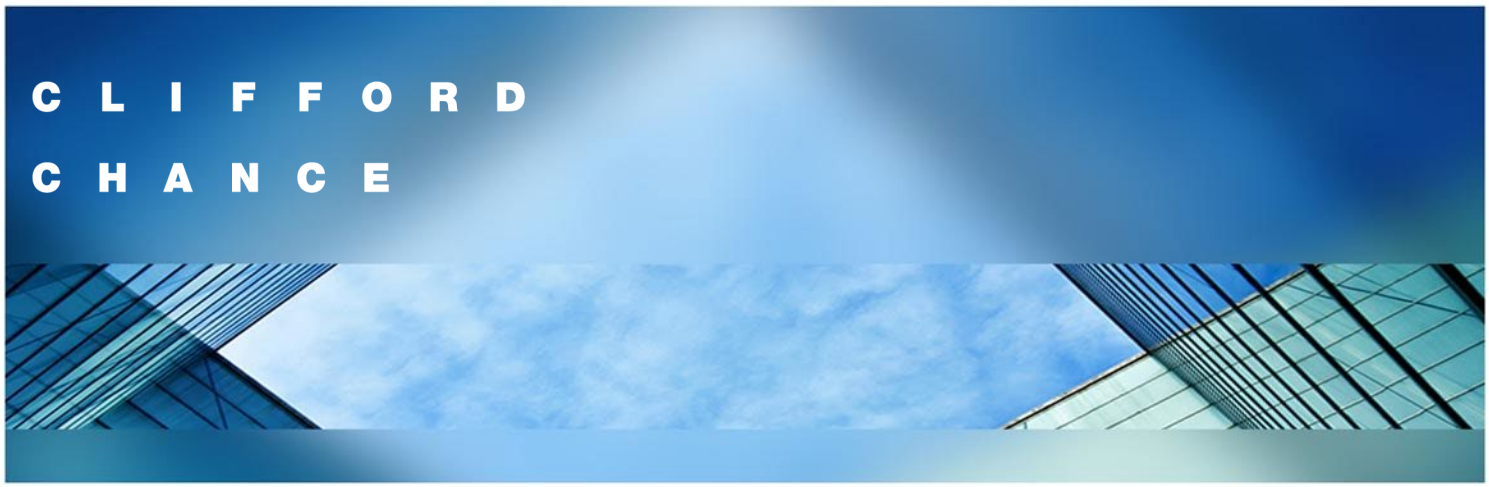

US SUPREME COURT ASKED TO RESOLVE CIRCUIT SPLIT OVER THE SCOPE OF THE FALSE CLAIMS ACT

The US Supreme Court has been asked to take up a case regarding whether a medical opinion "may be scrutinized and considered 'false'" and a violation of the False Claims Act ("FCA") even if it is not "objectively false."[1]

On September 16, 2020, Care Alternatives filed a petition for writ of certiorari in the US Supreme Court seeking review of the Third Circuit's decision in *United States ex rel. Druding v. Care Alternatives*, which held that the FCA did not require "objective falsehood." The US Chamber of Commerce and the Pharmaceutical Research and Manufacturers of America (PhMA) have filed an amicus brief supporting Care Alternatives' petition and asking the Supreme Court to take the case.

The Third Circuit's decision created a circuit split regarding the meaning of "false" under the FCA and provides the Supreme Court with an opportunity to resolve a disagreement among lower courts that has far-reaching implications for any individual or organization doing business with the US government. If the Third Circuit's view is upheld, then companies submitting claims to the federal government face a much higher risk of FCA claims based on a difference of professional opinion rather than objective falsity.

Background

The FCA provides that any person who "knowingly presents . . . a false or fraudulent claim for payment or approval" to the US government is liable.[2] Claims under the FCA can be brought by the government or by relators (whistleblowers), and the FCA's penalties can be draconian, including its provision allowing for treble

1 *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 100-01 (3d Cir. 2020).
2 31 U.S.C. § 3729(a)(1).

damages. As a result, almost one thousand cases are filed each year involving the countless industries that receive funding from the US government—from health care to defense contractors to financial institutions.[3]

Although the FCA defines "knowingly" as actual knowledge, deliberate ignorance, or reckless disregard of the false claim, it does not specifically define "false" or "fraudulent."[4] At issue in *Druding* was whether the "false" element under the FCA is restricted to "objective falsehood."

Druding involved the Medicare Hospice Benefit, which requires that a physician must first certify that a patient electing hospice care is terminally ill before a hospice provider is deemed eligible to receive Medicare funds.[5] Terminally ill is determined by a medical prognosis that the individual's life expectancy is six months or less if the illness runs its normal course. The physician must accompany this certification with "[c]linical information and other documentation that support the medical prognosis" and the hospice provider is "required to make certain that the physician's clinical judgment can be supported by clinical information and other documentation."[6]

The plaintiffs in *Druding* alleged that Care Alternatives admitted patients who were not eligible for hospice care. In support of their claim, the plaintiffs retained an expert who found that the documentation of 35% of the patients he examined did not support the certification for hospice care and that "any reasonable physician" would have reached the same conclusion.[7] Care Alternative's expert, on the other hand, opined that a physician could have reasonably found that every one of the examined patients were terminally ill and thus properly certified for hospice care.[8] The district court granted summary judgment for Care Alternatives because the plaintiffs did not show "objective falsehood" and that "mere difference of opinion between physicians without more, is not enough" to establish falsity.[9]

Circuit Split

The Third Circuit reversed the district court's decision, creating a circuit split on whether the FCA requires "objective falsehood." The Third Circuit held that because opinions could be considered false under common law, they similarly can be false under the FCA.[10] It held that expert testimony challenging a medical opinion is appropriate evidence to be considered by a jury.[11] In addition, the Third Circuit determined that a claim can be "false" under theories of both factual falsity (when there is evidence of factual inaccuracy in a claim) or legal falsity (when the claimant falsely certifies compliance with regulations that are conditions of payment).[12] The Third Circuit found that a disagreement between the medical experts is relevant to a

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3 *See* Dep't of Justice, Press Release, *Fraud Statistics—Overview: Oct. 1, 1986–Sept. 30, 2019* (Jan. 9, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.
4 31 U.S.C. § 3729(b)(1)(A).
5 *Druding*, 952 F.3d at 92-93.
6 *Id*. at 93 (quoting 42 C.F.R. § 418.22 and Hospice Quality Reporting Requirements, 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014)).
7 *Id*. at 94.
8 *Id*.
9 *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669, 685 (D.N.J. 2018).
10 *Druding*, 952 F.3d at 95-96.
11 *Id*. at 98.
12 *Id*. at 97.

theory of legal falsity because it can demonstrate that the required "clinical information and other documentation" did not support the certification.[13]

Shortly following *Druding*, the Ninth Circuit decided *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108 (9th Cir. 2020), based on similar reasoning. In Winter, the Ninth Circuit considered a Medicare provision that allowed for reimbursement of the costs of inpatient hospitalization if a physician certified that inpatient treatment was reasonable and necessary and the factors that led to the certification were adequately documented. Like the court in *Druding*, the Ninth Circuit noted that opinions can be fraudulent under common law and that the "objective falsehood" requirement is not supported by the text of the FCA.[14] In contrast, the Ninth Circuit held that, as under common law, opinions regarding medical necessity can be false if they are "not honestly held" or imply facts that do not exist.[15] The court also noted that its interpretation complied with the Supreme Court's refusal to "accept a rigid, restrictive reading" of the FCA and instruction that lower courts should resist "adopting a circumscribed view of what it means for a claim to be false."[16]

In contrast, the Eleventh Circuit held in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), that a Medicare Hospice Benefit claim that is based on a physician's medical judgment "cannot be 'false' . . . if the underlying clinical judgment does not reflect an objective falsehood."[17] The Eleventh Circuit explained that a "reasonable difference of opinion among physicians" is not enough to demonstrate falsehood, but that a plaintiff must prove objective falsehood by demonstrating, for example, that a physician did not review the medical records before making a certification, did not subjectively believe the certification, or when no reasonable physician could have concluded with the opinion in the certification.[18] In support of its decision, the Eleventh Circuit cited cases from the First, Fourth, Seventh, and Tenth Circuits that have articulated a similar "objective falsehood" requirement.[19]

The Third Circuit in *Druding* expressly disagreed with the Eleventh Circuit, reiterating that under common law, medical opinions can be false, and further noting that the Eleventh Circuit erred by ignoring the possibility of legal falsity. The Ninth Circuit in *Winter*, however, emphasized that its opinion was consistent with the Eleventh Circuit's reasoning in *AseraCare*, explaining that notwithstanding *AsperaCare's* "language about 'objective falsehoods,'" the opinion identified circumstances when a *subjective* medical opinion could also be false.[20]

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13 *Id*.
14 *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108, 1117 (9th Cir. 2020).
15 *Id*. at 1119.
16 *Id*. at 1116 (quoting *Universal Health Servs., Inc. v. United States ex rel, Escobar*, 136 S. Ct. 1989, 2002 (2016)).
17 *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1296-97 (11th Cir. 2019).
18 *Id*. at 1297.
19 *Id*. at 1297 n.11 (citing *United States ex rel. Loughren v. Unum Grp*., 613 F.3d 300 (1st Cir. 2010); *United States ex rel. Wilson v. Kellogg Brown & Root, Inc*., 525 F.3d 370 (4th Cir. 2008); *United States ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818 (7th Cir. 2011); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008)).
20 *Winter*, 953 F.3d at 1118 (quoting *AseraCare*, 938 F.3d at 1282 (emphases added by *Winter* court)). The Ninth Circuit also noted the distinction drawn by the court in *AseraCare* between medical opinions regarding medical necessity and medical opinions regarding terminal illness, which are more subjective and difficult to predict. Id. at 1119 (citing *AseraCare*, 938 F.3d at 1300 n.15).

Implications

As Care Alternatives' petition for Supreme Court review noted, the circuit split here is "outcome determinative: if petitioner were a hospice in Florida rather than New Jersey, this case would be over."[21] The inconsistent standards among lower courts creates confusion on a foundational element of a primary enforcement tool of the US government. Moreover, as Care Alternatives stressed, the Third Circuit's decision likely disincentivizes physicians from certifying a patient for hospice care—a decision that affects millions of Americans annually.[22]

Moreover, the US Chamber of Commerce's amicus brief emphasized the broader effects of the circuit split on businesses. It stressed that an objective falsity standard properly cabins liability by preventing the risk of treble damages and statutory penalties, including debarment from government contracting, "whenever a self-interested relator with a hired 'expert' second-guesses a subjective judgment or offers a different interpretation of a provision subject to several reasonable interpretations."[23] Beyond the medical context, the Third Circuit's decision could create liability for numerous other major industries, including, for example, technology companies applying for federal research grants based on studies that are alleged to be inaccurate or government contractors submitting reimbursement requests that are alleged to be unreasonable because they were not the lowest cost option.[24]

While both the Third and Ninth Circuits emphasized that under the FCA's scienter requirement, plaintiffs will still need to demonstrate that the defendant acted with actual knowledge, deliberate ignorance, or reckless disregard of the falsity,[25] that element provides little comfort to the business community since scienter does not need to be pleaded with particularity and courts rarely dismiss FCA claims for lack of scienter until the summary judgment phase, after protracted and costly discovery.[26] Defendants are therefore faced with "an impossible choice: pay millions of dollars to litigate the case to summary judgment or even trial, all while facing the prospect of treble damages—or settle."[27]

Respondents are expected to file a brief in opposition to the petition for writ of certiorari this fall and the Supreme Court will likely decide whether to grant certiorari in early 2021. All entities doing business in any form with the US government should pay close attention to further developments in this important area and consider the controls required to manage increased FCA risks in the event that the Supreme Court upholds the Third Circuit's interpretation of falsity.

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21 Petition for Writ of Certiorari at 12, *United States ex rel. Druding v. Care Alternatives*, No. 20-371 (Sept. 16, 2020).
22 *Id*. at 14.
23 Brief of Chamber of Commerce of the United States et al. as Amici Curiae Supporting Petitioners at 10-11, *United States ex rel. Druding v. Care Alternatives*, No. 20-371 (Oct. 23, 2020).
24 *Id*. at 14.
25 *Druding*, 952 F.3d at 96; Winter, 953 F.3d at 1117-18.
26 Brief of Chamber of Commerce of the United States et al. as Amici Curiae Supporting Petitioners at 20, *Druding*, No. 20-371.
27 *Id*.

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