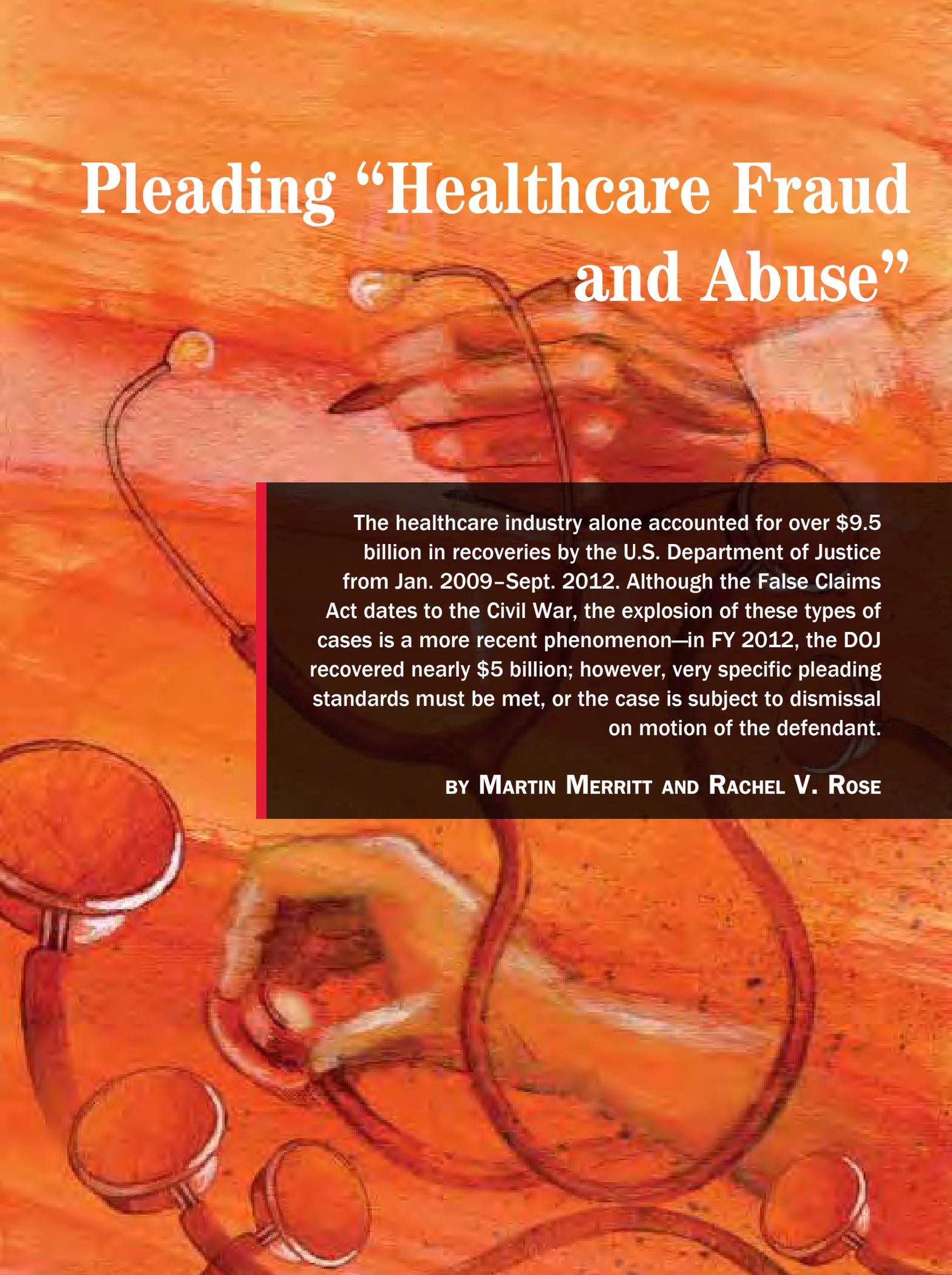


# Pleading “Healthcare Fraud and Abuse”

The background of the entire page is a textured, painterly illustration in shades of orange, red, and brown. It depicts a hand holding a stethoscope, with the chest piece resting on a surface. The style is expressive and somewhat abstract, with visible brushstrokes and a warm, glowing light source from the upper left.

The healthcare industry alone accounted for over \$9.5 billion in recoveries by the U.S. Department of Justice from Jan. 2009–Sept. 2012. Although the False Claims Act dates to the Civil War, the explosion of these types of cases is a more recent phenomenon—in FY 2012, the DOJ recovered nearly \$5 billion; however, very specific pleading standards must be met, or the case is subject to dismissal on motion of the defendant.

BY **MARTIN MERRITT AND RACHEL V. ROSE**

# Under the False Claims Act

## *Surviving Rule 9(b) and Rule 12(b)(6) Motions to Dismiss*

The False Claims Act (FCA)<sup>1</sup> is the government's primary antifraud litigation statute.<sup>2</sup> The healthcare industry alone accounted for over \$9.5 billion in recoveries by the U.S. Department of Justice (DOJ) from January 2009 through September 2012.<sup>3</sup> Although the FCA dates to the Civil War, the explosion of these types of cases is a more recent phenomenon.<sup>4</sup> In the early 1990s, the Office of the Inspector General (OIG) began cracking down on Stark Law and Anti-Kickback Statute violations with greater frequency.<sup>5</sup> Actions by private persons, which are authorized under the FCA to file *qui tam* (whistleblower) cases under 31 U.S.C. § 3730, also began to grow to the point that whistleblower actions now account for the lion's share of FCA litigation.<sup>6</sup> As a December 2012 DOJ press release indicated, the recoveries can be astronomical—in fiscal year (FY) 2012, the DOJ recovered nearly \$5 billion<sup>7</sup>; however, very specific pleading standards must be met, or the case is subject to dismissal on motion of the defendant.

The FCA is a *litigation* statute, which is distinct from other fraud and abuse statutes such as the Civil Monetary Penalties Law in two important ways: (1) FCA cases will always be pros-

ecuted in federal court, where the express language of a statute will be strictly construed<sup>8</sup> in accordance with the rules of civil procedure<sup>9</sup>; and (2) unlike the four other major Medicare fraud and abuse statutes (Stark Law, the Anti-Kickback Statute, Civil Monetary Penalties Law (CMPL), and the Exclusionary Statute), Congress did not “enable” the so-called alphabet agencies (e.g., the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), DOJ, and the OIG) to adopt U.S. *Code of Federal Regulations* concerning the FCA.<sup>10</sup> Although the FCA appears quite similar to the CMPL, it is not subject to administrative modification in the *Code of Federal Regulations* or the *Federal Register*.<sup>11</sup> Interpretation of the elements of the FCA, if any, must come from the courts, or amendments to the Act by Congress. For example, the complete revision of the public “disclosure bar” under 31 U.S.C. § 3730(e)(4)<sup>12</sup> does not address “retroactivity.” If Congress had enabled administrative rulemaking for the FCA, “retroactivity” could be addressed without additional acts of Congress. Unlike the other four major fraud and abuse statutes, modifications to the FCA are few and far between. It took 20 years of “misguided judicial decisions”<sup>13</sup> before Congress finally acted in the Fraud Enforcement and Recovery Act (FERA) of 2009 in which Congress amended multiple FCA provisions, including:

- Imposing liability for knowingly or recklessly retaining overpayments from the government, regardless of the presentment of a false statement, thereby expanding liability for “reverse” false claims;
- Creating liability for claims presented to entities administering government funds;
- Enabling the DOJ to conduct longer investigations by allowing the government's complaint to relate back to the filing of the relator's complaint; and
- Expanding the anti-retaliation provisions to also cover contractors and agents.<sup>14</sup>

Hence, initiation of FCA enforcement action is left to *qui*

*tam* relators and the DOJ acting under the executive branch. Interpretation of what Congress intended, if any, is left to the courts. Revision of the express wording of the text of the FCA is a power granted exclusively to Congress by the U.S. Constitution.

### Meeting the Pleading Threshold

The FCA is concerned with “protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money.” *United States ex rel. Vigil v. Nemet, Inc.*<sup>15</sup> “Without sufficient allegations of materially false claims, an FCA complaint fails to state a claim on which relief can be granted.”<sup>16</sup> The focus is thus on the alleged false claims, as the FCA “attaches liability, not to the underlying fraudulent activity, but to the ‘claim for payment.’”<sup>17</sup>

As a Pennsylvania U.S. district court recently observed:

*Before FERA, § 3729(a)(2) stated that liability attaches when a defendant “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(2) (1994) (emphasis added). The post-FERA version of the provision (now § 3729(a)(1)(B)) states that liability exists for any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B) (emphasis added). The new version broadens the intent required to trigger liability, because it creates the possibility of FCA liability even where a false statement or records is not made “for the purpose” of getting a false or fraudulent claim paid or approved by the federal government.”<sup>18</sup>*

Therefore, in order to establish a prima facie FCA claim under § 3729(a)(1), a plaintiff “must prove that ‘(1) defendant presented or caused to be presented to an agent of the United States a claim for payment’; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.”<sup>19</sup> Claims have been classified into the following categories: factually false/worthless services theory; legally false; and legally false by implied certification.<sup>20</sup> These categories are reflective of the FCA’s legislative history, whereby: “A false claim may take many forms, the most common being a claim for goods or services not provided or provided in violation of *contract terms, specification, statute or regulation.*”<sup>21</sup> Factually false claims occur when the submission for payment is based on goods not delivered or services not performed.<sup>22</sup> The U.S. Court of Appeals for the Third Circuit, in *United States ex rel. Wilkins v. United Health Group, Inc.*, acting in accordance with other circuits, recognized and delineated between express and implied legally false claims.<sup>23</sup>

Under the “express false certification” [legally false] theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to government payment in connection with the claim for payment of federal funds. Additionally, there is an “implied false certification” theory which occurs “when a claimant seeks and makes a claim for payment from the government without disclosing that it violated regulations that affected its eligibility for payment.” Basically indicating, “it[s] premised ‘on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules

that are a precondition to payment.”<sup>24</sup>

A fundamental example of a FCA cause of action under the legally false/express false certification theory is a claim submitted to the Centers for Medicare and Medicaid for payment with the terms and conditions defined by 42 C.F.R. § 424.510(d)(3). As a requirement of enrolling in Medicare and or Medicaid, providers are required to sign an enrollment application (Provider Agreement). Here, the signer, “attests that the information is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.”<sup>25</sup> Recently, the U.S. Court of Appeals for the First Circuit Court in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*,<sup>26</sup> and *United States ex rel. Westmoreland v. Amgen*,<sup>27</sup> provided express substantiation for upholding “legally false” claims and disregarding the distinction between the categories of “express” and “implied,” at least in the context of the Provider Agreement terms.

Still, regardless of the theory the claim is submitted under, Rule 9(b) heightened requirements must be met. Motions to Dismiss under Rule 12(b)(6) for failing to meet the heightened pleading requirements of Rule 9(b) in the FCA cases normally attack the pleading as deficient to state a claim under 31 U.S.C. § 3729.<sup>28</sup> This section lists the possible causes of action—the “seven deadly sins,” or the seven things a provider can do to get in trouble. Only four of these *normally* pertain to healthcare: (1) presenting a false or fraudulent claim; (2) using a false statement or record; (3) conspiracy; and (4) the reverse false claim.<sup>29</sup> Procedurally, the defense will challenge the pleading of causes of action under 31 U.S.C. § 3729 by way of Rules 9(b) and 12(b)(6) motions—which do not seek to establish the defendant “didn’t do it,” but instead, that the plaintiff has incorrectly pled the case.

Pleadings under the FCA must conform to the heightened pleading standard of Rule 9(b), and the pleading standard of Rule 12(b)(6) as announced by the U.S. Supreme Court in *Iqbal* and *Twombly*. Rule 9(b) requires specific allegations as to “who, what, when, where, and how” the Act has been violated. *Iqbal* and *Twombly* essentially supplant Rule 8’s “short, plain statement of the case” with a more rigorous requirement that the facts pled must allege a plausible cause of action.<sup>30</sup> Motions to Dismiss under Rules 9(b) and 12(b)(6) are normally filed together. It is rare to see one without the other.

### Rule 9(b) Motions

It is well established that the heightened pleading requirements of Rule 9(b) applies to claims brought under the FCA.<sup>31</sup> This requires pleading what is familiar to journalism 101 students as “who, what, when, where, why, and how.”<sup>32</sup> Although Rule 9(b) may be satisfied where “some questions remain unanswered [but] the complaint as a whole is sufficiently particular to pass muster under the FCA.”<sup>33</sup> As the U.S. Court of Appeals for the Fifth Circuit stated, Rule 9(b) requires “that a plaintiff set forth the ‘who, what, when, where, and how’ of the alleged fraud.” *United States ex rel. Steury v. Cardinal Health, Inc.*<sup>34</sup> “Because the linchpin of an FCA claim is a false claim, the ‘time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby’ must be stated in a complaint alleging violation of the FCA in order to satisfy Rule 9(b).” *United States ex rel. Rafizadeh v. Continental Common, Inc.*,<sup>35</sup> (internal quotations and citation omitted). While fraud must

be pled with particularity, it “may be pleaded without long or highly detailed particularity.”<sup>36</sup>

Given the “essentially punitive” nature of the damages available in FCA cases, “[t]he Supreme Court has cautioned that the False Claims Act was not designed to punish every type of fraud committed upon the government.”<sup>37</sup> The Act “imposes liability not for defrauding the government generally; it instead only prohibits a narrow species of fraudulent activity: ‘present[ing], or caus[ing] to be presented ... a false or fraudulent claim for payment or approval.’”<sup>38</sup> “Therefore, a central question in False Claims Act cases is whether the defendant ever presented a ‘false or fraudulent claim’ to the government.”<sup>39</sup> In the oft-quoted parlance of the U.S. Court of Appeals for the Eleventh Circuit, “[t]he submission of a [false] claim is ... the *sine qua non* of a False Claims Act violation.”<sup>40</sup>

Strict application of Rule 9(b) often poses a significant obstacle to healthcare *qui tam* whistleblowers who possess knowledge of an allegedly unlawful scheme, but cannot name a particular patient or health claim involved in the scheme.<sup>41</sup> Rule 9(b) requires the complaint to provide, among other fraud specifics, “details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, [and] the amount of money charged to the government.”<sup>42</sup> The rationale was explained by the U.S. Court of Appeals for the Eighth Circuit in this way: “The [FCA] is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward, and is not intended to create windfalls for people with secondhand knowledge of the wrongdoing.”<sup>43</sup> It is generally insufficient to plead a description of a kickback scheme, and then conclude, “fraud must be occurring.” In *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*,<sup>44</sup> the Eleventh Circuit concluded that allegations regarding a detailed scheme to defraud, absent specific allegations regarding the actual presentment<sup>45</sup> of false claims, fail to satisfy Rule 9(b)’s particularity requirement.

Nevertheless, the Fifth Circuit has also stated that the “time, place, contents, and identity standard is not a straitjacket for Rule 9(b),” concluding that Rule 9(b) is context-specific and flexible.<sup>46</sup> The Fifth Circuit recently noted that the standard for stating a claim for relief with particularity is lower in the FCA context than it is in the securities or common-law fraud contexts.<sup>47</sup>

As it now stands, a relator must plead as many facts as he or she is able, including details of the scheme, and either details of actual claims submitted, or facts providing sufficient indicia of reliability which reveal how, during the period the relator was employed, the relator came to know of facts, and which tend to establish the relator has personal knowledge of the submission of claims.

### **Rule 12(b)(6) *Iqbal/Twombly* Motions**

Given the applicability of the already heightened pleading requirement under Rule 9(b) to FCA cases, *Iqbal/Twombly*’s new emphasis on pleading facts seems to present little additional burden in pleading FCA cases. This notwithstanding, motions to dismiss in FCA cases almost always include both a Rule 9(b) and Rule 12(b)(6) motion. In order to satisfy Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which

relief can be granted. Fed. R. Civ. P. 12(b)(6).

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court recognized that “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555. Following these basic dictates, the Supreme Court, in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), subsequently defined a two-pronged approach to a court’s review of a motion to dismiss:

“First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* at 678. Thus, although “Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era ... it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” *Id.* at 678-79.

Second, the Supreme Court emphasized, “only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 679. “Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. *Id.*

If the Rule 9(b) and/or Rule 12(b)(6) motion(s) are denied, then the court has effectively handed the “keys to discovery” over to the parties.<sup>48</sup>

**Given the “essentially punitive” nature of the damages available in FCA cases, “[t]he Supreme Court has cautioned that the False Claims Act was not designed to punish every type of fraud committed upon the government.”**

### **Rule 15 Motions to Amend**

When a motion to dismiss is granted the trial court may, (and usually will) state whether the dismissal is with, or without prejudice to refiling, and if leave to amend is granted, how long the plaintiff has to file an amended pleading under Fed. R. Civ. P. Rule 15. If leave to amend is provided, additional motions to dismiss under Rules 9(b) and 12(b)(6) will likely follow.<sup>49</sup> Leave to amend is not automatic. Specifically, Rule 15(a) provides that leave to amend shall be freely given “when justice so requires.” A district court has the discretion to consider numerous factors in evaluating whether

to allow amendment, including the futility of amending, the party's repeated failure to cure deficiencies by previous amendments, undue delay, or bad faith.<sup>50</sup>

Because motions to dismiss are normally granted without a hearing, it is often difficult to know exactly why, or as to which element, the court found the complaint to be defective. Fighting blindly, relator's counsel may mistakenly redouble efforts to state facts already sufficiently pled. At least one court has held it is possible to say *too much, too incomprehensibly*. In *United States ex rel. Ellis v. City of Minneapolis*, No. 11-CV-0416 (D. Minn. 2012),<sup>51</sup> the trial court refused an amended complaint in an FCA for lack of compliance with Rule 8's "short, plain statement" requirement. "[A] complaint must include 'a short and plain statement' of the claim showing that the pleader is entitled to relief .... The words 'short and plain' are themselves short and plain, and they mean what they say: A complaint must be concise, and it must be clear."<sup>52</sup>

## Conclusion

It is well established that Fed. R. Civ. P. 8(a)(2), which requires a short, plain statement of jurisdiction, the claim, and demand for relief sought, is an insufficient threshold for an FCA cause of action. In addition to these basic *Iqbal/Twombly* requirements, as the courts have demonstrated, it is imperative that the relator, whether an individual or the government, meet the heightened pleading requirements under Rule 9(b). In short, a pleading as to "whom, what, when, where, why, and how," must include plausible factual allegations as to each link of the 31 U.S.C. § 3729 chain. This usually requires pleading "presentment" and/or "materiality" of specific statements or records involved, or pleading sufficient indicia of reliability that the pleader has knowledge that certain claims were presented. The exact pleading requirement often depends upon which version of the FCA applied when the violation occurred. Only then will a plaintiff's allegations survive a defendant's motion to dismiss under Rule 12(b). Providing specific information to clear the Rule 9(b) hurdle, as courts have found, meets the burden of stating a claim upon which relief can be granted in accordance with the FCA. ☉

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## Endnotes

<sup>1</sup>31 U.S.C. § 3729-2733.

<sup>2</sup>*Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989); *United States ex rel. Marcy v. Rowan Cos.*, 520 F.3d 384, 388 (5th Cir. 2008).

<sup>3</sup>OFFICE OF PUBLIC AFFAIRS, U.S. DOJ, JUSTICE DEPARTMENT RECOVERS NEARLY \$5 BILLION IN FALSE CLAIMS ACT CASES IN FISCAL YEAR 2012 (Dec. 4, 2012), available at [www.justice.gov](http://www.justice.gov) [hereinafter JUSTICE DEPARTMENT RECOVERS NEARLY \$5 BILLION IN FALSE CLAIMS ACT CASES IN FISCAL YEAR 2012].

<sup>4</sup>The FCA was of little import to the healthcare industry until the passage in 1965 of Titles XVII and XIX of the Social Security Act, when the government became an insurer, and private healthcare providers became government contractors in the care of the elderly and disabled poor. Until the 1986 Amendments, the FCA contained impediments which were difficult to overcome. The 1986 Amendments revitalized the Act by significantly expanding the ability of whistleblowers to receive monetary rewards for prosecuting *qui tam* actions against persons who had defrauded the federal government. In 2009, Congress passed the Fraud Enforcement and Recovery Act (FERA), the first significant amendment of the FCA since 1986. Not surprisingly, after a generation of litigation under the 1986 Amendments, Congress determined that revisions were necessary to improve the operation of the FCA. Congress displayed particular concern about misguided court decisions which, in the opinion of the Senate Judiciary Committee, were contrary to the intent of Congress when it passed the 1986 Amendments. FERA primarily addressed causes of action under 31 U.S.C. § 3729. In 2010 with the Patient Protection and Affordable Care Act (PPACA), Congress addressed jurisdictional requirements under § 3730. See Michael Tabb, THE IMPACT OF 2010 HEALTHCARE LEGISLATION ON FALSE CLAIMS ACT LITIGATION (2011), available at [www.greenellp.com/wp-content/uploads/2011/04/Michael-Tabb-PPACA-Amendments.pdf](http://www.greenellp.com/wp-content/uploads/2011/04/Michael-Tabb-PPACA-Amendments.pdf).

<sup>5</sup>Participating Medicare and Medicaid providers are *government contractors*, subject to strict rules for reimbursement. Providers are required to sign an agreement, as a condition of participation, that they have read and understood the rules. See 42 C.F.R. § 424.510(d) (3). A failure to follow the rules disqualifies a claim for reimbursement, even if the patient *actually needed the care provided*, and the charge was *completely reasonable*. Two such rules are Stark Law, 42 U.S.C. § 1395nn and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, which deal with prohibited referrals of patients. See [oig.hhs.gov/compliance/provider-compliance-training/files/Provider-Compliance-Training-Presentationv2.pdf](http://oig.hhs.gov/compliance/provider-compliance-training/files/Provider-Compliance-Training-Presentationv2.pdf).

<sup>6</sup>Under 31 U.S.C. § 3730, only (1) the U.S. attorney, or (2) a "private person" acting as a government whistleblower may file an FCA case. Other agencies such as HHS or the OIG are not authorized to directly file an FCA action.

<sup>7</sup>See JUSTICE DEPARTMENT RECOVERS NEARLY \$5 BILLION IN FALSE CLAIMS ACT CASES IN FISCAL YEAR 2012, *supra* note 3.

<sup>8</sup>CMPL enforcement actions are handled administratively, and often interpreted by agency rule. In 1994, for example, the HHS made clear the government may bring an administrative action simultaneously with an FCA case, as CMPL penalties are "in addition and other penalty prescribed by law." See 42 C.F.R. § 1003.108, 59 Fed. Reg. 32,126 (June 22, 1994). In FCA cases by contrast, even where the government wishes to argue *against* a whistleblower, on the grounds that following the express language would yield "absurd" results, HHS is powerless to adopt rules which alter the FCA. Thus, courts will strictly construe the statute as written. See *Little ex rel United States v. Shell Exploration*, No. 11-20320, \_\_\_ F.3d\_\_\_ (5th Cir. 2012) (holding a government employee whose job involves detecting fraud, meets the definition of "private person" for purposes of the whistleblower provisions of the FCA, even though it might be a felony for a government agent to profit from doing his job, and the government argued *in favor of dismissal*).

<sup>9</sup>A perfectly valid FCA claim may often suffer dismissal in court *on the basis of a pleading defect*, where the same claim might eas-

ily prevail if presented administratively. As the Fifth Circuit stated: “We apply Rule 9(b) to fraud complaints with ‘bite’ and ‘without apology.’” *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 186 (5th Cir. 2009). Given this added procedural difficulty, one might question why the government would ever file an FCA action at all? Why not simply use the CMPL? The simple answer seems to be, although the government *could* pursue a CMPL action instead of an FCA action, the government cannot pursue a claim it doesn’t know exists. Violations of many healthcare regulations require *inside knowledge*. This is the advantage of an FCA action. Frequently, the government first learns of the facts amounting to a violation when it is served a sealed FCA complaint by a *qui tam* whistleblower.

<sup>10</sup>If a particular statute enables agency rulemaking, the HHS and other agencies are authorized by the Administrative Procedure Act (APA) to adopt the *Code of Federal Regulations* (Stark Law, the CMPL, the Anti-Kickback Statute, and the Exclusionary Statute all enable these regulations. The FCA does not). Regulations have the same force as a statute and may be cited as primary authority by the courts. *See* 5 U.S.C. § 500 et seq. Pub. L. No. 79-404, 60 Stat. 237 (1946). *See Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (setting forth the legal test for determining whether to grant deference to a government agency’s interpretation of a statute which it administers). Problems arise, however when agencies such as the OIG issue “clarifications” which only seem more official because when have been published in the *Federal Register*. The *Federal Register* contains final regulations, but is often where the government simply “thinks out loud.” In the latter instance, the OIG may explain what the HHS *actually was trying to say* in a particular regulation (which was *supposed to clarify* its enabling statute). Separating primary authority (e.g., “final” rule published in the *Federal Register*, from a secondary authority, a simple “pronouncement” can be difficult; especially where a court has repeated (without adopting) an informal pronouncement as if it were primary authority. An example of this can be seen in *United States ex rel. Westmoreland v. Amgen*, No. 06-10972-WGY (D. Mass. 2011) where the court cites confusing OIG *Federal Register* “clarifications,” contradicting the *very meaning and effect* of the published Anti-Kickback Statute Safe Harbor at issue in the case: “If the requisite intent to willfully or knowingly solicit or offer a kickback is present, formal compliance with a safe harbor *is not sufficient* to avoid liability under the Anti-Kickback Statute.” *Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute*, 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999). In other words, according to the OIG’s informal pronouncement “compliance,” *vel non*, depends upon subjective state of mind. This seems to render the Safe Harbor *absolutely meaningless* (and summary judgment would be improper) because the trier of fact could always infer “intent,” regardless of strict Safe Harbor compliance. Although what the OIG and the *Westmorland* court wrote, *in context*, actually makes sense to an experienced health lawyer; these informal “pronouncements” can be very confusing out of context, or to the casual reader.

<sup>11</sup>David Freeman Engstrom, *Corralling Capture*, 36 HARV. J. PUB. L. & POLY 31(2012) (explaining that “regulatory capture is an idea at the center of virtually any discussion of the appropriate bal-

ance between Congress and administrative agencies.” Utilizing the DOJ’s involvement in FCA suits to demonstrate a lack of opacity, “[t]he DOJ makes frequent and critically important micro-level decisions about whether to join particular *qui tam* cases that are largely hidden from public view”) (citing David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 NW. U. L. REV. (forthcoming 2013).

<sup>12</sup>On Mar. 23, 2010, 31 U.S.C. § 3730(e)(4) was amended. As of Mar. 23, 2010, the public disclosure bar is no longer jurisdictional, but instead, and affirmative defense which can be waived by the DOJ. Legislation is silent as to retroactivity. *See* § 10104(j)(2) of the PPACA, Pub. L. No. 111-148, 124 Stat. 119.

<sup>13</sup>*See* S. REP. NO. 111-10, at 10-12 (Mar. 23, 2009) (specifically identifying *Allison Engine v. United States ex rel. Sanders*, 553 U.S. 662 (2008) and *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), among others, as cases which erroneously interpreted the 1986 Amendments to the FCA). To be fair, the three branches of government look to one another for guidance. To the extent the Supreme Court misinterpreted Congress’ meaning, the Court may have actually misunderstood OIG’s position as stated in the 1999 pronouncement on “intent,” which was echoed by the Court in *Allison Engine* in 2008, as discussed this article. *See infra* note 9, and accompanying text.

<sup>14</sup>FERA, Pub. L. No. 111-21, 123 Stat. 1617; 31 U.S.C. §§ 3729(a)(1)(G), 3729(b)(2)(A)(ii), 3730(h), 3731(c).

<sup>15</sup>639 F.3d 791, 796 (8th Cir. 2011).

<sup>16</sup>*Id.*

<sup>17</sup>*Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996), *cert. denied*, 519 U.S. 1115 (1997)).

<sup>18</sup>*United States ex rel. Spay v. CVS Caremark Corp.*, No. 09-4672, at \*70, n.30 (E.D. Pa. Dec. 20, 2012).

<sup>19</sup>*United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004); *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001)).

<sup>20</sup>*See In re Genesis Health Ventures, Inc.*, 112 F. App’x 140, 143 (3d Cir. 2004) (recognizing various types of false claims) and *Wilkins*, 659 F.3d at 305 (relaying legally false and factually false claims theories).

<sup>21</sup>S. REP. NO. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added).

<sup>22</sup>*Mikes v. Straus*, 274 F.3d 687, 696-97, 699-700 (2d Cir. 2001).

<sup>23</sup>*Wilkins*, 659 F.3d at 305.

<sup>24</sup>*Id.* (quoting *Mikes*, 274 F.3d at 699).

<sup>25</sup>42 C.F.R. § 424.510(d)(3).

<sup>26</sup>No. 10-1505, 2011 WL 2150191 (1st Cir. June 1, 2011).

<sup>27</sup>No. 10-1629 (1st Cir. July 22, 2011).

<sup>28</sup>*United States ex rel. Willard v. Humana Health Plan*, 336 F.3d 375, 384 (5th Cir. 2003) and *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999) (“To plead fraud with particularity a plaintiff must include the ‘time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby’”) (citations omitted); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d

899, 903 (5th Cir. 1997) (“At a minimum, Rule 9(b) requires that a plaintiff set forth the ‘who, what, when, where, and how’ of the alleged fraud.”) (citation omitted).

<sup>29</sup>Sections (D)—(F) are seldom alleged in healthcare FCA cases, and seem more appropriate in military supplies contracts, such as contracting for the delivery of goods, for example, where a truck arrives at a military loading dock and the clerk signs a receipt, but the truck leaves with the goods still on the truck, to be sold later.

<sup>30</sup>There is probably little distinction between pleading facts sufficient under the Rule 9(b) “heightened” pleading standard and those, which would be sufficient under the *Iqbal/Twombly* standard. In other words, *Iqbal/Twombly* basically seems to require (without expressly applying Rule 9(b)) that every case be tested under a “heightened” standard of pleading facts “who, what, when, where, and how” in order to state a cause of action. The Supreme Court holding in *Iqbal/Twombly* does impose the additional requirement that *conclusions* are to be disregarded.

**The U.S. Court of Appeals for the Fourth Circuit has held that “time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby” are the circumstances that must be pled with particularity. ... This set of information is often referred to as the “who, what, when, where, and how” of the alleged fraud.**

The FCA, 31 U.S.C. 3729, establishes liability when any person or entity improperly receives from or avoids payment (reverse false claims) to the federal government (tax fraud is excepted). The act provides liability where a person:

- (A) **knowingly presents**, or causes to be presented, a **false or fraudulent claim** for payment or approval;
- (B) **knowingly makes, uses**, or causes to be made or used, a **false record or statement** material to a **false or fraudulent claim**;
- (C) **conspires** to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
- (D) **has possession**, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be **delivered, less than all** of that money or property;
- (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) **knowingly buys**, or receives as a pledge of an obligation or debt, public **property from an officer or employee** of the Government, or a member of the Armed Forces, **who lawfully may not sell or pledge property**; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and **improperly avoids or decreases an obligation to pay** or transmit money or property **to the Government, is** liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation.

<sup>31</sup>A false claim allegation is an averment of fraud. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999) (Harrison I). Therefore, a complaint alleging false claims must comply with the heightened standard of *Federal Rule of Civil Procedure* 9(b), which requires a pleader to “state with particularity circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). The U.S. Court of Appeals for the Fourth Circuit has held that “time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby” are the circumstances that must be pled with particularity. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (quoting *Harrison I*, 176 F.3d at 784). This set of information is often referred to as the “who, what, when, where, and how” of the alleged fraud. *Id.* at 379 (internal quotation marks omitted). For example, a complaint is insufficient if it fails to allege specific claims submitted to the government and the dates on which those claims were submitted. *United States ex rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 526-27 (D. Md. 2006). Moreover, as to the “what” requirement, “a plaintiff must show a link between allegedly wrongful conduct and a claim for payment actually submitted to the government.” *United States ex rel. Dugan v. ADT Security Servs., Inc.*, No. DKC-03-3485, 2009 WL 3232080, at \*14 (D. Md. Sept. 29, 2009) (citing *Clausen*, 290 F.3d at 1311).

<sup>32</sup>*Five Ws and One H: The Secret to Complete News Stories*, [blog.journalistics.com/2010/five-ws-one-h](http://blog.journalistics.com/2010/five-ws-one-h).

<sup>33</sup>See *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007).

<sup>34</sup>625 F.3d 262, 266 (5th Cir. 2010).

<sup>35</sup>553 F.3d 869, 873 (5th Cir. 2008).

<sup>36</sup>*Guidry v. United States Tobacco Co.*, 188 F.3d 619, 632 (5th Cir. 1999).

<sup>37</sup>*United States v. McNinch*, 356 U.S. 595, 599 (1958).

<sup>38</sup>*United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (citation omitted); see also *Harrison I*, 176 F.3d 776, 785 (4th Cir. 1999) (“The statute attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the ‘claim for payment.’”) (citation omitted, emphasis added).

<sup>39</sup>*Harrison I*, 176 F.3d at 785.

<sup>40</sup>*United States ex rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (citation omitted).

<sup>41</sup>In fact, a common repleading error can be seen after a case has

been dismissed under Rule 9(b), but the relator misunderstood the reason. Typically, the relator adds more facts *about the scheme*, while adding nothing detailing *presentment* or *materiality* of the *claims involved*. Typically, the case is then dismissed with prejudice. See section on amended pleading under Rule 15, in this article, *infra*.

<sup>42</sup>See *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 42 (1st Cir. 2009).

<sup>43</sup>*United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003).

<sup>44</sup>290 F.3d 1301 (11th Cir. 2002).

<sup>45</sup>Congress amended the FCA in 2009 with FERA. Pub. L. No. 111-21, 123 Stat. 1617 (2009). Congress' decision to amend the FCA with FERA was in direct response to the Supreme Court's decision in *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) by which the Supreme Court sought to resolve a conflict between the U.S. Court of Appeals for the Sixth Circuit and the U.S. Court of Appeals for the District of Columbia (D.C.) Circuit regarding the proper interpretation of subsections (a)(2) and (a)(3) of the FCA. In *Allison Engine*, the district court had held that all three sections of former § 3729(a) required a showing that the false claim at issue had actually been presented to the government for liability to attach. *Allison Engine*, 471 F.3d 610, 613 (6th Cir. 2006). The Supreme Court stated that this opinion conflicted with the D.C. Circuit's holding in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004). *Allison Engine*, 553 U.S. at 668. In *Totten*, the district court dismissed the complaint alleging that the defendants violated subsection (a)(1) by submitting false invoices to Amtrak. *Totten*, 380 F.3d at 490. The D.C. Circuit affirmed, finding that "Amtrak is not the Government," and that under the plain language of § 3729(a)(1), "claims must be presented to an officer or employee of the Government before liability can attach." *Id.* at 490. With *Allison Engine*, the Supreme Court undertook to resolve this conflict. 553 U.S. at 668. It concluded that "it is insufficient for a plaintiff asserting a § 3729(a)(2) claim to show merely that '[t]he false statement's use ... result[ed] in obtaining or getting payment or approval of the claim,' or that 'government money was used to pay the false or fraudulent claim'" as the Sixth Circuit had held. *Id.* at

665 (citations omitted). Instead, the Supreme Court held that the focus should be on the defendant's intent. Thus, for a claim under subsection (a)(1), the plaintiff need not present evidence that the defendant himself presented the false claim to the government, but there must be evidence that the defendant submitted a false claim and that the claim was ultimately submitted to the government for payment or approval. Although Congress effectively overruled *Allison Engine* with FERA, many OIG interpretations published in the *Federal Register*, now stand as well-meaning, but incorrect attempt to apply *Allison Engine*. See *infra* note 9, and accompanying text.

<sup>46</sup>See *United States ex rel. Wall v. Vista Care*, No. 3:07-CV-604-M (N.D. Tex. 2011) (citing *Kanneganti*, 565 F.3d at 185).

<sup>47</sup>See *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (noting that in FCA cases, liability could be established where the pleading contains an indicia of reliability, though the precise amount of bills submitted may be missing).

<sup>48</sup>See T.S. Ellis & N. Shah, Iqbal, Twombly, and *What Comes Next: A Suggested Empirical Approach*, 114 PENN. ST. L. REV. PENN. STATIM 64 (2010), available at [www.pennstatelawreview.org/114/114%20Penn%20Statim%2064.pdf](http://www.pennstatelawreview.org/114/114%20Penn%20Statim%2064.pdf).

<sup>49</sup>The second order of dismissal is normally "with prejudice," thereby foreclosing the possibility of a third motion to dismiss. If a motion to amend is necessary, always include the amended pleading with the motion. Otherwise, the court of appeals will have nothing to consider in reviewing the trial courts abuse of discretion.

<sup>50</sup>*Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962).

<sup>51</sup>The third motion to amend filed by Blodgett's attorney was accompanied by a copy of the proposed amended complaint. But that supposedly "streamline[d]" amended complaint [ECF No. 67 at 2] weighed in at a remarkable 182 pages and 351 paragraphs—well over 100 pages longer than the original complaint, and over 20 pages longer than the pro se amended complaint that Judge Cynthia Leung rejected as failing to comply with Rule 8. Needless to say, the proposed amended complaint does not come close to complying with Rule 8, and thus Blodgett's motion to amend is denied.

<sup>52</sup>*Gurman v. Metropolitan Hous. & Redev. Auth.*, 842 F. Supp. 2d 1151, 1152 (D. Minn. 2011) (quoting Fed. R. Civ. P. 8(a)(2)).

