

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT**

United States Court of Appeals
Fif h Circuit

FILED

September 29, 2017

Lyle W. Cayce
Clerk

No. 15-41172

UNITED STATES OF AMERICA, EX REL., JOSHUA HARMAN,

Plaintiff - Appellee

v.

TRINITY INDUSTRIES INC.; TRINITY HIGHWAY PRODUCTS LLC,

Defendants - Appellants

Appeal from the United States District Court
for the Eastern Division of Texas

Before JOLLY, HIGGINBOTHAM, and GRAVES, Circuit Judges.

PATRICK E. HIGGINBOTHAM, Circuit Judge:

The trial in this case offers two narratives. One of a hardworking man who, angered by failures of guardrails installed across the United States—with sometimes devastating consequences—persuaded a Texas jury of a concealed cause of those failures. The other of the inventive genius of professors at Texas A&M’s Transportation Institute, who, over many years of study and testing, developed patented systems including guardrails that, while saving countless lives, cannot protect from all collisions at all angles and all speeds by all vehicles—guardrails that have been installed throughout the United States

No. 15-41172

with an approval from which the government has never wavered as it reimbursed states for the installation of a device integral to the system.

Despite a formal statement issued on the eve of trial from the government affirming that approval and a caution from this court that the case ought not proceed, seven jurors in a six-day trial in Marshall, Texas, found that the government had been defrauded. We will describe, but not decide, the substantial challenges to the jury's findings of liability and damages as an essential backdrop to the challenge we ultimately sustain, one that ends this litigation. We hold that the finding of fraud cannot stand for want of the element of materiality. Therefore, we reverse and render judgment as a matter of law for Trinity.

I.

Early highway guardrail systems helped prevent drivers from running off the road, attended by a lesser but significant risk—in a head-on collision with an automobile, the blunt ends of the guardrails could “spear” or penetrate vehicles’ passenger compartments. Attempts to mitigate this risk by burying the end of the guardrail were successful, but created a different risk; guardrails ceased to spear automobiles, but proved to act as a launch ramp, rolling out-of-control vehicles, sometimes back into traffic. As part of its many years of ongoing research and testing aimed at improving highway safety, engineers at the Texas A&M Transportation Institute (“TTI”) developed a guardrail “end terminal” system known as the ET-2000, which, with modification in 1999, became the ET-Plus.¹ In a head-on collision, the ET-Plus’ terminal (or extruder) head flattens and extrudes the guardrail away from the vehicle while simultaneously “gating” the vehicle by the sequential failures of the pre-drilled posts carefully laced and spaced to meet design specifications for the system,

¹ See Appendix A.

No. 15-41172

all to slow speeding vehicles to survivable stops and substantially lessen the risk posed by the rails. Trinity Highway Products, LLC, a subsidiary of Trinity Industries, Inc. (“Trinity”), manufactures the ET-Plus system under an exclusive licensing agreement with Texas A&M University—in short, TTI engineers the product and Trinity manufactures it according to TTI’s design. ET-Plus systems are sold to highway contractors and installed along many highways throughout the country.

The Federal Government subsidizes many state highway improvements, reimbursing states for the installation of guardrail end terminal systems meeting its standards. At times relevant here, acceptance by the Federal Highway Administration (“FHWA”) was a prerequisite to eligibility for federal reimbursement. FHWA could require testing of products, unless they “are nearly certain to be safe” or “so similar to currently accepted features that there is little doubt that they would perform acceptably.” And changes to approved systems must also be submitted for approval unless an exercise of good engineering judgment finds they were not significant.²

The original ET-Plus system was successfully tested by TTI, and on January 18, 2000, FHWA accepted the ET-Plus for use on the National Highway System. At that time, the ET-Plus was designed for 27¾-inch high guardrails. By 2005, the increase of vehicles with higher centers of gravity—e.g., SUVs—turned the research to taller guardrails. Trinity and TTI developed a modified ET-Plus system for use with 31-inch guardrails. TTI crash tested the new ET-Plus at the 31-inch height and prepared a report on the tests, which Trinity sent to FHWA. On September 2, 2005, FHWA approved the modified ET-Plus for the 31-inch guardrail height.

² This will be explained.

No. 15-41172

Before testing the new guardrail height, Trinity changed the guide channel width in the ET-Plus' terminal head from five inches to four inches, accompanied by necessary fabrication changes ("2005 changes"). Trinity contends that a modified version of the extruder head was included in the 31-inch guardrail system when it was crash tested in 2005. Trinity also maintains that it prepared and sent a detailed drawing of the ET-Plus head with the 2005 changes to TTI to be included in the report sent to FHWA. TTI did not include the drawing when it prepared the crash test report that Trinity later forwarded to FHWA. The body of the 2005 crash test report discussed the changes made to accommodate the 31-inch guardrail height, but not the changes in guide channel width or the related fabrication changes.³

Joshua Harman had been a customer of Trinity, purchasing their products and installing them in the eastern United States. Harman was also a one-time competitor of Trinity, manufacturing his own end terminal heads through SPIG and Selco, businesses he owned with his brother.⁴ SPIG and Selco failed. And Trinity sued Harman, once for patent infringement related to

³ Joshua Harman argues that Trinity has provided no proof that the head units tested in 2005 included one with the 2005 changes. Trinity maintains that such a head unit was included in the 2005 testing, as A&M Professor Dr. Bligh testified to at trial. In a videotaped deposition introduced into evidence during trial, FHWA representative Nicholas Artimovich explained that, after learning of the 2005 changes, he reviewed video footage from the 2005 testing and concluded that "the tests done in 2005 used a terminal head with [the narrower] feeder channel." There is no contrary evidence.

⁴ The district court excluded evidence that these heads were the source of many of Harman's problems, as unapproved SPIG heads were installed across the Commonwealth of Virginia with falsified documents to secure payment from the Virginia Department of Transportation. As a result, Virginia's State Materials Engineer removed Selco from the approved installers list. In a pretrial hearing, the district court said such evidence was "improper" and "a backdoor way to attack [Harman's] character." That ruling is not challenged on appeal.

No. 15-41172

SPIG-manufactured heads in 2011 and twice for defamation related to his campaign against the ET-Plus.⁵

Harman hoped to compete with Trinity and “with the entire industry” again in the future, admitting on cross-examination that he intended to use the proceeds from this litigation to recapitalize his business and begin manufacturing competing end terminals. Trinity presented evidence to the jury that an investment manager prepared a prospectus to pitch to potential SPIG investors in February 2014, advertising that a “[r]ecall of Trinity’s modified end terminals would mean removal and replacement of approximately one million units in the [United States], a one-billion-dollar revenue opportunity windfall for SPIG” and noting that SPIG had “[p]lans to capture 20 percent of the U.S. end terminal market in 18 to 24 months, then continue rapid growth to take market share from an exposed Trinity.”

Harman testified that he set out on a cross country trip looking for accidents involving guardrails; that he acquired between six and eight ET-Plus heads; and that he found five changes that he believed were causing the accidents. The primary change was the narrowing of the guide channel from five inches to four inches. Harman also noted a shortened guide channel and feeder chute; a narrower exit gap; a change from a flush “butt weld” to a “fillet weld,” diminishing the height of the extruder throat; and a steeper angle of the side plates.⁶ At trial, Harman claimed that all of these changes resulted in “a complete[ly] new product.” Unable to find records of FHWA approval for these changes, Harman presented his findings to FHWA in January 2012 via an

⁵ The patent suit settled. The defamation suits were each voluntarily dismissed by Trinity.

⁶ See Appendix B.

No. 15-41172

extensive PowerPoint presentation that included explanations of the 2005 changes and accident scene photographs.⁷

It is undisputed that, at that meeting, Harman discussed the change from a five- to four-inch guide channel, the shortening of the guide channel, the change in the exit gap from one and a half inches to one inch, the diminished height of the extruder chamber, and that “in [his] view, there had to be significant other changes as well.” Nicholas Artimovich, an FHWA representative, took photographs and measurements of the heads Harman provided at the meeting.

FHWA then met with Trinity in February 2012 to discuss Harman’s allegations. Trinity explained that, while the change in the guide channel width was inadvertently omitted from the report sent to FHWA, the May 2005 crash test was of an ET-Plus system with a modified terminal head. FHWA met twice more with Harman and his counsel. Around that same time, FHWA responded to inquiries about the ET-Plus from various state departments of transportation by confirming that the ET-Plus was eligible for reimbursement.

On March 6, 2012, Harman filed a sealed False Claims Act (“FCA”) suit in the Eastern District of Texas. The government reviewed the complaint and declined to intervene ten months later. The court then unsealed the complaint and discovery began. On March 13, 2014, as a July trial date loomed, Harman’s counsel requested that FHWA make its employees available for deposition (“*Touhy* request”). Harman argued that Trinity still had not disclosed the

⁷ The PowerPoint includes slides discussing the change from five- to four-inch feeder chute, a reduced rail height from 15.375 to 14.875 inches, a shorter, narrower feeder chute that intrudes into the extruder throat, “ledges” near the top and bottom of the extruder throat created by the feeder chute intrusion, a smaller exit gap, and pictures of what Harman argued was the resulting “throat lock.”

No. 15-41172

fabrication changes to the ET-Plus beyond the change from a five- to four-inch guide channel.⁸

On June 17, 2014, FHWA released an official memorandum that stated that it had “validated that the ET-Plus with the 4 inch guide channels was crash tested in May 2005,” that “[t]he Trinity ET-Plus with 4-inch guide channels became eligible for Federal reimbursement . . . on September 2, 2005,” and that there was “an unbroken chain of eligibility for Federal-aid reimbursement [that] has existed since September 2, 2005, and the ET-Plus continues to be eligible today.” On the same day, DOJ responded to Harman’s *Touhy* request by emailing a copy of the memorandum with the following cover note:

Please find attached a memorandum issued by FHWA today that addresses all of the issues raised by the parties in their respective requests for information. DOT believes that this should obviate the need for any sworn testimony from any government employees. If the parties disagree, please let me know at your earliest convenience.⁹

Trinity moved for summary judgment on the basis of the June 17, 2014 memorandum, which the district court denied from the bench.¹⁰

A jury trial commenced on July 14, 2014; four days into that trial the district court *sua sponte* ordered a mistrial, citing gamesmanship and

⁸ In this letter, Harman also repeated his list of fabrication changes that he alleged were still undisclosed. Specifically, Harman claimed that Trinity had not disclosed “(1) the change from a 5 inch rail feeder chute to a 4 inch rail chute; (2) changes to the exit gap; (3) changes to the feeder chute assembly; (4) changes to the feeder chute assembly length; and (5) other changes to the ET-Plus.”

⁹ For reasons not clear from the record, the district court excluded this statement from evidence, a ruling consistent with Harman’s contention that the opinion of the government does not matter.

¹⁰ Harman also moved for partial summary judgment, and his motion was likewise denied.

No. 15-41172

inappropriate conduct by both parties. Following the mistrial, Trinity asked this court for a writ of mandamus, which this court denied while warning:

This court is concerned that the trial court, despite numerous timely filings and motions by the defendant, has never issued a reasoned ruling rejecting the defendant's motions for judgment as a matter of law. On its face, FHWA's authoritative June 17, 2014 letter seems to compel the conclusion that FHWA, after due consideration of all the facts, found the defendant's product sufficiently compliant with federal safety standards and therefore fully eligible, in the past, present and future, for federal reimbursement claims. While we are not prepared to make the findings required to compel certification for interlocutory review by mandamus, a course that seems prudent, a strong argument can be made that the defendant's actions were neither material nor were any false claims based on false certifications presented to the government.¹¹

The case proceeded to trial for a second time the following Monday. After a six-day trial, the jury returned a verdict for Harman. The next day, facing widespread publicity of the verdict and inquiries of state Attorneys General, the government did not withdraw its approval of the ET-Plus units; rather, it sought independent testing of the units and confirmation by a separate joint task force that the units being tested were the same as those installed across the country. On November 17, 2014, Trinity renewed its motion for judgment as a matter of law under Rule 50(b).¹²

The independent testing ordered by FHWA was performed between December 10, 2014, and January 6, 2015. Awaiting the testing, Trinity suspended the sale of ET-Plus systems. A joint task force—consisting of state, federal, and foreign transportation experts—examined over one thousand existing ET-Plus installations across the country between November 2014 and January 2015 and concluded that: (1) “[t]here is no evidence to suggest that

¹¹ *In re Trinity Indus., Inc.*, No. 14-41067 (5th Cir. Oct. 10, 2014).

¹² FED. R. CIV. P. 50(b).

No. 15-41172

there are multiple versions [of the ET-Plus] on our nation’s roadways” and (2) the units that were crash tested were “representative of the devices installed across the country.”¹³ FHWA announced these findings in a March 11, 2015 press release. With that confirmation, the government’s approval of the units remained in place and Trinity renewed its sales.¹⁴

On June 9, 2015—after the results of the post-trial crash tests and dimensions studies were released—the district court denied Trinity’s motion for judgment as a matter of law and entered final judgment that same day for Harman and the United States in the amount of \$663,360,750—consisting of \$575,000,000 in trebled damages and \$138,360,750 in civil penalties for 16,771 false claims—plus an additional \$19,012,865 in attorney’s fees and costs. Trinity then moved for a new trial based on, among other things, the results of the post-trial crash tests and the findings of the joint task forces, which the district court denied on August 3, 2015.¹⁵ This appeal followed.

II.

“A district court’s resolution of a motion for new trial is reviewed for abuse of discretion, and [t]he district court abuses its discretion by denying a new trial only when there is an absolute absence of evidence to support the

¹³ FHWA and the American Association of State Highway and Transportation Officials (AASHTO) formed two joint task forces to investigate the ET-Plus. The second joint task force was assigned to “review[] a broad range of crash reports from multiple sources to determine if the ET-Plus has potential vulnerabilities that could compromise its ability to perform as designed.” That review has not yet been completed and published.

¹⁴ Of course, this evidence was not before the jury. But in denying Trinity’s Rule 50(b) motion, the district court relied on the post-trial test in ruling that, at the time of the June 17, 2014 memorandum, FHWA did not have enough information to approve the product. We disagree—FHWA, responsive to widespread news of the verdict and the resulting unease of states with the system leading to inquiries from states Attorneys General, ordered additional testing from independent testing labs, but did not withdraw its earlier decision. The results of those tests confirmed rather than undermined the earlier decision.

¹⁵ Trinity also claimed that a new trial was warranted on the basis of the excessive damages award, the court’s failure to submit the number of false claims to the jury, the excessive fines clause, and “because the verdict is against the weight of the evidence.”

No. 15-41172

jury's verdict.”¹⁶ “A motion for a new trial or to amend a judgment cannot be used to raise arguments which could, and should, have been made before the judgment issued.”¹⁷ Rule 60(b)(2) allows a party to seek post-judgment relief on the basis of “newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b).”¹⁸ “Moreover, [t]he newly discovered evidence must be in existence at the time of trial and not discovered until after trial.”¹⁹

While our review of the district court's denial of a Rule 50(b) renewed motion for judgment as a matter of law is *de novo*, “our standard of review with respect to a jury verdict is especially deferential.”²⁰ A party is only entitled to judgment as a matter of law on an issue where no reasonable jury would have had a legally sufficient evidentiary basis to find otherwise.²¹

III.

Trinity asked the district court and now this court for a new trial on the basis of newly discovered evidence—namely, the post-trial crash tests and the dimensions report. This evidence is compelling and rebuts much of Harman's case at trial. However, we need not consider the question of post-judgment relief under Rule 60(b) here because we find that Trinity is entitled to judgment as a matter of law on the issue of materiality. Thus, we advert to the

¹⁶ *McCaig v. Wells Fargo Bank (Texas), N.A.*, 788 F.3d 463, 472 (5th Cir. 2015) (quoting *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881 (5th Cir. 2013)) (internal quotation marks omitted).

¹⁷ *Garriot v. NCsoft Corp.*, 661 F.3d 243, 248 (5th Cir. 2011) (quoting *Simon v. United States*, 891 F.2d 1154, 1159 (5th Cir. 1990)) (internal quotation marks omitted).

¹⁸ FED. R. CIV. P. 60(b)(2).

¹⁹ *Gen. Universal Sys., Inc. v. Lee*, 379 F.3d 131, 158 (5th Cir. 2004) (quoting *Longden v. Sunderman*, 979 F.2d 1095, 1102-03 (5th Cir. 1992)) (internal quotation marks omitted).

²⁰ *Olibas v. Barclay*, 838 F.3d 442, 448 (5th Cir. 2016) (quoting *Evans v. Ford Motor Co.*, 484 F.3d 329, 334 (5th Cir. 2007)) (internal quotation marks omitted).

²¹ FED. R. CIV. P. 50(a)(1).

No. 15-41172

post-trial testing only in rejecting the district court's inferences from the government's decision to order the independent testing.

IV.

As we will show, the jury's findings on liability cannot stand for want of materiality. Before turning to liability, it is worth noting that Harman's failure to rebut the strong presumption against materiality also manifests in its effect on damages. The proper measure of the government's damages in an FCA action where the government received something other than what was promised is the standard formulation for contract damages: the difference between what was promised and what was received.²² At trial, Harman's damages expert calculated damages assuming the value of the ET-Plus units with the 2005 changes was limited to the scrap value of those units.²³ Using that figure, Harman's expert reached a total damages figure that was apparently adopted by the jury before statutory trebling.²⁴

²² *United States v. Bornstein*, 423 U.S. 303, 316 n.13 (1976).

²³ Importantly, Harman's damages expert did not testify that the value of the ET-Plus units was actually only the scrap value figure, but that he "was advised by counsel that the evidence presented in this trial will show that the units themselves have no value, but that I should provide and I was requested to provide a calculation of the scrap metal value simply to present to this Court and jury for their consideration." The expert further testified that "[t]here's no ascertainable value for a non-compliant ET-Plus unit that I could identify, so I cannot render an opinion with respect to what the actual benefit to the United States Government would be. . . . I have no expertise and – and render no opinion with respect to the actual benefit those units have to the United States Government. . . . The premise of my calculations is that the ET-Plus is not compliant with the Federal Highway Administration standards and that Trinity has certified that, in fact, during the damage period, it was compliant with the FHWA standards."

²⁴ Harman's damages expert testified that "the damages that range from the period March 6, 2006 through December 31, 2013, the total amount that I estimate that the U.S. Government reimbursed the states for their purchase of ET-Plus units is \$218,003,273. That value will be reduced by the jury's finding of what the value of a non-compliant ET-Plus unit will be, assuming there is a finding of liability in this matter. One value that they could consider is the value of the scrap metal that I've indicated before is a value of \$42,965,383. You would subtract whatever value the jury finds, but in this illustration here the scrap metal value being subtracted from the 218-million-dollar amount is a net damage to the U.S. Government of \$175,037,890." The jury found that the total amount of actual damages suffered by the United States was \$175,000,000.

No. 15-41172

The problem with this figure is that nothing in the record supports the scrap valuation of the ET-Plus. Instead, FHWA's continued approval of reimbursement for the ET-Plus at the same amount strongly suggests that the government, the supposedly aggrieved party, considers the value of the units with the 2005 changes to be identical to the value of previous ET-Plus units. If the government received units of equivalent value, and thus has already enjoyed the benefit of its bargain, then the proper measure of actual damages should be zero. Trinity could still face civil penalty assessments "of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1980" for each individual sale,²⁵ of course, and Trinity also claims error in the district court's refusal to allow the jury to determine the number of false claims. Regardless, no award of damages can stand because, as we will show, the determination of liability does not. And, as we need not, we say no more of this set of damage issues.

V.

Trinity argues that Harman failed to meet his burden on each element of a claim under the FCA, which imposes liability on individuals who defraud the federal government.²⁶ "In determining whether liability attaches under the FCA, this court asks '(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).'"²⁷ It is settled that state requests for reimbursement are claims for payment under the FCA. We address the other elements in turn.

²⁵ 31 U.S.C. § 3729(a)(1).

²⁶ 31 U.S.C. § 3729 *et seq.*; *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016).

²⁷ *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 475 (5th Cir. 2012) (quoting *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467 (5th Cir. 2009)).

No. 15-41172

A.

Trinity argues that Harman failed to carry his burden on proving that Trinity made “a false statement or [engaged in] a fraudulent course of conduct” that caused a false claim for payment to be presented to the United States.²⁸ Harman’s theory is that Trinity certified that the ET-Plus system with the 2005 changes complied with the FHWA testing requirements, and that these false certifications caused states to present resultantly false claims for reimbursement to FHWA. In response, Trinity argues that the ET-Plus met the required standards at all times and thus any certification of that fact was not a false statement.

Both parties’ falsity arguments turn on whether the modified ET-Plus with the 2005 changes complied with requirements set out in the National Cooperative Highway Research Program’s (“NCHRP”) Report 350 (“Report 350”), as adopted by FHWA. Report 350 contains protocols for testing highway features, including test parameters, test conditions, data acquisition, evaluation criteria, test documentation, implementation, and evaluation.

FHWA’s reliance on Report 350 grew out of the Intermodal Surface Transportation Efficiency Act of 1991 (“ISTEA”).²⁹ ISTEA required the Secretary of Transportation to “initiate a rulemaking proceeding to revise the guidelines and establish standards for installation of roadside barriers and other safety appurtenances,” and thereafter issue a final rule on the matter.³⁰ To comply with ISTEA, FHWA undertook a formal rulemaking process which resulted in a final rule in 1993. This rule formally added NCHRP Report 350

²⁸ *United States ex rel. Spicer v. Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014) (citing *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009)); accord 31 U.S.C. § 3729(a)(1)(B) (liability for person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” (emphasis added)).

²⁹ Pub.L. 102–240, Dec. 18, 1991, 105 Stat. 1914.

³⁰ *Id.* at Section 1073(a), (b); 23 U.S.C. § 109 note.

No. 15-41172

to the regulation's "Guides and references" section.³¹ That same year, FHWA produced a memorandum "[t]o further promulgate application of the guidelines in the NCHRP Report 350."

In 1997, FHWA issued a policy memorandum ("1997 Policy Memorandum") that read the 1993 rule and memorandum as a "strong indication" that, as of the following year, "FHWA would require all new installations of highway features on the National Highway System (NHS) that are covered in the NCHRP Report 350 to have been tested and found acceptable according to the guidelines in that report." Based on that understanding, FHWA stated its policy on compliance:

Except as modified below, all new or replacement safety features on the [National Highway System] covered by the guidelines in the NCHRP Report 350 that are included in projects advertised for bids or are included in work done by force-account or by State forces on or after October 1, 1998, *are to have been tested and evaluated and found acceptable in accordance with the guidelines in the NCHRP Report 350.*

In other words, the 1997 Policy Memorandum required that highway safety features demonstrate "acceptable crashworthy performance" in order to gain FHWA approval of their use on the nation's highways, and Report 350 provided the measure for crashworthiness. Harman and Trinity agree that "FHWA regulations require full compliance with Report 350[.]"

When Trinity sells an ET-Plus system, the invoices often include references to bills of lading, which Trinity agrees are "sometimes—but not

³¹ As the FHWA explains in its 1997 guidance: "Through a formal rulemaking process that culminated in a final rule in a notice in Volume 58, No. 135, of the Federal Register, dated July 16, 1993, the FHWA added Report 350 at paragraph 625.2(a)(13) of Title 23, Code of Federal Regulations (23 CFR). Since that time, the 'Guides and references' section of 23 CFR, Part 625, under which the NCHRP Report 350 was cited, has been removed. The NCHRP Report 350 is now cited in Section 16, Paragraph (a)(12) of the Non-Regulatory Supplement to the Federal-aid Policy Guide, Subchapter G, Part 625 (NS 23 CFR 625)."

No. 15-41172

always—accompanied by a certificate stating that the ET-Plus is ‘NCHRP Report 350 Compliant’ or ‘NCHRP Report 350 Tested and Approved.’” Many of these ET-Plus systems are sold to state departments of transportation, who can seek reimbursement from the federal government for systems placed on federal-aid highways.

The parties dispute the scope of disclosure required by Report 350. Harman asserts that the 1997 Policy Memorandum requires that all changes, even minor ones, must be disclosed so that FHWA can decide if testing is necessary, pointing to language in Report 350 that “seemingly minor variations in design details can adversely affect the safety performance of a feature.” Harman also emphasizes that, at trial, Trinity Highway Product’s President Gregory Mitchell “admitted” that “it was required to get approval from the FHWA for the changes but that it did not do so[.]”³² Based on this interpretation, Harman maintained at trial that the ET-Plus was not Report 350 compliant after the 2005 changes because Trinity never disclosed the changes to FHWA nor demonstrated that the modified ET-Plus had undergone adequate crash testing. Trinity, by contrast, argues that Report 350 did not require the disclosure of the 2005 changes because it only requires disclosing significant changes. Trinity further maintains that an ET-Plus system with the 2005 changes in its head was crash tested in 2005 during the 31-inch guardrail height tests and that the changes were obvious and fully disclosed to TTI, the inventor of the ET-Plus.

While Harman argues that FHWA policy requires that “any changes” be disclosed to FHWA, he does not direct us to any clear statement of such a

³² From its context, it is not clear whether the witness referenced the requirements in place at the time of trial or nine years prior when the changes to the ET-Plus were implemented—two years before he was employed by Trinity.

No. 15-41172

disclosure rule. Nor can we find any. Instead, Harman directs us to the following passage in the 1997 Policy Memorandum:

There are some features that, by their nature, are nearly certain to be safe and others that are so similar to currently accepted features that there is little doubt that they would perform acceptably. For these features, the FHWA may, on a case-by-case basis, not require qualification testing or may accept abbreviated or unique qualification procedures as the basis for their acceptance.

This passage, in isolation, could be read to require suppliers to alert FHWA to any new features or design changes, and could signify, as Harman would have it, that FHWA alone can determine whether additional testing is required. Yet another passage in Report 350 frustrates this reading:

It is not uncommon for a designer/tester to make design changes to a feature during the course of conducting the recommended test series or after successful completion of the test series. Changes are often made to improve performance or to reduce cost of the design or both. Questions then invariably arise as to the need to repeat any or all of the recommended tests. Good engineering judgment must be used in such instances. As a general rule, a test should be repeated if there is a reasonable uncertainty regarding the effect the change will have on the test.

The plain reading of this additional language is that engineers may use their judgment to determine that additional testing is not needed for certain design changes. Under Trinity's view, because a determination of whether to test requires "good engineering judgment," "it 'cannot be false' under the FCA." Harman responds that this passage does not speak directly to disclosure requirements, and that in any case there is no evidence that good engineering judgment was exercised.³³

³³ Harman argues that the 2005 changes were not motivated by good engineering judgment, but by profit. This profit motive argument is discussed in more detail below in connection with Harman's scienter argument. We note, however, that good engineering

No. 15-41172

While Harman is correct that this section does not address disclosure requirements, this uncertainty does not necessarily cut against Trinity. Indeed, the regulations as written accept that engineers need not disclose changes where, in their good engineering judgment, they deem further testing unnecessary. Disagreement over the quality of that judgment is not the stuff of fraud.

Trinity also points to the following language in the 1997 Policy Memorandum to support its contention that it was not required to report every change: “should the FHWA discover subsequent to the issuance of an acceptance letter . . . the device being marketed is *significantly* different from the version that was crash tested, it reserves the right to modify or revoke its acceptance.” As Trinity reads this language, non-significant modifications are permissible without seeking new approval;³⁴ the “good engineering judgment” passage would do no work if the policy required that every change be submitted to FHWA.

The jury was never instructed on the requirements of Report 350 regarding disclosures of changes to approved devices or further testing of modifications in approved devices. Indeed, the trial judge did not himself decide what Report 350 required until after the verdict. In denying Trinity’s Rule 50(b) motion, the district court concluded that “any changes [to roadside hardware] must be reviewed by and agreed to by the FHWA.” Applying that standard, the district court found that the jury had before it “substantial evidence” to support the conclusion that Trinity made false statements when

judgment and the desire to reduce costs—a goal which is explicitly contemplated by Report 350—are not necessarily mutually exclusive.

³⁴ According to Trinity, “modifications that render the product ‘significantly different’ would give FHWA the option to revoke its acceptance. By implication, *non*-significant modifications would not.”

No. 15-41172

it asserted the ET-Plus was Report 350 compliant.³⁵ Specifically, the district court relied on the “undisclosed [2005] changes” as substantial evidence that all post-2005 certifications of the ET-Plus’ Report 350 compliance were false. The court also found that the 2005 changes were not an exercise of “good engineering judgment” because Trinity made the decision to modify the ET-Plus, rather than TTI. The court then indicated that it found Trinity’s competing evidence unpersuasive. Finally, the court acknowledged that “[t]he jury was free to weigh such competing evidence, judge the credibility of the witnesses, and determine the veracity of the testimony presented.” We cannot know from the record how the jury interpreted Report 350. And there is a powerful argument that leaving to the jury the determination of the law and the facts did not include resolution of the uncertainty inherent in the language of the policy.

Despite the district court’s conclusions and Harman’s insistence that the 1997 Memorandum “makes it clear that disclosure is required and that the FHWA decides what tests to run,” the contrary authorities cited by Trinity drain much force from Harman’s claim that every change must be disclosed. There is a substantial argument that, during the relevant period, FHWA policy required disclosure of significant changes, and that significance is a matter of engineering judgment. This follows from the plain language of Report 350. While this puts the jury verdict and Harman’s falsity theory at risk, we need not decide that question today.

B.

Trinity argues that even if Report 350 required disclosure of every change, Harman still failed to prove that Trinity acted with the requisite

³⁵ Specifically, the district court found substantial evidence for the jury “to conclude that Trinity’s post-2005 certifications of the ET-Plus as FHWA approved and NCHRP Report 350 compliant were false.”

No. 15-41172

scienter. “The scienter requirement comes from § 3729(b)’s definition of the terms ‘knowing’ and ‘knowingly.’”³⁶ “Though the FCA is plain that ‘proof of specific intent to defraud’ is not necessary, that mens rea requirement is not met by mere negligence or even gross negligence.”³⁷ Rather, the relator must demonstrate that the defendant “acted with knowledge of the falsity of the statement, which is defined, at a minimum, as acting ‘in reckless disregard of the truth or falsity of the information.’”³⁸

Trinity maintains that it could not have acted knowingly or recklessly if it was acting pursuant to a reasonable interpretation of the disclosure requirements. As we have explained, Trinity contends that the 2005 changes did not have to be disclosed to FHWA. In the alternative, Trinity maintains that the disclosure requirements were ambiguous enough that its interpretation was reasonable. Trinity then claims that a “reasonable interpretation of any ambiguity inherent in [a] regulation[] ‘belies the scienter necessary to establish a claim of fraud.’”³⁹ Specifically, Trinity asserts that it reasonably relied on TTI’s “good engineering judgment” in determining that the 2005 changes were not significant—an action consistent with its purported understanding of Report 350.⁴⁰ The trial testimony of TTI engineers supports

³⁶ *United States ex rel. Longhi v. United States*, 575 F.3d 458, 468 (5th Cir. 2009).

³⁷ *United States ex rel. Farmer v. City of Hous.*, 523 F.3d 333, 338 (5th Cir. 2008) (quoting 31 U.S.C. § 3729(a)(2); and citing *United States v. Krizek*, 111 F.3d 934, 941-42 (D.C. Cir. 1997)).

³⁸ *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014) (citing 31 U.S.C. § 3729(b)(1)(A)(iii)).

³⁹ *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013). Trinity also cites *Safeco Ins. v. Burr*, 551 U.S. 47, 70 n.20 (2007), holding, in the context of the Fair Credit Reporting Act, “[w]here, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.”

⁴⁰ At trial, Trinity and TTI employees both agreed that TTI is “responsible for all design and testing of the ET-Plus sold in the United States” and that TTI “decides whether design changes should be crash-tested before sale.” At trial, Trinity’s President Gregory

No. 15-41172

this claim. Texas A&M engineering professor Dr. Bligh testified that the reduction in guide channel width led to an “enhanced, improved product,” and that TTI would have recommended evaluation or testing if they had any doubt about the changes’ impact.⁴¹ Dr. Bligh also testified that, based on his engineering judgment, he found no reason to “independently test” the four-inch ET-Plus head,⁴² and that the May 2005 tests were sufficient.⁴³ Another TTI employee at the time, Dr. Butth, agreed with this assessment, stating during trial that there was no need to run additional tests on the modified ET-Plus head because the May 2005 tests left “no question in [his] mind” about what additional tests would show.⁴⁴ Trinity pointed to an email that Trinity’s Vice President of International Sales, Brian Smith, sent to TTI engineers asking for “[their] thoughts on changing the 5-inch channel on the ET-Plus extruder head

Mitchell testified that Trinity has always relied and depended on TTI for their technical expertise regarding the ET-Plus.

⁴¹ Q. In your mind, Dr. Bligh, as you evaluated this decision to go from five to four inches, did you have any uncertainty whatsoever that this would be anything but a positive improvement?

A. No, sir, I did not.

Q. If you had that uncertainty, Dr. Bligh, what would you have done?

A. We – we either wouldn’t have recommended it or we would have recommended other types of evaluation and testing to make sure that those uncertainties were – were resolved and evaluated.

⁴² Q. Did you find any reason in your good engineering judgment to somehow independently test the ET-Plus extruder head with the four-inch guide channels?

A. No, sir.

Q. Was the test done on May 27, 2005 an opportunity to see that head installed on an ET-Plus system.

A. Yes, sir.

⁴³ Q. In your judgment as an engineer who submits crash test reports to the FHWA for consideration, was it your belief that [the May 2005] crash test met the 350 criteria?

A. Yes, it is.

Q. And how was that demonstrated?

A. The . . . data that was collected in the test was analyzed and . . . compared against the criteria that we have in Report 350.

⁴⁴ Dr. Butth stated there was no need for a crash test with a pickup truck because none of the changes to the ET-Plus head would have changed the result of previous tests with pickup trucks.

No. 15-41172

to a 4-inch channel” and requesting that “the sample extruder head be used in the ET 31 test that is scheduled for May 25 or 26.” Trinity also provided responses from multiple TTI engineers agreeing to the change, including an email noting that engineers at TTI’s Riverside campus were “in agreement . . . the head should work fine, and [they] [would] install it on the test on May 25/26.”

Finally, Trinity’s witnesses testified that its own business practice was to disclose changes of this type, and that the failure to do so here was inadvertent. In support of this argument, Trinity offered evidence that Trinity created a drawing of the modified head with the 4-inch channel that TTI received. Both Trinity and TTI maintain that the drawing was mistakenly omitted from the report sent to FHWA. Harman provided no contrary testimony.

Harman argues that there was sufficient evidence in the record for a reasonable jury to conclude that Trinity knowingly misstated compliance with FHWA regulations in marketing the ET-Plus or, at least, that its false statements were motivated by potential profits and not its understanding of the Report 350 requirements. During the trial, Harman presented evidence from which he maintains the jury could have reasonably inferred an intent to deceive purchasers and conceal the purported fraud. Specifically, Harman presented a 2004 email from then-Trinity Highway Products Vice President of Operations Steve Brown, noting a potential savings of “\$2/ET” or “\$50,000/year” from the five-inch to four-inch change. In the email, Brown stated “I’m feeling that we could make this change with no announcement.” Jurors also heard testimony by Smith, that it was “standard procedure” to communicate with FHWA about proposed changes, and from Mitchell, that he

No. 15-41172

understood the regulations to require Trinity to present proposed changes to the FHWA.⁴⁵

Harman also notes Trinity's failure to mention the changes to the ET-Plus to the FHWA before the May 2005 crash tests, to disclose all of the changes to the ET-Plus beyond the change in guide channel width even after Harman disclosed those other changes in his 2012 PowerPoint presentation,⁴⁶ and to disclose the five failed flared crash tests that Harman claimed deceived the government.⁴⁷ Harman argues that Trinity's "wrongful intent" is "evidenced by [its] own actions to conceal its fraud."

As with falsity, this question is far closer than Harman paints it. The email that serves as Harman's evidence of a profit motive also states that "we'll [sic] could get a better ET" and lists potential improvements as a result of the change. Moreover, Harman's profit motive argument is emptied of force in

⁴⁵ Q. Okay. Now, isn't it true, sir, that in order for Trinity to get approval for a modification of a product that Trinity must present the proposed change to the FHWA and then perform the tests required by the FHWA and then to truthfully and accurately report the results of the test; isn't that true, sir?

A. I believe that to be true, yes.

Q. And you did not do that in 2005, is that not true, sir?

A. Mistakenly, yes.

Q. Okay. And isn't it also true that it is the FHWA and only the FHWA that makes the decision whether a test should be done and what that test should be; isn't that also correct, sir?

A. That is correct.

Q. In fact, the FHWA specifically requires that, doesn't it?

A. Yes, it does.

...

Q. Now, it's true, sir, is it not, that the FHWA has made it very clear that if you put a product on the road and you get approval, that you must – you must disclose or certify that the product that you've – you're selling has not changed *in any significant degree*; isn't that correct, sir?

A. It is correct.

(emphasis added).

⁴⁶ Trinity's president testified that he did not recall discussing other changes and that the "conversation was focused on the 5- to 4-inch channel."

⁴⁷ Harman focused on the five failed crash tests in response to the government's eve-of-trial approval letter, making them relevant to the materiality issue, as we will explain.

No. 15-41172

context, where the “profit” would be only \$50,000 a year, less than one-tenth of one percent of Trinity’s gross profit. Such a sum lends little force to an inference of fraudulent intent. It also ignores the fact that Trinity’s entire highway products business only accounted for approximately 7-15% of Trinity’s revenue between 2006 and 2010.⁴⁸ Finally, Harman’s interpretation overlooks Trinity’s plan to confer with TTI about the changes. In his email, Smith expressed a willingness to “consider some pendulum or sled testing, if that’s what we need to convince TTI that we should roll this out.” Further, Smith stated that the change could be made with no announcement “[i]f TTI agrees.” There is no suggestion that these contemporaneous statements were untrue, and they indicate that Trinity planned to seek TTI’s engineering judgment on the changes before rolling out the modified ET-Plus head. And, more to the point, the evidence shows that Trinity did so. Indeed, there is evidence that TTI did exercise the “good engineering judgment” which Trinity sought and upon which it relied. That evidence was challenged only by counsel’s sometimes misleading assertions and cross-examination.⁴⁹

Finally, as mentioned, Trinity asserts that it transmitted a detailed drawing of the 2005 changes to TTI, which it intended to be included with other data in the crash test report submitted to FHWA. Trinity argues that TTI’s omission of the drawing was inadvertent, and its transmittal to TTI cuts against Harman’s claim that they intentionally hid the changes from the

⁴⁸ In investor presentations filed with the SEC, Trinity allocates its revenue across five different market groups, including the Construction Products Group (CPG), which comprises highway products, concrete & aggregates, and other. Trinity reported that the CPG was responsible for 18-27% of the company’s outside revenue from 2006 to 2010. Of that revenue, between 34-53% came from highway products (including highway guardrails and end terminals).

⁴⁹ For example, Harman’s counsel referred to Trinity as “TI,” for which he was admonished by the court due to concerns about confusing Trinity and TTI.

No. 15-41172

FHWA. Harman argues that despite this testimony, because he was unable to find a copy of the drawing, the jury was free to conclude that it did not exist.

There is a strong argument that a reasonable jury could not have found that Trinity, acting in reliance on TTI, possessed the requisite scienter in certifying compliance with Report 350, particularly in light of the Report 350's ambiguity. We need not make that decision today, for this judgment cannot stand for an even more compelling reason.

C.

Trinity argues that, in light of FHWA's express rejection of Harman's claim and continued reimbursement of state purchases of the ET-Plus, Harman has failed to carry his burden on materiality. Materiality under the FCA has been a topic of increasing scrutiny since the Supreme Court's decision in *Escobar*.⁵⁰ There, Justice Thomas, writing for a unanimous court, explained that "[t]he materiality standard is demanding" and "cannot be found where noncompliance is minor or insubstantial."⁵¹ In evaluating whether a misstatement is material, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive."⁵² Most importantly for this case:

[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.⁵³

⁵⁰ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

⁵¹ *Id.* at 2003.

⁵² *Id.*

⁵³ *Id.* at 2003-04.

No. 15-41172

Our approach to materiality, as stated in *Longhi*, is that “the FCA requires proof only that the defendant’s false statements ‘could have’ influenced the government’s pay decision or had the ‘potential’ to influence the government’s decision, not that the false statements actually did so,”⁵⁴ the so-called “natural tendency test.”⁵⁵ The Supreme Court approved this standard in *Escobar*, writing that “the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,”⁵⁶ and “look[s] to the effect on the likely *or actual* behavior of the recipient of the alleged misrepresentation.”⁵⁷ Here, FHWA insists that the 2005 changes did not affect the decision to purchase the end terminals either in the past or the future. Instead, the agency’s June 17, 2014 memorandum establishes that despite the modifications, the modified ET-Plus “became eligible [in 2005] and continues to be eligible].”

Our sister circuits offer guidance on the impact of the government’s continued payment. On remand, the First Circuit in *Escobar* applied “the holistic approach to materiality laid out by the Supreme Court”⁵⁸ in determining that the relator had met its burden on materiality, holding that, while a decision to pay in full despite actual knowledge that requirements were violated is very strong evidence against the materiality of those requirements, no single element is dispositive.⁵⁹ Unlike in the case we decide today, the court found no evidence that the relevant government agency had actual knowledge

⁵⁴ *United States ex rel. Longhi v. United States*, 575 F.3d 458, 469 (5th Cir. 2009).

⁵⁵ *Id.* at 470 (citing *United States v. Bourseau*, 531 F.3d 1159, 1171 (9th Cir. 2008)).

⁵⁶ *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted).

⁵⁷ *Id.* (internal quotation marks omitted) (emphasis added).

⁵⁸ *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110 (1st Cir. 2016).

⁵⁹ *Id.*

No. 15-41172

of any violations when it decided to pay the claims.⁶⁰ The court did not decide whether the government's actual knowledge alone disproves materiality.

A month later, in a case involving an alleged fraud on the Food and Drug Administration ("FDA"), the First Circuit affirmed dismissal under Rule 12(b)(6), writing that "[t]he fact that [the Centers for Medicare and Medicaid Services] [have] not denied reimbursement for [the device] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges."⁶¹ The court then turned from materiality to causation, emphasizing that the FDA did not withdraw its approval of the device in the six years following the relator's allegations and expressing its fear that allowing the FCA claims to go forward "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 be withdrawn from the market even when the FDA itself sees no reason to do so."⁶² While the court was addressing the causation element, given the conceptual juncture points of materiality and causation, its cautions remain forceful in the materiality context: "[t]he FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings."⁶³

In *Sanford-Brown*,⁶⁴ the Seventh Circuit affirmed dismissal of an FCA claim, finding a failure to establish the element of materiality where "the subsidizing agency and other federal agencies in this case 'have already

⁶⁰ The court noted that "Relator's Second Amended Complaint only cites reimbursements paid up to 'the filing of this litigation' on July 1, 2011. It would appear that [Massachusetts' Department of Public Health] did not conclusively discover the extent of the violations until March 2012, well after the commencement of the litigation." *Id.* at 112.

⁶¹ *D'Agnostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016).

No. 15-41172

examined [the for-profit higher education enterprise] multiple times over and concluded that neither administrative penalties nor termination was warranted.”⁶⁵

Even before *Escobar* hammered home the “rigorous” nature of materiality, the Seventh Circuit rejected an FCA claim where “[t]he government learned of [the] plaintiffs’ concerns, thoroughly investigated them, and determined that they were meritless.”⁶⁶ In *Marshall*, two relators brought an FCA suit against a military contractor, asserting that the company did not comply with its own specifications when manufacturing a part used in military helicopters.⁶⁷ The relators had reported their concerns to two government agents, one of whom then conducted an investigation into the manufacturing process.⁶⁸ At one point in the investigation, one of the defendant’s employees made a false statement about the manufacturing process, though the investigator noted that he was not misled by the statement and “even if the government was misled . . . , it has since been made aware of [defendant’s] actual practices yet continues to buy and use the [product].”⁶⁹ In the face of this evidence, the court found that “the government’s actual conduct suggests that the allegedly false statements were immaterial” and affirmed the district court’s finding of immateriality.⁷⁰

In *Kelly*,⁷¹ the Ninth Circuit addressed materiality under the FCA in connection with a government contractor’s internal accounting procedures.⁷²

⁶⁵ *Id.* (quoting *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 712 (7th Cir. 2015)).

⁶⁶ *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 563 (7th Cir. 2015).

⁶⁷ *Id.* at 558.

⁶⁸ *Id.* at 561.

⁶⁹ *Id.* at 561, 564

⁷⁰ *Id.* at 563-64.

⁷¹ *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017).

⁷² *Id.* at 328-29.

No. 15-41172

Relator Kelly, an analyst at Serco, “informed [the Department of Homeland Security] that Serco’s monthly cost reports were unreliable because they tracked costs manually and with a single charge code in violation of the guidelines” and “that Serco was falsifying its monthly reports to make its actual costs match the expected budget for the AWS Project.”⁷³ In affirming summary judgment for Serco, the court held that “[g]iven the demanding standard required for materiality under the FCA, the government’s acceptance of Serco’s reports despite their non-compliance with [the relevant guidelines], and the government’s payment of Serco’s public vouchers for its work . . . we conclude that no reasonable jury could return a verdict for Kelly on his implied false certification claim.”⁷⁴

In *McBride*,⁷⁵ a military morale, welfare, and recreation vendor inflated soldier headcount data and, as a result, received an outsized fee.⁷⁶ The district court granted summary judgment for the vendor, and the D.C. Circuit affirmed, in part because:

[W]e have the benefit of hindsight and should not ignore what actually occurred: the [Defense Contract Audit Agency] investigated [the relator’s] allegations and did not disallow any charged costs. In fact, [the vendor] continued to receive an award fee for exceptional performance . . . even after the Government learned of the allegations. This is “very strong evidence” that the requirements allegedly violated by the maintenance of inflated headcounts are not material.⁷⁷

In *Petratos*,⁷⁸ the relator alleged fraud on the FDA involving off-label uses of the drug Avastin and disclosed the alleged fraud to the relevant federal

⁷³ *Id.* at 329.

⁷⁴ *Id.* at 334.

⁷⁵ *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017).

⁷⁶ *Id.* at 1029.

⁷⁷ *Id.* at 1034 (citing *Escobar*, 136 S. Ct. at 2003).

⁷⁸ *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017).

No. 15-41172

agency.⁷⁹ In finding that it was not material to a payment decision, the court explained that:

Since that time, the FDA has not merely continued its approval of Avastin for the at-risk populations that Petratos claims are adversely affected by the undisclosed data, but has added three more approved indications for the drug. Nor did the FDA initiate proceedings to enforce its adverse-event reporting rules or require Genentech to change Avastin's FDA label, as Petratos claims may occur. And in those six years, the Department of Justice has taken no action against Genentech and declined to intervene in this suit.⁸⁰

The court noted that, “[i]n holding that [the relator] did not sufficiently plead materiality, we now join the many other federal courts that have recognized the heightened materiality standard after [*Escobar*].”⁸¹

The lesson we draw from these well-considered opinions is that, though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality. Notably, these cases do not fully address the gravity and clarity of the government's decision here. This system was installed throughout the United States, and the government's rejection of Harman's assertions, if in error, risked the lives on our nation's highways, not just undue expense. Where violations of the “certain requirements” described by *Escobar* involve potential for horrific loss of life and limb, the government has strong incentives to reject nonconforming products, and *Escobar*'s cautions have particular bite when deployed to decisions as here. Further, this case is not about inferring governmental approval from continued payment. Here, the government has never retracted its explicit approval, instead stating that an

⁷⁹ *Id.*

⁸⁰ *Id.* (emphasis omitted).

⁸¹ *Id.* at 492.

No. 15-41172

“unbroken chain of eligibility” has existed since 2005.

That said, there are and must be boundaries to government tolerance of a supplier’s failure to abide by its rules. A recent Ninth Circuit opinion offers guidance. In *Campie*,⁸² the Ninth Circuit reversed dismissal under Rule 12(b)(6) for failure to state a claim, holding that questions of materiality remained even where the FDA had continued to pay for the drug. There, the relator alleged that Gilead utilized an unapproved vendor in China for a critical component of its HIV drugs for at least two years before the FDA approved the vendor.⁸³ On appeal, Gilead argued that the government’s continued payment for the drugs after revelation of the alleged FDA violations demonstrated that “those violations were not material to its payment decision.”⁸⁴ The court rejected that argument at the pleading stage, finding that: (1) questions remained as to whether the approval by the FDA was itself procured by fraud; (2) there existed other potential reasons for continued approval that prevent judgment for the defendant on 12(b)(6); and (3) the continued payment came after the alleged noncompliance had terminated and “the government’s decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite noncompliance.”⁸⁵ The court also noted that as the parties dispute exactly what and when the government knew, calling into question its actual knowledge, the relator had “sufficiently plead[ed] materiality at this stage of the case.”⁸⁶

Trinity argues that “[w]hen the government learns of the alleged falsity, evaluates the relator’s allegations, and then formally approves the product, courts have uniformly held that there is no ‘material’ false statement.” Trinity

⁸² *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017).

⁸³ *Id.* at 895-96.

⁸⁴ *Id.* at 906.

⁸⁵ *Id.*

⁸⁶ *Id.* at 906-07.

No. 15-41172

also argues that the decision to continue approving and purchasing the product was not made by a low-level bureaucrat, but rather by FHWA itself, and thus has special force. Additionally, Trinity directs us to DOJ’s evaluation of the claim, contained in its response to Harman’s *Touhy* request, rejecting the request because the June 17, 2014 memorandum “addresses all of the issues raised by the parties . . . DOT believes that this should obviate the need for any sworn testimony from any government employees.” Because Harman’s claims were rejected by FHWA in an official memorandum, and because FHWA continues to pay for the ET-Plus to this day, Trinity argues that Harman has failed to carry his burden in establishing that any false statement was material to the government’s payment decision.

Harman counters that the post-revelation actions of the government are not determinative in an FCA action, even post-*Escobar*, and that the standard for materiality is holistic and no single element is dispositive. Harman further argues that the relevant decision makers—state departments of transportation who actually purchased the ET-Plus based on the false statements of compliance with Report 350—have either outright banned purchase or “have all but stopped buying the ET-Plus” in light of the trial verdict, which Harman argues cuts strongly in favor of a finding of materiality.

While we agree with our sister circuits that no single factor is outcome determinative, the “very strong evidence” here of FHWA’s continued payment remains un rebutted. The concerns of the several states in response to the verdict do no work here. The very inquiry is question-begging—the initial reticence of some state departments of transportation to purchase the ET-Plus units arose *after* the verdict and its widespread publicity. Such caution is understandable. Of course, unexplained information about the verdict alone would be material to decision makers. Recall that, responsive to those

No. 15-41172

concerns, the federal government itself halted sale after the verdict to await independent testing without ever retreating from its decision to continue reimbursing the ET-Plus system. Moreover, eleven states (including states which initially suspended use of the ET-Plus after trial) filed an amicus brief in support of Trinity in this action. Additionally, Harman filed nine additional *qui tam* lawsuits under state FCAs; of the nine states involved, all but one declined to intervene in the action.

Confronted with the reality that the government was aware of all the charges of noncompliance with Report 350 when it wrote its June 2014 memorandum, Harman argued at trial that the memorandum itself was procured by fraud. Specifically, Harman relied on the fact that Trinity failed to disclose all of the changes to the ET-Plus to FHWA, both in 2005 and in subsequent conversations with FHWA, and that Trinity deceived the government by concealing five failed flared crash tests. In sum, Harman contends that the jury had evidence before it that Trinity concealed changes to the ET-Plus both in 2005 and when called to account in 2012, and that concealment—when combined with other evidence in the record of the purported failures of the ET-Plus system on the nation’s highway and in flared crash tests—was sufficient to undercut FHWA’s 2014 position.

While FHWA’s decision to continue reimbursing ET-Plus units would be undermined if, as Harman alleges, FHWA acted unaware of the facts claimed to be fraud, undisputed evidence in the record does not bear that out. As we will explain, FHWA knew about changes to the guide channel width and attendant fabrication changes when it expressed its continued approval of the ET-Plus system. The memorandum stated FHWA’s position that even though Trinity “inadvertently omitted” information about the 2005 changes, “the ET-Plus w-beam guardrail end terminal became eligible on [September 2, 2005]

No. 15-41172

and continues to be eligible for Federal-aid reimbursement.” In fact, Harman’s own disclosures ensured that FHWA issued its June 17, 2014 memorandum with knowledge of the narrowed guide channel and related fabrication changes.

On arrival of the June 17 memorandum, failure to disclose five failed crash tests became a centerpiece of the trial, as Harman’s counsel reached for any facts that the government did not know when it sent the June memorandum and responded to the *Touhy* request.⁸⁷ He injected these failed tests countless times throughout the trial, starting with a reference during voir dire. The tests came up again in opening argument, where Harman’s counsel stated explicitly that FHWA’s 2014 approval memorandum was “based on critically withheld information, such as those five failures.” Harman’s counsel then told the jury:

[T]his fraud has gone over a period of about almost 10 years, and I’ve just barely touched the evidence, but I want you to know that you’re the first people in the United States of America that will get to hear the whole story. The Federal Highway Administration has not heard it. No one has heard it.

Harman’s counsel grilled his expert Dr. Coon, TTI’s Dr. Bligh, and Harman himself—all about tests that cast no light on the ET-Plus’ performance in the use for which it was approved. Counsel returned to the five failed tests during closing. Once again pointing out that the jury “are the very first people in America to see those five failed tests . . . before the FHWA even heard about them.” He then told jurors that Trinity ought to answer some questions, including why they did not tell FHWA about the five failed tests.⁸⁸

⁸⁷ The district court excluded evidence of the five failed tests in the first trial, as it did the photographs of various automobile encounters with guardrails. However, the district court reversed course in the second trial.

⁸⁸ Harman’s counsel continued: “They owe you an answer for that besides just waving their arms and saying it was experimental.”

No. 15-41172

But these “five failed tests” were actually of a distinct, experimental system—not the type of ET-Plus system on American roadways. Thus, this evidence does not in any way go to the government’s approval of the ET-Plus for its intended use on a tangent system. There was no obligation for Trinity to disclose and no evidence that the information was hidden from FHWA.

Remarkably, Harman’s argument is not that the five failed flared crash tests go to the fraud on which his claim is based—whether the ET-Plus was Report 350 compliant as Trinity certified. Rather, Harman argues that Trinity’s nondisclosure of those failures was a separate fraud, and thus the government’s continued approval of the modified ET-Plus was “procured by fraud.” But, as Harman’s expert Dr. Coon admitted at trial, the flared ET-Plus system was never commercialized or even submitted to FHWA for approval. Dr. Bligh explained that the five failed crash tests were part of an experiment as part of its ongoing research of new flared guardrail systems. Dr. Bligh explained that, because the system was flared rather than tangent—parallel—to the roadway, it posed distinct difficulties:

The commercial ET-Plus system is what we call a tangent terminal system. . . . [W]hen we’re developing a flared system, it’s a completely different geometry and configuration. And, in fact, in that particular situation, you would have the terminal significantly flaring away from the roadway. So it’s quite a difference in the configuration.

The results of those tests were that TTI determined that the ET-Plus head would not correct the weaknesses of a flared configuration, and instructions were given to installers to that effect. At best, these flared tests were only determinant of the range of safety concerns treatable by the ET-Plus as modified. That it would not mitigate the hazards of a distinct system (for which no disclosure was required) is not evidence of its utility in an approved system. Tests of the experimental system had no bearing on the government’s

No. 15-41172

approval of the system that was in place and working. In unchallenged testimony, Dr. Bligh explained that, since the testing did not offer a solution, the project was abandoned and the flared system was never submitted to FHWA for approval; that, in his experience at TTI, results of experimentation are not presented to FHWA; and that, although FHWA was aware that Trinity and TTI were searching for solutions to weaknesses of a distinct experimental system, FHWA never requested the results of those experiments, nor did they want them. Harman's counsel conflated the experimental flared system with the tangent system actually in use on American highways, creating the impression that the flared tests demonstrated something dangerous about the modified ET-Plus heads.⁸⁹ But returning the "five failed tests" to their context makes plain that the tests demonstrated no failure of the ET-Plus units but only showed an effort to mitigate the ongoing weaknesses of a distinct system—the flared system. Trinity and TTI did not submit a new system to FHWA for approval, they had no new system. Harman's reliance on these undisclosed failed tests as evidence of fraud was misplaced; they have no relevance here. The district was correct in excluding them in the first trial.

In sum, Harman's argument that FHWA's decision was procured by fraud because of the failure of Trinity and TTI to disclose the crash test failures

⁸⁹ This approach was most apparent in the examination of Dr. Bligh, where Harman's counsel asked the following while talking about the failed flared tests:

Q. How many times did you call the FHWA and say I've got these five failed tests on this prototype head, and I just wanted you to know what was happening? Did you do that?

A. No, we did not. We don't submit our R&D tests to FHWA.

Q. All right. Even when you've got a failure on a – on a product out in the highway and you hit it head-on just like you did in you test, you decided not to say anything about it, right?

A. No, sir. That is not a product that was on the highway. That was a research and development product for a flare terminal.

Q. Well, this head was on the highway, wasn't it?

A. The head is one component of a system.

No. 15-41172

of an experimental flared ET-Plus system is unavailing because: (1) those tests involved a different system than the tangent ET-Plus system that is at issue here; (2) FHWA does not require, and neither Trinity nor TTI have a history of disclosing, information regarding failed research and development experiments; and (3) FHWA was aware that Trinity and TTI were experimenting with a flared ET-Plus and did not request information on that project.⁹⁰

Reliance on these alleged omissions and misrepresentations was in error. Here, the relevant inquiry is not what Trinity disclosed, but what FHWA knew at the time it issued the June 17, 2014 memorandum, no matter the source. By that point, FHWA had seen Harman's extensive PowerPoint presentation, FHWA officials had taken measurements and photographed the ET-Plus head units that Harman had presented to them, and FHWA had access to the allegations made in Harman's complaint and reiterated in the *Touhy* request. Even if Trinity deliberately withheld information from FHWA, it does not mean that the government's decision that the ET-Plus remained eligible for reimbursement was the product of ignorance—Harman's PowerPoint presentation and the allegations in his FCA suit informed FHWA of the 2005 changes. And still FHWA paid because it was not persuaded by the allegations.

As we have explained, the government's position was clear before trial. By June 2014, FHWA had knowledge of all of Harman's allegations and still approved the ET-Plus. And, as the D.C. Circuit wrote in *McBride*, "we have the benefit of hindsight and should not ignore what actually occurred"⁹¹—given FHWA's unwavering position that the ET-Plus was and remains eligible for

⁹⁰ The False Claims Act does not contain an independent duty to disclose certain information. 31 U.S.C. § 3729. "There can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information." *United States ex rel. Berge v. Bd. of Trustees of Univ. of Ala.*, 104 F.3d 1453, 1461 (4th Cir. 1997).

⁹¹ *McBride*, 848 F.3d at 1034.

No. 15-41172

federal reimbursement, Trinity's alleged misstatements were not material to its payment decisions. The other evidence in the record, viewed most favorably to Harman, is insufficient to overcome this "very strong evidence."

This position was reaffirmed by extensive independent testing after trial that examined more than 1000 ET-Plus units across the country. After conducting crash tests of the ET-Plus with the 2005 changes, FHWA's determination that the ET-Plus is eligible for federal reimbursement has not changed to this day.⁹² While this post-trial evidence was not before the jury, the district court made use of it in denying post-trial relief to Trinity. This use was, unfortunately, selective. The district court treated the requests for post-trial testing as evidence that the government had insufficient information about the ET-Plus to determine its eligibility. In doing so, the court looked past the fact that the test results concluded that (1) the ET-Plus units tested after trial passed crash tests conducted pursuant to Report 350 criteria and (2) the ET-Plus units tested post trial were representative of those in service across the country. The district court's reliance on the post-verdict tests in its denial of a new trial was flawed in a more fundamental way. The verdict sent shock waves throughout the states. The testing responded to the concern provoked by the verdict. FHWA directed one outside testing facility to test the challenged system and a second to verify that the tested system was the same as systems installed throughout the United States, a conclusion that reaffirmed the government's view, one that never changed.

Finally, none of the factors that the Ninth Circuit found warranted caution in *Campie*⁹³ exist here. First, the record in this case leaves no question

⁹² The district court did not rely on the "five failed tests" in its post-verdict suggestion that the government was uncertain in its approval of the purchases, to its credit, and expressed concern pretrial over the late arriving assertion, efforts consistent with his able management of this litigation.

⁹³ *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017).

No. 15-41172

about “what the government knew and when.” Instead, the record demonstrates that FHWA continued to reimburse the ET-Plus units with full knowledge of Harman’s claims about the product’s purported deficiencies. Nor has Harman come forward with any evidence that FHWA’s decision was procured wrongfully—through collusion between Trinity and FHWA or some other form of corruption. Nothing in the record here supports an inference that FHWA’s approval was made to shield Trinity or FHWA itself from the consequences of past decisions. Nor has Trinity reformulated the ET-Plus to remove the 2005 changes. Rather, FHWA has not changed its position regarding the eligibility of the ET-Plus and still considers it eligible for reimbursement to this day, a weighty decision. Finally, it is plain that FHWA is no “captured agency.” The response of the Attorneys General of the several states and of the Justice Department itself make clear that the decision of the FHWA was made and adhered to with sensitivity to the interests of many levels of state and federal government.

VI.

Congress enacted the FCA to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy. The Act does so by aligning the interests of the government and that of the relator through a shared purse. That a relator seeks personal gain is embedded in the statute and should not, alone, cast doubt on his claims. That Harman was a one-time competitor of Trinity, with a past history of adversarial litigation, however, may raise an eyebrow. That his intended use for the proceeds from this litigation was to capitalize his failed businesses and fill the market void left by Trinity with a product sharing at least three of the “defects” he railed against at trial may give greater pause. But ultimately, the problems this case presents runs deeper.

No. 15-41172

The judgment before us falls far short of the FCA's true setting and fails to account for its congressional purpose in drawing upon private litigation to protect public coffers. The government has never been persuaded that it has been defrauded. It so advised Harman after his repeated meetings disclosing the changes in the product he says was wreaking havoc on America's highways, leaving him to file his own suit as was his statutory right. Following discovery, as he made his eve-of-trial *Touhy* request that the government produce officials to testify, the Department of Justice declined, once again sending the message that the government did not believe itself to be a victim of any fraud, a position from which it has not to this day retreated.

The force of this decision comes into focus as we bring to mind its stakes. The product here is of a class under constant development by dedicated engineering faculty and students at Texas A&M University in an ongoing effort to mitigate the risks on all the country's highways of leaving the road, at travel speed, into trees, creeks, and myriad other unyielding obstacles. At best these roadside barriers can only mitigate—they cannot erase the risks attending all unintended exits, nor can they assure safety at all speeds, angles, and weights. For example, even today, they are only required to be tested at collision speeds of 62 miles per hour. There have always been deadly accidents involving roadside barriers—an unfortunate reality of our automobile-centric culture.

The government has responded at every turn to Harman's challenge. In turning back his views and proofs, it balances the federal fisc, motorist safety, and other factors across the spectrum of myriad presentations to disclaim victim status. Such decision making is policy making, not the task of a seven-person jury—such a result confounds the premise of *qui tam* actions: that the government was the victim. The district court observed that to allow the government to forgive a completed fraud stands *qui tam* on its head.

No. 15-41172

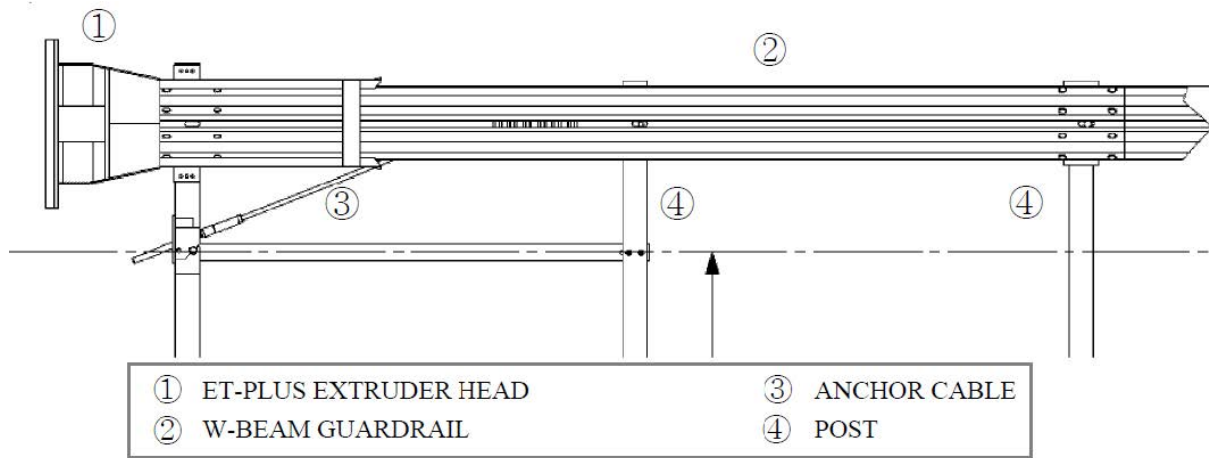
Respectfully, we must disagree with our able colleague who sits on the firing line. Rather, as we see it, it is the opposite.

It is charged that the accused product remains along nigh every highway in America, killing and maiming, but the government will not remove it. We can assume that this and contrary views are debatable, but we must accept that the choice among them lies beyond the reach of seven citizens of Marshall, Texas, able though they may be. As revered as is the jury in its resolution of historical fact, its determination of materiality cannot defy the contrary decision of the government, here said to be the victim, absent some reason to doubt the government's decision as genuine. For the demands of materiality adjust tensions between singular private interests and those of government and cabin the greed that fuels it. As the interests of the government and relator diverge, this congressionally created enlistment of private enforcement is increasingly ill served. When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all.

For the above reasons, we REVERSE and RENDER judgment as a matter of law for Trinity.

No. 15-41172

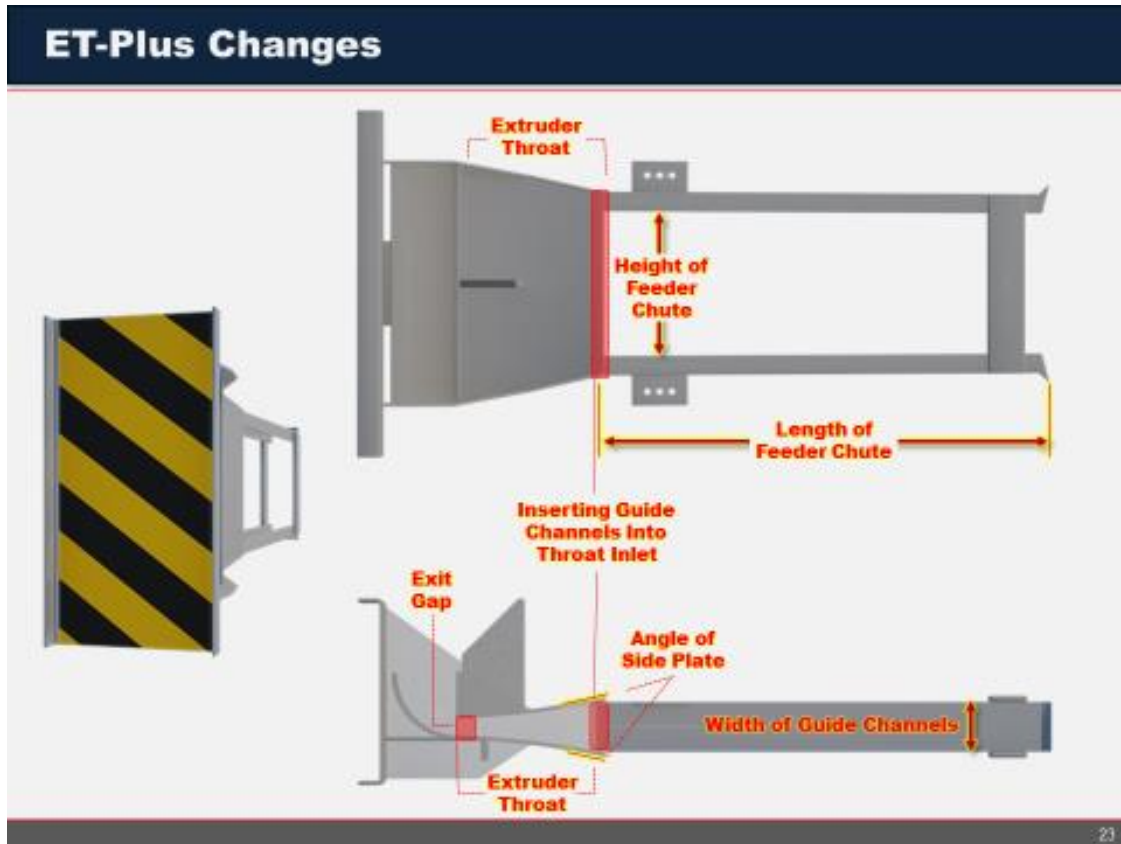
Appendix A



A diagram of the ET-Plus system prepared by TTI and Trinity.

No. 15-41172

Appendix B



A diagram prepared by Harman listing the purported changes to the ET-Plus terminal head in 2005.