# UNITED STATES OF AMERICA Before the SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933 Release No. 11367 / March 12, 2025

SECURITIES EXCHANGE ACT OF 1934 Release No. 102646 / March 12, 2025

ADMINISTRATIVE PROCEEDING File No. 3-22462

In the Matter of

Allarity Therapeutics, Inc.

Respondent.

ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission ("Commission") deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act") and Section 21C of the Securities Exchange Act of 1934 ("Exchange Act") against Allarity Therapeutics, Inc. ("Allarity" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings, Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds<sup>1</sup> that:

<sup>&</sup>lt;sup>1</sup> The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

#### **Summary**

This matter involves disclosure failures by Boston-based biopharmaceutical company, Allarity Therapeutics, Inc. ("Allarity" or the "Company"). Between February 2020 and February 2022, through the conduct of certain former officers, these disclosure failures concealed from the public a harsh critique levied by the Food and Drug Administration ("FDA") about the approval prospects for Allarity's flagship cancer drug candidate, dovitinib. Specifically, in February 2020, the FDA recommended that Allarity *not* submit its proposed drug application seeking approval to market and sell dovitinib, because the data was insufficient, and instead conduct a new drug trial—something Allarity had no intention of doing. Rather than reveal the FDA's admonitions, Allarity made false and misleading claims about dovitinib's efficacy and likelihood of approval in its efforts to raise money from investors to stay afloat.

Ultimately, Allarity submitted its drug application on December 21, 2021, without conducting a new trial as recommended by the FDA. The Allarity press release announcing the submission of its drug application did not disclose that the FDA had advised against the submission. The same day Allarity submitted its drug application, Allarity announced that it had listed its stock on the NASDAQ stock exchange and secured a \$20 million investment from a single investor, largely premised on Allarity having a viable drug application for dovitinib. That investor, like the public, was unaware that dovitinib had no chance of approval absent a new trial.

Then, on February 18, 2022, Allarity revealed for the first time a problem with its drug application, announcing that the FDA had refused to even *review* the application. The next trading day, Allarity's share price closed down approximately 31%. As a result of the conduct described herein, Allarity violated Sections 17(a)(2) and (3) of the Securities Act and Section 13(a) of the Exchange Act and Rule 13a-11 thereunder.

#### Respondent

1. **Allarity**, a Delaware corporation, is a small biopharmaceutical company with a principal place of business in Boston, Massachusetts. From at least October 2020 to the present, Allarity maintained a U.S. office in Massachusetts. Before October 2020, Allarity maintained a U.S. office in Scottsdale, Arizona. Allarity's common stock is registered under Section 12(b) of the Exchange Act and has traded on the NASDAQ stock exchange under the symbol "ALLR" since December 21, 2021. Prior to December 2021, Allarity was a Danish company and operated under the names Oncology Venture A/S and Allarity Therapeutics A/S, both of which traded on a Swedish stock exchange.

#### **Relevant Individuals**

2. **Stefano R. Carchedi ("Carchedi")**, age 63, was the Chief Executive Officer ("CEO"), President, and Board Member for Allarity or its predecessor from September 2019 to June 2022, when he was terminated for the conduct described herein. Before joining Allarity, Carchedi worked in various senior positions, including as CEO, for numerous pharmaceutical companies since 1989. Currently, he serves as Chairman of the Board for a privately held

manufacturer and distributor of laboratory equipment. Carchedi is a resident of Lower Gwynedd, Pennsylvania.

- 3. **Marie L. Foegh ("Foegh")**, age 81, was the Chief Medical Officer of Allarity or its predecessor from May 2017 to March 2024. She is presently employed as a physician in Denmark, and as an independent pharmaceutical consultant and expert witness. She also currently serves as Chairman of the Board of a Danish pharmaceutical packaging company. She is a licensed medical doctor in the District of Columbia, Maryland, and Virginia. Foegh is a resident of New York City, East Patchogue, New York, and Denmark.
- 4. **James G. Cullem ("Cullem")**, age 55, was Allarity's CEO from June 2022 to December 2023. He was also the Chief Business Officer from December 2021 to June 2022, the Senior Vice President of corporate development from October 2019 to December 2021, and a board member from June 2022 to January 2024 for Allarity and/or its predecessor. Presently, he works for a consulting firm to the life sciences industry. He is a licensed attorney in Massachusetts and a resident of Newburyport, Massachusetts.

# **Background on the FDA Approval Process**

- 5. Before a drug can be marketed and sold in the U.S., a drug company must obtain approval from the FDA. According to the FDA, it will only approve a drug if it is safe and there is "substantial evidence" consisting of "adequate and well-controlled" trials demonstrating that the drug is effective for its intended use in humans. To demonstrate the safety and efficacy of a drug, pharmaceutical companies conduct human clinical trials in three phases. Phase III trials, the largest and most expensive of the three phases, are supposed to provide sufficient evidence of safety and efficacy to enable the FDA to evaluate the overall risk-benefit relationship of the drug.
- 6. Drug trials can be "superiority" trials (which seek to demonstrate that the test drug is *more* effective than the comparison drug) or "non-inferiority" trials (which seek to demonstrate that the efficacy of the test drug is within a clinically acceptable margin (the "non-inferiority margin") of the efficacy of the comparison drug). Per published FDA guidance, this "non-inferiority margin" must be specified before the trial begins to avoid the potential bias created by already knowing the trial results when the non-inferiority margin is set.
- 7. Typically, clinical trials for cancer drugs, like dovitinib, measure efficacy in terms of (1) overall survival ("OS") (the length of time from the start of treatment to patient death) or (2) progression-free survival ("PFS") (the length of time from the start of treatment and the earlier of tumor growth or patient death). Assessing tumor growth, and thus PFS, requires more subjectivity on the part of the investigator than OS; consequently, FDA guidance states that OS is the optimal endpoint.
- 8. If a pharmaceutical company believes it has generated sufficient evidence of safety and efficacy, it may seek approval to market and sell its drug to the public. It does so by submitting a New Drug Application ("NDA") to the FDA. Within 60 days of a company submitting an NDA, the FDA must either "file" the NDA, meaning the FDA deems it sufficiently complete to permit a substantive review, or issue a Refusal to File ("RTF") letter.

An RTF letter is typically reserved for circumstances where the NDA is incomplete because it does not on its face contain certain required information or where the required content is presented in an unusable form. An RTF also may be warranted when a single trial underpins a submitted NDA, but the FDA has advised the drug company previously that more than one trial would be required.

### **Dovitinib's Success was Material to Allarity**

- 9. Allarity is a biopharmaceutical company focused on pairing cancer drug candidates that have been abandoned or shelved by other companies with a proprietary genetic test Allarity developed (called the Drug Response Predictor), thus targeting patients most likely to benefit from a particular cancer drug. One such drug candidate was dovitinib.
- 10. Dovitinib originally was developed by another pharmaceutical company, Company A, for the treatment of advanced renal cell carcinoma, a particularly deadly form of kidney cancer. Company A ceased developing dovitinib after a 2013 Phase III trial failed to show that dovitinib was more effective than (or superior to) a comparator drug ("the Dovitinib Trial"). In 2018, Allarity licensed dovitinib from Company A.
- 11. Dovitinib's hoped-for approval by the FDA was material to Allarity because the company had yet to have a drug approved for sale to the public. As a result, at all relevant times, the estimated likelihood of dovitinib's success factored heavily into Allarity's business prospects. As Allarity itself acknowledged in 2021 public filings with the Commission: "[i]f we are unable to submit an NDA to the U.S. FDA for our therapeutic candidate dovitinib... or if we experience significant delays in doing so," or "[i]f we are unable to... receive marketing approval for... dovitinib...our business could be substantially harmed."

# **The FDA Admonishes Allarity**

- 12. On December 23, 2019, Allarity requested a meeting with FDA staff to discuss Allarity's analysis of the Dovitinib Trial data and the anticipated filing of the dovitinib NDA (the "FDA Meeting"). In its meeting request, Allarity communicated to the FDA its plan to rely on a retrospective, non-inferiority analysis of PFS from the Dovitinib Trial and solicited the FDA's feedback on various questions. Although this plan contravened published FDA guidance, Allarity chose to rely on a *non-inferiority* analysis of PFS because the Dovitinib Trial had already failed to show dovitinib was *superior* to the comparator drug on either PFS or OS.
- 13. The FDA responded in writing on February 14, 2020, saying in the preamble of the written comments: "We do not agree with your plan to submit an NDA based on a retrospective non-inferiority analysis of a trial that failed to demonstrate superiority. There are multiple issues with your proposal. . ." Those issues included Allarity's proposal to: 1) define the non-inferiority margin for their analysis *after* the Dovitinib Trial had concluded and 2) analyze PFS rather than OS. The FDA took issue with Allarity's analysis because it was susceptible to manipulation for two reasons: one, Allarity was proposing to define the non-inferiority margin for its analysis *after* it already knew the results of the Dovitinib Trial; and two,

Allarity was planning to assess the more subjective of the two study endpoints, PFS (rather than OS).

- Agency agree that the proposed clinical data supporting the proposed safety and efficacy claims are adequate to support the submission of the NDA for the proposed indication?" The FDA responded, "No," and referenced the preamble again. Allarity also specifically asked: "Does the Agency agree that this statistical approach is adequate to support the filing of dovitinib in the proposed indication?" The FDA again responded, "No." Indeed, for all eleven written questions posed by Allarity to the FDA, the FDA referenced back to the preamble in its responses, thereby putting Allarity on notice that the FDA was highly unlikely to even *accept* the dovitinib NDA for substantive review, much less *approve* it. As Allarity's Chief Science Officer noted in an email dated February 15, 2020, the published guidance referenced in the FDA's February 14, 2020 written response appeared to be an "insurmountable hurdle" because it prohibited the exact analysis Allarity planned to rely on in the dovitinib NDA.
- 15. On February 20, 2020, Allarity and consultants retained by Allarity met in person with FDA staff ("FDA Meeting"). The minutes of the FDA Meeting summarized the parties' main discussion points, stating: "FDA reiterated that unplanned determination of non-inferiority following failure to show superiority would not suffice for demonstrating non-inferiority of dovitinib and that PFS is not an appropriate endpoint for a non-inferiority trial. The FDA recommended that [Allarity] prospectively plan and conduct a new trial." In an email to an Allarity consultant dated May 6, 2020, Foegh described the FDA Meeting minutes as "pretty negative in terms of filing" with "[n]early every answer to our questions [ending] with Do not file the NDA."
- 16. Allarity's consultants who attended the FDA Meeting took notes of their own. One set of notes memorialized that:
  - a. "FDA essentially claimed that there was simply no efficacy (or, insufficient efficacy) with dovitinib,"
  - b. "sounded like FDA doesn't want to see dovitinib get on the market,"
  - c. "Several different times, and in different ways, FDA reiterated that the 'non-inferiority approach'...was invalid....FDA further stated that the 'use' of PFS and the definition of disease progression was invalid for / impossible to use with an NI approach."
  - d. "[Allarity] was told by FDA that . . . the possible submission of an NDA was 'delaying the inevitable."

#### A different consultant's notes observed that:

- e. "FDA reiterated its position that the trial that the NDA is based upon did not demonstrate superiority and that [Allarity] cannot now use the data and apply it to non-inferiority trial." [emphasis in original]
- f. "the [FDA] is asking [Allarity] not to submit the NDA," and
- g. "FDA stated that they do not currently advise submitting an application[.]"

# Allarity Did Not Disclose the FDA's Recommendations

- Allarity issued a press release on March 20, 2020, purporting to update the public on the FDA Meeting. However, this press release painted a wholly inaccurate and incomplete picture of the meeting. One, it falsely claimed: "FDA indicated that they would accept the NDA filing if submitted, and provided additional guidance regarding the submission[.]" In actuality, the FDA had recommended that Allarity not submit the dovitinib NDA and had threatened not to accept the NDA if it were filed. Two, the press release represented that: "[Allarity] plans to use the data from the [Dovitinib Trial] to prove that Dovitinib is in fact 'non-inferior' to [the comparison drug for the treatment of [renal cell carcinoma], and expects that Dovitinib will be approved by the FDA as a safe and efficacious drug[.]" In truth, the FDA had outright rejected this plan and told Allarity that dovitinib would not be approved on such data. Three, the press release stated that the FDA "provided input on the 'non-inferiority' margin" and "discussed progression free survival (PFS) as an endpoint for 'non-inferiority,'" but misleadingly omitted the FDA's *actual* input—i.e., that Allarity's proposed analysis was invalid and unusable. Finally, the press release failed to disclose the crux of the FDA's feedback—the recommendation that Allarity conduct a new trial prior to submitting its NDA. By omitting this information Allarity misrepresented the strength of the dovitinib NDA and its likelihood of approval.
- 18. On March 30, 2020, Allarity's Board of Directors met. Carchedi presented at the Board meeting, and, according to the Board minutes, falsely characterized the FDA Meeting as "positive"— withholding from the Board the FDA's admonishment not to submit the dovitinib NDA and instead conduct a new trial. At no point ahead of filing the dovitinib NDA in December 2021 did management ever alert the Board to the FDA's criticisms despite dovitinib's undeniable importance to Allarity's business prospects.
- 19. On February 16, 2021, Company A requested a copy of the FDA Meeting minutes. Rather than provide Company A with an unadulterated copy of the minutes pursuant to a non-disclosure agreement in place between the companies, Carchedi and Cullem undertook to redact any negative information from the minutes. When Cullem circulated the proposed redactions internally on March 5, 2021, he explained "I have redacted (blackout text) any of the FDA comments about unwillingness to accept non-inferiority etc." Cullem then sent Company A the heavily redacted version of the minutes on March 18, 2021.
- 20. On or about August 23, 2021 and November 23, 2021, Allarity published on its website two "Interim reports," one of which it also filed with the Commission, for the purpose of disclosing information about its proposed move from Denmark to the U.S. and the exchange of shares traded on the Swedish stock exchange for shares that would trade on NASDAQ. In the Interim reports, Allarity misrepresented that the FDA Meeting "provided guidance to the Company regarding its potential path to approval" and "[b]ased on this feedback from the FDA, Allarity plans to file a New Drug Application ("NDA") for the approval of dovitinib . . . during 2021" (emphasis added). This was misleading because the FDA's feedback had been *not* to submit the dovitinib NDA but instead to conduct a new trial. The Interim reports also misrepresented dovitinib as having "shown identical clinical activity to [the comparator drug]" in the Dovitinib Trial. This claim was misleading for three reasons: 1) Allarity's post-hoc, non-

inferiority analysis of the Dovitinib Trial did not even assess whether dovitinib had "identical clinical activity" to the comparator drug —a more exacting standard than non-inferiority; 2) it omitted that the Dovitinib Trial had failed to show dovitinib was *superior* to the comparator drug on either PFS or OS; and 3) it neglected to disclose that the FDA had rejected Allarity's proposal to use the Dovitinib Trial to demonstrate dovitinib's efficacy. In the Interim reports, Carchedi falsely stated that the Interim reports provided a "fair and true overview" of Allarity's "operations, financial position and results" and described the "material risks and uncertainties" faced by Allarity.

- On November 4, 2021, Allarity filed with the Commission a Form S-4 Registration Statement containing a prospectus in anticipation of listing its stock on NASDAQ. On December 16, 2021, Allarity filed with the Commission a Form S-1 Registration Statement containing a prospectus in connection with a \$20 million investment from an investor, allowing the investor to offer and sell the Allarity shares it would receive in exchange for its investment in the company. Both prospectuses touted dovitinib's purported "therapeutic equivalence to" the already-approved comparison drug and claimed the Dovitinib Trial had "established that dovitinib is non-inferior to [the comparison drug] with respect to PFS and OS." These statements were misleading because they omitted the FDA's professed disagreement with Allarity's efficacy claims. Further, the December 16 prospectus provided the false assurance that "we anticipate...approval of our [NDA]," even though the FDA had previously told Allarity that it did not agree with Allarity's plan to submit an NDA based on a retrospective non-inferiority analysis of the Dovitinib Trial. This same prospectus also listed the FDA's requirements for drug approval based on retrospective analyses, but misleadingly failed to mention that the FDA had told Allarity that the proposed dovitinib NDA had not met such requirements. Carchedi signed the Registration Statements for both prospectuses.
- 22. Throughout 2021, Allarity maintained and periodically updated a slide deck to use in discussions with investors and prospective investors. In this slide deck, Allarity falsely claimed dovitinib's efficacy had been demonstrated in a Phase III trial. Allarity provided a copy of this slide deck to a prospective investor in March 2021, and to at least two prospective investors in October 2021. One of these prospective investors ultimately invested \$20 million in Allarity in December 2021. Allarity's efficacy claim was misleading because the FDA expressly advised Allarity that the Dovitinib Trial could not be used to demonstrate dovitinib's efficacy for purposes of approval. The slide deck also misleadingly touted that Allarity had selected renal cell carcinoma as the lead indication ". . . for <u>fastest path to approval</u>" (emphasis in original) of the dovitinib NDA, but omitted the FDA's recommendation not to submit the dovitinib NDA at all and to instead conduct a new trial. This slide deck was also posted to Allarity's website and filed with the Commission as an exhibit to Form 8-K on January 18, 2022.
- 23. On December 21, 2021, Allarity submitted its NDA for dovitinib. The NDA did not contain data from a new trial, as recommended by the FDA, and was premised on an after-the-fact, non-inferiority analysis of the Dovitinib Trial, which the FDA had warned Allarity against using. Nevertheless, the press release issued by Allarity on December 22 heralding the milestone did not disclose the FDA's prior criticisms of the data, its admonishment not to submit the NDA, or its recommendation to conduct a new trial. Also, on December 21, Allarity announced it had secured \$20 million in funding from a single investor and that its stock had

begun trading on NASDAQ.

- 24. On January 27, 2022, FDA staff and Allarity spoke by phone. Referring back to its statements from the FDA Meeting, FDA staff again advised Allarity that the dovitinib NDA was riddled with issues—each of which would render it unapprovable—and recommended Allarity withdraw the NDA. Allarity refused, but never disclosed to investors that the FDA had recommended it withdraw the NDA.
- 25. As threatened, the FDA issued Allarity a RTF letter on February 15, 2022. Via the letter, the FDA declined to proceed with a substantive review of the dovitinib NDA because a retrospective, non-inferiority analysis of a failed superiority trial cannot be used to demonstrate PFS—the same warning the FDA had communicated to Allarity at the in-person FDA Meeting in 2020. When Allarity's Chairman of the Board received a copy of the RTF letter on or about February 18, 2022, he immediately emailed Cullem saying: "I'm interested to know who advised us to file against the crystal clear advice of the FDA." Cullem and Carchedi then spoke to the Chairman by phone and explained that securing the \$20 million investment in December 2021 had been crucial to Allarity avoiding bankruptcy and filing the NDA had been crucial to the investor providing funding.
- 26. On February 18, 2022, Allarity, for the first time, publicly revealed a problem with its NDA, announcing its receipt of the RTF letter. The press release again failed to disclose to investors that the FDA had threatened Allarity with this very outcome years before, in 2020. The next trading day, February 22, 2022, Allarity's stock price closed down approximately 31%—the largest one-day drop in the stock's history up to that point.
- 27. Allarity then abandoned its development of dovitinib as a stand-alone treatment for kidney cancer in or around August 2022.

# **Violations**

- 28. As a result of the conduct described above, Allarity violated Section 17(a)(2) of the Securities Act which proscribes, in the offer or sale of a security, obtaining "money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." In addition, as a result of the conduct described above, Allarity violated Section 17(a)(3) of the Securities Act, which proscribes, in the offer or sale of a security, engaging "in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."
- 29. Also as a result of the conduct described above, Allarity violated Section 13(a) of the Exchange Act and Rule 13a-11 thereunder, which require every issuer of a security registered pursuant to Section 12 of the Exchange Act to file with the Commission current reports on Form 8-K in compliance with applicable Commission rules and regulations.

# **Undertakings**

Respondent has undertaken to:

In connection with this action and any related judicial or administrative proceeding or investigation commenced by the Commission or to which the Commission is a party, (i) agree to use its best efforts to cause Respondent's current and former employees, officers, and directors to be interviewed by the Commission staff at such times and places as the staff requests upon reasonable notice; (ii) agree to use its best efforts to cause Respondent's current and former employees, officers, and directors to appear and testify truthfully and completely in such investigations, depositions, hearings, or trials as may be reasonably requested by the Commission staff; (iii) accept service by mail or email of notices or subpoenas issued by the Commission to Respondent for documents or testimony at depositions, hearings, or trials, or in connection with any related investigation by Commission staff; (iv) appoint Allarity's undersigned attorney as agent to receive service of such notices and subpoenas; (v) with respect to such notices and subpoenas, waive the territorial limits on service contained in Rule 45 of the Federal Rules of Civil Procedure and any applicable local rules, provided that the party requesting the testimony reimburses Allarity's travel, lodging, and subsistence expenses at the then-prevailing U.S. Government per diem rates; and (vi) consent to personal jurisdiction over Allarity in any United States District Court for purposes of enforcing any such subpoena.

In determining whether to accept the Offer, the Commission has considered these undertakings.

#### IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Allarity's Offer.

Accordingly, it is hereby ORDERED that:

- A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent Allarity cease and desist from committing or causing any violations and any future violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act and Section 13(a) of the Exchange Act and Rule 13a-11 thereunder.
- B. Respondent Allarity shall, within 30 days of the entry of this Order, pay a civil penalty of \$2,500,000 to the Securities and Exchange Commission. The Commission may distribute civil money penalties collected in this proceeding if, in its discretion, the Commission orders the establishment of a Fair Fund pursuant to 15 U.S.C. § 7246, Section 308(a) of the Sarbanes-Oxley Act of 2002. Such Fair Fund may be added to or combined with any other fair fund created in a related parallel proceeding arising from the same underlying facts as alleged herein. The Commission will hold funds paid pursuant to this paragraph in an account at the United States Treasury pending a decision whether the Commission, in its discretion, will seek to distribute funds or, subject to Exchange Act Section 21F(g)(3), transfer them to the general fund

of the United States Treasury. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717.

Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <a href="http://www.sec.gov/about/offices/ofm.htm">http://www.sec.gov/about/offices/ofm.htm</a>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center Accounts Receivable Branch HQ Bldg., Room 181, AMZ-341 6500 South MacArthur Boulevard Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Allarity Therapeutics, Inc. as the Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to John T. Dugan, Associate Director, Division of Enforcement, Securities and Exchange Commission, Boston Regional Office, 33 Arch Street, 24<sup>th</sup> Floor, Boston, MA 02110-1424.

C. Regardless of whether the Commission in its discretion orders the creation of a Fair Fund for the penalties ordered in this proceeding, amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman Secretary