WORTHLESS SERVICES AND DRUGS IS A VIABLE THEORY OF RECOVERY UNDER THE FALSE CLAIMS ACT: ESTABLISHING A UNIFORM STANDARD FOR COURTS TO ADOPT

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INTRODUCTION

An estimated ten percent of federal government spending, or approximately $350 billion a year, is lost due to fraud.[1] In order to help detect and discourage this fraud, Congress enacted the False Claims Act (the "FCA").[2] Although the FCA started as a way to redress and deter fraud committed by military contractors, it quickly moved into the realm of health care fraud. In 2023, Medicare spending is expected to top $1 trillion, but an estimated ten percent of Medicare spending is lost to fraud.[3] In the past ten years, from 2011 to 2020, the Department of Justice ("DOJ") recovered $24.75 billion in health care fraud cases.[4] With

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[1] Joel D. Hesch, *Understanding the "Original Source Exception" to the False Claims Act's "Public Disclosure Bar" in Light of the Supreme Court's Ruling in* Rockwell v. United States, 7 DEPAUL BUS. & COM. L.J. 1, 1 n.3 (2008) [hereinafter Hesch, *Understanding the "Original Source Exception*"]; OFF. OF MGMT. & BUDGET, BUDGET OF THE U.S. GOVERNMENT FOR FISCAL YEAR 2022 1, 41 (2021).

[2] 31 U.S.C.A. §§ 3729-3733 (West). Under the *qui tam* provisions of the FCA, relators (also called "whistleblowers") file *qui tam* suits on behalf of the government against individuals or entities that are committing fraud against the government. *Id.* at § 3730(b)(1). These relators are often former employees with insider knowledge regarding the fraud at question. *See* Hesch, *Understanding the "Original Source Exception*," *supra* note 1, at 2 n.9. Because of the recovery scheme, under the *qui tam* provisions, these provisions have become the government's best tool for fighting fraud. *See* Joel D. Hesch, *Breaking the Siege: Restoring Equity and Statutory Intent to the Process of Determining* Qui Tam *Relator Awards Under the False Claims Act*, 29 T.M. COOLEY L. REV. 217, 232 (2012) [hereinafter Hesch, *Breaking the Siege*].

[3] Joel D. Hesch, *Allowing Whistleblowers to Copy Company Documents to File* Qui Tam *Complaints Under the False Claims Act When Reporting Medicare Fraud*, 13 LIBERTY U. L. REV. 265, 267 (2019).

[4] The government keeps track of all FCA cases and recoveries, including the amount paid to whistleblowers. Press Release, Civ. Div., U.S. Dep't of Just., Fraud Statistics – Health and Human Services: October 1, 1986 - September 30, 2020 (https://www.justice.gov/opa/press-release/file/1354316/download)

healthcare spending taking such a large amount of the annual budget, Congress has a vested interest in making sure that taxpayer dollars are not spent on worthless services.

Medicare patients are often the target of unscrupulous healthcare providers because the elderly are easily taken advantage of and the government has limited auditing or oversight protections in place. It is estimated that ten percent of America's elderly are abused in this way every year.[5] Examples of fraudulent billing for worthless services include nursing homes not feeding patients or changing soiled linens.[6] Examples of worthless drugs include both pharmaceutical manufacturing companies delivering unsafe and even harmful drugs,[7] or healthcare providers administering drugs that are expired or adulterated.[8]

[https://perma.cc/AH7P-5GQN]. Of note, $21.9 billion of this amount was recovered in cases initiated by *qui tam* complaints.

[5] Ron Acierno et al., *Prevalence and Correlates of Emotional, Physical, Sexual, and Financial Abuse and Potential Neglect in the United States: The National Elder Mistreatment Study*, 100 AM. J. PUB. HEALTH 292, 292 (2010).

[6] *See, e.g.*, Press Release, Civ. Div., U.S. Dep't of Just., Signature HealthCARE to Pay More Than $30 Million to Resolve False Claims Act Allegations Related to Rehabilitation Therapy (June 8, 2018) (https://www.justice.gov/opa/pr/signature-healthcare-pay-more-30-million-resolve-false-claims-act-allegations-related) [https://perma.cc/KYR8-JMM6]; Press Release, Civ. Div., U.S. Dep't of Just., Vanguard Healthcare Agrees to Resolve Federal and State False Claims Act Liability (Feb. 27, 2019) (https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability) [https://perma.cc/MB83-R257]; Press Release, Civ. Div., U.S. Dep't of Just., Life Care Centers of America Inc. Agrees to Pay $145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services (Oct. 24, 2016) (https://www.justice.gov/opa/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act-allegations) [https://perma.cc/2YY2-PUUW]. As a result, the DOJ created the Elder Justice Initiative and National Nursing Home Initiative within the Fraud Section of the DOJ. This group uses the FCA to help protect the elderly from abuse and abysmal care. Their website can be found at https://www.justice.gov/elderjustice [https://perma.cc/ME7N-2ZPX].

[7] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 896 (9th Cir. 2017). For example, certain medication in a pill form was found to contain harmful contaminants such as lead and arsenic. *Id.*

[8] *See* Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC, 417 F. Supp. 3d 531, 537 (E.D. Pa. 2019) (involving allegations that a drug company was providing Medicare patients with drugs that did not comply with cGMPs, which rendered them adulterated); Davis v. Main St. Fam. Pharmacy, LLC, No. 5:16CV45-MW/GRJ, 2016 WL 9051172, at *3 (N.D. Fla. May 19, 2016) (involving adulterated injections that were essentially worthless); Amerisource Corp. v. United States, No. 04-610C, 2005 WL 6112630, at *1 (Fed. Cl. Nov. 15, 2005) (involving allegations that a drug company was providing elderly patients with expired drugs, which were worthless).

There are four elements to establish liability under the FCA, and if all are met, the defendant must pay triple damages plus civil penalties.[9] They consist of: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due."[10] Courts have sometimes placed violations into three categories: (1) express false certification,[11] (2) implied false certification,[12] and (3) worthless services or goods.[13] However, these theories are merely nomenclature. A defendant is not liable based upon a label or theory of liability, but whether the four essential elements of the statute are met. Indeed, the Supreme Court has recognized that Congress intended that the FCA would "reach all types of fraud, without qualification, that might result in financial

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[9] 31 U.S.C.A. § 3729(a) (flush language) (West).

[10] United States *ex rel.* Hendow v. Univ. of Phx.*,* 461 F.3d 1166, 1174 (9th Cir. 2006).

[11] Under the express false certification theory, "a government payee 'falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.'" United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (quoting Mikes v. Straus, 274 F.3d 687, 698 (2d Cir. 2001)). To succeed under the false certification theory, the plaintiff must show that a defendant's certification of compliance with a particular law or statute was a condition for payment, and the defendant knowingly lied when making the certification. *See generally id.* at 1217-19. *See also* United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1269 (D.C. Cir. 2010) (Under implied certification, a claim for payment does not have to contain "express contractual language specifically linking compliance to eligibility for payment," but merely proof "that the contractor withheld information about its noncompliance with material contractual requirements."); United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 383 (1st Cir. 2011) ("Under the implied certification theory, a claim is false when the claimant makes no express certification of 'compliance with a statute or regulation, but by submitting a claim for payment, implies that it has complied with any preconditions to payment' contained in statutes or regulations." (quoting United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 63, 66 (Mass. Dist. Ct. 2010), *rev'd*, 647 F.3d 377 (1st Cir. 2011))).

[12] Under the implied false certification theory, "when a defendant submit[ted] a claim, it impliedly certifie[d] compliance with all conditions of payment. But if that claim fail[ed] to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement . . ., the defendant . . . made a misrepresentation that render[ed] the claim 'false or fraudulent' under § 3729(a)(1)(A)." Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1995 (2016) ("[T]he implied false certification theory can be a basis for liability.").

[13] Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001), *abrogated by* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

loss to the Government."[14] The submission of worthless services or drugs, which is the topic of this Article, clearly satisfies each of the four FCA elements. An allegation that defendants violated the FCA by submitting claims for worthless services is not predicated upon an express or implied certification of compliance with a requirement. Instead, liability for worthless services is based on the knowing request for federal funds for services or goods that have no value.[15] The key is whether a defendant's particular inclusion of worthless services or drugs into proffered performance meets the four statutory elements. Where courts veer off is by focusing upon whether the worthless services or drugs render the entirety of performance worthless rather than whether the defendant supplied worthless services or drugs.[16] It is not an all-or-nothing approach. If one aspect of the performance is worthless, a defendant is liable because the four statutory elements are still met. Rather, the worthless services doctrine often boils down to a function of damages. If the worthless services or drugs render the entirety of the performance worthless, damages are the full contract value. If the worthless services only affect a portion of the performance, damages may be the portion of the contract that are affected.

This Article addresses the doctrine of worthless services as it applies to medical procedures or drugs. Because this theory of FCA liability has not yet been uniformly adopted or applied by the courts, its scope and application are unclear. This Article proposes a reasoned and uniform standard for courts to adopt in terms of both liability and damages. In order to succeed under the worthless services theory of liability, the court need not find that a defendant certified compliance, but rather liability attaches when some or all of "the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."[17] Again, the label of a liability theory is not controlling; if a particular service or drug delivered under a government program is worthless, the request for payment for that service or drug is a false claim.[18] A

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[14] Cook Cnty. v. United States *ex rel.* Chandler, 538 U.S. 119, 129 (2003) (quoting United States v. Neifert-White Co., 390 U.S. 228, 232 (1968)).

[15] *Mikes*, 274 F.3d at 702.

[16] *Id.* at 702-03.

[17] *Id.* at 703.

[18] 31 U.S.C.A. § 3729(a)(1)(A)-(B) (West).

defendant is liable under the FCA if just some aspect of the service was worthless even if other aspects of associated services had value because it remains a violation of the statutory elements of the Act. Again, the nomenclature or theory of liability does not control, but rather whether the four elements of the FCA are met. This Article demonstrates why the FCA requirements are met when performance includes particular worthless services, goods, or drugs.

In this Article, Section I explains the purposes and provisions of the FCA. Section II reviews the current unsettled case law surrounding the circuit courts of appeals for the worthless theories of liability under the FCA. Section III argues that the courts need to adopt the worthless services and drugs theories of liability. Section IV provides a framework for courts to use in creating a standard bright-line rule for the worthless services and worthless drugs doctrines, including an example. Section VI presents the conclusion.

I. THE PURPOSES AND PROVISIONS OF THE FCA

The False Claims Act was enacted by President Abraham Lincoln in 1863[19] in response to the military suffering from staggering amounts of fraud.[20] For example, "[f]or sugar [the government] often got sand."[21] To combat this fraud against the

[19] S. REP. NO. 99-345, at 8 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5273. "The False Claims Act of 1863 was adopted during the Civil War in order to combat fraud and price-gouging in war procurement contracts." United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 649 (D.C. Cir. 1994) (citation omitted).

[20] *See* CLAIRE M. SYLVIA, THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 2:6, at 42 (2d ed. 2010).

[21] Michael Neal, Note, *Securities Whistleblowing Under Dodd-Frank: Neglecting the Power of "Enterprising Privateers" in Favor of the "Slow-Going Public Vessel"*, 15 LEWIS & CLARK L. REV. 1107, 1110 (2011) (alteration in original) (quoting SYLVIA, *supra* note 20, § 2:6, at 42-43).

military,[22] Congress enacted the FCA.[23] It is striking that the FCA was enacted 150 years ago to address worthless goods being provided to the military. Since that time, the FCA has become the government's best tool for preventing and rectifying fraud against the government.[24] The FCA requires a person or company that knowingly submits false claims for payment under any federal contract or program to repay three times the amount of funds wrongfully obtained, plus civil penalties of up to $10,000 for each

[22] *See* United States v. Gen. Elec., 808 F. Supp. 580, 581 (S.D. Ohio 1992) ("There is historical evidence that [at the Battle of Gettysburg] a critical position known as Little Roundtop was almost overrun by Confederate troops because of a lack of Union rifles and ammunition. Armament which had been purchased from private suppliers arrived in boxes that contained only sawdust." (footnote omitted)).

[23] *See* United States v. Northrop Corp., 59 F.3d 953, 963 (9th Cir. 1995) (citing S. Rep. No. 99-345, at 2-3 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5267-68).

[24] Hesch, *Breaking the Siege*, *supra* note 2, at 232. The FCA also has unique and powerful *qui tam* provisions that permit a private individual to bring an action on behalf of the federal government. 31 U.S.C.A. § 3730(b)(1) (West). A relator must file a *qui tam* complaint in order to be eligible to receive a reward under the FCA provisions. § 3730(b)(1)-(2). Congress created a reward scheme for relators based on whether the government intervenes in the case and whether the relator contributes to the government's case. § 3730(d)(1)-(2). Accordingly, the FCA encourages whistleblowers to not only inform the government of allegations of fraud but also to participate in *qui tam* actions and even pursue the entire case alone if the government elects to decline. *See generally* Hesch, *Breaking the Siege*, *supra* note 2, at 233. Congress vested the relator with the right to pursue the action if the government declines. § 3730(b)(4) ("Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—(A) proceed with the action, in which case the action shall be conducted by the Government; or (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action."); § 3730(c)(3) ("If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action.").

false claim.[25] The FCA also prohibits making or using false statements or records material to false claims for payment.[26]

While the FCA started as a way to combat fraud committed by military contractors, it has become the best tool for combatting fraud involving Medicare and Medicaid as well.[27] Studies show that around ten percent of claims submitted to Medicare are fraudulent.[28] With Medicare spending set to top $1 trillion in 2023, it is vital that the government prohibit fraudulent claims as much as possible.[29] One area of healthcare that is rife with Medicare and Medicaid fraud is health care service providers. Nursing homes in particular often involve the care of patients that are on Medicaid. The nursing home cares for the patient and many of the expenses are submitted to Medicaid for reimbursement. Unfortunately, there have been a number of instances in which nursing homes have provided inadequate care for patients; yet, the health care providers submit claims for reimbursement of the full value of the services to Medicaid.[30] As a result, the government pays health care service

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[25] 31 U.S.C.A. § 3729(a)(1)(A)-(G) (West). If there is a violation, the FCA provides that such person "is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus [three] times the amount of damages which the Government sustains because of the act of that person." *Id.* (footnote omitted). When the FCA was amended in 2009, the liability sections were renumbered from (a)(1)-(7) to (a)(1)(A)-(G). The amount of civil penalties has been increased from time to time to account for inflation. Effective November 2, 2015 (the date of enactment of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. No. 114-74, § 701 ("2015 Amendments")), the penalties increased from a minimum-maximum per-claim penalty of $5,500 and $11,000 to $10,781 and $21,563. In January 2020, these amounts were increased to $11,665 and $23,331. 15 C.F.R. § 6.3 (2020); Civil Monetary Penalty Adjustments for Inflation, 85 Fed. Reg. 207, 208 (Jan. 3, 2020) (to be codified at 15 C.F.R. pt. 6).

[26] 31 U.S.C.A. § 3729(a)(1)(A)-(B) (West).

[27] Joel D. Hesch, *Allowing Whistleblowers to Copy Company Documents to File* Qui Tam *Complaints Under the False Claims Act When Reporting Medicare Fraud*, 13 LIBERTY U. L. REV. 265, 265 (2019).

[28] *Id.* at 267.

[29] *Id.* (citing *Government Spending Details*, USGOVERNMENTSPENDING.COM, https://www.usgovernmentspending.com/year_spending_2017USbn_XXbs7n_10 [https://perma.cc/U7SW-ZZP3] (last visited Feb. 3, 2019), and accompanying charts).

[30] For example, see United States *ex rel.* Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 703-05, 709-10 (7th Cir. 2014).

providers the full value for services that were actually deficient. In addition, some drug companies manufacture drugs that they know are contaminated or adulterated; however, they still submit claims to the federal government for full reimbursement.[31] Similarly, hospitals or other providers misuse drugs by giving patients expired drugs or administering them in a manner outside of the manufacturer's recommendations, which is potentially dangerous.[32]

In response to these types of cases, the government typically relies upon three different theories of liability under the FCA: the express false certification theory, the implied false certification theory, and the worthless services theory. The express false certification theory is fairly straightforward and well-accepted because it necessarily meets all four statutory requirements.[33] Although the different circuit courts of appeals had different standards for the implied false certification theory,[34] the Supreme Court held the theory to be valid and established a uniform standard for the theory in *Universal Health Services, Inc. v. United States ex rel. Escobar*.[35] However, confusion amongst the circuits exists today regarding the scope and applicability of the worthless services theory of liability. While some circuit courts have adopted the worthless doctrine, others have either deferred adopting the theory[36] or have yet to address it. Of the courts that have adopted this theory of liability, the Second and Ninth Circuits disagree about the standard for what constitutes a worthless service.[37] The circuits also disagree regarding whether a worthless services claim can succeed when the worthless services are part of bundled

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[31] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 896-99 (9th Cir. 2017). For example, a certain medication in a pill form was found to contain harmful contaminants such as lead and arsenic. *Id.* at 896.

[32] *See supra* note 8.

[33] *See supra* note 11.

[34] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1996, 1998 (2016) (resolving "disagreement among the Courts of Appeals over the validity and scope of the implied false certification theory").

[35] *Id.* at 1995 ("[T]he implied false certification theory can be a basis for liability.").

[36] United States *ex rel.* Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 709-10 (7th Cir. 2014).

[37] Michael R. Crowe, *The Road to* Momence *and* Houser*: When Are Services "Worthless" in Skilled Nursing Facilities?*, 16 NO. 6 J. HEALTH CARE COMPLIANCE 5, 8 (2014).

services.[38] Additionally, the few circuits addressing the application of this theory to drugs have applied varying standards for determining whether the drug is worthless. Below is a discussion of the status of the law followed by a proposed standard.

II. STATUS OF THE LAW

As explained above, there is no uniform application of the "worthless services doctrine." Some circuits have accepted the worthless services doctrine, while some circuits have either deferred adopting the doctrine or not yet taken up the issue. In addition, some district courts have tried to set standards in between the two extremes.[39] A consistent and uniform standard will allow relators, health care providers, and the government to know when certain actions will subject health care providers to liability under the FCA. In addition, the quality of life of millions of elderly or poor patients around the country is at stake. The following section outlines the different approaches taken by the circuit courts of appeals in addressing the worthless services doctrine. The Article then proposes a uniform standard.

The Second Circuit Court of Appeals addressed the worthless services doctrine in one of the most cited cases regarding this issue—*Mikes v. Straus*.[40] In that case, a medical partnership that was studying pulmonology hired a pulmonologist to help it conduct studies and take care of the patients involved in those studies.[41] The partnership fired the pulmonologist, and she filed suit against the partnership under the *qui tam* provisions of the FCA based on the partnership submitting substandard spirometry tests.[42] The court looked at whether the claims for payment for substandard spirometry tests were claims for worthless services under the FCA.[43] The court held that, in order to be considered worthless, the

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[38] *Id.* at 6, 13.
[39] *Id.* at 13.
[40] Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001).
[41] *Id.* at 692.
[42] *Id.* at 692-93.
[43] *Id.* at 702-03.

service must be so deficient as to be completely worthless.[44] The court held that the plaintiff did not sufficiently show that the tests were in fact completely worthless.[45]

Importantly, this court began to establish the jurisprudence regarding the worthless services doctrine; however, it fell short in extending the doctrine to its fullest measure and otherwise failed to provide sufficient guidance for its application.[46] The court correctly ruled that the worthless services theory is a separate theory of liability from the false certification theories. But the court was wrong to the extent it created any extra-FCA elements to the FCA. Indeed, the court's decision must not be read to require the entirety of the services provided to be completely worthless. Rather, as explained below, if a portion of the services were worthless, the defendant should be liable for the portion of the contract or services that were worthless provided that the four essential elements of the FCA are satisfied. A defendant cannot escape FCA liability for worthless services merely because it also provided some services that had value. Again, if the particular services that are worthless satisfy the four elements of the FCA, the defendant is liable, period. It really boils down to calculating damages, i.e., whether full contract value or a portion of the contract.

Similar to the Second Circuit, the Sixth Circuit has also adopted the worthless services doctrine under the FCA.[47] In *Chesbrough v. VPA, P.C.*, a radiology company contracted with an at-home service provider to conduct radiology tests.[48] The company submitted to Medicaid claims for payment of these radiology tests, which consisted of images produced by the provider.[49] A relator brought a claim under the FCA and alleged that the radiology tests were defective.[50] When analyzing the tests under the worthless services theory of liability, the court found that five of the tests were so poorly done that they were worthless; therefore, these five tests could be subject to liability under the FCA.[51] In reaching its

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[44] *Id.* at 703.
[45] *Id.*
[46] Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001).
[47] Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011).
[48] *Id.* at 464-65.
[49] *Id.* at 464.
[50] *Id.* at 465.
[51] *Id.* at 468-69.

decision, the court correctly held that if a portion of the contract or services provided, i.e., certain tests, were worthless, then the defendant is liable under the FCA for those worthless services provided; the defendant does not escape liability because it also provided tests with medical value.[52] However, the court dismissed the claim because there was no evidence that the defendants actually submitted claims to Medicaid for those tests.[53] Nonetheless, the Sixth Circuit recognized the worthless services doctrine as a valid theory of liability under the FCA.[54] It also recognized that the issue really is one of damages and the portion of the contract affected by the worthless service.

The Seventh Circuit deferred answering the question of whether worthless services were a viable theory of liability, although it did recognize that several circuits had adopted the worthless services doctrine.[55] In *Absher*, a nurse brought a *qui tam* complaint against a nursing home for its deplorable care of residents.[56] The nurses alleged that patients suffered from bedsores, inconsistent administering of medication, and cleanliness problems with both food and water.[57] After explaining the worthless services doctrine, the court declined to make a decision on whether or not to adopt it because the plaintiffs did not show that the services were worthless.[58]

The Ninth Circuit has recognized the worthless services doctrine, although its analysis of the doctrine was limited. In 2001, the Ninth Circuit recognized that a claim under the worthless services doctrine did exist, and it adopted the theory of liability.[59] In that case, a relator brought claims under the FCA against a lab

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[52] *Chesbrough*, 655 F.3d at 468-69.

[53] Chesbrough v. VPA, P.C., 655 F.3d 461, 472 (6th Cir. 2011).

[54] *Id.* at 468-69.

[55] United States *ex rel.* Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 709 (7th Cir. 2014).

[56] *Id.* at 704.

[57] *Id.* at 704-05.

[58] *Id.* at 710.

[59] United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001).

that tested human specimens (e.g., blood).[60] The relator alleged that if the lab's control sample fell outside of the allowable standard of error, the lab would falsify results and bill Medicaid for the tests.[61] The court recognized that the plaintiff could make a valid claim under the worthless services doctrine, and the court allowed the plaintiff to amend his complaint to make this argument.[62]

The Eighth Circuit has recognized the worthless services theory of liability.[63] In that case, relators alleged that Hypoguard blood glucose tests and strips were defective; therefore, many of the distributors' claims for reimbursement for the tests and strips to Medicaid were false and subject to FCA liability.[64] The court recognized the worthless services theory of liability under the FCA, but it held that the sale of a defective product did not satisfy the standard required because the tests were not worthless.[65] It should be noted, however, that the FCA does not require that services or goods be worthless to be an FCA violation. Even supplying inferior goods or knowingly substituting goods or services is an FCA violation.

The analysis of the current case law above demonstrates the need for a uniform rule pertaining to the so-called worthless services doctrine.

A. Worthless Drugs Theory

Few courts have addressed whether the worthless services theory applies to claims for payment for worthless drugs. The Third Circuit addressed this issue in *United States ex rel. Petratos v. Genentech Inc.* In this case, Genentech created the drug Avastin to combat cancer, and Medicare reimbursed Genentech $1.13 billion a year for Avastin.[66] Petratos, the former head of the department of health care data analytics for Genentech, filed a *qui tam* suit and alleged that Genentech submitted false claims for reimbursement

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[60] *Id.* at 1050-51.

[61] *Id.* at 1050.

[62] *Id.* at 1053-54.

[63] United States *ex rel.* Roop v. Hypoguard USA, Inc., 559 F.3d 818, 824 (8th Cir. 2009).

[64] *Id.* at 820.

[65] *Id.* at 824.

[66] United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 485 (3d Cir. 2017).

to the government.[67] Specifically, he alleged that Genentech did not disclose important data to the FDA showing that the side effects of Avastin were more severe for some patients than originally thought.[68] He alleged that Genentech developed a data suppression strategy where it disregarded negative data in order to "mitigate its 'business risk.'"[69]

The court held that the relator did not state a claim under the FCA and dismissed the case.[70] Petratos argued that, had Genentech disclosed the negative data to the FDA, Medicare would have found the claims to not be "reasonable and necessary" and therefore ineligible for reimbursement.[71] The court reasoned that a finding that a drug is "reasonable and necessary" is not based on FDA approval alone; rather, the court looks to "accepted standards of medical practice and the medical circumstances of the *individual case*."[72] Along similar lines, the court also held that Medicare places emphasis on an individual's physician's determination of what is reasonable and necessary as opposed to just FDA certification.[73] Therefore, the court found that Petratos's claim failed the materiality element of his FCA claim because he did not show that the government would not have reimbursed the claim if it knew of the deficiencies.[74] However, the decision by this court is only partially correct. An FDA-approved drug may still be worthless if it is adulterated or otherwise administered in an unsafe manner. Similarly, even if a drug is not worthless, it may still violate the FCA if it is not what the contract required.

The Ninth Circuit addressed a very similar factual scenario in *United States ex rel. Campie v. Gilead Sciences, Inc.*, yet it reached the opposite conclusion of the Third Circuit. Gilead Sciences, Inc. is

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[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *Id.* at 494.

[71] *Id.* at 487.

[72] United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 487-88 (3d Cir. 2017) (quoting Medicare Benefit Pol'y Manual, ch. 15, § 50.4.3 (emphases added)).

[73] *Id.* at 488-89.

[74] *Id.* at 490.

a company that produces anti-HIV drug therapies.[75] Gilead submitted drug applications to the FDA for several new drugs, and it stated in the application that it would use certain facilities in Canada, Germany, the United States, and South Korea to purchase the ingredient emtricitabine (FTC) for these drugs.[76] However, relators Jeff and Sherilyn Campie alleged that Gilead instead used Synthetics China to acquire FTC.[77] Two years later, Gilead sought FDA approval to use China Synthetics as its supplier; however, the relators alleged that Gilead lied about its internal testing in order to get FDA approval.[78] One internal test of the FTC "showed the presence of arsenic, chromium and nickel contaminants" in the drugs.[79]

The Ninth Circuit Court of Appeals reversed the district court and held that the relators did state a valid claim under the FCA.[80] The court organized its analysis based on the four elements of a claim under the FCA.[81] The first element of an FCA claim is a false claim or fraudulent course of conduct.[82] Because the claim involved goods, the court first looked at liability under the false certification theory for determining whether a false claim was submitted.[83] The court held that the relators did state a claim under the false certification theory because Gilead made specific false representations when seeking approval by the FDA and omitted information important to compliance with FDA standards.[84] Next, the court found that the relators adequately alleged scienter because Gilead lied about test results and deliberately tried to hide

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[75] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 895 (9th Cir. 2017).

[76] *Id.* at 896.

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.* at 909.

[81] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 902-07 (9th Cir. 2017).

[82] 31 U.S.C.A. § 3729(a)(1)(A)-(B).

[83] The court distinguished a case involving contaminated drugs from a worthless services case because the case involved goods. *Gilead Scis.*, 862 F.3d at 900-01. "But, unlike the situation in *Lee*, where a claim for medically 'worthless' drugs does not require a showing of 'false certification,' a claim for nonconforming goods must include an intentionally false statement or fraudulent course of conduct that was material to the government's decision to pay." *Id.* (internal citations omitted).

[84] *Id.* at 902-03.

its fraud.[85] Under the materiality element, the court found that violating the FDA's standards for drug approval has drastic effects on the ability for a company to be reimbursed; moreover, Gilead did more than simply violate the FDA's regulatory scheme.[86] Finally, the court found that the claims submitted to the government were false.[87]

Courts should adopt similar reasoning of the Ninth Circuit in *Gilead Sciences, Inc.* and expand the worthless services theory of liability to include worthless drugs.[88] While the Third Circuit Court of Appeals is correct that FDA approval is not the only factor that ensures the government will reimburse a claim, the FCA is the statutory scheme that Congress has chosen to prohibit fraud against the government—not the FDA. Moreover, as articulated by the Ninth Circuit, intentionally omitting data from the FDA greatly impacts whether the FDA approves a drug.[89] And, although this is not the only factor considered when Medicare makes a decision with respect to reimbursement, FDA approval has a significant impact on the decision.[90]

However, a court should not tie itself to only holding drug manufacturers liable under the FCA if they were required, either expressly or impliedly, to comply with government statutes. When a drug manufacturer knowingly makes a drug that is worthless and

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[85] *Id.* at 904.

[86] *Id.* at 905-06. Again, the court disagreed with the Fourth Circuit's decision in *Omnicare* because it found that the case involved more than just a violation of the regulatory scheme. *Id.* at 904. The court stated that, just as the Fourth Circuit argued that the purpose of the FCA was not to enforce compliance with regulations of the FDA, the purpose of the FDA is not to prohibit fraud. *Id.* at 905. Therefore, it did not make sense to dismiss the claim simply because it could be categorized as solely falling under the FDA. *Id.*

[87] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 902 (9th Cir. 2017).

[88] *Id.* at 904-07. It should also be noted that many of these claims involving FDA approval may alternatively be successfully brought under the express or implied certification theories of liability. *Id.* at 900-02. As the Ninth Circuit did in *Gilead Sciences*, courts should find that drug manufacturers that either expressly certified compliance with FDA requirements or implied that they complied with statutory requirements should be held accountable under the FCA. *Id.* at 902-04.

[89] *See id.*

[90] *Id.*

charges the federal government for it, the government is paying for a worthless drug—it is as if the drug manufacturer did not give the patient a drug at all. Similarly, if an entity improperly substitutes a different drug, it may be liable.

III. THE CORRECT APPROACH TO THE WORTHLESS SERVICES DOCTRINE

Supplying the government with worthless services, goods or drugs are each viable theories of liability under the FCA. Indeed, regardless of whether a label of "worthless services" is used to categorize a theory of liability, a defendant is liable under the FCA by knowingly supplying the government with worthless services, goods or drugs that are material to the agreement. This is because the FCA does not require a particular theory or any extra-statutory requirement for liability to attach. It is settled that a defendant will be found liable under the FCA if the following four elements are met: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due."[91] Thus, the worthless services or drugs theory works in concert with the statutory framework: if all four elements are met, the defendant is liable.

Courts must be careful not to conflate the calculation of damages with liability and should not rule that the entirety of the agreement must be deemed worthless to hold a defendant liable under the FCA for supplying worthless services or drugs. As shown below, the FCA captures liability and provides for a measure of damages when only a portion of the agreement contains worthless services or drugs because all four elements of an FCA violation are met.

A. The Existence of a False Claim or Fraudulent Conduct

The FCA generally imposes civil liability where a defendant knowingly presents to the government a "false or fraudulent claim" or "a false record or statement material to an obligation" owed to the government.[92] A false claim or statement can "take many forms," including "claim[s] . . . provided in violation of contract

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[91] United States *ex rel.* Hendow v. Univ. of Phx.*,* 461 F.3d 1166, 1174 (9th Cir. 2006).

[92] 31 U.S.C.A. § 3729(a)(1)(A)-(B), (G).

terms, specification, statute, or regulation."[93] Accordingly, adopting the worthless services and drugs theory of liability is exactly what Congress had in mind 150 years ago when military contractors were supplying sand instead of sugar,[94] and it is what the Supreme Court said regarding how the FCA was designed to capture all types of fraud.[95] Simply put, if a defendant knowingly provides worthless drugs or services as part of performance, it constitutes a fraudulent course of conduct and a basis for FCA liability.

With respect to any requirement under the FCA that there also must be a "claim" for payment, the worthless services and drug theories satisfy it. At least with respect to the 1986 version of the FCA, each liability provision contained some form of a false "claim" requirement.[96] Thus, courts had held that proof of a false "claim" is required,[97] and stated a false claim is "the *sine qua non* of [an FCA] violation."[98] However, in 2009, Congress amended one of the

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[93] S. REP. NO. 99-345, at 9 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. *See* Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999) (Claims may be false "in a variety of ways."). There are four main liability provisions in the FCA, and the 1986 version required presentment or use of a false "claim." Joel D. Hesch, *Understanding the Revised Reverse False Claims Provision of the False Claims Act and Why No Proof of a False Claim Is Required*, 53 UIC J. MARSHALL L. REV. 461, 465–66 (2021) ("The four most commonly used FCA liability provisions contained in the 1986 version of the FCA that render a person liable are as follows: '(A) knowingly presents, or causes to be presented, a false or fraudulent **claim** for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent **claim**; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or . . . (G) 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, ...'" (emphasis added) (citations omitted) (quoting 31 U.S.C. § 3729(a)(1)(A)-(C), (G) (1986).)).

[94] Michael Neal, Note, *Securities Whistleblowing Under Dodd-Frank: Neglecting the Power of "Enterprising Privateers" in Favor of the "Slow-Going Public Vessel"*, 15 LEWIS & CLARK L. REV. 1107, 1110 (2011) (alterations in original) (quoting Sylvia, *supra* note 20, § 2:6, at 42-43).

[95] Cook Cnty. v. United States *ex rel.* Chandler, 538 U.S. 119, 129 (2003) (quoting United States v. Neifert-White Co., 390 U.S. 228, 232 (1968)).

[96] *See id.*

[97] *Supra* notes 93-94.

[98] United States *ex rel.* Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) ("Not all fraudulent conduct gives rise to liability under the FCA. '[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's

liability provisions to eliminate the requirement to present or use a false "claim."[99] In doing so, "Congress closed a major loophole by introducing the first liability provision that no longer required proof of any type of a false claim, record, or statement."[100] "Today, the 2009 version of § 3729(a)(1)(G) reaches every kind of fraud scheme, provided that the plaintiff can establish the defendant knows it is retaining government funds it is not entitled to keep *regardless* of how it *obtained* them."[101] "In conjunction with the full FCA, the 2009 version of § 3729(a)(1)(G) reads":

> any person who . . . knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty . . . , plus [three] times the amount of damages which the Government sustains because of the act of that person.[102]

"Now, any fraudulent scheme resulting in a company knowingly *retaining* funds is covered by the FCA, and there is no need to tie the funds to any initial claim for payment or the use of any false record or statement to retain them."[103]

Even with respect to the other liability provisions still requiring a false claim, the worthless services doctrine theory clearly satisfies it as well. When the defendant requests payment for services or drugs, the entire claim or request for payment containing a worthless service or drug is tainted. The request for payment containing worthless services or drugs is the claim. The fact that the claim contains worthless services or goods is the very nature of this doctrine, which renders the claim false.

What separates the worthless services or drugs doctrines from the express or implied certification liability theories is that when a defendant provides worthless services or drugs, there is no need to

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wrongful payment, but to the 'claim for payment.' Evidence of an actual false claim is 'the *sine qua non* of a False Claims Act violation.'" (citation omitted)).

[99] 31 U.S.C.A. § 3729(a)(1)(A), (G) (West).

[100] Hesch, *supra* note 93, at 463 ("Thus, the adage that a false claim is the *sine qua non* of an FCA violation is no longer true, at least with respect to the 2009 version of the so-called reverse false claim provision.").

[101] *Id.*

[102] *Id.* at 468.

[103] *Id.* at 463.

further prove that they also *certified compliance* (directly or implicitly). Rather, the worthless services and drugs theory properly satisfies both the fraudulent course of conduct and any claim element because the worthless services taint the entire claim for payment.

This is precisely why the worthless services theory was enacted by Congress 150 years ago. For instance, at the enactment of the FCA during the Civil War, the government may have had an oral contract to supply bags of sugar, salt, meat, and vegetables for a fixed amount. No statute or regulation addressed the topic, and the defendant did not certify that it was providing sugar instead of sand or make any statements regarding the quality of the food items. Nevertheless, a cheating contractor cannot escape FCA liability simply because (a) it neither certified it complied with the conditions of the agreement or (b) the entirety of the production was not completely worthless since some of the other food items were satisfactory. In this Civil War example, the supplier engaged in a fraudulent course of conduct, and the entire claim for payment was tainted. The government may recover the value of the sugar without needing to prove that the contractor either expressly or implicitly certified that it was providing sugar. In addition, because the defendants knowingly supplied worthless goods (sand instead of sugar), it violated the FCA even though some aspects of performance were not worthless. In short, the entirety of the goods or services need not be completely worthless for the FCA to apply. Thus, worthless services theory fills the gap where an express or implied certification may be lacking, but a defendant otherwise is liable under the FCA.

In sum, providing worthless services or drugs is a viable theory of recovery designed to be included within the FCA framework. By its nature, supplying worthless services or drugs is a fraudulent course of conduct and taints the claim for payment. Thus, it satisfies the first of four elements under the FCA.[104]

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[104] Moreover, performance need not be worthless to constitute a FCA violation if all four elements are met. Again, FCA liability is predicated upon the four statutory

B. Scienter

The second FCA element is scienter. A defendant is only liable if it acted with guilty *knowledge*.[105] The FCA allows for three different standards to satisfy the scienter element; the defendant must: "(i) ha[ve] actual knowledge [of the falsity] of information; (ii) act[] in deliberate ignorance of the truth or falsity of the information [provided]; or (iii) act[] in reckless disregard of the truth or falsity of the information."[106] Therefore, the government must prove the defendant had knowledge of the worthless service or drug by satisfying one of these three definitions of knowledge under the FCA.

This element keeps the worthless services theory from over-reaching. At the same time, if the defendant knew that it provided worthless services or drugs, it can hardly expect to escape liability any more than if they supply the military with sand instead of sugar.

C. Materiality

The materiality element imputed by the statute[107] and defined by the Supreme Court[108] ensures that inconsequential breaches of a contract are not actionable. The FCA itself defines materiality to mean if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[109] When evaluating the material element, the Supreme Court has stated that it is a demanding standard.[110] Moreover,

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elements and not a label or theory of liability. *See* United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1166, 1174 (9th Cir. 2006).

[105] *Id.* at 1174-75. *See also* Hesch, *Breaking the Siege, supra* note 2, at 237 n.117.

[106] 31 U.S.C.A. § 3729(b)(1)(A) (West).

[107] 31 U.S.C.A. § 3729(b)(4) (West).

[108] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 (2016).

[109] 31 U.S.C.A. § 3729(b)(4) (West).

[110] *Universal Health Servs., Inc.*, 136 S. Ct. at 2003.

> "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.' Materiality also 'cannot be found where noncompliance is minor or insubstantial.' Proof of materiality can include whether 'the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated."[111]

The Supreme Court elaborated on the factors that lower courts should consider in determining materiality under the FCA.[112] The Court stated that "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."[113] In short, the Supreme Court determined that defendants are liable under the FCA for violating statutory or regulatory requirements, whether or not those requirements were actually designated as conditions of payment.[114] The Court explained some of the evidence relevant to the materiality issue: (1) "the Government's decision to expressly identify a provision as a condition of payment" and (2) "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."[115] Moreover, (3) materiality "cannot be found where noncompliance is minor or insubstantial."[116] However,

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[111] United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 905 (9th Cir. 2017) (citation omitted) (quoting *Universal Health Serv. Inc.*, 136 S. Ct. at 2003).

[112] *Universal Health Servs., Inc.*, 136 S. Ct. at 1995-96.

[113] *Id.* at 1995.

[114] Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1996 (2016).

[115] *Id.* at 2003.

[116] *Id.* at 1995.

being minor or insubstantial is not simply a function of the portion of the agreement that is deficient. For instance, a defendant might deliver a new fighter plane with a contract value of $100 million, but it knowingly delivered defective seat belts on the airplane. Even though the seat belts amount to less than one percent of the total cost, there is no doubt that seat belts are material to the agreement. If it is an important part of the bargain, it is material. The same is true for the sand example from the Civil War; even if the sugar was only 5% of the contract (or $25,000), the requirement to supply sugar was still material. Again, the portion of the value is not controlling. Rather, it is whether it was an important aspect of the agreement.

In sum, if a service or drug was a material part of the contract or services provided and the defendant knew it was supplying services or drugs that were worthless, this element is satisfied. A defendant can hardly complain about being subject to the FCA if it knowingly supplied worthless services or drugs that were material to performance and something the government bargained for.

D. Damages

Finally, damages are also an element.[117] The False Claims Act provides that any person who violates the FCA is liable for "[three] times the amount of damages which the Government sustains *because of the act of that person*" in addition to civil penalties.[118] Although the FCA does not specify how to calculate damages, the Supreme Court has recognized that the purpose of damages, even as multiplied, under the Act is to make the government "completely whole" for money taken from it by fraud.[119]

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[117] Liability also exists for submitting a false claim even if there is not a payout. Specifically, the FCA awards civil penalties in the absence of any actual loss. 31 U.S.C.A. § 3729(a)(1)(A) (West). Thus, "proof of damage to the government is not required when a plaintiff is seeking only civil penalties under the FCA." Joel D. Hesch, *A Comprehensive Analysis of the False Claims Act's Unique Statute of Limitations: The Supreme Court's Ruling in* Cochise Consultancy, Inc. *Was A Good Start but Left Much to Do*, 70 SYRACUSE L. REV. 773, 780 (2020) (citing United States *ex rel.* Howard v. Lockheed Martin Corp., 14 F. Supp. 3d 982, 994 (S.D. Ohio 2014)). This Article, however, focuses on recouping loss due to false claims in addition to civil penalties.

[118] 31 U.S.C.A. § 3729(a)(1)(G) (West) (emphasis added).

[119] United States *ex rel.* Marcus v. Hess, 317 U.S. 537, 551-52 (1943); *accord* United States v. Neifert-White Co., 390 U.S. 228, 232 (1968) ("Debates at the time suggest that the Act was intended to reach all types of fraud, without qualification, that might result

Because the goal is to make the government whole and capture all forms of injury, courts employ different damage calculations based upon the type of fraud and injury suffered to cover all of the harm suffered because of the bad acts of a defendant. Indeed, legislative intent states "[n]o single rule can be, or should be, stated for the determination of damages under the [FCA]."[120] Thus, damages are determined on a case-by-case basis.[121]

The measure of damages for worthless services depends upon whether the entire performance is rendered worthless or only a portion of the contract is worthless. First, when the worthless services or drugs taint the overall value of the performance, the measure of damages is the total contract value because the government did not get what it bargained for or the purpose of the award. Courts apply this same approach when a defendant either

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in financial loss to the Government. In its present form[,] the Act is broadly phrased to reach any person who makes or causes to be made 'any claim upon or against' the United States, or who makes a false 'bill, receipt, * * * claim, * * * affidavit or deposition' for the purpose of 'obtaining or aiding to obtain the payment or approval of' such a false claim. In the various contexts in which questions of the proper construction of the Act have been presented, the Court has consistently refused to accept a rigid, restrictive reading, even at the time when the statute imposed criminal sanctions as well as civil." (footnote omitted)).

[120] S. REP. NO. 96-615, at 4 (1980).

[121] United States v. Killough, 848 F.2d 1523, 1532 (11th Cir. 1988). In the run-of-the-mill FCA case, courts apply the benefit of the bargain approach, whereby "the measure of the government's damages would be the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful." United States v. Woodbury, 359 F.2d 370, 379 (9th Cir. 1966). *See also* United States *ex rel.* Roby v. Boeing Co., 302 F.3d 637, 646 (6th Cir. 2002) ("FCA damages 'typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.'" (quoting United States *ex rel.* Compton v. Midwest Specialties, Inc., 142 F.3d 296, 304 (6th Cir. 1998))); United States v. Sound Sols. Windows & Doors, Inc., No. 09 C 6948, 2017 WL 9517514, at *7 (N.D. Ill. May 11, 2017), *report and recommendation adopted*, No. 09 C 6948, 2017 WL 6723765 (N.D. Ill. Dec. 18, 2017) ("In most False Claims Act cases, 'damages are measured as they would be in a run-of-the-mine breach-of-contract case—using a "benefit-of-the-bargain" calculation in which a determination is made of the difference between the value that the government received and the amount that it paid." (first quoting United States *ex rel.* Feldman v. van Gorp, 697 F.3d 78, 87 (2d Cir. 2012); then citing United States v. Woodbury, 359 F.2d 370, 379 (9th Cir. 1966) ("Ordinarily the measure of the government's damages would be the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.")).

fraudulently induced the contract or was not eligible for a grant or contract reserved for a certain class of participants (minority owned or small businesses).[122] The measure of damages is the total contract value even if performance was otherwise satisfactory, because the government did not get what it bargained for or the purpose of the award.[123] In short, when the performance is entirely worthless, courts have to assess the full contract value as the measure of damages.[124] As an example in the Medicare context, damages include the full amount paid for medically unnecessary procedures,[125] or the amount of the entire claims when complying with a statute was a condition of payment.[126]

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[122] *See* United States v. Anghaie, 633 F. App'x 514, 518-19 (11th Cir. 2015) (holding that the full value of grant when entity was not eligible under the Small Business Technology Transfer program); United States v. R.J. Zavoral & Sons, Inc., No. 12-668, 2014 WL 5361991, at *40 (D. Minn. Oct. 21, 2014) (misrepresenting itself as an eligible firm under section 8(a) of the Small Business Act); United States v. Leahy, 464 F.3d 773, 793-94 (7th Cir. 2006) (discussing how a contract required use of minority- or women-run businesses). *See also* Thomas E. Daley III, *Calculating Intangibles: Assessing the Argument for Actual Damages Equal to the Contract's Total Value*, 46 PUB. CONT. L.J. 385, 401 (2017) ("*Actual Damages Should be Equal to the Full Value of the Contract When a Business Fraudulently Certifies Itself as Eligible for a Socio-Economic Set-Aside Contract*[.]The concept of awarding damages equal to the full value of a contract when a contractor has capably performed all work required under the contract may seem unconventional. However, in order to properly deter fraud, compensate the government 'completely for the costs, delays, and inconveniences occasioned by fraudulent claims,' and provide restitution, courts should account for the intangible benefit the government loses when contractors utilize fraud-in-the-inducement to obtain socioeconomic set-aside contracts. In conjunction with the 'presumption of loss' rule, actual damages should be equal to the full contract value." (footnotes omitted)). *But cf.* United States *ex rel.* Wall v. Circle C Constr., LLC, No. 14-6150, 2016 WL 423750, at *2 (6th Cir. Feb. 4, 2016) (rejecting full contract value of $260,000 when a portion of the contract was governed by the Davis-Bacon Act resulting in underpaying engineers by only $10,000).

[123] *Supra* note 122.

[124] United States *ex rel.* Compton v. Midwest Specialties, Inc., 142 F.3d 296, 304 (6th Cir. 1998) (assessing the full contract value when contractor delivered defective brake-shoe kits for jeeps); United States *ex rel.* Roby v. Boeing Co., 302 F.3d 637, 647-48 (6th Cir. 2002) (assessing the full contract value when contractor delivered a helicopter with a defective transmission that cause it to crash). *See also* United States v. J-M Mfg. Co., No. EDCV 06-55-GW, 2018 WL 1801258, at *19 (C.D. Cal. Apr. 12, 2018) (holding that goods or services can be legally worthless to the government if, for example, they are dangerous to use, or the damages from the contractor's breach are not calculable in terms of market value).

[125] United States v. Acadiana Cardiology, LLC, 2014 WL 1323388, *1 (W.D. La. 2014).

[126] United States v. Rogan, 459 F. Supp. 2d 692, 726 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

Second, when only a portion of the performance is tainted by worthless services or drugs, the court must assess an appropriate measure of damages. It very well might be a portion of the value of the agreement. In the Civil War sugar example, if the sugar was five percent of the contract value or $25,000, then damages might be $25,000. However, damages can be more depending upon the harm. For instance, if it cost the government $50,000 to replace the missing sugar, damages would be the amount suffered or $50,000. The point is that a court must assess the amount of damages on a case-by-case basis. Merely because the worthless services or drugs is a portion of the contract and does not render the entirety of the performance worthless does not mean there is no liability. Rather, the function of damages is where a court ensures that the worthless services theory does not overreach. Again, the worthless services theory is not all or nothing. When the worthless services taint the agreement but to not render it completely worthless, the court assigns damages based upon "damages which the Government sustains *because of the act of that person.*"[127]

1. Damages When Drugs are Bundled or Billed under a Diagnosis Related Group

The harder question is determining damages when claims for services or drugs are bundled into a set or fixed amount regardless of the actual costs to perform. This Article argues that FCA damages in a bundled setting are the full contract value if the services or drugs are harmful or significantly affect the treatment. However, if only a portion of the contract was tainted by worthless services or drugs, a court may calculate damages in any appropriate manner consistent with the aim of the FCA, such as on a prorated basis associated with the amount of the tainted services or drugs. But a defendant may not totally escape FCA damages merely because a provider was paid on a fixed amount basis.

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[127] 31 U.S.C.A. § 3729(a)(1)(G) (West) (emphasis added).

Increasingly, federal healthcare programs are reimbursed as bundled services.[128] Up until the mid-1980s, Medicare reimbursed health care providers based upon their actual costs.[129] Essentially, Medicare paid for every service rendered, including every x-ray, aspirin, Band-Aid, and alcohol swab associated with the treatment. Unfortunately, this leads to unscrupulous hospitals keeping patients as long as possible and providing needless services.[130] To control costs, Medicare implemented a new system, known as the Inpatient Prospective Payment System ("IPPS"), which paid hospitals fixed payments based upon the expected average cost to treat a particular illness.[131] This encouraged hospitals to become more efficient since they received a set amount regardless of whether it cost more or less to treat a particular patient.[132] The amount of payment depended upon the illness being treated. "The IPPS divides medical conditions into categories of related illnesses called 'diagnosis-related groups' ('DRGs')."[133] Thus, under the DRG approach, Medicare pays a pre-set amount based upon the particular IPPS condition a patient is being treated for.[134]

Although the DRG approach was designed to eliminate unscrupulous contractors over-providing and over-billing Medicare because all costs were covered, the DRG approach has created the opposite fraudulent scheme of under-providing patients with necessary services or drugs. Because the provider gets the same fee

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[128] This was a factor in the court's analysis in *United States v. Houser*. United States v. Houser, 754 F.3d 1335, 1346 (11th Cir. 2014). Because the claims were bundled, the court held that it was even more difficult to allocate a percentage of the claim to fraud. *Id.* However, this again allows the provider to provide deficient services while avoiding liability for Medicaid reimbursements. The court should determine how much of the bundle is attributed to the service in question, and then determine whether there is FCA liability for that service. If the service was deficient, the defendant knew the service was deficient, and the defendant submitted a claim for reimbursement to the government, the court should find that there is FCA liability. The same principle applies to capitated payments, *i.e.*, paying a provider a set amount per patient that participates in a program. United States *ex rel.* White v. Mobile Care EMS & Transp., Inc., No. 1:15-cv-555, 2021 WL 4844063, at *12-13 (S.D. Ohio Oct. 18, 2021) (holding that a defendant is liable under the FCA notwithstanding that the government may not have paid more because the defendant unlawfully received more).

[129] New Lifecare Hosps. LLC v. Azar, 417 F. Supp. 3d 31, 35 (D.D.C. 2019).

[130] *Id.*

[131] *Id.* at 35-36.

[132] *Id.* at 36.

[133] *Id.* (quoting Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 49 (D.C. Cir. 2015).

[134] *New Lifecare Hosps.,* 417 F. Supp. 3d at 36.

whether or not it supplies a patient with a drug that otherwise might be given to a Medicare patient, unscrupulous providers might skip the drug or give an expired or tainted drug in its place to save costs. The worthless services or drugs theory clearly covers and includes DRG or bundled services because it constitutes a fraudulent course of conduct that taints any claim for payment provided the defendant acted with scienter, and the service or drug was material. The only question is how to assess damages in a bundled setting.

It is anticipated that a defendant might argue that no FCA damages exist because the government is not out of pocket any funds since it would have paid someone the same bundled rate. However, as shown above, FCA damages are determined on a case-by-case basis to capture the full harm to the government, which would include the harm suffered by the intended recipient of the services or drugs. Even if the government would have paid a set fee of $500 to any provider to treat a certain illness, the use of worthless services or goods in the process taints the entirety of the agreement. It is not enough to escape responsibility to argue that the government would have paid the money anyway, just to an honest provider instead of a dishonest one. The following example identifies the correct approach to damages under a DRG code.

Assume that a patient had a condition that requires treatment and the DRG code pays the provider a flat $500 regardless of its costs. Assume also that the provider administers an adulterated drug in the treatment. If the patient does not recover and needs an additional treatment, damages clearly would include the cost of the second procedure. But what if there is not a second treatment to replace the first one because the patient may not have been aware that the first one was defective or if later symptoms were not associated with the first lacking treatment because it was unknown that the drug was adulterated or the cause of complications? A provider may admit that it used a worthless drug but still argue that the government was not harmed because it would have still paid $500 to another provider using a drug that was not adulterated. The defendant may also try arguing that because some

of the treatment had some value, the entirety of the treatment was not worthless.

It is clear that knowingly providing an adulterated drug constitutes a fraudulent course of conduct, and the provider was paid the full $500 for proper treatment of a Medicare patient. Under the worthless services or drugs theory, the provider is liable under the FCA. The measure of damages, however, may depend on a few things. First, if the worthless drug rendered the entire service worthless because it was potentially dangerous to the patient, the damages are the full amount of the claim (or in this case $500). Indeed, the patient did suffer by being administered a worthless drug even if not quantifiable in the regular methodology. No patient would knowingly take an adulterated or worthless drug, and the value of the service or drug is tainted. A patient receiving a tainted drug would also suffer emotionally for fear of hidden harm that might occur or might not be readily associated with the improper drug. Thus, damages should not be measured solely upon the out-of-pocket cost to the government.[135] Here, the government paid the provider with the expectation that they would not supply a patient with worthless or adulterated drugs.

If it could be conclusively established the drug was not actually harmful and the patient recovered in the same manner as if the drug was administered properly, then damages might be calculated as the proportional value of the worthless drug to the amount of the payment. For instance, absent other harm or loss, if the drug was ten percent of the treatment, the provider should repay ten percent of the DRG payment. Again, damages need to be assessed on a case-by-case basis depending upon all of the circumstances and any and all harm suffered.

In short, damages are not limited to the known out-of-pocket cost of the government. Two possible measures of damages include (1) the full contract value if the drug was potentially harmful or sufficiently tainted the treatment to be worthless, and (b) the proportional value in appropriate instances where the patient was not at risk and otherwise received helpful treatment. The court has

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[135] Indeed, in other settings, damages for awarding a grant to an entity not eligible is the full value of the grant because the government lost the opportunity to give the money to one who would have used it in the manner expected. United States *ex rel.* Feldman v. van Gorp, 697 F.3d 78 (2d Cir. 2012).

sound discretion in determining appropriate damages, but it would be an abuse of discretion to clear the defendant of FCA damages simply because the payment was in a bundled manner.

The United States took this position in a Statement of Interest in a *qui tam* case, *United States ex rel. Simpson v. Bayer Corp.*[136] In *Bayer Corp.*, the relator alleged, among other things, that the defendant induced healthcare providers to use unnecessary quantities of a drug billed to the government through bundled DRG payments.[137] The defendant took the position that because the government paid for the drug at issue through a bundled DRG payment, any underlying violations could not have increased the amount the government paid and, therefore, could not be material to the government's decision to pay the claim under the FCA.[138] Although the United States took no position on the merits of the *Bayer Corp*. relator's case, it went out of its way to file a Statement of Interest to clarify the government's position that fraudulent billing through bundled payments constitutes a violation of the FCA.[139] The government stated:

> Congress established bundled payment mechanisms to control health care costs. The Defendants' effort to insulate themselves from civil liability under the FCA transforms this cost-control program into permission to engage in fraud in connection with the provision of goods and services that comprise that bundle. *The Court should hold that material violations remain material regardless of whether the Government pays the claims through a bundled payment.*[140]

The court completely agreed with the United States and relator and "rejected [defendant]'s assertion of a bright-line rule immunizing claims made pursuant to the DRG system from FCA

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[136] *See* United States' Statement of Interest at p. 1, United States *ex rel*. Simpson v. Bayer Corp., 376 F. Supp. 3d 392 (D.N.J. 2019) (No. 05-3895).

[137] United States *ex rel.* Simpson v. Bayer Corp., 376 F. Supp. 3d 392, 398-99 (D.N.J. 2019).

[138] *Id.* at 401, 410.

[139] Statement of Interest, *supra* note 136, at 3, 16.

[140] *Id.* at 16 (emphasis added).

liability."[141] The court explained that the materiality focus "is not the *amount* of payment, but rather the 'Government's payment *decision*.'"[142] "Put differently, the [] inquiry does not ask whether the cost of a noncompliant item would have affected the Government's payment decision; it asks whether the noncompliance itself would have affected that decision."[143] According to the court:

> All fraud is disguised—until it is not. That the alleged fraud involving [drugs that are] hidden from the Government by virtue of the DRG system does not insulate [defendants] from liability for that fraud as a matter of law. Indeed, among 'Congress's primary goals' in enacting the *qui tam* provisions of the FCA were 'encouraging disclosure and aiding prosecution of fraud' of which the Government would otherwise remain unaware.[144]

Courts around the country have reached this same conclusion. For example, in *United States v. Medtronic, Inc.*,[145] the court reasoned that, "the amount paid by the government for a spinal surgery is not affected by whether one or more of the [noncompliant devices] . . . are used," and, therefore, does not defeat FCA liability.[146] That is because use of the DRG system, "does not mean that the government . . . in establishing general payment policies, has assigned no value to," those devices.[147]

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[141] *Bayer Corp.*, 376 F. Supp. 3d at 414.

[142] *Id.* at 410.

[143] United States *ex rel.* Simpson v. Bayer Corp., 376 F. Supp. 3d 392, 410 (D.N.J. 2019) (emphasis in original).

[144] *Id.* at 416 (emphasis added) (citing United States *ex rel.* Mistick PBT v. Housing Auth. of Pittsburgh, 186 F.3d 376, 391 (3d Cir. 1999)).

[145] United States *ex rel.* Dan Abrams Co. LLC v. Medtronic, Inc., No. LA CV15-01212, 2017 WL 4023092 (C.D. Cal. Sept. 11, 2017).

[146] *Id.* at *10.

[147] *Id. See also* United States *ex rel.* Morris v. Crist, No. C-2-97-1395, 2000 WL 432781, at *5 (S.D. Ohio Mar. 29, 2000) (rejecting a hospital's DRG defense to an FCA claim arising from non-allowable for-profit research costs, finding the argument "fail[ed] to take into account the contents of the entire bill sent to Medicare," and concluding that "the entire bill represents a claim against the United States to be paid or approved"); United States *ex rel.* Drakeford v. Tuomey, 792 F.3d 364, 386 (4th Cir. 2015) (finding that, for purposes of calculating damages, each UB "can constitute a discrete fraudulent claim under the FCA," because "each time [defendant] submitted to Medicare a UB-92/04 form asking for reimbursement for a prohibited referral, it was knowingly asking the government to pay an amount that, by law, it could not pay"); Commonwealth *ex rel.*

Finally, the fact that Medicare follows a pay and chase process[148] does not give providers a free pass to administer worthless services or drugs that CMS prohibits using. In addition, because the provider concealed the information, patients may have been harmed from the drugs but not been able to determine the cause. For instance, a cancer patient might get an infection during the time they are treated with a powerful drug. Because their immune systems are known to be weakened, doctors are not likely to assume that the cause was bacteria in the SDV resulting from reusing SDVs on multiple patients. Rather, the patient will be treated for the new illness without appreciating the cause. Thus, the government likely had to pay for other treatments or complications of the illness caused by the drug without knowing it. The provider cannot be allowed to benefit from the fraud simply because it disguised the treatment, and the government was harmed because the practice is known to lead to infections and thus increased costs.

In sum, DRG does not mean no damages exist. This Article has demonstrated that there are multiple ways a court can assess damages in a bundled setting. However, it would be an abuse of

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Martino-Fleming v. S. Bay Mental Health Ctr., Inc., 334 F. Supp. 3d 394, 408-09 (D. Mass. 2018) (holding that Massachusetts sufficiently alleged a state law FCA claim against health care provider, despite the fact that false claims did not increase the reimbursement amount, noting that, "[a]lthough the contractors are paid a fixed rate . . . , the claims . . . are paid with government money"); United States *ex rel.* White v. Mobile Care EMS & Transp., Inc., No. 15-cv-555, 2021 WL 4844063, at *13-14 (S.D. Ohio Oct. 18, 2021) (refusing to dismiss case based upon capitated payments because, "[t]o be sure, the federal government may not pay more, but the Defendants may receive more of the federal funds" than entitled (emphasis in original)).

[148] *E.g.*, Godecke v. Kinetic Concepts, Inc., 937 F.3d 1201, 1206 (9th Cir. 2019) ("Because Medicare is required to pay claims submitted within just a few weeks of receipt of the claim, the Medicare program has historically paid claims quickly without verifying the accuracy of the claims before payment. Medicare accepts claims as submitted by providers as being a true representation that the claim either qualifies for reimbursement or does not qualify and automatically pays those claims represented as qualifying. Medicare must then seek reimbursement or recoupment if it later determines that the claim should not have been paid. This payment system has become known as 'pay and chase,' and relies on the honesty of providers and the accuracy of the claims they submit.").

discretion to assess no damages simply because the payment was in a bundled manner or on a fixed amount basis.

IV. A HYPOTHETICAL AND EXAMPLE ANALYSIS OF THE UNIFORM STANDARD FOR WORTHLESS SERVICES AND DRUGS

To show how this entire framework can be applied to a factual scenario, this Article presents the following hypothetical followed by an analysis that a court could use in implementing the standard. Consider this example. To save costs, Hospital XYZ uses drugs from single-use or single-dose vials ("SDVs") on multiple patients, notwithstanding that the SDVs do not have preservatives and the instructions with the SDVs expressly state that they are for single use only. Not only has the Centers for Disease Control and Prevention ("CDC") repeatedly condemned this practice,[149] but United States Pharmacopoeia ("USP"),[150] which is a leading

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[149] *See* Ctr. for Disease Control & Prevention, *See Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients*, 50 MORBIDITY & MORTALITY WKLY. REP. NO. RR-5, at 19 (Apr. 27, 2001), https://www.cdc.gov/mmwr/PDF/rr/rr5005.pdf, [https://perma.cc/2JU2-5MB2] available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm [https://perma.cc/Q3RM-Z4VC]; CDC Letter to Sean Tunis, Acting Chief Medical Officer of CMS, CMS (July 5, 2002), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter02-43.pdf [https://perma.cc/NA7J-RLJY]; Jane D. Siegel et al., *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, CDC, https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html [https://perma.cc/9EG3-YLDS] (last updated July 2019); *Protect Patients Against Preventable Harm from Improper Use of Single–Dose/Single–Use Vials*, CDC (May 2, 2012) https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html [https://perma.cc/33BJ-3Z8Q]; *CDC's Position: Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials*, CDC (May 2, 2012) https://www.cdc.gov/injectionsafety/PDF/CDC-SDV-Position05022012.pdf [https://perma.cc/YWL8-J7UW].

[150] The United States Pharmacopoeia ("USP") is a compendia that establishes standards for drugs—and health care providers are required to comply with those standards. In 2008, in response to the documented health risks, USP established a national standard and protocol that prohibited using SDVs on multiple patients (unless they were "repackaged" in a highly controlled, sterile environment under ISO Class 5 conditions). In particular, the compendia states that "[o]pened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened . . . and any remaining contents must be discarded" and that "[o[pened [SDVs] shall not be stored for any time period." U.S. Pharmacopeial Convention, Revision Bulletin on General Chapters <797> Pharmaceutical Compounding - Sterile Preparations (Apr. 24, 2020),

compendium establishing acceptable practices in medicine, prohibits it unless conducted in specified sterile labs (which Hospital XYZ admits it does not even own). Reusing SDVs has been documented to cause patient harm.[151] Specifically, using SDVs on multiple patients has resulted in viral infection outbreaks.[152] Moreover, the plaintiffs have shown that using SDVs on multiple patients provides no medical benefit to the patient. Accordingly, CMS prohibits using SDVs on multiple patients.[153]

Once caught using SDVs on multiple patients outside of the sterile conditions required by USP, Hospital XYZ argues that it is still not liable under the FCA. The hospital makes two arguments. First, it argues that the particular drugs from SDVs are part of a larger treatments plan, and therefore not completely worthless. The hospital essentially argues that because other aspects of the treatment had value, the worthless services and drug doctrines cannot apply; even if a patient knew that the SDVs were being administered against good practices, and even prohibited by the CDC and Medicare, the patient would have refused treatment. Second, the hospital argues that there are no monetary damages because the hospital was paid a fixed price for treating the patients under a DRG payment system, and the government would have paid the exact same amount for treating the patient (with or

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https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-797-rb-notice-20200424.pdf [https://perma.cc/9M52-LETL]. In short, unless within the narrow "repackaging" exception, the USP bans using SDVs on multiple patients and mandates that SDVs be discarded immediately after first use.

[151] U.S. DEP'T OF HEALTH & HUM. SERVS., SELECTION OF THE APPROPRIATE PACKAGE TYPE TERMS AND RECOMMENDATIONS FOR LABELING INJECTABLE MEDICAL PRODUCTS PACKAGED IN MULTIPLE-DOSE, SINGLE-DOSE, AND SINGLE-PATIENT-USE CONTAINERS FOR HUMAN USE GUIDANCE FOR INDUSTRY 2 (Oct. 2018), https://www.fda.gov/downloads/Drugs/Guidances/UCM468228.pdf [https://perma.cc/VSC8-QFEP] (considering this practice to be unsafe).

[152] *Id.*

[153] U.S. DEP'T OF HEALTH & HUM. SERVS., CNTRS. FOR MEDICARE & MEDICAID SERVS., OFFICE OF CLINICAL STANDARDS AND QUALITY/SURVEY & CERTIFICATION GROUP, SAFE USE OF SINGLE DOSE/SINGLE USE MEDICATIONS TO PREVENT HEALTHCARE-ASSOCIATED INFECTIONS, (June 15, 2012), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/Survey-and-Cert-Letter-12-35.pdf [https://perma.cc/79YL-CVR4].

without this particular drug). In other words, the government was willing to pay a fixed amount, and that is exactly the amount it paid. The patient was treated, and thus, the government is not out any money, regardless of which provider performed the treatments. Below is the correct analysis of liability and damages.

A. The False Claims Act

Under the FCA, a defendant will be found liable if the following four elements are met: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due."[154]

1. A False Claim

The first element, that there must be a false statement or fraudulent course of conduct, is met. As demonstrated above, proving worthless drugs were provided is a viable way of establishing liability under the False Claims Act. Indeed, providing unsafe, and thereby worthless, drugs is a fraudulent course of conduct.[155] Under this theory, a defendant is liable if any material aspect of the service is worthless. Specifically, a defendant is liable under the FCA if a particular drug is worthless even if only a part of a larger overall treatment. Even if other aspects of the service (or other administered drugs) have value, at a minimum, the government is entitled to FCA damages for the portion of the services, in this case drugs, which are worthless.

Here, the particular drug designated as SDV is worthless. Specifically, the drug was adulterated or contaminated. Indeed, the Hospital did not follow the guidelines set by Medicare, Medicaid, and CMS when administering the SDVs to multiple patients. However, even more importantly, the plaintiffs have shown that administering the SDVs to multiple patients results in the SDVs having no medical benefit or value to the patient, even if this particular drug did not cause illness. Not only does the service provide no value because it is adulterated and against protocols to even administer, but it can result in viral infections in the patients.

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[154] United States *ex rel.* Hendow v. Univ. of Phx.*,* 461 F.3d 1166, 1174 (9th Cir. 2006).
[155] 31 U.S.C.A. § 3729(b)(2)(A) (West).

Therefore, the court should find that Hospital XYZ's administering of multiple SDVs is a "fraudulent course of conduct" in violation of the FCA's first element. The government also could readily satisfy any claim requirement. For the FCA provisions still requiring a claim, the request for reimbursement for the DRG payment is the claim.[156] The claim was tainted by the worthless drug. In addition, the 2009 version of subpart G no longer requires a claim.

2. The Requisite Scienter

The court should also find that Hospital XYZ's actions satisfy the scienter element of the FCA. The FCA provides three different ways that a claim may satisfy the scienter element; the defendant must: "(1) ha[ve] actual knowledge of the falsity of information; (2) act[] in deliberate ignorance of the truth or falsity of the information; or (3) act[] in reckless disregard of the truth or falsity of the information."[157] Essentially, in order to satisfy this element, the government must show that the defendant engaged in a fraudulent course of conduct with *knowledge* that the claim was in fact false.[158] Here, Hospital XYZ had knowledge of how the SDVs were being administered. It also knew that a SDV may not be used on multiple patients. It nevertheless decided to administer SDVs to multiple patients in order to save costs. Also, it was the employees of Hospital XYZ that were administering the SDVs in this way. Moreover, Hospital XYZ knew the required standards in administering SDVs (especially considering it is getting reimbursements for them), so it knows that its administration of the SDVs violates government guidelines. Therefore, Hospital XYZ has actual knowledge that its claims are in fact false, and it satisfies the scienter element.[159]

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[156] *See supra* notes 92-104 and accompanying text.

[157] 31 U.S.C.A. § 3729(b)(1)(A) (West).

[158] *Id. See also* Hesch, *Breaking the Siege*, *supra* note 2, at 237 n.117 (quoting United States *ex rel.* Green v. Northrop Corp., 59 F.3d 953, 963 (9th Cir. 1995)).

[159] It is also well known that giving SDVs to multiple patients is known to have caused patient harm. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 151, at 2.

3. The Materiality Element

The court should find that Hospital XYZ's administering of SDVs to multiple patients is a material part of the claim. The fact that Hospital XYZ is being reimbursed for administering SDVs to the patients, when in fact multiple patients are given the same SDV, clearly has a tendency to influence the government in granting the reimbursement. If it was disclosed that Hospital XYZ was acting in a way that contradicts both CDC and USP guidelines and has been documented as causing patient harm, the federal government would not allow the drug to be used. Indeed, no patient would willingly accept a drug indented for only one patient when such practices have been documented to harm patients.[160] Similarly, the government could not possibly agree to subject the elderly or poor to such violations of good medical practices. Moreover, Hospital XYZ deliberately is not informing the government (or patients) of how it is administering the SDVs because it knows that it is "cutting corners" in violation of the CDC and USP.

4. The Government Payment Element

The payment element is also met even though it was reimbursed from the government under a DRG system. Although it is true that the Hospital was paid a fixed amount per day for treatment, the fact is that Hospital XYZ is engaged in a fraudulent course of conduct by administering drugs in unlawful and harmful ways that are worthless. If the government knew that the hospital was violating these medical standards, it would be inclined to not pay a full reimbursement for the drugs (and possibly take other actions for providing worthless or adulterated drugs); indeed, taxpayers should not be required to pay the full price of a drug while the hospital saves money through the inefficient and unsafe administration of the drug. Even if another entity would have received the same fee, it would have used a medically necessary and safe drug. The government and patient both lost the opportunity to

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[160] Davis v. Main St. Fam. Pharmacy, LLC, No. 5:16cv45, 2016 WL 9051172, at *3 (N.D. Fla. May 19, 2016) ("The adulterated injection was worthless, and neither Davis nor anyone else in their right mind would have paid any money for it had they known that it was adulterated.").

be given a drug meeting required healthcare standards. Hospital XYZ used a worthless drug and cannot be paid full price. Even though it may be hard to show out-of-pocket costs or if actual harm occurred, *i.e.,* the patient's healing was slowed or a bacterial infection occurred, that is not the test for whether a drug administered improperly is allowed or should be paid for. Thus, the government (and the patient) was harmed by not knowing if medically sound practices were followed, and the risk of harm looms heavy. Again, no patient would have willingly agreed to accept the misused SDV if they had been told in advance.

This Article argues that because misusing SDVs has proven harmful to patients in the past, it is potentially dangerous, and damages are the full payment of the DRG.[161] A court should not reward a provider knowingly using potentially harmful drugs on unwitting Medicare patients by allowing full payment, even under a DRG payment system. That stands the Medicare program on its head.

In sum, providing worthless drugs satisfies all of the elements of the FCA. Courts should adopt the worthless drugs doctrine and apply it even when some aspect of the overall services may have value. In doing so, courts will protect the interests of the FCA by prohibiting health service providers and drug manufacturers from obtaining government reimbursements for worthless drugs. Additionally, patients must be protected from the harm that can be caused by these worthless services or drugs. Hospital XYZ should be found liable under the worthless drugs theory of liability of the FCA. The court should also assess a proper measure of damages on a case-by-case basis, which may include the full contract value or a portion of the contract.

CONCLUSION

The False Claims Act is the government's primary tool in combating government fraud. The FCA was initially designed to

[161] If a court were to disagree (based upon the quality of the overall treatment), it should nevertheless apportion damages based upon the proportionate value of the worthless drugs.

wipe out a fraudulent scheme whereby worthless goods were supplied to the military during the Civil War. Today, in the healthcare industry, some health care providers commit fraud by submitting false claims to Medicare and Medicaid for reimbursement for worthless services or drugs. Traditionally, courts relied upon express false certification and implied false certification as theories of liability, but they have begun recognizing that there should be a third theory, adding the fraudulent course of conduct of supplying worthless services or drugs when it might not be possible to tie the misconduct to an express or implied certification. This Article proposed that worthless services, drugs, or goods is a viable theory of liability under the False Claims Act. Indeed, it demonstrated that FCA liability is not dependent upon a label or theory of liability, but whether the four statutory elements are met: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due."[162] Although courts tend to place violations into categories, named theories are merely nomenclatures. A defendant is not liable based upon a label or theory of liability, but whether the four essential elements of the statute are met. If a defendant knowingly supplies worthless services or drugs that are material to the agreement, it is liable under the FCA. The worthless services or drugs need not render the entirety of performance worthless. If one aspect of the performance is worthless, a defendant is liable because the four FCA statutory elements are still met. Rather, the worthless services doctrine often boils down to a function of damages. This Article provided a framework for the courts to use to assess the proper measure of damages for worthless services or drugs, including when payment is part of a bundle or fixed amount.

[162] United States *ex rel.* Hendow v. Univ. of Phx.*,* 461 F.3d 1166, 1174 (9th Cir. 2006).