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# The Misuse of the FCA to Enforce cGMP ( Current Good Manufacturing Practice) Violations

KYLE FAGET, ESQ.
Clinical Compliance Counsel, The Boston Scientific Corporation, USA

## Introduction

Since the civil False Claims Act ("FCA") was amended in 1986, the statute has evolved into a seemingly limitless weapon for enforcing other statutes and regulations applicable to every industry that accepts any form of government funding. Whether or not using one statute to enforce another is sound jurisprudence is another issue, however. In the field of health care, for example, the safety and effectiveness of drugs and devices is typically regulated by the Food Drug and Cosmetic Act ("FDCA"). Nonetheless, the FCA has been used recently in actions where the allegations include off-label promotion of drugs, kick-backs, and violations of good manufacturing practices ("cGMP") by linking the alleged violation with the government reimbursement under Medicare and Medicaid. In particular, using the FCA to allege violations of cGMP is fraught with problems.

In the wake of both GlaxoSmithKline's ("GSK") $750 million settlement with the District of Massachusetts' United States Attorney's Office and Ranbaxy's $500 million dollar settlement with the District of Maryland for allegedly releasing into the stream of commerce adulterated drugs in violation of current good manufacturing practices, an open and pressing question is whether or not the FCA may be used to enforce FDCA cGMP and/or quality system regulation ("QSR") violations.[1] What is clear is that the next era of FCA actions may focus on the enforcement of c/GMP/QSR by using the FCA to enforce the FDCA.

## cGMP/QSR Statutory Background

The manufacture of drugs and medical devices is heavily regulated. Under the FDCA, the Secretary of Health and Human Services is empowered to "prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture . . . of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act."[2] Consistent with this statutory mandate, the Secretary has created a "quality system regulation," or "QSR," that sets forth current good manufacturing practice requirements, commonly referred to as cGMPs.[3]

QSR "govern[s] the methods used in, and the facilities and controls used for, the . . . manufacture . . . of all finished devices intended for human use," and is "intended to ensure that finished devices will be safe and effective and otherwise in compliance with

[1] *United States ex rel. Eckard v. GloxoSmithKLINE*, No. 10-cv-10375, 2010 WL 4339999 (D. Mass. Oct. 26, 2010); *U.S. ex rel. Thakur v. Ranbaxy Laboratories Limited*, Case No. JFM-07-962 (D. Md. 2013); *United States. v. Ranbaxy USA, Inc.*, JFM-13-CR-0238 (D. Md. 2013); *United States v. Ranbaxy Laboratories, Ltd., et al.* , Case No. JFM-12-250 (D. Md. 2013).

[2] 21 U.S.C. § 360j(f)(1)(A).
[3] *See* 21 C.F.R. § 820.1(a)(1), (c).

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the [FDCA]."[4] These regulations require manufacturers to establish specifications and controls for quality and safety.[5] The FDA's Medical Device Quality Systems Manual specifies:

[cGMPs] require that domestic or foreign manufacturers have a quality system for the design and production of medical devices intended for commercial distribution in the United States. The regulation requires that various specifications and controls be established for devices; that devices be designed under a quality system to meet these specifications; that devices be manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed.[6]

The regulations are flexible, however. The FDA notes that "'[e]ach manufacturer shall establish and maintain a quality system that is appropriate for the specific device(s) designed or manufactured, and that meets the requirements of this part.' The word 'appropriate' signals that the rule is a flexible regulation."[7] The FDA explains:

FDA has identified in the QS regulation the essential elements that a quality system shall embody for design, production and distribution, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices and production processes, it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.[8]

Indeed, it is not practical for the FDA to delineate quality system elements for each of the numerous devices on the market. Instead, general objectives are specified, and manufacturers are left to determine the best methods to attain quality objectives.[9]

The Food and Drug Administration ("FDA") also requires that drug-makers' manufacturing facilities comply with cGMPs, which establish the minimum requirements for the methods, facilities, and controls used in manufacturing and processing human drugs, in order to prevent the production of unsafe and ineffective products.[10] To ensure compliance, the agency conducts inspections, periodically and in conjunction with drug applications. Compliance with the cGMP requirements assures that drugs and devices meet the safety requirements of the FDCA, and have the quality, purity, identity and strength characteristics that they purport or are represented to possess. Drugs and devices not manufactured, processed, packaged, or held in conformance with cGMP requirements are deemed adulterated within the meaning of 21 U.S.C. § 351 (a)(2)(B).

Because the FDCA does not provide a definition of what constitutes cGMP, the determination of what constitutes cGMP is often a matter of judgment and

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[4] *Id.* at § 820.1(a)(1).
[5] *See* 21 C.F.R. § 820.20-75.
[6] Medical Device Quality Systems Manual, *The Quality System Regulation*, available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/ucm122391.htm (last visited June 8, 2011).
[7] *Id.* (quoting 21 C.F.R. at § 820.5).
[8] *Id.*
[9] *Id.*
[10] *See* 21 C.F.R. § 210-11.

interpretation.[11] Indeed, the FDA uses the concept of "current" GMP to continuously advance the best practices within the industry and to advance practices not yet used in the industry but which the FDA determines could improve manufacturing controls and drug or device product integrity.[12] As a result, the FDA establishes GMP requirements informally via speeches, guidance documents, FDA investigators' inspection observations, and letters to manufacturers.[13] Therefore, a conclusion by a field investigator that a particular practice violates cGMP may reflect miscommunication between the agency and industry.[14] A violation may also result from a good faith technical dispute about what cGMP requires in a particular setting.[15]

As noted, and significantly, failure to comply with the QSR "renders a device adulterated under section 501(h)" of the FDCA, and "[s]uch a device, as well as any person responsible for the failure to comply, is subject to regulatory action."[16] Under 21 U.S.C. § 351 (a)(2)(B), a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

**FDA Enforcement Actions**

The FDA is responsible for investigating violations of the FDCA, including those related to adulterated drugs and devices.[17] The FDA may exercise its enforcement authority, derived from 21 U.S.C. § 331, when a prohibited act has been identified. Prohibited acts include interstate shipment of adulterated drugs and devices and selling devices not made in conformance with QSR requirements.[18] The FDA has three primary enforcement tools available to combat FDCA violations. These tools include advisory actions, such as letters; administrative actions, such as recalls and civil penalties; and judicial actions, such as seizures, injunctions, and criminal prosecutions.[19]

*A. Advisory Actions*

Generally, the FDA is not required to warn individuals or companies regarding its position that a regulatory violation has occurred prior to undertaking enforcement actions.[20] FDA-issued letters, which are informal and advisory in nature, are issued with the expectation that most firms will voluntarily comply with the law.[21] If an FDA inspector finds "significant objectionable conditions," the FDA will typically issue a

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[11] Erika King, *The Authority Of a Court to Order Disgorgement for Violations of the Current Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act*, 68 Food & Drug L.J. 149, 151 (2003).
[12] *Id*. at 154.
[13] *Id*.
[14] *Id*.
[15] *Id.*
[16] *See* 21 C.F.R. at § 820.1(c).
[17] *See* 21 U.S.C. § 372(a)(1) (authorizing the Secretary of Health and Human Services "to conduct examinations and investigations for the purpose of [the FDCA]").
[18] 21 U.S.C § 331(a).
[19] *See* Nancy Mathewson, *Prohibited Acts and Enforcement Tools*, 65 Food & Drug L.J. 545, 546 (2010).
[20] *See* §§ 332, 333(f)(1)(A), 334(a)(2)(D); FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 4-1-1 (March 2010), available at http:// www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProcedaresManual/UCM074330.pdf (last visited May 10, 2011). The FDA is required to provide written notification when it discovers that products fail to comply with a performance standard or contain impermissible radioactivity. *Id.*
[21] FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 4-1-1 (March 2010), available at http:// www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProcedaresManual/UCM074330.pdf (last visited May 10, 2011).

Form 483, which lists "inspectional observations" but does not constitute a finding of cGMP violations.[22] Should the drug or device maker not promptly address those observations (or if the FDA finds a flagrant violation), the FDA may issue a Warning Letter, which constitutes a finding of cGMP non-compliance and puts the manufacturer on notice that an enforcement or regulatory action could be forthcoming if the violations are not remedied promptly.[23] A Warning Letter is addressed to the highest known company official and includes: the title "WARNING LETTER"; the inspection dates (if applicable); a description of the violative condition, practice, or product, including the section of law and/or regulation violated; acknowledgement of any corrections promised during an inspection; a request for correction and a written response within a specific period of time after the date of the receipt of the letter (usually 15 working days); a warning statement that failure to correct the violative condition(s) may result in enforcement action without further notice; and notice that other Federal Agencies will be advised of the Warning Letter.[24]

*B. Administrative Actions*

If the FDA determines that a device is adulterated, the agency may order that the device be detained for up to 20 to 30 days if necessary to institute an enforcement action, such as a product seizure or an injunction.[25] The FDA may also choose to request a product recall.[26] Typically, the FDA will issue a recall when the agency believes that there is a grave public health issue at stake.[27]

The FDA may elect to institute an administrative proceeding against a drug or device company seeking civil monetary penalties.[28] The FDA is afforded subpoena power, which includes the ability to require attendance of witnesses and the production of evidence relating to the matter being investigated.[29] After notice and an opportunity for a full administrative hearing,[30] the FDA may impose civil monetary penalties for significant QSR violations ranging from $15,000 per violation up to a maximum of $1,000,000 in a given proceeding.[31]

*C. Other Enforcement Mechanisms*

The FDA has an expansive toolkit short of seeking judicial intervention that assist the agency in its enforcement efforts. For example, if the FDA determines that a device presents an unreasonable risk of substantial harm, the agency may issue notification orders, which order a party to notify all healthcare professionals of the risk.[32] Should a firm choose not to comply with the FDA's notification order, the FDA may issue its own safety alert or warning.[33] Through publicity, the FDA may pressure a firm to voluntarily

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[22] *Id.*; 21 U.S.C. § 374(b).
[23] FDA Office of Regulatory Affairs, Regulatory Procedures Manual, § 4-1 (March 2010), available at http:// www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProcedaresManual/UCM074330.pdf (last visited July 1, 2013).
[24] *Id.* at § 4-1-10.
[25] 21 U.S.C. § 334(g)(1).
[26] 21 C.F.R. § 7.40 (2010).
[27] *Id.*
[28] *See* 21 U.S.C. 333(f).
[29] *See* Nancy Mathewson, *Prohibited Acts and Enforcement Tools*, 65 Food & Drug L.J. 545, 548 (2010); *see, also* 21 C.F.R. Part 17 (2009).
[30] *See* Pub. L. No. 79-404, 60 Stat. 237 (1946).
[31] 21 U.S.C. § 333(g); *see* 21 C.F.R. Part 17 (2009).
[32] 21 U.S.C. § 360h(a).
[33] *See* Mathewson, *Supra* note 9, at 551; Food and Drug Administration, Alerts and Notices (Medical Devices), *available at* http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm (last visited June 2, 2011).

recall its product.[34] The FDA may also issue a premarket approval suspension or withdrawal if evidence exists that a device is unsafe or ineffective or does not conform to GMP regulation requirements.[35] If the FDA determines that a device presents an unreasonable risk of illness or injury, the agency may institute proceedings to ban the device.[36]

*D. Judicial Enforcement.*

Enforcement actions include seizure, injunctive relief (consent decrees), and imposition of civil penalties. A drug or device may be seized under 21 U.S.C. § 334(a)(2)(D), which states that any adulterated or misbranded device "shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found."

A statutory injunction proceeding is brought under the FDCA, 21 U.S.C. § 332(a), to permanently enjoin a company from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351 (a)(2)(B); (b) violating 21 U.S.C. § 331 (k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351 (a)(2)(B); and (c) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(c).

Generally, 21 U.S.C. § 333(f)(1)(A) confers civil liability upon "any person who violates a requirement of [the FDCA] which relates to devices . . . for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding."

*E. Voluntary compliance*

Finally, while the FDA recommends that component manufacturers voluntarily follow the QSR, it does not require them to do so. The FDA itself views the QSR as providing broad flexibility to device manufacturers:

Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. [37]

In essence, the FDA expects device makers to employ their best judgment when designing state-of-the-art manufacturing processes. At the same time, by putting the onus on device makers to make and adhere to a set of standards, the FDA avoids articulating a specific set of mandates that could decrease the incentive for manufactures to formulate the best practices possible.

**FCA Overview**

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[34] *See* 21 C.F.R. Part 7 (2009).
[35] 21 U.S.C. § 360e(e).
[36] 21 U.S.C. § 360f ; 21 C.F.R. Part 895 (2009).
[37] *See* FDA Device Advice, Quality Systems Regulations, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm* (last visited April 8, 2011).

Originally enacted during the Civil War to abate fraud against the government by unscrupulous contractors, the False Claims Act ("FCA") "prohibits the knowing submission of false or fraudulent claims for payment . . . to the federal government."[38] Specifically, under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government."[39] Additionally, the FCA imposes liability upon any person who "conspires to commit a violation of [any substantive section of the FCA]."[40] The FCA also prohibits "reverse false claims," rendering liable any person who "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 who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[41]

**FCA Enforcement**

Unlike the FDCA, which can be enforced by the United States only, the FCA may be enforced by the United States or a private person, known as a relator.[42] In qui tam actions brought by relators, the United States has "an opportunity to evaluate the relator's complaint and decide whether to assume primary responsibility for prosecuting the action."[43] If the United States chooses not to intervene, the relator may continue to pursue the action on his or her own behalf and collect a portion of any damages awarded.[44] Under the 1986 amendment, Congress increased the incentives for relators to file qui tam actions and increased the penalties associated with FCA violations. If the FCA is found to have been violated, defendants are liable for three times the government's damages plus a civil penalty of $5500-$11,000 for each false or fraudulent claim submitted.[45] A relator is entitled to 15 to 25 percent of the recovery if the government has chosen to intervene or 25 to 30 percent of the recovery if the government declined to intervene.[46]

**FCA Liability**

Importantly, not all fraudulent conduct gives rise to FCA liability.[47] As one court has recognized, "the statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment'."[48] "Evidence of an actual false claim is the sine qua non of a False Claims Act violation."[49] A defendant violates the FCA only when he has presented to the government a false or fraudulent claim, defined as "any request or demand . . . for money or property."[50]

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[38] *United States v. Pfizer*, 507 F.3d 720, 726 (1st Cir. 2007) (citing 31 U.S.C. § 3729(a)).
[39] *See* 31 U.S.C. § 3729(a)(1)(A)-(B).
[40] *See* 31 U.S.C. § 3729(a)(1)(C).
[41] 31 U.S.C. § 3729(a)(1)(G).
[42] *Pfizer*, 507 F.3d at 727.
[43] *Id*. (citing 31 U.S.C. § 3730(b)(2), (b)(4), (c)(1)).
[44] *See United States ex rel. Poteet v. Bahler Med.*, 619 F.3d 104, 107 (1st Cir. 2010) (citing 31 U.S.C. § 3730(d)).
[45] 31 U.S.C. § 3729(a).
[46] 31 U.S.C. §3730(d).
[47] *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004).
[48] *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995).
[49] *Karvelas*, 360 F.3d at 225; *Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) ("At a minimum, the FCA requires proof of an objective falsehood.").
[50] 31 U.S.C. § 3729(b)(2)(A); *Karvelas*, 360 F.3d at 225; *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) ("It is only those claims for money or property to which a defendant is not entitled that are 'false' for purposes of the False Claims Act.").

Accordingly, the FCA is not a vehicle for policing every violation of a federal statute or regulation.[51] Indeed, an FCA violation can be predicated on a defendant's violation of a statute or regulation only if compliance with that statute or regulation is a condition of government payment.[52] Moreover, Courts have rejected FCA claims that are premised on expressions of opinion or professional or business judgments.[53]

*1. Factually or Legally False (express certification or implied certification)*

In *United States v. Johnson & Johnson*, No. 07cv10288, 2011 WL 673925 (D. Mass. Feb. 25, 2011), the Court identified "three bases on which a claim may be 'false or fraudulent' for purposes of the FCA: (1) factual falsity; (2) legal falsity under an 'express' certification theory; and (3) legal falsity under an 'implied' certification theory."[54]

*a. Factually False Claims*

A claim is "factually false" when the "goods or services are either incorrectly described" or the claim is for goods or services that were never provided. A claim cannot be considered "false" under the FCA unless it constitutes an objective falsehood furnished in violation of a rule, regulation, contractual agreement, or standard.[55]

*b. Express Certification*

Under the "express" certification theory, a claim is legally false "when the party making the claim for payment expressly represents compliance with a contract, statute or regulation, and such compliance is a precondition to payment."[56] The certification need not be in any particular form, "so long as the statement of compliance was knowingly false when made."[57] Absent a certification of past compliance where such compliance is a precondition of payment, the alleged legal falsity of claims for government payment must be analyzed under an implied certification analysis.[58]

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[51] *Allison Engine Co. v. United States*, 553 U.S. 662, 669 (2008) (declining to expand the FCA beyond its "intended role of combating fraud against the government"); *Pfizer*, 507 F.3d at 727 ("FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim.").

[52] *See, e.g.*, *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) ("We have thus repeatedly upheld the dismissal of false-certification claims (implied or express) when a contractor's compliance with federal statutes, regulations or contract provisions was not a 'condition' or 'prerequisite' for payment under a contract."); *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("[W]hile the [FCA] is intended to reach all types of fraud, without qualification, that might result in financial loss to the Government . . . it does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions.").

[53] *See, e.g.*, *Mann v. Heckler & Koch Defense*, 630 F.3d 338, 346 (4th Cir. 2010) ("These sorts of [business] disagreements occur all the time, but they do not rise to the level of fraud unless there is a claim made on the public fisc that misrepresents the quality of a product . . . . Without such a misrepresentation, [plaintiff] opposed nothing more than a non-fraudulent business decision , and this cannot form the basis of an FCA action.") (citing *United States ex rel. Owens v. First Kuwaiti Gen'l Trading & Contracting Co.*, 612 F.3d 724, 734 (4th Cir. 2010).

[54] *Johnson & Johnson*, 2011 WL 673925, at *10 (citing *United States ex rel. Hutcheson v. Blackstone Med.*, *Inc.*, 694 F. Supp. 2d 48, 61 (D. Mass 2010), *overruled by United States ex. rel. Susan Hutcheson and Phillip Brown v. Blackstone Medical, Inc.*, No. 10-1505 (1st Cir. June 1, 2001)(rejecting the distinction between a factually and a legally false claim).

[55] *See, e.g.*, *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J. concurring).

[56] *Johnson & Johnson*, 2011 WL 673925, at *10.; *United States ex rel. Hutcheson v. Blackstone Medical Inc.*, 694 F. Supp. 2d 48, 62 (D. Mass. 2010) *overruled by United States ex. rel. Susan Hutcheson and Phillip Brown v. Blackstone Medical, Inc.*, No. 10-1505 (1st Cir. June 1, 2001); *Mikes*, 274 F.3d at 698 (2d Cir. 2001) ("An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.").

[57] *Johnson & Johnson*, 2011 WL 673925, at *10.

[58] *See U.S. ex rel. Kennedy v. Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 945-47 (N.D. Ill. 2009); *U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1217-18 (10th Cir. 2008).

*c. Implied Certification*

Under the "implied" certification theory, a claim is "legally false" when "the claimant implies that it has complied with all of the stated conditions for payment."[59] Courts have held that a claim is legally false under an implied certification theory where a claimant makes no express statement about compliance with a statute or regulation, but by submitting a claim for payment, implies that he or she has complied with any preconditions to payment.[60] The idea under this theory is that the government paid funds to a party but would not have paid those funds had it known of the offender's violation of a law or regulation.[61] The argument holds that the claim submitted for funds under the conditions described contained an implied certification of compliance with the law or regulation and was, therefore, fraudulent.[62] Another way of understanding the principle of implied certification is that a manufacturer will be held liable under the FCA when he or she fails to comply with another statute whose compliance is required for reimbursement.[63] Unlike "express" certification, which relies on actual statements of compliance, the analysis in the "implied" certification theory "focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a *prerequisite* to the government's payment."[64]

**Materiality**

Regardless of whether or not a claim is construed as factually or legally false, courts have "long held that the FCA is subject to a judicially-imposed requirement that the alleged false claim or statement be material."[65] A false statement is material if it has "a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property."[66] Materiality involves a determination of the weight that the decision-maker would have given particular information. *Unum Grp.*, 613 F.3d at 308. Generally, liability will not be found under the FCA unless plaintiffs can prove (1) the false statement or claim was essential to the government's funding decision, (2) the government specifically relied on the falsity, or (3) the falsity caused the government to pay out sums it would not have otherwise paid.[67] For example, in *United States ex rel.*

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[59] *Johnson & Johnson*, 2011 WL 673925, at *10-11.

[60] *See United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002).

[61] *See United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002).

[62] *Cf. United States ex. rel. Susan Hutcheson and Phillip Brown v. Blackstone Medical, Inc.*, No. 10-1505 (1st Cir. June 1, 2001) adhering to the express language of the statute in dismissing other courts' development of an implied certification theory).

[63] *See In re Pharma. Indus. Average Wholesale Price Litig.,* 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (Saris, J.) (holding that hospitals submitted legally false claims under an implied certification theory for Medicaid reimbursement when they failed to comply with the Anti-Kickback Statute ("AKS") because Medicare requires compliance with the AKS).

[64] *United States ex rel. Conner v. Salina Reg. Health*, 543 F.3d 1211, 1218 (10th Cir. 2008); *see also United States v. Science Apps. Int'l*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) ("[W]e hold that to establish the existence of a "false or fraudulent" claim on the basis of implied certification of a contractual condition, the FCA plaintiff—here the government—must show that the contractor withheld information about its noncompliance with material contractual requirements.").

[65] *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 307 (1st Cir. 2010).

[66] 31 U.S.C. § 3729(b)(4); *Unum Grp.*, 613 F.3d at 307 (citations omitted). Prior to the FERA amendments, the United States Supreme Court decided in *Allison Engine Co. v. United States ex. rel. Sanders,* 471 F.3d 610, 622-23 (2008), that liability for false statements supporting false claims was limited to fraudulent statements designed "to get" false claims paid or approved "by the Government." FERA's materiality requirement replaced *Allison Engine's* intent requirement and incorporated the materiality standard already applied by numerous courts in FCA cases. John T. Boese, Civil False Claims & *Qui Tam* Actions 1-75, 7-77 (3d ed. 2010); *see attachment A*. Therefore, "FERA's explicit inclusion of this requirement in Sections 3729(a)(1)(B) and (G) should not affect the ultimate outcome in [FCA] cases." *Id.* at 1-78. Plaintiffs' allegations fail under both the pre-FERA and post-FERA requirements of the FCA.

[67] John T. Boese, Civil False Claims & *Qui Tam* Actions 2-166 (3d ed. 2010).

*Sanders v. North American Bus Industries, Inc.,* 546 F.3d 288 (4th Cir. 2008), the court held that the relator's allegations focused on details that were unimportant to the government's decision to pay or not to pay, and fell well short of what would be required to satisfy a materiality standard.

cGMP Violation Must be Material to the Government's Reimbursement Decision

**Causation**

Courts have applied principles of tort causation to the False Claims Act. Indeed, "[T]he FCA does not provide a special definition for causation, and neither the Supreme Court nor any Circuit Court of Appeals has grafted such a special definition on the FCA. Absent an FCA-specific definition of causation, the Court will apply common-law tort causation concepts...."[68] Most courts have adopted a proximate cause approach to FCA violations as opposed to a but-for analysis. That is, a person will be liable for all normal consequences of that person's conduct unless the intervening event in the causal chain is unforeseeable.[69]

**Using the FCA as an Impermissible means to Enforce the FDCA**

*a. Implied Private Right of Action: Is there a right?*

Under the FDCA, there is no express private right of action allowing a citizen to bring an action for violation of the Act. Moreover, it is unlikely that any court would imply a private right of action under the FDCA. Indeed, since the mid-1970s, the Supreme Court has incrementally restricted the ability of courts to imply a private right of action under federal statutes.[70] For example, in *Cort v. Ash*, 422 U.S. 66, 70-75 (1975), a stockholder brought a civil action for relief under a criminal statute prohibiting corporations from making contributions or expenditures in connection with any Presidential election where no private violation or remedy was articulated in the statute. When the company advertised in a way that was potentially impermissible under the statute, the court determined that no private right of action was implied. Moreover, the *Cort* court articulated a four factor test for determining if a statute warrants a private right of action: (1) whether the plaintiff is "'one of the class for whose especial benefit the statute was enacted"; (2) whether there is evidence of explicit or implicit legislative intent to create a remedy; (3) whether implying a right of action would be "consistent with the underlying purposes of the legislative scheme"; and (4) whether the cause of action is one "traditionally relegated to state law . . . so that it would be inappropriate to infer a right of action based solely on federal law."[71]

Over the next several years, the Supreme Court narrowed the original four factor test. In a liquidated assets action brought under 17(a) of the Securities Exchange Act, *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575 (1978), the Court articulated three factors for determining whether or not a private right of action is permissible under a statute. These factors include determining whether the "language and focus of the statute, its legislative history, and its purpose" confer a private right of action.[72] Nonetheless, the Court opined,

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[68] *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 at *4 (D. Mass. Aug. 22, 2003).

[69] *See United States ex rel. Sikkenga v. Regence Blue Cross Blue Shield*, 472 F.3d 702, 714 (10th Cir. 2006) (nothing that"[s]uch an approach is useful in analyzing causation under § 3729 as well, and provides a familiar test—that of proximate causation—to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA"); *United States ex rel. Baker v. Cmty. Health Sys.*, 709 F. Supp. 2d 1084 (D.N.M. 2010).

[70] *Louis Ebinger*, *Sarbanes-Oxley Section 510(A): No Implied Private Right of Action, and a Call to Congress for an Express Private Right of Action to Enhance Analyst Disclosure*, 93 Iowa L. Rev. 1919, 1930, 1934 (2008).

[71] *Cort*, at 422 U.S. at 78.

[72] *Touche*, 442 U.S. 575-76.

the "central inquiry remains whether Congress intended to create, either expressly or by implication, a private cause of action."[73]

When holding that the discriminatory-impact provision of Title VI of the Civil Rights Act of 1964 did not contain an implied private right of action, in *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001), the Court determined that congressional intent is the sole criterion for determining whether or not a statute confers a private right of action. The court opined, "Without [statutory intent], a right of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute."[74] More recently, in *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 161-62 (2008), the Court refused to expand an existing implied private right of action in the context of securities litigation when the Court determined that section 10(b) of the Securities Exchange Act and SEC Rule 10b-5 did not imply a private right of action. What is clear from the case law development on this point is that one dispositive question exists when inquiring whether or not a statute confers a private right of action, namely, "whether Congress intended to create, either expressly or by implication, a private cause of action."[75]

As applied to the FDCA, it seems unlikely that any reviewing court would imply a right for a private citizen to bring an action against a corporation for violating the cGMP. Such actions are uniquely reserved for the FDA. Indeed, the multifaceted arsenal at the disposal of the FDA makes the agency uniquely positioned to enforce its governing statute and not a private citizen. Moreover, only the FDA can determine when a cGMP violation has occurred in the first instance, which cabins enforcement even further away from private litigants. Nonetheless, recent case law suggests that private litigants may make an end run around the prohibition against implying a private right of action under the FDCA by invoking the FCA.

*b. Without the FDCA, Litigants Invoke the FCA*

Following the announcement of GlaxoSmithKline's ("GSK") $750 million settlement with the District of Massachusetts' USAO for allegedly releasing into the stream of commerce adulterated drugs due to cGMP violations, whether or not the False Claims Act ("FCA") may be used by private citizens to enforce cGMP and/or QSR violations under the FDCA is an open question. *United States ex rel. Eckard v. GloxoSmithKLINE*, No. 10-cv-10375, 2010 WL 4339999 (D. Mass. Oct. 26, 2010). Following the GSK settlement, in *United States of America v. McNeil-PPC, Inc., et al.*, No. 11-1745 (E.D. Pa. March 10, 2011), the McNeil-PPC Inc. division of Johnson & Johnson entered into a consent decree of permanent injunction with the federal government for manufacturing violations at three plants that resulted in several over-the-counter products being recalled and one plant being shut down. The federal government alleged that McNeil and two employees violated the FDCA by placing adulterated drugs into interstate commerce and causing drugs held for sale to become adulterated. Notably, the consent decree specifically stipulates that entry of the Decree does not foreclose claims arising under the FCA.

The concept that a relator may bring a cGMP claim under the FCA is not new. As early as October 2004, the National Conference for Relators' Counsel hosted a panel

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[73] *Id*. at 575; *see also Santa Clara Pueblo v. Martinez,* 436 U.S. 49, 64 (1978) (noting that implying a right where a statute is silent as to the right is impermissible when stating that "implying a private right of action on the basis of congressional silence is a hazardous enterprise, at best."); *Cent. Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 174-76 (1994).

[74] *Id*. at 286-87 ("Having sworn off the habit of venturing beyond Congress's intent [in determining whether to imply a private right of action], we will not accept respondents' invitation to have one last drink." *Id*. at 287).

[75] *Touche*, 442 U.S. at 575.

discussion entitled, "The Federal Food, Drug and Cosmetic Act and Its Application to Qui Tam: Pharmaceutical and Medical Device Cases."[76] The panel's moderator published an article, *CGMP Violations may be the Basis for QUI TAM Lawsuits in the United States*,[77] the same year. In *United States ex rel. Paul G. King v. Alcon Laboratories, Inc.*, 22 F.R.D. 568, 569 (N.D. Tex. 2005), despite being dismissed for failure to plead with the requisite particularity under FRCP 9(b), the relator claimed that defendants violated sections 3729(a) (1) and (a)(2) of the FCA knowingly and intentionally by choosing to operate in a manner that did not comply with the FDA's cGMP.

To protect against interference with the FDA's exercise of this discretion, Congress prohibited "private litigants" from "fil[ing] suits for noncompliance with the medical device provisions" of the FDCA.[78] As stated by the Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001), the FDA's "flexibility" in deciding whether and how to enforce the FDCA "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives."

In *In re Medtronic, Inc.*, for example, a group of plaintiffs asserted manufacturing-defect claims against Medtronic premised on alleged failures to adhere to particular internal quality protocols used in welding leads. The Minnesota federal court rejected plaintiffs' argument, noting that the FDCA regulations are "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claims."[79] The court continued:

Plaintiffs allege that Medtronic's welding techniques were "defective," but they have not pleaded how that welding technique violated the CGMPs or QSR. This is likely because the CGMPs and QSR do not provide such a fine level of detail concerning the manufacture of defibrillator leads (or most other medical devices). . . . . Plaintiffs simply have not identified any specific requirements in the CGMPs/QSR that were purportedly violated by Medtronic. Without any such specified requirement, Plaintiffs necessarily seek to impose requirements that differ from the CGMPs/QSR.[80]

What is clear from the statute is that only the United States has statutory authority to enforce the cGMP and/or QSR violations under the FDCA:[81] "The FDCA leaves no doubt that it is the Federal Government rather than private litigants [that is] authorized to file suit for noncompliance with the medical device provisions in the FDCA."[82]

*c. FCA's Remedial Scheme Applied to an FDCA Violation*

As discussed above, if the FCA is found to have been violated, defendants are liable for three times the government's damages plus a civil penalty of $5500-$11,000 for each false or fraudulent claim submitted.[83] A relator is entitled to a 15-25 percent of the recovery if the government chose to intervene or 25-30 percent of the recovery if the

[76] Taxpayers Against Fraud, *National Conference for Relators' Counsel*, http://www.taf.org/conferenceprogram.htm (last visited March 18, 2011).
[77] Kenneth Nolan, *CGMP Violations may be the Basis for QUI TAM Lawsuits in the Unite States*, 8 Qual Assur J. 167-71 (2004).
[78] *Id.* at 349 n.4 (citing 21 U.S.C. 337(a)).
[79] 592 F. Supp. 2d at 1157.
[80] *Id.* at 1158.
[81] *Id.* at § 337(a); *see United States v. Utah Med. Prods., Inc.*, 404 F. Supp. 2d 1315, 1317 (D. Utah 2005) (denying injunctive action brought by the United States on behalf of the FDA against a medical device manufacturer for alleged violations of the QSR).
[82] *In re Medtronic, Inc. Sprint Fidelis Leads Products Liabiilty Litigation*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009).
[83] 31 U.S.C. § 3729(a).

government declined to intervene.[84] Whereas the FCA and the FDCA's damages may both be characterized as punitive, they are different.

In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784-86 (2000), the Supreme Court, breaking with its historical understanding of FCA damages as remedial, labeled the Act's treble damages as "punitive." As was noted in *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639 (1981), "[T]he very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers." Courts have allowed the FDA to impose disgorgement of profits as part of the government's relief in actions arising from violations under the FDCA.[85] While treble damages and disgorgement of profits may both be punitive in nature in the contexts discussed herein, disgorgement of profits is a far cry from treble damages. Moreover, had Congress intended for cGMP violations to be met with treble damages, such a remedial structure could have been so legislated; it was not. Therefore, imposition of treble damages is inappropriate in the context of cGMP violations. Because allegations of cGMP violations often result from a lack of shared understanding about the precise and current nature of the requirements, or from a genuine good faith disagreement about technical requirements and not "egregious behavior" deserving of an extraordinary remedy, treble damages under the FCA are unwarranted in this context.[86]

**Conclusion**

Because only the FDA can determine whether a cGMP violation has occurred in the first instance, proceedings to enforce or restrain violations of the FDCA must be brought by the United States.[87] Private plaintiffs should not be able use the FCA to make an "end run" around the jurisdictional limitations of the FDCA and pursue alleged violations of the FDCA under the guise of an FCA suit.[88] Because private citizens have no private cause of action under the FDCA to challenge alleged FDCA violations, any efforts to use the FCA as a "back door" to private FDCA enforcement should be preempted by the FDCA. Consistent with FDA guidance, federal courts have held that allegations related to internal testing and quality-assurance protocols do not constitute an FDCA violation. Moreover, the punitive structure of the FCA does not mirror that of the FDCA, so imposition of the FCA onto FDCA inappropriately punishes the defendant drug or device maker. Such punishment lacks wisdom when cGMP is a flexible process in the first instance. The appropriate remedy for cGMP and QSR violations lies with the United States and the FDA, not with private parties.

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**Kyle Faget** is a graduate of the University of Michigan Law School and currently Counsel at Boston Scientific Corporation, and worked as an associate in Government Enforcement at Ropes & Gray LLP prior to going in-house.

**Boston Scientific Corporation** (abbreviated BSC), is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a range of interventional medical specialties, including interventional cardiology, peripheral interventions, neuromodulation, neurovascular intervention, electrophysiology, cardiac surgery, vascular surgery, endoscopy, oncology, urology and gynecology.

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[84] 31 U.S.C. §3730(d).

[85] *See United States v. RxDepot Inc.*, (2006); *United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005); *see also United States v. Universal Management Servs. Inc.*, 191 F.3d 750 (6th Cir. 1999).

[86] *See* King, *Supra* note 10, at 167.

[87] *See* 21 U.S.C. § 337(a); *see Utah Med. Prods., Inc.*, 404 F. Supp. 2d at 1317.

[88] *See In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) (rejecting plaintiffs' attempt "to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder.")