UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

AH KIT TOO, Individually and on behalf of all others similarly situated,

Plaintiff,

vs.

ROCKWELL MEDICAL, INC., ROBERT L. CHIOINI, and THOMAS E. KLEMA,

Defendants.

No. 1:18-cv-04253

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

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Lead Plaintiffs Robert Spock and Duck Pond Partners LP (collectively, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Rockwell Medical, Inc. ("Rockwell" or the "Company"), Robert L. Chioini and Thomas E. Klema (collectively, "Defendants"), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Rockwell, analysts' reports and advisories about the Company, consultation with experts, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. This is a federal securities class action (the "Action") on behalf of a class (the "Class") of investors who purchased or otherwise acquired Rockwell securities between November 8, 2017 through June 26, 2018, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officers.

2. Rockwell operates as an integrated biopharmaceutical company targeting end-stage renal and chronic kidney diseases in the United States and internationally. The Company's lead branded drug is Triferic, an iron maintenance therapy that replaces the iron lost by patients during hemodialysis treatment.

3. For most of its history, Rockwell has been run de facto by a single individual, the founder, Defendant Robert L. Chioini ("Chioini"). Chioini, who was terminated during the Class Period, designed Rockwell such that critical information about the Company was often known only by him. He also designed the Company such that no effective checks on the Company's disclosures existed. Chioini divided the Company into informational and operational silos, and withheld critical information about the Company from certain members of the board and the Company's auditors.

4. Beginning in late 2015, Rockwell began to seek to have the Centers for Medicare & Medicaid Services ("CMS") (part of the Department of Health and Human Services), reimburse dialysis providers separately for their use of Triferic, rather than having CMS reimburse the providers for Triferic as part of a bundled payment for all goods and services provided in a standard dialysis treatment. Obtaining such separate reimbursement from CMS for this drug was critical to Rockwell's success—without such separate reimbursement, dialysis providers had no incentive (and indeed had financial reasons not) to adopt Triferic.

5. Throughout the Class Period, the Company misled investors to believe that its internal controls over financial reporting were adequate, when in fact Chioini was well aware that the Company's controls had a material weakness that could lead it to make material misstatements about its business. That material weakness ultimately resulted in significant harm to investors during the Class Period. While throughout 2016, 2017 and early 2018, Rockwell repeatedly assured investors that CMS was likely to approve separate reimbursement for Triferic, in late March 2018, CMS informed Rockwell definitively through Rockwell's CMS lobbyist that CMS would not be approving separate reimbursement. After learning of this critical rejection, Chioini failed to inform investors or the Company's auditor. In fact, the Company omitted this

information in public statements in April and May. For example, in its Quarterly Report for the first quarter of 2018, filed in mid-May, Rockwell continued to assure investors that CMS was likely to approve separate reimbursement for Triferic, even though the Company had been informed over a month earlier that CMS would not be approving such reimbursement. Moreover, Rockwell failed to make adjustments to its reserves to account for this development, and so knowingly misstated its reserves in its 2018 10-Q. These statements all flatly violated the securities laws.

6. On June 27, 2018, during pre-market hours, Rockwell disclosed that its public auditor, Plante & Moran, PLLC (Plante & Moran), resigned its position with the Company over Rockwell's pursuit of separate reimbursement status for Triferic. The disclosure attached a letter from Plante & Moran detailing the auditors' conclusions that Rockwell had made material misstatements in its 2018 10-Q as a result of its failure to disclose that CMS had denied separate reimbursement for Triferic.

7. On this news, Rockwell's stock price fell $0.85 per share, or over 16%, over two consecutive trading days to close at $4.41 per share on June 28, 2018, damaging investors.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

9. The claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and § 27 of the Exchange Act (15 U.S.C. § 78aa).

11. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). The Company conducts business, and a significant portion of Defendants' actions and subsequent damages took place, within this District.

12. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

13. Plaintiffs, as set forth in previously filed certifications, acquired Rockwell securities at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Rockwell is incorporated in Michigan and its principal executive offices are located at 30142 Wixom Road, Wixom, Michigan 48393. Rockwell's common shares trade on NASDAQ under the ticker symbol "RMTI."

15. Defendant Chioini founded Rockwell and served as its CEO from February 1997 until terminated on May 22, 2018.

16. Defendant Thomas E. Klema ("Klema") served as Chief Financial Officer, Treasurer and Secretary of Rockwell during the Class Period until terminated on May 25, 2018.

17. Defendants Chioini and Klema are sometimes collectively referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of the Company's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability

and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

A. Background

19. Rockwell operates as an integrated biopharmaceutical company targeting end-stage renal and chronic kidney diseases in the United States and internationally. The Company develops and markets products for use in hemodialysis treatment.

20. Hemodialysis treatment performs for patients the work of the kidneys. A dialysis machine dilutes concentrated solution with purified water to form a solution called "dialysate." Dialysate is pumped through an artificial kidney or filter (a "dialyzer") while the patient's blood is pumped through a semi-permeable membrane inside the dialyzer in the opposite direction the dialysate is flowing. The treatment typically infuses calcium, magnesium and potassium into the patient's blood and removes waste. A patient's physician chooses proper concentrations of dialysate ingredients based on the patient's individual needs. In addition to using dialysis concentrates for dialysate, dialysis providers also use other products such as blood tubing, fistula needles, dialyzers, drugs dressings, cleaning agents and other supplies. Rockwell sells concentrate for dialysate, as well as many of the other products used in dialysis treatment.

21. A common side effect of dialysis treatment in chronic patients is iron deficiency anemia. The Company's lead branded drug, Triferic, is an iron maintenance therapy that replaces the iron lost by patients during hemodialysis treatment. The Company claims Triferic

has clinical benefits over current iron replacement treatments. While humans need iron, free iron is toxic and can cause inflammation, infection, and other complications. Accordingly, iron must be bound to a protective shell, called a ligand, for safe transportation within the body. Triferic iron is bound to pyrophosphate, which serves as a ligand for iron. Also, unlike nurse IV iron administration, Triferic is administered via dialysate directly to the bone marrow, delivering iron in a manner that potentially avoids iron storage in the liver. Triferic is formulated to replace the five to seven milligrams of iron that is lost during every dialysis treatment.

22. Under Section 1881(b)(14) of the Social Security Act, which became effective in 2011, CMS reimburses dialysis providers at a flat "bundled" rate that covers all the goods and services provided in a standard dialysis treatment. That is, dialysis providers receive a single payment per dialysis treatment; CMS does not reimburse providers for individual drugs, such as Triferic, included in the bundle of goods and services given to patients in dialysis treatment. Accordingly, a dialysis provider gains nothing, other things being equal, by switching from one component in the dialysis bundle to another clinically superior version of that component—CMS would reimburse the provider the same amount even if it provided patients a clinically superior drug as part of their dialysis treatment.

23. Indeed, for a dialysis provider to convert its operations to implement a new drug in their treatments is costly. Accordingly, dialysis providers have an incentive not to adopt new drugs that merely offer improved clinical benefits.

24. To address this problem, when implementing its bundled reimbursement scheme, CMS created a formal pathway, called the Transitional Drug Add-on Payment Adjustment (codified at 42 C.F.R. 413.234(c)), for new innovative therapies to receive "separate reimbursement" or a "transitional payment" (a separate payment from CMS outside of the

bundled payment) for a 2-year period so that dialysis providers would have an incentive to make those therapies available to patients.

B. Defendant Chioini Systematically Kept Key Information about Rockwell to Himself and a Few Loyalists, Leaving Rockwell with Inadequate Disclosure Controls at All Relevant Times

25. Chioini founded Rockwell and took the Company public pursuant to a governance structure that guaranteed that he would retain near-total control of the Company. Chioini served as both CEO and Chairman of the board. As the Company itself recently admitted in its counterclaim ("Rockwell's Counterclaim" or "Counterclaim") in a suit by Chioini against the Company,[1] Chioini installed a board of directors consisting of individuals close and loyal to Chioini (which Rockwell has labelled in its Counterclaim his "cronies") who had little experience in the industry and little reason beyond their loyalty to Chioini to serve as board members. Chioini staggered shareholder director elections so as to preclude a large proportion of the board from being replaced at any time.

26. As Rockwell has stated in Rockwell's Counterclaim, in managing Rockwell, Chioini kept employees in "informational and organizational silos," and strongly discouraged information sharing amongst members of the organization so that no one except Chioini and Klema had a clear picture of the Company's full operation or short and long-term business strategies. "To the extent that Rockwell had any long-term strategic plan or annual business plan under Chioini, it was completely in his (and potentially Klema's) mind."

27. Rockwell's board, led by Chioini's "cronies," certainly provided no check on his disclosures. For example, board members Patrick Bagley and Ronald Boyd personally oversaw at least one investigation into their own misconduct alleged by a shareholder who submitted a

[1] Rockwell Medical Inc.'s Answer, Affirmative Defenses, Counterclaims, and Jury Demand [ECF No. 5], *Chioini v. Rockwell Medical*, No. 2:18-cv-11884 (E.D. Mich. July 2, 2018).

bona fide shareholder demand. Chioini and these members of the board concealed the existence of this "investigation" into the shareholder demand for years, and ultimately exonerated themselves.

28. As a result of this siloing, and this consolidation of material information about the Company and its status and direction by the Individual Defendants, Rockwell manifestly lacked a system designed to ensure the effectiveness of the Company's disclosure controls and procedures. The Company was designed such that critical information about the Company could be known only to Chioini, and no effective auditing or other systemic controls existed to ensure that he disclosed such critical information about the Company to investors pursuant to applicable laws and regulations.

C. Rockwell's Attempted Launch of Triferic in September 2015 Failed Because It Had Not Obtained Separate CMS Reimbursement for Triferic

29. In September 2015, Rockwell announced that it was launching Triferic commercially. In October 2015, CMS released final rules detailing reimbursement policies for services provided to Medicare beneficiaries, and Rockwell interpreted these rules as providing that Triferic would be reimbursed as part of the dialysis bundle. In late 2015, Rockwell asked CMS to confirm that Triferic did not qualify for transitional add-on reimbursement, and CMS confirmed this in January 2016.

30. Rockwell's launch of Triferic in 2015 was not successful. As the Company admitted in its Annual Report to the SEC on Form 10-K for 2015, "Triferic sales in 2015 were not material." The Company failed to obtain any large customers or to make any material sales.

31. The primary reason for the failed launch of Triferic is clear. In the absence of separate reimbursement approval for Triferic, dialysis service providers were not incentivized to

adopt Triferic, and indeed were incentivized not to adopt Triferic given the costs of converting their treatments to incorporate Triferic.

D. Rockwell Repeatedly Assured Investors that It Was Likely to Obtain Separate CMS Reimbursement for Triferic

32. Immediately upon learning in late 2015 that Triferic would be included in the CMS bundled payment, Rockwell began to seek separate reimbursement for Triferic. According to Rockwell, the Company engaged in direct discussions with CMS and with Medicare policymakers in an effort to secure this separate reimbursement.

33. Rockwell did not hesitate to create a strong expectation among investors that CMS would approve Triferic for separate reimbursement. On its February 29, 2016 conference call to investors, Rockwell stated, "We fe[el] that Triferic me[ets] the criteria to be granted a transitional add-on payment, which would place Triferic reimbursement outside of the bundle for a period of time."

34. Likewise, in its Quarterly Reports on Form 10-Q for the first, second and third quarters of 2016, filed on May 10, August 9, and November 7, 2016, respectively, Rockwell told investors, "We believe Triferic meets the criteria for add-on reimbursement . . . ."

35. Beginning in its 2017 Annual Report on Form 10-K, Rockwell went a step further and informed investors that the Company believed there was a "high likelihood" that CMS would approve separate reimbursement for Triferic:

> We believe add-on reimbursement status is warranted for new innovative therapies such as Triferic so that patients have access to them and so that companies will commit the time and monetary resources to innovation in the renal space. We also believe that there is legal support in the Protecting Access to Medicare Act of 2014 for our position, and there is precedent for CMS granting add-on reimbursement status to a recent therapy after initially placing it in the bundle payment. CMS itself has stated that add-on reimbursement status for new innovative therapies is important. Triferic has received strong Congressional support for transitional add-on reimbursement status from multiple members of Congress, who have requested in writing that CMS and the Secretary of the

> Department of Health and Human Services provide it. Triferic has also received support from patient advocacy groups and dialysis service providers. Management believes there is high likelihood that Triferic receives transitional add-on reimbursement status, and that Triferic will become the standard of care for iron maintenance therapy in both the United States and globally regardless of reimbursement status, but that transitional add-on reimbursement would accelerate sales and adoption in the United States commercial market.

36. Rockwell also informed investors that "[u]ntil the add-on reimbursement status issue is resolved for Triferic, we do not anticipate realizing significant revenues from it."

37. Rockwell continued to tell investors "we believe that Triferic will receive separate reimbursement" in its Quarterly Reports on Form 10-Q for the first, second and third quarters of 2017, filed on May 9, August 9, and November 8, 2017, respectively, and in its Annual Report on Form 10-K for the fiscal year 2017, filed on March 15, 2018.

E. In March 2018, Rockwell CEO Chioini Learned that CMS Would Not Provide Separate Reimbursement for Triferic, but Misled Investors About This Development

38. On March 24, 2018, Rockwell's CMS lobbyist Steven Stranne wrote an email to Anand Shah, Chief Medical Officer at CMS in which Stranne asked for feedback on Rockwell's "proposal" to CMS submitted in October 2017. This proposal was for a "demonstration project" that was the latest vehicle through which Rockwell sought separate reimbursement for Triferic from CMS.

39. On March 27, 2018, Shah wrote an email (attached as Exhibit 1) to Rockwell's paid lobbyist Steven Stranne in which he informed Rockwell unequivocally that CMS would not approve Triferic for separate reimbursement: "We have carefully reviewed your concept and submitted materials. Unfortunately, given the other initiatives CMS has underway, we will not be able to pursue this model."

40. Stranne immediately conveyed CMS's refusal to approve separate reimbursement for Triferic to the management of Rockwell, including to Rockwell's CEO, Defendant Chioini.

41. Rather than filing a Current Report on Form 8-K, or otherwise informing investors of this critical negative development in the Company's efforts to commercialize Triferic, Defendants Chioini and Klema hid this information from investors.

42. On May 7, 2018 at 4:35 PM, Chioini sent an email to Stranne asking him to review his notes for the May 10, 2018 call with investors. Chioini suggested that he tell investors "[r]egarding the timing for receiving an approval from CMS on the demo project, we are hopeful that we will hear from them sometime in this second quarter." Stranne replied in an email to Chioini on May 8, 2018 at 2:39 AM "to be sensitive to how this might sound if read by people at CMS like Dr. Shah. CMS said 'no'."

43. On May 10, 2018, Rockwell disclosed that it had "received a letter dated April 24, 2018 from the Securities and Exchange Commission requesting certain information generally with respect to the status of CMS's determination of separate reimbursement status for Triferic and our current decision not to actively market and sell Triferic without such separate reimbursement."

44. However, in Rockwell's Quarterly Report on Form 10-Q for the first quarter of 2018, filed on May 10, 2018 ("Q1 2018 10-Q"), Rockwell flatly misled investors about its failure to obtain separate reimbursement for Triferic from CMS. Rockwell continued to assure investors that based on "conversations with high level officials," CMS was likely to approve Triferic, when in fact, Rockwell knew that CMS already had refused to approve Triferic for separate reimbursement.

45. Indeed, investors were materially misled by Rockwell's Q1 2018 10-Q. For example, immediately following Rockwell's filing of the Q1 2018 10-Q, on May 10, 2018, analyst Craig Hallum Capital Group LLC wrote:

> Our attention continues to be focused on the potential add-on payment for Triferic. While reimbursement events are difficult to predict, management continues to be confident based on their conversations and progress so far.

46. By failing to disclose that CMS had rejected Rockwell's attempt to obtain separate reimbursement for Triferic, Rockwell also misled investors in the Q1 2018 10-Q about its calculation of reserves for losses, and about its controls on financial reporting. Indeed, upon learning of Rockwell's failure to disclose the email from CMS rejecting Rockwell's efforts to obtain separate reimbursement, Rockwell's own auditor, Plante & Moran, resigned, and detailed in an e-mail to Rockwell the ways in which Rockwell's failure to disclose this information rendered its Q1 2018 10-Q false and misleading. As Plante & Moran explained, Rockwell misstated its reserves in the Q1 2018 10-Q by at least $400,000:

> Management's estimate of reserves for slow-moving and obsolete Triferic inventory is determined based on a weighted average probability model that considers anticipated product launch dates, current sales projections, and product expiration dates. Rockwell management represented that the factors used in its determination of the Q1 reserves reflected the best information and estimates available as of the10-Q filing date. In estimating these reserves for Q1, Rockwell assigned a 50 percent probability weighting to outcomes dependent on near-term approval of Triferic special reimbursement status. Elimination of those outcomes from the Q1 reserve analysis model would have suggested additional reserves recognizable in Q1 totaling approximately $400,000.

47. By failing to disclose that CMS had rejected Rockwell's attempt to obtain separate reimbursement for Triferic, and failing to adjust its reserves accordingly, Rockwell also manifested an evident material weakness in its internal controls over financial reporting, which Rockwell likewise failed to disclose in the Q1 2018 10-Q. As Plante & Moran noted:

> The above-referenced e-mail provides significant evidence regarding Rockwell's ongoing pursuit of Triferic special reimbursement status that was not given consideration in determining inventory reserves, classification and disclosures. This failure to consider all known facts and evidence regarding these matters is a deficiency in operation and effectiveness of Rockwell's financial reporting and disclosure controls that we consider to be a material weakness in those controls.

F. When Rockwell Informed Investors that the SEC Was Investigating the Company's Disclosures Regarding the Status of CMS's Determination of Separate Reimbursement Status for Triferic, Rockwell's Stock Price Fell

48. On May 10, 2018, risks and consequences of Rockwell's utter lack of internal controls on its disclosures began to materialize. On May 10, 2018, in its Q1 2018 10-Q, Rockwell revealed that the SEC was seeking information about the status of CMS's determination of separate reimbursement status for Triferic. Specifically, the Company stated that it had "received a letter dated April 24, 2018 from the Securities and Exchange Commission requesting certain information generally with respect to the status of CMS's determination of separate reimbursement status for Triferic and our current decision not to actively market and sell Triferic without such separate reimbursement." This disclosure clearly indicated to investors that the SEC was investigating whether the Company adequately had disclosed the status of CMS's determination of separate reimbursement status for Triferic. Indeed, the Company has since admitted in Rockwell's Counterclaim that the inquiry concerns "various disclosures regarding Triferic made under Chioini's and Klema's direction." Thus, this May 10, 2018 disclosure was a partial revelation of the Company's lack of adequate internal controls, and/or a materialization of the risk of an investigation that was concealed by the Company's assurances regarding the adequacy of its internal controls.

49. On this news, Rockwell's stock price fell $0.35 per share, or over 6.13%, to close at $5.36 per share on May 10, 2018, damaging investors.

G. After the Independent Directors of the Board Conducted an Investigation of Rockwell and Its Management, the Company Fired Defendants Chioini and Klema

50. In early 2018, following settlement agreements with activist shareholders unwilling to accept Chioini's iron grip on Rockwell, Chioini was forced to include five genuinely independent and experienced directors (the "Independent Directors") on Rockwell's

board. In March 2018, the Independent Directors forced the board to meet to evaluate Rockwell's performance and the performance of Chioini. After the Company received news in April 2018 that the SEC would investigate the Company's disclosures relating to CMS's determination of separate reimbursement status for Triferic, the board scheduled the firing of Chioini to occur at a board meeting on May 30, 2018.

51. Chioini appears to have gained news of his imminent termination, and preemptively filed a confidential "whistleblower" complaint with the SEC, alleging that the Independent Directors had been acting inappropriately and had hidden information from the Company in an effort to seize control of Rockwell. Chioini and Klema then demanded a special meeting of the board to call for an investigation of the allegations.

52. On May 22, 2018, the board held a special meeting, and used the occasion to move up by one week its termination of Chioini. After informing Chioini of his termination, Chioini and Klema fled to his office, locked the door, and used the Company's SEC filing codes to file an unauthorized Current Report on Form 8-K in which they publicly contested the Board's termination of Chioini.

53. Later that day on May 22, 2018, during aftermarket hours, Rockwell's board announced that Defendant Chioini, Rockwell's President and CEO, had been terminated effective immediately.

54. On May 23, 2018, at 11:26 a.m. Eastern Time, Defendant Chioini issued a press release entitled, "Rockwell Medical CEO Issues Press Release," which contained a letter to shareholders giving his account of the circumstances surrounding his termination.

55. On May 23, 2018, as a result of the utter chaos at Rockwell created by Defendants Chioini and Klema, NASDAQ took the highly unusual step of halting trading of the Company's

stock: "trading in the company's stock has been halted today, May 23, 2018, at 09:23:14 Eastern Time for 'news pending' at a last sale price of $5.94." Rockwell eventually obtained an injunction preventing Chioini and Klema from making further statements purportedly on behalf of the Company.

56. Chioini's termination, and the chaos that ensued, followed and resulted in significant part from the SEC's announcement that it was investigating the Company's disclosures relating to CMS's determination of separate reimbursement status for Triferic. Thus, these May 22 and May 23, 2018 disclosures constituted a partial revelation of the Company's lack of adequate internal controls, and/or a materialization of the risk of an investigation that was concealed by the Company's assurances regarding the adequacy of its internal controls.

57. On this news, upon resumption of trading on May 25, 2018, Rockwell's stock price fell $0.37 per share, or over 6%, over two consecutive trading days to close at $5.57 per share on May 29, 2018, damaging investors.

H. When Investors Learned that CMS Had Denied Separate Reimbursement for Triferic, Rockwell's Stock Price Collapsed Again

58. On June 27, 2018, during pre-market hours, Rockwell filed a Form 8-K with the SEC revealing the resignation of Plante & Moran, effective immediately. An attachment to the Form 8-K contained a letter from the auditor to Rockwell, dated June 22, 2018. The letter attached the e-mail, dated March 27, 2018, from CMS to Rockwell's lobbyist, denying separate reimbursement status for Triferic. (*See* Exhibit 1.) In that e-mail, CMS stated that it reviewed the Company's proposal for separate reimbursement status, and "[u]nfortunately, given the other initiatives CMS has underway, we will not be able to pursue this model." According to the auditor, "this e-mail and its contents are inconsistent with representations made to us by Rockwell, orally and in writing." The auditor's letter stated that due to the e-mail from CMS, the

estimated reserves in the Q1 2018 10-Q were misstated and had not been corrected, there was a material weakness in Rockwell's internal controls over financial reporting, Defendants Chioini's and Klema's SOX certifications attached to the Q1 2018 10-Q were "inconsistent with the facts in existence at the time of filing," and statements within the Q1 2018 10-Q "regarding the status of Rockwell's request for separate reimbursement with CMS and the prospects for reversal of CMS's decisions," "should [have been] clearer and more transparent."

59. On this news, Rockwell's stock price fell $0.74 per share, or 14.07%, to close at $4.52 per share on June 27, 2018, and fell $0.11 per share, or 2.43%, to close at $4.41 per share on June 28, 2018. Overall, Rockwell's stock price fell $0.85 per share, or over 16%, over two consecutive trading days, on heavy trading, damaging investors.

60. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

61. On November 8, 2017, the Company filed its Quarterly Report on Form 10-Q for the third quarter of 2017 (the "Q3 2017 10-Q") with the SEC. The Q3 2017 10-Q stated:

> As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.
>
> [. . .]
>
> [Certifications by Defendants Chioini and Klema:] The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures . . . and internal control over financial reporting . . . for the registrant and have [d]esigned such internal control over financial reporting . . . to provide reasonable assurance regarding the reliability of

> financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles . . . .

Rockwell made the same or substantially similar statements in its Annual Report on Form 10-K for 2017, filed March 15, 2018, and its Quarterly Report on Form 10-Q for the first quarter of 2018.

62. The statements referenced in ¶ 61 above were materially false and/or misleading because Defendants Chioini and Klema knew that the Company's disclosure controls and procedures were not effective, as they knew that the controls were inadequate to prevent the Company from misleading investors regarding CMS's approval of separate reimbursement for Triferic and from misrepresenting the adequacy of its reserves.

63. On April 5, 2018, the Company issued a press release in which it made the following statements:

> Rockwell's recent FDA approved drug Triferic is indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Triferic delivers iron to patients during their regular dialysis treatment, using dialysate as the delivery mechanism. Triferic has demonstrated that it safely and effectively delivers sufficient iron to the bone marrow and maintains hemoglobin, without increasing iron stores (ferritin). Rockwell intends to market Triferic to hemodialysis patients in the U.S. dialysis market and globally.

The Company made the same or substantially similar statements in its May 2, 2018 press release.

64. The statements referenced in ¶ 63 above were materially false and/or misleading because Rockwell was aware that CMS had rejected Rockwell's proposal for separate reimbursement for Triferic, yet omitted this information from its discussion of its marketing efforts for Triferic.

65. On May 10, 2018, the Company filed its Q1 2018 10-Q with the SEC, which provided the Company's first quarter 2018 financial results and position. The Q1 2018 10-Q stated:

> Although we cannot be certain, we believe that Triferic has the potential to be granted separate reimbursement by CMS as a result of our extensive efforts in working with policy makers to secure separate reimbursement. We have had in-depth discussions with high level officials within the current administration, key members of Congress, patient advocacy groups and industry stakeholders regarding the merits of Triferic and about why this innovative therapy should receive separate reimbursement. Our efforts have resulted in strong support for separate reimbursement for Triferic. We have submitted information to CMS that highlights the improved clinical benefits that Triferic provides to patients, as well as the significant cost savings Triferic delivers to both Medicare and dialysis providers. We cannot predict the outcome or timing of CMS's process and there can be no assurance of if or when we might receive separate reimbursement for Triferic from CMS.
>
> [. . .]
>
> If CMS does not award us separate reimbursement for Triferic during 2018 or further extends its review of Triferic for separate reimbursement or should we not realize commercial sales during 2018 or 2019, some or all of our current investment in Triferic finished goods inventory and some of our Triferic API inventory will likely need to be written off, which would not have a material negative impact on our cash flow but would have a material adverse impact on our reported results of operations and financial position.

66. The Q1 2018 10-Q also noted that the Company "received a letter dated April 24, 2018 from the Securities and Exchange Commission requesting certain information generally with respect to the status of CMS's determination of separate reimbursement status for Triferic and our current decision not to actively market and sell Triferic without such separate reimbursement."

67. The statements referenced in ¶¶ 65-66 above were materially false and/or misleading because Rockwell was aware that CMS had rejected Rockwell's proposal for separate reimbursement for Triferic.

68. The Q1 2018 10-Q also stated:

> As of March 31, 2018, we had $5.9 million of Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved $4.8 million. In the first quarter of 2018, we reserved an additional $1.3 million (included within our $4.8 million reserve) resulting in a remaining net book value of $1.1 million of Triferic finished goods inventory as of March 31, 2018.
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> [. . .]
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> [Certifications by Defendants Chioini and Klema:] Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

69. The statements referenced in ¶ 68 above were materially false and/or misleading because Defendants knew that their reserve figures failed to account for CMS's denial of separate reimbursement for Triferic, and so did not fairly present in all material respects the financial condition of the Company.

VI. ADDITIONAL SCIENTER ALLEGATIONS

70. Rockwell, Chioini and Klema each knew of the false and misleading nature of the statements discussed above, or at a minimum was reckless for not knowing these matters. By virtue of their high-level positions, Chioini and Klema's knowledge may be imputed to Rockwell.

A. Chioini Was Informed Directly that CMS Had Refused Separate Reimbursement for Triferic

71. Rockwell's CMS lobbyist Steven Stranne immediately conveyed CMS's refusal to approve separate reimbursement for Triferic to the management of Rockwell, including to Rockwell's CEO, Defendant Chioini, prior to Chioini's review and certification of the 2018 10-Q. On May 7, 2018 at 4:35 PM, Chioini sent an email to Stranne asking him to review his notes for the May 10, 2018 call with investors. Chioini suggested that he tell investors "[r]egarding the timing for receiving an approval from CMS on the demo project, we are hopeful

that we will hear from them sometime in this second quarter." Stranne replied in an email to Chioini on May 8, 2018 at 2:39 AM "to be sensitive to how this might sound if read by people at CMS like Dr. Shah. CMS said 'no'."

72. Indeed, Rockwell has admitted that Defendant Chioini, while Rockwell's CEO, learned that CMS had denied separate reimbursement for Triferic, yet withheld this information from the Board and from the Company's independent auditor. On June 29, 2018, Rockwell issued a press release entitled, "Rockwell Medical Provides Investor Update," stating that "it appears that Chioini and perhaps others withheld information regarding Triferic from the Company's auditor, corporate counsel and five independent directors of the Board."

B. Given the Importance of Separate Reimbursement for Triferic, the Notion that the CEO and CFO Did Not Know of CMS's Denial of Separate Reimbursement Would Be Absurd

73. Defendant Chioini served as CEO of Rockwell at all relevant times and was a Director of Rockwell throughout the Class Period. As CEO, Chioini was the head of Rockwell's management and operations teams. Chioini, by virtue of his responsibilities and activities as CEO and Director of the Company, was privy to all material information concerning Triferic and reimbursement for Triferic, including CMS's refusal to approve Triferic for separate reimbursement.

74. Defendant Klema served as CFO of Rockwell at all relevant times and likewise served as a Director of Rockwell throughout the Class Period. Klema, as CFO, was privy to, and participated in, all matters directly impacting the financial health of Rockwell, including information concerning reimbursement for Triferic and CMS's refusal to approve Triferic for separate reimbursement.

75. The core of Rockwell's business is the manufacturing and sale of its primary drug product, Triferic. Given the key importance of Triferic to Rockwell's business, strategy, and

valuation, Defendants Rockwell, Chioini and Klema each had knowledge of all material information affecting reimbursement for Triferic, including information concerning reimbursement for Triferic and CMS's refusal to approve Triferic for separate reimbursement.

C. A Confidential Witness Has Confirmed that Chioini Was Highly Focused on Obtaining Separate Reimbursement for Triferic

76. A confidential witness ("CW") has confirmed that Chioini was highly focused on obtaining separate reimbursement from CMS for Triferic, and was well aware of all major developments in that effort. CW was Executive Director of Marketing at Triferic from 2013 to May 2016. According to CW, Chioini learned in September 2015 about the possibility of obtaining separate reimbursement from CMS for Triferic, and "from that point on, it was all about that. It was all about that pricing." Chioini "was all in on this. He was tenacious about it." According to CW, Rockwell was "Chioini's baby" and "[e]very decision made in the company, and I do mean everyone, was made by Rob." Chioini ran Rockwell "like a private company."

D. SOX Certifications

77. Defendants Chioini and Klema each signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") for the 2018 10-Q referenced in Part V above during their tenure as CEO and CFO. In these certifications, Chioini and Klema each certified that he had reviewed the SEC filing and determined that it contained no false or misleading statements or omissions. The certifications also stated that the Individuals Defendants had designed controls to ensure that all material information (such as critical decisions by CMS regarding Triferic's reimbursement status) would be made known to them:

> The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures . . . for the registrant and have [d]esigned such disclosure controls and procedures . . . to ensure that material information relating to the registrant, including its consolidated subsidiaries, is

> made known to us by others within those entities, particularly during the period in which this report is being prepared . . . .

That is, the Individual Defendants certified that they were responsible for designing and maintaining disclosure controls, and so were highly familiar with such controls and any material weaknesses in those controls.

VII. CLASS ACTION ALLEGATIONS

78. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Rockwell securities publicly traded on the NASDAQ during the Class Period (the "Class"), and were damaged upon the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

79. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Rockwell securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

80. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

81. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

82. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- whether the prices of Rockwell securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.

83. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

84. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Rockwell securities are traded in an efficient market;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased and/or sold Rockwell securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

85. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

86. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

VIII. COUNT ONE

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

87. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

88. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

89. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

90. The Company and the Individual Defendants violated § 10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

- engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Rockwell securities during the Class Period.

91. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated in, or acquiesced in, the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants, by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

92. The Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiffs and the Class.

93. As a result of the foregoing, the market price of Rockwell securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Rockwell securities during

the Class Period in purchasing Rockwell securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

94. Had Plaintiffs and the other members of the Class been aware that the market price of Rockwell securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information that the Company and the Individual Defendants did not disclose, they would not have purchased Rockwell securities at the artificially inflated prices at which they did, or at all.

95. As a result of the wrongful conduct alleged herein, Plaintiffs and the other members of the Class have suffered damages in an amount to be established at trial.

96. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchases of Rockwell securities during the Class Period.

IX. COUNT TWO

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

97. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

98. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

99. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the

Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

100. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Rockwell securities.

101. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

102. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

XI. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury in this Action.

Dated: December 10, 2018

Respectfully submitted,

POMERANTZ LLP

/s/ Austin P. Van

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed with the Court's electronic case filing (ECF) system on December 10, 2018, which caused an electronic copy of this document to be served on all counsel of record in this matter.

/s/ Austin P. Van
Austin P. Van

EXHIBIT 1

To: Steven Stranne[SStranne@Polsirelli.com]
From: Shah, Anand (CMS/CMMI)
Sent: Tue 3/27/2018 2:43:15 PM
Subject: RE: Innovation Demo for ESRD

Hi Steve –

Thank you for your note on Rockwell's proposal.

We have carefully reviewed your concept and submitted materials. Unfortunately, given the other initiatives CMS has underway, we will not be able to pursue this model.

I appreciate you and Rob Chioini coming to CMMI to present Rockwell's idea, as well as the continued follow up with us.

Anand

Anand Shah, MD, MPH
Chief Medical Officer
Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services

From: Steven Stranne [mailto:SStranne@Polsinelli.com]
Sent: Saturday, March 24, 2018 4:51 PM
To: Shah, Anand (CMS/CMMI) <Anand.Shah1@cms.hhs.gov>
Subject: Innovation Demo for ESRD

Dr. Shah, I am writing to follow up on the proposal we submitted in October of 2017 for a potential CMMI project for new, transformative therapies that are likely to significantly control overall costs and improve care for Medicare beneficiaries with end stage renal disease (ESRD). Thanks again for meeting with us, along with your colleagues in the Innovation Center, in November, 2017.

As time continues to pass, I urge you and the CMS leadership team to adopt and expedite this proposal. The demonstration would enable the Agency to select, evaluate, and support transformative innovations like Triferic that have reasonable pricing and that show promise to improve care, reduce complications, and save the Medicare program money. The Agency would retain significant control over decisions involving the innovations to be selected for the demonstration and the ongoing payment policies. We need to break down barriers to innovations that can deliver value, save federal resources, and improve care in this vulnerable and expensive patient population. Our proposal would result in good policy that would disrupt and refine the counterproductive aspects of the status quo.

As you may recall, there is significant support for our proposal in the ESRD community and in Congress. Although this list is not inclusive, recall that well-respected patient advocacy groups such as the American Association of Kidney Patients (AAKP) and Dialysis Patient Citizens (DPC) support this proposal. In addition to a number of other stakeholders in the provider and ESRD communities, many Members of Congress in the House and Senate have communicated their support through letters and other means, including but not limited to Chairman Brady and his staff.

Please let us know what we can do to be helpful. This proposal provides a straightforward way to ensure that the Medicare program can identify and harness reasonably-priced innovation in a way that improves lives and holds down overall health costs. That seems to fall squarely within the Administration's objectives and the Innovation Center's mission. We encourage you to adopt this proposal and to do so quickly. Thanks again for your help, Steve

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