CA No. 15-16380

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

UNITED STATES ex rel. JEFFREY CAMPIE and SHERILYN CAMPIE,

Plaintiffs-Appellants,

v.

GILEAD SCIENCES, INC.,

Defendant-Appellee.

On Appeal from the United States District Court

for the Northern District of California, No. 3:11-cv-941-EMC (Honorable Edward M. Chen)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF APPELLEE'S PETITION FOR REHEARING OR REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Washington Legal Foundation (WLF) states that it is a non-profit corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

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INTRODUCTION AND INTERESTS OF AMICUS CURIAE

Washington Legal Foundation (WLF) is a public interest law firm and policy center headquartered in Washington, D.C., with supporters in all 50 States, including many in the State of California. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

To that end, WLF has frequently appeared as *amicus curiae* in federal court in cases concerning the proper scope and application of the False Claims Act (FCA), 31 U.S.C. § 3729 et seq. See, e.g., Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016); Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 559 U.S. 280 (2010); Allison Engine Co. v. United States ex rel. Sanders, 128 U.S. 2123 (2008); United States ex rel. Harmon v. Trinity Industries, Inc., No. 15-41172 (5th Cir., dec. pending).

WLF does not condone fraud against the United States, however it may occur. WLF is concerned, however, that excessive FCA liability in recent decades

¹ Pursuant to Fed. R. App. P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief. The brief is filed with the consent of all parties.

has spawned abusive litigation against businesses, both large and small, to the detriment of free enterprise, employees, shareholders, and consumers. WLF believes that the Supreme Court's *Escobar* decision properly balances the need to prevent fraud against the United States with the need to ensure that private litigants do not use the FCA to extort unwarranted settlements from reputable government contractors. In particular, *Escobar* held that a relator's *qui tam* suit should not be permitted to pass beyond the pleadings stage unless the relator adequately pleads facts demonstrating that any allegedly false claims were "material" to the Government's decision to pay the claim. *Escobar* emphasized that the materiality test is both "demanding" and "rigorous" and is not met unless the relator's factual allegations demonstrate that the alleged misrepresentation "likely" induced the Government to pay the claim. *Escobar*, 136 U.S. at 2002-03.

The panel's decision fails to apply *Escobar*'s demanding materiality requirements. It reinstated the claims of Relators Jeffrey Campie, *et al.*, despite their failure to allege any facts demonstrating that the misrepresentations they allege likely would have caused the Government to pay claims that it would not otherwise have paid. The decision sharply conflicts with the decisions of other appeals courts that have faithfully adhered to *Escobar*. The mischief that will arise from the decision is far-ranging; WLF is concerned that the decision is likely to be

applied to a broad range of industries that conduct business with the Government and to expose them to liability under the FCA for even inconsequential violations of federal regulatory requirements. *En banc* review is warranted to prevent that result and to resolve the conflict between the panel decision and the decisions of numerous other appeals courts.

This Court has long recognized materiality as one of the "essential" elements of an FCA claim:

[T]he essential elements of False Claims Act liability remain the same [regardless of the FCA theory of liability being pursued]: (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.

United States ex rel. Hendow v. University of Phoenix, 461 F. 3d 1166, 1174 (9th Cir. 2006). Unless a relator alleges facts sufficient to establish the requisite materiality, an FCA defendant is entitled to dismissal on the pleadings.

In *Escobar*, many industry groups expressed fears that if the Court endorsed the implied false certification theory as a basis for establishing falsity in an FCA claim, the business community would be exposed to virtually unlimited FCA liability. *Id.* at 2002. The Court sought "to allay [those] concerns," even as it held that the implied false certification theory can be a basis for liability, by stating that "other parts of the False Claims Act" properly cabin potential FCA liability. *Ibid*.

It explained:

"[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent," concerns about fair notice and open-ended liability "can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." Those requirements are rigorous.

Ibid (quoting United States v. SAIC, 626 F.3d 1257, 1269 (D.C. Cir. 2010)).

Numerous federal appeals courts have addressed the metes and bounds of the FCA materiality requirement in the wake of the *Escobar* decision. The panel's interpretation of that decision conflicts sharply with the understanding of other appeals courts.

STATEMENT OF THE CASE

This rehearing petition involves an issue of exceptional importance regarding the scope of the FCA. Defendant Gilead Sciences, Inc. manufactures a number of life-saving HIV medicines. Relators acknowledge that the three medications at issue here—Atripla, Emtriva, and Truvada—have at all relevant times been approved by the Food and Drug Administration (FDA) as safe and effective for their intended uses. They allege, however, that Gilead engaged in manufacturing practices that violated several FDA regulations, including the Good Manufacturing Practices regulations. 21 C.F.R. §§ 210-211. Relators claim that Gilead violated the FCA by seeking and obtaining reimbursement for medications

supplied under a variety of Government programs (e.g., Medicare and programs operated by the Department of Veterans Affairs) despite its awareness of those regulatory infractions.

Relators' claims focus largely on Gilead's decision for a time to procure FTC (the active ingredient in the HIV medications at issue) from a supplier named Synthetics China. Relators advance three theories under which claims submitted by Gilead should be deemed "false" for FCA purposes: (1) promissory fraud—Gilead obtained FDA approval for distribution of its products (a prerequisite to Government payments for those products) by falsely stating how it intended to obtain FTC, thereby rendering "false" all subsequent claims for payment; (2) implied false certification—Gilead implicitly certified that its drugs were approved for distribution, when it knew otherwise; and (3) factually false certification—the drugs Gilead delivered were not what had been promised. Op. 13.

The district court dismissed Relators' Second Amended Complaint for failure to state a claim, but the panel reversed based on its conclusion that Relators "alleged sufficient facts under the False Claims Act to state a claim for relief that is plausible on its face." Op. 30. While acknowledging that Gilead had challenged throughout these proceedings the adequacy of Relators' materiality allegations, the

panel stated that those challenges were "matters of proof, not legal grounds to dismiss relators' complaint." Op. 29. It declined to address whether Gilead's alleged false statements were actually material to the Government, stating, "[a]lthough it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us." *Ibid.* The panel concluded, "In sum, relators allege more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations, … sufficiently pleading materiality at this stage." *Ibid.* (citing *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017)).

SUMMARY OF ARGUMENT

Rehearing *en banc* is warranted. The panel's holding that Relators have adequately alleged materiality is directly at odds with the "rigorous" and "demanding" materiality standards established by the Supreme Court in *Escobar*. Relators have alleged no facts indicating that the federal government deems the alleged regulatory violations at issue here sufficiently serious that, when it becomes aware that a company has engaged in such practices, it routinely refuses to pay claims submitted by the company and/or seeks to recoup payments previously made. Indeed, Relators concede that the Government has not sought to

revoke its approval of Gilead's New Drug Applications (NDAs) for the drugs in question and continues to pay billions of dollars for those drugs. Nor has the Department of Justice (DOJ) sought to intervene in this action in support of Relators. *Escobar* termed that state of affairs as "very strong evidence" that the alleged violations are not sufficiently material to support an FCA claim. *Escobar*, 136 S. Ct. at 2003.

The panel concluded that it was premature to evaluate materiality at the pleadings stage, stating that Gilead's challenges to materiality were "matters of proof, not legal grounds to dismiss relators' complaint." Op. 29. That statement directly contradicts *Escobar*'s conclusion that the "rigorous" materiality standard is not "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss" and that dismissal is warranted unless relators "plead[] facts to support allegations of materiality" with "plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Escobar*, 136 S. Ct. at 2004 n.6.

Review also is warranted because the panel has interpreted *Escobar* in a manner that conflicts sharply with the interpretation adopted by every other federal appeals court that has addressed that decision's teachings regarding materiality. The First, Third, Fifth, Seventh, and D.C. Circuits have each concluded that the FCA's "demanding" materiality requirements mandate dismissal when, as here, a

relator has failed to come forward with factual allegations demonstrating that the federal government deems a contractor's alleged regulatory infractions to be sufficiently severe that it routinely refuses to pay claims in cases involving similar infractions and/or has sought to recapture funds previously paid.

REASONS FOR GRANTING THE PETITION

I. REHEARING EN BANC IS WARRANTED BECAUSE THE PANEL'S MATERIALITY HOLDING IS DIRECTLY AT ODDS WITH THE SUPREME COURT'S RECENT ESCOBAR DECISION

Relators contend that Gilead defrauded the Government of many billions of dollars it paid for medications in the increasingly successful fight against AIDS. The Government has been aware of those allegations since at least 2010, when Relators filed their FCA claims under seal. Given the magnitude of the alleged fraud, one would reasonably expect the Government—had it deemed the regulatory infractions alleged by Relators to be "material"—to have taken decisive action against Gilead. Decisive actions likely would have included ceasing the multibillion-dollar annual payments to Gilead for the drugs, seeking to recoup some or all of the fraudulently obtained funds, and revoking approval for continued distribution of drugs by a company that obtained FDA approval through fraudulent means.

Yet, the Second Amended Complaint alleges no such government actions.

Nor does it include any factual allegations 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" that the FCA defendant is alleged to have violated. *Escobar*, 136 S. Ct. at 2003. In the absence of factual allegations sufficient to satisfy *Escobar*'s "demanding" materiality requirement, the district court properly dismissed Relator's claims on the pleadings. *Ashcroft v. Iqbal*, 446 U.S. 662, 678 (2008) (a complaint cannot survive a motion to dismiss based on claims that state legal conclusions, unsupported by specific factual allegations that render the claims plausible). Nothing in the complaint renders plausible Relators' claim that Gilead's alleged regulatory violations were sufficiently material to prompt the Government to cease payment.

The panel acknowledged that despite its awareness of Relators' allegations, FDA has at all relevant times continued to approve marketing of the Gilead drugs in question, and that "FDA approval is 'the *sine qua non*' of federal funding here." Op. 25 (quoting *Hendow*, 461 F.3d at 1176). The panel nonetheless discounted the importance of FDA approval to the materiality question, stating that "just as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government fisc." Op. 26. It argued that "[m]ere FDA approval cannot preclude False Claims Act liability" and that "to

read too much into the FDA's continued approval ... would allow Gilead to use the allegedly fraudulently obtained FDA approval as a shield against liability for fraud." Op. 26, 28. The panel fails to explain, however, how it is "plausible" that the allegedly false statements were material to FDA product approval if FDA never considered withdrawing that approval even after learning of Relators' fraud allegations.

The panel also discounted the significance of continued FDA approval by asserting that "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs." Op. 28. That observation actually cuts strongly against the panel's materiality conclusion. Fraud allegations against Gilead, if believed and deemed sufficiently serious, undoubtedly would cause government officials to question whether to permit continued marketing and reimbursement. If, despite knowledge of those allegations, FDA officials believe that public-health considerations mandate continued availability of life-saving drugs, and if officials at the Centers for Medicaid and Medicare Services (CMS) believe that similar considerations require continued reimbursement for allegedly tainted drugs, that is strong evidence that government officials do not deem the

allegations to be material to their marketing and payment decisions.²

As the Supreme Court explained in *Escobar*:

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. ... [I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements are violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

136 S. Ct. at 2003-04.

Relators' materiality allegations are further undermined by the failure of the Department of Justice (DOJ) to intervene in this lawsuit despite being provided

[T]he conflict [between the FDA's own efforts to police fraud and suits by private litigants alleging fraud against the FDA] stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims.

Buckman, 531 U.S. at 348. *See also, id.* at 354 (Stevens, J., concurring in judgment) (private suits alleging that FDA product-approval decision were procured by fraud are unauthorized unless FDA later determines that fraud occurred).

² The Supreme Court has repeatedly cautioned against permitting litigants to second-guess federal agency decisionmaking based on fraud-on-the-agency allegations. In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Court barred private litigants from challenging a manufacturer's right to market a medical device by asserting that the manufacturer had obtained federal marketing authority by defrauding FDA. The Court explained:

ample opportunity to examine Relators' claims and despite the potential for a gargantuan judgment for the United States if Relators' claims were to prevail. Indeed, DOJ has repeatedly argued in court proceedings that its decision regarding whether to intervene in an FCA action is an important factor in determining the materiality of false claims. See, e.g., United States ex rel. Badr v. Triple Canopy, Inc., Fourth Cir. No. 13-2190, Supplemental Brief for the United States at 15 (Dkt. 78, Aug. 19, 2016) ("The Army did not renew its contracts with Triple Canopy [following receipt of the relator's false-claims allegations], and the United States intervened in the relator's qui tam action. These actions confirm the significance of the violations and the importance the government attaches to them."); *United* States ex rel. Hinkle v. Caris Healthcare, L.P., E.D. Tenn. No. 14-212, United States Complaint in Intervention at 25 (Dkt. 57, Oct. 11, 2016). Both the Third and Fourth Circuit's agree that DOJ's decision regarding intervention is an important determinant of materiality. United States ex rel. Petratos v. Genentech, Inc., 855 F.3d 481, 490 (3d Cir. 2017); United States ex rel. Badr v. Triple Canopy, Inc., 857 F.3d 174, 179 (4th Cir. 2017) (DOJ's decision to "immediately intervene in the litigation" is evidence that the FCA defendant's falsehood was material and

"affected the Government's decision to pay.").3

Finally, the panel's assertion that Gilead's challenges to materiality "are matters of proof, not legal grounds to dismiss relators' complaint," Op. 29, directly contradicts *Escobar*'s teaching. The Supreme Court held that the FCA's materiality requirement was both "rigorous" and "demanding," Escobar, 136 S. Ct. at 2002-03, that "strict enforcement" of the requirement was important to alleviate "concerns about fair notice and open-ended liability" under the FCA, id. at 2002, and that materiality is not "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss." *Id.* at 2004 n.6. Pleading rules required Relators to include in their complaint factual allegations supporting their legal conclusion that Gilead's allegedly false claims were material to the decision of government officials to pay for Gilead's life-saving medications. In the absence of such allegations, the district court properly dismissed the complaint. *Ibid*. The panel stated that evidence regarding whether "the government regularly pays this type of claim in full despite actual knowledge" of the regulatory violations alleged by

³ The panel asserted that DOJ "submitted a brief as amicus curiae supporting reversal of the district court." Op. 11. That assertion is incorrect. DOJ's brief took issue with several of the district court's legal conclusions regarding what constitutes a false statement under the FCA, but it expressly declined to take a position regarding whether Relators' Second Amended Complaint should be dismissed for failure to state a claim. DOJ Br. 1-2.

Relators "is not before us," Op. 29, an acknowledgment that Relators' Second Amended Complaint failed to include factual allegations to support their materiality claim. That failure should have led the panel to affirm the dismissal on materiality grounds.

II. REHEARING EN BANC IS WARRANTED BECAUSE THE MATERIALITY HOLDING SHARPLY CONFLICTS WITH OTHER APPEALS COURTS' INTERPRETATIONS OF ESCOBAR

The Supreme Court's decision last year in Escobar led numerous federal appeals courts to re-examine the FCA's materiality requirement. The panel's decision sharply conflicts with post-Escobar decisions from at least five other circuits, all of which have concluded that the FCA's "demanding" materiality requirements mandate dismissal when, as here, a relator has failed to come forward with factual allegations indicating that the federal government deems a contractor's alleged regulatory infractions to be sufficiently severe that it routinely refuses to pay claims in cases involving similar infractions and/or has sought to recapture funds previously paid. Indeed, the First Circuit last month expressly criticized the Ninth Circuit's decision to permit Relators to proceed with their fraud-on-the-FDA claim, observing that the panel "offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation in which a fully informed FDA has not itself even hinted at doing anything." United States ex

*5 (1st Cir. 2017). *En banc* review is warranted to permit the Court to decide whether it wishes to remain an outlier on this important FCA issue.

In an earlier decision, the First Circuit relied on *Escobar* to affirm dismissal on the pleadings of an FCA claim against a medical-device manufacturer. D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016). The manufacturer allegedly obtained FDA approval for its device by making fraudulent representations to the agency. The court held that "FDA's failure to actually withdraw its approval of [the device] in the face of [the relator's] allegations" precluded the relator from asserting a promissory fraud claim against the manufacturer because "[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." Id. at 6. The Ninth Circuit panel cited but made no effort to distinguish D'Agostino, merely responding that "FDA approval cannot preclude False Claims Act liability, especially where, as here, the allegedly false claims procured certain approvals in the first instance." Op. 26.

The First Circuit's later *Nargol* decision reaffirmed *D'Agostino* and severely criticized this Court's interpretation of the materiality requirement set forth in

Escobar. Affirming dismissal of a fraud-on-the-FDA claim against a medical device manufacturer, the First Circuit held that FDA's decision not to "withdraw or even suspend" its product approval "in the wake of Relators' [fraud] allegations ... renders a claim of materiality implausible." Nargol, 2017 WL 3167622 at *3. The First Circuit noted that "Campie offers no rebuttal at all to D'Agostino's observation that six jurors should not be able to overrule the FDA" and that Campie "decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solution can be envisioned, even in theory." Id. at *5.

The panel's understanding of *Escobar* also conflicts sharply with that of the Third Circuit in *Petratos*. Citing failure to adequately plead materiality, the Third Circuit affirmed dismissal of a relator's FCA claims against a drug manufacturer who allegedly caused doctors to submit false Medicare claims by providing false information regarding the health risks of its drug. *Petratos*, 855 F.3d at 489-93. Noting that the Government, following receipt of the relators's allegations, continued to reimburse all claims submitted for payment, the court concluded that the relator had failed to establish that the defendant's false statements were material to the payment of claims. *Ibid*. The Third Circuit observed, "In holding that Petratos did not sufficiently plead materiality, we now join the many other

federal courts that have recognized the heightened materiality standard after [*Escobar*]." *Id.* at 492 (citing cases).

Other circuits have recognized that heightened materiality standard in contexts not involving FDA-approved medical products. In *United States v*. Sanford-Brown, Ltd., 840 F.3d 445, 447-48 (7th Cir. 2016), the Seventh Circuit cited failure to adequately demonstrate materiality as a basis for affirming the dismissal of an FCA claim filed against a for-profit college. Citing Escobar's description of the materiality standard as "rigorous" and "demanding," the appeals court held that "even assuming [the relator's] allegations are true," the relator failed to establish materiality because he failed to present evidence that "the government's decision to pay [the college] would likely or actually have been different had it known of [the college's] alleged noncompliance with Title IV regulations." Id. at 447. That holding contrasts sharply with the ruling of the panel, which *overturned* dismissal of the Relator's claims because of the alleged absence of evidence regarding whether "the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated." Op. 29.

The panel's understanding of the FCA materiality requirement also conflicts with a recent D.C. Circuit opinion. In *United States ex rel. McBride v. Halliburton*

Co., 848 F.3d 1027 (D.C. Cir. 2017), the appeals court affirmed dismissal of an FCA complaint against a military contractor, ruling that the relator had failed to demonstrate that the false reports submitted by the contractor to government officials were material to the Government's decision to pay the contractor's invoices. Although the relator alleged that the false reports were material, the court deemed that allegation insufficient to establish her claim. 848 F.3d at 1033 (stating that the relator "offers no evidence in support of [her materiality claim] other than her own say-so, which is clearly insufficient"). The court also held that the fact that government officials "investigated [the relator's] allegations and "did not disallow any charged costs," was "'very strong evidence' that the [regulatory] requirements allegedly violated by [the submission of false reports] are not material." Id. at 1034 (quoting Escobar, 136 S. Ct. at 2003). See also Abbott v. BP Exploration & Production, Inc., 851 F.3d 384, 388 (5th Cir. 2017) (affirming dismissal of FCA claim for failure to establish materiality, concluding that the Government decision to permit contractor to continue work after investigating Relators' allegations of regulatory noncompliance "represents 'strong evidence' that the requirements in those regulations are not material") (quoting Escobar, 136 S. Ct. at 2004).

In sum, the panel decision conflicts sharply with the holdings of at least five

other circuits regarding the materiality standard imposed by *Escobar* on FCA

relators. The decisions of the Fifth, Seventh, and D.C. Circuits—none of which

involved FCA claims filed against companies in the pharmaceutical industry—well

illustrate the potential applicability of the panel's aberrant materiality standard to a

broad range of industries that conduct business with the government. The panel's

decision is likely to serve as a magnet for FCA filings within the Ninth Circuit and

to expose a broad array of government contractors to FCA claims for even

inconsequential violations of federal regulatory requirements. En banc review of

the panel decision is particularly warranted in light of its likely significant impact

across the entire business community.

CONCLUSION

WLF requests that the Court grant the petition for rehearing *en banc*.

Respectfully submitted,

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Dated: August 31, 2017

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation. Pursuant

to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rules 29-2 and 32-1, I hereby

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/s/ Richard A. Samp

Richard A. Samp

Attorney for Washington Legal Foundation

Dated: August 31, 2017

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 31st day of August, 2017, I electronically filed the foregoing brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court for the U.S. Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp Richard A. Samp