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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex rel.* FRANK SOLIS, PLAINTIFF, v. MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP., and MERCK & CO., DEFENDANTS.	CASE NO. 2:09-cv-3010-MCE-JFM **PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA'S AMICUS BRIEF** Date: September 18, 2014 Time: 2:00 p.m. Assigned to: Hon. Morrison C. England. Jr. Location: Courtroom 7, 14th Floor

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives. In 2013 alone, PhRMA's members invested an estimated $51.1 billion in efforts to discover and develop new medicines. PhRMA frequently files *amicus curiae* briefs in cases raising matters of significance to its members.

PhRMA has a substantial interest in ensuring that the courts fully protect pharmaceutical manufacturers' First Amendment rights. This case raises serious First Amendment concerns because relator's and the United States' construction of the False Claims Act ("FCA") imposes liability on manufacturers for engaging in truthful speech about "off-label" uses of their drugs, *i.e.*, particular uses of an FDA-approved medication that the FDA has not yet approved. The First Amendment unquestionably protects such truthful and non-misleading speech. *E.g.*, *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011). Physicians may lawfully prescribe FDA-approved drugs to treat any condition or disease, including unapproved uses, based on their independent medical judgment. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *accord* SAC ¶ 38. Indeed, many unapproved uses are integral to the practice of medicine, and reflect the standard of patient care. *E.g.*, Joseph W. Cranston et al., *Report of the Council on Scientific Affairs: Unlabeled Indications of Food and Drug Administration-Approved Drugs*, 32 Drug Info. J. 1049, 1050 (1998). The prevalence of unapproved—but fully legal—uses of many FDA-approved prescription medicines to treat patients makes it critical that healthcare professionals have access to accurate, comprehensive, and current information about such uses.

INTRODUCTION

The False Claims Act imposes liability on those who "knowingly . . . cause[] to be presented, a false or fraudulent claim for payment" to the U.S. Government. 31 U.S.C. § 3729(a)(1)(A). Relator and the United States contend that the FCA is so broad that it imposes treble damages on pharmaceutical manufacturers just for speaking truthfully about unapproved

uses of their FDA-approved drugs. *E.g.*, Opp. 2, 5, 7; SOI 8-9.[1]

Notably, neither relator nor the government alleges that the speech at issue here—relaying reprinted articles about unapproved uses of the drug Integrilin from peer-reviewed journals, and summarizing the results of clinical trials—was false or misleading. Relator and the United States do not even agree on *why* the FCA proscribes this speech, or how this speech somehow causes others to submit false claims. But their interpretations of the FCA share a critical flaw: both threaten core First Amendment rights and should be rejected under principles of constitutional avoidance. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988).

ARGUMENT

I. THIS COURT SHOULD REJECT RELATOR'S AND THE UNITED STATES' INTERPRETATIONS OF THE FCA TO AVOID FIRST AMENDMENT PROBLEMS

A. Relator's Interpretation of the FCA Is Constitutionally Suspect

Relator's primary interpretation of the FCA raises a fundamental constitutional concern. According to relator, a manufacturer's truthful speech about an unapproved use of an FDA-approved drug subjects the manufacturer to FCA liability because a *different* statute, the Federal Food, Drug, and Cosmetics Act ("FDCA"), allegedly makes it categorically "illegal to promote drugs for any uses other than those approved by the FDA." Opp. 7 (citing FDCA "misbranding" provision and related FDA regulations); *accord* SAC ¶ 38. All "[c]laims influenced by" a manufacturer's off-label promotion allegedly are "false because they effectively ask the government to pay for illegal activity." Opp. 5; *see id.* 9-10. According to relator, therefore, manufacturers face FCA liability because their "unlawful" speech taints virtually any ensuing Medicare reimbursement claims for unapproved uses and renders those claims "false." *Id.* at 2, 5.[2]

This Court should reject relator's interpretation, which rests on a constitutionally dubious

[1] "Opp." refers to Relator's Opposition to Defendants' Motion to Dismiss Relator's Second Amended Complaint (Dkt. # 123). "SOI" refers to the United States' Statement of Interest (Dkt. # 120). "MTD Br." refers to Defendants Scherling's and Merck's Memorandum of Points and Authorities to Support Their Motion to Dismiss (Dkt. # 113).

[2] Notably, relator interprets the FDCA to mean that truthful speech about unapproved uses *itself* is illegal, not that such speech is mere evidence of an FDCA violation for misbranding under 21 U.S.C. § 352. *Cf. United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012).

construction of the FDCA that other courts have refused to accept. The FDCA does not prohibit off-label promotion. *See, e.g.*, *Caronia v. United States*, 703 F.3d 149, 160 (2d Cir. 2012). As the Second Circuit explained in *Caronia*, interpreting "the FDCA's misbranding provisions to prohibit manufacturer promotion" of unapproved uses "would unconstitutionally restrict free speech." *Id.* at 168; *accord Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *6 (D.S.C. 2013) (court "cannot" accept claims "premise[d]" on the theory "that off-label promotion is illegal under the FDCA").

These constitutional concerns are well-founded: "Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell*, 131 S. Ct. at 2659. Interpreting the FDCA to punish manufacturers for truthfully speaking about unapproved uses impermissibly restricts speech based on its content and the identity of the speaker, and thus triggers heightened scrutiny. *Caronia*, 703 F.3d at 164-65. The restriction is speaker-based because other individuals and entities—such as insurance companies, other doctors, and the government itself, among others—can and do speak to the same audiences about unapproved uses without running afoul of the law. *Id.* at 165 ("the FDCA permits physicians and academics, for example, to speak about off-label use without consequence"). The restriction thus "has the effect of preventing [pharmaceutical manufacturers]—and only [pharmaceutical manufacturers]—from communicating with physicians in an effective and informative manner." *Id.* (quoting *Sorrell*, 131 S. Ct. at 2663).[3] And the restriction is content-based because it penalizes companies for disseminating information only about unapproved uses.[4]

These First Amendment concerns apply with particular force to the speech that relator targets here. The Complaint alleges that the manufacturer merely distributed reprints of medical studies published in reputable independent journals like *Cardiology*, the *American Heart Journal*, and the *American Journal of Cardiology*, and sent letters accurately relaying summaries of clinical

[3] The United States attempts to limit *Caronia* to criminal cases involving FDCA prosecutions and *Sorrell* to "the standard of review for a particular state statute" in a case involving a different procedural posture. SOI 11-12 & n.2. Even a cursory glance at those opinions, however, reveals that both consider manufacturers' speech about uses of prescription drugs to be speech the First Amendment protects.

[4] Restrictions on speech about unapproved uses do not survive under the commercial-speech rubric either, because "in the fields of medicine and public health . . . information can save lives." *Sorrell*, 131 S. Ct. at 2664; *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371-77 (2002) (invalidating statutory ban on promoting unapproved "compounded" drugs).

trial results about unapproved uses of Integrilin. SAC ¶¶ 49-56; *accord* Opp. 7. Relator does not contend that any of this speech was false at the time; at most, the Complaint asserts that the results of two later studies allegedly were inconsistent with earlier studies the manufacturer distributed. *See* SAC ¶¶ 58-62. Nor is there any question that the authors of the reprints, the studies' investigators, physicians, or anyone other than manufacturers can speak about the reprints and trial results as much as they wish. Indeed, everyone but manufacturers can talk to physicians about prescribing Integrilin for unapproved uses without penalty. *See Caronia*, 703 F.3d at 165. Relator even concedes that the manufacturer can distribute reprints promoting unapproved uses so long as physicians request such information. Opp. 8. Yet under relator's view, manufacturers violate the FDCA—and thus the FCA—by "induc[ing] physicians to ask about off-label uses of Integrilin" and providing accurate information in response. *Id.* at 2.

If that is what the FDCA means, it is hard to imagine a more discriminatory restriction on speech that performs a vital role in the practice of medicine. The government long ago "admit[ted] to the importance of ensuring the availability of [peer-reviewed medical journal articles discussing unapproved uses] to physicians and health care providers making prescription and treatment decisions." *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999), *vacated as moot by* 202 F.3d 331 (D.C. Cir. 2000). And "the fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech." *Sorrell*, 131 S. Ct. at 2670-71 (internal quotation marks omitted).

This Court should thus adopt one of the many plausible interpretations of the FCA and/or the FDCA that would avoid this constitutional problem. This Court could construe the FDCA as prohibiting, at most, only false speech. *See Caronia*, 703 F.3d at 165 n.10. Or this Court could hold that purported violations of the FDCA for promoting an unapproved drug cannot be a predicate for FCA liability, because such FDCA violations are independent of the FCA and cannot render a claim "false." Truthful and non-misleading speech about unapproved uses cannot be a violation of any requirement that is a condition of payment under any federal healthcare program.

B. The Government's Interpretation of the FCA Creates Grave First Amendment Problems

The United States puts a different spin on when a manufacturer's truthful speech about unapproved uses of FDA-approved drugs may trigger FCA liability, but the government's interpretation fares no better under the First Amendment. In the government's view, manufacturers' truthful speech to physicians about unapproved uses will often make manufacturers liable for "knowingly . . . caus[ing]" a false claim "to be presented" for reimbursement under 31 U.S.C. § 3729(a)(1)(A). So long as it is "reasonably foreseeable that [manufacturers'] conduct or statements would influence the submission of [] false claims" for reimbursement, manufacturers may be liable for inciting such unlawful conduct. SOI 9. And, according to the government, manufacturers invariably play a foreseeable role in prompting the submission of "false" claims because "the very reason a pharmaceutical company employs sales representatives is in the hope of influencing prescriber behavior." *Id.* at 8. The government does not (and cannot) contest that it is lawful and indeed routine for physicians to prescribe FDA-approved drugs for unapproved uses. Rather, the government suggests that manufacturers are prompting the submission of reimbursement claims that are "false" because the claims are "ineligible for payment in light of applicable law." *Id.* at 9.

Numerous Supreme Court decisions underscore the severe First Amendment consequences of applying the government's interpretation of FCA causation to penalize manufacturers for their speech, and support the direct causation requirement for which defendants advocate. MTD Br. 12-15. "The mere tendency of speech to encourage unlawful acts is not a sufficient reason for banning it." *Ashcroft v. Free Speech Coalition*, 535 U.S. 234, 253 (2002). Even advocacy of unlawful conduct—as opposed to mere "influence," SOI 9—ordinarily cannot be punished.

Thus, "[t]he government may suppress speech for advocating . . . a violation of law *only if* such advocacy is directed to inciting or producing imminent lawless action and is likely to incite or produce such action." *Free Speech Coalition*, 535 U.S. at 253 (internal quotation marks omitted) (emphasis added). A direct causal nexus between the speech at issue and the unlawful conduct is required; a "remote connection between speech that might encourage thoughts or

impulses" and unlawful conduct is not enough. *Id.* "Without a significantly stronger, more direct connection, the Government may not prohibit speech on the ground that it may encourage [others] to engage in illegal conduct." *Id.* at 253-54; *see also Hess v. Indiana*, 414 U.S. 105, 108-09 (1973) (per curiam); *Brandenburg v. Ohio*, 395 U.S. 444, 447-48 (1969) (per curiam). In other words, longstanding First Amendment precedent seriously calls the government's interpretation of the FCA into question: "to prevent the punishment . . . of entirely innocent, lawfully useful speech, *the First Amendment may . . . bar [] the imposition of liability on the basis of mere foreseeability or knowledge* that the information one imparts could be misused for an impermissible purpose." *Rice v. Paladin Enters., Inc.*, 128 F.3d 233, 247 (4th Cir. 1997) (emphasis added).

The government's reading of the FCA, as applied to manufacturers' truthful speech, raises particular constitutional concerns under the facts pled here. The manufacturer's speech as set out in the Complaint falls far short of expressly advocating the submission of false claims. Nor did the manufacturer engage in speech that would prompt others to submit false claims. The manufacturer did not tell physicians that prescriptions for the unapproved use at issue were reimbursable under Medicare or other federal programs. Nor did the manufacturer urge physicians to seek reimbursement for ineligible prescriptions. Quite the contrary: the manufacturer accurately disclosed that the unapproved use was *not* FDA-approved. *E.g.*, SAC Exs. 4, 5. All the manufacturer here allegedly did was circulate reprints of peer-reviewed journal articles and relay accurate summaries of clinical tests.

Physicians who received the reprints or other information from the manufacturer in this case received precisely the type of educational information that a trained physician would wish to receive about his patients. Physicians were not only free to disregard these reprints; their Hippocratic Oath obligated them to use their own, independent medical judgment as to whether a given prescription was warranted. And after those physicians prescribed the FDA-approved drug for an unapproved use, hospitals then made additional, independent determinations whether the prescriptions were reimbursable. Only after that did hospitals submit claims to the government. In sum, the remote and highly attenuated link between the manufacturer's truthful speech and the hospital's ultimate decision to submit a reimbursement claim make this the quintessential case

where imposing liability would raise serious First Amendment issues.

The United States points to various cases suggesting that causation under the FCA reflects common-law tort concepts of foreseeability. SOI 8-9, 11. But none of those cases involves an attempt to impose FCA liability based on truthful speech that purportedly prompted a false claim. Those cases have no bearing on the First Amendment problems that arise in this particular case.

The government remarkably contends that "[t]he First Amendment Is Not Implicated Here And Poses No Limitation On Off-Label Marketing Claims Under the FCA" because "off-label promotion by a pharmaceutical company can be *evidence* of that defendant's having caused physicians to submit false claims." SOI 11. But that contention flies in the face of the government's contention earlier in its brief that manufacturers are liable when it is "reasonably foreseeable" that their "*statements* would influence the submission of [] false claims." *Id.* at 9 (emphasis added). Tellingly, the United States does not—and cannot—point to any act (other than truthful speech) by the manufacturer that allegedly "caused physicians to submit false claims." The *only* basis for liability identified in the Complaint is the manufacturer's speech itself—as relator repeatedly acknowledges. *E.g.*, Opp. 2, 5, 7. That should foreclose the United States' ill-conceived effort to recast this case. *See Caronia*, 703 F.3d at 161 (rejecting similar effort by the government to distinguish between using speech as "evidence" of unlawful activity and punishing the speech itself).

In all events, the cases the government cites (SOI 11) for the proposition that the First Amendment allows the use of speech as "evidence" of wrongdoing are inapposite. The underlying wrongdoing at issue in those cases involves something *other than* speech. *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), used the defendant's speech as evidence that racial animus motivated the defendant's violent assault on the victim and warranted an enhanced sentence for hate crimes. *Id.* at 489. *Whittaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), similarly used the petitioner's speech as evidence of the petitioner's intent to unlawfully introduce a new drug into interstate commerce without FDA approval. *Id.* at 952-53. *Mitchell* and *Whittaker* thus used an actor's speech as evidence that the actor engaged in *other* unlawful conduct. But here, the only conduct relator and the government seek to penalize is the manufacturer's speech itself.

CONCLUSION

For the reasons set forth above and in defendants' brief, this Court should dismiss relator's complaint with prejudice.

Dated: August 15, 2014

Respectfully submitted,

By _/s/ David J. Weiner_____

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