Nos. 13-1088, 13-1089

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

UNITED STATES OF AMERICA ex rel. HELEN GE,

Plaintiff-Appellant,

v.

TAKEDA PHARMACEUTICAL CO.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE UNITED STATES

These cases involve allegations that defendant Takeda Pharmaceutical Company is liable under the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, for failing to comply with a federal statute that requires drug manufacturers to report to the Food and Drug Administration ("FDA") adverse events associated with drugs that they manufacture. The district court dismissed the relator's complaints, concluding that she failed to plead her claims with sufficient particularity and to state a claim upon which relief could be granted. In concluding that the relator failed to state a claim, the district court indicated that the existence of a regulatory mechanism that allows citizens to petition FDA could preclude liability under the FCA. The district court further suggested that FCA liability could never be premised on a failure to comply with FDA's adverse event reporting requirements. Its reasoning on these points is mistaken, and were this Court to adopt such reasoning, the government's enforcement of the FCA could be significantly impaired.

Per Fed. R. App. P. 29(a), the government is participating as amicus curiae on appeal to provide the Court with its views on the proper interpretation of the FCA, which is the government's primary tool to combat fraud and recover losses due to fraud in federal programs. The United States takes no position on the district court's fact-bound dismissal of the relator's complaints under Fed. R. Civ. P. 9(b). If the Court agrees with the district court's disposition of that issue, there would be no need to resolve the issues underlying the court's ruling under Rule 12(b)(6) that we address here.

STATEMENT OF FACTS

A. THE FALSE CLAIMS ACT

The False Claims Act, 31 U.S.C. § 3729, *et seq.*, prohibits the submission of false or fraudulent claims for payment to the United States or the making of false statements for the purpose of causing a false claim to be paid. A violation of the FCA occurs, *inter alia*, when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

In addition, the FCA prohibits a variety of related practices involving government funds and property. *See* 31 U.S.C. § 3729(a)(1)(A)-(G). A person who violates the FCA is liable to the United States for civil penalties and for three times the amount of the government's damages. 31 U.S.C. § 3729(a)(1).

Suits to collect statutory damages and penalties may be brought either by the Attorney General of the United States, or by a private person (known as a relator) in the name of the United States, in an action commonly referred to as a *qui tam* suit. 31 U.S.C. § 3730(a) and (b)(1); *see also Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 769-78 (2000). When a *qui tam* action is filed, the government may intervene and take over the case "within 60 days after it receives both the complaint and the material evidence and information," 31 U.S.C. § 3730(b)(2), or "at a later date upon a showing of good cause," 31 U.S.C. § 3730(c)(3). If the government declines to intervene, the relator conducts the litigation, and if a *qui tam* suit results in civil penalties, those penalties are divided between the government and the relator. 31 U.S.C. § 3730(d).

B. OTHER STATUTORY PROVISIONS

1. Under the Federal Food, Drug, and Cosmetic Act, FDA must approve a new drug as safe and effective for the intended use before a manufacturer may market the drug in the United States. *See* 21 U.S.C. § 355. Pharmaceutical companies that market drugs with approved applications are required to forward reports of adverse events associated with such drugs to FDA. *See* 21 C.F.R. §§ 314.80, 314.98(a); *see also* 21 U.S.C. §§ 355(k), 331(e). Serious and unexpected adverse event reports must be submitted to FDA within 15 calendar days from the initial receipt of information. *See* 21 C.F.R. § 314.80(c)(l)(i). All other previously known adverse events, including serious events already accounted for in a drug's labeling, are conveyed to the FDA via periodic reports. *See id.* § 314.80(c)(2). If a pharmaceutical company fails to comply with the adverse event reporting requirements, FDA may initiate proceedings to withdraw approval of the drug, seek an injunction, or pursue criminal prosecution. *See* 21 U.S.C. §§ 332, 333(a), 355(e).

2. FDA approval is relevant to reimbursement for drugs under some government programs, including the Medicare program administered by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services, and the Medicaid program, administered jointly by CMS and the States. For example, statutory provisions concerning coverage of outpatient drugs under the Medicaid program and the Medicare Part D voluntary insurance program for self-administered prescription drugs generally make FDA approval a precondition for coverage and payment (with certain narrow exceptions). *See* 42 U.S.C. § 1396r-8(k)(2)(A) (Medicaid Drug Rebate Program, defining "covered outpatient drug"); 42 U.S.C. § 1395w-102(e)(1) (Medicare Part D, defining "covered part D drug"). For Medicare Part B's medical insurance program, CMS has set out interpretive guidance making reimbursement generally contingent on FDA approval.[1] *See* Medicare Benefit Policy Manual, CMS Pub. 100-2 ("Medicare Manual"), Chap. 15, Section 50.4,

[1] This guidance does not govern reimbursement for drugs used in an anticancer chemotherapeutic regimen. *See* Medicare Manual, Section 50.4.5.

available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html (last checked Aug. 1, 2013).

C. PROCEEDINGS IN THIS CASE

Relator Helen Ge commenced these *qui tam* actions against her former employer, Takeda Pharmaceuticals Co. ("Takeda"), alleging that Takeda failed to report adverse events associated with several drugs that Takeda manufactures, in violation of applicable FDA requirements. *See* Appendix 12, Second Amended Complaint (SAC), Docket # 17, Case No. 10-11043 (D. Mass.); Appendix 128, Second Amended Complaint, Docket # 28, Case No. 11-10343 (D. Mass.). The relator alleged that "[h]ad Takeda not submitted false reports or records to the FDA, the FDA would have either withdrawn approval of Actos, or would not have recommended Actos as the safer alternative to Avandia [a competing drug], which at minimum, would have resulted in far fewer submissions of claims for Actos to Government Healthcare Programs." Appendix 44-45, Docket # 17, ¶ 91, Case No. 10-11043; *see also* Appendix 191, Docket # 28, ¶ 162, Case No.

11-10343. The relator brought claims under the False Claims Act, alleging that Takeda had "knowingly caus[ed] to be presented false claims to Government Healthcare Programs" by healthcare providers and states, as well as conspired to defraud the government. *See* Appendix 72-74, Docket # 17, ¶ 161-176, Case No. 10-11043 (citing 31 U.S.C. § 3729(a)(1)(A), (B), (C)); *see also* Appendix 193-195, Docket # 28, ¶ 167-182, Case No. 11-10343. In both cases, the United States declined to intervene. *See* Appendix 2, Docket # 13, Case No. 10-11043; Appendix 7, Docket # 11, Case No. 11-10343.

The district court granted Takeda's motion to dismiss. *See* Addendum 64-76, Docket # 45-46.[2] The court held that the relator failed to state her claim with the requisite specificity under Rule 9(b), because she "failed to allege the specific details of any claims that were allegedly rendered 'false' as a result" of the alleged fraud on FDA. *See* Addendum

[2] On the parties' joint motion, the relator's two cases were transferred to be handled by the same judge. *See* Docket # 29, 32, Case No. 11-10343 (D. Mass.). Subsequent filings, including the district court's order granting that motion, were consolidated, with identical versions filed separately in each case. *See* Docket # 24, 25, 45-46, Case No. 10-11043; Docket # 34-35, 44, Case No. 11-10343.

71-72. The court further rejected the relator's theory that "all of the claims for these particular drugs in the relevant years were rendered false by Takeda's failure to properly report adverse events," reasoning that the relator had not made specific factual allegations to support an inference that FDA would have withdrawn approval from all four drugs immediately upon receiving the proper adverse reports. *Id.* at 72 (noting that FDA is not required to withdraw approval in response to failures to report).

Next, the court concluded that the relator had failed to state a claim under Rule 12(b)(6). Addendum 73-74. The court reasoned that the relator had not made out a claim that defendant had "misrepresented compliance with a material precondition of payment." *Id.* at 73. The court characterized the relator as alleging "that every claim for the drugs at issue contained an implied representation of compliance with these reporting requirements." *Id.* The court agreed that claims may be false under the FCA based on an implied representation of compliance with a precondition of payment, but suggested that the relator's complaints were insufficient

because she "relies on a blind, unsupported assertion that the claims at issue included such an implied representation as to compliance with reporting requirements." *Id.* at 73-74. The court went on to "[a]ssum[e] that the unspecified claims . . . do include such an implied representation." *Id.* at 74. However, the court concluded that it was "simply not the case" that "compliance with the reporting requirements was a material precondition of payment," suggesting that this was the case because the FDA "has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements," and need not impose the harshest remedy of withdrawal of a drug's approval. *Id.* The court pointed to FDA "enforcement procedures" that it concluded "have for many years allowed for citizens to petition FDA to bring action against specific violators," and stated that "[i]t is through that mechanism, rather than an FCA lawsuit, that relator should have brought the reporting issues illuminated in the complaints to the attention of the FDA." *Id.* Thus, the court dismissed the complaints under Rule 12(b)(6) "[b]ecause relator has not adequately established that compliance with adverse-event

reporting procedures was a material precondition to payment of the claims at issue." *Id.*

The relator filed an unsuccessful motion for reconsideration. Docket # 48. These appeals followed.

SUMMARY OF ARGUMENT

As explained below, the district court erred in significant aspects of its legal analysis. Under the False Claims Act, a false statement is material if it has "a natural tendency to influence" or is "capable of influencing" the government's decision to provide federal funds or property. Accordingly, where a defendant misrepresents its compliance with a legal requirement that authorizes the government to deny payment, that statement is material, even if the government had the discretion to consider other enforcement alternatives other than withholding payment.

For this reason, to the extent that the court considered the existence of alternative administrative mechanisms for uncovering or remedying fraud relevant to the existence of False Claims Act liability, it was mistaken. The False Claims Act has no exception to liability where a particular agency has

discretion to pursue administrative remedies for the alleged fraudulent conduct or where a whistleblower has multiple mechanisms for alerting the government to a potential fraud.

For similar reasons, the district court also erred in suggesting that a drug manufacturer's failure to report adverse events to FDA, as required by federal law, could never form the basis of False Claims Act liability. Although rare, there are circumstances where such failures could trigger liability under the Act. For example, if the unreported adverse events are so serious that the FDA would have withdrawn a drug's approval for all indications had these events been properly reported, the failure to report would be material to the government's payment decisions concerning claims under the Medicare and Medicaid programs, since claims for drugs for which FDA approval has been withdrawn are ineligible for payment under these programs. Under such circumstances, False Claims Act liability could exist, and the district court erred in suggesting a *per se* rule against liability based on the failure to report adverse events to the FDA.

ARGUMENT

I. A FALSE STATEMENT IS MATERIAL IF IT HAS A NATURAL TENDENCY TO AFFECT, OR IS CAPABLE OF AFFECTING, THE GOVERNMENT'S PAYMENT DECISION.

Under the FCA, liability exists for knowingly causing a third party to submit a false or fraudulent claim for payment or knowingly causing a false statement material to such a claim. *See* 31 U.S.C. § 3729(a)(1)(A) & (B). A false statement is "material" if it has a natural tendency to influence, or is capable of influencing, the government's payment decision. *See id.* § 3729(b)(4). A false statement that "is integral to a causal chain leading to payment" may prompt FCA liability, even where that statement is not included in the actual claim for government funds. *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (concluding that where such a "causal chain" exists, "it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork").

The statute covers not only affirmative false statements, but also material omissions. *See United States v. TDC Mgmt. Corp., Inc.*, 288 F.3d 421, 426 (D.C. Cir. 2002). Moreover, a false statement need not be made directly

to the agency responsible for making payment decisions in order to give rise to FCA liability. *See United States v. Caremark, Inc.*, 634 F.3d 808, 817 (5th Cir. 2011) (concluding that FCA liability could be based on defendant's false statements to state Medicaid agencies that would cause those state agencies to impair their obligations to the federal government)[3]; *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 16 (D. Mass. 2007) (noting that "the FCA covers indirect bilking of the federal government" and concluding that FCA liability could exist where "the submission by doctors and pharmacists of false pharmaceutical claims to Medicare and Medicaid was not only a foreseeable and substantial factor in

[3] *Caremark* concerned the pre-2009 version of 31 U.S.C. § 3729(a)(7), which then imposed liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." Congress amended § 3729 in 2009, *see* Pub. L. No. 111-21 § 4, 123 Stat. 1617, and a similar provision is now codified at 31 U.S.C. § 3729(a)(1)(G), imposing liability for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government." As with claims under § 3729(a)(1)(A) and (B), neither § 3729(a)(7) nor its successor contains any requirement that a false statement be made directly to the government entity responsible for payment decisions.

the government's loss, but also it was an intended consequence of the alleged scheme of fraud") (internal quotation marks omitted).

Thus, where a defendant makes a false statement about its compliance with a legal requirement that authorizes the government to deny payment, the defendant has made a material misrepresentation that can give rise to FCA liability, regardless of whether the government would have withheld payment, or pursued some other course, had it been aware of the defendant's noncompliance. An agency's decision to continue funding even after discovering a misrepresentation does not preclude the conclusion that the misrepresentation had a natural tendency to affect the government's payment decision. *See United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 916-17 (4th Cir. 2003) (reasoning that materiality depends not on effect of falsehood when discovered, but rather on "whether a false statement has a 'natural tendency' or is 'capable of influencing' a government funding decision," and noting that FCA liability may exist even where "a government entity might choose to continue funding the contract despite earlier wrongdoing

by the contractor"). Thus, the key question is not whether, in light of the defendant's false statement about its compliance, the agency did or had to deny payment, but rather whether the agency was permitted to deny payment. If so, then the defendant's false statement had a natural tendency to affect the government's payment decision and may serve as a basis for FCA liability.

II. ALTERNATIVE ADMINISTRATIVE REMEDIES DO NOT PRECLUDE FALSE CLAIMS ACT LIABILITY.

Consistent with these principles, the existence of alternative administrative remedies or mechanisms to report fraud does not affect, let alone preclude, the availability of False Claims Act liability, and to the extent the district court concluded otherwise, it erred. *See* Addendum 74 (pointing to FDA-specific citizen petition provisions, *see* 21 C.F.R. §§ 10.25(a), 10.30, and stating that "[i]t is through that mechanism, rather than an FCA lawsuit, that relator should have brought the reporting issues illuminated in the complaints to the attention of the FDA").

The text of the FCA provides no exemption from liability simply because there exists a parallel, agency-specific mechanism for uncovering

or addressing fraud. *See* 31 U.S.C. § 3729 (imposing liability on "any person" who commits various forms of fraudulent activity). However, the FCA does specify an "exclusion" for "claims, records, or statements made under the Internal Revenue Code of 1986," *id.* § 3729(d), and bars certain *qui tam* actions, including those "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party," *id.* § 3730(e). These exceptions indicate Congress' ability to narrow the realm of FCA liability when it wants to do so, and its intent to so narrow FCA liability only in the specified circumstances. *See, e.g., Commissioner of Internal Revenue v. Clark*, 489 U.S. 726, 739-40 (1989) ("In construing [statutory] provisions . . . in which a general statement of policy is qualified by an exception, we usually read the exception narrowly in order to preserve the primary operation of the provision."); *A.H. Phillips, Inc. v. Walling*, 324 U.S. 490, 493 (1945) (cautioning against extending statutory exemptions "to other than those plainly and unmistakably within its terms"). Otherwise, as the expansive language of the FCA indicates,

Congress intended the FCA to "'broadly . . . protect the funds and property of the Government from fraudulent claims.'" *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (quoting *Rainwater v. United States*, 356 U.S. 590, 592 (1958) ("By any ordinary standard the language of the Act is certainly comprehensive enough to achieve this purpose.")).

Indeed, Congress has made clear that it intends to allow the government to choose among various remedies, both statutory and administrative, to combat fraud in federal programs. In 1986, in the same month that Congress amended the FCA, it also enacted the Program Fraud Civil Remedies Act ("PFCRA"), an administrative remedy which expressly imposes liability for the submission of false claims. *See* 31 U.S.C. § 3802(a)(1). The PFCRA creates administrative remedies for false claims "in addition to any other remedy that may be prescribed by law." 31 U.S.C. § 3802(a)(1); *see also Vermont Agency of Natural Resources*, 529 U.S. at 786 n.17 ("[T]here is no question that the PFCRA was designed to operate in tandem with the FCA. Not only was it enacted at virtually the same time as the FCA was amended in 1986, but its scope is virtually identical to that of the

FCA."). Thus, the PFCRA provides further evidence that Congress saw no conflict between allowing the government multiple options – be they through agency-specific regulatory remedies or the government-wide mechanisms of the PFCRA or FCA – to combat fraud in government programs.

On the other hand, there is no evidence of congressional intent to make the availability of an action under the FCA turn on whether the alleged conduct might also be addressed through regulatory schemes, such as FDA's citizen petition provision. Indeed, the Eighth Circuit recently held that a complex regulatory regime at the disposal of the Department of Education did not render FCA liability unavailable in connection with failure to comply with Education regulations. *See United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410 (8th Cir. 2012). The Eighth Circuit made clear that "a complex regime of regulatory sanctions" did not "preclude[] the Attorney General from suing under the FCA," and "agree[d] with the government that 'Congress intended to allow

the government to choose among a variety of remedies, both statutory and administrative, to combat fraud.'" *Id.* at 415.

Thus, False Claims Act liability may be present regardless of whether the agency has the discretion to also pursue administrative remedies for the alleged fraudulent conduct and regardless of whether a whistleblower has multiple mechanisms, including FDA's citizen petition provision, for alerting the government to a potential fraud. [4]

III. FCA LIABILITY MAY IN RARE INSTANCES RESULT FROM FAILURE TO COMPLY WITH FDA ADVERSE EVENT REPORTING REQUIREMENTS.

The district court erred to the extent it stated that a failure to report adverse events associated with a drug to FDA could never be material to a government entity's decision to pay claims for that drug, and thus could never serve as the basis of FCA liability. *See* Addendum 74 (indicating that it was "simply not the case" that "compliance with the reporting requirements was a material precondition of payment"). Although likely

[4] Potential relators can, of course, notify FDA directly of a company's failure to report adverse events via FDA's regional consumer complaint coordinators or via the Center for Drug Evaluation and Research's Division of Drug Information, and the Department of Health and Human Services encourages them to do so.

to occur rarely, there are circumstances in which such failures will be material to the government's decision to pay claims the defendant has caused to be submitted, thus triggering FCA liability.

Simply alleging that a company failed to comply with FDA's adverse event reporting requirements is insufficient to state an FCA claim. However, it is possible that a failure to disclose adverse events to FDA, as required by federal law, will be material to governmental decisions to pay claims for the associated drugs, and thus may trigger FCA liability. Such a failure may in certain circumstances cause the government to pay claims for drugs that, had there been compliance with FDA's reporting requirements, would have been ineligible for payment.

The statutes establishing criteria for reimbursement by CMS for the Medicare and Medicaid programs illustrate this possibility. Compliance with the adverse event reporting requirements is not, in itself, a material precondition of payment under Medicare or Medicaid; reimbursement for prescription drugs is not conditioned on a pharmaceutical company's compliance with these requirements. However, where the concealed

adverse events are so serious and unexpected that FDA, would have, for example, withdrawn its approval of the drug for all indications had it known about the concealed information, claims for reimbursement for that drug would be ineligible for payment.[5] Reimbursement under Medicare and Medicaid is generally contingent on the drug's approval by FDA as safe and effective for at least one indication. *See* 42 U.S.C. § 1396r-8(k)(2)(A) (Medicaid requirement that a drug receive FDA approval as a precondition of payment, with certain narrow exceptions); 42 U.S.C. § 1395w-102(e)(1) (Medicare Part D, same); Medicare Benefit Policy Manual, CMS Pub. 100-2, Chap. 15, Section 50.4 (Medicare Part B).[6]

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[5] There may also be other circumstances in which a failure to report adverse events could prompt agency action that would lead to claims for reimbursement for the relevant drugs becoming ineligible for payment. This brief does not attempt to provide an exhaustive catalog of viable theories of FCA liability.

[6] The exceptions to the general requirement that a covered outpatient or Part D drug have FDA approval as a condition of CMS reimbursement would not extend to situations where a covered outpatient or Part D drug was required to receive FDA approval in order to be marketed in the United States, the manufacturer obtained such approval, and then such approval was withdrawn. *See* 42 U.S.C. § 1396r-8(k)(2)(A)(ii), (iii) (establishing exceptions to Medicaid's definition of "covered outpatient

Continued on next page.

Where CMS would not have paid claims for a particular drug had adverse events been properly reported, the failure to report adverse events to the FDA would be an omission capable of influencing the payment of the claim by CMS, thus triggering FCA liability. This is true even though the claims submitted to the government would be rendered false or fraudulent by a "multi-stage process." *Main*, 426 F.3d at 916. As the Seventh Circuit explained, fraud in the first stage of a "multi-stage process" leading to the submission of ineligible claims may still incur FCA liability. *See id.* (concluding that a university's fraud in procuring a declaration of eligibility to participate in federal loan and grant programs – "phase one" – could render it liable under the FCA since subsequent claims submitted by students premised on that declaration – "phase-two applications" – "would not have been granted had the truth been told earlier, for all disbursements depended on the phase-one finding that the University was an eligible institution"). Thus, the district court erred to the extent that it suggested

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drugs" for certain drugs in use before 1962); 42 U.S.C. § 1395w-102(e)(1)(A) (incorporating the same exceptions into the definition of covered Part D drug).

there existed a bright line rule that failure to report adverse events can never serve as a basis for False Claims Act liability. *See* Addendum 74. As noted above, while it would be a rare circumstance where the nondisclosure of adverse events would be material to CMS's payment decisions, a *per se* bar to FCA liability is inappropriate.

CONCLUSION

For the foregoing reasons, this Court should reject the district court's reasoning to the extent it concluded that the existence of an alternative regulatory scheme that could bring fraud to light precludes FCA liability, and that failure to report adverse events to the FDA can never form the basis of FCA liability.

Respectfully submitted,

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AUGUST 2013

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Palatino Linotype, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) and 29(d) because it contains 3,849 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ Melissa N. Patterson
MELISSA N. PATTERSON

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2013, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Melissa N. Patterson
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