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UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and the STATES OF ARKANSAS, CALIFORNIA, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN ex rel. FRANK SOLIS, Plaintiffs, vs. MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP., Defendants.	2:09 - CV - 3010 MCE JFM UNITED STATES' STATEMENT OF INTEREST IN OPPOSITION TO *AMICUS CURIAE* BRIEF SUBMITTED BY PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA

The United States respectfully appreciates the opportunity to submit this response to the *amicus curiae* brief filed by the Pharmaceutical Research & Manufacturers of America (PhRMA).

It is important to make clear precisely what PhRMA, like the defendants in this case, contends that the First Amendment provides: a constitutional right to knowingly cause other parties to submit false claims to the government, as long as a party does so by its speech. This radical position has never been endorsed by any court and is not supported by any precedent.

Nothing in PhRMA's brief establishes any violation of the First Amendment. As the United States made clear in its previous statement of interest, the False Claims Act (FCA) does not impose liability for speech, in and of itself. Thus, off-label promotion by a manufacturer is not by itself a violation of federal law. The promotion of an approved drug for an unapproved use, without more, does not violate the False Claims Act, nor is it among the comprehensive list of prohibited acts in the Food, Drug, and Cosmetics Act (FDCA). *See* 21 U.S.C. § 331. Essentially, the FDCA prohibits misbranding of a drug, 21 U.S.C. § 331(a-c), and the FCA imposes liability for knowingly submitting false claims for payment, or causing others to do so.[1]/ 31 U.S.C. § 3729(a)(1)(A). As to the FCA, off-label promotional activity can be evidence of how a defendant caused the submission of false claims or its scienter. Using evidence of off-label marketing in this way does not run afoul of the First Amendment. *See Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993).[2]/ In other words, promotional speech may be used as evidence to prove that a manufacturer knowingly caused the drug to be put to a certain use and billed to a Government health care program for such use, under circumstances in which the use is not covered and the claim is not eligible for reimbursement.

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[1] Indeed, liability under § 3729(a)(1)(A) does not require proof of a false statement at all.

[2] PhRMA attempts to distinguish *Mitchell* by arguing that "the underlying wrongdoing ... involves something other than speech." PhRMA Br. at 7 (emphasis omitted). *Mitchell* itself, however, makes no such distinction.

Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011), cited by PhRMA, is not to the contrary. That case involved a state statute that directly prohibited certain forms of drug marketing, which the FCA does not do. Nothing in *Sorrell* restricts the ability of the government to seek redress for the submission of false claims for payment, or causing others to do so. Similarly, nothing in *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012), bars an FCA action of this sort. The Court in *Caronia* overturned a criminal conviction under the FDCA on the grounds that mistakes in the jury instructions led to the defendant improperly being convicted solely on the basis of his speech (in the form of marketing activities). Despite PhRMA's erroneous attempt in its brief to conflate the standards for criminal liability in *Caronia* and for civil liability under the FCA, the fact is that submission of false claims for payment (or causing others to do so) was simply not an element of the crime or otherwise at issue in *Caronia*. Far from prohibiting the use of speech as evidence of intent to influence the submission of false claims, *Caronia* explicitly permits it, stating that "we assume, without deciding, that such use of evidence of speech is permissible." *Id.* at 162 n.9.

PhRMA tries to get around this distinction by equating the causation of the submission of false claims with simple speech. If a course of conduct were constitutionally protected as long as it was effectuated through the use of speech, vast areas of federal and state law would be invalidated. For example, the Sherman Act's basic criminal prohibition against "contact[]s, combination[s] ..., and conspirac[ies] in restraint of trade" (15 U.S.C. § 1) would become largely uneforceable, because anti-competitive agreements are normally carried out through and embodied in speech among the participants. Similarly, criminal conspiracy law would fall by the wayside, if statements by two parties agreeing to a criminal course of action were to be treated as protected speech. PhRMA attempts to reduce the impact of its overbroad approach to First Amendment protection by suggesting that this Court could apply it only to "truthful" speech, but these examples show that that limitation would do nothing to cabin the problems inherent in PhRMA's extreme view of the law, since the types of statements that underlie anti-competitive agreements and criminal conspiracies may all be perfectly truthful.

This of course is not the law; no court has interpreted the First Amendment as broadly as PhRMA suggests. The Ninth Circuit, for instance, has expressly ruled that there is no First Amendment right to disseminate truthful information describing how to manufacture illegal drugs:

> Barnett appears to argue as follows:
>
> > 1. The first amendment protects speech including the printed word.
> > 2. Barnett sells printed instructions for the manufacture of phencyclidine.
> > 3. Therefore, the first amendment protects Barnett's sale of printed instructions for the manufacture of phencyclidine.
>
> This specious syllogism finds no support in the law.

United States v. Barnett, 667 F.2d 835, 842 (9th Cir. 1982). Similarly, the Fourth Circuit has held instead that

> speech which, in its effect, is tantamount to legitimately proscribable nonexpressive conduct may itself be legitimately proscribed, punished, or regulated incidentally to the constitutional enforcement of generally applicable statutes.
> ...
>
> Were the First Amendment to bar or to limit government regulation of such 'speech brigaded with action,' the government would be powerless to protect the public from countless of even the most pernicious criminal acts and civil wrongs.

Rice v. Paladin Enterprises, Inc., 128 F.3d 233, 243, 244 (4th Cir. 1997) (citation omitted). The *Rice* court also made clear that its ruling extended in the criminal context to the use of speech in aiding and abetting others in illegal conduct.

> Indeed, every court that has addressed the issue, including this court, has held that the First Amendment does not necessarily pose a bar to liability for aiding and abetting a crime, even when such aiding and abetting takes the form of the spoken or written word.

Id. at 244. A court in this district cited *Barnett* and *Rice* in holding, in a criminal case, that "the First Amendment does not protect those who aid and abet criminal conduct by the dissemination of printed materials that incite crimes." *United States v. Hempfling*, 431 F.Supp.2d 1069, 1083 (E.D.Cal. 2006). This is precisely analogous to civil liability for causing another party to submit

false claims for payment – via the dissemination of printed materials. This court ought to follow this precedent and reject PhRMA's argument, and it should hold that speech that serves as a conduit for violations of the law is not constitutionally protected.

It is of course possible that in individual cases, the allegations as to off-label promotion may not be sufficient to satisfy F.R. Civ. P. 9(b) as to a defendant's scienter or causation. This is a pleading issue, however, not a constitutional deficiency. The Government takes no position on the adequacy of the allegations in this case.

CONCLUSION

As noted above, the United States of America takes no position on the defendants' motions pursuant to F.R.Civ.P. 9(b) or 12(b)(1). If the Court reaches the remaining arguments in the motions to dismiss, the United States respectfully requests that the Court consider its views as to the issues herein.

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Respectfully Submitted,

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