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13 UNITED STATES DISTRICT COURT FOR THE  
14 EASTERN DISTRICT OF CALIFORNIA

15 UNITED STATES OF AMERICA and the )  
16 STATES OF ARKANSAS, CALIFORNIA,) )  
DELAWARE, DISTRICT OF )  
17 COLUMBIA, FLORIDA, GEORGIA, ) )  
HAWAII, ILLINOIS, INDIANA, ) )  
18 LOUISIANA, MASSACHUSETTS, ) )  
MICHIGAN, MONTANA, NEVADA, ) )  
19 NEW HAMPSHIRE, NEW JERSEY, ) )  
NEW MEXICO, NEW YORK, ) )  
20 OKLAHOMA, RHODE ISLAND, ) )  
TENNESSEE, TEXAS, VIRGINIA, and ) )  
21 WISCONSIN ex rel. FRANK SOLIS, ) )

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UNITED STATES' STATEMENT OF  
INTEREST IN OPPOSITION TO *AMICUS*  
*CURIAE* BRIEF SUBMITTED BY  
PHARMACEUTICAL RESEARCH &  
MANUFACTURERS OF AMERICA

22 Plaintiffs, ) )

23 vs. ) )

24 MILLENNIUM ) )  
PHARMACEUTICALS, INC., ) )  
25 SCHERING-PLOUGH CORP., ) )

26 Defendants. ) )  
27 ) )

28 UNITED STATES' STATEMENT OF INTEREST IN OPPOSITION TO *AMICUS CURIAE* BRIEF SUBMITTED BY  
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA

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

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

8 Nothing in PhRMA's brief establishes any violation of the First Amendment. As the  
9 United States made clear in its previous statement of interest, the False Claims Act (FCA) does  
10 not impose liability for speech, in and of itself. Thus, off-label promotion by a manufacturer is  
11 not by itself a violation of federal law. The promotion of an approved drug for an unapproved  
12 use, without more, does not violate the False Claims Act, nor is it among the comprehensive list  
13 of prohibited acts in the Food, Drug, and Cosmetics Act (FDCA). *See* 21 U.S.C. § 331.  
14 Essentially, the FDCA prohibits misbranding of a drug, 21 U.S.C. § 331(a-c), and the FCA  
15 imposes liability for knowingly submitting false claims for payment, or causing others to do so.<sup>1/</sup>  
16 31 U.S.C. § 3729(a)(1)(A). As to the FCA, off-label promotional activity can be evidence of  
17 how a defendant caused the submission of false claims or its scienter. Using evidence of off-  
18 label marketing in this way does not run afoul of the First Amendment. *See Wisconsin v.*  
19 *Mitchell*, 508 U.S. 476, 489 (1993).<sup>2/</sup> In other words, promotional speech may be used as  
20 evidence to prove that a manufacturer knowingly caused the drug to be put to a certain use and  
21 billed to a Government health care program for such use, under circumstances in which the use is  
22 not covered and the claim is not eligible for reimbursement.

23  
24  
25 <sup>1</sup> Indeed, liability under § 3729(a)(1)(A) does not require proof of a false statement at all.

26 <sup>2</sup> PhRMA attempts to distinguish *Mitchell* by arguing that “the underlying wrongdoing ...  
27 involves something other than speech.” PhRMA Br. at 7 (emphasis omitted). *Mitchell* itself,  
28 however, makes no such distinction.

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

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

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

5 Barnett appears to argue as follows:

- 6 1. The first amendment protects speech including the printed word.
- 7 2. Barnett sells printed instructions for the manufacture of phencyclidine.
- 8 3. Therefore, the first amendment protects Barnett's sale of printed instructions for the manufacture of phencyclidine.

9 This specious syllogism finds no support in the law.

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

12 speech which, in its effect, is tantamount to legitimately  
13 proscribable nonexpressive conduct may itself be legitimately  
14 proscribed, punished, or regulated incidentally to the constitutional  
enforcement of generally applicable statutes.

15 ...

16 Were the First Amendment to bar or to limit government  
17 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.

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

21 Indeed, every court that has addressed the issue, including this  
22 court, has held that the First Amendment does not necessarily pose  
23 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.

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

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

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

8 **CONCLUSION**

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

13  
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15 Respectfully Submitted,

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