



U.S. Department of Justice

*United States Attorney
Southern District of New York*

*86 Chambers Street, Third Floor
New York, New York 10007*

August 22, 2017

BY ECF AND BY HAND

The Honorable Colleen McMahon
Chief United States District Judge
500 Pearl Street, Room 2550
New York, NY 10007

Re: *United States v. US Bioservices Corp.*, 17 Civ. 6353

Dear Judge McMahon:

This Office represents plaintiff the United States (the “Government”) in the above-referenced civil False Claims Act case filed earlier today. This case arises from the involvement of defendant US Bioservices Corp. (“US Bio”) in an arrangement set up by Novartis Pharmaceuticals Corp. (“Novartis”) to allocate Exjade patient referrals based on refill rates.

Here, we respectfully set forth the background information, *see infra* Pt. A, in connection with making two requests on behalf of the Government. *First*, pursuant to Rule 13 of this District’s Rules for Division of Business Among District Judges (the “Related Cases Rule”), we respectfully request that the Court accepts this as a “related case” to *U.S. ex rel. Kester v. Novartis Pharm. Cop.*, 11 Civ. 8196 (CM), which was litigated and resolved before Your Honor. *See infra* Pt. B. *Second*, in the event that the Court accepts this as a “related case,” we respectfully submit – for the Court’s review and approval – a fully-executed Stipulation and Order of Settlement Dismissal (the “US Bio Stipulation”), which, as explained below, will fully resolve all claims in this case.¹ *See infra* Pt. C.

A. Background

As the Court is aware, the *Kester* case was filed under seal in 2011 by *qui tam* relator David Kester. Mr. Kester, who had worked in marketing for Novartis, alleged that Novartis had set up kickback arrangements with pharmacies in relation to a number of different drugs. According to Mr. Kester, these arrangements violated the Anti-Kickback Statute (the “AKS”), 42 U.S.C. 1370b(7)(b), and the False Claims Act (the “FCA”), 31 U.S.C. § 3729 *et seq.* *See* Stipulation and Order of Settlement and Dismissal filed on November 20, 2015, [Dkt. 504] at 1.

As relevant here, Mr. Kester’s original *qui tam* complaint alleged that Novartis and three specialty pharmacies – Accredo Health Group, BioScrip, Inc., and US Bio – engaged in a kickback arrangement in relation to the distribution of Novartis’s iron chelation drug Exjade. This Office investigated these Exjade allegations and ultimately intervened against Novartis,

¹ For the Court’s convenience, we are attaching to the hand-delivered copy of this letter copies of the Government’s Complaint in this case and the US Bio Stipulation as, respectively, Exhibits A and B to this letter.

Accredo, and BioScrip in the *Kester* case. Specifically, the Government alleged that Novartis, Accredo, and BioScrip violated the AKS and the FCA by participating in this arrangement in connection with the sale of Exjade to government program beneficiaries. *See id.* at 2.

As the Court is aware, the Government ultimately reached settlements with each of those defendants. Specifically, the Government settled its claims (i) against BioScrip in January 2014, (ii) against Accredo in April 2015, and (iii) against Novartis on November 20, 2015. In the meantime, Mr. Kester filed a second amended *qui tam* complaint on January 30, 2014. While Mr. Kester maintained his claims against Novartis arising from its Exjade relationship with US Bio, he voluntarily dismissed his claim against US Bio's corporate parent arising from US Bio's involvement with Exjade.

After the *Kester* litigation was fully resolved, this Office, together with the representatives of the States of New York and Washington, began investigating US Bio's involvement with Exjade. As part of the investigation, we had numerous discussions with US Bio and interviewed former US Bio employees who had knowledge of US Bio's involvement with Exjade. Further, to address statute of limitations issues, the parties entered into a series of tolling agreements, pursuant to which US Bio agreed to toll FCA claims as of August 1, 2016.

As set forth in the enclosed Complaint, the core allegation is that, from August 2010 to March 2012,² US Bio violated the AKS and the FCA by participating in an arrangement with Novartis under which US Bio could receive more Exjade patient referrals and related benefits in return for achieving a higher Exjade refill percentage than Accredo and BioScrip. More specifically, the Government alleges that the prospect of additional Exjade patient referrals was an improper inducement for US Bio to recommend to patients to order Exjade refills.

B. This Case Is a "Related" to the *Kester* Case under the Related Cases Rule

This District's Related Cases Rule provides that a civil case may "be deemed related to [another] civil case" where "the interests of justice and efficiency will be served." In making the "relatedness" determination, the Court may take into account, *inter alia*, (1) whether "the actions concern the same or substantially similar parties, property, transactions or events;" (2) if "there is substantial factual overlap;" and (3) whether, "absent a determination of relatedness," there could be "a substantial duplication of effort and expense."

Here, each of these factors is present. First, the Government's claims in this case concern US Bio's participation in an arrangement with Novartis relating to the allocation of Exjade patient referrals. This is the part of core conduct at issue in *Kester*. Second, there is "substantial factual overlap" between this case and the *Kester* case because both relate to how US Bio and other EPASS pharmacies competed for Exjade patient referrals. Finally, this Court became familiar with the factual and legal issues involved with the Exjade arrangements through its adjudication of a dozen or more legal and discovery motions in *Kester* before the parties reached a complete resolution. Thus, there would be duplication of efforts if another court were to preside over this case and review the proposed settlement. For these reasons, we respectfully request that Your Honor accept this case as "related" to the *Kester* case.

² Under the FCA, the Government can assert a claim against US Bio for acts that occurred after August 1, 2010, *i.e.*, six years before the tolling period. *See* 31 U.S.C. § 3731(b)(1).

C. The Proposed Settlement Should Be Approved

Under the proposed settlement, US Bio has agreed to pay approximately \$10.6 million to the Government to resolve the allegations in this case. *See* US Bio Stipulation ¶ 3. Further, as part of an overall resolution, US Bio also has reached agreements in principle with the States to pay a total of approximately \$2.8 million to resolve the States' claims for the same conduct under their respective civil fraud laws. Finally, as part of the proposed settlement with the Government, US Bio has agreed to admit a number of facts concerning its relationship with Novartis relating to the distribution of Exjade. *See* US Bio Stipulation ¶ 2.

This proposed settlement is the result of extensive, arms' length negotiations among experienced counsel. Further, as there is no pending *qui tam* case,³ the proposed settlement will fully resolve all claims in this case. Accordingly, we respectfully request that the Court approve and enter the US Bio Stipulation.

* * *

We thank the Court for its review of this letter and the enclosed papers. For the reasons set forth above, we respectfully request that the Court (i) accept this case as "related" to the *Kester* case, and (ii) approve and enter the proposed US Bio Stipulation.

Respectfully,

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³ As noted above, David Kester voluntarily dismissed in January 2014 the FCA claims that he had asserted against Amerisource Bergen, the corporate parent of US Bio, arising from US Bio's involvement with Exjade. Prior to finalizing this settlement, this Office was in contact with Mr. Kester's counsel, and counsel advised that Mr. Kester does not intend to file any *qui tam* claim against US Bio or seek a relator share of this settlement.