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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 **PHRMA'S RESPONSE TO THE UNITED STATES' OPPOSITION TO PHRMA'S AMICUS BRIEF** Date: October 16, 2014 Time: 2:00 p.m. Assigned to: Hon. Morrison C. England. Jr. Location: Courtroom 7, 14th Floor

Because the government grossly misstates PhRMA's argument, it is indeed "important to make clear precisely what PhRMA . . . contends that the First Amendment provides." USG Opp. 2. PhRMA's position is that for a party's speech to "knowingly caus[e]" someone else to submit a false claim under the False Claims Act (FCA), the First Amendment demands a *direct causal nexus* between the speech and the claim. PhRMA Br. 5-6. That nexus is absent here. The speech at issue does not urge or instruct others to submit false claims. All the manufacturer did was share with doctors copies of medical articles published in leading peer-reviewed journals discussing an unapproved use of an FDA-approved drug. It is undisputed that this speech is *truthful*. Such speech may educate doctors, who may exercise their medical judgment and prescribe FDA-approved drugs for unapproved uses to treat patients. But such physician conduct is not just lawful. It is so central to the practice of modern medicine that doctors may thwart the standard of care if they do *not* prescribe FDA-approved drugs for unapproved uses that would be appropriate for the patient. *Id.* at 1. This Court should thus hold that manufacturers cannot face FCA liability for sharing truthful information with doctors about unapproved uses of FDA-approved drugs.[1]

Rather than respond to this argument, the government attacks a straw man: it accuses PhRMA of advocating a First Amendment right to shield *all* speech from sanction, no matter how closely connected to unlawful conduct. USG Opp. 2-3. But there is an obvious distinction between speech (even truthful speech) that incites illicit conduct—which is unprotected—and speech that encourages lawful conduct in the form of medically appropriate treatment—which the First Amendment plainly protects. The government's interpretation of the FCA runs roughshod over this difference, and is at least as radical as the position the government invents for PhRMA.

The dangers of the government's position bear repeating. The government states that speech may expose a party to treble damages for "knowingly caus[ing]" the submission of a false claim if it is "reasonably foreseeable that the . . . statements would influence" the submission of a claim that is not "eligible for payment in light of applicable law." SOI 9; *accord* USG Opp. 2. Taken to its logical conclusion, the government's interpretation has no rational stopping point.

[1] "USG Opp." is the United States' Statement of Interest in Opposition to PhRMA's *Amicus* Brief (Dkt. # 141). "PhRMA Br." is PhRMA's *Amicus* Brief (Dkt # 137). "SOI" is the United States' Statement of Interest (Dkt. # 120).

FCA liability would attach to *any* speech to doctors about any unapproved use of any FDA-approved medicine. Fellow doctors, patient advocacy groups, insurance companies, and the medical journals themselves all foreseeably distribute the same information to doctors as manufacturers do. They all would be just as liable for inciting false claims under the government's stated theory. Because the government's interpretation punishes truthful speech that underpins modern medicine and helps save lives, this Court should resoundingly reject it.

1. Far from "never be[ing] endorsed by any court," USG Opp. 2, PhRMA's position finds substantial support in Supreme Court cases (albeit ones the government ignores). The Supreme Court has held that if the government wants to punish speech due to its purported link to unlawful conduct, there must be a *direct connection* between the speech and conduct. PhRMA Br. 5-6 (citing cases). Mere "reasonabl[e] foreseeability" that speech might "influence" unlawful conduct is insufficient. That is why the government cannot bar speech advocating unlawfulness in the abstract. *Brandenburg v. Ohio*, 395 U.S. 444, 447-48 (1969) (per curiam). Likewise, speech that has some "tendency . . . to encourage unlawful acts," or that "increases the chance an unlawful act will be committed at some indefinite future time," cannot be proscribed. *Ashcroft v. Free Speech Coalition*, 535 U.S. 234, 253 (2002) (quotation omitted). Such speech expresses discrete ideas that warrant First Amendment protection even if the speech indirectly encourages unlawful conduct. *See Rice v. Paladin Enters., Inc.*, 128 F.3d 233, 243 (4th Cir. 1997).

Requiring a close causal connection between speech and unlawful conduct does not immunize speech that incites or aids crimes, which is the epitome of speech intimately tied to unlawful conduct. *Cf.* USG Opp. 3-4. Speech aiding and abetting a crime is an instrument of the crime: it actively "assist[s] the perpetrators." *United States v. Barnett*, 667 F.2d 835, 841 (9th Cir. 1982) (quotations omitted). An agreement among conspirators is "an invitation to engage in an illegal exchange." *Brown v. Hartlage*, 456 U.S. 45, 55 (1982). And conveying facts about how to make an illegal drug or how to commit murder for hire is "instrumental in and intertwined with the performance of criminal activity." *Rice*, 128 F.3d at 245 (quotations omitted). As the government previously represented, "'[C]ulpability in such cases is premised, not on defendants' 'advocacy' of criminal conduct, but on [their] successful efforts to assist others by detailing to them the means of

accomplishing the crimes.'" *Id.* at 246 (quoting DOJ report).

This case vividly demonstrates the perils of allowing the government to trample the bright constitutional line between speech that directly incites unlawful conduct and speech that does not. The government disturbingly sees a "precise[] analog[ue]" between the "dissemination of printed materials that incite crimes" and "civil liability for causing another party to submit false claims . . . via the dissemination of printed materials." USG Opp. 4-5 (quotation omitted). Disseminating instructions on how to commit tax evasion induces others to *break the law*. *United States v. Hempfling*, 431 F. Supp. 2d 1069, 1074 (E.D. Cal. 2006). But disseminating medical journal articles about clinical trial results at most may encourage others to engage in conduct that is *lawful*—and beneficial to public health and patient care. If doctors decide, based on their medical judgment, to prescribe drugs for unapproved uses, that is legal and what doctors *should* do under their Hippocratic Oaths. To be sure, hospitals may submit reimbursement claims for those prescriptions, which the government may deem ineligible for reimbursement and thus "false." USG Opp. 2; SOI 9. But hospitals are not getting instruction in how to submit "false" claims from articles about clinical trials that hospitals never received, let alone received from manufacturers.

The government's interpretation is boundless and would open the floodgates to FCA liability for virtually anyone in the medical field. Physicians receive reprints of peer-reviewed medical journal articles about unapproved uses of FDA-approved drugs from any number of sources, any of whom would be similarly liable under the government's theory of FCA liability. The journals themselves disseminate these articles to subscribers, many of whom are physicians. Physicians share articles with each other. Patient advocacy groups and insurance companies also often distribute medical journal reprints to treating physicians. Under the government's unbounded theory, the FCA would be transformed into a mechanism for regulating and punishing truthful speech about scientific developments emanating from any of these sources. That result obviously raises serious constitutional problems, especially since there are less intrusive ways to prohibit false claims. Requiring a direct causal nexus between speech and a false claim still serves the government's interest in punishing those who induce others to submit false claims. And "if the Government could achieve its interests in a manner that . . . restricts less speech, the Government

1 must do so." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002).[2]

2 2. The government argues that, under *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), speech 3 may be evidence of the defendant's wrongful intent. USG Opp. 2. That is true but irrelevant. 4 *Mitchell* establishes that speech may be evidence of intent *if the defendant committed unlawful* 5 *conduct* and the speech directly bears on the defendant's motive. The government denies that 6 *Mitchell* distinguished between punishing speech versus conduct. *Id.* at 2 n.2. But *Mitchell* could 7 not be clearer. The defendant was prosecuted for "criminal conduct"—assault. 508 U.S. at 485. 8 The Supreme Court upheld a statute that used the defendant's speech just before the assault 9 ("There goes a white boy; go get him") to "enhance[] the maximum penalty for conduct motivated 10 by a discriminatory point of view." *Id.* at 480-86. The Court reasoned that the state was not just 11 punishing speech; it was punishing the defendant for committing a hate crime, and his speech 12 showed racial animus. *Id.* at 484-87. Because the statute "aimed at conduct unprotected by the 13 First Amendment," it was constitutional—unlike "the ordinance struck down in *R.A.V.* [*v. St.* 14 *Paul*]," which "was explicitly directed at expression" and thus unconstitutional. *Id.* at 487.

15 *Mitchell* is no help to the government here, because the government is not using 16 manufacturers' speech as evidence of any unlawful conduct by manufacturers. Defendants never 17 submitted any false claims themselves, or committed any other crime. The government accuses 18 defendants of *causing others* to submit false claims, but the means by which manufacturers 19 purportedly did so is by speaking—as the government's allegations confirm. The government 20 seeks to impose "civil liability for causing another party to submit false claims for payment—*via* 21 *the dissemination of printed materials*." USG Opp. 5 (emphasis added). The government asserts 22 that "*speech* that serves as a conduit for violations of the law is not constitutionally protected." *Id.* 23 (emphasis added). The government targets "statements" that "would influence the submission of 24 [] false claims." SOI 9. And defendants' speech is the only basis for liability that relator's 25 Complaint identifies. PhRMA Br. 7. That distinguishes this case from *Mitchell*, and makes this

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27 [2] The government reiterates that *Sorrell* and *Caronia* did not involve the FCA. USG Opp. 3. That does not change those cases' core holding that the First Amendment protects manufacturers' speech about unapproved uses of FDA-approved drugs. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011); *Caronia v. United States*, 703 F.3d 149, 28 163 (2d Cir. 2012). Nor does that holding depend on which statute the government invokes to try to limit this speech.

case no different from others where the government unconstitutionally punished speech that had no direct link to someone else's unlawful conduct. The Second Circuit condemned the government's last attempt to dodge First Amendment problems by denying that it was targeting speech. *Caronia*, 703 F.3d at 161. Because "the record ma[de] clear that the government prosecuted [defendant] *for* his [speech]," the government was not using "speech as evidence of intent." *Id.* The government's identical ploy should fare no better here.

* * *

PhRMA respectfully asks this Court to reject the government's interpretation. This Court should hold that manufacturers who communicate truthfully to doctors about unapproved uses of FDA-approved drugs, when doctors may legally prescribe such drugs, cannot be liable under the FCA because this speech does not *directly* cause the submission of any false claim. This Court also should reject relator's interpretation, which equally offends the First Amendment. Relator asserts that the Food, Drug, and Cosmetic Act (FDCA) categorically prohibits manufacturers' speech about unapproved uses of FDA-approved drugs. Even the government rejects that theory: "[O]ff-label promotion by a manufacturer is not by itself a violation of federal law." USG Opp. 2.

Dated: September 9, 2014

Respectfully submitted,

By __/s/ David J. Weiner______________

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