

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA, <i>ex rel.</i>))	
CHARLES DONIGIAN,))	
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Plaintiff,))	
))	
v.))	Civil Action No. 06-11166-DPW
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ST. JUDE MEDICAL, INC.,))	
))	
Defendant.))	
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**MEMORANDUM IN SUPPORT OF
MOTION OF THE UNITED STATES TO INTERVENE**

The United States moves, pursuant to the False Claims Act, 31 U.S.C. § 3730(c)(3), to intervene for good cause as to certain of the claims in this *qui tam* action against defendant St. Jude Medical, Inc. (“St. Jude”). The relator brought this action on behalf of the government alleging that St. Jude, a manufacturer of pacemakers and other heart devices, used post-market studies and device registries as mechanisms to pay physicians illegal kickbacks for using its products. These payments allegedly caused the submission of false claims in violation of the False Claims Act, 31 U.S.C. §§ 3729-33. Having found good cause to allege that St. Jude caused the submission of false claims by using four post-market programs – the AWARE, ASSIST, and HOUSECALL PLUS studies, and the ACT registry – as kickback vehicles, the United States now seeks to intervene in Count I of the Third Amended Complaint and take over the action as to those four programs. The United States intends to file its own complaint in intervention on or before August 31, 2010.

The relator assents to this motion, and, as further explained below, government intervention at this stage will not prejudice the defendant or this proceeding because the case is

still at an early procedural stage, prior to any hearing or ruling on St. Jude's motion to dismiss the relator's complaint and prior to any discovery.

BACKGROUND

St. Jude has known since October 2005 of the United States' investigation of St. Jude's use of post-market programs to induce physicians to implant St. Jude products. *See* St. Jude Medical, Inc.'s Memorandum of Law in Support of Its Motion to Dismiss at 6 (June 22, 2010, Docket No. 61). The United States has issued multiple document subpoenas to St. Jude. *See* accompanying Declaration of Gregg Shapiro ("Shapiro Dec."), ¶ 2. In response to those subpoenas, St. Jude produced documents over a period of several years, including five separate productions containing thousands of pages of documents in 2010 alone. *See id.*, ¶ 3. The United States and St. Jude also have had numerous meetings to discuss the United States' preliminary findings and St. Jude's responses to those findings. *See id.*, ¶ 4. The most recent of those meetings occurred, at St. Jude's request, on August 6, 2009, and July 22, 2010. *See id.*

On December 22, 2009, the United States filed a notice that its investigation was not complete and that it was not intervening at that time. On January 19, 2010, the Court lifted the seal on the relator's complaint. Since December 2009, the government has completed its investigation by interviewing additional witnesses and reviewing additional documents. *See* Shapiro Dec., ¶ 5. Based on that investigation, the United States has now determined that it has good cause to intervene concerning the four St. Jude post-market programs referenced above.

ARGUMENT

Good cause exists to permit the United States to intervene because the United States now has determined that the facts merit intervention, because the relator, for whom the statutory

“good cause” requirement was created, assents to this motion, and because intervention at this stage will not unduly prejudice St. Jude or this proceeding.

Under the False Claims Act, a private person, known as the relator, may file a civil action on behalf of himself and the United States government. 31 U.S.C. § 3730(b)(1). The complaint must be filed *in camera* and remain under seal for at least 60 days, subject to court-approved extensions. *Id.* § 3730(b)(2), (3). Before the intervention deadline, the government must “proceed with the action, in which case the action shall be conducted by the Government,” or “notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.” *Id.* § 3730(b)(4). In this case, the relator has been conducting the action since January 2010. The False Claim Act further provides, however, that “the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.” *Id.* § 3730(c)(3). The United States now seeks to intervene because it has determined that it would be in the public interest for the government to conduct the litigation brought on its behalf as to St. Jude’s use of the AWARE, ASSIST, and HOUSECALL PLUS studies, and of the ACT registry.

The purpose of the good cause requirement is to “protect the interests of the relator.” *United States ex rel. Stone v. Rockwell Int’l Corp.*, 950 F. Supp. 1046, 1049 (D. Colo. 1996). Under 31 U.S.C. § 3730(d), a relator may be awarded 25-30% of any recovery if the relator proceeds alone, but only 15-25% of the recovery if the government intervenes in the action. Thus, the *Stone* court observed, “[g]overnment intervention late in the proceedings may be unfair to a relator who has expended considerable resources to advance the case and then lose up to half

of the reward for bringing the action.” *Id.* Here, since the relator assents, the purpose of the good cause requirement has been satisfied.

Furthermore, good cause exists where, as here, the reason for the government’s delay is that it was continuing to investigate the relator’s allegations and conducting discussions with the defendant. It would disadvantage relators, defendants, and federal taxpayers if the government rushed to make an intervention decision without an adequate opportunity to engage in discussions with a defendant or to obtain and evaluate substantial evidence. Accordingly, it is not unusual for the government to intervene later, after completing its investigation or in light of additional evidence sufficient to make an informed decision about whether to intervene. *See, e.g., Stone*, 950 F. Supp. at 1048-49 (allowing government to intervene five years after seal was lifted because government had reviewed new evidence, relator assented to government’s motion, and case was “still in a very preliminary stage”); *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 2005 WL 2667207, at *3 (N.D. Ill. Oct. 17, 2005) (allowing government’s motion to intervene more than two years after filing notice of declination, given “new and significant evidence obtained by the relator during discovery,” and given lack of “undue prejudice to the parties or proceeding” caused by late intervention). Here, when the seal was lifted in January 2010, the United States had not completed its investigation of the relator’s allegations. Since then, the government has interviewed additional witnesses and reviewed thousands of pages of newly produced documents. Intervention at this stage, when discovery has not begun and the United States intends to file its complaint in intervention promptly, will not prejudice St. Jude or the proceeding. *See, e.g., United States ex rel. Roberts v. Sunrise Senior Living, Inc.*, 2009 WL 499764, at *1 (D. Ariz. Feb. 26, 2009) (permitting United States to intervene after prior

declination where defendants had not answered relator's complaint and no formal discovery had occurred); *United States ex rel. Hall v. Schwartzmann*, 887 F. Supp. 60, 62 (E.D.N.Y. 1995) (same). Intervention also will serve the public interest in having the United States litigate for itself those claims that it has determined to be meritorious.

CONCLUSION

For the foregoing reasons, the Court should permit the United States to intervene on Count I of the Third Amended Complaint as to the AWARE, ASSIST, and HOUSECALL PLUS studies, and the ACT registry.

Respectfully submitted,

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Dated: August 5, 2010

Certificate of Service

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants, on August 5, 2010.

/s/ Gregg Shapiro
Gregg Shapiro
Assistant U.S. Attorney