

Nos. 98-2843 & 98-3524 (Consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

JOAN P. LUCKEY, an individual, and ex. rel.
the UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

BAXTER HEALTHCARE CORPORATION,

Defendant-Appellee.

On Appeal from the United States District Court for the
Northern District of Illinois, Eastern Division, No. 95 C 509
Hon. Ruben Castillo, Judge Presiding

**CONSOLIDATED BRIEF OF DEFENDANT-APPELLEE
BAXTER HEALTHCARE CORPORATION**

Javier H. Rubinstein
Bettina Getz
Jeffrey W. Sarles
MAYER, BROWN & PLATT
190 South LaSalle Street
Chicago, Illinois 60603
(312) 782-0600

*Counsel for Defendant-Appellee
Baxter Healthcare Corporation*

**CERTIFICATE OF INTEREST
OF DEFENDANT-APPELLEE PURSUANT TO RULE 26.1**

Baxter Healthcare Corporation (“Baxter Healthcare”), defendant-appellee herein, is the only person, association, firm, partnership or corporation represented by the undersigned counsel. Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Baxter Healthcare states that its parent corporation is Baxter International, Inc. Baxter International owns 100% of the issued and outstanding stock of Baxter Healthcare. The law firms who have appeared on behalf of Baxter Healthcare in this case are Mayer, Brown & Platt and Seyfarth, Shaw, Fairweather & Geraldson. Mayer, Brown & Platt is the only law firm representing Baxter Healthcare in connection with this appeal.

Javier H. Rubinstein
Bettina Getz
Jeffrey W. Sarles
MAYER, BROWN & PLATT
190 South LaSalle Street
Chicago, Illinois 60603
(312) 782-0600

*Counsel for Defendant-Appellee
Baxter Healthcare Corporation*

DATED: January 8, 1999

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JURISDICTIONAL STATEMENT

Appellant's jurisdictional statement is complete and correct.

STATEMENT OF ISSUES

A. Whether the district court's judgment should be summarily affirmed based on Appellant's violation of Circuit Rule 30.

B. Whether the district court properly entered summary judgment in favor of Baxter on plaintiff's claim that Baxter violated the False Claims Act, 31 U.S.C. § 3729, based on her failure to present any evidence that Baxter ever submitted a "false claim for payment" to the United States Government, or that it did so "knowingly."

C. Whether the district court properly entered summary judgment in favor of Baxter on plaintiff's retaliatory discharge claim under 31 U.S.C. § 3730 based on her failure to establish (1) that she engaged in any activity protected by the False Claims Act, (2) that Baxter was aware that she was engaged in any protected activity, and (3) that Baxter's reasons for terminating her employment were pretextual.

D. Whether the district court abused its discretion in awarding Baxter its costs pursuant to Fed. R. Civ. P. 54(d).

STATEMENT OF THE CASE

A. Course of Proceedings.

1. This is an action under the False Claims Act, 31 U.S.C. § 3729, *et seq.* Plaintiff alleges that the procedures used by the Baxter Screening Laboratory (BSL) to screen for dilution of blood plasma samples sent to BSL for viral marker testing were inadequate and that Baxter "knowingly and intentionally, or with reckless disregard, sold plasma products which [were] not . . . adequately tested for the presence of viral contaminants to the United States of America." Plaintiff also alleges that Baxter "expressly and

impliedly guaranteed” to the U.S. Government that Baxter “adequately and effectively tested for the presence of viral contaminants,” and that Baxter otherwise “represented to the United States Government that it complied with all applicable code of Federal Regulations [sic].” R. 70, ¶¶ 83, 84(k). Finally, plaintiff claims that, in violation of 31 U.S.C. § 3730(h), Baxter terminated her employment in “retaliation” for pursuing or investigating alleged false claims by Baxter to the Government.

The Government declined to prosecute plaintiff’s claims, and after the close of discovery, Baxter moved for summary judgment on both counts of plaintiff’s Second Amended Complaint. On the FCA claim, Baxter sought summary judgment because plaintiff could not establish that Baxter ever presented a “false claim” for payment to the U.S. Government, and that even if she could, plaintiff could not show that Baxter ever did so “knowingly.” On the retaliation claim, Baxter sought summary judgment because (1) plaintiff had not engaged in any conduct protected by the FCA, (2) her termination could not have been in “retaliation” for protected conduct since Baxter was never aware that she engaged in protected conduct, and (3) the reasons for her termination had nothing to do with any protected conduct.

2. On April 20, 1998, the district court granted Baxter’s motion.¹ With respect to the FCA claim, the district court held that plaintiff failed to establish (1) that Baxter had ever presented a false claim for payment, (2) that Baxter had ever violated any federal laws, and (3) that even if plaintiff could prove those points, she failed to establish that Baxter had ever “knowingly” presented a false claim to the Government.

¹ As explained *infra* at 17-19, Appellant has included in her Appendix a copy of the district court’s *original* summary judgment opinion, rather than the *amended* opinion under review by this Court. All references in this Brief are to the district court’s amended opinion, as reported at 2 F. Supp. 2d 1034 (attached hereto at App. A).

a. As to Baxter's sales to the Federal Supply System (FSS) (which cover all but four of Baxter's government sales during the relevant period), the district court held that the FSS Contract (R. 75, Ex. 6(A)) contained no certifications, representations or requirements concerning Baxter's plasma testing. The court rejected plaintiff's contention that Baxter impliedly certified its compliance with all federal regulations and laws every time it made a request for payment under the FSS Contract, since it "improperly broadens the intended reach of the FCA." Op. 1045. The district court also held that "Luckey has failed to demonstrate that Baxter's compliance with any statute or regulation was a material condition to receiving payment from the government," and that "there is no evidence that Baxter's practice violated the heart of its agreement with the government." *Ibid.*

As to Baxter's four remaining sales to the Defense Logistics Agency (DLA), the district court noted that Baxter certified it would comply "with the requirements of the Federal Food, Drug and Cosmetic Act, as amended and regulations promulgated thereunder." Op. 1046. The court held, however, that even if this amounted to a "claim" of regulatory compliance, there was no evidence that Baxter ever violated any federal regulations, both because "Luckey has not pointed to any regulation, statute or contract provision requiring Baxter to implement certain procedures when screening their plasma samples," and because "a review of the regulations fails to indicate that a certain type of plasma screening is required." Op. 1045, 1047. The court also pointed out that "Luckey's complaint with Baxter's practices focuses only on one level of what Baxter describes as a multi-level safeguard process . . .," but noted that it "need not resolve these issues, however, as we find that Luckey cannot satisfy the remaining elements of the FCA." *Ibid.*

The district court next held that even if plaintiff could prove a regulatory violation, such violations could not give rise to FCA liability given "the well-established principle that the FCA is not a vehicle for

regulatory compliance.” Op. 1044. The court also held that “Luckey presents insufficient evidence to demonstrate that her dispute with Baxter’s whole blood testing process is anything other than a matter of scientific judgment,” and that “mere deviation from scientific norms is insufficient to support an FCA action.” Op. 1047-1048.

The district court separately concluded that even if plaintiff could establish that Baxter ever presented a false claim for payment, she also “failed to demonstrate” that Baxter did so “knowingly,” or “that Baxter’s tardiness in implementing the [saline test at issue] was part of a scheme to defraud the Government. The FCA prevents this Court from converting what at best can be called Baxter’s negligence into a lie.” Op. 1049. Finally, the court concluded that “[e]ven if Luckey could overcome this defect—which she cannot—her claim would still suffer the fatal flaw of ambiguity” since federal “regulations were silent on th[e] issue” of saline testing. *Ibid.* Thus, the court held “that while Luckey has produced evidence from which a trier of fact could infer that Baxter was utilizing outdated procedures in screening its plasma samples, there is no evidence that would allow a reasonable jury to conclude that Baxter was committing fraud as required by the FCA.” Op. 1049-1050.

b. With respect to plaintiff’s retaliation claim, the district court held that plaintiff failed to meet each of the three requirements necessary to establish a violation of 31 U.S.C. § 3730(h). *First*, the court held that plaintiff’s complaints about BSL’s saline testing procedures were not protected by the FCA since they were not aimed at exposing any fraud on the Government:

While Luckey was concerned about Baxter's testing procedures and its discipline of her, there is no evidence that Luckey's activities were related to exposing a fraud upon the government. We acknowledge Ms. Luckey's efforts as laudable and note that Baxter's current testing incorporates the suggestions that Luckey raised for years. * * * We decline to extend general investigations of regulatory non-compliance into per se employee investigations of an employer's alleged fraud upon the government.

Op. 1052.

Second, the district court held that even if plaintiff engaged in protected activity, there was no evidence that Baxter was aware of any protected activity. As the court explained:

the employer must be on notice, not only of the voiced concerns and investigations of the employee, but that the employee's actions are related to the employer's alleged false claims to the government. In other words, the employee must, at least to some degree, couch her concerns or investigation in terms of funds her employer fraudulently obtained from the government. This is the element missing from Luckey's complaints. There is no denying that Luckey's concerns were consistent and ongoing. Unfortunately, Luckey has failed to draw this Court's attention to any evidence that she gave Baxter notice that she believed their activities were fraudulent.

Op. 1055. In particular, the court cited the fact that "there was no evidence that Baxter was aware that Luckey had contacted the government, was investigating possible fraud, or was even contemplating participation in a fraud investigation." Op. 1054.

Finally, the court held that plaintiff's own subjective belief that her termination was retaliatory was "insufficient to create a genuine issue of material fact," particularly since:

Baxter has presented extensive evidence that it legitimately believed that Luckey's personal skills were lacking, and that her supervisors received complaints that Luckey made inappropriate racial remarks, and offended and harassed her coworkers. Luckey denies making some of the statements, and disputes that her coworkers found her behavior offensive, but she cannot ignore the concrete evidence that her coworkers did in fact complain about her. Having determined that her beliefs are insufficient evidence of Baxter's unlawful intent, we further find that Baxter has presented sufficient evidence to show that its motives for terminating Luckey were neither improper nor pretextual. Accordingly, we find that Luckey cannot satisfy the elements of a retaliatory *qui tam* action." Op. 1057.

3. On April 30, 1998, plaintiff moved for reconsideration. R. 110. On May 26, 1998, the United States filed an *amicus curiae* brief, which stated up front that “[w]e do *not* seek reconsideration of the Court’s underlying holding.” (R. 118, at p. 1 (emphasis in original)), but sought amendment of the court’s opinion to remove certain conclusions of law that the Government felt were unnecessary given plaintiff’s complete failure of proof. The Government conceded, however, that plaintiff’s FCA claim failed as a matter of law

The relator failed to identify any statute or regulation existing during the time period covered by the complaint that required Baxter to perform [total protein] tests. Relator also failed to demonstrate that Baxter’s contractual mandate to supply safe blood plasma encompassed a duty to perform this test. Absent any proved explicit or implicit government requirement that such a test be performed, any claims submitted to the United States for blood plasma performed without such a test could not have been “false or fraudulent” within the meaning of the False Claims Act’s liability sections, 31 U.S.C. § 3729(a), as a matter of law.

Id. at 3.

On June 19, 1998, the court granted the Government’s request in part, and amended its opinion. See App. B hereto. In an order dated June 24, 1998 (which also is not included in Appellant’s Appendix), the court denied plaintiff’s motion to reconsider on the ground that “Plaintiff’s motion to reconsider introduces no newly discovered evidence or manifest errors of law or fact.” See App. C hereto.

4. On May 19, 1998, Baxter submitted its bill of costs to the district court totaling \$20,013.48. Plaintiff opposed the bill of costs on the grounds that “1. Plaintiff’s action was reasonable and brought in good faith. 2. Plaintiff’s action involved complex issues concerning the testing and manufacturing of plasma products. 3. Awarding costs to Defendant would dissuade whistle blowers such as plaintiff in this case from bringing reasonable actions for the common good if they risk payment of substantial trial costs

for defeat.” R. 122. Plaintiff did not challenge any specific cost items. On July 30, 1998, the court approved Baxter’s Bill of Costs, and held that:

The arguments made by plaintiff do not provide adequate grounds to justify a denial of costs. None of the three reasons raised in plaintiff’s pleadings relates to any inability to pay costs or any impropriety by Baxter. The reasons that plaintiff offers relating to her alleged good faith and the nature of a qui tam whistle blower action, are insufficient as a matter of law to justify a denial of costs.

App. A-56.

On August 10, 1998, plaintiff moved for reconsideration of the cost award, arguing for the first time that costs should not be awarded based on plaintiff’s financial condition. On September 23, 1998, the court denied plaintiff’s motion, holding that “plaintiffs’ motion has not shown any manifest error of law or fact or any newly discovered evidence. Plaintiff has improperly sought to submit facts which were known to plaintiff prior to the court’s ruling to reargue the court’s ruling. This type of piecemeal litigation is improper.”

R. 138.

B. Statement of Facts.

Baxter is a medical products and services company, and a leader in the development of biologics, including the life-saving plasma derivatives needed to clot blood and to provide antibodies against disease. Baxter obtains its plasma from two sources: “source plasma” is collected from donors at FDA-licensed plasma collection centers, and is drawn directly through an automated plasmapheresis (or “autopheresis”) process that extracts whole blood from donors, removes the plasma and reinfuses the remaining blood components back to the donor. “Recovered plasma” is received from blood banks, which remove it from donations of whole blood and perform their own plasma testing. Baxter’s 12(M) Stmt. (R. 74), ¶¶ 23-24.

1. Through its Hyland Division, Baxter processes and sells medical therapies processed from human plasma, including clotting factors for treating hemophilia and albumin for treating medical conditions such as shock. The plasma used to develop these therapies is drawn from human donors at FDA-licensed collection centers. Some of this plasma is processed at Hyland's facilities in California and at an affiliated facility in Belgium, using a process in which units of plasma are pooled and then separated into their various biologic components. 12(M) ¶¶ 2, 22, 24.

To guard against the possibility that donated plasma used in the fractionation process may contain viruses, redundant safeguards are utilized at every stage of this process, including (1) screening of donors prior to donation; (2) testing of plasma samples to screen for certain viral markers; (3) repeat testing of pooled plasma for certain viral markers, including the markers for Hepatitis B, Hepatitis C and HIV; and (4) viral inactivation and/or removal processes using chemical and physical treatments (such as use of alcohol, chemical solvents and heat treatment) during the processing of plasma into various therapeutic derivatives. 12(M) ¶¶ 25-38, 33-41.

If a plasma sample tests positive for a viral marker, it is rejected by Baxter and the donor is disqualified from subsequent donation. If a plasma sample tests negative, the unit of plasma associated with the sample is sent to Baxter's plasma processing facilities for pooling with other units of plasma. These pools are then tested once again for the same viral markers previously tested at BSL. Any lot of pooled plasma that tests positive for the presence of any viral marker is discarded. 12(M) ¶¶ 25-38, 33-41. If the pool tests negative, it is then subjected to a series of viral inactivation and/or removal procedures during processing. 12(M) ¶¶ 35, 39-41.

After Baxter has processed plasma into finished therapies, Baxter sends samples of each lot of certain plasma-based therapies, such as Hemofil[®] M, to the FDA's Center for Biologics Evaluation and Research ("CBER"). CBER must authorize release of each lot (unless exempted) before it may be distributed. FDA regulations also require that certain viral marker tests be performed, including tests for Hepatitis B surface antigen, and antibodies to HIV.

2. Baxter's sales of plasma derivatives to the Government comprise but a small fraction of Baxter's overall sales. During the period January 1, 1990 through May 1, 1995, Baxter sold a variety of plasma derivatives to the V.A. for use in its hospitals. These sales (which comprised all of Baxter's sales to the Government except four) were made pursuant to a single Federal Supply Schedule ("FSS") Contract with the Department of Veterans' Affairs. 12(M) ¶¶ 10-12. The "Federal Supply Schedule program . . . 'provides Federal agencies with a simplified process of acquiring commonly used supplies and services in varying quantities.'" *Best Power Tech. Sales Corp. v. Austin*, 984 F.2d 1172, 1173 (Fed. Cir. 1993) (quoting 48 C.F.R. § 38.101(a) (1991)). Under the FSS program, "[t]he schedule contracting office issues publications, titled Federal Supply Schedules, containing the information necessary for placing delivery orders with the contractors. Ordering offices issue delivery orders directly to the schedule contractors for the required supplies or services." 48 Fed. Reg. 42102, § 8.401 (1983).

Under the FSS Contract, purchasing agents can call or write Baxter to order any plasma derivative identified in the Contract at a pre-specified price without negotiation. The FSS Contract is comprised of a Price List and a host of standard terms and representations on issues such as Affirmative Action, Procurement Integrity and Baxter's eligibility as a Government contractor. 12(M) ¶ 12. The FSS Contract contains no requirement concerning the testing or manufacture of any plasma derivative, except that each

derivative be FDA-licensed. The Contract disclaims “any implied warranty and any warranty of merchantability of fitness for a particular purpose” beyond that set forth in Baxter’s labels and product inserts, and further states that “[a]ll warranties are specifically excluded.” 12(M), Ex. A at B000017. The plasma derivatives sold by Baxter to the Government included FDA-approved labels and inserts, none of which contained any representations as to specific tests performed by Baxter. 12(M) ¶ 47. Certain labels and inserts also warned that “testing methods presently available are not sensitive enough to detect all units of potentially infectious plasma,” and that “the risk of viral infectivity from this product cannot be totally eliminated.” See 12(M) Stmt., Exs. 8-19.

On four occasions, Baxter contracted with the DLA to sell a specific plasma derivative. Like the FSS Contract, the DLA Contracts contain no requirement for testing of Baxter’s plasma derivatives. They required that each plasma derivative be FDA-approved, and that each lot have the necessary approval. The DLA documentation (but not the FSS Contract) also referred to an “Interim Commercial Item Description” of plasma derivatives prepared by the General Services Administration which required each manufacturer to comply with all applicable laws. The DLA Contracts specify that “[a]ll implied warranties of merchantability and ‘fitness for a particular purpose’ are excluded from any obligation contained in this contract.” 12(M) ¶¶ 15, 20.

3. In processing its plasma derivatives, Baxter relies in part on source plasma, which is drawn directly from donors through an autopheresis process that extracts whole blood from donors, removes the plasma and reinfuses the remaining blood components back to the donor. This process results in larger volumes of fluid removal as compared with routine blood donation. Thus, saline solution (*i.e.*, saline water)

is used at the end of the procedure to provide the donor with fluid to replace the lost volume of plasma and to prevent possible adverse reactions to the plasma donor. 12(M) ¶¶ 23, 29, 48.

By 1990, it was discovered that in very rare instances source plasma samples sent to the BSL for testing contained small amounts of saline solution, thereby potentially diluting the sample. Although Baxter performs repeat viral marker tests on pooled plasma units and performs a variety of additional viral inactivation procedures, and despite the fact that FDA regulations do not require any test to screen for saline dilution of plasma samples, BSL adopted protocols requiring that all plasma samples be screened for possible saline dilution. These protocols required screening samples of source plasma using a combination of visual inspection, screening for low levels of alanine aminotransferase (ALT) (a liver enzyme) and, depending on the judgment of technicians and supervisors, a Total Protein Test. BSL could reject the underlying unit of plasma based on visual inspection or low ALT test results. In 1995, Baxter modified BSL's procedures to automatically require total protein testing in certain circumstances. 12(M) ¶¶ 36-37, 50-52, 58.

4. On April 4, 1995, following an FDA inspection of BSL's facility in Round Lake, Illinois, and a local field-office inspection report that raised issues about BSL's screening procedures for saline dilution, the FDA issued a report concluding "that under current regulations for EAR [error and accident reports], testing laboratories and collection facilities are not required to report identified instances of saline

contamination,” and that “current regulations [do] not require reporting of the saline contamination through either the EAR or MDR [medical device] reporting systems.”² 12(M) ¶¶ 59-60.

The FDA also “concluded that the inspection findings did not provide sufficient information to determine existence of an imminent danger to health” and did not warrant any enforcement action against Baxter. 12(M) ¶ 60. At no stage of its investigation did the FDA suggest that Baxter made any false statements to the Government about its plasma testing, or had failed to disclose any information that was required to be disclosed under federal law.

5. Joan Luckey was hired by the BSL on December 9, 1991 as a Technician-III. 12(M) ¶ 64. Luckey was never employed at any other Baxter facility, and never worked at any plasma processing facility. Her duties and responsibilities at BSL included verification of test results, “troubleshooting” equipment problems, and assisting other technicians. 12(M) ¶ 64. As a Baxter employee, she also was responsible “for reporting incidents which might have an effect on test results.” 12(M) ¶ 66. According to plaintiff, as part of her duties she also “participated in the updating and revision of the currently released Total Protein SOPs,” would “identify problems and determine the corrective actions required in ALT and [Total Protein] processing,” and “proactively suggested improvements for the laboratory to increase effectiveness and safety.” Ex. 29 to 12(M) Stmt. As explained to a subsequent prospective employer, plaintiff’s work at

² Error and accident reports (EARs) are required by the FDA in the case of “errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product.” 21 C.F.R. § 600.14(a). Medical Device Reports (MDRs) are required by the FDA to “report deaths and serious injuries to which a device has or may have caused or contributed,” or to “report certain device malfunctions.” 21 C.F.R. § 803.1(a). Such reports “assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.” *Ibid.*

Baxter included “all aspects of equipment operation, maintenance and troubleshooting . . . SOP’s . . . and the writing and revision of SOPs.” She also included among her “Specific Contributions” “[a] project involved in saline dilution of samples. I submitted a protocol.” 12(M) ¶ 87.

In April 1993, Luckey received two verbal warnings for laboratory errors. See, *e.g.*, 12(M) ¶ 21. On August 16, 1994, she received another warning for three laboratory errors. *Id.* ¶ 23. In 1994, Luckey’s supervisors received several complaints from co-workers that Luckey had made harassing and discriminatory remarks. For instance, in June 1994, one month after a female employee of Indian ancestry received a promotion that Luckey had sought, Luckey’s co-workers complained that she had circulated a document accusing BSL of only promoting employees who were “married, under 40, Indian and pregnant.” Op. 1039. Another of her co-workers complained that she had made disparaging remarks about Middle Eastern males. *Ibid.* Luckey was warned by her supervisors about these statements on June 22, 1994. *Ibid.* On December 28, 1994, Luckey also received a written warning for distributing to co-workers magnetic cards which “bore the motto ‘We won’t be promoted’ and the acronym ‘V.I.P.S-N.I.P.S’, which Luckey explained stood for the phrase ‘Very Important People Slated With No Personal Skills.’” *Id.* at 1040. “After several coworkers complained that the magnets were offensive, Luckey was issued a written warning that such conduct violated BSL’s policy on distribution, solicitation and vending, constituted harassment of other workers, and was defamatory of BSL. *Ibid.*”

Finally, on March 25, 1995, a female co-worker reported that Luckey, while complaining of her failure to receive a merit-based salary increase, had made a threatening remark. Op. 1041. Another co-worker separately complained that Luckey had threatened to “shut down the BSL” and “was going to get

rid of” various BSL supervisors. *Ibid.* On March 27, 1995, shortly after these threats were reported to Baxter management, Luckey was suspended on the ground that she posed a threat to the safety of the workplace. 12(M) ¶ 69. With the concurrence of senior Baxter management, Luckey’s employment at BSL was terminated effective April 18, 1995. 12(M) ¶ 71. At no time prior to plaintiff’s termination was Baxter aware that she was involved in any investigation into possible fraud or false claims to the Government, or that she was contemplating the filing of a *qui tam* suit. 12(M) ¶¶ 72-85.

SUMMARY OF ARGUMENT

I. The district court’s summary judgment and costs decisions should summarily be affirmed based on plaintiff’s flagrant and multiple violations of Circuit Rule 30. For instance, plaintiff failed to attach the final, amended summary judgment decision under review by this Court. While plaintiff included the court’s *original* summary judgment ruling, she misleadingly fails to inform this Court that the court’s decision was in fact *amended* in response to the Government’s *amicus* request for amendment. She also failed to include a copy of the court’s order denying her motion to reconsider (which she is appealing). And to make matters worse, her Brief falsely certifies that no other Rule 30 materials existed. This Court repeatedly has warned of the importance of complying with Rule 30 and the consequences of non-compliance, including summary affirmance in civil cases. Such sanctions plainly are warranted here.

II. The district court properly entered summary judgment on plaintiff’s FCA claim as a matter of law, both because of plaintiff’s failure to establish that Baxter ever presented a false claim for payment to the United States Government, and also because she failed to offer any evidence that Baxter could have done so “knowingly.” As the district court held, and the Government conceded in its *amicus curiae* brief

to the district court, plaintiff “failed to identify any statute or regulation existing during the time period covered by the complaint that required Baxter to perform the [saline] tests” that she alleges should have been performed. Govt. Br. (R. 118), p. 3. Indeed, federal law and Baxter’s government contracts say nothing about saline dilution or testing. Thus, “any claims submitted to the United States for blood plasma performed without such a test could not have been ‘false or fraudulent’ within the meaning of the False Claims Act’s liability sections, 31 U.S.C. § 3729(a), as a matter of law.” Govt. Br., p. 3.

In her Opening Brief, plaintiff argues that Baxter falsely claimed to have tested “each unit” of plasma for HIV and Hepatitis. This assertion is both false and misleading. As plaintiff admitted in the district court, *every* unit of plasma sent to BSL is tested for HIV, Hepatitis and other viral contaminants using a battery of FDA-approved tests. After it is tested at BSL, the plasma is tested *again* after it is pooled, and is then subjected to series of viral inactivation treatments that remove any viral contaminants that may have escaped detection. In short, plaintiff has not, and cannot, point to any false claim by Baxter concerning its plasma testing.

There also is not a shred of evidence that Baxter’s multiple safeguards against viral transmission ever failed to function properly, or that Baxter ever sold *any* plasma therapies to the Government containing any viral contaminants. Indeed, the FDA inspected BSL in 1995 and never once suggested that Baxter had failed to test any units of plasma for viral contaminants or that Baxter violated any federal laws or regulations. Plaintiff’s entire case is simply a fiction.

Plaintiff’s assertion that units of plasma were “not tested” by Baxter is really just a disguised attempt to challenge the *reliability* of BSL’s pre-1995 saline testing procedures. The accuracy of those

procedures, however, and whether Baxter should have used different procedures, are questions of scientific judgment that lie beyond the purview of the FCA. What matters here, from an FCA perspective, is that Baxter never *lied* to the Government about its testing procedures, and never submitted a false claim for payment to the Government based on any false claims about those procedures.

But *even if* plaintiff could somehow prove that Baxter presented a “false claim” to the Government, her FCA claim still would fail as a matter of law given her inability to prove that Baxter did so “knowingly.” Indeed, because there are no federal regulations requiring saline testing, and since Baxter’s government contracts say nothing about plasma testing, Baxter could not “knowingly” have lied about its testing procedures as a matter of law. There was nothing for Baxter to lie *about*. Thus, as the district court properly held, no reasonable jury could possibly find that Baxter violated the FCA as a matter of law.

III. The district court also properly entered summary judgment on plaintiff’s retaliatory discharge claim for at least three independently dispositive reasons. *First*, because plaintiff’s complaints about saline dilution were not aimed at exposing any fraud on the Government, she did not engage in any activity protected by the FCA. *Second*, even if plaintiff engaged in protected activity, it is undisputed that she never informed anyone at Baxter that she was investigating possible fraud or false claims. Her efforts to modify BSL’s saline testing procedures were simply part of her job. Because Baxter had no knowledge that plaintiff was engaged in any protected activity, it could not have “retaliated” against her within the meaning of the FCA as a matter of law. *Third*, plaintiff also offered no evidence to dispute the fact that her termination resulted from repeated co-worker complaints of offensive behavior, racial slurs, and threats that plaintiff would “get rid of” her co-workers and supervisors. While plaintiff may deny that she engaged in

such offensive behavior, the undisputed fact remains that she was *not* terminated “because of” any activity protected by the FCA.

IV. Plaintiff’s Opening Brief provides no basis for challenging the district court’s award of costs. Plaintiff only challenges the awarding of costs based on her poor financial condition. However, plaintiff never raised this ground in opposition to Baxter’s Bill of Costs. Instead, she raised this point for the first time in a motion to reconsider. The district court denied the motion to reconsider because plaintiff did not allege any manifest error of fact or law, and did not present any newly discovered evidence. Plaintiff’s Opening Brief raises no challenge to this ruling. Nor does it point to any abuse of discretion by the district court. The district court’s cost award should therefore be summarily affirmed.

ARGUMENT

I. The District Court’s Rulings Should Be Summarily Affirmed Based On Appellant’s Multiple Violations of The Mandatory Requirements of Circuit Rule 30.

The district court’s summary judgment and cost decisions should be summarily affirmed because of plaintiff’s blatant violation of Circuit Rule 30. Plaintiff’s Brief fails to append the judgments and opinions under review by this Court. While Appellant’s Rule 30 Appendix includes the district court’s *original* summary judgment decision, she failed to include the district court’s final summary judgment opinion, which was *amended* in response to the Government’s *amicus* request. She also failed to include the court’s decision denying her motion to reconsider (which she is appealing).

Circuit Rule 30(a) mandates that “the appellant shall submit, bound with the main brief, an appendix containing the judgment or order under review and any opinion * * * upon the rendering of that judgment, decree, or order.” Rule 30(b) also requires inclusion in a separate appendix all other pertinent opinions and

orders “that address the issues sought to be raised.” Finally, Rule 30(d) requires appellant’s counsel to certify that “all of the materials required by parts (a) and (b) of this rule are included.”

The “purpose” of Rule 30 is to enable the Court “to have all necessary documents before it as it considers the parties’ arguments and renders its decision.” *Hill v. Porter Mem. Hosp.*, 90 F.3d 220, 225-26 (7th Cir. 1996). As this Court recently lamented in *Pabst Brewing Co., Inc. v. Corrao*, 1998 WL 787354, at *3 n.1 (7th Cir. 1998) (in which this Court issued an order to show cause why counsel should not be sanctioned for violating Rule 30), “[w]e are at a loss to understand what it is that could be unclear about Rule 30, or what language would drive home the point even more strongly that the judges of this court need to have before them all rulings from the tribunal from which the appeal is being taken.” Compliance with Rule 30 is “vital to the appellate task.” *United States v. Evans*, 131 F.3d 1192, 1194 (7th Cir. 1997). Without the actual opinion under review, this Court “cannot intelligently prepare for argument or render a decision.” *Mortell v. Mortell Co.*, 887 F.2d 1322, 1327 (7th Cir. 1989). See also *Urso v. United States*, 72 F.3d 59, 62 (7th Cir. 1995) (proper review not possible “without knowing why” the district court ruled as it did). “Transgression of these rules is not a ‘nit-picky’ violation,” but rather “goes to the heart of this court’s decision-making process.” *Hill*, 90 F.3d at 226.

Accordingly, this Court repeatedly has warned of the importance of complying with Rule 30, and of the consequences of non-compliance, including the admonition that “[c]ivil cases *may be summarily affirmed* when the appellant does not furnish the court with the decision he seeks to have reviewed.” *Evans*, 131 F.3d at 1194 (emphasis added).

In this case, plaintiff not only disregarded Rule 30 and this Court's admonitions, but also submitted a certificate affirming that the Appendix to the Brief "contains the materials required by Circuit Rule 30(a). There are no additional materials as described in Circuit Rule 30(b)." As explained above, this certificate is plainly false. While plaintiff included the district court's order of June 24, 1998 which discussed the Government's request for amendment (A-48 to A-54), she fails to attach the district court's order of June 19, 1998 (App. B hereto) which explained *how* the district court's decision of April 20, 1998 was amended. Without that order, this Court would have no way of knowing what is contained in the district court's judgment under review. She also failed to include a copy of the district court's order denying her motion to reconsider the summary judgment ruling (which she has appealed). See App. C hereto. Without it, this Court again would have no way of knowing why her motion to reconsider was denied.

A false Rule 30 certificate by itself provides "a sufficient reason to affirm without reaching the merits [because] [t]he court must be able to rely on counsel to furnish the district court's explanation of the decision under review." *Mortell*, 887 F.2d at 1327 (summarily affirming on that basis).

Summary affirmance is especially appropriate here since plaintiff's failure to attach the actual decision of the district court under review creates the misleading impression not only that the decision she attached was under review by this Court (which it is not), but that the Government has objected to the ruling under review, when in fact the Government conceded that plaintiff's claim failed as a matter of law, and that the court amended its opinion *pursuant to the Government's motion*. *None* of this is mentioned in plaintiff's Brief. Such blatant violations of Rule 30 warrant summary affirmance of the district court's decisions.

II. The District Court’s Summary Judgment as to Plaintiff’s FCA Claim Should Be Affirmed Given Plaintiff’s Failure to Prove That Baxter Ever Violated the FCA.

To prove that Baxter violated the FCA, plaintiff must prove that Baxter “knowingly present[ed] or cause[d] to be presented” to the United States Government a “false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1). “What constitutes the FCA offense is the knowing presentation of a claim that is either fraudulent or simply false.” *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996), *cert. denied*, 117 S. Ct. 958 (1997).

To prove that a false claim was “knowingly” made to the Government, plaintiff must demonstrate that Baxter, in connection with a claim for payment, “(1) had actual knowledge of the information at issue; (2) acted in deliberate ignorance of the truth or falsity of that information; or (3) acted in reckless disregard of the truth or falsity of the information.” *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995), *cert. denied*, 516 U.S. 1114 (1996) (citing 31 U.S.C. § 3729(b)). Accord *United States ex rel. Rueter v. Sparks*, 939 F. Supp. 636, 638 (C.D. Ill. 1996) (same). As this Court explained in *Hindo*, the FCA requires the “‘knowing presentation of a claim that is either fraudulent or simply false.’ *In short, the claim must be a lie.*” 65 F.3d at 613 (quoting *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420 (9th Cir. 1991)) (emphasis added).

Because a false “claim” for payment must “knowingly” be made, the party accused of the claim must know that the claim in question actually was made. For this reason, generalized statements are “not the type of representation required by the statute.” *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321 (9th Cir. 1995). Instead, a “false claim” must be clear and specific, and not merely an opinion or ambiguous statement. A “claim” must be “a statement of fact that can be said to be either true

or false.” *Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795, 810 (D. Utah 1988). A claim also cannot “knowingly” be false unless the speaker actually and contemporaneously understands precisely what is being claimed, and unless the truth or falsity of the representation can objectively be ascertained at the time. See, e.g., *United States v. Anderson*, 579 F.2d 455, 460 (8th Cir.), cert. denied, 439 U.S. 980 (1978); *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980). Thus, “[f]or a *qui tam* action to survive summary judgment, the plaintiff must produce sufficient evidence to support an inference of knowing fraud.” *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815 (9th Cir. 1995), cert. denied, 516 U.S. 1043 (1996). Finally, the claim must be a “material” one that “has a natural tendency to influence agency action or is capable of influencing agency action.” *United States ex rel. Berge v. Board of Trustees of Univ. of Alabama*, 104 F.3d 1453, 1460 (4th Cir.), cert. denied, 118 S. Ct. 301 (1997).

In this case, the district court held that plaintiff failed to establish *any* of these elements as a matter of law. As demonstrated below, the court’s decision is undoubtedly correct, and should be affirmed.

A. The District Court Properly Held That Plaintiff Failed To Establish That Baxter Ever Presented A False Claim To The United States Government.

From the beginning, plaintiff’s FCA claim has been a moving target, changing at every turn as additional discovery disclosed the plain inadequacies of each consecutive theory of recovery. In her Second Amended Complaint, for instance, plaintiff alleged that BSL’s screening procedures for saline dilution were inadequate, that Baxter “knowingly and intentionally, or with reckless disregard, sold plasma products which [were] not . . . adequately tested for the presence of viral contaminants to the United States of America,” and that Baxter “expressly and impliedly guaranteed” to the Government that Baxter “adequately and effectively tested for the presence of viral contaminants.” R. 70, ¶¶ 83, 84(k). When confronted with

the fact that Baxter never represented to *anyone* that it had “adequately and effectively tested” its plasma products (whatever that means), plaintiff switched horses, opposing summary judgment instead on the ground that Baxter had violated “applicable federal regulations” by failing to test all of its plasma samples using a Total Protein Test to screen for saline dilution. R. 91, pp. 44-50.

Now, on appeal, plaintiff’s theory again has “evolved.” Faced with the Government’s post-judgment concession that “relator did not identify any regulations that arguably required the defendant to institute TPT testing” (R. 118, at 8), and the district court’s finding that no regulations required the testing she advocates, plaintiff has all but abandoned her original claim that Baxter should have tested its plasma samples using the Total Protein Test. Instead, she now argues for the first time that “*regardless* of which specific saline-screening procedures were utilized” by BSL (Br. 18 (emphasis added)), Baxter falsely claimed to the Government that it tested “each unit” of plasma for HIV and Hepatitis “before pooling,” and that Baxter “knew it had not tested each unit of plasma before pooling and had not complied with applicable regulations in performing the testing procedures.” Br. 19.

Plaintiff’s latest iteration of her claim fails for at least three reasons. *First*, because she never raised it in opposition to Baxter’s summary judgment motion, she has waived it for purposes of appeal. *Second*, there is not a *shred of evidence* that Baxter ever failed to test *any* unit of plasma for HIV or Hepatitis. And *third*, plaintiff’s new argument should be rejected because it is nothing more than a thinly veiled challenge to the accuracy of BSL’s pre-1995 saline testing procedures — a scientific dispute that even plaintiff tacitly concedes (at 17-18) is beyond the scope of the FCA.

1. Plaintiff Waived Her “No Testing” Argument By Failing To Raise It In Opposition to Baxter’s Summary Judgment Motion.

In opposing Baxter’s summary judgment motion, plaintiff never once argued that Baxter failed to test any of its plasma samples for HIV or Hepatitis. Nor does her complaint allege that. In fact, it was *undisputed by plaintiff* in the district court that every plasma sample received at BSL is tested for HIV and Hepatitis (among other things) using FDA-approved tests. See 12(M) ¶ 33. Indeed, plaintiff actually admitted in her 12(N) Statement “that BSL performed tests for various viral markers including HIV, Hepatitis B and Hepatitis C during the relevant time period,” and “that the practice of Baxter was to reject an individual’s plasma if that individual tested positive for viral markers.” R. 93, at 11. It also is undisputed that BSL protocols required that every plasma sample be screened for possible saline dilution. 12(M) ¶¶ 50-52. And it also was uncontested that every viral marker test used by Baxter “has undergone a rigorous evaluation process and has been approved by a branch of the FDA specializing in such assays.” 12(M), ¶ 34. Even plaintiff’s purported expert, Dr. Statland, testified he had “no problem” with Baxter’s “hepatitis testing or their HIV testing.” R. 100, Ex. 32, p. 366. All that plaintiff disputed was “the *effectiveness and accuracy* of the test methods which were utilized at BSL during the relevant time period.” 12(N) ¶ 33 (emphasis added). It was not until plaintiff filed her motion to reconsider that she argued for the first time that Baxter somehow falsely claimed to have tested its units of plasma for HIV and Hepatitis. See R. 110, at 2-3.

It is well established, however, that arguments not presented in opposition to a summary judgment motion are waived for purposes of appeal.³ It also is settled that arguments first raised in a motion to reconsider the entry of summary judgment are waived for purposes of appeal.⁴ In the words of the Ninth Circuit, “[r]aising an issue for the first time in a motion to reconsider is not considered adequate preservation of the issue at a summary judgment stage.” *Intercontinental Travel Marketing, Inc. v. FDIC*, 45 F.3d 1278, 1286 (9th Cir. 1994). “It is not the purpose of allowing motions for reconsideration to enable a party to complete presenting his case after the court has ruled against him.” *Frietsch v. Refco, Inc.*, 56 F.3d 825, 828 (7th Cir. 1995) (argument waived for purposes of appeal).

In this case, having failed to properly argue below that Baxter falsely claimed to have tested “each unit” of its plasma for HIV and Hepatitis, plaintiff has waived that argument for appeal.

2. Plaintiff Offered No Evidence That Baxter Ever Failed To Test Any Unit Of Plasma For HIV or Hepatitis.

It is undisputed that BSL tests each and every plasma sample it receives for HIV and Hepatitis using FDA-approved viral marker tests. 12(M) ¶ 33. It also is undisputed that Baxter does not accept any unit of plasma unless a sample from that unit tests negative for all viral markers, including HIV antibody and Hepatitis B surface antigen. 12(M) ¶¶ 33, 35. If any sample tests positive for any of these viral markers,

³ See, e.g., *Trnka v. Local Union No. 688, United Auto., Aerospace & Agric. Implement Workers*, 30 F.3d 60, 62-63 (7th Cir. 1994); *Hayden v. La-Z-Boy Chair Co.*, 9 F.3d 617, 621 (7th Cir. 1993), *cert. denied*, 511 U.S. 1004 (1994); *Edward E. Gillen Co. v. City of Lake Forest*, 3 F.3d 192, 196 (7th Cir. 1993).

⁴ See, e.g., *Highlands Ins. Co. v. Lewis Rail Serv. Co.*, 10 F.3d 1247, 1251 (7th Cir. 1993); *Rudell v. Comprehensive Accounting Corp.*, 802 F.2d 926, 933 (7th Cir. 1986), *cert. denied*, 480 U.S. 507 (1987); *Publishers Resource, Inc. v. Walker-Davis Publications, Inc.*, 762 F.2d 557, 561 (7th Cir. 1985).

the entire unit is then discarded by Baxter. *Ibid.* It also is uncontested that all plasma samples received at BSL are inspected for possible saline dilution in at least two different departments at BSL (only one of which plaintiff worked in). 12(N) ¶¶ 28, 83; R. 100, Ex. 33 at 21-24, 29-32, 37, 50, 63-65.

Notwithstanding this uncontradicted evidence, plaintiff astonishingly argues now that Baxter supposedly sold plasma to the federal Government that never was tested for HIV or Hepatitis. This argument is patently false. Indeed, none of the evidence cited by plaintiff even remotely supports this claim. All that plaintiff cites is her own uncorroborated testimony about an alleged incident that occurred in May 1994, when a plasma sample was tested by BSL as valid, but later failed a total protein test after the original results were released. Br. 17. This testimony, however, proves nothing. First of all, there is no corroborating evidence that this alleged incident ever occurred. Moreover, there is no evidence that the unit of plasma was not retested after the sample supposedly failed the Total Protein Test, or that the unit of plasma in question was ever even used by Baxter. Plaintiff also never offered any evidence regarding the *extent* of the saline dilution in the incident she alleges, or whether the dilution was sufficient to produce inaccurate viral marker test results. She also offered no evidence as to the amount of saline dilution that could potentially yield false negative viral marker test results with the particular test kits used by BSL.⁵

⁵ Plaintiff asserts that “Baxter’s own Laboratory Director [Dr. Albertson] admitted that if the laboratory tests are performed on samples containing all or part saline, rather than all plasma, the testing methods of Baxter Screening Laboratory are ‘inappropriate, invalid and unacceptable.’” Br. 17. That is *not* what Dr. Albertson said. He only was asked *hypothetically* about whether valid test results could be obtained if the test samples were comprised “only” of saline. Dr. Albertson never testified (nor did any other witness) that a *partially* saline-diluted sample would produce inaccurate test results. As the district court noted, plaintiff offered no such evidence.

Without such evidence, however, plaintiff has no basis for claiming that *any* sample she suspected of being saline diluted was “not tested” for HIV or Hepatitis.

While plaintiff proclaims throughout her Brief that “the evidence is irrefutable that . . . colorless ‘plasma’ samples passing through Baxter Screening Laboratory were in fact merely saline,” there is no evidence to support her claim. Instead, all that plaintiff offers is mere speculation — and it is well-established that “[a] party must present more than mere speculation or conjecture to defeat a summary judgment motion.” *Sybron Transition Corp. v. Security Ins. Co.*, 107 F.3d 1250, 1255 (7th Cir. 1997).

The absurdity of plaintiff’s “no-testing” argument is especially apparent when one considers the undisputed fact that the viral tests performed at BSL are but a small part of Baxter’s extensive program of repeat viral marker testing and viral inactivation. Throughout her Brief, plaintiff tries myopically to focus this Court’s attention only on the viral marker tests performed at BSL “before pooling” — in other words, *before* the units of plasma are pooled for manufacturing of plasma derivatives. Plaintiff thus seeks to take the viral marker tests at BSL entirely out of context, and to ignore the rest of Baxter’s extensive and repetitive viral testing program, misleadingly insinuating that the testing at BSL was the only defense against the risk of viral transmission. In fact, it is undisputed that *after* plasma samples are screened at BSL, Baxter conducts repeat viral marker tests on its plasma pools using the *same* state-of-the-art viral marker tests used at BSL.⁶ 12(M) ¶ 39. It also is undisputed that during the processing of Baxter’s plasma derivatives,

⁶ Plaintiff cites her own testimony that supervisors allegedly told her not to test certain plasma samples using the Total Protein Test. Br. 20, 24. Without exception, however, the instances she cites

these plasma pools are then subjected to chemical and physical treatments to remove or inactivate *any* viruses that might remain, in addition to the earlier safety procedures. 12(M) ¶ 40. These procedures completely remove or inactivate the viruses screened at BSL, including HIV and Hepatitis. R. 75, Ex. 35, pp. 122-27. The net result of this multi-level process of viral testing and inactivation is a system of “redundant” safeguards against the ultimate risk of viral transmission. *Id.* at 172.

Given this unchallenged evidence, and the absence of any proof that Baxter’s viral screening system ever failed to function properly, plaintiff’s insinuation that BSL’s saline tests somehow posed a threat to the public safety is absurd. Indeed, even *after* plaintiff reported her allegations to the Government (*in camera*), the FDA conducted an inspection of BSL’s viral testing program, including its saline testing procedures. After completing the inspection, the FDA concluded “that under current regulations for EAR, testing laboratories and collection facilities *are not required* to report identified instances of saline contamination,” and that “current regulations [*do*] *not require* reporting of the saline contamination through either the EAR or MDR reporting systems.” 12(M) ¶¶ 59-60 (emphasis added). The FDA also “concluded that the inspection findings did not provide sufficient information to determine the existence of an imminent danger to health” and did not warrant any enforcement action against Baxter. *Ibid.* The FDA also never once suggested that Baxter made any false statements to the Government about its viral testing program, or had violated any federal laws or regulations. In short, plaintiff’s FCA claim is flatly contradicted by the undisputed facts.

(assuming they occurred) involved cases where samples *passed* BSL’s existing saline test protocols, but plaintiff nonetheless insisted that the samples be total protein tested because she still suspected them of being saline diluted. All that this testimony shows, however, is that plaintiff disagreed with the reliability of BSL’s existing saline testing procedures.

In her Brief, plaintiff cites a series of generally worded regulations, none of which make any reference to saline testing. But even if those regulations could be read to encompass saline-related testing, that still would be not enough to prove that Baxter made a “false claim” about its viral testing procedures for at least three reasons. *First*, as the district court held, it is a “well-established principle that the FCA is not a vehicle for regulatory compliance.” Op. 1044. Accord, *e.g.*, *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996) (holding that “[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit,” and that “[m]ere regulatory violations do not give rise to a viable FCA action”).

Second, Baxter’s contracts themselves confirm that Baxter never made any “false claims” to the Government about regulatory compliance. Indeed, the FSS Contract contained a specific regulatory enforcement mechanism which provided that the contract would remain in effect “unless the FDA makes an institutional decision that . . . violations of federal law are serious enough in their affect of the quality . . . that regulatory action to force involuntary correction is warranted.” Op. 1046. In this case, the FDA has *never* accused Baxter of violating federal law. Nor has the Government ever sought to invoke this contractual mechanism. Thus, as the district court noted, “[t]his provision contradicts any attempt by Luckey to demonstrate that regulatory compliance was a prerequisite to receiving payment from the government.” *Ibid.*

Finally, because *none* of the regulations cited by plaintiff say anything about saline testing, Baxter's failure to adopt the saline testing procedures she advocates cannot constitute a "false claim" as a matter of law. A statement only can constitute a "false claim" if it contains an "objective . . . definition" (*Tyger Constr. Co. v. United States*, 28 Fed. Cl. 35, 56 (Ct. Cl. 1993)), and is a "statement of fact that can be said to be either true or false." *Boisjoly*, 706 F. Supp. at 810. For this reason, "[i]mprecise statements or differences in interpretation growing out of a disputed legal question are not false under the FCA." *U.S. ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 986 (E.D. Wis. 1998). In this case, because federal law is totally silent on the subject of saline testing, BSL's failure to use a particular saline testing method cannot amount to a "false claim" of regulatory compliance as a matter of law.

In short, there is simply no evidence to support plaintiff's newly-minted argument that Baxter ever falsely claimed to have tested "each unit" of its plasma for HIV or Hepatitis. To the contrary, the uncontradicted evidence presented to the district court overwhelmingly confirms that the plasma therapies Baxter sold to the Government were tested in strict accordance with (and actually exceeded) the requirements of federal law. More importantly, no reasonable jury could possibly conclude that Baxter ever knowingly lied to the Government about its plasma testing.

3. Plaintiff's FCA Claim Improperly Raises A Scientific Dispute Over The Accuracy Of BSL's Pre-1995 Saline Testing Procedures.

Plaintiff does not challenge the district court's conclusion that the FCA is not a vehicle for resolving scientific disputes. Rather, she argues that "[t]his body of law cannot apply where under no reasonable interpretation could all donations of plasma be deemed tested." Br. 18 (emphasis in original) This attempted distinction, however, is merely a sham. When plaintiff argues that units of plasma were "not tested" by

Baxter for HIV or Hepatitis, what she *really* is arguing in disguise is that samples were tested for HIV and Hepatitis which were saline diluted, and that BSL's saline testing procedures were inadequate to detect the saline dilution. Br. 18. The *adequacy* of BSL's saline testing procedures, however, is precisely the scientific question that the district court properly held is beyond FCA scrutiny.

Regardless of how she tries to dress it up, plaintiff's FCA claim unavoidably requires an assessment of the scientific adequacy of BSL's pre-1995 saline testing procedures. Indeed, even plaintiff's Opening Brief concedes that to prove Baxter knowingly presented a false claim, she would first have to show that "Baxter knew its saline screening BSL's saline testing procedures prior to 1995 were 'unreliable.'" Br. 20. In fact, plaintiff's "expert," Bernard Statland, was designated specifically to testify that BSL's saline testing procedures were "unreliable" and failed to meet the applicable "standard of care." R. 94, Ex. M.⁷ As the district court held, however, "[e]ven if we were to accept Mr. Statland's testimony, the teachings of

⁷ Throughout her Brief, plaintiff relies on the testimony of her two purported experts below, Bernard Statland and Ralph Nash. Plaintiff fails to inform this Court, however, that the testimony of both "experts" was excluded by the district court as inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Op. 1048. The court held that Statland's testimony was inadmissible both "as an ultimate conclusion" and because he "was unable to point to any study requiring such testing, any facility--governmental or otherwise--that utilized [total protein] testing, nor was he aware of any article or study that had ever criticized Baxter's procedures for screening for saline-diluted samples." *Ibid.* As to Nash, who was offered by plaintiff to identify the "claims" that Baxter supposedly made to the Government, the court held that "[b]ecause the import of Mr. Nash's testimony represents nothing more than the drawing of inferences from the evidence, we find it is inadmissible." *Id.* at 1048 n.8. Plaintiff has not challenged these rulings, and thus has waived any claim to the admissibility of her "expert's" testimony. See, e.g., *United States v. Magana*, 118 F.3d 1173, 1198 n.15 (7th Cir. 1997) ("Arguments not raised in an opening brief are waived"); *Marie O. v. Edgar*, 131 F.3d 610, 614 n.7 (7th Cir. 1997) (same); *Walker v. Wallace Auto Sales, Inc.*, 155 F.3d 927, 930 n.4 (7th Cir. 1998) (same). Having waived any arguments concerning the admissibility of her experts' testimony, plaintiff cannot now rely on the testimony of those experts to attack the district court's summary judgment ruling.

[*United States ex rel. Milam v. Regents of Univ. of Cal.*, 912 F. Supp. 868 (D.Md.1995)] and [*United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420 (9th Cir. 1991)] demonstrate that the mere deviation from scientific norms is insufficient to support an FCA action.” Op. 1047-1048.

B. The District Court Also Properly Held That Plaintiff Did Not, and Could Not, Establish That Baxter Ever “Knowingly” Presented A False Claim.

Because the essential ingredient of any FCA claim is the “knowing” presentation of a “false claim,” it is well-established that “[f]or a *qui tam* action to survive summary judgment, the plaintiff must produce sufficient evidence to support an inference of knowing fraud.” *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815 (9th Cir. 1995), *cert. denied*, 516 U.S. 1043 (1996). Accord *United States ex rel. Stevens v. McGinnis, Inc.*, 1994 WL 799421, at *8 (S.D. Ohio 1994) (“Where Relator fails to produce evidence establishing the existence of a question of fact as to the central issue of whether a knowing submission of false information has been made . . . summary judgment in favor of [the defendant] is appropriate”). In this case, even if plaintiff’s criticisms of Baxter’s saline testing procedures were valid, her FCA claim still would fail because “there is no evidence indicating that Baxter lied about [those procedures] to the government.” Op. 1048.

To begin with, Baxter could not “knowingly” have “lied” about its saline testing procedures since “[t]here is no indication that the contracts or regulations required the type of testing advocated by Luckey, or subjected Baxter to penalties for failing to disclose its refusal to utilize this testing.” Op. 1048. Indeed, Baxter’s contracts with the federal Government say nothing about plasma testing. Likewise, the federal regulations cited by plaintiff are entirely silent on the subject. Even the FDA concluded in 1995 that Baxter

was under no obligation to report instances of saline dilution. 12(M) ¶¶ 59-60. Accordingly, it follows as a matter of law that Baxter could not “knowingly” have lied to the Government about its saline test procedures. Simply put, there was nothing for Baxter to “lie” about.

Under similar circumstances, courts consistently have rejected FCA claims as a matter of law. For instance, in *United States v. Napco International, Inc.*, 835 F. Supp. 493 (D. Minn. 1993), the Government alleged that the defendant falsely certified it had sold “American-made” goods to Turkey even though some of the materials used to make those goods were originally manufactured in the United States, but procured from abroad. Although the contractor certified to the Government “that the material supplied on this invoice is wholly of U.S.A. origin,” the court held that there was no FCA violation since the applicable regulations had “not directly addressed the issue of foreign procurement of materials originally manufactured in the United States.” *Id.* at 498.

Similarly, in *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1074 (9th Cir. 1998), the court of appeals held that an authorization of specialty pay which violated V.H.A. guidelines did not constitute a “knowing” false claim because “[a]bsent evidence that the defendants knew that the V.H.A. Guidelines on which they relied did not apply, or that the defendants were deliberately indifferent to or recklessly disregarding of the alleged inapplicability of those provisions, no False Claims Act liability can be found.” See also *United States ex rel. Milam v. Regents of the Univ. of California*, 912 F. Supp. 868, 884 (D. Md. 1995) (holding that defendant did not violate the FCA in failing to disclose certain information to the Government since disclosure “was not required by law” in the first place); *United States ex rel. Weinberger v. Equifax, Inc.*, 557 F.2d 456, 461 (5th Cir. 1977), *cert. denied*, 434 U.S. 1035

(1978) (holding that the defendant, a detective agency, did not violate the FCA in misrepresenting its eligibility to serve as a Government credit bureau since the Government had never clearly specified that “it would not employ detective agencies when it contracted for the work”). Although prominently cited by the district court, plaintiff’s Opening Brief notably makes no mention of these cases at all.

In this case, the notion that Baxter would somehow lie to the Government about saline dilution or the viral marker tests performed at BSL makes no sense, particularly since Baxter *repeatedly* tests its plasma for the presence of viral markers and also then subjects the plasma to viral inactivation procedures that are not even required by federal regulations. To be sure, 42 C.F.R. § 606.140 entitles the Government to expect that all plasma therapies sold to the Government will be tested for HIV and Hepatitis. But in this case, it is undisputed that *all* plasma derivatives sold by Baxter to the Government have been *repeatedly tested* for HIV, Hepatitis and other viral contaminants, and then subjected to viral inactivation procedures not even required by federal law. There also is not a shred of evidence that Baxter ever failed to detect or inactivate *any* viral contaminants in *any* plasma derivative sold to the Government.

In sum, as the district court held, and as the Government conceded in its *amicus curiae* brief to the district court, no reasonable jury could find that Baxter ever knowingly presented a false claim in connection with any of its sales of plasma therapies to the United States Government. Thus, as Judge Kocoras recently wrote, the district court’s decision in this case properly “echoes the holding [of this Court in] *Hindo*,” and “strikes an appropriate balance for evaluating the merits of *qui tam* claims.” *United States ex rel. Dihu v. IIT Research Institute*, 1998 WL 299390, *5 (N.D. Ill. 1998). The district court’s summary judgment in favor of Baxter as to plaintiff’s FCA claim should be affirmed.

III. THE DISTRICT COURT PROPERLY ENTERED SUMMARY JUDGMENT IN FAVOR OF BAXTER ON PLAINTIFF’S RETALIATION CLAIM.

Under 31 U.S.C. § 3730(h), plaintiff can only recover for retaliation if she establishes that (1) she engaged in activity protected by the FCA, *i.e.*, activity “in furtherance of an [FCA] action”; (2) Baxter was aware she was engaging in protected activity; and (3) her employment was terminated in retaliation for engaging in that activity. See *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994), *cert. denied*, 513 U.S. 1154 (1995); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996). The district court held that plaintiff failed to establish any of these requirements. Its decision should be affirmed.

A. Plaintiff Was Not Engaged In Any Protected FCA Conduct.

To recover for “retaliation” under the FCA, it is not enough for plaintiff to prove she was discharged for a reason she thinks is “unfair.” This is not a state law action for retaliatory discharge. Nor is it an employment discrimination case. The FCA provides only *one* prohibited reason for discharge—retaliation *for activity protected by the Act*. In this case, plaintiff can only recover for “retaliation” if she proves she was terminated specifically “because” she engaged in protected activity. *Robertson*, 32 F.3d at 951. Plaintiff’s efforts to modify BSL’s saline testing procedures were not “protected activity” for at least two reasons. *First*, as the district court held, plaintiff’s conduct was not aimed at exposing any fraud on the Government, and thus was not “in furtherance of an action” under the FCA:

In the case at bar, Luckey’s conduct was consistently directed at convincing Baxter to upgrade its procedures to include testing for saline-diluted samples. This is evidenced by the proposals Luckey submitted and her complaints to her supervisors and Baxter management. While Luckey was concerned about Baxter’s testing procedures and its

discipline of her, there is no evidence that Luckey's activities were related to exposing a fraud upon the government.

Op. 1052. Accord *Moor-Jankowski v. Board of Trustees of New York Univ.*, 1998 WL 474084, *10 (S.D.N.Y. 1998) (no protected activity alleged where plaintiffs did not claim they "took any steps directed at exposing a fraud upon the government") (citing decision below).

Plaintiff argues that she was engaged in protected activity because her complaints about saline testing could potentially have provided the basis of an FCA action, and that in her own mind, she was "motivated by her desire to protect the ultimate consumer and to expose the fraud perpetrated by Baxter."

Br. 23. That, even if true, is not enough. As the district court held, activities are protected by the FCA only if they are aimed at "exposing a fraud upon the government." Op. 1050.⁸

In her Brief, plaintiff mischaracterizes the district court's decision, arguing that "there is no requirement within the FCA that the plaintiff must have known at the time of her investigation that it could lead to a claim under the FCA." Br. 22. That is not, however, what the district court held. Indeed, to claim the protections of the FCA, a plaintiff need not know that her investigation could lead to "a claim under the FCA." Instead, as the district court explained, what the statute requires is that the plaintiff's investigation be targeted *explicitly* at what the FCA prohibits, *i.e.*, "fraud" and "false claims." That is where plaintiff's case fails, for there is no evidence that she *ever* complained of fraud or false claims.

⁸ In her Brief, plaintiff makes the statement, without any citations to the record, that "[s]he informed [her co-workers] of the misrepresentation that Baxter was making regarding the testing of its products and potential legal ramifications." Br. 28. This statement is not only devoid of any support in the record, but is also *completely false*. There is no record evidence that plaintiff *ever* complained to *anyone* at Baxter about any "misrepresentation that Baxter was making regarding the testing of its products and potential legal ramifications."

Plaintiff's efforts to modify BSL's saline testing protocols also were not protected by the FCA since they fell within the scope of her duties as a Baxter employee. Nowhere in her Opening Brief does plaintiff deny that. *All* Baxter employees are responsible "for reporting incidents which might have an effect on test results." 12(M) ¶ 66. Even in her self-appraisals, plaintiff noted that as part of her job she "participated in the updating and revision of the currently released Total Protein SOPs," would "identify problems and determine the corrective actions required in ALT and [Total Protein] processing," and "proactively suggested improvements for the laboratory to increase effectiveness and safety." See Ex. 29 to 12(M). In a résumé submitted to a prospective employer *after* her termination, plaintiff described her job at BSL as including "all aspects of equipment operation, maintenance and troubleshooting . . . and the writing and revision of SOPs." She also cited among her "Specific Contributions" "[a] project involved in saline dilution of samples. I submitted a protocol." See Ex. 27 to 12(M).

Under similar circumstances, courts consistently have held that activities within the scope of a plaintiff's employment are not protected by the FCA. See, *e.g.*, *Robertson*, 32 F.3d at 951 (plaintiff did not engage in protected activity since "the record contains no evidence that [relator] expressed any concerns to his superiors other than those typically raised as part of a contract administrator's job"); *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514 (10th Cir. 1996) (relator's complaints about Medicaid non-compliance did not constitute protected activity since Medicaid compliance was part of relator's duties, and because "the monitoring and reporting activities described in plaintiff's complaint were exactly those activities plaintiff was required to undertake in fulfillment of her job duties");

X Corp. v. Doe, 816 F. Supp. 1086, 1095-96 (E.D. Va. 1993) (inside counsel’s warnings of potential qui tam liability did not constitute protected activity since they were part of his job responsibilities). In short, plaintiff’s efforts to modify BSL’s testing procedures did not constitute protected activity as a matter of law.

B. Baxter Could Not Have Retaliated Against Plaintiff Since Baxter Was Unaware That She Ever Engaged In Allegedly Protected Activity.

Even if plaintiff could prove that she engaged in protected activity, her retaliation claim still would fail given the undisputed fact that Baxter was totally unaware that she engaged in such activity.

Since a plaintiff can prove “retaliation” under the FCA only if she proves that she was terminated “because” she engaged in activity protected by the FCA, “[t]he legislative history [of § 3730(h)] makes clear that a ‘whistleblower must show the employer had knowledge the employee engaged in ‘protected activity.’” *Robertson*, 32 F.3d at 951 (quoting S. Rep. No. 345, 99th Cong., 2d Sess. 35 (1986) (reprinted in 1986 U.S.C.C.A.N. 5266, 5300)). For precisely this reason, § 3730(h) has been carefully limited only to cases where “the employee *told the employer* that she was concerned about the company *defrauding the government.*” *Robertson*, 32 F.3d at 951 (emphasis added).⁹

For instance, in *Robertson*, the discharged employee “admitted that he never used the terms ‘illegal,’ ‘unlawful,’ or ‘qui tam action’ in characterizing his concerns” about the employer’s conduct. 32 F.3d at 951. The employee’s supervisors also “testified that they had no knowledge of any activity by *Robertson* in furtherance of a qui tam investigation. Moreover, [the employee] conceded that he kept his

⁹ Plaintiff accuses the district court of requiring her to “establish Baxter’s knowledge that she was investigating an FCA action.” Br. 24-26. The district court required no such thing. All the court required was proof that Baxter was aware she engaged in protected activity, i.e., that she was investigating fraud or false claims to the Government — nothing more. Op. 1050-1051.

qui tam intentions to himself.” *Id.* at 952. On these facts, the Fifth Circuit held there could be no retaliation under § 3730(h) since the employee

failed to present sufficient evidence to support a finding that [defendant] was aware that his investigations were in furtherance of a qui tam action. Without such knowledge, [defendant] could not possess the retaliatory intent necessary to establish a violation of the whistleblower provision of the False Claims Act. The district court therefore properly granted [defendant’s] motion for judgment as a matter of law on [relator’s] retaliation claim.

Ibid. Similarly, in *Ramseyer*, 90 F.3d at 1522, the Tenth Circuit affirmed summary judgment for the defendant where the “plaintiff took no steps to put defendants on notice that she was acting ‘in furtherance of’ an FCA action — *e.g.*, that ‘she was furthering or intending to further an FCA action rather than merely warning the defendants of the consequences of their conduct.’” 90 F.3d at 1522. Accord, *e.g.*, *Hopper*, 91 F.3d at 1269 (rejecting retaliation claim where the relator never gave any indication she was investigating possible fraud by employer).

In addition to the fact that plaintiff’s conduct was within the scope of her employment, it also is undisputed that when she discussed the subject of saline dilution with other Baxter employees, she *never* indicated she was engaged in *any* investigation into possible fraud or false claims to the Government. 12(M) ¶¶ 72-77. Plaintiff also offered no evidence to counter the testimony unequivocally establishing that Baxter had no knowledge of any investigation by plaintiff into fraud or false claims.¹⁰ Indeed, because Baxter’s sales of plasma derivatives to the Government comprised only a small fraction of its overall sales, Baxter

¹⁰ Since plaintiff failed to offer any affidavits or other evidence to counter Baxter’s affidavit testimony, the testimony offered by Baxter must be accepted as true. See, *e.g.*, *Curtis v. Bembenek*, 48 F.3d 281, 286 (7th Cir. 1995) (“unless the nonmoving party counters with affidavits of his or her own, the facts asserted in the movant’s affidavits will be treated as true”).

had no reason to assume that plaintiff's efforts to modify BSL's saline testing procedures had anything to do with claims by Baxter to the Government, particularly since she had no involvement in Baxter's Government sales, and had no way of even knowing what claims, if any, Baxter was making about its plasma therapies.

In a last-ditch attempt to show that Baxter had the sort of knowledge required by the FCA, plaintiff points to testimony by Julie Wetterman, a BSL supervisor, that the alleged problem of saline dilution "involved regulatory risks, regulatory exposure and liability." Br. 26. It is well-established, however, that complaints of regulatory non-compliance do not constitute protected activity under the FCA. As the D.C. Circuit recently held in *United States ex rel. Yesudian v. Howard University*, 153 F.3d 731, 740 (D.C. Cir. 1998), "[m]ere dissatisfaction with one's treatment on the job is not, of course, enough. *Nor is an employee's investigation of nothing more than his employer's non-compliance with federal or state regulations.*" (Emphasis added). In any event, as a review of her testimony will confirm, Wetterman *never* testified that she believed plaintiff's concerns about saline dilution involved any possible "regulatory exposure" or "liability" for BSL.

Plaintiff also cites the deposition of Dan Garrett, one of her co-workers, in which he testified that plaintiff threatened "to take everybody to court," and that she had threatened litigation before. See Br. 26. Garrett's testimony, however, is taken completely out of context. As the district court found, Garrett merely testified that plaintiff had told him "she was going to file an *age discrimination* suit." *Id.* at 138 (emphasis added). See also Op. 1039. Plaintiff also never offered any evidence to counter Garrett's unequivocal testimony (R. 75, Ex. 25), that plaintiff *never* mentioned that she was investigating any fraud or false claims

by Baxter. In short, plaintiff offered no evidence from which a jury could reasonably conclude that Baxter knew she had engaged in any protected activity.

In her Brief, plaintiff relies heavily on the D.C. Circuit's recent decision in *Yesudian*. If anything, however, *Yesudian* only further confirms that plaintiff's retaliation claim fails as a matter of law. In *Yesudian*, the court held that a plaintiff need not know her investigation could lead to the filing of a *qui tam* suit, and that "there is no requirement that a plaintiff tell, or threaten, his employer that he will report his allegations to the government—or to anyone outside of the employing institution." 153 F.3d at 743. The district court below did not hold otherwise. In fact, the D.C. Circuit's opinion is fully consistent with the district court's decision. Like the district court, the D.C. Circuit held that "[t]he employee must show that: (a) 'the employer had knowledge the employee was engaged in protected activity'; and (b) 'the retaliation was motivated, at least in part, by the employee's engaging in [that] protected activity.'" *Id.* at 736 (citations omitted). The court of appeals also went on to explain that:

the kind of knowledge the defendant must have mirrors the kind of activity in which the plaintiff must be engaged. What defendant must know is that plaintiff is engaged in protected activity as defined above — that is, in activity that reasonably could lead to a False Claims Act case. As already discussed, such activity includes the investigation of "false or fraudulent claims" made to federal grantees like Howard.

Id. at 742. The D.C. Circuit then went out of its way to emphasize that the cases relied on by the district court below — including *Hopper*, *Robertson* and *Ramseyer* — were not "to the contrary." *Id.* at 744. In sharp contrast to those cases, the D.C. Circuit explained that "the nature of *Yesudian*'s charges *could not have been mistaken for a complaint about mere regulatory compliance*. He asserted a *classic false*

claim by contending that Parker [his supervisor] was ‘falsifying’ time and attendance records so that his assistant would be paid for work she did not do.” 153 F.3d at 744-45 (emphasis added).

Unlike *Yesudian*, plaintiff here *never* asserted a “classic false claim,” *i.e.*, she never accused Baxter of defrauding anyone or submitting false claims to the Government. Instead, her professed concerns all were couched in terms of promoting product safety and modifying Baxter’s testing procedures — issues having no intrinsic connection to any possible fraud. Although she certainly raised issues about saline dilution with co-workers and supervisors, those issues always were stated in terms of seeking to modify Baxter’s saline-related testing procedures — *never* in terms of any lies to the Government to procure payment of a claim. 12(M) ¶¶ 53-55. For instance, plaintiff submitted proposed modifications to Baxter’s saline-related testing protocols, and stated that such modifications would fully have resolved her concerns. As she stated in response to her 1995 performance appraisal (Ex. 29 to 12(M) Stmt.):

The visible improvements that have taken place within the last year in the issue of saline contamination are due directly to my unceasing efforts to stop the approval of essentially untested plasma for use in plasma products. *It is unfortunately not totally corrected, although I have suggested detailed means for accomplishing this* (Protocol BSL-PR-094-XX). (Emphasis added).

In sum, the district court was undeniably correct in holding that no reasonable jury could find that Baxter was on notice that plaintiff was engaged in protected activity. Plaintiff’s retaliation claim thus fails as a matter of law.

C. Plaintiff Offered No Evidence Showing Her Termination Was Pretextual.

As recounted by the district court in great detail (Op. 1038-1041), Baxter offered extensive evidence below establishing that plaintiff’s termination resulted from the fact that, long before she ever

complained about saline dilution, plaintiff's co-workers repeatedly complained to Baxter management of ethnic slurs, harassment, offensive conduct, and demeaning comments about other employees, and ultimately of threats that she would "get rid of" various co-workers and supervisors — threats that led Baxter management genuinely to fear for the safety and well-being of its employees. Notably, plaintiff never offered *any* affidavit testimony to counter this evidence. Even now, all that she offers is her unadorned speculation of "a growing concern of plaintiff's supervisors at Baxter ... that plaintiff was getting too close to the truth and she was beginning to voice that truth to other employees." Br. 27. What is missing from plaintiff's brief, however, is any *evidence* to support that tale.

While plaintiff may dispute that she threatened, harassed or acted offensively toward her co-workers, she "cannot ignore the concrete evidence that her co-workers did in fact complain about her." Op. 1057. Indeed, plaintiff presented literally nothing to support her claim of retaliation other than her own subjective beliefs, which plainly "are insufficient evidence of Baxter's unlawful intent." *Ibid.* The district court thus was undoubtedly correct in holding "that Baxter has presented sufficient evidence to show that its motives for terminating Luckey were neither improper nor pretextual." *Ibid.* In any event, because the undisputed facts decisively confirm that plaintiff was *not* terminated because of any protected activity by her, the district court's summary judgment on plaintiff's retaliatory discharge claim should be affirmed.

IV. The District Court's Award of Costs Should Be Affirmed.

Baxter submitted a bill of costs to the district court pursuant to Fed. R. Civ. P. 54(d), totaling \$20,013.48. Plaintiff did not challenge any of the cost items (mostly deposition transcript expenses) contained in the Bill of Costs. Instead, she merely argued that "1. Plaintiff's action was reasonable and

brought in good faith. 2. Plaintiff's action involved complex issues concerning the testing and manufacturing of plasma products. 3. Awarding costs to Defendant would dissuade whistle blowers such as plaintiff in this case from bringing reasonable actions for the common good if they risk payment of substantial trial costs for defeat." R. 122. The district court rejected plaintiff's arguments, holding that "[t]he arguments made by plaintiff do not provide adequate grounds to justify a denial of costs. None of the three reasons raised in plaintiff's pleadings relates to any inability to pay costs or any impropriety by Baxter. The reasons that plaintiff offers relating to her alleged good faith and the nature of a qui tam whistle blower action, are insufficient as a matter of law to justify a denial of costs." App. A-56

On appeal, plaintiff argues that the district court should not have awarded costs because her weak financial condition somehow precludes such an award. Br. 30-31. But plaintiff never presented that argument in opposing Baxter's bill of costs. Instead, she raised that argument for the first time in seeking reconsideration. As explained above (at 23-24), however, arguments raised for the first time in a motion to reconsider are waived for purposes of appeal. Moreover, it is well established that in order to warrant reconsideration pursuant to Fed. R. Civ. P. 59(e), the movant "must clearly establish either a manifest error of law or fact or must present newly-discovered evidence." *LB Credit Corp. v. Resolution Trust Corp.*, 49 F.3d 1263, 1267 (7th Cir. 1995). Movants cannot "use a Rule 59 motion to present new theories, . . . or submit previously available evidence." *King v. Cooke*, 26 F.3d 720, 726 (7th Cir. 1994), *cert. denied*, 514 U.S. 1023 (1995).

In this case, plaintiff's motion to reconsider did not even *allege*, much less establish, that the district court committed any manifest error of fact or law in awarding Baxter its costs. Nor did the motion purport

to present the court with any previously unavailable evidence. Accordingly, the district court unremarkably denied plaintiff's motion on the ground that "plaintiffs' motion has not shown any manifest error of law or fact or any newly discovered evidence. Plaintiff has improperly sought to submit facts which were known to plaintiff prior to the court's ruling to reargue the court's ruling. This type of piecemeal litigation is improper." R. 138. Plaintiff's Opening Brief notably offers no challenge to this denial of her motion to reconsider. The district court's cost award should therefore be affirmed.

CONCLUSION

The judgment of the district court dated April 20, 1998 (as amended on June 24, 1998) and its cost award of July 30, 1998, should be affirmed.

Javier H. Rubinstein
Bettina Getz
Jeffrey W. Sarles
MAYER, BROWN & PLATT
190 South LaSalle Street
Chicago, Illinois 60603
(312) 782-0600

*Counsel for Defendant-Appellee
Baxter Healthcare Corporation*

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