

cGMP Violations Should Not Be Used as a Basis for FCA Actions Absent Fraud

*Kyle Faget**

I. INTRODUCTION

Since Congress amended the False Claims Act (FCA) in 1986, the statute has evolved into a seemingly boundless weapon for enforcing other statutes and regulations applicable to every industry that accepts any form of government funding. Use of the FCA by the Department of Justice (DOJ) and by private citizens bringing actions on behalf of the U.S. government to enforce other statutes and regulations is particularly evident in the field of health care.¹ The FCA has been utilized in actions where the allegations include off-label promotion of drugs, kickbacks, and violations of current good manufacturing practices (cGMPs) by linking the alleged violation with the government reimbursement under Medicare and Medicaid. cGMP violations, however, are historically enforced by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act (FDCA), which regulates the safety and effectiveness of drugs and devices. Whether alleged cGMP violations are subject to enforcement by the FDA under the FDCA or by the DOJ and private citizens on behalf of the United States government under the FCA, or both, has been heavily debated recently.²

* Kyle Faget is a graduate of the University of Michigan Law School, is 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 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.

1. See John T. Brennan, Jr. & Michael W. Paddock, *Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards*, 2 J. HEALTH & LIFE SCI. L. 37, 40 (2008).

2. Heather Banuelos, *More Scrutiny for cGMP Violations*, CONTRACT PHARMA (May 6, 2013), http://www.contractpharma.com/issues/2013-05/view_fda-watch/more-scrutiny-for-cgmp-violations/.

The DOJ successfully used the FCA as the statutory hook to enable its enforcement authority in an action against GlaxoSmithKline (GSK)³ and Ranbaxy USA, Inc.⁴ DOJ alleged that both companies released adulterated drugs into the stream of commerce in violation of FDCA cGMPs.⁵ The action against GSK resulted in a \$750 million settlement with the United States Attorney's Office for the District of Massachusetts;⁶ Ranbaxy settled with the District of Maryland for \$500 million.⁷ These enforcement actions seem to indicate that the FCA may be used to enforce FDCA cGMP, quality system regulation (QSR) violations, or both.⁸ However, in February 2014, the Fourth Circuit in *United States ex rel. Rostholder v. Omnicare, Inc.* seemingly put the brakes on DOJ's ability to invoke the FCA to enforce cGMP violations when the court held that "adulterated drugs are not barred from reimbursement by Medicare and Medicaid and, therefore, claims for reimbursement for these drugs cannot be 'false' under the FCA."⁹ While the *Rostholder* decision may indicate that using the FCA to enforce the FDCA—and cGMP violations specifically—may not be the fertile ground for sweeping DOJ enforcement as originally imagined; the decision may have simply clarified that the DOJ's enforcement reach is limited to fraud on the FDA, which may include underlying cGMP violations.

This Article examines the statutory background of cGMPs and QSRs, considers enforcement of cGMP violations by both the FDA under the FDCA and the DOJ under the FCA, and proposes that fraudulent and felonious violations of cGMPs should be enforced by the DOJ under the FCA because DOJ has the resources and the expertise to investigate and prosecute such violations. Non-fraudulent cGMP violations, on the

3. See generally Settlement Agreement, *United States ex rel. Eckard v. GlaxoSmithKline*, No. 10-cv-10375 (D. Mass. Oct. 26, 2010), 2010 WL 4339999 [hereinafter GSK Settlement Agreement] (agreeing, in part, to release GSK from potential FCA liability).

4. See generally Settlement Agreement, *United States ex rel. Thakur v. Ranbaxy Labs., Ltd.* No. JFM-07-962 (D. Md. May 13, 2013) [hereinafter Ranbaxy Settlement Agreement], available at <http://www.justice.gov/iso/opa/resources/692013513142957691677.pdf> (agreeing, in part, to release Ranbaxy Laboratories, Ltd. from potential FCA liability).

5. See GSK Settlement Agreement, *supra* note 3; Ranbaxy Settlement Agreement, *supra* note 4.

6. GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant, U.S. DEP'T OF JUSTICE (Oct. 26, 2010), <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>.

7. Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA, U.S. DEP'T OF JUSTICE (May 13, 2013), <http://www.justice.gov/opa/pr/2013/May/13-civ-542.html>.

8. See generally GSK Settlement Agreement, *supra* note 3; Ranbaxy Settlement Agreement, *supra* note 4. See also Consent Decree of Permanent Injunction, *United States v. McNeil-PPC, Inc.*, No. 11-1745 (E.D. Pa. March 10, 2011) [hereinafter McNeil-PPC, Inc. Consent Decree], available at <http://media.npr.org/assets/blogs/health/images/2011/03/mcneilconsentdecree.pdf>.

9. *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 703 (4th Cir. 2014).

other hand, should be enforced by the FDA under the FDCA because the FDA has both the subject matter expertise and the statutory mandate to regulate drugs and medical devices.

II. STATUTORY BACKGROUND OF CGMPs AND QSRs

The government heavily regulates the manufacturing of drugs and medical devices. Under the FDCA, the Secretary of Health and Human Services may

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].¹⁰

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.¹¹ The FDA has statutory authority to enforce violations of the FDCA.

A. Setting QSR and cGMP Standards

QSRs “govern the methods used in, and the facilities and controls used for, the . . . manufacture . . . of all finished devices intended for human use,” and are “intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA].”¹² These regulations require manufacturers to establish specifications and controls for quality and safety.¹³ 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 an-

10. 21 U.S.C. § 360j(f)(1)(A) (2012).

11. *See* 21 C.F.R. §§ 820.1(a)(1), (c) (2010).

12. 21 C.F.R. § 820.1(a)(1) (2010).

13. *See* 21 C.F.R. §§ 820.20–820.75 (2014).

alyzed to identify and correct quality problems; and that complaints be processed.¹⁴

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’ means that the rule is a flexible regulation.”¹⁵ 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.¹⁶

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.¹⁷

The 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.¹⁸ 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).¹⁹

14. ANDREW LOWERY ET AL., U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE QUALITY SYSTEMS MANUAL: A SMALL ENTITY COMPLIANCE GUIDE at 1-1 (1st ed. 1996), available at <http://www.gmp-compliance.org/guidemgr/files/MDQS.manual.pdf>.

15. *Id.* at 1-2 (quoting 21 C.F.R. at § 820.5).

16. *Id.*

17. *Id.*

18. *See* 21 C.F.R. §§ 210–11 (2011).

19. 21 U.S.C. § 351(a)(2)(B) (2012).

Because the FDCA does not provide a definition of what constitutes cGMPs, the determination of what constitutes cGMPs is often a matter of judgment and interpretation.²⁰ The FDA uses the concept of “current” GMP to continuously advance industry best practices and to advance practices not yet used in the industry but that the FDA determines could improve manufacturing controls and drug or device product integrity.²⁰ As a result, the FDA establishes cGMP requirements informally via speeches, guidance documents, FDA investigators’ inspection observations, and letters to manufacturers.²¹ A violation may “result from a good faith technical dispute about what cGMP requires in a particular setting.”²² Theoretically, a conclusion by a field investigator that a particular practice violates cGMP may reflect nothing more than miscommunication between the agency and industry.²³

Significantly, as noted, 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.”²⁴ Under 21 U.S.C. § 351(a)(2)(B), a drug is adulterated if:

[T]he 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 possess²⁵

Once the FDA deems a drug or device adulterated, the FDA has several enforcement tools in its arsenal to remedy the manufacturing failure and to protect consumers from exposure to the drug.

B. FDA’s cGMP Violation Enforcement Tools

The FDA is responsible for investigating violations of the FDCA, including those related to adulterated drugs and devices.²⁶ The Agency may exercise its enforcement authority, derived from 21 U.S.C. § 331,

20. *Id.* at 154.

21. *Id.*

22. *Id.*

23. *Id.*

24. 21 C.F.R. § 820.1(c) (2010).

25. 21 U.S.C. § 351(a)(2)(B) (2012).

26. *See* 21 U.S.C. § 372(a)(1) (2009) (authorizing the Secretary of Health and Human Services “to conduct examinations and investigations for the purpose of [the FDCA]”).

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 or cGMP requirements.²⁷ 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.²⁸ In addition, the FDA relies on voluntary compliance and informal enforcement mechanisms.

1. Advisory Actions

Although the FDA may undertake formal regulatory action in order to enforce its statute,²⁹ in practice the FDA tends to follow a more informal path when pursuing corporate compliance with its statute, which includes issuing informal advisory actions. For example, if an FDA inspector finds “significant objectionable conditions,” during an on-site inspection, the FDA will typically issue a Form 483, which lists “inspectional observations”³⁰ but does not constitute a finding of cGMP violations.³¹ The Form 483 is informal and advisory in nature, and is issued with the expectation that most firms will voluntarily comply with the law by ameliorating the deficiencies observed.³² Should the drug or device maker not promptly address those observations—or if the FDA finds a more serious violation—the FDA may issue a Warning Letter.³³ The Warning Letter constitutes an FDA finding of cGMP noncompliance and puts the

27. 21 U.S.C. § 331(a) (2013).

28. See Nancy Mathewson, *Prohibited Acts and Enforcement Tools*, 65 FOOD & DRUG L.J. 545, 546 (2010).

29. See 21 U.S.C. § 332 (2014); 21 U.S.C. § 333(f)(1)(A) (2012); 21 U.S.C. § 334(a)(2)(D) (2012). See also U.S. FOOD & DRUG ADMIN. OFFICE OF REGULATORY AFFAIRS, REGULATORY PROCEDURES MANUAL ch. 4 (2012), available at <http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/default.htm> [hereinafter FDA MANUAL]. However, 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.*

30. U.S. FOOD & DRUG ADMIN., *Inspection Procedures, in* INVESTIGATIONS OPERATIONS MANUAL at ch. 5.2 (2014), available at <http://www.fda.gov/iceci/inspections/iom/ucm122530.htm>

31. See *id.*; see also 21 U.S.C. § 374(b) (2012).

32. FDA MANUAL, *supra* note 30, at § 4-1-1.

33. The FDA issues a Warning Letter to the highest known company official, which includes: (1) the title “WARNING LETTER”; (2) the inspection dates (if applicable); (3) a description of the violative condition, practice, or product, including the section of law and/or regulation violated; (4) acknowledgement of any corrections promised during an inspection; (5) a request for correction and a written response within a specific period of time after the date of the receipt of the letter (usually fifteen working days); (6) a warning statement that failure to correct the violative condition(s) may result in enforcement action without further notice; and (7) notice that other federal agencies will be advised of the Warning Letter. See FDA MANUAL, *supra* note 30, at ch. 4.

manufacturer on notice that an enforcement or regulatory action could be forthcoming if the violations are not promptly remedied.³⁴

2. Administrative Actions

If the FDA determines that a device is adulterated, the agency may order that the device be detained for up to twenty to thirty days if necessary to institute a judicial enforcement action, such as a product seizure or an injunction.³⁵ The FDA may also choose to request a product recall.³⁶ Typically, the FDA will issue a recall when the Agency believes that there is a grave public health issue at stake.³⁷

The FDA may elect to institute an administrative proceeding against a drug or device company seeking civil monetary penalties.³⁸ The FDA holds subpoena power, which includes the ability to require attendance of witnesses and the production of evidence relating to the matter being investigated.³⁹ After notice and an opportunity for a full administrative hearing,⁴⁰ 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.⁴¹

3. 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.”⁴²

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

34. FDA MANUAL, *supra* note 30, at §§ 4-1, 4-1-10.

35. 21 U.S.C. § 334(g)(1) (2012).

36. 21 C.F.R. § 7.40 (2010).

37. *Id.*

38. *See* 21 U.S.C. § 333(f) (2012).

39. *See* Mathewson, *supra* note 29, at 548; *see also* 21 C.F.R. § 17 (2009).

40. *See* 21 C.F.R. §§ 17.13, 17.33(a) (2009).

41. 21 U.S.C. § 333(b)(7) (2012); *see also* 21 C.F.R. § 17.2 (2014).

42. 21 U.S.C. § 334(a)(2)(D) (2012).

one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); or (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).

Civil liability under 21 U.S.C. § 333(f)(1)(A) is conferred 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.”⁴³

4. Voluntary Compliance and Other Enforcement Mechanisms

The FDA has additional options short of invoking an administrative proceeding or 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 unreasonable risk identified.⁴⁴ Should a firm choose not to comply with the FDA’s notification order, the FDA may issue its own safety alert or warning.⁴⁵ Through publicity, the FDA may pressure a firm to voluntarily recall its product.⁴⁶ The FDA may also issue a pre-market approval suspension or withdrawal if evidence exists that a device is unsafe or ineffective or does not conform to GMP regulation requirements.⁴⁷ If the FDA determines that a device presents an unreasonable risk of illness or injury, the agency may institute proceedings to ban the device.⁴⁸

Finally, while the FDA recommends that component manufacturers voluntarily follow the QSR and cGMP, it does not specify how to do so with any level of granularity. 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

43. 21 U.S.C. § 333(f)(1)(A) (2012).

44. 21 U.S.C. § 360(h)(a) (2012).

45. See Mathewson, *supra* note 29, at 551; see generally *Medical Device Safety Communications*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm> (last visited Aug. 24, 2014).

46. See 21 C.F.R. § 7 (2009).

47. 21 U.S.C. § 360(e) (2012).

48. 21 U.S.C. § 360(f) (2012); 21 C.F.R. § 895 (2009).

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.⁴⁹

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 manufacturers to formulate the best practices possible.

III. THE FALSE CLAIMS ACT

A. Statutory Background of the False Claims Act

Originally enacted during the Civil War to abate fraud against the government by unscrupulous contractors, the FCA “prohibits the knowing submission of false or fraudulent claims for payment . . . to the federal government.”⁵⁰ 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.”⁵¹ Additionally, the FCA imposes liability on any person who “conspires to commit a violation of [any substantive section of the FCA].”⁵² 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 [g]overnment,” or who “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the [g]overnment.”⁵³

B. Enforcement of the FCA

Unlike the FDCA, which can be enforced by the United States exclusively, the FCA may be enforced by the United States, or by a private person, known as a “relator,” in a *qui tam* action, acting on behalf of the

49. See Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/default.htm> (last updated June 30, 2014).

50. *United States v. Pfizer*, 507 F.3d 720, 726 (1st Cir. 2007) (citing 31 U.S.C. § 3729(a)).

51. See 31 U.S.C. §§ 3729(a)(1)(A)–(B) (2009).

52. See *id.* § 3729(a)(1)(C).

53. *Id.* § 3729(a)(1)(G).

United States.⁵⁴ 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.”⁵⁵ 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.⁵⁶ Under the 1986 amendment, Congress increased the incentives for relators to file qui tam actions and increased the penalties associated with FCA violations.⁵⁷ By violating the FCA, defendants are liable for three times the government’s damages plus a civil penalty of \$5,500–\$10,000 for each false or fraudulent claim submitted to the government for reimbursement.⁵⁸ A relator is entitled to 15%–25% of the recovery if the government chose to intervene or 25%–30% of the recovery if the government declined to intervene.⁵⁹

Importantly, “not all fraudulent conduct gives rise to FCA liability.”⁶⁰ As one court has recognized, “[T]he statute attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the ‘claim for payment.’”⁶¹ “Evidence of an actual false claim is the sine qua non of a False Claims Act violation.”⁶² 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.”⁶³

Accordingly, the FCA is not a vehicle for policing every violation of a federal statute or regulation.⁶⁴ Indeed, an FCA violation can be predicated on a defendant’s violation of a statute or regulation only if compli-

54. *Pfizer*, 507 F.3d at 727.

55. *Id.* (citing 31 U.S.C. §§ 3730(b)(2), (b)(4), (c)(1)).

56. See *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010) (citing 31 U.S.C. § 3730(d)).

57. Pub. L. No. 99-562, 100 Stat. 3153 (1986).

58. 31 U.S.C. § 3729(a) (2009).

59. 31 U.S.C. § 3730(d) (2010).

60. *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004).

61. *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995).

62. *Karvelas*, 360 F.3d at 225 (internal citation omitted); see also *United States ex rel. 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.”).

63. 31 U.S.C. § 3729(b)(2)(A) (2009); see also *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.”).

64. *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”); *United States v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007) (“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.”).

ance with that statute or regulation is a condition of government payment.⁶⁵ Moreover, courts have rejected FCA claims that are premised on expressions of opinion or professional or business judgments.⁶⁶

1. The FDA May Enforce Claims that are Factually False, Legally False by Express Certification, or Legally False by Implied Certification

The DOJ may enforce claims that are factually false, legally false by express certification, or legally false by implied certification.⁶⁷

(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.”⁶⁸ 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.⁶⁹ For example, a factually false claim would occur if a health care provider submitted a claim for reimbursement to Medicare for services performed when no services were actually performed.

(b). Legally False Claims Under 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

65. *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.”).

66. *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))).

67. In *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 125 (D. Mass. 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.”

68. *Mikes*, 274 F.3d at 697.

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

a precondition to payment,” yet compliance has not occurred.⁷⁰ The certification need not be in any particular form “so long as the statement of compliance was knowingly false when made.”⁷¹ Absent a certification of past compliance with a specific contract, statute or regulation, where such compliance is a precondition of payment, the alleged legal falsity of a claim for government payment must be analyzed under an implied certification theory.⁷²

(c). Legally False Claims Under 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.”⁷³ 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 contract, statute, or regulation that is a precondition to payment.⁷⁴ The idea under this theory is that the government paid funds to a party, but the government would not have paid those funds had it known of the offending claimant’s violation of a law or regulation.⁷⁵ 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.⁷⁶

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 for which compliance is required for

70. *Johnson & Johnson*, 765 F. Supp. 2d at 125 (internal citation omitted); see also *United States ex rel. Hutcheson v. Blackstone Med. Inc.*, 694 F. Supp. 2d 48, 62 (D. Mass. 2010) *overruled by United States ex rel. Susan Hutcheson & Phillip Brown v. Blackstone Med., 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.”).

71. *Johnson & Johnson*, 765 F. Supp. 2d at 125 (internal citation omitted).

72. See *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 945–47 (N.D. Ill. 2009); *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217–18 (10th Cir. 2008).

73. *Johnson & Johnson*, 765 F. Supp. 2d at 125.

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

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

76. Cf. *United States ex rel. Susan Hutcheson & Phillip Brown v. Blackstone Med., 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).

reimbursement.⁷⁷ 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.”⁷⁸

2. The Materiality Requirement

Regardless of whether 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.”⁷⁹ 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.”⁸⁰ Materiality involves a “determination of the weight that the decision-maker would have given particular information.”⁸¹

Liability is not typically 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; and (3) the falsity caused the government to pay out sums it would not have otherwise paid.⁸² For example, in *United States ex rel. Sanders v. North American Bus Industries, Inc.*,⁸³ the court held that the relator’s allegations that a false claim for payment had been made focused on details that were unimportant to the government’s decision to pay or not to

77. See *In re Pharma. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (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).

78. *United States ex rel. Conner v. Salina Reg’l. Health Ctr.*, 543 F.3d 1211, 1218 (10th Cir. 2008) (emphasis added); 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.”).

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

80. 31 U.S.C. § 3729(b)(4) (2009). Prior to the FERA amendments, the United States Supreme Court decided in *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 668–69 (2008), that liability for false statements supporting false claims was limited to fraudulent statements designed “to get” false claims paid or approved “by the [g]overnment.” *Id.* 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). 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.

81. *Unum Grp.*, 613 F.3d at 308.

82. BOESE, *supra* note 81, at 2-166.

83. *United States ex rel. Sanders v. N. Am. Bus Indus., Inc.*, 546 F.3d 288 (4th Cir. 2008).

pay, and fell well short of what would be required to satisfy a materiality standard.

3. The Causation Requirement

After a reviewing court determines that a false statement was made and that the falsity was material to the government's decision to pay, the courts apply principles of tort law to the False Claims Act to see if causation exists. 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."⁸⁴ Most courts have adopted a proximate cause approach to FCA violations as opposed to a "but for" analysis.⁸⁵ 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.⁸⁶

IV. USING THE FCA TO ENFORCE THE FDCA

Given the statutory background of cGMPs and QSRs, the enforcement mechanisms available to the FDA, and the subject matter expertise the Agency can draw upon, it follows that non-fraudulent cGMP violations should be enforced by the FDA under mechanisms afforded to the agency. No private right of action exists for FDCA enforcement. On the other hand, fraudulent and felonious violations of cGMPs should be enforced by the DOJ or relators on behalf of the United States, which have the resources and the expertise to investigate and prosecute such violations either via federal prosecutors or the relator's private counsel. The existence of fraudulent and felonious behavior is the trigger for DOJ involvement in the context of cGMP violations, not the per se existence of an underlying violation.

84. United States *ex rel.* Franklin v. Parke-Davis, No. Civ.A. 96-11651PBS, 2003 WL 22048255 at *4 (D. Mass. Aug. 22, 2003).

85. *See, e.g.,* United States v. Hibbs, 568 F.2d 347, 349-51 (3d Cir. 1977) (holding that the "but for" causation element would not be applied, but rather a causal connection should be utilized when assessing a false claim allegation); *see also* United States *ex rel.* Schwedt v. Planning Research Corp., 59 F.3d 196 (D.C. Cir. 1995).

86. *See* United States *ex rel.* Sikkenga v. Regence Blue Cross Blue Shield, 472 F.3d 702, 714 (10th Cir. 2006) (noting that "[s]uch an approach is useful in analysing 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"); *see also* United States *ex rel.* Baker v. Cmty. Health Sys., 709 F. Supp. 2d 1084 (D.N.M. 2010).

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 a violation of the Act. Moreover, it is unlikely that any court would imply a private right of action under the FDCA. Since the mid-1970s, the Supreme Court has incrementally restricted the ability of courts to imply a private right of action under federal statutes.⁸⁷

For example, in *Cort v. Ash*, 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.⁸⁸ 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.⁸⁹ Moreover, in *Cort*, the 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.”⁹⁰

Over the next several years, the Supreme Court narrowed the original four-factor test. In *Touche Ross & Co.*⁹¹—a liquidated assets action brought under § 17(a) of the Securities Exchange Act—the Court articulated three factors for determining whether 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.⁹² Nonetheless, the Court opined, the “central inquiry remains whether Congress intended to create, either expressly or by implication, a private cause of action.”⁹³

87. 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).

88. *Cort v. Ash*, 422 U.S. 66, 70–75 (1975).

89. *Id.*

90. *Id.* at 78.

91. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575 (1978).

92. *Id.* at 575–76.

93. *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

When the Court in *Alexander v. Sandoval*⁹⁴ held that the discriminatory impact provision of Title VI of the Civil Rights Act of 1964 did not contain an implied private right of action, the Court determined that congressional intent is the sole criterion for determining whether 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.”⁹⁵ More recently, in *Stoneridge Investment Partners v. Scientific–Atlanta, Inc.*, the Court refused to expand an existing implied private right of action in the context of securities litigation when the Court determined that § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 did not imply a private right of action.⁹⁶

What is clear from the case law on this point is that one dispositive question exists when inquiring whether a statute confers a private right of action; namely, “whether Congress intended to create, either expressly or by implication, a private cause of action.”⁹⁷ 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 because such actions are uniquely reserved for the FDA. The multifaceted arsenal at the disposal of the FDA makes the agency uniquely positioned to enforce its governing statute in ways that a private citizen is not. Moreover, only the FDA is statutorily empowered to 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.

1. Without the Right to Invoke the FDCA, Litigants Invoke the FCA

Following the announcement of GSK’s \$750 million settlement with the United States Attorney’s Office (USAO) for the District of Massachusetts for allegedly releasing adulterated drugs into the stream of commerce due to cGMP violations, whether the FCA may be used by private citizens to enforce cGMP violations,⁹⁸ QSR violations, or both

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).

94. *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001).

95. *Id.* at 286–87.

96. *See Stoneridge Inv. Partners v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 161–62 (2008).

97. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575 (1978).

98. GSK Settlement Agreement, *supra* note 3.

under the FDCA became an open question. Following the GSK settlement, in *United States v. McNeil-PPC, Inc.*, the McNeil-PPC Inc. (McNeil) 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.⁹⁹ 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.¹⁰⁰ Notably, the consent decree specifically stipulates that entry of the decree does not foreclose claims arising under the FCA. Thus, the consent decree held open the possibility that a private citizen could bring a claim against the party even though a partial resolution was reached.

The concept that a relator may bring a cGMP claim under the FCA is not new. In October 2004, the National Conference for Relators' Counsel hosted a panel discussion entitled, "The Federal Food, Drug and Cosmetic Act and Its Application to Qui Tam: Pharmaceutical and Medical Device Cases." During the same year, the panel's moderator published an article, *cGMP Violations May Be the Basis for Qui Tam Lawsuits in the United States*.¹⁰¹ In *United States ex rel. Paul G. King v. Alcon Laboratories, Inc.*, 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 by knowingly and intentionally choosing to operate in a manner that did not comply with the FDA's cGMP.¹⁰²

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.¹⁰³ As stated by the Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 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."¹⁰⁴

99. *United States v. McNeil-PPC, Inc.*, No. 11-1745 (E.D. Pa. Mar. 10, 2011).

100. *Id.*

101. See Kenneth Nolan, *CGMP Violations May Be the Basis for Qui Tam Lawsuits in the United States*, 8 QUAL. ASSUR. J. 167 (2004).

102. *United States ex rel. Paul G. King v. Alcon Labs., Inc.*, 232 F.R.D. 568, 569 (N.D. Tex. 2005).

103. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (citing 21 U.S.C. § 337(a)).

104. *Id.* at 349.

In *In re Medtronic, Inc.*,¹⁰⁵ 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 district 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."¹⁰⁶ 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.¹⁰⁷

What is clear from the statute is that only the United States via the FDA has statutory authority to enforce the cGMP and/or QSR violations under the FDCA.¹⁰⁸ "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."¹⁰⁹

2. FCA's Remedial Scheme Applied to an FDCA Violation

The remedial schemes flowing from a violation of the FCA and the FDCA differ, suggesting that there is a different level of culpability accorded to violating one statute or the other. Liability under the FCA may include treble damages, whereas liability for FDCA violations may result in disgorgement of profits. As discussed above, if the FCA is violated, defendants are liable for three times the government's damages (treble damages) plus a civil penalty of \$5,500–\$10,000 for each false or fraudulent claim submitted.¹¹⁰ A relator is entitled to a 15%–25% share of the

105. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009).

106. *Id.*

107. *Id.* at 1158.

108. *Id.* at 1161 (referring to 21 U.S.C. § 337(a)); *see also* *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).

109. *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1161 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001)).

110. 31 U.S.C. § 3729(a) (2009).

recovery if the government chooses to intervene or 25%–30% of the recovery if the government declines to intervene.¹¹¹

In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Supreme Court, breaking with its historical understanding of FCA damages as remedial, labeled the Act’s treble damages as “punitive.”¹¹² As was noted in *Texas Industries, Inc. v. Radcliff Materials, Inc.*, “[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.”¹¹³ 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.¹¹⁴ While treble damages and disgorgement of profits may both be considered 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 legislated; however, it was not. Given the flexible nature of the FDCA as applied to cGMP and the lack of legislation regarding treble damages, such harsh treatment is arguably unwarranted and inappropriate in the context of cGMP violations. It is hard to imagine the imposition of treble damages for cGMP violations resulting 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; these are not “egregious behavior(s)” deserving of such an extraordinary remedy.¹¹⁵

3. cGMP Violations After *Rostholder*

In *United States ex rel. Rostholder*, the reviewing court held that noncompliance with cGMPs will not give rise to an FCA violation because compliance with the cGMPs is not required for payment by Medicare and Medicaid.¹¹⁶ In the Statement of Interest¹¹⁷ filed in connection with the *Rostholder* proceedings, the government framed the issue of whether a cGMP violation may give rise to an FCA claim in terms of

111. 31 U.S.C. § 3730(d) (2010).

112. *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784–86 (2000).

113. *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639 (1981).

114. *See, e.g., United States v. RxDepot Inc.*, No. 05-5003 (10th Cir. 2006); *United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005); *United States v. Universal Mgmt. Servs. Inc.*, 191 F.3d 750 (6th Cir. 1999).

115. *See King & Walsh, supra* note 19, at 167.

116. *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014).

117. A Statement of Interest is a formal filing made to a reviewing court by the United States when the United States is not a party to an action but has a vested interest in the outcome of the case.

whether or not the deficiencies involved would impact the government's decision to pay a claim for a given drug.¹¹⁸

(a). *The Rostholder Holding's Implications for cGMP Violations*

Proceedings to enforce or restrain violations of the FDCA must be brought by the FDA because only the FDA is statutorily empowered to determine whether a cGMP violation has occurred in the first instance.¹¹⁹ As such, private plaintiffs should not be able to 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.¹²⁰ In *Rostholder*, the court made a more global comment regarding the appropriateness of using the FCA to enforce cGMP violations when the court noted, "When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.'"¹²¹ 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.

Not only did the *Rostholder* court identify the statutory argument for limiting the use of the FCA to enforce cGMP violations, the court also noted that noncompliance with cGMPs will not give rise to an FCA violation because compliance with the cGMPs is not required for payment by Medicare and Medicaid. Therefore, noncompliance with a cGMP is not sufficient to constitute a false statement as contemplated by the FCA.¹²² What is required for a drug to be covered or for payment to issue from Medicare and Medicaid is that a drug be approved for safety and effectiveness under the FDCA.¹²³

118. United States' Statement of Interest As to Defendants' Motion to Dismiss at 3–4, United States *ex rel.* *Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014) (No. CCB-07-1283), 2011 WL 10857612 [hereinafter U.S. Statement of Interest].

119. See 21 U.S.C. § 337(a) (2014); see also United States v. Utah Med. Prods., Inc., 404 F. Supp. 2d 1315, 1317 (D. Utah 2005).

120. 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").

121. United States *ex rel.* *Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (quoting United States *ex rel.* *Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011)).

122. *Id.* at 701–02.

123. *Id.* See also 21 U.S.C. § 355 (2013); 42 U.S.C. § 1396r-8(k)(2)(A)(i) (2014) (Medicaid); 42 U.S.C. § 1395w-102(e) (2014) (Medicare Part D); 42 C.F.R. § 423.100 (2013) (defining Medicare Part D drug).

(b). *The Government's Statement of Interest in Rostholder Links cGMP Violations with FCA Claims to the Government's Decision to Pay Claims for Products*

In its Statement of Interest, the government frames the issue of whether a cGMP violation may give rise to an FCA claim in terms of whether or not the deficiencies involved would impact the government's decision to pay a claim for a given drug.¹²⁴ The government concludes that "cGMP regulations may, in certain circumstances, be material to the government's decision whether to pay for the affected products."¹²⁵ These circumstances include "violations of cGMP regulations . . . where the violations are significant, substantial, and give rise to actual discrepancies in the composition or functioning of the product."¹²⁶ The government goes on to argue that some drugs may be so affected by the cGMP violations that the drug is essentially worthless and, therefore, ineligible for payment by the government.¹²⁷

According to the court in *Rostholder*, whether a false claim exists or not depends on whether compliance with the underlying regulation is a precondition of payment.¹²⁸ In contrast, in its Statement of Interest, the government is focused on the fact that certain deficiencies in a drug would materially impact the government's decision to pay for the drug, and suggests that compliance with a regulation could in fact, in certain situations, be a precondition of payment.¹²⁹

The *Rostholder* court's theory of liability and the government's concern about reimbursement in certain situations where a drug is deficient can be read together, rather than at odds. It is not that noncompliance with a regulation gives rise to an FCA violation per se; rather, noncompliance with a regulation may, if coupled with fraudulent behavior, give rise to an FCA violation. It is the fraud that is the hook for the claim, not the violation of the regulation, even though fraud may be committed in the context of noncompliance with a regulation. In other words, fraud may be the basis for a cGMP violation, and then, and only then, would an FCA claim be triggered.

124. U.S. Statement of Interest, *supra* note 119, at 3–4.

125. *Id.*

126. *Id.*

127. *Id.*; see, e.g., *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011).

128. *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701–02 (4th Cir. 2014).

129. U.S. Statement of Interest, *supra* note 119, at 4.

(c). *DOJ Interventions in cGMP Violation Cases Occur Under Egregious and Fraudulent Circumstances*

Under the *Rostholder* court's theory of liability, the DOJ or a relator could have a cognizable FCA claim if the FDA would have withdrawn its approval of a drug or device had it been in a position to make such a determination but could not due to fraudulent representations made to the FDA. Whether a drug or device is properly approved as safe and effective may be called into question if fraudulent representations are made to the FDA resulting in drugs and devices being released into the market that are so unsafe and so ineffective that the FDA would have withdrawn approval but for the fraudulent representations made to the agency. In this scenario, submitting a claim for reimbursement for drugs or devices that are defective to the point that the FDA would have withdrawn its approval of the drug or device is arguably a false claim and, therefore, appropriately subject to FCA allegations even under *Rostholder*. In fact, this is sound jurisprudence and sound policy being born out in practice. A small sampling of the existing body of cGMP case law demonstrates that the FCA is successfully invoked in exactly these kinds of scenarios. The DOJ has intervened and relators have only recovered under the FCA in the most egregious cGMP violation cases and in cases where there exists clear fraud on the FDA.

In *United States ex rel. Cheryl Eckard v. GlaxoSmithKline*, GSK was accused of knowingly selling contaminated drugs made at its manufacturing facility in Puerto Rico from 2001–2005.¹³⁰ GSK's plant was alleged to have used a water system infected with microbial contamination, resulting in products being made under unsterile conditions.¹³¹ The plant undertook production and bottling of tablets of varying strength or lacking therapeutic effect wholesale, and the plant had a history of product mix-ups resulting in commingling of drug products.¹³² Additionally, the plant failed to report important safety data to the FDA.¹³³ The cGMP violations involved rose to the level of criminal prosecution, albeit declined via a Side Letter Agreement in exchange for full performance of the Plea Agreement.¹³⁴

More recently, in *United States v. Ranbaxy Laboratories, Ltd.*, Ranbaxy settled criminal and civil allegations that the generic manufacturer knowingly introduced drugs produced from a facility with

130. GSK Settlement Agreement, *supra* note 3.

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

longstanding cGMP failures into interstate commerce.¹³⁵ Specifically, Ranbaxy was cited for having incomplete testing records, an inadequate stability testing program, failing to disclose relevant information to the FDA during inspection, failing to maintain sterile manufacturing conditions, and failing to file timely field alerts (a required FDA submission upon a manufacturer discovering a drug product poses safety threats).¹³⁶

In both the *GlaxoSmithKline* case and the *Ranbaxy* case, one may safely conclude that the FDA—were it properly informed of the deficiencies at stake—would have withdrawn approval of the adulterated drugs under 21 U.S.C. § 355, which would have rendered the drugs ineligible for payment under the Medicare and Medicaid statutes.¹³⁷ The same conclusion cannot be drawn from the underlying facts in *Rostholder*.¹³⁸

In *Rostholder*, the relator alleged that Omnicare packaged both penicillin and non-penicillin products in the same building without complying with the cGMP, which required separation and controls be in place to prevent cross-contamination.¹³⁹ The cGMP violation led the FDA to issue a warning letter, and the company purportedly disposed of \$19 million dollars of pharmaceutical inventory.¹⁴⁰

B. The FDA Should Have Oversight over Garden Variety cGMP Violations; DOJ over cGMP Violations of a Fraudulent Nature

When contrasting the underlying facts in *Rostholder* to *GlaxoSmithKline* and *Ranbaxy*, it becomes clear that the violations at stake are of a very different nature. In *Rostholder*, the cGMP violations included what are colloquially understood as garden-variety cGMP violations, and the conditions underlying the violations were not based in fraud or false statements. Thus, the FDA was perfectly positioned to identify and act on the violations. In fact, the FDA was able to investigate and remediate the issue within two visits to the site.¹⁴¹ The FDA's ameliorative actions indicate that the cGMP violation involved did not rise to the level of the FDA needing to withdraw approval of the drugs, regardless of

135. Ranbaxy Settlement Agreement, *supra* note 4.

136. *Id.*

137. See 42 U.S.C. § 1396r-8(k)(2)(A)(i) (2014) (Medicaid); 42 U.S.C. § 1395w-102(e) (Medicare Part D) (2014); 42 C.F.R. § 423.100 (2013) (defining Medicare Part D drug).

138. United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014).

139. *Id.*

140. *Id.* at 698.

141. *Id.*

whether the drug was adulterated within the meaning of FDCA.¹⁴² In situations resembling *Rostholder*, the FDA is the appropriate arm of the government to address the regulatory violations.

What distinguishes *GlaxoSmithKline* and *Ranbaxy* from *Rostholder* is the fraudulent conduct at issue and the consequences of that conduct. If there is a place for the DOJ and relators to initiate actions to enforce the FDCA using the FCA, the actions should be restricted to cases where there either exists some evidence of criminal intent to defraud the FDA, significant and reckless disregard for the truth of statements made to FDA, or systemic, pervasive, and long-standing cGMP failures where a real threat to patient harm exists. In such instances, companies have engaged in felonious FDCA adulteration, and the DOJ has the requisite experience and resources to adequately investigate and prosecute such companies. The government's Statement of Interest admits:

The United States readily acknowledges that not every violation of the Food Drug & Cosmetic Act is a *per se* violation of the FCA because not every regulatory violation has a nexus to payment. Rather, where the defendant has engaged in a fraudulent course of conduct involving such violations, the touchstone is whether the defendant's conduct compromised "the reliability and trustworthiness of a claim" such that it might cause the government to actually refuse payment.¹⁴³

In other words, the issue at stake in a cGMP violation case that implicates the FCA is not the underlying cGMP violation *per se*, but rather the fraudulent conduct giving rise to an egregious cGMP violation such that, were the facts known to the FDA, the drug or device would have been withdrawn from the marketplace because the egregiousness of the violation indicates that the drug was either unsafe or ineffective. In either case, the claim for payment would have been denied.

This analysis is bolstered in light of the 2013 DOJ announcement that it would be increasing enforcement against pharmaceutical manufacturers by examining violations of cGMPs that create an unacceptable risk of harm to consumers and the public.¹⁴⁴ The DOJ's interest appears to be in felonious cGMP violations that the FDA cannot manage on its own

142. See 21 U.S.C. § 331 (2013); 21 U.S.C. § 351(a)(2)(B) (2012); 21 C.F.R. § 210.1 (2011) (failure to comply with the cGMP renders a drug "adulterated").

143. U.S. Statement of Interest, *supra* note 119, at 5.

144. Deputy Assistant General Maame Ewusi-Mensah Frimpong Speaks at the 2013 CBI Pharmaceutical Compliance Congress, U.S. DEP'T OF JUSTICE (Jan. 29, 2013), <http://www.justice.gov/iso/opa/civil/speeches/2013/civ-speech-130129.html>.

due to the underlying fraudulent behavior on the part of the manufacturer.

V. CONCLUSION

In instances where companies have engaged in felonious FDCA adulteration, the DOJ has the requisite experience and resources to adequately investigate and prosecute such violations. In these cases, the DOJ can rely on the FDA's subject matter expertise for guidance regarding cGMP violations. Enforcement of egregious and felonious cGMP violations by the FDA would require significant time and resources from the agency and, in the end, would still require relying upon the DOJ for prosecution. Moreover, it is not clear that the FDA would have access to information that could uncover such fraudulent behavior, whereas relators would have access to such information. Thus, the DOJ and the FDA perform must work hand in hand when enforcing the FDCA via the FCA. That said, the DOJ should not initiate cGMP violation actions in the absence of fraud and without input from the FDA. Were the DOJ to take up garden-variety cGMP violations, the DOJ would essentially be acting as the FDA, which would be unfortunate given the DOJ's lack of subject matter expertise. It is in everyone's best interest to have cGMP violations defined and enforced by the agency with the best information in the field; namely, the FDA.