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Filed September 29, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 98-3552

UNITED STATES OF AMERICA,
ex rel. ERDEM I. CANTEKIN, an individual

v.

UNIVERSITY OF PITTSBURGH, a non-profit Pennsylvania
corporation; CHILDREN'S HOSPITAL OF PITTSBURGH, a
non-profit Pennsylvania corporation; CHARLES D.
BLUESTONE, an individual;

United States of America, ex rel. Erdem I. Cant ekin,
Appellant

(Amended pursuant to Clerk's order dated 1/7/99)

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. No. 91-cv-00715)
District Judge: Hon. Donald E. Ziegler, Chief Judge

Argued June 17, 1999

BEFORE: NYGAARD, STAPLETON and COWEN,
Circuit Judges

(Filed September 29, 1999)

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University of Pittsburgh, a non-
profit Pennsylvania corporation

OPINION OF THE COURT

COWEN, Circuit Judge.

This case concerns a medical researcher's failure to disclose his industry funding on a number of grant applications that he submitted to the National Institutes of Health (NIH). The undisclosed funding included several million dollars from pharmaceutical companies making the drugs that the NIH paid the researcher to evaluate.

On this appeal we must determine when a private party can properly bring a suit under the False Claims Act's qui tam provision, 31 U.S.C. S 3730(b), which allows an individual to sue on the government's behalf for damages caused by another party's false claims. Congress has changed several times the rules limiting when a private party can bring a qui tam suit under the False Claims Act. We must resolve which of two versions of the Act apply to the various grant applications that the researcher submitted to the NIH and what effect each version has on the claims it controls.

A recent Supreme Court decision, *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 117 S.Ct. 1871 (1997), discussed the retroactivity of the 1986 Grassley Amendments, Congress's latest change to the Act's qui tam rules. Applying *Hughes*, the District Court concluded that Erdem Cantekin, the appellant, could not pursue qui tam claims based on grant applications that Charles Bluestone, the researcher and appellee, submitted before October 27, 1986. Although our reasoning differs from the District Court's, we will affirm its ruling on these applications submitted in 1986 or earlier.

For Cantekin's remaining qui tam claim, which was based on an application submitted after the effective date of the 1986 amendments, the District Court granted summary judgment in favor of Bluestone and the other defendants because the Court concluded that Bluestone did not knowingly omit his industry funding from the application. Contrary to the District Court, we conclude that genuine factual disputes preclude summary judgment on whether Bluestone knowingly submitted a false claim.¹

I

Both the appellant, Erdem Cantekin, and the appellee,

1. The University of Pittsburgh and Children's Hospital of Pittsburgh joined Bluestone in applying for various grants and were also named as defendants. For convenience, we have referred throughout our opinion to the claims against Bluestone, but our analysis applies equally to the other named defendants.

Charles Bluestone, are professors of otolaryngology at the University of Pittsburgh's medical school and have worked together on research since the early 1970s. As part of their collaboration, they created the Otitis Media Research Center to investigate acute otitis media and otitis media with effusion, two ear diseases common in children.

Much of the research they conducted together focused on testing the effectiveness of various antibiotics, such as amoxicillin, in treating the different types of otitis media. This research was particularly significant because while the drugs are widely used, controversy continues about the desirability and effectiveness of using antibiotics for these conditions. Not only are there medical reasons for worrying about unwarranted use of antibiotics, but also according to Cantekin's brief, the public spends over half a billion dollars annually buying antibiotics to treat the various forms of otitis media.

To pursue the research on antibiotics, Bluestone submitted numerous grant applications to the NIH throughout the 1970s and 1980s and ultimately was awarded approximately \$17.4 million. At the same time, Bluestone began receiving funding from various pharmaceutical companies to test the effectiveness of their antibiotics in treating otitis media. Collectively, this industry funding totaled approximately \$3.4 million.

Cantekin claims that as early as 1976, he raised with Bluestone his failure to list his industry funding on his NIH grant applications, but Bluestone allegedly brushed him off, saying that he was not going to tell the "federal feather merchants" because it was "none of their business" and would "muddy up the waters." App. at 523. Cantekin also disputed Bluestone's interpretation of research results, in particular the results of several industry-funded studies.

In May of 1987, Cantekin wrote to the NIH complaining about Bluestone's conduct, but the NIH chose to take no action, instead deferring to an investigation conducted by the University of Pittsburgh. When the university announced on June 22, 1987 that it had cleared Bluestone of any wrongdoing, the NIH dropped the matter. Dissatisfied with the university's investigation and with the

NIH's reliance on it, Cantekin later testified before the United States House of Representatives at hearings investigating scientific fraud in federally funded research.

While the congressional report from the hearings was pending, the NIH decided to conduct its own inquiry into Bluestone's conduct. The resulting report by Howard Hyatt, then director of the NIH's Division of Management Survey and Review, concluded that Bluestone and the Otitis Media Research Center had "not generally disclosed to NIH the extent of its industry-sponsored research." App. at 508. But Hyatt continued that since the grant instructions were ambiguous, Bluestone's conduct was excusable. Hyatt also rejected Cantekin's claim that Bluestone's research results were biased.

On September 10, 1990, the House released its report, which discussed ten cases where grant recipients had engaged in misconduct. See H.R. Rep. No. 101-688, Are Scientific Misconduct and Conflict of Interest Hazardous to Our Health?, 19th Report, Committee on Government Operations, 101st Cong., 2d Sess. (Sept. 10, 1990). Bluestone's case was included among the ten. The House report excoriated both the University of Pittsburgh's investigation as well as Hyatt's report and challenged many of their findings. Several months later, in December of 1990, the NIH issued a new report by the agency's recently created Office of Scientific Integrity (OSI), which had reopened the agency's inquiry into Bluestone's conduct. Dr. Suzanne Hadley, then Acting Deputy Director of OSI, was in charge of this second NIH investigation. Her affidavit explained that the OSI report

recommended that the Director of NIH require that Dr. Bluestone be placed on a period of five years of administrative oversight for having failed to disclose his private pharmaceutical company research to NIH and having analyzed the data from NIH-funded research in a manner biased towards the effectiveness of the antibiotics he had evaluated with public monies.

App. at 481.

To illuminate how Bluestone's failure to disclose his industry funding could have affected the NIH's approval of

his grants, Cantekin provided the following overview of the application process. Applications are first assigned to one of several institutes within the NIH. In Bluestone's case, his applications were sent to the National Institute for Neurological, Communication Disorders, and Stroke, which then forwarded them to the Communication Disorders Review Committee (CDRC), one of the review committees within the institute. A review committee is the body primarily responsible for evaluating the merits of applications like Bluestone's. Each review committee is composed of experts who are not NIH employees and are paid per diem for evaluating the applications. Frequently, the review committee members have themselves received NIH grants in conducting their own research.

The review committee takes two votes on an application. The first vote is to "approve" or "disapprove" the requested grant; receiving approval at this stage, however, does not assure that the application will be funded. The application may still be rejected based on the second vote, which establishes a "priority score." To determine the priority score, each member of the review committee gives the proposal a score between 1, for the highest priority, and 5 for the lowest. Each member's score is then added together, the total is divided by the number of members, and the resulting average is multiplied by 100, yielding the final priority score. Thus, the highest priority score possible is 100 and the lowest 500.

In 1984, Bluestone and Children's Hospital of Pittsburgh submitted an application to extend an earlier grant by five years. Their first request for an extension received a priority score of 154 and was not funded, but later Bluestone and the Otitis Media Research Center submitted a revised application that received a priority score of 131, which was good enough to receive funding.

If we combine the NIH's method of calculating the priority score and the rough guideline that an application with a score of 154 or higher would not receive funding, at least around the time that Bluestone's application was considered, we can see that one or two members can easily raise an applicant's priority score above the cut-off for funding. For example, votes of 1, 1, 1, 1, and 5 yield a

priority score of 180; and votes of 1, 2, 1, 1, and 3 yield a score of 160. Even votes of 1, 1, 1, 1, and 3 could place an applicant on the edge of rejection with a priority score of 140.

After the priority vote, an executive secretary, who functions as a staff member for the committee, writes a report describing the review committee's deliberations and submits the report to the Council of the Institute. The council receives applications from the various review committees within the institute and makes the final determination of which applications will be funded. Council members, like the review committee members, are not NIH employees and are chosen for their expertise in their field. Unlike the review committee members, however, council members are appointed to serve for four-year terms.

Once a multi-year grant has been approved for funding, NIH assigns the grant to a "program administrator," who is in charge of administering the grant. Each year the grant's principal investigator, Bluestone in our case, and the grantee institution must submit a special continuing application, or progress report. These progress reports are "noncompetitive" in that funding during the allotted time has already been approved. The purpose of the progress reports is to inform the NIH of how the research is advancing, identify the amount of the budget for the next year, and provide information about key personnel engaged in the research.

Two of the five members of an NIH review committee that voted to approve one of Bluestone's grants stated in affidavits that if they had known about his industry funding, it would have affected their decision. Dr. Perkell, one of the review committee members, said that Bluestone's undisclosed industry funds were not "common knowledge." He continued:

[I]t is my opinion that had Dr. Bluestone disclosed his relationships with the private pharmaceutical industry, the competing renewal application of NS 16337 which came before the Review Committee of which I was a member would have been evaluated more critically with regards to: demands on investigator time, possible

conflicts of interest, the effects of bias on the value of the proposed studies, safeguards in the study design to ensure unbiased interpretation and evaluation of the results of the proposed studies. The more critical evaluation would have had an impact on the recommendation for approval and on the priority score. The impact on the priority score I gave would have been material and negative. In my opinion, based on my knowledge of past behavior of my fellow members of the Review Committee in evaluating and assigning priority scores to several hundred other applications the impact on the overall priority funding score would have been material and negative.

App. at 473-74.

Dr. Schwartz, the chair of the review committee, also stated in an affidavit that she was unaware of Bluestone's industry funding and that had she known, it would have had a "material and negative" effect on her evaluation of the application. She explained that a researcher who receives substantial funding from a pharmaceutical company can be subtly biased in favor of finding that the company's drugs are effective. Disclosure of this potential source of bias is important to reviewers even if the grant might be ultimately approved since the review committee might not approve the application until certain additional safeguards are implemented. "When bias, or potential bias, are revealed by disclosure of a funding source with a vested interest in the outcome of the research, reviewers are alerted to look for defects in the experimental design which could compromise the work proposed." App. at 1125. Elsewhere, she explained:

A bias experimenter can still perform valid work, but the experiments must be carefully designed so that enrolled patients are randomly assigned to different test groups, objective criteria for measuring function are used, and both subject and observer are blinded as to which experimental condition (i.e. new drug, current standard drug, or other control substance) applied to a particular subject. Appropriate statistical tests must be applied to the data to assure that interpretations of efficacy of the test drugs are valid.

Id.

The three other members of the review committee, Drs. Miller, Meyerhoff, and Goode, all submitted affidavits saying that they were aware of Bluestone's industry funding. Dr. Miller, for example, stated that "I was fully aware that Dr. Bluestone was receiving very substantial support from private pharmaceutical companies to do drug efficacy studies. . . . I was not at all troubled by the fact that Dr. Bluestone was receiving such funding." App. 1104-05.

None of the three, however, informed Drs. Perkell or Schwartz of this outside funding. Dr. Schwartz's affidavit notes that the other committee members did not mention Bluestone's undisclosed funding at the review committee meetings, nor did they "raise the issue of possible conflicts of interest or of the adequacy of safeguards to control against bias in the interpretation of study results..." App. at 1125.

II

We have jurisdiction pursuant to 28 U.S.C. S 1291, and we exercise plenary review of a district court's grant of summary judgment. *Barnes v. American Tobacco Co.*, 161 F.3d 127, 138 (3d Cir. 1998). On a motion for summary judgment, a court must determine whether the evidence shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Factual disputes invoked to resist summary judgment must be both material in the sense of bearing on an essential element of the plaintiff's claim and genuine in the sense that a reasonable jury could find in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-251, 106 S.Ct. 2505, 2510-12 (1986). A court should not prevent a case from being presented to the jury simply because the court favors one of several reasonable views of the evidence, for "the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249, 106 S.Ct. at 2511.

III

We begin with the threshold issue of which grant applications can be subject to a qui tam suit. Prior to the 1986 amendments to the False Claims Act, a private party was barred from bringing a qui tam suit if the action was "based on evidence or information the Government had when the action was brought." 31 U.S.C. S 3730(b)(4) (1982 ed.). The government itself, of course, could still bring suit for such a violation; only private parties were barred from seeking recovery. The implicit logic of the pre-1986 law was that if the government had the relevant information before the plaintiff initiated suit, then the government must be aware of the false claims and didn't need the assistance of private parties to ferret them out. And if the government knew about the information yet did nothing, then the government probably thought the suit meritless, and any private action was apt to be spurious, driven only by the lure of the Act's sizable damages.

Despite the pre-1986 law's legitimate aim of preventing spurious suits, its bar for qui tam suits imperfectly achieved its purposes for a variety of reasons: 1) the government lacks the resources to investigate and prosecute all false claims even when the government has information revealing fraud; 2) a government official who is deemed to "have" the information may not recognize the connection between the information and a particular false claim; 3) the official may have an interest in not bringing the fraud to light for a number of reasons, such as an interest in protecting the official's or the agency's reputation; and 4) other mechanisms, more directly focused on the merits of a suit, are available for filtering out spurious claims. Congress was also concerned that under the old law, whistleblowers who came forward and exposed fraud to government officials before filing suit were later being barred from bringing a qui tam suit. Indeed, as our discussion below makes clear, Cantekin's case itself illustrates this consequence of the pre-1986 law.

With the enactment of the Grassley Amendments, Congress generally gave greater scope to qui tam suits. Among other changes, such as increasing the damages from double to treble the harm caused, and increasing the

percentage that a qui tam plaintiff received of those damages, compare 31 U.S.C. SS 3730(a) and (c) (1982 ed.) with 31 U.S.C. SS 3730(d)(1) and (2), the amendments also eliminated the old law's bar to qui tam suits.

Instead of prohibiting all qui tam suits that are based on information the government "has" when the suit is brought, the Grassley Amendments introduced a new standard: a qui tam suit will be barred only if it is based on information that was "publicly disclosed" at various hearings, in certain types of reports, or by the media. 31 U.S.C. S 3730(e)(4)(A). Information that the government "has," but that was never publicly disclosed, does not bar a qui tam suit. Even if there is "public disclosure" within the meaning of the Grassley Amendments, a qui tam suit can still go forward if the plaintiff is an original source of that publicly disclosed information. 31 U.S.C. S 3730(e)(4)(B). An original source is defined as someone who has "direct and independent knowledge" of the information and who has "voluntarily provided" the government with the information before the suit was initiated. *Id.*

Groundless suits are addressed in part by provisions requiring that all qui tam plaintiffs submit sealed information to the government before the suit proceeds. After reviewing this information, the government can decide whether to join the suit, allow the private party to continue alone, or, most significantly, dismiss the suit. See 31 U.S.C. SS 3730(b)(2) and (c)(2)(A).

In *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 117 S.Ct. 1871 (1997), the Supreme Court held that the 1986 amendments did not apply retroactively to conduct occurring prior to the amendment's effective date. The Court stated in a footnote, however, that since in *Hughes* both the "false claim submission" and the "disclosure to the government" of the fraud occurred before the effective date of the 1986 amendments, the Court did not have to address which of the two events should be used for determining retroactivity. 520 U.S. at 946, n. 4, 117 S.Ct. at 1876, n.4.

In applying *Hughes*, the District Court concluded that for all of *Bluestone's* grant applications submitted prior to the

1986 effective date, the date of "disclosure to the government" also occurred before October 27, 1986. Thus, the District Court decided that, as in Hughes, it did not have to resolve whether the disclosure date or the date of submission controls.

Although the parties sharply dispute whether there was "disclosure to the government" prior to the 1986 effective date, we need not resolve the issue. We conclude that even though the Supreme Court did not expressly reach in Hughes whether retroactivity is determined based on the submission date or the disclosure date, the Court's analysis strongly supports using the former, i.e., the date the allegedly false claim was submitted. And once we use the submission date and apply the pre-1986 law to all grant applications submitted prior to the October 27, 1986 effective date, there can be no doubt that before Cantekin began his qui tam suit, the government "had" the information upon which it was based.

By the time Cantekin filed his complaint in the District Court on April 29, 1991, the House had conducted its hearings and issued its report, and the NIH had issued both Hyatt's memo and the later report by the Office of Scientific Integrity. These events unquestionably establish that the government had the information on which Cantekin's suit was based.² Thus, the only live issue is why we should use the submission date for determining retroactivity.

When the Supreme Court concluded in Hughes that the Grassley Amendments should not be applied retroactively,

2. Cantekin objects that when the District Court granted summary judgment against his pre-1986 claims, the Court erred by converting a 12(b)(6) motion into a motion for summary judgment without first giving adequate notice and an opportunity to respond. See, e.g., *Rose v. Bartle*, 871 F.2d 331, 342 (3d Cir. 1989). Cantekin raised this point in a motion for reconsideration, but the District Court rejected the argument, noting that under *Rose* a failure to give notice can be excused if "harmless." *Id.* Since we evaluate retroactivity based on the submission date, and since it is undisputed that Cantekin's suit was filed after the NIH and Congressional investigations, we conclude that any error stemming from the conversion of the motion was indeed harmless.

the Court recognized that knowingly submitting a false claim is illegal under both versions of the statute. The Court also noted that under both the amended statute and the previous statute, the total amount of a defendant's liability does not depend on who sued; the defendant must pay the same amount regardless of whether the government or a qui tam relator brought the action. Nonetheless, the Supreme Court reasoned that the amendment's change in when qui tam suits can be brought does impose new penalties on defendants.

While we acknowledge that the monetary liability faced by an FCA defendant is the same whether the action is brought by the Government or by a qui tam relator, the 1986 amendment eliminates a defense to a qui tam suit -- prior disclosure to the Government -- and therefore changes the substance of the existing cause of action for qui tam defendants by "attach[ing] a new disability, in respect to transactions or considerations already past."

520 U.S. at 948, 117 S.Ct. at 1877 (citations omitted). After noting that the 1986 amendments eliminate a defense, the Court commented that the amendments also in effect create a new cause of action because the courts are open to an expanded class of plaintiffs.

We think this reasoning would be in deep tension, if not outright conflict, with using the date of disclosure instead of the date of submission for determining retroactivity. Our primary rationale is very simple. If we invoked the disclosure date to apply the amendments to a false claim submitted before the amendment's effective date, then the new penalties listed by the Court, i.e., the loss of a defense and the creation of a new cause of action, would be imposed after the defendant acted. The reason that using the disclosure date would have this effect is that the defendant's conduct ends with submitting the false claims; the defendant is not the one, or at least not usually, who makes the disclosure to the government. Since the Court rejected in *Hughes* an application of the Grassley Amendments that would allow the law to "attach new disabilities" to conduct committed prior to the amendment's

passage, we think the Court implicitly foreclosed using the disclosure date.

Another problem with using the date of "disclosure to the government" to determine retroactivity is that it is not clear what test should be applied to determine that date. The Supreme Court's phrase "disclosure to the government," straddles the 1986 amendment's "public disclosure" language and the pre-1986 standard of "information the government had." By speaking of disclosure "to" the government, rather than disclosure "by" the government, the Supreme Court's language may suggest that the Court was referring to the pre-1986 "government knowledge" test. The "government knowledge" test is primarily focused on what other people release to the government while the amendment's "public disclosure" test has a substantial emphasis on information released by government. On the other hand, the Supreme Court's phrase, "disclosure to the government," does not accurately capture the pre-1986 law since the government could "have" the information within the meaning of the pre-1986 test based on what the government learned from its own investigative efforts. And by speaking of "disclosure," and not information the government "has," the Supreme Court's language is suggestive of the "public disclosure" test.

Regardless of how one parses the language, however, the real problem is that choosing between the pre- and post-1986 standards injects a kind of circularity into the retroactivity analysis. To determine the date of "disclosure to the government," we must apply either the pre-or post-1986 test in order to decide whether we will apply the pre-or post-1986 test to the alleged false claim. This awkward need to stipulate at the outset what our analysis is supposed to decide reinforces our conclusion that the date the claim was submitted should determine the retroactivity of the Grassley Amendments.³

3. It is true that a court could apply pre-1986 law to assign a date to the "disclosure to the government" and yet still find that post-1986 law should ultimately control the claim. For example, suppose that after the defendant submitted a false claim in 1985, the plaintiff informed the government of the fraud in 1987, filed a qui tam suit in 1988, and

The District Court noted in passing that a Ninth Circuit opinion, decided before the Supreme Court's opinion in Hughes, relied on the disclosure date for determining the retroactivity of the Grassley Amendments. See United States ex rel. Anderson v. Northern Telecom., Inc., 52 F.3d 810, 814 (9th Cir. 1995). The main problem with Anderson is that its reasoning rested heavily on the point that "the 1986 amendment did not change the legal consequences of [defendant] Northern Telecom's conduct." 52 F.3d at 814. Since Hughes rejected that position and emphasized that the Grassley Amendments do "attach new disabilities" to a defendant's past conduct, we think that Anderson's authority has been undermined. In short, we conclude that we should use the date the claim was submitted for determining the retroactivity of the Grassley Amendment's "public disclosure" bar to qui tam suits.

Did Bluestone knowingly submit false claims?

Not all of Cantekin's claims were based on grant applications submitted prior to October 27, 1986. On January 28, 1987, Bluestone submitted a new grant application without listing his industry funding, and he again failed to disclose when he revised the application on May 1, 1987. The District Court dismissed Cantekin's qui

qualified as an original source. Even if we applied the pre-1986 law to date "disclosure to the government," we would not bar the plaintiff's suit. This follows because the date that the government learned of the fraud, i.e., sometime in 1987, was after the effective date of the 1986 amendments. And once we applied the amended law, we would see that the plaintiff could go forward with the suit since the plaintiff is an original source, and no public disclosure occurred aside from the plaintiff's suit.

The circularity of our presupposing pre-1986 law isn't really eliminated, however, just because in a certain class of cases using the pre-1986 law to assign a date to disclosure leads us to apply post-1986 law. We still need a justification for applying the pre-1986 law at the outset when it may foreclose many claims that the post-1986 disclosure test would not. We could, of course, appeal to the considerations cited in Hughes for using the pre-1986 law. But once we adopt those arguments, we have reason to abandon the "date of disclosure" altogether as a way of determining retroactivity.

tam claim based on this revised application because the Court concluded on summary judgment that the evidence "does not permit a finding that Dr. Bluestone`knowingly' submitted false or fraudulent claims to the government." App. at 1627.

The False Claims Act defines "knowing" and "knowingly" as including a defendant's "actual knowledge," "deliberate ignorance," or "reckless disregard" of the truth or falsity of information in the defendant's claim to the government. 31 U.S.C. S 3729(b). The statute adds that "no proof of specific intent to defraud is required." Id. In applying these standards to the record before us, we must heed the basic rule that a defendant's state of mind typically should not be decided on summary judgment. See, e.g. , Hunt v. Cromartie, ___ U.S. ___, 119 S.Ct. 1545, 1552 (1999).

The District Court's primary rationale for granting summary judgment was that the grant application and instructions were unclear. Before we address whether the instructions are ambiguous, or more properly whether there is no genuine dispute that they are, we note that Cantekin stated in his affidavit that he specifically informed Bluestone that he should disclose his private funding.

In 1976, when Dr. Bluestone and I were applying for various NIH grants, I raised with Dr. Bluestone the question whether he, as principal investigator, should not be disclosing to NIH his other research support, especially from pharmaceutical companies. Dr. Bluestone replied that it was "none of their business," and that he was not going to tell the "federal feather merchants" because it would "muddy up the waters." Dr. Bluestone added that "idiots like Buckminster Ranney would not understand." Dr. Buckminster Ranney was an NIH-employee working with the National Institute of Neurological, Communicative Disorders, and Stroke ("NINCDS") with whom Dr. Bluestone had dealt.

App. at 523. This affidavit not only creates a genuine dispute that Bluestone "knowingly" omitted his industry funding, but it also provides evidence that Bluestone had the specific intent to defraud, proof of which is not required for a violation of the False Claims Act.

Even apart from the evidence that Bluestone was specifically informed that he should disclose his industry funding, we conclude that there is ample evidence that the instructions are clear. Other members of Bluestone's Otitis Media Research Center correctly followed the instructions and disclosed their outside research funding, including private sources. App. at 38. Similarly, one of the NIH review committee members, Schwartz, stated in his affidavit that:

I have written or helped to write numerous NIH grant applications for fellowships, research grants, program projects and training grants. As principal investigator I have held an R01 grant from NIH which has been continuously funded since 1972 involving seven competing renewals and several revised resubmissions . . . I have always found directions for completing the "other support" pages of NIH grant applications to be unambiguous.

App. at 439-40. Another member of the review committee, Perkell, submitted a similar affidavit saying that he had applied for and received a number of NIH grants and found the "other support" section to be unambiguous.

A review of the instructions themselves suggests that they clearly indicate that industry funding should be disclosed. On the page that instructs applicants to list their "other support," the form provides:

For each of the professionals named on page 2, list, in three separate groups: (1) active support; (2) applications pending review and/or funding; (3) applications planned or being prepared for submission. Include all Federal, non-Federal, and institutional grant and contract support. If none, state "NONE." For each item give the source of support, identifying number, project title, name of principal investigator / program director, time or percent of effort on the project by professional named, annual direct costs, and entire period of support. (If part of a larger project, provide the titles of both the parent grant and the subproject and give the annual direct costs for each.) Briefly describe the contents of each item listed. If any of these overlap, duplicate, or are being replaced or

supplemented by the present application, justify and delineate the nature and extent of the scientific and budgetary overlaps and boundaries.

App. at 1196 (emphasis in original). The instructions specifically request that the applicant list "all... non-Federal... support" and give detailed information about each grant.

In concluding that the instructions were ambiguous, the District Court relied on Hyatt's report, which cited an earlier version of the instructions and said that "many institutions were found to interpret those instructions improperly." App. at 509. Hyatt explained that the NIH changed the instructions to avoid ambiguities.

The District Court's reliance on Hyatt's memo is problematic for a number of reasons. First, Bluestone's post-1986 grant applications used the improved instructions. Second, even if potential confusion from the earlier applications was relevant, perhaps because the earlier instructions gave Bluestone erroneous expectations, we seriously question whether the earlier instructions were ambiguous. The instructions that Hyatt claimed were ambiguous read in part:

List all research support for each individual including requests now being considered, as well as any proposals being planned, regardless of relevance to this application. Include also current awards, research career program awards, training grants, regardless of the source of support.

App. at 509. Hyatt apparently believed that these instructions were ambiguous because, unlike the improved instructions, they did not specifically refer to "non-Federal" sources. The instructions did, however, direct applicants to list "all" research support "regardless of source" and "regardless of relevance." Hyatt claimed that "many" institutions had incorrectly interpreted the earlier instructions, but the drafter of the NIH forms testified that he could not recall any specific case, except Bluestone's of course, where a researcher misunderstood what was required by the "other support" question.

Third, the House report sharply criticized Hyatt's conclusions and explained that:

NIH officials were incorrect in describing the content of the NIH forms; the section regarding "Other Support" was revised in late 1979 and revised forms, containing the more explicit language were available to applicants in 1980 or 1981, depending on the type of application.

App. at 38.

Fourth, Dr. Hadley, the Acting Deputy Director of the NIH's Office of Scientific Integrity, asserted in her affidavit that she had not encountered any evidence that applicants found the instructions to be ambiguous.

In my opinion and based on my [prior] experience as an Executive Secretary [who works with review committees in evaluating grant applications,]... there was never any problem with ambiguity in PHS instructions on how to complete the "Other Support" section of a PHS Grant Application or Continuation Application. From Fall, 1979 on, the instructions explicitly required the disclosure of all sources of support, both federal and non-federal.

App. at 482.

Finally, one can infer that Bluestone, a highly-educated professional, would have been aware that the NIH might be interested in his industry ties when the agency decided whether to award him substantial funding to test a key drug in a half-billion dollar industry. As Cantekin points out, people are likely to give much greater weight to NIH research than to the findings of companies making the drugs at issue. Given this greater public trust in the results of government-funded research, and the undeniable risks of bias, the government clearly has a strong interest in ensuring that it acts as an impartial investigator, especially when investigating treatments that have a disputed efficacy and a high aggregate cost. Bluestone can be reasonably expected to know of the government's heightened interest in avoiding bias. As a scientist, he must be fully aware that rooting out potential sources of bias in our interpretations of empirical data is central to scientific inquiry.

The District Court and the appellees' next argument is that in the materials accompanying some of Bluestone's applications, there were references to his industry funding. These references were by no means complete disclosures of the grants he was receiving from pharmaceutical companies, nor did the references include the full information, such as the amount of the funding, that was requested in the "Other Support" section of the grant application. Furthermore, many of the references that the appellees rely upon were included with "progress reports," which were submitted after a grant was approved. But the most important point is that scattered references buried in voluminous accompanying materials do not comply with the application's disclosure requirements.

When a reviewer is faced with complex proposals that include large masses of accompanying information, it makes sense to insist that the applicants must disclose in one place the applicant's other grants that may raise conflicts of interests or impose competing demands on the applicant's time. A reviewer who is reading an applicant's accompanying journal article may not notice, while engrossed in the details of a specialized scientific issue, a fleeting reference to private funding and think of its significance for potential conflicts of interest. Applications distill and organize information for a reason.

Evidence in the record bears out this point. One of the review committee members, Perkell, stated in his affidavit that:

As a grant reviewer and evaluator I have always looked to the "Other Support" pages to form an estimate of the percentage of effort the Principal Investigator and other investigators have available to do the proposed work, to look for possible overlap between proposed projects and others already funded or pending, and to identify possible conflicts of interest or possible sources of bias in the experiments. These factors are important to me in evaluating an application as a whole and in assigning it a priority score.

App. at 472. Schwartz, another review committee member, likewise stated in her affidavit that she relies on the "Other

Support" section to gauge how much time the applicant has to spend on the research, whether the proposal is duplicative, and what conflicts of interest the applicant might have. Despite the references Bluestone cites in the accompanying materials, neither Schwartz nor Perkell was aware of Bluestone's industry funding, and both said it would have affected their evaluation of his application.

The District Court's last reason for concluding that Bluestone did not knowingly submit a false claim is that he sent a letter on June 23, 1987 to Elkins, his program administrator, listing his industry funding. We find the District Court's reliance on this letter unconvincing. Not only was it written months after Bluestone submitted his application in January and May of 1987, but more important, the letter was only sent after he was under investigation. Given that Bluestone only sent the letter after Cantekin made his allegations to the NIH and the university, the timing of the letter tends to reinforce, not undermine, Cantekin's allegations that Bluestone knew that he was supposed to disclose his industry funding. One can easily infer that the letter was not an expression of an honest oversight, but an attempt to cover up prior misconduct and limit its damage.

Cantekin alleges that program administrators' interests are more closely allied with grant applicants' than any other NIH official, so it is noteworthy that Bluestone chose to notify Elkins, and Elkins alone, at the NIH. Reading the evidence in the light most favorable to the nonmoving party, if Bluestone calculated that disclosure to Elkins would be the least damaging step he could take, his judgment apparently proved correct since the letter he sent to Elkins was never forwarded beyond the program-administration offices.

Another problem with relying on Bluestone's letter to Elkins as a way of exonerating him for submitting a false claim is that the False Claims Act has a specific provision dealing with someone who comes forward and discloses his or her false claims. The statute provides that:

[I]f the court finds that --

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

31 U.S.C. S 3729(a)(7).

The first point worth noting is that this provision merely reduces the defendant's liability from treble to double damages; it does not exonerate a defendant for a violation. Second, Bluestone's letter of June 23 was more than 30 days after the date he made his false statements. Third, Bluestone's letter was sent after he was under investigation, and thus he arguably cannot satisfy subsection (C). It also may be open to dispute whether he has "fully cooperated" or provided "all information" that he knew about the violation.

Taking up a different issue, the District Court cited *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996) for the proposition that a "technical violation of rules and regulations of an agency is not actionable under the FCA." App. at 1627. What the Ninth Circuit held in *Hopper*, however, was that not every regulatory violation is tantamount to making a knowingly

false statement to the government. Since the regulatory violation in Hopper did not involve making a knowingly false statement in a claim submitted to the government, the court held there was no violation of the False Claims Act. Thus, Hopper does not stand for the proposition that before a court allows a suit to proceed under the False Claims Act, it must weigh how serious it thinks a particular knowing falsehood was in a claim submitted to the government.

Although we reject the District Court's reading of Hopper, the Court's remark about "technical violations" suggests two slightly different objections: Bluestone's omissions were not material, and even if they were, they did not cause any damages to the government. We will consider first the materiality objection.

Courts have held that claims under the False Claims Act are subject to a judicially imposed materiality requirement. See, e.g., *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999). And the Supreme Court recently held in *Neder v. United States, _U.S._*, 119 S.Ct. 1827 (1999) that there is a materiality requirement under the federal mail-fraud, wire-fraud, and bank-fraud statutes. In a footnote, the Supreme Court indicated, however, that the term "false statement," unlike "fraudulent statement," does not imply a materiality requirement. *Neder*, 119 S.Ct. at 1840 n.7. Given that the False Claims Act prohibits merely making a knowingly false claim and does not require a specific intent to defraud, perhaps *Neder* argues against a materiality requirement. In any event, we need not decide whether there is a materiality requirement under the False Claims Act, because even if there is, we think it is clear that Bluestone's failure to disclose his industry funding would readily qualify as material. In *Neder*, the Supreme Court quoted from the Restatement (Second) of Torts, which provides two alternatives for showing that a matter is material:

(a) a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question: or

(b) the maker of the representation knows or has reason to know that its recipient regards or is likely to

regard the matter as important in determining his choice of action, although a reasonable man would not so regard it.

Neder, 119 S.Ct. at 1840 n.5 (quoting Restatement (Second) of Torts S 538 (1976)).

As recounted above, industry funding is relevant for assessing conflicts of interest, how much time an applicant has to devote to the requested NIH grant, and how the research fits within a broader research program. Because the NIH specifically requests the information on its form, and because the value of this information is readily apparent, we think that the information is material: a reasonable NIH grant applicant would know that the NIH regards the information as important.

We turn now to the issue of damages. Even if the letter to Elkins does little to undermine Cantekin's claim that Bluestone knowingly submit false claims, the appellees argue that the letter still shows that his earlier failure to disclose caused no harm. Bluestone sent the letter to Elkins on June 23, 1987, but his pending post-1986 application was not finally approved until February 4, 1988, when he was awarded \$321,137. The appellees argue, therefore, that no harm could have been caused because Bluestone disclosed his industry funding before any grant money was dispensed for his post-1986 grant application.

The first problem with this argument is that, as noted above, the letter to Elkins never left the program-administration offices, so the information about Bluestone's industry funding never reached the review committee or any other decisionmaker involved in approving Bluestone's grant. Thus, we do not know whether the review committee or the council of the institute would have approved the grant if they had known about the information included in the letter. Given that two committee members who reviewed Bluestone's application in 1984 and 1985 would have assigned lower priority scores to his application, and given that one member's vote can effectively deny funding, we think whether the grant would have been approved and what damages were incurred raise genuine factual

disputes. We also want to point out that even if the review committee and council would have approved the application once they knew about the industry funding, they still might have imposed additional safeguards or requirements. Having not been informed, they did not have an opportunity to consider these other intermediate steps.

It may seem unfair to hold Bluestone accountable for the decision made in the program-administration offices not to pass along Bluestone's letter. As noted above, however, the statute expressly provides a mechanism for dealing with a defendant who reveals his false claim. Since this provision merely reduces the defendant's liability for the damages actually caused, and since, in any event, Bluestone may not satisfy the prerequisites, Bluestone remains liable for the harm that in fact was caused to the government as a result of his false statements.

It is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes. See, e.g., W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* S 44 (5th ed. 1984). Analysis of intervening causes is often used as a way of evaluating and assigning responsibility for harm caused. *Id.* Given that Bluestone only sent his letter after he was under the pressure of investigation, his letter does little to lessen his culpability, and therefore, the fact that the letter was not forwarded is not plausibly treated as an intervening cause. To the extent that analysis of intervening causes focuses on the foreseeability of a putative intervening cause, we think it is significant that Bluestone chose to send the letter to Elkins, his program administrator, who did not decide whether he would receive funding for his application. Bluestone did not, for instance, submit another revised application as he did earlier in the spring. In short, the fact that the letter was not forwarded was a risk that Bluestone assumed when he submitted the claims.

The appellees have directed our attention to several cases discussing causation requirements under the False Claims Act. In *United States v. First Nat'l Bank of Cicero*, 957 F.2d 1362 (7th Cir. 1992) the court held that the government

only needed to show that it would not have made a payment "but for" the false statement. In reaching that holding, the Seventh Circuit expressly disagreed with *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977), which, according to Cicero, imposed a more stringent causation requirement. Specifically, Cicero said that in addition to requiring that the government would not have paid the claim but for the false statement, Hibbs effectively held that the "subject matter of the false statement . . . be the source of the government's loss." 957 F.2d at 1373 (citing Hibbs, 568 F.2d at 349, 351). We need not decide either whether Hibbs should be read as imposing such a requirement, or whether Hibbs is consistent with the changes made in the False Claims Act since that decision. We think it suffices to point out that both standards can be satisfied: as we concluded in our discussion of damages, Cantekin has presented evidence that Bluestone's grant might not have been approved but for his false statements about his industry funding (or that the grant would have been approved with additional restrictions or requirements). And the content of Bluestone's omissions about his industry funding could have made the difference in whether his grant was approved or not, so even under the Seventh Circuit's reading of Hibbs, the "subject matter of the false statement" could have been the source of the government's loss.

IV

For the foregoing reasons, we will affirm the order of the District Court dated February 9, 1998 and reverse the order dated September 4, 1998. Each party to bear its own costs.

STAPLETON, Circuit Judge, concurring:

Because, in my view, (1) the uncontradicted evidence establishes that responsible government employees knew of the private funding and alleged conflict of interest prior to the effective date of the Grassley Amendments; (2) the instructions to applicants are clear and unambiguous on their face; and (3) Dr. Cantekin's affidavit alone establishes a dispute of fact as to whether Dr. Bluestone knowingly submitted false claims, I join the judgment of the Court.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit