

IN THE UNITED STATES COURT OF APPEALS  
FOR THE SEVENTH CIRCUIT

---

No. 23-2134

---

UNITED STATES, *et al.*, *ex rel.*, RONALD J. STRECK,  
*Plaintiff-Appellee, Cross-Appellant,*

v.

ELI LILLY AND COMPANY,  
*Defendant-Appellant, Cross-Appellee.*

---

On Appeal from the United States District Court  
for the Northern District of Illinois  
Case No. 1:14-cv-09412  
Hon. Harry D. Leinenweber

---

**BRIEF OF THE ANTI-FRAUD COALITION AS *AMICUS CURIAE*  
SUPPORTING AN AFFIRMANCE IN FAVOR OF PLAINTIFF-APPELLEE  
(FILED WITH CONSENT OF PARTIES)**

---

Jacklyn DeMar  
THE ANTI-FRAUD COALITION  
1220 19th Street, N.W., Suite 501  
Washington, DC 20036  
Tel: (202) 296-4826  
Fax: (202) 296-4838  
[jdemar@taf.org](mailto:jdemar@taf.org)

David J. Chizewer  
Roger A. Lewis  
Harleen Kaur  
GOLDBERG KOHN LTD.  
55 East Monroe Street, Suite 3300  
Chicago, Illinois 60603  
Tel: (312) 201-4000  
Fax: (312) 332-2196  
[david.chizewer@goldbergkohn.com](mailto:david.chizewer@goldbergkohn.com)  
[roger.lewis@goldbergkohn.com](mailto:roger.lewis@goldbergkohn.com)  
[harleen.kaur@goldbergkohn.com](mailto:harleen.kaur@goldbergkohn.com)

*Counsel for The Anti-Fraud Coalition as  
Amicus Curiae*

Appellate Court No: 23-2134

Short Caption: United States, et al., ex rel., Streck v. Eli Lilly and Company

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

**PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

The Anti-Fraud Coalition - Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Goldberg Kohn Ltd.

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ David J. Chizewer Date: 03/01/2024

Attorney's Printed Name: David J. Chizewer

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes  No

Address: Goldberg Kohn Ltd., 55 East Monroe Street, Suite 3300

Chicago, IL 60603

Phone Number: (312) 201-4000 Fax Number: (312) 332-2196

E-Mail Address: david.chizewer@goldbergkohn.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 23-2134

Short Caption: United States, et al., ex rel., Streck v. Eli Lilly and Company

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

**PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):  
The Anti-Fraud Coalition - Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:  
Goldberg Kohn Ltd.

(Note: Jacklyn DeMar, the undersigned, is employed directly by The Anti-Fraud Coalition)

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Jacklyn DeMar Date: 03/01/2024

Attorney's Printed Name: Jacklyn DeMar

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes  No

Address: 1220 19th Street, N.W., Suite 501

Washington, DC 20036

Phone Number: (202) 296-4826 Fax Number: (202) 296-4838

E-Mail Address: jdemar@taf.org

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 23-2134

Short Caption: United States, et al., ex rel., Streck v. Eli Lilly and Company

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

**PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):  
The Anti-Fraud Coalition - Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:  
Goldberg Kohn Ltd.

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Roger A. Lewis Date: 03/01/2024

Attorney's Printed Name: Roger A. Lewis

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes  No

Address: Goldberg Kohn Ltd., 55 East Monroe Street, Suite 3300

Chicago, IL 60603

Phone Number: (312) 201-4000 Fax Number: (312) 332-2196

E-Mail Address: roger.lewis@goldbergkohn.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 23-2134

Short Caption: United States, et al., ex rel., Streck v. Eli Lilly and Company

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):  
The Anti-Fraud Coalition - Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:  
Goldberg Kohn Ltd.

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Harleen Kaur Date: 03/01/2024

Attorney's Printed Name: Harleen Kaur

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes  No

Address: Goldberg Kohn Ltd., 55 East Monroe Street, Suite 3300

Chicago, IL 60603

Phone Number: (312) 201-4000 Fax Number: (312) 332-2196

E-Mail Address: harleen.kaur@goldbergkohn.com

**DISCLOSURE OF CORPORATE AFFILIATIONS  
AND FINANCIAL INTEREST**

Pursuant to Federal Rule of Appellate Procedure 26.1, The Anti-Fraud Coalition states that it is a corporation organized under Section 501(c)(3) of the Internal Revenue Code. It has no parent corporation and no stock owned by a publicly owned company. The Anti-Fraud Coalition represents no parties in this matter and has no pecuniary interest in its outcome. The Anti-Fraud Coalition, however, has an institutional interest in the effectiveness and correct interpretation of the federal False Claims Act.

## TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES .....	iii
STATEMENT OF INTEREST .....	1
INTRODUCTION .....	1
ARGUMENT .....	3
I. The Complexity Of A Regulatory Regime Does Not Warrant Leniency Towards The Regulated Party. ....	3
II. Telling The Government In Advance What You Are Doing Does Not Immunize A Defendant From FCA Liability. ....	7
A. Government Knowledge Is Not A Defense To FCA Liability. ....	7
B. A Jury Can Weigh The Extent To Which The Government’s Response To Information About Defendant’s Conduct Negates Scierter. ....	9
1. Defendants Must Clearly And Completely Describe The Challenged Conduct. ....	10
2. Defendants Must Make The Relevant Government Officials Aware Of The Challenged Conduct. ....	11
3. Defendants Must Know That The Government Approves Of The Challenged Conduct. ....	13
III. Courts Are Not Equipped To Determine The Reasonableness Of Parties Not Before Them. ....	14
A. A Single Court’s Pronouncement On What Is “Reasonable” Does Not Definitively Determine A Defendant’s Reasonableness. ....	15
B. Only The Trier of Fact Is Responsible For Weighing The Strength Of Evidence. ....	17
CONCLUSION .....	20

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

**TABLE OF AUTHORITIES**

	<u>Page</u>
<b>Cases</b>	
<i>Ali v. Hickman</i> , 584 F.3d 1174 (9th Cir. 2009) .....	16, 17
<i>Graham Cnty. Soil &amp; Water Conservation Dist. v. United States ex rel. Wilson</i> , 559 U.S. 280 (2010).....	8
<i>In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. &amp; Antitrust Litig.</i> , 44 F.4th 959 (10th Cir. 2022), cert. denied sub nom. <i>Sanofi-Aventis U. S., LLC v. Mylan, Inc.</i> , 143 S. Ct. 1748 (2023) .....	4
<i>Kisor v. Wilkie</i> , 139 S. Ct. 2400 (2019).....	5
<i>Korematsu v. United States</i> , 323 U.S. 214 (1944), abrogated by <i>Trump v. Hawaii</i> , 585 U.S. 667 (2018).....	16
<i>Marina Mercy Hosp. v. Harris</i> , 633 F.2d 1301 (9th Cir. 1980) .....	5, 6
<i>Ne. Hosp. Corp. v. Sebelius</i> , 657 F.3d 1 (D.C. Cir. 2011).....	5
<i>United States ex rel. Becker v. Westinghouse Savannah River Co.</i> , 305 F.3d 284 (4th Cir. 2002) .....	10, 11
<i>United States ex rel. Burlbaw v. Orenduff</i> , 548 F.3d 931 (10th Cir. 2008) .....	10, 11, 13
<i>United States ex rel. Butler v. Hughes Helicopters, Inc.</i> , 71 F.3d 321 (9th Cir. 1995) .....	11
<i>United States ex rel. Campie v. Gilead Scis., Inc.</i> , 862 F.3d 890 (9th Cir. 2017) .....	19

*United States ex rel. Cantekin v. Univ. of Pittsburgh*,  
192 F.3d 402 (3d Cir. 1999), *superseded by statute on other grounds* .....14

*United States ex rel. Cimino v. Int’l Bus. Machines Corp.*,  
3 F.4th 412 (D.C. Cir. 2021)..... 18, 19, 20

*United States ex rel. Costner v. URS Consultants, Inc.*,  
317 F.3d 883 (8th Cir. 2003) ..... 10, 11

*United States ex rel. Druding v. Care Alternatives*,  
81 F.4th 361 (3d Cir. 2023)..... 19, 20

*United States ex rel. Durchholz v. FKW Inc.*,  
189 F.3d 542 (7th Cir. 1999) ..... 9, 10, 11, 13

*United States ex rel. Feldman v. Van Gorp*,  
697 F.3d 78 (2d Cir. 2012) .....12

*United States ex rel. Foreman v. AECOM*,  
19 F.4th 85 (2d Cir. 2021), *cert. denied*, 142 S. Ct. 2679 (2022) .....19

*United States ex rel. Hagood v. Sonoma Cnty. Water Agency*,  
929 F.2d 1416 (9th Cir. 1991) ..... 10, 13

*United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*,  
985 F.2d 1148 (2d Cir. 1993) .....10

*United States ex rel. Lamers v. City of Green Bay*,  
168 F.3d 1013 (7th Cir. 1999) .....8

*United States ex rel. Oliver v. Parsons Co.*,  
195 F.3d 457 (9th Cir. 1999) .....5

*United States ex rel. Prose v. Molina Healthcare of Ill., Inc.*,  
17 F.4th 732 (7th Cir. 2021), *cert. denied sub nom. Molina Healthcare of Ill., Inc. v. Prose*, 143 S. Ct. 352 (2022) ..... 18, 19

*United States ex rel. Schutte v. SuperValu Inc.*,  
598 U.S. 739 (2023).....6

*United States ex rel. Spay v. CVS Caremark Corp.*,  
875 F.3d 746 (3d Cir. 2017) ..... 10, 13

*United States ex rel. Streck v. Allergan, Inc.*,  
746 F. App’x 101 (3d Cir. 2018)..... 14, 15

*United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*,  
34 F.4th 507 (6th Cir. 2022).....20

*United States ex rel. Wang v. FMC Corp.*,  
975 F.2d 1412 (9th Cir. 1992), *overruled on other grounds by*  
*United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d  
1121 (9th Cir. 2015) ..... 11, 13

*United States ex rel. Wisconsin v. Dean*,  
729 F.2d 1100 (7th Cir. 1984) .....7, 8

*United States v. Batson*,  
706 F.2d 657 (5th Cir. 1983) .....6

*United States v. Rogan*,  
517 F.3d 449 (7th Cir. 2008) .....12

*United States v. Southland Mgmt. Corp.*,  
326 F.3d 669 (5th Cir. 2003) .....10

*Universal Health Services, Inc. v. United States ex rel. Escobar*,  
579 U.S. 176 (2016)..... 17, 18

*Washington v. Smith*,  
219 F.3d 620 (7th Cir. 2000) .....16

**Statutes**

28 U.S.C. § 2254(d) .....16

31 U.S.C. § 232(C).....7

31 U.S.C. § 3730(e)(2).....9

31 U.S.C. § 3730(e)(4).....8

31 U.S.C. § 3730(e)(4)(B) .....8

False Claims Act, ch. 377, 57 Stat. 608 (1943) .....7

**Other Authorities**

Lisa D. Ellis, *The Need to Treat the Ailing U.S. Pharmaceutical Pricing System*, Harvard T.H. Chan School of Public Health (Mar. 14, 2019) .....4

Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer By Any Other Name Does Not Sound as Sweet*, 45 Idaho L. Rev. 41 (2008).....12

Press Release, U.S. Dep’t of Justice, *False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023* (Feb. 22, 2024) .....1, 2

**Rules**

Federal Rule of Appellate Procedure 29(a)(2).....1

Federal Rule of Appellate Procedure 29(a)(4)(E).....1

## STATEMENT OF INTEREST

*Amicus curiae* The Anti-Fraud Coalition (“TAF Coalition”) is a nonprofit public interest organization dedicated to combating fraud against the government and protecting public resources through public-private partnerships. TAF Coalition is committed to preserving effective anti-fraud legislation at the federal and state levels. The organization has worked to publicize the *qui tam* provisions of the False Claims Act (“FCA”), regularly participates in litigation as *amicus curiae*, and has provided testimony to Congress about ways to improve the FCA. TAF Coalition is supported by whistleblowers and their counsel, by membership dues and fees, and by private donations. TAF Coalition is the 501(c)(3) arm of Taxpayers Against Fraud, which was founded in 1986.<sup>1</sup>

## INTRODUCTION

The Department of Justice, relators and TAF Coalition—the *amicus* party here—often extoll the FCA as the government’s most important and potent enforcement tool for combatting fraud. The \$2.68 billions of dollars in recovery in 2023 alone prove that point. Press Release, U.S. Dep’t of Justice, *False Claims Act*

---

<sup>1</sup> Under Federal Rule of Appellate Procedure 29(a)(2), *Amicus Curiae* files this brief with the consent of the parties. In addition, pursuant to Rule 29(a)(4)(E), *Amicus Curiae* represents that no party’s counsel has authored this brief in whole or in part; no party or party’s counsel has contributed money that was intended to fund preparing or submitting the brief; and no person other than *Amicus Curiae*, its members, or its counsel has contributed money that was intended to fund preparing or submitting the brief.

*Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023* (Feb. 22, 2024), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023>. But the FCA does much more than rectify existing fraud. It also sets expectations for how people working for government contractors should act when performing our country's business. The FCA gives courts and juries the opportunity to flesh out concepts of good faith and fair dealing, and to demarcate the differences between honest mistakes and manipulative behavior.

The issue in this appeal is not whether defendant Eli Lilly paid the proper amount of drug price rebates to federal and state Medicaid programs. Apparently, it did not. Instead, the central question is whether the defendant sincerely and reasonably believed it was paying the right amount. According to the defendant, its so-called "reasonable" behavior resolves in its favor each element of FCA liability: falsity, materiality and scienter. Regardless of which element is being addressed, FCA cases often turn on the question of what a defendant believed at the time it submitted a claim to the government. Thus, it is important to explore how courts should resolve this issue generally.

Evaluating the integrity and credibility behind a defendant's explanation of its behavior is typically the job of the trier of fact. Here, the jury performed that function, and rendered a verdict for the Relator. But the defendant wants this Court

to take this function away from the jury based largely on a set of common defense talking points:

1. The extreme complexity of the regulatory regime at issue;
2. Disclosures that the defendant made to the government contemporaneously with its conduct;
3. The government's response (or non-response) to those disclosures; and
4. Another court's purported endorsement of the "reasonableness" of the conduct at issue.

This *amicus* brief provides guidance as to how to evaluate these four common "defenses" so as to enforce the FCA in the manner, and only in the manner, prescribed and intended.

## ARGUMENT

### **I. The Complexity Of A Regulatory Regime Does Not Warrant Leniency Towards The Regulated Party.**

Defendants in FCA cases often complain about: (1) complicated regulatory schemes that govern their conduct; (2) the lack of clear guidance; and (3) the harsh treble damages and penalties they believe are imposed on reasonable efforts to navigate a maze of rules.

The enforcement of the FCA is not so inflexible that it cannot account for such concerns in an appropriate case. Courts and juries can tell the difference between

honest attempts at regulatory compliance and manipulative interpretation of rules only to avoid negative financial consequences.

No one doing business with the government should be surprised by a complicated regulatory environment. Indeed, it is often the complicated nature of business itself that drives the need for complicated regulatory schemes. Drug companies, of their own volition, invent sophisticated pricing models to take advantage of stratified demand in the marketplace, and wide variance in ability to pay for the products. Lisa D. Ellis, *The Need to Treat the Ailing U.S. Pharmaceutical Pricing System*, Harvard T.H. Chan School of Public Health (Mar. 14, 2019), <https://www.hsph.harvard.edu/ecpe/united-states-pharmaceutical-pricing/>.

(discussing the complexity of drug pricing); *see also In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 965 (10th Cir. 2022), *cert. denied sub nom. Sanofi-Aventis U. S., LLC v. Mylan, Inc.*, 143 S. Ct. 1748 (2023) (same). Companies with the sophistication to create and implement these complicated pricing schemes should not be calling for leniency in application of the resulting regulations (*see* No. 23-2134, ECF No. 37 (“Eli Lilly Br.”) at 1, 2, 10, 11). Leniency in the face of regulatory complexity would undermine enforcement under a plethora of complex government regulations in industries as varied as health care, telecommunications, energy, and commodity pricing, just to name a few.

Agency statutes and regulations can be tedious to comprehend because of their intricacies. Yet, a seemingly impenetrable text at first blush should not deter contractors from digging deeper into the meaning. The Supreme Court has recently noted that while there may be rules that lead to confusion or appear overly complex, such rules can be dissected and comprehended. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (“Agency regulations can sometimes make the eyes glaze over. But hard interpretive conundrums, even relating to complex rules, can often be solved.”). And, certainly, a complex regulatory regime does not mean that every provision in the regulations is ambiguous. *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 24 (D.C. Cir. 2011) (Kavanaugh, J., concurring) (“Complexity in the code as a whole does not mean ambiguity in a specific provision. . . . [T]he fact that it takes a while to figure out the meaning of a specific statutory provision based on its text and context is not the same as ambiguity.”). If courts are required to undertake a searching examination of complex regulations, surely the companies deriving pecuniary benefits from a regulatory regime should conduct as thorough an inquiry.

Consistent with *Kisor*, courts typically reject the “complexity” excuse. *See, e.g., United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) (finding defendant subject to FCA liability under federal Cost Accounting Standards, which were “unquestionably technical and complex” regulations); *Marina Mercy Hosp. v. Harris*, 633 F.2d 1301, 1304 (9th Cir. 1980) (enforcing

Medicare regulation despite complexity of cost provisions); *United States v. Batson*, 706 F.2d 657, 683 (5th Cir. 1983) (enforcing cotton pricing regulations despite complexity). Under Eli Lilly’s argument, there would be little to stop bad actors—regardless of their resources and sophistication—from using intricate government rules as an excuse to overbill or underpay the government.

Like Eli Lilly, the defendants in *SuperValu* faced regulations regarding the calculations of drug prices. The Supreme Court did not buy defendant’s complexity excuse. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 753 (2023) (“Although the terms, in isolation, may have been somewhat ambiguous, that ambiguity does not preclude respondents from having learned their correct meaning—or, at least, becoming aware of a substantial likelihood of the terms’ correct meaning.”). Sophisticated defendants like Eli Lilly—with operations in over a dozen countries and tens of billions in revenue—have a responsibility to understand the intended meaning of a regulatory provision, regardless of its contextual complexity, and act in alignment with the broader purpose of that regulation.

Courts should expect a truly and legitimately confused contractor to explain why its interpretation of a regulation is one which serves the purpose of the regulatory scheme and provides at least some intended benefit to the government or the protected parties. When a contractor’s interpretation conveniently provides a

financial benefit to itself, but offers none of the intended regulatory protection, a jury can decide whether the contractor knew or should have known that its interpretation was wrong.

## **II. Telling The Government In Advance What You Are Doing Does Not Immunize A Defendant From FCA Liability.**

The government's knowledge of a defendant's conduct is not, by itself, a defense to FCA liability. Instead, when the government is silent after receiving notification of the defendant's conduct, defendants argue that such silence means either that the government approves of the conduct, or that it must not matter. Of course, the strength of a defendant's argument depends on the specificity of the notification, the clarity of the government's approval, and/or the sensibility in concluding the conduct does not matter. To the extent doubt exists as to any of these issues, the jury must decide. That is precisely what happened in this case.

### **A. Government Knowledge Is Not A Defense To FCA Liability.**

In 1943, the FCA was amended to bar *qui tam* actions that were “based upon evidence or information in the possession of the United States, or any agency, officer or employee thereof, at the time such suit was brought . . . .” FCA, ch. 377, 57 Stat. 608, 609 (1943) (codified at 31 U.S.C. § 232(C)). *Qui tam* actions were precluded even if the information the government had in its possession had been provided to it by the relator. *See, e.g., United States ex rel. Wisconsin v. Dean*, 729 F.2d 1100, 1103-04 (7th Cir. 1984) (holding that Wisconsin's provision of information to the

federal government as required by law barred it from subsequently pursuing a *qui tam* action). However, the so-called “government knowledge bar” proved too limiting, precisely for reasons that Eli Lilly tries to revitalize in its appeal: that an FCA case could be dismissed because someone in the government possesses some relevant information—even when the relevant government officials were not aware of the information and/or the information indicated that the defendant was committing fraud. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294 (2010) (“In the years that followed the 1943 amendment, the volume and efficacy of *qui tam* litigation dwindled.”).

Partly in response to this unwanted result, Congress again amended the FCA in 1986 to replace the “government knowledge bar” with the current “public disclosure bar.” *See United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1016 (7th Cir. 1999) (“After *Dean*, Congress decided once again that the FCA *qui tam* system was out of whack and amended the jurisdictional requirements . . . .”). The public disclosure bar, 31 U.S.C. § 3730(e)(4), stops an FCA case only if the disclosure travels beyond even relevant officials, to the public at large. Even then, a *qui tam* case based on public information may still proceed if the person bringing the case is an “original source” of the information. 31 U.S.C. § 3730(e)(4)(B). Congress retained the government knowledge bar only for cases brought against members of Congress, the judiciary, and senior government

officials. *See* 31 U.S.C. § 3730(e)(2). Thus, there is no room to assert that “government knowledge” alone bars an FCA suit.

**B. A Jury Can Weigh The Extent To Which The Government’s Response To Information About Defendant’s Conduct Negates Scienter.**

Even after elimination of the “government knowledge bar,” FCA defendants continue to make hay of the government’s silence or acquiescence in the face of some notification about a defendant’s conduct. Defendants want to infer from the government’s non-reaction that it approved defendant’s conduct, and that any claims submitted were not “knowingly” false. However, this “government knowledge inference” does not automatically exempt sophisticated companies from FCA liability. Defendants cannot simply (1) write letters that do not clearly and completely describe the relevant conduct, (2) send these letters to the non-authoritative government employees, and then (3) assume that the government’s lack of clarification or correction is tantamount to explicit approval. *See* *Eli Lilly Br.* at 59-62, 70-72.

Instead, to assess the government knowledge inference, the court examines whether the defendant was forthcoming with the relevant government officials, whether those relevant officials actually approved the defendant’s conduct, and whether the defendant was aware of the approval at the time it submitted the claim. *See United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999)

(“If the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim.”); *accord United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 758 (3d Cir. 2017); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 951-52 (10th Cir. 2008); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 683-84 (5th Cir. 2003) (Jones, J. concurring); *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993); *United States ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991).

**1. Defendants Must Clearly And Completely Describe The Challenged Conduct.**

Courts and juries can tell the difference between a sincere request for guidance and a contrived set-up for a later excuse when one is caught trying to feign, and then exploit, confusion. Unless the defendant has made a *full* disclosure of all relevant information, the government knowledge inference cannot serve to demonstrate a defendant’s lack of scienter. The inference does not apply where the government did not prescribe and was not aware of the relevant conduct. *See, e.g., Durcholz*, 189 F.3d at 545 (defendants were following government’s explicit directions); *Burlbaw*, 548 F.3d at 953-54 (defendant complied with the government’s instructions); *United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883,

887-88 (8th Cir. 2003) (defendant worked closely with EPA); *Becker*, 305 F.3d at 289 (government directed defendant to take the steps it did); *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995) (“the only reasonable conclusion a jury could draw from the evidence was that [defendant] and the Army had so completely cooperated and shared all information . . . that [defendant] did not ‘knowingly’ submit false claims . . . .”); *United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (government and defendant working together to solve a problem), *overruled on other grounds by United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121 (9th Cir. 2015).

## **2. Defendants Must Make The Relevant Government Officials Aware Of The Challenged Conduct.**

Further, the government knowledge inference cannot apply unless a defendant discloses its conduct to the *relevant* government officials. *See Durholz*, 189 F.3d at 545 (defendant disclosed conduct to government officials with authority to sign contract before defendant engaged in conduct); *Burlbaw*, 548 F.3d at 953-54 (“the undisputed evidence in the record indicates that NMSU was completely forthcoming with the DoE—the very agency on whose analysis the DoD uncritically relied. . . . [I]t is undisputed that the DoE had accurate data from which to ‘verify’ whether NMSU met the definition of a ‘minority institution’ . . . .”).

Where the defendant provides its information to government officials with no role in deciding whether to approve or deny the claims, the government's knowledge cannot be relevant to the scienter analysis. Otherwise, a defendant who intended to defraud the government could evade liability by finding a sympathetic government employee (or one simply willing to take no action), regardless of that person's authority or relationship with the underlying program or activity. See Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer By Any Other Name Does Not Sound as Sweet*, 45 Idaho L. Rev. 41, \*59 (2008).

For similar reasons, even the knowledge and inaction of the government official responsible for approving or denying payments does not automatically negate materiality or scienter. "The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by insisting that persons who send bills to the Treasury tell the truth." *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008); see also *United States ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 95 (2d Cir. 2012) (following *Rogan* and concluding that jury verdict was not clearly erroneous where it did not accept testimony of official regarding materiality over agency's guidelines and instructions).

### **3. Defendants Must Know That The Government Approves Of The Challenged Conduct.**

Finally, for the government knowledge inference to apply, the defendant must know, not merely assume, that the government approved of the challenged conduct at the time claims based on that conduct were submitted. The responsible official or officials must have taken some affirmative action to approve of the defendant's conduct, by, for example, working with the defendant to solve the problem, *Wang*, 975 F.2d at 1421, or directing the defendant to take a particular action, *Durcholz*, 189 F.3d at 545, *Burlbaw*, 548 F.3d at 956-57 (defendant did not merely accept oral advice from an unauthorized agent but rather "reasonably relied upon written assurances of the governmental agency responsible for administering the program . . . ."). *See also Spay*, 875 F.3d at 759 (government knowledge inference does not apply where government, though aware of the challenged conduct, did not make defendant aware of acquiescence to the propriety of the challenged conduct).

Moreover, the defendant's state of mind is evaluated at the time the claim was submitted, so the government's affirmation of the challenged conduct must be made available to the defendant prior to the defendant's submission of claims. *Burlbaw*, 548 F.3d at 951-52; *Durcholz*, 189 F.3d at 545; *Hagood*, 929 F.2d at 1421. A defendant cannot, for example, fail to disclose its fraudulent business practices to the government for years, and then, one month after its conduct is visibly challenged in an FCA case, suddenly send its disclosure letter to the government agency in an

effort to take advantage of the government knowledge inference. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 414 (3d Cir. 1999) (rejecting argument that defendant’s letter purporting to disclose industry funding months after application and after he was under investigation exonerated defendant), *superseded by statute on other grounds*. Rather, defendants with lucrative government contracts must be absolutely sure that the government approves of their conduct before engaging in behavior that routinely reduces the amount of money paid to the government or increases the payments they received from the government. The relevant government official’s silence or lack of response to letters disclosing a defendant’s methodology does not dispositively indicate the explicit approval of defendant’s challenged conduct.

### **III. Courts Are Not Equipped To Determine The Reasonableness Of Parties Not Before Them.**

Defendant Eli Lilly relies on an unpublished opinion by the Third Circuit, issued in 2018, as evidence that its price calculations were at least “reasonable,” if not correct. *Eli Lilly Br. 3*, 43-44. The Third Circuit, in examining the scienter of *other manufacturers*, held that those manufacturers’ exclusion of price appreciation credits from the AMP was not an objectively unreasonable interpretation of the law. *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App’x 101, 110 (3d Cir. 2018) (“Although we are not prepared to say that this is the best interpretation of the statute, we nevertheless are confident that—at the very least—it was not objectively

unreasonable to act in accordance with such an interpretation between the years of 2004 and 2012.”). Eli Lilly overvalues this opinion given that (1) neither Eli Lilly’s knowledge and actions nor the operative regulations were addressed in *Allergan*; and (2) the Third Circuit’s opinion is unpublished and non-binding.

One non-binding court decision supporting the reasonableness of a regulatory interpretation is not irrefutable evidence that a defendant actually believed it was acting in accordance with the applicable regulations. The *Allergan* decision came down long after Eli Lilly began the conduct at issue; the decision did not examine Eli Lilly’s conduct or state of mind; and it is not binding in this Court. Notably, even courts may, on occasion, draw conclusions that are not merely wrong, but “objectively unreasonable.” A defendant cannot use a single, non-binding court decision as the definitive statement on the reasonableness of its own conduct.

**A. A Single Court’s Pronouncement On What Is “Reasonable” Does Not Definitively Determine A Defendant’s Reasonableness.**

It is well understood that courts can make grave mistakes and adopt unreasonable views of a defendant’s conduct. Thus, to the extent a non-binding court decision supports the reasonableness of a defendant’s regulatory interpretation, that decision comprises only some evidence that the defendant did not “know” its own interpretation was wrong. Rather, that court decision must be viewed in light of all other evidence that bears on what the defendant “knew” or should have clearly

known regarding its actual obligations to the government. A non-binding court decision alone is not the definitive guidepost for a party's conduct.

As far as court decisions failing to provide reliable guidance, consider as an (albeit extreme) example, the Supreme Court's decision in *Korematsu v. United States*, 323 U.S. 214, 223 (1944) (“Korematsu was not excluded from the Military Area because of hostility to him or his race. He was excluded because we are at war with the Japanese Empire . . . and felt constrained to take proper security measures, because [the military and Congress] decided that the military urgency of the situation demanded that all citizens of Japanese ancestry be segregated from the West Coast temporarily . . . .”); *abrogated by Trump v. Hawaii*, 585 U.S. 667, 710 (2018) (“*Korematsu* was gravely wrong the day it was decided, has been overruled in the court of history, and—to be clear—‘has no place in law under the Constitution.’”).

More fundamentally, in habeas corpus petitions, under the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA), as codified in 28 U.S.C. § 2254(d), a federal court cannot grant a petitioner relief unless it concludes that the state courts misapplied clearly established law and their misapplication was “unreasonable.” *Washington v. Smith*, 219 F.3d 620, 628 (7th Cir. 2000) (“[W]e must determine that the state-court decision was both incorrect *and* unreasonable before we can issue a writ of habeas corpus.”); *accord Ali v. Hickman*, 584 F.3d 1174, 1196 (9th Cir.

2009) (reversing district court and panel of state appellate court, on habeas petition, finding that “both the California Court of Appeal and the district court clearly erred . . . [and that] the California appellate court’s finding . . . was an unreasonable determination of the facts in light of the evidence presented in the state court proceedings”). In other words, the AEDPA contemplates that courts will act unreasonably. Therefore, the determination of a panel of three Judges, or even two separate courts, on a certain interpretation of law is not a dispositive determination of reasonableness and certainly does not dispositively determine the scienter of a party who was not even before that court.

**B. Only The Trier of Fact Is Responsible For Weighing The Strength Of Evidence.**

In *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016) (a 9-0 decision in favor of the relator), the Supreme Court addressed the various types of claims that can be regarded as false. *Id.* at 186-87. It held that a “false” claim need not contain an express false statement; it could be false in its omission of information, or for what it implies from the information actually provided. *Id.* at 186-88. In an effort to caveat the breadth of its holding, the Supreme Court made clear that a “rigorous” analysis must be applied to the “materiality” of the falsity, whether that falsity is affirmative or implied. In *dicta*, the Court further expanded on materiality by making the following statement:

[I]f 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.

*Id.* at 195. This pronouncement is not part of the holding.<sup>2</sup> In any event, the suggestion that government action is strong evidence does not mean it is dispositive evidence.

There are many reasons why the government may pay a claim despite knowing that it is materially false. Many court of appeals decisions issued subsequent to *Escobar* have acknowledged as much. *United States ex rel. Prose v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732, 743-744 (7th Cir. 2021), *cert. denied sub nom. Molina Healthcare of Ill., Inc. v. Prose*, 143 S. Ct. 352 (2022) (“In short, facts matter” when determining FCA materiality, and “Molina’s barebones assertion that the government was aware of all material facts is not enough to sweep away the elaborate facts that [relator] furnished. . . . Many things could explain the government’s continued contracting with Molina. It may have expected to purge the underserved NF [Nursing Facility] enrollees from the books; it may have needed time to work out a way not to prejudice Medicaid recipients who had nothing to do with this problem.”); *United States ex rel. Cimino v. Int’l Bus. Machines Corp.*,

---

<sup>2</sup> It is also wrong. It is not the role of a reviewing court to decide in advance the relative strength of hypothetical evidence in a future case, without any context.

3 F.4th 412, 423 (D.C. Cir. 2021) (“It is also plausible that the IRS could have later learned of IBM’s fraud and continued to pay for the licenses for any number of reasons that do not render IBM’s fraud immaterial. For example, the IRS may have felt obligated to pay until it received a legal determination that it was relieved of the agreement’s terms.”); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (“[T]here 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. . . . [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 continued noncompliance.”).

Indeed, at least five circuits have recognized that there are myriad reasons why the government will continue to pay contractors despite knowledge of FCA allegations, or even with actual knowledge of material fraud. *See Molina Healthcare*, 17 F.4th at 743-744 (7th Cir.); *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 115 (2d Cir. 2021) (“[I]t makes sense not to place much weight on the government’s response in the wake of such litigation because, prior to discovery and a formal court ruling, the relator’s allegations are just that—allegations, and the government may not necessarily have knowledge of all the material facts.”), *cert. denied*, 142 S. Ct. 2679 (2022); *United States ex rel. Druding v.*

*Care Alternatives*, 81 F.4th 361, 375 (3d Cir. 2023) (“[W]e recognize that ‘the Government may not want to prematurely end a relationship with a contractor over unproven allegations.’”) (citing *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 517 (6th Cir. 2022)); *Cimino*, 3 F.4th at 423 (D.C. Cir.). At least nine circuits have emphasized that no one factor is dispositive in the materiality analysis. See *Care Alternatives*, 81 F.4th at 367, n.1 (collecting cases). Based on the evidence presented in a particular case, the jury can decide how to weigh government action when evaluating materiality.

### CONCLUSION

In this case, the District Court, and the jury, were made aware of: (1) Eli Lilly’s efforts to notify the government and (2) the government’s response. The jury reached the reasonable conclusion that Eli Lilly knowingly underpaid the rebates it owed. There is no legal or factual reason to disturb that finding.

Date: March 1, 2024

Respectfully submitted,

THE ANTI-FRAUD COALITION

By           /s/ David J. Chizewer          

Jacklyn DeMar  
THE ANTI-FRAUD COALITION  
1220 19th Street, N.W., Suite 501  
Washington, DC 20036  
Tel: (202) 296-4826  
Fax: (202) 296-4838  
*jdemar@taf.org*

David J. Chizewer  
Roger A. Lewis  
Harleen Kaur  
GOLDBERG KOHN LTD.  
55 East Monroe Street, Suite 3300  
Chicago, Illinois 60603  
Tel: (312) 201-4000  
Fax: (312) 332-2196  
*david.chizewer@goldbergkohn.com*  
*roger.lewis@goldbergkohn.com*  
*harleen.kaur@goldbergkohn.com*

*Counsel for The Anti-Fraud Coalition as  
Amicus Curiae*

## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief conforms to the word limitations contained in Fed. R. App. P. 29(a)(5) as modified by Circuit Rule 29 because, excluding the parts of this brief exempted by Fed. R. App. P. 32(f), this brief contains 4,695 words.

I hereby also certify that this document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Word 2016 in 14-point Times New Roman font.

Date: March 1, 2024

By           /s/ David J. Chizewer            
David J. Chizewer

*Counsel for The Anti-Fraud Coalition as  
Amicus Curiae*

