IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA, et al. ex rel. JOHN R. BORZILLERI, M.D., Plaintiffs,	:	14-CV-00031(WES)
vs.	:	United States Courthouse Providence, Rhode Island
BAYER HEALTHCARE PHARMACEUTICALS, INC., et al, Defendants.	:	Thursday, September 26, 2019 3:00 p.m.

TRANSCRIPT OF CIVIL CAUSE FOR MOTION HEARING
BEFORE THE HONORABLE WILLIAM E. SMITH
UNITED STATES CHIEF DISTRICT COURT JUDGE

A P P E A R A N C E S:

For the Plaintiff (United States of America):	ZACHARY A. CUNHA, AUSA Office of the U.S. Attorney 50 Kennedy Plaza, 8th Floor Providence, RI 02903
For the Plaintiff (John R. Borzilleri, MD, Relator):	MARYANN SMITH, ESQ. 4 Seneca Court Acton, MA 01720

Court Reporter: Lisa Schwam, CSR, CRR, RPR, RMR
One Exchange Terrace
Providence, RI 02903

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(In open court)

THE COURT: All right. Good afternoon. We're here in the matter of the United States, ex rel., John R. Borzilleri, M.D., vs. Bayer Healthcare Pharmaceuticals, et al. And we're here on the government's motion to dismiss the complaint pursuant to Section 3730(c)(2)(A) of the False Claims Act.

Let's have counsel identify themselves for the record, please.

MR. CUNHA: Good afternoon, your Honor. Zachary Cunha on behalf of the United States.

MS. SMITH: Good afternoon, your Honor. Maryann Smith on behalf of the Relator John Borzilleri.

THE COURT: Okay.

MS. ROCHA: Good afternoon, your Honor. Pat Rocha representing Novartis Pharmaceuticals Corporation. And with me this afternoon is Nadia Patel from Arent Fox, who has been admitted pro hac vice.

THE COURT: Okay. Thank you very much.

MS. FLORENCE: Good afternoon, your Honor. Maya Florence from Skadden Arps on behalf of defendant Biogen, Inc. And with me is local counsel Christian Jenner from Partridge Snow & Hahn.

THE COURT: Okay. Thank you.

MR. FRIEDMAN: Good afternoon. Laurence

Freedman from Mintz Levin representing CIGNA. With me is Mary Dunn, local counsel for CIGNA.

MR. FEE: Good afternoon, your Honor. Michael Fee, Latham & Watkins, for UnitedHealthcare. And with me is Richard Lumley from Burns & Levinson in Providence, Rhode Island.

THE COURT: Okay. Anybody else need to enter an appearance?

MS. di MARZO: Your Honor, Giulia di Marzo on behalf of Bayer.

MR. SHAY: Good afternoon, your Honor. Justin Shay, local counsel for Bayer.

THE COURT: Okay. Anybody else?

MS. O'CONNOR: Good morning, your Honor. Sarah O'Connor from Williams & Connolly on behalf of the various CVS defendants. And with me is our local counsel Marissa Janton from Whelan Corrente.

THE COURT: Okay. Good.

MR. McCARTHY: Good afternoon, your Honor. Ryan McCarthy from Morgan Lewis for Express Scripts.

MR. ROBINSON: Michael Robinson for Humana.

MR. GAINOR: Good afternoon, your Honor. Ryan Gainor for Teva Pharmaceuticals.

THE COURT: Anybody else?

All right. So my understanding is that,

Mr. Cunha, you're going to proceed first. And then Ms. Smith, you're going to speak. And none of the others I think have indicated a desire to speak; is that right?

(No response)

THE COURT: Okay. Mr. Cunha.

MR. CUNHA: Thank you, your Honor. As the Court noted, we're here on what I would term the relatively infrequent, but very far from unprecedented, invocation of the government's clear statutory authority embodied in 31 U.S.C. 3730(c)(2)(A) to involuntarily dismiss a qui tam suit over the objection of a relator.

There's a threshold issue, as we've addressed in the briefing, as to what standard applies to a motion of this kind. The government's position is that the D.C. Circuit's *Swift* standard, under which the government has full discretion to dismiss, is the correct measure. But we also maintain that even if this Court disagrees and follows the path of the Ninth Circuit in the *Sequoia Orange* line of cases, that the government amply meets the still-broadly deferential requirement to identify a valid government purpose, primarily, the expenditure of government resources both in monitoring this case and as a participant in third-party discovery were the litigation to proceed.

And accordingly, the Court can decline to take a position on which standard applies and still find that dismissal is warranted and appropriate in this case.

And in that regard, while it's obviously not controlling on this court, it's in our view highly persuasive that one other court, the Southern District of New York, confronting the same motion in what is effectively, for all present purposes, the same case brought by the same relator, has already recently determined that dismissal under the government's (c)(2)(A) authority is appropriate and, in that case, has done so without an in-court hearing.

I'd like to briefly address, your Honor, the reasons why, in the government's view, the *Swift* standard is correct, why in the alternative we meet the *Sequoia Orange* standard and how, under either rubric, relator has come forward with nothing that would overcome the government's clear right to dismiss.

With respect to the *Swift* standard that has been adopted also in the Fifth Circuit and the Fourth Circuit, the standard of an unfettered right to dismiss a qui tam lawsuit is consistent with the Supreme Court's decision in *Heckler vs. Chaney* and general principles of deference to prosecutorial discretion decisions by the executive.

It avoids any separation-of-powers concerns. And it is also consistent with the plain language of the statute which, in this particular instance, provides for the government to dismiss the action notwithstanding the objections of the relator so long as they have an opportunity to be heard in opposition to the motion.

That's very sharply in contrast with the language that the same Congress enacted with respect to the (c)(2)(B) provisions of the False Claims Act which apply when the government attempts to settle a False Act Claim case over the objection of the relator. That provision provides a specific role for review by the Court and a specific standard for that review. There is no such provision in (c)(2)(A) which supports the notion that the government's right to dismiss a case of this kind is not circumscribe.

It is also consistent, the notion of an unfettered right of dismissal, with the very unusual nature of the qui tam mechanism itself where the relator is not suing to remedy an injury to themselves but an injury to the government which always remains, as the Supreme Court has said, the real party in interest in litigation. And the notion that the government retains the power to say, respectfully, in

this instance, we don't want this suit in the government's name for the government's benefit to remedy a claim wrong to the government to go forward, is entirely consistent with the statutory scheme.

In the alternative, your Honor, we meet the *Sequoia Orange* standard. First and foremost, we have identified a valid governmental purpose; the resource burden of monitoring and participating in this case should it go forward that is rationally related to dismissal, that has been accepted as a valid government purpose justifying dismissal under (c)(2)(A) in the *Sequoia Orange* case itself, the *Ridenour* case in the Tenth Circuit, the *Nasuti* case in the District of Massachusetts, at least at the -- that case proceeded through a report and recommendation by the magistrate judge who applied the *Sequoia Orange* standard before ultimately being dismissed by the district court which favored the *Swift* standard. That that has also been found a justifiable reason in the *Spigelman* case out of the Northern District of Illinois and indeed in *Swift* itself.

And most recently, approximately two weeks ago, by the Third Circuit in a case called *United States ex Rel Chang v. Children's Advocacy Center of Delaware* which, although it did not decide which standard to

apply finding that the government met either standard, endorsed that again as a valid purpose justifying dismissal under (c)(2)(A).

Indeed, it was considered a valid purpose justifying dismissal in the *Stovall vs. Webster* case that relator purports to rely on, not in the decision that relator points to in his opposition briefing, but in the ultimate decision of the district court which concluded that dismissal was appropriate and that the government, in fact, because of its claim of resource burden, was entitled to a dismissal as requested.

We have also cited a perceived relative lack of merit to the claims or a lack of substantiation of the claims based on the government's investigation and, therefore, a remote likelihood of recovery, as well as the conduct of the relator in the course of investigation. Frankly, any one of those, but particularly the resource allocation argument which has been accepted in multiple courts, justified dismissal here.

Both the Department of Justice and the Centers for Medicaid and Medicare Services would bear a substantial burden were this case to go forward in time, in resources and perhaps equally, if not more importantly, in other cases and investigations that

cannot be brought or pursued because resources are being devoted to this litigation.

To successfully oppose a (c)(2)(A) application, the courts are fairly uniform, if not exclusively uniform, in concluding that a relator must make a showing that is tantamount to fraud on the court under the *Swift* line of cases or conduct that is fraudulent, arbitrary and capricious or illegal under the *Sequoia Orange* standard. And I think that's best articulated in the *Toomer* case out of the District of Idaho.

And relator's arguments, giving them the most generous possible interpretation, are effectively threefold. First, there's a challenge to the adequacy of the government's investigation. That's a baseless challenge. We've articulated the breadth, length and extent of this investigation which involved two United States Attorney's Offices, multiple federal agencies, agency expertise, external expert consultancy and the retrieval and review of hundreds of thousands of pages of responsive materials as well as the review and interview of multiple witnesses on the subject matter of this investigation. Relator has nothing factually to challenge that assertion.

The second argument that relator makes is a disagreement on the merits as to the government's view

of the case. And that is a rationale that has repeatedly been found insufficient to overcome the government's request to dismiss. Under both the *Swift* standard, it's not really a question of balancing given the unfettered discretion, but under the *Sequoia Orange* line of cases that's been found repeatedly insufficient to overcome a request to dismiss.

And the last is baseless conjecture that for some reason CMS, Centers for Medicare and Medicaid Services, as the responsible administrative entity overseeing the program, has a conflict of interest or may be attempting to obstruct the investigation in some way. These are all, again, conjectural, speculative bases for which relator has proffered no factual basis and that cannot make out any of the showings under either *Swift* or *Sequoia Orange*.

It's fair to say, your Honor, that the overwhelming majority of (c)(2)(A) cases ultimately endorse dismissal. Even those that have questioned it or that have required or requested a heightened throwing -- forgive me, a heightened showing such as the *Thrower* case that relator cites out of the Ninth Circuit, and it's currently up on appeal, involved situations where there's no dispute that the government's investigation was cursory, minimal or

nonexistent.

In the *Thrower* case, I think the allegation was that the government reviewed the complaint and perhaps interviewed the relator. And that's a very far cry from what went on in this investigation, as we've set forth in the briefing. Once again, speculation is not enough. I would point the Court specifically to the *Nasuti* case out of the District of Massachusetts. In that case, the relator alleged that there was corruption between employees of the United States Department of Agriculture and farmers in Massachusetts who received federal grants. He went so far as to actually name or attempt to name USDA officials as defendants in that lawsuit and to claim that it was all a manner of collusion. Ultimately, that was based on nothing more than speculation and, ultimately, the magistrate judge in the district court correctly found that insufficient to overcome the government's request to dismiss, as should be the case here.

In sum, your Honor, we have articulated under either standard a legitimate basis for the dismissal of this case, and we ask that the Court grant our motion under (c)(2)(A). If the Court has any questions, I'm happy to address them.

THE COURT: Just a couple very brief questions.

There are also a couple of common law claims here under state law, I take it, for unjust enrichment and fraud. I think your position is that there's no standing under the False Claims Act to bring those here.

But I would take it that you would not object to the dismissal of those counts without prejudice to the ability to refile those in state court; is that correct?

MR. CUNHA: That is correct, your Honor. I don't think we would take a position on the refiling of those claims.

THE COURT: All right. I don't have any further -- and just to reiterate, there really isn't a need for me, if I agree with the government's position, to decide which of those two standards apply because your position is that under either standard, the case should be dismissed, correct?

MR. CUNHA: Absolutely, your Honor.

THE COURT: Okay. All right. Thank you.

MR. CUNHA: Thank you.

THE COURT: All right. Ms. Smith.

MS. SMITH: Thank you, your Honor. Your Honor, may it please the Court. My name is Maryann Smith, and I'm representing the relator in this action.

The cumulative amount of money in this case at

issue is massive; over $18 billion in excess fees charged to Medicare Part D over the past decade, just for one category of drugs, older multiple sclerosis drugs. Due to exploding costs, patients and families have been losing access to drugs and facing health problems and financial ruin.

In this case, Dr. Borzilleri, the relator, a stock analyst who has both an MD and an MBA, had been noticing disturbing trends in pharmaceutical prices. He started to focus on older drugs for multiple sclerosis, drugs that has been around for years using formulas that have not changed and for which usage has been decreasing. MS drugs have an extremely competitive market. In the past decade, they have gone from four MS drugs to over a dozen. In a normal free market, the prices of older drugs should be going down.

However, from the time Medicare Part D began in 2006, the prices of these older drugs have increased tenfold. In fact, just since this case was filed in 2014, prices of the older drugs have doubled even though their usage has declined over 50 percent in the past decade.

In 2013, Dr. Borzilleri attended a conference at which corporate insiders discussed a service fee arrangement developed between pharmaceutical companies

and PBMs, also known as pharmacy benefit manufacturers, after Medicaid Part D was enacted. PBMs were originally designed to negotiate discounts for drugs for consumers and then PBMs would keep some of the discounts, also called rebates, as their profits.

However, after Medicaid Part D was enacted in 2006, the PBMs quietly shifted their entire business plan to service fees, which are a percentage of the list price of the drug. So if the price of the drug goes up, then both the pharmaceutical company and the PBMs make more money.

Dr. Borzilleri realized that the service fee arrangement is actually a kickback scheme. The service fees wildly exceed the fair-market value that is required by statute. This is because under the law there is no limit on the amount of bona fide service fees that can be charged because they are not regulated and the government cannot negotiate them. That is the key to this whole scheme. The fees are excluded from the Part D negotiated price.

So if the PBMs are paid with fees generated by increased prices, the PBMs and the pharmaceutical companies benefit and the costs are passed on to the government through Medicare and to the taxpayer. And there's more. Four PBMs now control 90 percent of Part

D. That includes the plan sponsors, which are the insurance companies, and also the specialty pharmacies who mail the specialty drugs to consumers.

Two recent incidents support Dr. Borzilleri's theory. In 2018, two PBMs, CVS and Ezrex, admitted for the first time that they are making very little money from rebates. There are only two ways for PBMs to make money on brand drugs in Part D; either through rebates or fees.

Similarly, 2018 pharma lobby and PBM lobby reports indicated that 90 percent of the PBM brand drug revenues come from fees. Dr. Borzilleri did thorough investigations to confirm his theories and then he filed this case in 2014.

Now, it is clear from the pleadings that the government and the Relator did disagree about the government's choice of what and who to investigate. That is fairly common in qui tam cases. The government did not investigate the two central allegations which are the kickback path involving massive service fees and the catastrophic portion of the Medicare Part D program. Instead, the government investigation focused on reports filed with CMFs, which is the Center for Medicare and Medicaid Services, however, these excess service fees would not be reported to CMS. Only the

plan sponsor, the insurance entity, has to report fees.

THE COURT: Ms. Smith, I want to give you your opportunity, but I'm afraid that you're going into a lot of issues about the merits as you see them of Dr. Borzilleri's case here.

MS. SMITH: Right.

THE COURT: But what I really need you to do, if you can, if you have anything to offer, is suggest to me or explain to me how either of these two standards, which don't seem too far apart in terms of what they require a Relator to show in order to defeat the government's motion to dismiss, how they are met here. And what that means, as I read it, is you have to come forward with some kind of showing that the government's decision is fraudulent or arbitrary, capricious or illegal in some fashion. Not just that you disagree with it and not just that you think that Dr. Borzilleri's argument had merit that the government, for whatever reason, failed to see, but you've got to come up with something pretty powerful that shows me that the government is acting in a fraudulent or illegal manner here. I haven't seen anything that suggests that.

So I'm just asking you now, as straight forwardly as I can, what's your best showing that

there's fraud or illegality here in the government's decision?

MS. SMITH: Okay. It is Relator's contention that the government didn't find anything because it didn't look in the right places.

THE COURT: Okay. That's incompetence; that's not fraud or illegal or even arbitrary and capricious. That's just incompetence. I'm not saying they're incompetent, but that's what you're alleging.

I mean, as I see it, that's about as bad as that is. That's basically alleging that they have been incompetent in their investigation.

MS. SMITH: I would make an assertion that it comes under the arbitrary category.

THE COURT: Okay. In order to be arbitrary and capricious, there has to be some conscious decision made or not just negligence, if you will, but something higher than that. What is it?

MS. SMITH: Well, one of the issues here with this case and with qui tam cases, generally, is that the government does not share with Relators the specifics of its investigation. I was on the phone call when the DOJ explained that they were not going to take this matter themselves, and we asked them about what you investigated, who did you talk to, what kinds

of documents did you get. And they said we're not going to tell you any of that.

So it's very hard for the Relator to argue in this kind of case because very little information is given to the Relator. But from what we do know, we know that they didn't look in the places that Dr. Borzilleri felt were the places where the fraud would be hidden. They looked -- there are many ways to hide the fees, and they didn't look in the places where Dr. Borzilleri suggested, which were the direct contact and direct contracts between the PBMs and the pharmaceutical companies.

So clearly the Relator feels that the *Swift* case is distinguishable from this case. The Swift case only involved about $6,000 and the government argued that it wasn't worth pursuing -- government resources would be spent pursuing $6,000. In the present case, we maintain that this is in the neighborhood of $18 billion, which is far larger.

And moreover, two cases decided in April of this year after the briefs in this case were filed do undercut the government's argument. In April in a case of first impression in the Third Circuit, the Eastern District of Pennsylvania joined the Ninth and Tenth Circuits in holding that the government cannot simply

exercise unfettered discretion to dismiss a qui tam action. And the name of that case is *United States vs. EMD Serono*. And I have a cite for it which it's CV-16-5594, 2019 WL 1468934, Eastern District of Pennsylvania, April 3rd, 2019.

The court in that case agreed with the 2005 *Ridenhour* case and the Sequoia Orange approach that the government's dismissal of a qui tam action is appropriate only if the government has a valid governmental purpose and dismissal is rationally related to accomplishing it. Courts are now requiring under Sequoia Orange a balancing of the government's use of resources versus the amount that could be gained by pursuing the case.

Finally, in another case decided in April of this year in the Southern District of Illinois, *U.S. ex rel Cimznhca* -- I'm going to have to spell that for you -- C-i-m-z-n-h-c-a, the district court judge denied the government's motion to dismiss because the government did not do a cost-benefit analysis to analyze the costs it would likely incur versus the potential in recovery that would flow to the government if the case were to proceed. I have a cite for that. You ready? It's number 17-CV-765-SMY-MAB, Southern District of New York, April 15th, 2019.

The DOJ takes very few whistleblower cases, yet since 1986 Relators have recovered over $2.4 billion for the federal government in claims in which the DOJ chose not to intervene. The practical effect of the DOJ's recent efforts under the Grantson memo to dismiss these cases is to extinguish thousands of whistleblower cases whether meritorious or not. In fact, two weeks ago, on September 4th, 2019, Senator Chuck Grassley wrote a letter to Attorney General William Barr indicating his concerns about the DOJ's efforts to dismiss greater numbers of qui tam cases after the Grantson memo.

Congress gave whistleblowers the ability to proceed with claims on their own precisely for situations in which the DOJ would not or could not pursue the case. If there is no merit to Dr. Borzilleri's claims, we will know soon enough. The pharmaceutical companies and PBMs definitely have the resources to mount a vigorous defense.

I would urge this Court to consider the congressional intent of the False Claims Act and to join the Ninth and Tenth Circuit and the Eastern District of Pennsylvania and Southern District of Illinois, to ensure that crime against the government will not pay.

Thank you, your Honor. If you have any more questions, I'd be happy to answer them.

THE COURT: No. Thank you very much, Ms. Smith.

MS. SMITH: Okay.

MR. CUNHA: Your Honor, may I very briefly reply?

THE COURT: Okay. Briefly.

MR. CUNHA: I'll be exceedingly brief.

THE COURT: Okay.

MR. CUNHA: First, although, as the Court points out, it is irrelevant for purposes of this motion, I just want to state very clearly for the record the government's position that we would like nothing more than to recover in a False Claims Act to the tune of $18 billion were such fraud present. We investigated these claims thoroughly and exhaustively.

Relator is mistaken as to our alleged failure to investigate one of his primary theories which we, indeed, devoted substantial resources to. But as the Court has pointed out, that's irrelevant for purposes of this motion.

I was surprised to hear counsel indicate that the Third Circuit has adopted the *Sequoia Orange* standard. First, because in the *Chang* case from the Third Circuit that I cited two weeks ago, the Third

Circuit Court of Appeals was explicit, "We need not take a side in the circuit split because the Relator fails even the more restrictive standard."

I was also somewhat surprised to hear *EMD Serono* cited, although pleasantly, because I think if the Court looks at the *EMD Serono* case out of the Eastern District of Pennsylvania which was, in fact, cited in Judge Furman's decision from the Southern District of New York dismissing Relator's companion case, the court in that case ultimately concluded that merit was -- or alleged merit was insufficient to overcome the government's claim that resources could be better devoted elsewhere. The court in that case ultimately granted the government's motion under (c)(2)(A), and the Court should do so in this case as well.

THE COURT: All right. Thank you all very much.

Does anybody else need to say anything? Okay.

DR. BORZILLERI: Am I allowed to say something as a Relator?

THE COURT: No, no. You have to speak through your attorney in court.

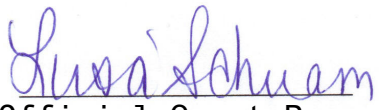
All right. So I'll take this under advisement, and I'll get you an order in short order. Thank you.

COURTROOM DEPUTY: All rise.

(Time noted: 3:32 p.m.)

CERTIFICATION

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.



Official Court Reporter November 4, 2019