval process is obviously overbroad and gratuitous, because there is no need to give the manufacturer an “incentive” to do what it is already doing. Banning only speech about non-submitted off-label uses is much more “narrowly tailored to achieve the desired objective.” *Fox*, 492 U.S. at 480. Indeed, such a tailored ban would *increase* the incentive to go through the approval process because it would allow a manufacturer to speak about additional uses once they have initiated it. Equally true, the Government could ban only speech about off-label uses that are not well established, using as a guide whether those uses have made it into official drug compendia. *See* 42 U.S.C. § 1396r–8(k)(6).

Finally, again, the Government could require disclaimers that the off-label uses have not been approved by the FDA. If that information inhibits their use, the Government would have accomplished its goal of providing incentives for FDA

approval. In all events, it would provide physicians with information they need to make informed decisions about off-label uses, furthering the purposes of the First Amendment, rather than defeating those purposes through paternalistic suppression. Thus, again, the disclaimer option must be used unless the Government can prove it would be ineffective.

## CONCLUSION

For the foregoing reasons, WLF respectfully requests that this Court overturn Alfred Caronia's conviction as a violation of the First Amendment.

Date: April 22, 2010

Respectfully submitted,

/s/ Michael A. Carvin

Michael A. Carvin

Eric E. Murphy

JONES DAY

51 Louisiana Avenue, N.W.

Washington, D.C. 20001-2113

(202) 879-3939

macarvin@jonesday.com

eemurphy@jonesday.com

Of Counsel:

Daniel J. Popeo

Richard A. Samp

Washington Legal Foundation

2009 Massachusetts Avenue, N.W.

Washington, D.C. 20036

(202) 588-0302

*Attorneys for Amicus Curiae*

*Washington Legal Foundation*

## **CERTIFICATE OF COMPLIANCE**

This brief complies with the type-volume limitation in Federal Rule of Appellate Procedures 29(d) and 32(a)(7)(B)(i). It contains 6,959 words as counted by the word-processing system used to prepare the brief, exclusive of the parts of the brief exempted from the type-volume limitation by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

/s/ Michael A. Carvin

*Attorney for Amicus Curiae  
Washington Legal Foundation*

## CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2010, I filed the foregoing Amicus Brief of Washington Legal Foundation via email and UPS overnight delivery with the Clerk of the United States Court of Appeals for the Second Circuit. I also certify that I served two copies of this Brief via email and UPS overnight delivery on:

Jennifer L. McCann, Esq.  
Law Offices of Thomas F. Liotti  
600 Old Country Rd.  
Garden City, NY 11530

*Counsel for Appellant Alfred Caronia*

Martin E. Coffey, Esq.  
U.S. Attorney's Office  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, NY 11201

*Counsel for Appellee United States*

/s/ Michael A. Carvin

*Attorney for Amicus Curiae  
Washington Legal Foundation*