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UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,  
*ex rel.* FRANK SOLIS,

Plaintiff,

v.

MILLENIU PHARMACEUTICALS,  
INC., SCHERING-PLOUGH CORP.,  
and MERCK & CO.,

Defendants.

No. 2:09-cv-3010-MCE-JFM

**ORDER**

Through the motion presently before this Court, the Pharmaceutical Research & Manufacturers of America (“PhRMA”) seeks leave to file an amicus brief in support of Defendants’ Motions to Dismiss (ECF No. 113, 114, 116). According to PhRMA’s proposed brief, it is a voluntary, nonprofit association representing the nation’s leading research-based pharmaceutical and biotechnology companies.

Plaintiff’s underlying lawsuit, brought pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. § 3729, et seq., alleges that the three named pharmaceutical defendants fraudulently marketed and/or promoted the use of two drugs, Integrilin and Avelox, for so-called “off label” uses not approved by the Food and Drug Administration. Defendants have brought three separate motions attacking the viability

1 of Plaintiff's Second Amended Complaint in accordance with Federal Rule of Civil  
2 Procedure 12(b)(1), 12(b)(6), and 9(b). According to PhRMA, it has a substantial  
3 interest in ensuring that the Court fully protects pharmaceutical manufacturers' First  
4 Amendment Rights in ruling on those motions to dismiss. PhRMA claims the present  
5 case raises serious First Amendment concerns because the construction of the Federal  
6 False Claims Act advanced by Relator and by the United States seeks to impose liability  
7 on manufacturers for engaging in truthful speech about "off-label" uses of their drugs.  
8 PhRMA's proposed amicus brief seeks to address those concerns.

9 Other than alleging that Defendants themselves could have presented the First  
10 Amendment issues advanced by PhRMA themselves, and arguing that the proposed  
11 brief is "nothing more than an unauthorized sur reply" (Opp'n, 2:6-7), neither the United  
12 States nor the Relator (which joined in the Government's opposition), offer much in the  
13 way of any substantive opposition to PhRMA's motion. Defendants themselves have  
14 submitted no opposition.

15 As PhRMA points out, whether to permit an amicus filing rests solely within this  
16 Court's discretion, with "great liberality" typically exercised in permitting amicus curiae  
17 briefing in the context of a pending case. In re Roxford Foods Litig., 790 F. Supp. 987,  
18 997 (E.D. Cal. 1991). Given that liberal standard, and after considering the merits of  
19 PhRMA's position and the government's opposition, the Court exercises its discretion in  
20 favor of permitting the requested amicus filing since it believes that PhRMA's briefing  
21 may aid the proper disposition of this case. PhRMA's Motion for Leave to File Amicus  
22 Brief (ECF No. 130) is accordingly GRANTED. Not later than five (5) days following the  
23 date this Order is electronically filed, PhRMA is ordered to file its proposed amicus brief.  
24 Opposition, if any, to the amicus brief shall be filed not later than August 28, 2014 and  
25 shall not exceed ten (10) pages in length. PhRMA's last day to submit a reply to any  
26 such opposition shall be September 9, 2014. That reply will be limited to five (5) pages.  
27 The hearing on Defendants' Motions to Dismiss (ECF Nos. 113, 114 and 116), as well as  
28 on Defendant Millenium's Motion to Strike (ECF No. 117), shall be continued from

1 August 21, 2014, to September 18, 2014, at 2:00 p.m. to accommodate the above-  
2 referenced amicus briefing.

3 IT IS SO ORDERED.

4 Dated: August 13, 2014

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MORRISON C. ENGLAND, JR., CHIEF JUDGE  
UNITED STATES DISTRICT COURT

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