No. 23-1134

In the Supreme Court of the United States

MARK HABELT, INDIVIDUALLY AND ON BEHALF OF OTHERS SIMILARLY SITUATED, PETITIONER

v.

IRHYTHM TECHNOLOGIES INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF IN OPPOSITION TO CERTIORARI

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QUESTION PRESENTED

Whether, if petitioner has not forfeited the question by failing even to mention in his merits briefs below the Federal Rule of Civil Procedure that he now says is dispositive, a putative member of an uncertified securities fraud class has standing to appeal the district court's dismissal of the lead plaintiff's complaint, where no class has been certified, the complaint contains no allegations about him personally, and the dismissal does not otherwise bind him from pursuing his own claims, solely because his name appears in the caption.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, counsel for Respondents states that iRhythm Technologies, Inc. does not have a parent corporation and no publicly-held corporation owns more than ten percent of its stock. Respondents Kevin M. King, Michael J. Coyle, and Douglas J. Devine are each natural persons.

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JURISDICTION

Although Habelt correctly describes the timely filing of his petition for certiorari under 28 U.S.C. § 1254(1), this Court lacks Article III jurisdiction over Habelt's petition due to his lack of standing. See *infra* at 12-17.

INTRODUCTION

Habelt's petition does not come close to satisfying the criteria for certiorari, and even if the question presented were otherwise cert worthy, a raft of Article III, forfeiture, and other vehicle problems would preclude this Court from deciding it.

Habelt asks this Court to grant review and to hold that a putative class member may appeal the *pre-class certification* dismissal of someone else's complaint—even if that complaint contains no allegations about him personally and the dismissal does not bind him. In rejecting that position, the court of appeals simply held that, until a class is certified, putative class members are not "parties" and thus have no cognizable interest in the resolution of another person's case. Pet. 9a (citing *Smith* v. *Bayer Corp.*, 564 U.S. 299, 313 (2011)). As this Court has explained, it is "surely erroneous" to think that "a nonnamed class member is a party to the class-action litigation *before the class is certified*." *Bayer*, 564 U.S. at 313 (citation omitted). Yet Habelt never grapples with this problem.

Beyond this difficulty, Habelt has major vehicle issues and no credible claim of a circuit split. His petition rests on the premise that the Ninth Circuit "depart[ed] from how other courts of appeals have read" Federal Rule of Civil Procedure 10(a), which by his lights makes case captions dispositive of party status. Pet. 3. But Habelt never mentioned Rule 10(a) before the merits panel below. The only Rule 10 cited in his Ninth Circuit merits briefs was *SEC Rule 10b-5*. And since he "did not raise [Rule 10(a)]," the court below "did not address it," it is "forfeited" (*United States* v.

Jones, 565 U.S. 400, 413 (2012)), and this Court's "traditional rule" "precludes a grant of certiorari" (*United States* v. *Williams*, 504 U.S. 36, 41 (1992)).

Beyond Habelt's forfeiture troubles, Article III would preclude this Court from exercising jurisdiction. *Habelt* was not bound by the dismissal of the complaint of *another entity* (the Public Employees' Retirement System of Mississippi (PERSM)) and cannot otherwise show "an actual or imminent injury that is 'fairly traceable' *to the judgment below*" and redressable by a favorable ruling—which "an appealing litigant must demonstrate" to satisfy Article III. *Food Mktg. Inst.* v. *Argus Leader Media*, 588 U.S. 427, 432-433 (2019) (emphasis added) (citation omitted).

What's more, the body of the operative complaint says literally nothing about Habelt, let alone that he suffered a particularized injury. It does not allege, for example, that he bought iRhythm stock or was injured by respondents' alleged securities law violations. To be sure, the *petition* says "there is no question" that he has a financial interest in PERSM's case (Pet. 21), and the complaint suggests that other, unnamed individuals bought iRhythm's stock during the Class Period (see App., *infra*, at 113a (reproducing Second Amended Complaint, No. 3:21-cv-00776-EMC (N.D. Cal.))). Yet class-action plaintiffs "must allege * * * that they personally have been injured, not that injury has been suffered by other, unidentified members of the class." *Warth* v. *Seldin*, 422 U.S. 490, 502 (1975). If Habelt filed a carbon copy of PERSM's complaint in district court today, it would be dismissed for failing to allege that he personally was injured. That Article III deficiency is not cured by seeking certiorari.

As to the alleged circuit split, the Ninth Circuit did not break from other circuits over Rule 10(a)'s interpretation—which, again, the court had no occasion to consider, because Habelt's merits brief did not cite it. Habelt says he was a party solely because he appeared in the dismissed complaint's caption, but he concedes that "the longstanding practice of both this Court and the courts of appeals has been to 'look behind [the] names that symbolize the parties' in a caption." Pet. 12 (quoting *United States* v. *I.C.C.*, 337 U.S. 426, 430 (1949)). All three circuit judges below agreed with the uniform view that the caption is "probative," but not "dispositive." Pet. 9a n.2 (citing *Williams* v. *Bradshaw*, 459 F.3d 846, 849 (8th Cir. 2006)); Pet. 12a (Bennett, J., dissenting) (citing *Williams*). They divided only over *application* of that rule—which, under Rule 10 of this Court, is not the stuff of certiorari.

Habelt wrongly suggests that "[m]ost circuits look outside the caption *only* to identify defendants." Pet. 12 (emphasis added). No circuit uses that "only" modifier or applies a defendant-specific rule. Rather, all apply the general rule that "in determining whether a *party* is named properly in a complaint, courts are not bound necessarily by the caption." *E.g.*, *Whitley* v. *U.S. Air Force*, 932 F.2d 971, *1 (7th Cir. 1991) (emphasis added). Habelt's cases apply this rule to defendants, but none *limits* it to defendants or suggests another rule for plaintiffs.

Habelt is also incorrect that three circuits refuse to "look past the caption to determine plaintiff party status." Pet. 13. Each cited case accords the caption non-dispositive weight before ruling against plaintiff status. *E.g.*, *Abraugh* v. *Altimus*, 26 F.4th 298, 303 (5th Cir. 2022) (putative party was not a plaintiff even "accept[ing] that omission as a named party in the

caption of the complaint is not necessarily 'determinative'"). Many cases mirror the ruling below in denying plaintiff status where the "parties" section of the complaint never mentions the putative plaintiff. *Williams*, 459 F.3d at 849; see Pet. 9a. But no circuit applies Habelt's "caption über alles" theory that someone never mentioned in the body of the complaint can be a party if only listed in the caption.

Remarkably, Habelt criticizes the court of appeals for "reason[ing] that 'a person or entity can be named in the caption of a complaint without necessarily becoming a party.'" Pet. 16 (quoting Pet. 8a). But the court was quoting this Court's decision in *United States ex rel. Eisenstein* v. *City of New York*, 556 U.S. 928, 935 (2009), which held that the United States was not a plaintiff despite appearing in the caption. Compare *ibid.* ("A person or entity can be named in the caption of a complaint without necessarily becoming a party to the action."), with Pet. 8a (quoting *Eisenstein*). Rather than address this difficulty, Habelt uses a "citations omitted" parenthetical to conceal it. Pet. 16. But as *Eisenstein* confirmed, it is black-letter law that "the caption is not determinative as to the identity of the parties," and that rule applies to plaintiffs and defendants alike. 5A Wright & Miller, Federal Practice and Procedure § 1321 (2004).

Habelt says the ruling below implicates a split on the non-party "standing to appeal" doctrine, claiming that other circuits, unlike the Ninth, would consider his "interest" in the appeal. But the Ninth Circuit test for non-party standing explicitly considers the "equities," which often include the non-party's "legitimate interest in the outcome of the appeal." *E.g.*, *S.E.C.* v. *Wencke*, 783 F.2d 829, 834 (9th Cir. 1986). These cases, which Habelt ignores, belie any split. Similarly,

even the circuits that Habelt likes would not find that a putative class member has a sufficient "interest" to support non-party standing *pre*-class certification. And the Ninth Circuit also ruled that Habelt failed to show that he sufficiently participated in the district court proceedings—"[h]is involvement * * * all but ceased with the filing of the initial complaint" (Pet. 10a)—an independent ground for dismissing his claims, on which the circuits are united.

Finally, both decisions below were plainly correct. As *Eisenstein* confirms, appearing in a caption does not, without more, make someone a party. The Ninth Circuit correctly applied that settled rule in holding that Habelt was not a plaintiff where the dismissed complaint lacked any allegation about *him* and where—unlike in *Devlin* v. *Scardelletti*, 536 U.S. 1 (2002)—no class was ever certified. The court below also correctly held that Habelt, who neither litigated nor was bound by the district court's order, did not satisfy the criteria for non-party standing.

Likewise, the district court correctly dismissed PERSM's claims on multiple grounds, including that the Private Securities Litigation Reform Act of 1995 (PSLRA) protects forward-looking statements offered during an uncertain regulatory process, and the "independent reason" that PERSM failed adequately to allege scienter. Pet. 74a. Each ruling faithfully applied the law, confirming that nothing would change if Habelt were (incorrectly) deemed a party.

Certiorari should be denied.

STATEMENT

A. The parties and the complaint

Respondent iRhythm is a digital healthcare company focused on diagnosing cardiac arrhythmias. As relevant here, one of iRhythm's cardiac monitoring services combines a patch-based, wearable biosensor that continuously records electrocardiogram data with proprietary, FDA-approved analytics to help physicians diagnose arrhythmias. A significant portion of iRhythm's revenue comes from third-party payor reimbursements—i.e., from health insurers and government programs such as Medicare.

iRhythm has experienced significant fluctuations in third-party payor reimbursement rates for its services. After one surprising (and since superseded) decrease in those rates, its stock price fell. Habelt sued, accusing iRhythm and a former chief executive officers of violating the securities laws by making optimistic, forward-looking statements about iRhythm's expected rates during the regulatory process.

Because Habelt filed a putative securities class action, the PSLRA applied, including its "provisions on selection of lead plaintiff and lead counsel." *Cohen* v. *U.S. Dist. Ct. for N. Dist. of California*, 586 F.3d 703, 709 (9th Cir. 2009). Congress designed the PSLRA "to curb abusive securities-fraud lawsuits" (*Amgen Inc.* v. *Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 476 (2013)), including "manipulation by class action lawyers of the clients whom they purportedly represent," and giving control of class-action litigation to those who win the "race to the courthouse." Securities Litigation Reform, Joint Explanatory Statement of the Committee of Conference, H.R. CONF. REP. NO. 104-396, at 31, 33 (1995). Accordingly, Congress required

district courts to "appoint as lead plaintiff the member or members of the purported plaintiff class" who are "most capable of adequately representing the interests of class members." 15 U.S.C. § 78u-4(a)(3)(B)(i). When a lead plaintiff is chosen, it gains "control" over the litigation. *In re BankAmerica Corp. Sec. Litig.*, 263 F.3d 795, 801 (8th Cir. 2001).

Here, three putative class members including PERSM but *not* Habelt moved for lead plaintiff status. PERSM's motion was granted, and the court approved its selection of counsel (Pet. 6a-7a) in an order that barred anyone other than PERSM's counsel from "work[ing] on this action for the putative class without prior [court] approval." Pet. 87a. Thereafter, PERSM conducted the entirety of the district court litigation—Habelt "did not participate." Pet. 7a.

PERSM then filed an amended complaint that superseded Habelt's and rendered it "non-existent." Pet. 9a. The amended complaint identified PERSM as the plaintiff, recited its alleged injuries, and named additional iRhythm officers as defendants. Dkt. No. 46, No. 3:21-cv-00776-EMC (N.D. Cal.). (For convenience, we refer to defendants as "iRhythm" or "respondents.") Nowhere did the complaint allege any injury to Habelt. The section labeled "Parties" did not mention him. *Id.* ¶¶27-33. In fact, the entire body of the complaint never mentioned him. Even the prefatory "Table of Definitions" referenced only PERSM, defining it as both "Lead Plaintiff" and "Plaintiff." *Id.* at ii, iii.

PERSM later filed a second amended complaint—the operative pleading here—which again nullified all previous complaints. See App., *infra*, at 1a-123a. That complaint too listed PERSM as the plaintiff and

identified its alleged losses. And it too "made no reference to Habelt, to his alleged losses, or to his individual claims, including in [the] subsection titled 'Parties.'" Pet. 7a. In fact, beyond the caption, the entire document "makes mention neither of Habelt nor of his individual claims." Pet. 9a.

PERSM's complaint sought to hold iRhythm liable for statements allegedly made during the regulatory rate-making that preceded the surprise decrease in iRhythm's reimbursement rates. "In lieu of filing an answer, and before any class was certified," iRhythm moved to dismiss the complaint. Pet. 7a.

As iRhythm explained, PERSM's claims targeted optimistic, forward-looking, or true statements made in regulatory proceedings. Most of the statements were protected by the PSLRA's "safe harbor," as they conveyed iRhythm's forward-looking views and were accompanied by significant cautionary language. See 15 U.S.C. § 78u-5(c)(1). Other challenged statements were inactionable opinions, inadequately alleged to be misleading, or insufficiently supported by allegations of scienter or loss causation.

B. The district court's decision

The district court granted iRhythm's motion to dismiss in full. As the court explained, PERSM's "central theory of fraud * * * amount[ed] to a challenge to the sufficiency of Defendants' disclosures regarding the risks that Defendants faced in obtaining a favorable decision through the regulatory process." Pet. 52a. Under the PSLRA's safe harbor, PERSM could not hold iRhythm liable for tentative, couched statements regarding its expectations concerning the reimbursement rates, as those statements conveyed iRhythm's

"forward-looking" views and were accompanied by extensive "cautionary language." Pet. 55a-66a. Other challenged statements "d[id] not contain material misrepresentations" (Pet. 70a), and PERSM also failed to state a claim for the "independent reason" that it did not adequately allege scienter (Pet. 74a).

PERSM did not appeal. Instead, without complying with the district court's order that anyone other than PERSM's counsel who wanted to "work on this action for the putative class" obtain "prior approval" (Pet. 87a), Habelt filed a notice of appeal purporting to appeal the dismissal of PERSM's complaint.

C. The court of appeals' decision

iRhythm moved to dismiss the appeal. A motions panel denied the motion without prejudice (and without issuing an opinion), but invited iRhythm to raise the same arguments before the merits panel.

Before the merits panel, iRhythm pointed out that Habelt was not a proper appellant, both because he could not satisfy the "standing to appeal" doctrine and because he lacked Article III standing. *United States ex rel. Alexander Volkhoff, LLC* v. *Janssen Pharmaceutica N.V.*, 945 F.3d 1237, 1241 (9th Cir. 2020) (prudential "standing to appeal" doctrine echoes, but "is distinct from * * * constitutional standing"). Under the "standing to appeal" doctrine, Habelt was not a proper appellant because he was not a party. See *ibid.* No class was ever certified; the district court simply dismissed PERSM's complaint, the body of which never mentioned Habelt. And since Habelt was absent from the district court proceedings and no class had been certified, he was not bound by the judgment and could not show the "exceptional circumstances" required to obtain non-party standing to appeal.

Further, because Habelt had suffered no "actual or imminent injury" that was "'fairly traceable' to the judgment below" and "'redress[able] by a favorable ruling,'" he lacked Article III standing to appeal. *Argus Leader Media*, 288 U.S. at 432-433 (citation omitted). Habelt was not bound by the dismissal, and thus had no "injury" that was traceable to it. Finally, iRhythm explained that, if Habelt had standing, the district court had correctly dismissed PERSM's claims on the merits.

The Ninth Circuit dismissed the appeal. It began by quoting this Court's "well settled" "rule that only parties to a lawsuit, or those that properly become parties, may appeal an adverse judgment." Pet. 7a (quoting *Marino* v. *Ortiz*, 484 U.S. 301, 304 (1988)). Then, noting that a case's caption is mainly a handle to identify it, the court observed that "[a person] can be named in the caption of a complaint without necessarily becoming a party to the action." Pet. 8a (quoting *Eisenstein*, 556 U.S. at 935).

The court then stated that the complaint's caption, while "probative," was "not dispositive," and that Federal Rules of Civil Procedure 25(c)-(d) "expressly contemplate" that captions "may be disconnected from the substance of the proceedings." Pet. 8a, 9a n.2. The "more important indication" of party status, the court noted, it what is alleged in "[t]he body of the operative pleading," which here "makes mention neither of Habelt nor of his individual claims." Pet. 9a. And while "an unnamed member of a *certified* class may be considered a party" for purposes of "'appealing an adverse judgment,' the 'definition of the term "party"' does not cover an unnamed class member '*before the class is certified*.'" *Ibid*. (quoting *Bayer*, 564 U.S. at 313, and *Devlin*, 536 U.S. at 7, 16 n.1) (cleaned up).

The court also rejected Habelt's position that "exceptional circumstances" warranted granting him "standing to appeal as a non-party"—a "high bar." Pet. 10a. Habelt's involvement in the case "'all but ceased with the filing of the' initial complaint," and "the equities" likewise disfavored allowing him to appeal: he was "not bound by the district court's judgment," and although this Court has instructed non-parties to "follow the 'better practice' of 'seeking intervention for purposes of appeal,'" "Habelt filed no motion to intervene." Pet. 10a, 11a (citations omitted).

Although Judge Bennett dissented, he agreed that "the mere inclusion of Habelt's name in the * * * caption is not dispositive." Pet. 13a (citing *Williams*, 459 F.3d at 849). He simply took issue with the majority's fact-bound conclusion that Habelt, while "not specifically named in the [complaint's] body," was not "covered by its substantive allegations." Pet. 14a, 13a.

REASONS FOR DENYING THE PETITION

I. Review should be denied because Habelt lacks Article III standing.

Before turning to the many other bases for denying certiorari, we begin with a fundamental jurisdictional defect: Habelt lacks Article III standing. The problem is two-fold. First, because the complaint here was dismissed before any class was certified, Habelt was not bound or injured by the district court's judgment. Second, the complaint he wishes to press contains no allegations about him personally. Each problem independently defeats jurisdiction.

A. Habelt was not bound by the district court judgment dismissing PERSM's complaint, and thus lacks standing to appeal it.

It is of course axiomatic that every plaintiff "bears the burden of establishing standing as of the time he brought [his] lawsuit *and* maintaining it thereafter." *Carney* v. *Adams*, 592 U.S. 53, 59 (2020) (emphasis added). In addition, "[t]o show standing under Article III, an *appealing* litigant must demonstrate that it has suffered an actual or imminent injury that is 'fairly traceable' *to the judgment below* and that could be 'redressed by a favorable ruling.'" *Argus Leader Media*, 588 U.S. at 432-433 (emphasis added) (citation omitted).

That bedrock standing rule poses an insurmountable problem for Habelt, as he cannot show an injury traceable *to the district court's judgment*. He was not a party to the complaint that PERSM filed and the district court dismissed. And as the court of appeals noted (Pet. 10a), all "agree[]" that he was "not bound by the district court's judgment" dismissing that complaint, which (in all events) did not formally resolve any claims that he may have against iRhythm. See *Schwarzschild* v. *Tse*, 69 F.3d 293, 297 (9th Cir. 1995) (pre-certification dismissal does not bind putative class members). Since Habelt has no injury traceable to the judgment, he cannot appeal it.[1]

It is no answer for Habelt to say that his potential claims may be untimely. If his individual claim is "untimely" (*ibid.*), that "indirect effect * * * results not

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[1] Given that settled principle, Habelt's suggestion that he "may be precluded from pursuing another appeal by res judicata" is simply false. Pet. 22.

from the judgment itself but from counsel's refusal or failure to file a new complaint" (*Plumbers, Pipefitters & MES Loc. Union No. 392 Pension Fund* v. *Fairfax Fin. Holdings Ltd.*, 433 F. App'x 28, 30 (2d Cir. 2011)). That is, any untimeliness problem is one of Habelt's own making, not one "'fairly traceable' *to the judgment below*" (*Argus Leader Media*, 588 U.S. at 432-433).

Nor is it any answer to say that this case is a putative class action. The district court dismissed the operative complaint *before* class certification. And as this Court has repeatedly emphasized, "[t]hat a suit may be a class action adds nothing to the question of standing." *Spokeo, Inc.* v. *Robins,* 578 U.S. 330, 338 n.6 (2016), as revised (May 24, 2016) (quoting *Simon* v. *Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 40, n.20 (1976)). Instead, the question before the appellate court (including this one) is always whether the appellant has an injury caused by the order below. Here, Habelt cannot establish that injury, as the district court's pre-certification dismissal did not resolve *his* claims—he was not bound by that judgment, and he has no other injury fairly traceable to it. For that reason alone, certiorari should be denied.

B. The operative complaint does not allege that Habelt personally suffered any injury traceable to respondents' alleged wrongs.

But there is more. Even if Habelt had standing to appeal the dismissal of PERSM's complaint (in a judgment that did not bind him), that complaint does not allege that he personally "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision"—the "'irreducible constitutional minimum' of standing." *Spokeo*, 578 U.S. at

338 (quoting *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)).

It is settled that "the injury-in-fact requirement" requires a plaintiff to allege an injury that is both "concrete and particularized," and that a *particularized* injury "must affect the plaintiff in a personal and individual way." *Id*. at 334, 339 (collecting cases). It is also settled that, to satisfy Article III, class-action plaintiffs "must allege * * * that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Warth*, 422 U.S. at 502; accord *Spokeo*, 578 U.S. at 338 n.6.

Under decisions such as *Warth* and *Spokeo*, Habelt lacks standing because the complaint that he hopes to resurrect nowhere alleges that he *personally* suffered any injury. As the court below observed, "the body of the operative pleading" here contains "no reference to Habelt, to his alleged losses, or to his individual claims." Pet. 9a, 7a. The closest it comes is generic class allegations that other purchasers of iRhythm's stock were injured, without mentioning Habelt. App., *infra*, at 113a. But that is exactly what *Warth* and *Spokeo* deem insufficient.

Habelt tries to obscure this point by declaring a "financial stake" (Pet. i) in this case, but his assertions appear nowhere in the complaint.[2] For example, his

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[2] Nor are these the only assertions in Habelt's briefs that are not properly before the Court. For example, his statement that "he took up the mantle of appealing on behalf of the putative class" "with PERSM's consent" (Pet. 3) is not only legally irrelevant, but pure *ipse dixit*. Habelt has never introduced evidence to support this assertion. Nor

petition asserts that he "purchased iRhythm stock" in 2020 and 2021, and "suffered significant losses following the Zio XT rate announcement" (Pet. 6); that there is "no question that Habelt, like PERSM, invested in iRhythm and lost money," or "that these losses were caused by Respondents' alleged misrepresentations" (Pet. 10); and that there is "no question" that "he has a clear stake in this appeal" (Pet. 21). Yet there is "no question" that *none* of these assertions appears in the complaint, which recounts only PERSM's alleged injuries. In effect, Habelt's purported "financial stake" is being a member of an uncertified class, which does not confer standing. And Habelt does not challenge the rule that his complaint was "supersede[d]" and became "non-existent" upon the filing of an amended complaint (Pet. 9a), which in any case correctly states longstanding hornbook law. See 6 Wright & Miller, Federal Practice & Procedure § 1476 ("Once an amended pleading is interposed, the original pleading no longer performs any function in the case.").

To state the obvious, neither extra-record allegations nor allegations about others can support standing. An "original pleading, once superseded, cannot be utilized to cure defects in the amended pleading." *Ibid.* And if Habelt filed an exact copy of PERSM's complaint in district court today, *Warth* and *Spokeo* would require dismissing it for failing to allege that *he* was injured. Habelt could not rely on alleged injuries to PERSM or others to support *his* claim. See also *Spokeo*, 578 U.S. at 338 (where "case is at the pleading

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did he attempt to intervene or to replace PERSM as lead plaintiff, let alone with the requisite "prior approval" of the district court. Pet. 87a. He simply filed a notice of appeal.

stage," plaintiff "must 'clearly *** allege facts demonstrating'" standing (quoting *Warth*, 422 U.S. at 518)).

That Habelt is attempting to defend the dismissed complaint on appeal cannot overcome its failure to allege a personalized injury—or the mandates of Article III, which place on him, "the party invoking federal jurisdiction" (*Spokeo*, 578 U.S. at 338), the burden of both "establishing" *and* "maintaining" standing on appeal (*Carney*, 592 U.S. at 59). And because that complaint does not "demonstrate the requisite case or controversy between [him] personally and respondents," Habelt may not "seek relief on behalf of himself or any other [class] member." *Warth*, 422 U.S. at 502 (quoting *O'Shea* v. *Littleton*, 414 U.S. 488, 494 (1974)).

II. Review should be denied because the central theory of Habelt's petition has been forfeited.

Review would not be warranted even if this Court had jurisdiction. The petition rests almost entirely on Federal Rule of Civil Procedure 10(a), which governs case captions. Applying that rule "as written," Habelt declares, produces a "different *** result." Pet. 11. He invokes Rule 10(a) repeatedly; it is the centerpiece of both his overall case for review and his claim that the ruling below "deepens" a circuit split in which (we are told) the Ninth Circuit has broken from "most courts of appeals" over the rule's "interpretation." Pet. 4, 2.

Habelt's arguments would come as some surprise to the merits panel below, which had no occasion to interpret Rule 10(a)—because Habelt did not cite it. Thus, even if Habelt's newfound theory were correct (and it is not, see *infra* at 29-31), the Court should not take up a forfeited theory.

It is settled that when a "question was not raised in the Court of Appeals," it "is not properly before" this Court. *Delta Air Lines, Inc.* v. *August*, 450 U.S. 346, 362 (1981); accord *Adickes* v. *S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970) (the Court "will not ordinarily consider" issues "neither raised before nor considered" below); *United States* v. *United Foods, Inc.*, 533 U.S. 405, 417 (2001) (the Court will not "allow a petitioner to assert new substantive arguments attacking, rather than defending, the judgment when those arguments were not pressed" or "passed upon" below); *Jones*, 565 U.S. at 413. This Court is "a court of review, not of first view." *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.9 (2005). And under the Court's "traditional rule," where a question "was not pressed or passed upon below," that "precludes a grant of certiorari." *Williams*, 504 U.S. at 41. Such questions are "forfeited." *Jones*, 565 U.S. at 413.

These principles confirm that certiorari should be denied, as Habelt has forfeited any argument that Rule 10(a) makes the complaint's caption dispositive of party status. Habelt never even *cited* Rule 10(a) in his merits briefs below, much less argued that it compelled a ruling in his favor. See Dkt. 10, No. 22-15660 (9th Cir.) (opening brief); Dkt. 37 (reply brief). The only Rule 10 cited in his merits briefs was SEC Rule 10b-5. *E.g.*, Dkt. 10 at 5. Nor did the court below pass on the meaning of Rule 10(a) on its own initiative. Indeed, not even the *dissent* cited Rule 10(a).

Nor (if it mattered) is there any excuse for Habelt's failure to cite the procedural rule that he now deems dispositive. From the moment that he attempted to appeal the dismissal of PERSM's complaint, respondents vigorously contended that he was not a party and

lacked standing to appeal. That is why the Ninth Circuit ruled on that basis. If Rule 10 truly required treating Habelt as a party or otherwise gave him standing to appeal, he had every reason—and in all events was required—to raise that argument before the merits panel below. *Greenwood* v. *F.A.A.*, 28 F.3d 971, 977 (9th Cir. 1994) ("We will not manufacture arguments for an appellant."); *Webb* v. *Frawley*, 906 F.3d 569, 581 (7th Cir. 2018) (appellant "waived any counterarguments he may have had by not responding to [appellee]'s argument on this topic in his reply brief"). Habelt's failure to do so "precludes a grant of certiorari." *Williams*, 504 U.S. at 41.

III. Review should be denied because Habelt's alleged circuit splits are illusory.

Given that Habelt did not invoke Rule 10(a) below, it comes as little surprise that the Ninth Circuit did not address it. And given that the Ninth Circuit did not address it, it comes as little surprise that its decision did not "depart[] from how other courts of appeals have read Rule 10(a)," or "deepen" a split over its "interpretation." Pet. 3, 4. To state the obvious, a court cannot deepen a split of authority on an issue without addressing it.

Even setting that aside, however, whether Rule 10 makes the caption alone determinative of party status is not the subject of any circuit split. Nor is that surprising, given *Eisenstein*'s clear teaching, followed by the court below (Pet. 8a), that "[a] person or entity can be named in the caption of a complaint without necessarily becoming a party." 556 U.S. at 935. As noted, in quoting that portion of the decision below, Habelt uses a "citation omitted" to disguise the court's quotation of *Eisenstein*. Pet. 16. But as *Eisenstein* confirms,

that rule is black-letter law, and it has long been the rule in both the Ninth Circuit and others. *E.g.*, *United States* v. *99.66 Acres of Land*, 970 F.2d 651, 659 n.4 (9th Cir. 1992) ("[T]he caption of the complaint is not finally determinative of party status or interest in the proceedings."); *Williams*, 459 F.3d at 849 (the "caption is not determinative").

A. There is no circuit split over the weight of case captions in determining party status.

Habelt admits, as he must, that his theory that the caption alone controls conflicts with the circuits' uniform practice of "'look[ing] behind [the] names that symbolize the parties' in a caption." Pet. 12 (citation omitted). Hoping to avoid that practice, he says some circuits treat plaintiffs and defendants differently, applying the rule "only" when evaluating whether a putative *defendant* is a party. *Ibid.* ("Most circuits look outside the caption only to identify defendants."). Habelt's cases do not support that proposition. The cited split is illusory.

In *Whitley* v. *U.S. Air Force*, for example, the Seventh Circuit had to determine whether certain putative defendants were in fact defendants. 932 F.2d 971, *1. Whether a party was a proper plaintiff simply was not before the court. But in answering the question that was presented, the court applied a general rule: "in determining whether a *party* is named properly in a complaint, courts are not bound necessarily by the caption." *Ibid.* (emphasis added). Nowhere did the court suggest that it would look beyond the caption to determine "only" the *defendant's* status—its reasoning indicates that the same rule applies to any "party." See *ibid.* The same is true of *Ordower* v. *Feldman*,

826 F.2d 1569, 1571 (7th Cir. 1987), which (again) involved the application of that general rule to defendants but (again) in no way purported to *limit* that rule to defendants.

So too for Habelt's Tenth and D.C. Circuit cases. In *Trackwell* v. *U.S. Government*, 472 F.3d 1242, 1243-1244 (10th Cir. 2007), the court explained that "when the identity of the defendants is unclear from the caption, courts may look to the body of the complaint to determine who the intended and proper defendants are." But nowhere did the court suggest that looking to the complaint was permissible to determine "only" defendants' status, or that another rule would apply to plaintiffs. The same is true of *Bayer* v. *U.S. Department of Treasury*, 956 F.2d 330, 334 (D.C. Cir. 1992).

Habelt next misrepresents the law of the Second, Fifth, and Eighth Circuits, suggesting that they categorically *refuse* to "look past the caption to determine plaintiff party status." Pet. 13. Not so. Rather, each circuit agrees that the caption is accorded weight, but is not dispositive, often before ruling *against* plaintiff status on the facts presented. For example, in *Williams*—which both the majority (Pet. 9a n.2) and the dissent (Pet. 12a) below cited with approval—the Eighth Circuit denied party status in part because the section of the complaint that was labeled "parties" did not mention the putative plaintiff—exactly the situation here. 459 F.3d at 849. Likewise, in ruling against a putative plaintiff in *Abraugh* v. *Altimus*, 26 F.4th 298, 303 (5th Cir. 2022), the Fifth Circuit "accept[ed] that omission as a named party in the caption" was "not necessarily 'determinative as to the identity of the parties.'" Finally, the Second Circuit in *Hernandez-Avila* v. *Averill*, 725 F.2d 25, 28-29 (2d Cir.

1984), did not treat the caption as dispositive, but instead looked to the case's procedural history before concluding that the putative party was not a plaintiff below—as did the Ninth Circuit here. Pet. 9a.

To be sure, some courts emphasize that the caption "is entitled to considerable weight when determining who the plaintiffs to a suit are since plaintiffs draft complaints." *Williams*, 459 F.3d at 849; see Pet. 14. As discussed above, however, none of those courts treats the caption alone as dispositive; all consider the body of the complaint too. Moreover, all three circuit judges below endorsed the uniform view that the caption is "probative," but not "dispositive," citing Habelt's leading authority. Pet. 9a n.2 (citing *Williams*, 459 F.3d at 849); Pet. 12a (Bennett, J., dissenting) (same). That judges might disagree over the *application* of such a standard does not warrant certiorari. See Rule 10 ("certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law"). And insofar as being the party that drafted the complaint matters (see Pet. 9), it was PERSM—not Habelt—that drafted the operative complaint here. Critically, PERSM's complaint excluded Habelt not only in the "parties" section and in its definitions for "Lead Plaintiff" and "Plaintiff," but in the rest of the complaint's body as well.

In sum, all circuits, including the Ninth, accord the caption non-dispositive weight in determining party status. No circuit holds that courts may look past the caption to determine "only" defendants' status. And no circuit grants putative plaintiffs party status based solely on the caption, where the body of the operative

complaint does not even mention that individual. Accordingly, as one would expect after this Court's decision in *Eisenstein*, there is no split.

B. Habelt's petition does not implicate any circuit split on non-party standing.

Habelt's next alleged circuit split—based on "varying standards" governing when *non*-parties have standing to appeal (Pet. 17)—is equally illusory. Rather, as in *Osage Wind, LLC* v. *Osage Minerals Council*, any "tension among the circuits does not warrant further review" because Habelt's putative appeal was not "proper under any circuit's approach." See U.S. Invitation Br. 12 (No. 17-1237).

The Ninth Circuit recognizes non-party standing "when (1) the appellant, though not a party, participated in the district court proceedings, and (2) the equities of the case weigh in favor of hearing the appeal." *Hilao* v. *Est. of Marcos*, 393 F.3d 987, 992 (9th Cir. 2004) (citation omitted). Habelt says "the Ninth Circuit, unlike [some] other circuits, explicitly does not consider a nonparty's interest," and thus "overlook[ed]" his "stake here." Pet. 22. Not so, on both counts.[3]

First, regardless of any differences in labels or verbiage, the Ninth Circuit most certainly considers the non-party's substantive interest when evaluating "the equities of the case." Second, other circuits would *not*

[3] As explained below (at 28), Habelt does not identify any split over the "participation" portion of that test. That raises an independent vehicle problem, given the Ninth Circuit's alternative holding on that requirement.

treat Habelt as having any cognizable "interest" in appealing on these facts. For both reasons, Habelt's petition does not implicate any split.

In *S.E.C.* v. *Lincoln Thrift Ass'n*, 577 F.2d 600, 603 (9th Cir. 1978), for example, the Ninth Circuit permitted non-party creditors to appeal the denial of a motion to wind up a receivership and transfer proceedings to bankruptcy court. Given the possible liquidation of the company, the court granted standing due to the non-parties' "*legitimate interest* in whether the case was transferred to a bankruptcy court or in election of trustees or in appointment of a creditors' committee." *Ibid*. (emphasis added). Similarly, in *Wencke*, the Ninth Circuit reasoned "that non-party standing to appeal was proper for nonparty creditors" who possessed a "'legitimate interest' in the outcome of the appeal." 783 F.2d at 834 (quoting *Lincoln Thrift*, 577 F.2d at 603).

But not every "interest" supports non-party standing. For example, when the Philippines argued that it was "not bound by [a] settlement agreement, its argument for nonparty appellate standing to challenge that same agreement collapse[d]." *Hilao*, 393 F.3d at 993. That shows that some "interests" are not sufficiently weighty to support standing to appeal when considered on a case-by-case basis; it does not show a substantive difference in the underlying tests. Cf. *id* at 994 ("inconvenience to the Republic" "pending the resolution of an interpleader action in the High Court of Singapore" did not justify non-party standing). Likewise here, the court found that Habelt lacked a sufficient interest because he was "not bound by the district court's judgment." Pet. 10a. And the dissent, rather than recognizing "that the Ninth Circuit breaks rank with other circuits" (Pet. 4), simply cited

cases from other circuits in reasoning that the equities favored Habelt. Pet. 23a ("Other circuits have reached similar results."). That does not establish a split over the law.

Habelt never discusses the above cases (or any others) applying the Ninth Circuit's approach, but they flatly contradict his assertion that the Ninth Circuit ignores non-parties' interests in appealing. Pet. 22. Habelt's disagreement with the case-specific application of that rule here does not warrant granting certiorari. Rule 10.

Even the circuit decisions that Habelt says support his position would not recognize non-party standing here. His leading case agrees that a "nonparty may not appeal * * * when it is clear that it has no interest affected by the judgment." *Off. Comm. of Unsecured Creditors of WorldCom, Inc.* v. *S.E.C.*, 467 F.3d 73, 78 (2d Cir. 2006) (Sotomayor, J.). As explained above, the district court's pre-class certification dismissal did not resolve or otherwise limit any interests or claims that Habelt has against iRhythm. By definition, those interests were not "affected by" the judgment.

Moreover, the Second Circuit does not deem all purported interests sufficient to support standing to appeal. Rather, standing is afforded "only to certain non-parties who are not technically bound by a judgment, but whose legal rights are directly implicated by its entry." *Plumbers, Pipefitters & MES Loc. Union No. 392 Pension Fund*, 433 F. App'x at 30; see *Karaha Bodas Co.* v. *Perusahaan Pertambangan Minyak Dan Gas Bumi Negara*, 313 F.3d 70, 81 (2d Cir. 2002) (nonparty Republic of Indonesia could appeal judgment that allowed a party to garnish property that the Re-

public allegedly owned); *United States* v. *International Brotherhood of Teamsters, Chauffeurs, Warehousemen & Helpers of America, AFL-CIO*, 931 F.2d 177, 183-184 (2d Cir. 1991) (non-party union affiliates could appeal order that directly affected their practices). That rule is entirely consistent with the decision below, which found that the district court's pre-certification dismissal did not affect Habelt's legal rights. Pet. 10a.

Habelt's other authorities are equally irrelevant. For example, he cannot rely on decisions finding non-party standing where non-party children sought to appeal an order directing them to be deported to a different caregiver (*Sanchez* v. *R.G.L.*, 761 F.3d 495, 499 (5th Cir. 2014)); where a non-party tribe (the Osage Nation) "in fact own[ed] the beneficial interest in the mineral estate that [wa]s the subject of th[e] appeal" (*United States* v. *Osage Wind, LLC*, 871 F.3d 1078, 1085 (10th Cir. 2017)); where a non-party raised "the presumptive right of access to judicial documents" (*Doe* v. *Pub. Citizen*, 749 F.3d 246, 261 (4th Cir. 2014)); or where non-party parents of a rape victim brought a § 1983 action to garnish "proceeds" obtained by the perpetrator after he was arrested (*Curtis* v. *City of Des Moines*, 995 F.2d 125, 128 (8th Cir. 1993)). In each of these cases, the challenged order "conclude[d] the rights of the affected person" in a definitive way (*S.E.C.* v. *Enterprise Trust Co.*, 559 F.3d 649, 651 (7th Cir. 2009))—to remain in the country, to benefit from a mineral estate, to receive judicial documents, and to obtain proceeds from a wrongdoer.

Here, by contrast, the appealed order did not "conclude" Habelt's rights against iRhythm at all. Rather, this case resembles Habelt's authorities *denying* non-party standing where the challenged order did not

bind the putative appellant or otherwise affect its assets. Take *Broidy Cap. Mgmt. LLC* v. *Muzin*, 61 F.4th 984, 993 (D.C. Cir. 2023), where Qatar sought to appeal an order that ran against another party. There, as here, "as a nonparty to the underlying suit, Qatar [wa]s not 'bound' by that order," and thus lacked a cognizable interest in appealing it. *Ibid.*; see also *United States* v. *Stoerr*, 695 F.3d 271, 276 (3d Cir. 2012) (request for restitution by putative appellant against defendant was insufficient to appeal criminal sentence that did not specifically "aggrieve" him).

That holds true even if Habelt tries to reframe his alleged interest around the concern that "any claims brought in a subsequent lawsuit might be untimely." Pet. 22. The Second Circuit has rejected that *exact* reasoning, stating: "[An] [a]ppellant's disappointment and erroneous views regarding the effects of the judgment" on the timeliness of a later suit "simply do not confer it with standing to pursue [an] appeal." *Plumbers, Pipefitters & MES Loc. Union No. 392 Pension Fund*, 433 F. App'x at 30. The Ninth Circuit likewise does not allow putative appellants to bootstrap timing concerns into appellate standing, saying instead that such plaintiffs (and their "sophisticated counsel") "should have made arrangements" to "file their own action in a limited time period if necessity required." *Emps.-Teamsters Loc. Nos. 175 & 505 Pension Tr. Fund* v. *Anchor Cap. Advisors*, 498 F.3d 920, 925 (9th Cir. 2007). Habelt cites no decision that conflicts with that reasoning.

The Ninth Circuit's test does not just "read like some of these other approaches" (Pet. 21)—it *is* like those approaches, both generally and as applied here. Because no circuit would find that Habelt had an interest in a judgment against another party that did

not resolve his claims, he raises no viable split for review.

C. Habelt's petition has an independent vehicle problem, as he did not sufficiently participate in the district court proceedings.

Habelt's petition also has an independent vehicle problem. The Ninth Circuit requires putative nonparty appellants to show not only that the equities favor allowing them to appeal, but also that they sufficiently "participated in the district court proceedings." *Hilao*, 393 F.3d at 992. Yet Habelt did not satisfy that independent requirement, as his minimal participation "'all but ceased with the filing of the' initial complaint." Pet. 10a (quoting *Volkhoff*, 945 F.3d at 1242). Notably, Habelt does not allege any circuit split over that requirement. *E.g.*, Pet. 31 (asserting a split over "whether a court should consider the nonparty's stake in the outcome"). Indeed, the case that supposedly "acknowledge[s]" his alleged split says "courts have consistently required the nonparty to have *participated* in the case before the district court." *Kimberly Regenesis, LLC* v. *Lee County*, 64 F.4th 1253, 1261 (11th Cir. 2023) (collecting cases from Third, Fourth, Fifth, Eighth, Ninth, Tenth, and D.C. Circuits).

Review is thus unwarranted because, regardless of whether the circuits' tests might produce different results "in a hypothetical case, the differences are immaterial here." *Osage Wind*, U.S. Invitation Br. 14. The court below has already ruled that Habelt failed to satisfy a distinct and independent requirement for non-party standing to appeal, and the circuits uniformly agree on that requirement. That broad agreement on an independent ground for affirmance makes this case an especially poor candidate for certiorari.

IV. Review should be denied because the decisions below are correct.

Finally, each ruling below is correct on the merits —and for several independent reasons. Habelt essentially ignores that PERSM's complaint was dismissed pre-class certification, leaving him unbound by the judgment. Once that becomes clear, the remaining merits analysis is straightforward. And even if Habelt somehow had standing to appeal, the district court correctly rejected these securities claims on multiple independent grounds—meaning a ruling in his favor on the question presented would only prolong a case that has rightly been brought to an end.

A. The Ninth Circuit correctly held that Habelt was not a party.

The Ninth Circuit sensibly assesses whether someone is a party by evaluating the substantive allegations in "the body of the complaint." *Yeseta* v. *Baima*, 837 F.2d 380, 383 (9th Cir. 1988). That approach reflects the practical reality that "[t]he caption of an action is only the handle to identify it" (*Hoffman* v. *Halden*, 268 F.2d 280, 303-304 (9th Cir. 1959), overruled in unrelated part, *Cohen* v. *Norris*, 300 F.2d 24 (9th Cir. 1962)), and is often kept static for reasons of administrative convenience. Further, it accords with this Court's teaching that "[a] person or entity can be named in the caption of a complaint without necessarily becoming a party." *Eisenstein*, 556 U.S. at 935.

Were the issue not forfeited, *Eisenstein* would put to rest Habelt's view that Federal Rule of Civil Procedure 10(a) makes the complaint's caption not only relevant but dispositive, and "[t]he body of the [complaint]" here "makes clear that PERSM is the sole plaintiff"—it "makes mention neither of Habelt nor of

his individual claims." Pet. 9a. Further, because he is a stranger to that complaint, he was not a party to its dismissal—regardless of his vestigial presence on the caption. See *Eisenstein*, 556 U.S. at 935 (quoting 5A Wright & Miller, Federal Practice & Procedure § 1321 (2004)).

Critically, the complaint's generalized class allegations did not make Habelt a party because no class was ever certified. This Court has recognized that a "party" can include class members *post*-certification, as such individuals are then "bound by" any judgment. *Devlin*, 536 U.S. at 10. But the Court has rejected the "argument that a nonnamed class member is a party to the class-action litigation *before the class is certified*" as "novel and surely incorrect." *Bayer*, 564 U.S. at 313 (citation omitted). Habelt's position depends on that "novel and surely incorrect" view. But since he has neither provided any reason to diverge from *Bayer* nor suggested that it be overruled, that too confirms that certiorari should be denied.

That Habelt was not bound by the district court's judgment forecloses his suggestion that "due process" and "justice" require granting him standing to appeal. Pet. 25, 26. Habelt had notice that he needed to intervene after PERSM filed multiple complaints that nowhere listed him as a party. And the Ninth Circuit referenced Rule 25 to illustrate the elasticity of case captions—it did not *violate* that rule by pointing out that Habelt was not a party. *Contra* Pet. 27.

Habelt's suggestion that PERSM and the district court "treated him as a party" "at every turn" is nonsensical. Pet. 25. PERSM drafted several complaints that—in underlined, bolded, and capitalized letters—specifically identified the "**PARTIES**" to the lawsuit.

Habelt is nowhere to be found in those complaints, which were filed by PERSM's counsel, not Habelt's.

Similarly, the general rule that the PSLRA does not "prohibit the addition of named plaintiffs to aid the lead plaintiff" (*Hevesi* v. *Citigroup Inc.*, 366 F.3d 70, 83 (2d Cir. 2004)) does not answer whether a particular complaint includes such additional plaintiffs. Here, the body of the operative complaint does not mention Habelt, much less identify him as a plaintiff. Habelt also fails to explain how he could be a plaintiff where the district court required anyone wishing to aid PERSM to obtain the court's "prior approval" (Pet. 87a)—which Habelt never sought, let alone received. The notion that PERSM "assent[ed]" to his taking the helm (Pet. 24) is both unsupported by the record and contrary to that order.

In short, the issue is not that the court below made "inference[s]" about PERSM's complaint (Pet. 24)—it is that the operative complaint includes *no* substantive allegations from which to draw any inferences in Habelt's favor. Cf. *Cho* v. *Blackberry Ltd.*, 991 F.3d 155, 160-162 (2d Cir. 2021) (Pet. 24, 32) (complaint specifically discussed additional plaintiffs and their injuries). He points only to the caption, but that does not cut it. *Eisenstein*, 556 U.S. at 935.

B. The Ninth Circuit correctly held that Habelt lacked non-party standing to appeal.

Habelt likewise did not establish either pre-requisite to appeal as a non-party.

First, the equities did not favor non-party standing. The district court's judgment did not bind Habelt, and thus posed no barrier to his ability to seek relief on his

own—if indeed he had a valid interest in doing so, which the operative complaint does not allege. Habelt cites no decision in which a non-party was granted standing based on an unpled financial interest in an *uncertified* class action. His ode to non-parties with real interests in the underlying dispute (Pet. 28-31) simply ignores that, as a putative class member, he lacks any such interest.

No other conclusion could make sense of *Devlin*'s holding that class members are parties only *after* class certification, when they are "bound by" any subsequent judgment and thus entitled to appeal it. 536 U.S. at 10. *Devlin* would be pointless if putative class members could *also* appeal at the *pre*-class certification stage under the doctrine of non-party standing. Not surprisingly, no circuit has so held.

Second, Habelt did not sufficiently participate in the proceedings below—a requirement widely applied across the circuits. Habelt criticizes the Ninth Circuit for "cherry-picking" his lack of participation from the record. Pet. 30. But there are lots of cherries to pick:

- "[h]is involvement in the matter below all but ceased with the filing of the initial complaint";
- "[h]e did not apply to be appointed lead plaintiff";
- he did not "challenge PERSM's motion for appointment as lead plaintiff";
- he did not "otherwise participate in the suit after PERSM's appointment" (Pet. 10a); and
- he did not seek the district court's "prior approval," as required for his counsel to "work on this action for the putative class" (Pet. 87a).

In short, the record powerfully shows that Habelt did not sufficiently participate below—a point confirmed by his failure to identify *any* case allowing standing to appeal in similar circumstances. Cf. *Osage Wind*, 871 F.3d at 1085 (putative appellant immediately moved to intervene in the district court).

China Agritech v. *Resh*, 584 U.S. 732 (2018) (Pet. 30-31), is not to the contrary. The Court there held that *class* allegations in later suits are not tolled until the denial of class certification; the decision says nothing about the impact of a judgment on members of an uncertified class. Insofar as Habelt (and his counsel) specifically wanted to pursue an appeal on behalf of the class, they were welcome to intervene for that purpose, and their failure to do so does not indicate that the system is "unworkable." Pet. 28. Habelt lacks a cognizable interest in pursuing the claims of other putative class members. As this Court has explained, "seek[ing] intervention for purposes of appeal" is the "better practice." *Marino*, 484 U.S. at 304.

C. The district court correctly held that iRhythm was entitled to dismissal on the merits.

Finally, Habelt would have no prospect of prevailing on the merits even if he could somehow overcome his many other problems. PERSM's complaint largely attacked iRhythm's forward-looking predictions and opinions regarding the potential outcomes of an ongoing regulatory ratemaking. In dismissing those claims, the district court applied the sensible rule that such statements do "not ordinarily invoke a duty to disclose or provide a basis for a securities fraud claim," because "anyone—including research analysts—at-

tempting to predict the judgment of [the regulator] engages, by definition, in a problematic exercise distinguishable from the normal investment decision." *Epstein* v. *Wash. Energy Co.*, 83 F.3d 1136, 1141-1142 (9th Cir. 1996). The court also correctly held that the challenged statements were either protected by the PSLRA's "safe harbor," see 15 U.S.C. § 78u-5(c)(1), inactionable opinions, or not adequately alleged to be misleading. Pet. 74a. In addition, the court held that PERSM failed to "allege facts to support a strong inference of scienter"—an "independent reason" on which the entire "SAC fails." *Ibid.*

The dissent below misapplied the law and misconstrued the record in suggesting that three of the eighteen challenged statements should be remanded for further consideration. For example, he suggested that the statement that "CMS 'ha[s] everything they can get from us'" was potentially false and thus a possible basis for liability. Pet. 26a. But as the district court noted, when viewed in context, that statement was accurate: the speaker identified precisely the information that was purportedly omitted by identifying the items that had *not* been given to CMS. Pet. 67a-68a ("King expressly noted that iRhythm did not generate invoices that showed component costs."). Likewise, the remaining statements were paired with significant risk disclosures and concerned inactionable predictions and opinions about whether iRhythm's rates were likely to be altered. Pet. 56a-66a. By zooming in on sentence "fragments" to suggest otherwise (Pet. 59a), the dissent misses that context—and ultimately "the mark." Pet. 67a. Finally, even the dissent did not find that the district court should have denied the motion to dismiss, instead saying only that

the plaintiffs' allegations of scienter should be reconsidered on remand (Pet. 29a n.18)—where iRhythm would also have additional unaddressed contentions, such as PERSM's failure to allege loss causation.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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AUGUST 2024

APPENDIX

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United States District Court
Northern District of California
San Francisco Division

CASE NO.: 3:21-CV-00776-EMC

MARK HABELT, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

IRHYTHM TECHNOLOGIES, INC., *et. al.*

Defendants.

CLASS ACTION

HON. EDWARD MILTON CHEN

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE SECURITIES LAWS

JURY TRIAL DEMANDED

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TABLE OF DEFINITIONS

Term or Acronym	Definition
AECG	Long-term Ambulatory Electrocardiogram Device
AMA	American Medical Association
Bardy	Bardy Diagnostics, Inc.
BioTelemetry	BioTelemetry, Inc.
CAM patch	Bardy Diagnostics, Inc.'s Carnation Ambulatory Monitor patch
CardioNet	CardioNet, Inc.
CEO	Chief Executive Office
CFO	Chief Financial Officer
CMS	Centers for Medicare and Medicaid Services
Class Period	August 4, 2020 to July 13, 2021
Company	iRhythm Technologies Inc.
Complaint	Amended Complaint
Coyle	Defendant Michael Coyle
CPT	Current Procedural Technology Codes
Devine	Defendant Douglas Devine
Dr. Bloschichak	Dr. Andrew Bloschichak
Dr. Freeman	Dr. L. Neal Freeman
Dr. Quinn	Dr. Bruce Quinn

Term or Acronym	Definition
ECG	A conventional electrocardiogram
Exchange Act	The Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
Hill-Rom	Hill-Rom, Inc.
IDTF	Independent Diagnostic and Testing Facility
Indirect allocator	The standardized allowance CMS allows companies to recoup in reimbursement rates based on the historical ratios of indirect-to-direct costs, clinical labor costs, and work performed by physicians.
Individual Defendants	Defendants Kevin King, Michael Coyle, and Douglas Devine
iRhythm	iRhythm Technologies Inc. or the Company
IRTC	The ticker symbol for iRhythm's common stock traded on the NASDAQ.
King	Defendant Kevin M. King
Lead Plaintiff	Lead Plaintiff Public Employees' Retirement System of Mississippi

Term or Acronym	Definition
LifeWatch	LifeWatch Services, Inc.
MAC	Medicare Administrative Contractor
MCDA	Muller Consulting & Data Analytics, LLC
MCOT	Mobile Continuous Outpatient Telemetry
Muller	James Muller
Novitas	Novitas Solutions Inc.
PCBAs	Printed Circuit Board Assemblies
PE	The Medicare Physician Fee Schedule Practice Expense
PE rates	Payment rates established by CMS' standard cost methodology for services based on actual, direct costs of providing a service and a standardized fixed amount for indirect costs.
PFS	CMS' Medicare Physician Fee Schedule
Plaintiff	Lead Plaintiff Public Employees' Retirement System of Mississippi
Preventice	Preventice Solutions Inc.
Proposed Rule	Center for Medicare and Medicaid Services' proposed

Term or Acronym	Definition
	rule for the PFS applicable in 2021, released on August 3, 2020.
R&D	Research and Development Expenses
RUC	The AMA's Resource-Based Relative Value Scale Update Committee
SEC	U.S. Securities and Exchange Commission
SG&A	Selling, General and Administrative Expenses
Zio XT	The Zio XT patch or iRhythm's core product

Lead Plaintiff Public Employees' Retirement System of Mississippi (referred to herein as "Lead Plaintiff" or "Plaintiff"), individually and on behalf of all other persons similarly situated, by its undersigned attorneys, for its Second Amended Complaint (the "Complaint") against Defendants (defined below), alleges the following based upon personal knowledge as to those allegations concerning Lead Plaintiff and, as to all other matters, the investigation conducted by and through its attorneys, including, among other things, a review of Defendants' public statements and filings made with the U.S. Securities and Exchange Commission (the "SEC"), wire and press releases either issued by or regarding iRhythm Technologies Inc. ("iRhythm" or the "Company"), analysts' reports, information obtained from experts on coding, coverage and reimbursement rates associated with the Centers for Medicare and Medicaid Services ("CMS"), including Dr. L. Neal Freeman ("Freeman") and James Muller ("Muller") of Muller Consulting & Data Analytics, LLC, facts disclosed in the merger litigation between Bardy Diagnostics, Inc. ("Bardy") and Hill-Rom, Inc. ("Hill-Rom") in the Delaware Chancery Court, interviews conducted with former employees of the Company, and other information obtainable on the internet. Lead Plaintiff believes that substantial evidentiary support exists for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

1. This is a federal securities class action on behalf of a class consisting of all persons who purchased or otherwise acquired iRhythm's common stock between August 4, 2020 and July 13, 2021, both dates inclusive (the "Class Period") seeking to recover

damages caused by Defendants' violations of the federal securities laws and pursue remedies under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. iRhythm is a digital healthcare company that focuses on providing long-term ambulatory electrocardiogram ("AECG") devices that purport to diagnose cardiac arrhythmias. Unlike traditional devices that usually provide between 24 and 48 hours of monitoring, AECG devices can provide up to 14 days of electrocardiographic data that is scanned and analyzed by the Company's cardiac technicians, and then presented in a report to a doctor for diagnosis. iRhythm derives virtually all of its revenue from its core product, the Zio XT patch (hereafter the "Zio XT"), a water-resistant wearable patch-based biosensor incorporated with a monitor that is affixed to a patient's chest. While the Company aspires to develop and market a more advanced monitor that provides real-time monitoring, it has been unable to gain a foothold in the market for more sophisticated devices. As a result, iRhythm relied upon the Zio XT for over 85% of its total revenue.

3. Throughout the Class Period, all of the Company's Zio XT revenue was directly or indirectly tied to Medicare reimbursement rates. Accordingly, it was vital that Defendants were forthright with iRhythm investors about rate negotiations and the factors impacting those rates. At least 25% of the Company's total revenue was tied to servicing Medicare patients, and was directly impacted by Medicare reimbursement rates. The remaining sales to commercial payors were indirectly tied to Medicare reimbursement rates. Commercial payors typically

pay between 1.5 times to 2 times the rate set by CMS in a Medicare Physician Fee Schedule ("PFS") released annually. Moreover, the economic literature and a consensus of experts, including the opinions of Lead Plaintiff's expert, Dr. Freeman, confirms that commercial payors renegotiate rates as a multiple of the effective Medicare rate. Hence, if CMS reduces the reimbursement rate for any medical device or service in the PFS, then commercial rates also reduce proportionally as they are renegotiated over the following one to three years based on the going rate for Medicare reimbursement.

4. Medicare reimbursement rates are set using Current Procedural Technology codes ("CPT codes"), and CMS oversees reimbursement policy, including the adoption and pricing of CPT codes for medical services. Before the Class Period began, CMS delegated the pricing authority for AECG devices to a local Medicare Administrative Contractor ("MAC") known as Novitas Solutions Inc. ("Novitas"). Initially, Novitas set the reimbursement rate for the Zio XT at $311. However, Defendants knew that this initial rate set by Novitas was at risk because it was temporary, was criticized by industry experts, and was dramatically out of line with the rates set by virtually all the other MACs for similar products. Indeed, Defendants knew that the rate set by Novitas was an outlier because the Company's proposal for inflated rates was rejected by all the other MACs even before the Class Period began.

5. On August 3, 2020, after significant lobbying by iRhythm and medical associations, CMS released the Proposed Rule for the PFS covering 2021 (hereafter the "Proposed Rule"). The Proposed Rule initially identified a potentially favorable rate for

AECGs based upon a different medical device used as a proxy, but made clear that the data submitted by iRhythm and the industry was insufficient to establish national pricing. To establish national pricing, the Proposed Rule indicated that CMS would require actual invoices to substantiate rates representative of commercial pricing.

6. Like all federal rulemaking, CMS' Proposed Rule was subject to a notice and comment period. During that period, on October 5, 2020, a highly respected consultancy, Muller Consulting & Data Analytics, LLC ("MCDA") submitted as a comment a comprehensive and devastating report about the reimbursement rates identified in the Proposed Rule for 2021. Among other things, MCDA's report concluded that:

- The actual direct costs of the proxy device were significantly higher than the Zio XT, and the proxy device was far more complex and bore no clinical similarity to the Zio XT.
- An examination of an actual invoice from a direct competitor of iRhythm's demonstrated that the actual cost of the Zio XT ranged between $58.78 and $68.22.
- The actual reimbursement rates for the Zio XT based on CMS' standard cost methodology ranged between $75.26 and $85.85 because iRhythm improperly included prohibited, indirect costs for Selling, General and Administrative ("SG&A") expenses and Research and Development ("R&D") expenses to support the inflated reimbursement rates.

- Adoption of the proposed rate would have very serious, negative real-world consequences for taxpayers because in addition to $10.55 million for reimbursable direct costs, the proposed rate would subsidize an additional $32.58 million for unreimbursable SG&A expenses and $6.77 million for unreimbursable R&D expenses.
- A senior executive at another AECG device manufacturer admitted that industry participants had no incentive to provide an actual invoice because the actual cost of AECG devices was trending downwards.

7. A well-qualified expert on Medicare reimbursement rates, CPT codes, auditing and compliance retained by Lead Plaintiff, Dr. Freeman, corroborated these findings. Dr. Freeman is a member of the American Medical Association's ("AMA") CPT Advisory Committee. Specifically, as set forth in ¶¶122-134 below, Dr. Freeman affirmed that the invoice from iRhythm's direct competitor demonstrates that the rate in the Proposed Rule was significantly inflated, and that the other medical device used as a proxy had significantly higher actual direct costs and lacked clinical similarity to the Zio XT.

8. Instead of coming clean with investors about threats to Zio XT pricing, between August 2020 and December 2020, iRhythm's then Chief Executive Officer ("CEO") Kevin M. King ("King") falsely told investors that the Company had submitted "invoices" to support the reimbursement rates, that CMS "ha[s] everything they can get from us," that the Company's engagement with CMS was "so thorough and so

complete," and that the Company had "provided all of the necessary information and feedback" to CMS.

9. On December 1, 2020, CMS released a Final Rule for the PFS (hereafter the "Final Rule") rejecting the high initial proposed rate because of the risks that were known to Defendants. Specifically, the Final Rule concluded that "we are unable to identify accurate national pricing" "given the conflicting information and assertions provided by commenters." It also decided against using the irrelevant proxy price, emphasized the need to see an actual invoice to set commercial pricing, and delegated the decision to set reimbursement rates back to Novitas.

10. On this news, iRhythm's stock price declined by over 20% from its previous day closing price of $240.64 to close at $192.21 on December 2, 2020. The Company's stock price declined again on December 3, 2020 to close at $184.50, and again declined on December 4, 2020 to close at $180.80.

11. On December 2, 2020, King held another conference call with investors to address the Final Rule, and made even more brazenly false statements in response to pointed analyst questions. King falsely minimized the setback by claiming that "this is not a rate cut," blamed the agency's well-established cost methodology as a "rigid framework" that required "invoices" for categories that do not exist, and referred to non-existent "new data" that the Company would use to "shoot[]" for an even higher reimbursement rate. King further misrepresented that there would be absolutely no impact on the rates set by iRhythm's commercial payors if the Medicare rate was reduced. Within two weeks of making these additional statements that misled investors, King resigned from

his position as CEO and was replaced by Defendant Michael Coyle ("Coyle").

12. On January 29, 2021, Novitas set reimbursement rates for the Zio XT that reduced the previous rate of $311 set by the MAC down to an average rate within the range of $73.82 and $89.36.

13. Upon the announcement of Novitas' massive rate cut for the Zio XT, the Company's stock price declined by nearly 33% to close at $168.42 on January 29, 2021 from its previous day closing price of $251 on January 28, 2021, on heavy trading volume.

14. Between January 2021 and April 2021, the Company and its competitors met with both Novitas and CMS numerous times in an effort to convince them to raise reimbursement rates. According to evidence that emerged in litigation between one of iRhythm's direct competitors and its acquirer, high-level executives believed that the industry had only one opportunity to convince Novitas to set higher rates in early 2021. That same litigation—which consists of a trial record of 824 exhibits, live testimony from numerous fact and expert witnesses, and deposition testimony of 18 witnesses—revealed additional evidence to support a strong inference of scienter in this case, including the following:

- The Chief Financial Officer ("CFO") of one of iRhythm's direct competitors, represented by the same law firm that represents iRhythm in this Action, admitted under oath that the cost of the device—the largest component of total direct costs—was trending downwards, demonstrating that industry participants had no incentive to provide CMS the requested

invoice because doing so would justify rather than undermine a rate cut.

- Industry participants were on notice in late 2020 that Novitas' initial high rates were at serious risk.
- Expert analysis and testimony confirmed that iRhythm would lose up to 60% of its current revenue in the absence of a rate increase and run out of cash to sustain its operations in a very short amount of time.

15. Confidential Witness 1 ("CW1"), a senior executive at the Company who directly reported to King and Coyle and served as the Executive Vice President ("EVP") of Payer Relations and Market Access at iRhythm from July 2017 to May 2021, confirms that Defendants knew material, adverse information that rendered their Class Period statements false and misleading when made. CW1 is a reimbursement expert, who strategized and oversaw the Company's policies and practices for seeking reimbursement from CMS, Novitas and commercial payors, interfaced with CMS and the MACs concerning reimbursement rates, and regularly interacted with and advised the Individual Defendants concerning the rates for the Zio XT and the Company's reimbursement strategy. According to CW1:

- The Company did not provide CMS with an invoice and made no attempt, at any point, to break down the costs of the various components of the Zio XT device and associated service, even though Defendants could discern what the actual cost of each component was;

- Defendants knew that MCDA's analysis was correct, and further knew that iRhythm folded inappropriate indirect costs for SG&A expenses and R&D expenses in its proposed reimbursement rates for the Zio XT;
- In 2017, iRhythm hired and consulted with an industry expert, Dr. Bruce Quinn ("Dr. Quinn") of Bruce Quinn Associates LLC, who reported to iRhythm that: (a) the previous reimbursement rate set by Novitas was an outlier; (b) CMS would be laser-focused on assessing the core costs of each component of the Zio XT and would require Defendants to substantiate the respective costs; and therefore, (c) the Company would face major challenges with its chosen reimbursement strategy going forward;
- Based on high-level conversations with the Executive Medical Director of Novitas, Defendants knew that Novitas agreed with MCDA's analysis and ultimately set the reimbursement rates to closely match with MCDA's methodology, removing inappropriate indirect costs for SG&A expenses and R&D expenses;
- In February 2021, the Executive Medical Director of Novitas told Coyle that iRhythm's proposal for setting reimbursement rates was unacceptable, and that Novitas would not consider any alternative methodology that deviated from CMS' standard cost methodology unless and until Defendants first convinced all the other MACs that the alternative was reliable and valid; and

- The Individual Defendants understood at the outset that any reduction in Medicare reimbursement rates would detrimentally affect the rates for commercial contracts as well.

16. Between January 2021 and April 2021, Coyle provided investors with a series of excuses designed to deflect attention from the Company's repeated failure to provide a proper invoice that supported the Zio XT's costs. Coyle repeatedly claimed that the clinical superiority of AECG devices, including an "advanced analytic platform" with "machine learned algorithms," the time spent by a cardiac technician to analyze the scanned information from the Zio XT, the fully integrated nature of the Company's business model, and other administrative costs, substantiated inflated reimbursement rates. None of this was true. Coyle was on notice of the fact that similar arguments were made by similar providers and CMS rejected them over a decade ago. Coyle failed to disclose that the largest cost component of the CPT codes, the Zio XT device itself, was trending downwards, and did not admit to investors that iRhythm sought to shift prohibited indirect costs for SG&A expenses and R&D expenses to taxpayers, in direct violation of federal regulations. Coyle also failed to disclose material, adverse information that he learned from his own communications with the Executive Medical Director of Novitas in the beginning of 2021, and continued to make materially false and misleading statements that were undermined by facts that he learned from those communications.

17. On April 10, 2021, Novitas further refined its rates in response to the intense lobbying, rejecting the inflated rates urged by iRhythm and its peers but

modestly raising the reimbursement rate for the Zio XT to approximately $115, a figure that was still over 60% less than what iRhythm reaped before the Class Period.

18. On this news, the price of the Company's stock again plunged by over 39% to close at $80.36 on April 12, 2021 from its previous day closing price of $132.76 on April 9, 2021.

19. On June 1, 2021, after less than five months of service, Coyle abruptly resigned from his position as CEO and the Company's Board of Directors. Defendant Douglas Devine, ("Devine"), who then served as the Company's CFO, replaced Coyle as the Company's interim CEO. Devine continued to make similar misrepresentations in his short stint at the Company before the Company appointed yet another CEO in the fall of 2021.

20. Upon the announcement of Coyle's departure, the Company's stock price declined by nearly 18% to close at $62.77 on June 2, 2021 from its previous day closing price of $76.25 on June 1, 2021.

21. On July 13, 2021, CMS released the proposed rule that includes updated payment policies, payment rates, and other provisions effective on January 1, 2022. In this new proposed rule, CMS explicitly stated that "we remain concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be." External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 86 Fed. Reg. 39178-79 (July 23, 2021). It again emphasized that relevant information such as actual invoices, a more appropriate proxy input or other pertinent information "would be ideal

for us to use in establishing fair and stable pricing for these services." *Id.* It yet again stressed that "in the absence of such additional and actionable information (*that is, information that provides further context to information that has already been considered*) we are proposing to maintain contractor pricing for these services." *Id.* (Emphasis added).

22. In reaction to this final disclosure, which confirmed that iRhythm had not provided the information it claimed it had provided to CMS during the Class Period, on July 14, 2021, the price of the Company's common stock declined by nearly 9% to close at $53.90 from its previous day closing price of $59.07, on heavy trading volume.

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

JURISDICTION AND VENUE

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

25. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

26. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b). The Company has its principal place of business in San Francisco, California, and the other Defendants reside in this District. Many of the

acts and transactions that constitute the alleged violations of the law, including the dissemination to the public of materially false and misleading statements of fact, also occurred in this District.

27. 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 a national securities exchange.

PARTIES

28. During the Class Period, Lead Plaintiff suffered an estimated loss of $1.809 million in reliance on Defendants' misleading statements. ECF No. 22-3 at 2. Lead Plaintiff was damaged upon the disclosure and/or materialization of the risks concealed by Defendants' Class Period misrepresentations and omissions.

29. Defendant iRhythm is incorporated under the laws of the State of Delaware, with its principal place of business located in San Francisco. iRhythm's common stock trades on the NASDAQ under the ticker symbol "IRTC."

30. Defendant King officially served as the CEO of the Company from July 2012 until January 12, 2021. On December 14, 2020, iRhythm abruptly announced that King would retire as the Company's CEO in January 2021. This abrupt resignation came less than two weeks after CMS announced, on December 1, 2020, its Final Rule on payment policies, payment rates and other services furnished under the PFS on or after January 1, 2021. King made the

misleading statements in response to analyst questions identified in Paragraphs 148 through 168.

31. Defendant Coyle became the CEO of the Company on January 12, 2021. On June 1, 2021, Coyle abruptly and unexpectedly resigned from his position as CEO and a member of the Company's Board of Directors. Coyle made the misleading statements in response to analyst questions identified in Paragraphs 169 through 170, Paragraphs 172 through 173, Paragraphs 176 through 179, and signed the Annual Report that was filed with the SEC and contained the misleading statements identified in Paragraph 171.

32. Defendant Devine served as the Company's CFO from June 2020 to June 2021. On June 1, 2021, Devine began to serve as iRhythm's interim CEO. Devine made the misleading statements in response to analyst questions identified in Paragraphs 174 through 175, Paragraphs 180 through 183, and signed the Annual Report that was filed with the SEC and contained the misleading statements identified in Paragraph 171.

33. The Defendants referenced above in ¶30 through ¶32 are sometimes referred to herein collectively as the "Individual Defendants."

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

SUBSTANTIVE ALLEGATIONS

A. Background

1. iRhythm and its Core Product

35. iRhythm is a digital healthcare company that focuses on AECG devices that seek to diagnose cardiac arrhythmias. The Company went public in 2006 and began commercial operations in 2009 after receiving clearance from the United States Food and Drug Administration ("FDA").

36. Unlike a conventional electrocardiogram ("ECG") test that connects wires to a recording device and provides monitoring between 24 to 48 hours, an AECG attaches to the body and records up to 14 days of electrocardiographic data. AECGs are used to detect heart arrhythmias—abnormal rhythms that cause the heart to beat too fast, too slow, or irregularly. Some heart arrhythmias are harmless, while others can cause serious complications such as a stroke.

37. The Zio XT is iRhythm's core product, and accounts for at least 85% of its total revenue. It is a water-resistant, wearable patch-based biosensor combined with a monitor that is attached to a

patient's chest and records a patient's heart rhythm continuously for up to 14 days.

38. At the end of up to 14 days of continuous monitoring, the patient mails the Zio XT to iRhythm's Independent Diagnostic and Testing Facility ("IDTF"), where a cardiac technician scans the data and generates a report using iRhythm's proprietary software. Physicians are then provided with the cardiac technician's report and utilize the report to diagnose the patient's condition.

39. The Zio XT has several drawbacks. It does not transmit data in real-time, and there is a large lag between the time that monitoring begins and the time the data is ultimately provided to a physician for a diagnosis. Further, because many hospitals already employ their own ECG technicians, they are disincentivized from prescribing iRhythm's Zio XT, which requires them to unnecessarily pay for iRhythm's cardiac technicians to review data first.

40. Moreover, the Zio XT is a fairly basic medical device that consists of a biosensor that detects cardiac rhythm, a memory card, and a patch to affix the device onto the patient's chest.

2. iRhythm's Precarious Revenue Strategy

41. Despite these drawbacks, since receiving clearance from the FDA in 2009, the Zio XT gained a foothold in the AECG market, in part because it was one of the first extended wear monitoring devices on the market.

42. In those early days, because iRhythm was the only manufacturer offering an extended-wear ECG monitoring device, it could essentially name its own price in negotiations with third parties, leading to

excessively high reimbursement payments from both Medicare and third-party commercial payors. This is no longer the case, as other manufacturers now offer similar devices.

43. iRhythm's only other product of any significance is the Zio AT patch that the Company began to develop in the middle of 2017. The Zio AT is an external extended-wear ECG monitoring device that purports to provide real-time monitoring and transmittal of data, as opposed to the delayed monitoring services that the Zio XT provides. The Zio AT, however, has failed to establish a foothold in the market and accounts for only 10% of iRhythm's revenues. As a result, iRhythm remains almost exclusively dependent on reimbursement rates and resulting revenues generated by the Zio XT.

44. Indeed, nearly all of iRhythm's revenue is derived from the Zio XT, and the vast majority of the revenue is not through the sale of the device to physicians and hospitals, but by seeking reimbursement from third-party payors for scanning analysis and reporting performed by cardiac technicians at its IDTF in Houston, Texas.

45. Direct reimbursement from Medicare related services accounts for approximately 25% of iRhythm's revenue. The rest of iRhythm's revenue comes from commercial contracts with third-party payors. These third-party payors, however, take their cues from the Medicare reimbursement rates, and any change in the Medicare reimbursement rates generally impacts the price paid by commercial payors. This impact is not immediate because parties are bound by existing contracts but will inevitably materialize when commercial contracts are renewed.

3. iRhythm's Early Success Invites Competition

46. The high reimbursement rates from Novitas, combined with the simplicity of the Zio XT itself, invited competition, as several competitors moved to exploit the AECG market.

47. The AECG market came to be dominated by iRhythm, Bardy, BioTelemetry, Inc. ("BioTelemetry") and Preventice Solutions Inc. ("Preventice"). iRhythm's competitors were quick to make improvements to the weaknesses of the Zio XT by adopting better patch placement, increasing the number of sensors, reducing the time-to-reporting, and increasing rhythm-recording clarity. Very quickly, the Zio XT began to lose its edge to newer and more advanced AECG devices.

48. Indeed, as early as 2018, scientific journals compared the Zio XT to devices produced by the Company's competitors, including Bardy's Carnation Ambulatory Monitor ("CAM"), and found that the CAM patch "identified significantly more arrhythmias and resulted in better, more informed clinical decision-making" than the Zio XT. *Results of head-to-head comparison of patch-based arrhythmia monitors announced*, CARDIAC RHYTHM NEWS, May 16, 2018, https://cardiacrhythmnews.com/patch-based-arrhythmia-monitors/; *see also* Robert Rho, Mark Vossler, Susan Blancher, & Jeanne E. Poole, *Comparison of 2 ambulatory patch ECG monitors: The benefit of the P-wave and signal clarity*, 203 Am. Heart J. 109 (2018).

49. Criticism was not limited to outside of the industry, but also levied by iRhythm's own competitors and former employees:

- "We have the best algorithm in the business... some of the buzz words that get investors excited don't matter to physicians... everyone has automation on the backend." – Current senior executive at a large extended wear ECG monitoring company.
- "[Major product] has never been compared to another patch to measure performance, and that is intentional by [major provider] because it is the same thing for all the patches. They only show diagnostic yield relative to a standard Holter to compare performance, which is an easy comp." – Current senior executive at a large extended wear ECG monitoring company.
- "iRhythm benefitted from being the only player in the space for a long time... now you have a whole host of people all at the same time... we're doing it with a more accurate monitor. iRhythm is 'spewing a lot of hot air on these analyst calls.'" – Current senior employee at a smaller patch competitor who was formerly an employee of iRhythm.
- "[The device] was a cool idea, and that device is super easy to copy. [All the companies are] doing the same thing [now]." – Former sales representative at a large extended wear ECG monitoring company.

See October 5, 2020 MCDA Report, pp. 46-48, available at https://www.regulations.gov/comment/CMS-2020-0088-27016.

50. iRhythm's competitors did not just improve upon the technology, but also developed a better

business model by manufacturing a diversified product line. BioTelemetry and Preventice predominantly focus on Mobile Continuous Outpatient Telemetry ("MCOT") devices that measure and record heart rhythms between 10 to 30 days, with only 9% and 15% of their annual revenue dependent on AECG devices comparable to the Zio XT. BioTelemetry and Preventice were also recently acquired by international behemoths that provide a much larger financial support structure than iRhythm has. BioTelemetry merged with Koninklijke Philips N.V.—one of the largest multinational conglomerates in the world that focuses on health technology—in February 2021. Similarly, Preventice was acquired by Boston Scientific Corporation in January 2021. Bardy is in the process of merging with Hill-Rom, an established hospital bed and medical device manufacturer based in Chicago, Illinois with billions of dollars in revenue. Hence, iRhythm stands alone as completely exposed to a crippling impact from reimbursement rate cuts for the Zio XT.

B. The Regulatory Landscape for Reimbursement Rates

51. Medicare is administered by the Department of Health and Human Services through the CMS and its contractors. CMS and its contractors pay for outpatient medical services according to the PFS. One of the principal aims of CMS when it sets rates is to lower the costs of healthcare. Each calendar year, the CMS releases a proposed rule that updates payment policies, payment rates and other provisions for services provided under the Medicare PFS that applies to the following calendar year.

52. Medicare sets rates for reimbursement of medical devices and related services through CPT codes. CMS, as an arm of the Department of Health and Human Services, creates and administers the reimbursement policy for Medicare, and oversees the adoption and pricing of CPT codes for medical services. Commercial payors usually pay reimbursement rates that are one and a half times to two times the amount set by CMS for the CPT codes.

53. New services that are based on novel technologies are assigned Temporary Category III CPT codes, and CMS typically delegates pricing authority to local MACs, which are private organizations within designated regions that are authorized by CMS to set pricing for Category III CPT codes.

54. After iRhythm received FDA approval for the Zio XT in 2009, the Company applied for a set of Category III CPT codes, for which it received approval in 2011, with an implementation date of January 2012.

55. Category III CPT codes are not based on an intense evaluation process to determine reimbursement rates unlike permanent Category I codes, but instead are "contractor priced," which means that their reimbursement rate is established by each of the MACs in their respective regions.

56. Industry participants typically work with the CPT Editorial Panel of the AMA to lobby CMS for permanent Category I codes and help establish that a service constitutes "standard of care" for the purposes of reimbursement. The AMA's Resource-Based Relative Value Scale Update Committee (hereafter the "RUC") recommends the adoption of Category I

codes and related pricing to CMS. While CMS gives weight to the RUC's input and recommendations, it is not obligated to accept the RUC's recommendation in the final rule, and it can modify pricing based on its own analysis or delegate pricing to MACs in the final rule. Indeed, it is beyond dispute that CMS' process for developing rates is "iterative," and builds upon input from all participants, including those who submit information in the notice-and-comment period.

57. iRhythm only needed to secure a favorable rate from one MAC and then leverage that rate to seek higher reimbursement from third-party commercial payors. iRhythm was able to secure that favorable reimbursement rate from Novitas Solutions, which administered Region JH for CMS, and agreed to a $316 allowable fee (later adjusted to $311) for the Zio XT. iRhythm subsequently set up an IDTF in Houston, over which Novitas presides, and leveraged its Novitas rate to obtain high rates from commercial payors.

58. Notably, the reimbursement rates set by Novitas before the Class Period began were significantly outside the norm of rates set by other MACs for ECG monitoring devices. In fact, Novitas' rates were 6.5 times higher than the median reimbursement rate set by other MACs in other jurisdictions.

59. Under the Administrative Procedures Act, federal agencies are required to provide notice of proposed rules that are published in the Federal Register, and interested parties are usually required to be given the opportunity to participate in the rule-making process by submitting data, arguments, or

other information. A proposed rule can thus be modified in light of public comment, so long as the final rule promulgated by the agency is a natural outgrowth of the substance of the proposed rule. A final rule is considered a logical outgrowth of a proposed rule when parties should have anticipated that a change was possible based on the information received during the notice-and-comment period between the proposed rule and the final rule.

60. Federal law does not require agencies to finalize any proposed rule. Instead, "[a]gencies, are free—*indeed, they are encouraged*—to modify proposed rules as a result of the comments they receive." *Ne. Maryland Waste Disposal Auth. v. E.P.A.*, 358 F.3d 936, 951 (D.C. Cir. 2004) (emphasis added). The notice-and-comment period ensures that an agency's rules are tested with diverse public comments, and any affected party is allowed an opportunity to develop evidence to support its objections and thereby improve the final rule promulgated. Comments received by a federal agency are, in fact, expected to affect the outcome of a final rule.

C. The Proposed Rule for 2021

61. On August 3, 2020, CMS released the Proposed Rule for the Medicare PFS applicable on or after January 1, 2021. *See* External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93XX0, 93XX1, 93XX2, 93XX3, 93XX4, 93XX5, 93XX6, and 93XX7), 85 Fed. Reg. 50164 (Aug. 17, 2020). The Proposed Rule was followed by a several monthslong notice-and-comment period that was expected to culminate in the release of the Final Rule at the end of the year. The Proposed Rule identified

two new Category I codes related to AECG devices. Category I CPT codes 93XX0-93XX7 were expected to replace Category III CPT codes 0295T-0298T.

62. Based on the RUC's recommendation, CMS proposed reimbursement rates of $375.83 for CPT code 93XX2 and $386.16 for CPT code 93XX6. However, neither the RUC nor CMS received an actual invoice from iRhythm or any other industry participant that substantiated claims that the device actually cost hundreds of dollars. Without such information, the RUC resorted to the weighted mean of actual payment that iRhythm received from claims submitted to insurers to seek reimbursement for the device. However, in the Proposed Rule, CMS acknowledged that it received certain insurer claims data, but emphasized that "we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice." *Id*. at 50165. For this reason, CMS proposed to use a "crosswalk," whereby an existing device is used to supply a "proxy price." The device that the CMS considered for a "crosswalk" was an externally programmable implanted sacral neurostimulator, a device implanted inside the body and used to treat and improve urinary and fecal continence. While CMS acknowledged in the Proposed Rule that the neurostimulator was not clinically similar to AECG devices, CMS noted that it was "the closest match from a pricing perspective to employ as a proxy *until we are able to arrive at an invoice* that is representative of commercial market pricing." *Id*. at 50166 (emphasis added).

D. The October 5, 2020 MCDA Report

63. MCDA is a consulting firm based in Washington, D.C that was founded by Mr. James

Muller, and specializes in U.S. healthcare policy and data research. Mr. Muller has 13 years of experience in healthcare reimbursement policy, quality measurement, patient clinical profiling and analysis, and modeling of current healthcare affairs. His experience includes replicating and modeling the PFS Practice Expense ("PE") rate-setting methodology. The PE component is composed of the resources involved in furnishing medical services. Lead Plaintiff consulted with Mr. Muller in connection with the claims asserted in this Action.

64. On October 5, 2020, MCDA submitted a detailed 89-page report to CMS that opposed the proposed payment reimbursement rates for CPT codes 93XX2—which are for devices that last between 48 hours and 7 days—and 93XX6—which are for devices that last between 7 days and 15 days. MCDA's report was submitted to CMS in the notice-and-comment period between the announcement of CMS' Proposed Rule in August 2020 and CMS' Final Rule in December 2020.

65. MCDA argued that the Proposed Rule's preliminary rates for the CPT codes associated with the Zio XT were four times higher than permitted under CMS' standard PE cost accounting methodology. CMS' standard PE cost methodology establishes payment rates for services based on a bottom-up analysis of the direct costs of providing a service but standardizes and limits reimbursement for indirect costs such as marketing and promotion, research and development, software development, and other corporate overhead (hereafter the specific direct costs and the standardized, limited indirect allowance are called "PE rates").

66. According to MCDA, CMS calculates the PE rates primarily by identifying the "direct costs" of a device/service, which are the costs and labor employed to manufacture the product. CMS does not, however, allow companies to include individual "indirect costs" such as sales and marketing expenses. Instead, it only allows a standardized allowance for indirect costs, which is otherwise known as the "indirect allocator." Importantly, the indirect allocator standardizes the amount a company can receive in indirect costs through a metric based on the historical surveyed ratios of indirect-to-direct costs, clinical labor costs, and work performed by physicians, and does not allow companies to simply include all indirect costs, as that would incentivize companies to incur unnecessary indirect costs and inflate their reimbursement rates.

67. MCDA analyzed the costs identified in iRhythm's financial statements to determine the amount of iRhythm's indirect costs, to ascertain whether such costs were impermissibly being included in the proposed reimbursement rates. It then subtracted the inappropriate indirect costs to calculate the actual direct costs of the Zio XT patch. According to MCDA, these calculations showed that the proposed reimbursement rates for the Zio XT were grossly inflated.

68. iRhythm could not get away with such inflation if it submitted traditional invoice data to CMS like most companies, because such invoices would allow CMS to clearly identify the direct cost of each component in a device or service. To obscure the truth, iRhythm declined to submit actual invoices, instead providing CMS with insurance claim and cost data that showed only the total cost charged to third-

party payors without any breakdown of the cost of the different components of the Zio XT. According to MCDA, this was improper because it concealed required information about the actual direct input costs for the Zio XT. *See* October 5, 2020 MCDA Report, at p. 3.

69. MCDA then analyzed invoice data from iRhythm's competitors to calculate the true direct costs of the Zio XT that iRhythm should have, but did not, identify by providing its own invoices to CMS. MCDA also reviewed interviews with executives at iRhythm's competitors, who stated that the true cost of the Zio XT was dramatically less than the reimbursement rates in the Proposed Rule, and Defendants knew this fact, which is why they chose not to provide CMS with any traditional invoice data. MCDA further reviewed the analysis of a well-qualified Robotics Engineer, who was also a user of the Zio XT, and the Robotics Engineer confirmed that the actual cost of the Zio XT was far lower than the rates identified in the Proposed Rule. Finally, MCDA outlined the economic distortions and adverse consequences that would result if CMS finalized the rates of $375.83 for 93XX2 and $386.16 for 93XX6.

70. Ultimately, MCDA concluded that the actual PE rates should be approximately $66.25 for CPT code 93XX2 and $82.66 for CPT code 93XX6, compared to the Proposed Rule's rates of $375.83 for CPT code 93XX2 and $386.16 for CPT code 93XX6.

1. Analysis of Proxy Items

71. MCDA first analyzed the Proposed Rule's use of a "proxy" input—the externally programmable implanted neurostimulator—and concluded that the proxy input lacked clinical and technical relevance to

extended wear AECG devices like the Zio XT. MCDA noted that the proxy input was chosen solely because it was the closest supply item in price ($416.85 total cost per service compared to iRhythm's claim that its services involving the Zio XT cost $413.24).

72. MCDA identified the disparities between the proxy input and AECG devices. Neurostimulators are highly complex FDA approved devices implanted into the body with high-powered batteries that can last for five to seven years and can be controlled wirelessly with a smartphone. In contrast, the Zio XT is not approved for implantation into the body, lasts for only 14 days, and will not interface with a smartphone.

73. Moreover, the neurostimulator is far more complex than an AECG device because it is a medical treatment, not just a diagnostic tool. The Zio XT is a basic electrode and printed circuit board enclosed by plastic that collects and stores a small amount of data to be downloaded at a later date and lasts for only 14 days. In contrast, the neurostimulator is a complex wireless device planted inside the body with an operating system that, instead of simply observing and storing data, acts on the body by applying a controlled electric current to the sacral nerve to improve urinary and fecal continence.

74. Accordingly, MCDA found that the proxy input served as a grossly inappropriate comparator for the Zio XT.

2. Direct Cost of the Zio XT Patch

75. In challenging the Proposed Rule's rates for the Zio XT, MCDA first examined how CMS calculates reimbursement rates. Specifically, MCDA analyzed previous rulings by CMS and found that the

standard CMS methodological principles relevant to the valuation of actual costs are:

- Indirect costs incurred by the provider billing the service are not included as direct inputs.
- A direct input must be exclusively used for one service at one time. If an input into a service can be used for multiple services simultaneously, then it is an indirect cost that cannot be included.
- If a direct input into a service can be used in multiple services (but exclusively for one at a time), then that input is a direct equipment input.

76. MCDA calculated the "true" direct cost of the Zio XT by identifying the overall costs to furnish the Zio XT—the total operating expenses—and then subtracted inappropriate indirect costs, such as R&D costs and SG&A costs. Throughout its calculations, MCDA used iRhythm's 2019 10-K to identify the actual "direct costs" for the Zio XT based on the Company's "cost of revenue," as well as indirect costs such as R&D costs and SG&A costs.

77. MCDA pointed out that, by iRhythm's own admission in its 2019 10-K filing, the Company's "cost of revenue" included prohibited indirect costs such as equipment and infrastructure expenses, and amortization of internal-use software. As a result, while MCDA attempted to remove all prohibited indirect costs from the total direct cost figure, it was unable to do so, making MCDA's calculations likely higher than the true total direct cost of the Zio XT.

78. However, when MCDA subtracted the Company's SG&A costs and R&D costs, it was able to

determine that the actual direct cost of the Zio XT patch was $41.17 per service.

79. MCDA also put together a table to outline these direct cost calculations:

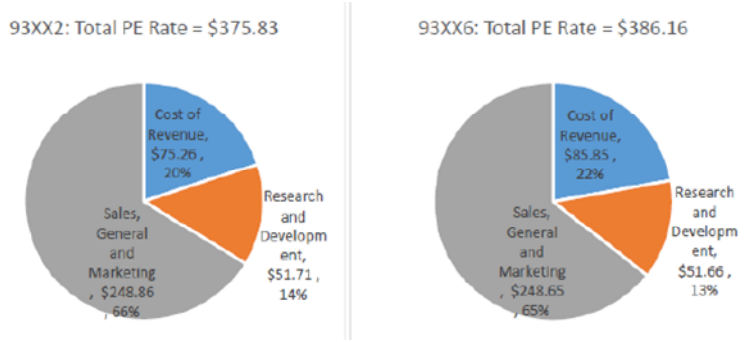
			Other Directs to Exclude			Est Cost per Service net of Other Directs	Adjustment to Align with Proxy Code	Patch Supply Input		
Cost Category	Total Costs (10-K 2019 Costs)	Est. Cost per Service	93XX2	93XX6	50/50 Blend			Incl All Costs	Excl Sales, General & Administrative	Excl R&D
Cost of Revenue	$ 52,485,000	$ 90.85	$ 43.91	$ 54.73	$ 49.32	$ 41.53	0.99134	$ 41.17	$ 41.17	$ 41.17
Research & Development	$ 37,299,000	$ 64.56				$ 64.56	0.99134	$ 64.00	$ 64.00	n/a
Sales, General & Administrative	$ 179,523,000	$ 310.75				$ 310.75	0.99134	$ 308.06	n/a	n/a
TOTAL	*$ 269,307,000*	*$ 466.17*				*$ 416.85*	*0.99134*	*$ 413.24*	*$ 105.18*	*$ 41.17*

80. MCDA then calculated the PE rates for the Zio XT by utilizing CMS' own practice expense rate-setting methodology, but adjusting to remove the SG&A and R&D costs that iRhythm had inappropriately folded into its claimed costs.

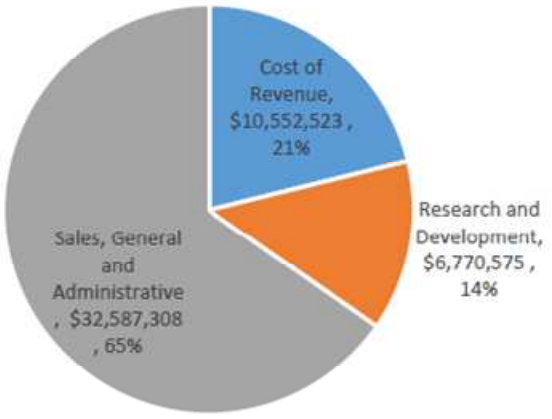
81. Removing the inappropriately-included indirect costs decreased the baseline PE rates to $75.26 for CPT code 93XX2 and $85.85 for CPT code 93XX6:

	Direct Supply Input	93XX2		93XX6	
		>48 hour - 7 Days		>7 - 15 Days	
Scenario	Assumption	PE RVU	PE Rate	PE RVU	PE Rate
CMS Published	$ 413.24	11.65	$ 375.83	11.97	$ 386.16
Baseline - Include all Costs including Sales, General & Administrative and R&D	$ 413.24	11.65	$ 375.83	11.97	$ 386.16
Include Cost of Revenue and Research & Development	$ 105.18	3.94	$ 126.97	4.26	$ 137.51
Include only Cost of Revenue	$ 41.17	2.33	$ 75.26	2.66	$ 85.85

82. As a result, MCDA found that, under the proposed reimbursement rates, only 20% of CPT code 93XX2's proposed rate and 22% of CPT code 93XX6's proposed rate was attributable to the actual cost of revenue, while the rest simply represented prohibited indirect costs:



83. These inflated rates would have very serious, negative real-world consequences for taxpayers. According to MCDA, implementation of the inflated reimbursement rates would mean that Medicare would pay iRhythm approximately $49.9 million, only $10.55 million of which actually amounted to reimbursable direct costs of the Zio XT, and the rest impermissibly subsidized SG&A expenses ($32.58 million) and R&D expenses ($6.77 million):



84. MCDA also reviewed analysis by a well-qualified Robotics Engineer, who examined iRhythm's patents to estimate the cost of the Zio XT.

The Robotics Engineer had over 30 years of experience in the design, production, procurement, and management of subcontractors utilizing Printed Circuit Board Assemblies ("PCBAs")—the primary electronic component of the Zio XT patch. Additionally, the engineer was a past user of the Zio XT himself and was therefore familiar with the device as a consumer.

85. The Robotics Engineer estimated that the Bill of Materials to produce each PCBA when produced in bulk volume was "most likely no more than $30-40, and was extremely unlikely to be higher than $50 per unit[.]" *See* October 5, 2020 MCDA Report, at p. 24. The Robotics Engineer's estimate acknowledged that there may be additional costs associated with shipping and refurbishing the product, but that those costs were unlikely to be more than $30-40.

86. After fully analyzing the Zio XT, the Robotics Engineer concluded that "[e]ven if there was significant undercounting of cost drivers ... the cost to manufacture the most expensive physical component of the Zio XT device is relatively low." *Id*.

87. Ultimately, the Robotics Engineer concluded that, if each PCBA were used only once, the total cost per unit—including shipping and refurbishing—would be no more than $80-90. Because, however, the PCBAs are designed to be re-used multiple times, the $80-90 cost would decrease further over time.

3. Comparison with Similar Devices

88. MCDA also reviewed comparable AECG devices and their invoices to calculate comparable PE rates. Critically, MCDA compared the efficacy of the comparable devices to the Zio XT to demonstrate that

they were comparable devices. For example, MCDA compared the Zio XT to BioTelemetry's ePatch 2.0 because it was the second largest biller to Medicare, after the Zio XT. As the following table illustrates, the ePatch has all of the features of the Zio XT (and then some):

	ePatch™	Zio® XT[1]
Extended Holter	✓	✓
Comprehensive Product Portfolio	✓	
Record Up to 14 Days	✓	✓
Channels	Single or 3-Channel	Single only
If Patch Peels Off	Reapply Fresh Patch	Service Ends
Number of Replacement Patches Included	Up to 2	
Alternate Non-patch Option* (ePatch sensor with lead wire adapter)	✓	
Mail-Back Option	✓	
In-office Uploads**	✓	

89. However, actual invoice data from BioTelemetry indicates a reimbursement rate much lower than that proposed initially for Zio XT. Applying the standard methodology for calculating reimbursement rates to this data, MCDA arrived at a PE rate for CPT code 93XX2 that ranged between $58.78 to $68.22, and a PE rate for CPT code 93XX6 that ranged between $69.60 to $85.21.

90. MCDA repeated this process to compare the Zio XT to two other ECG monitoring devices: ScottCare's novi+ and Cardiac Insight's Cardea

SOLO System. With ScottCare's novi+, MCDA reviewed a purchase invoice and a contract to calculate its PE rates. MCDA was unable to obtain a quote or purchase invoice for Cardiac Insight's Cardea SOLO System, and instead used the GSA Advantage website's list of product pages, along with Cardiac Insight's own published financial case studies to calculate the appropriate PE rates.

91. Using the same analysis, MCDA found that ScottCare's novi+ PE rates for CPT code 93XX2 ranged from $80.91 to $87.43, and for CPT code 93XX6 ranged from $111.00 to $119.44. For Cardiac Insight's Cardea SOLO System, MCDA arrived at a PE rate for CPT code 93XX2 that ranged between $163.30 to $177.12. MCDA took care to note that Cardea SOLO patches attained the highest PE rate because—unlike the other ECG monitoring devices, including iRhythm's Zio XT— "Cardiac Insight chooses to sell their patches as a one-use disposable supply and not re-use them across multiple services." *See* October 5, 2020 MCDA Report, at p. 6.

92. The following table provides a full breakdown of direct costs and PE rates based on quotes and purchase invoices for the comparable ECG monitoring devices:

	93XX2 (>48 hours to 7 days)			93XX6 (>7 days to 15 days)		
	Total Direct Costs	PE RVU	PE Rate	Total Direct Costs	PE RVU	PE Rate
Current CMS Proposal	***$457.15***	***11.65***	***$ 375.83***	***$467.97***	***11.97***	***$ 386.16***
BioTelemetry ePatch®						
ePatch® 3-year Useful Life / Software Low Tier / Software 2-Year Useful Life	$ 72.63	2.02	$ 65.20	$ 92.56	2.52	$ 81.30
ePatch® 3-year Useful Life / Software Mid Tier / Software 2-Year Useful Life	$ 73.93	2.05	$ 66.25	$ 94.25	2.56	$ 82.66
ePatch® 3-year Useful Life / Software High Tier / Software 2-Year Useful Life	$ 76.37	2.11	$ 68.22	$ 97.40	2.64	$ 85.21
ePatch® 5-year Useful Life / Software Low Tier / Software 2-Year Useful Life	$ 66.70	1.87	$ 60.41	$ 80.69	2.22	$ 71.71
ePatch® 5-year Useful Life / Software Mid Tier / Software 2-Year Useful Life	$ 68.00	1.91	$ 61.46	$ 82.38	2.27	$ 73.08
ePatch® 5-year Useful Life / Software High Tier / Software 2-Year Useful Life	$ 70.44	1.97	$ 63.43	$ 85.53	2.34	$ 75.62
ePatch® 3-year Useful Life / Software Low Tier / Software 5-Year Useful Life	$ 70.61	1.97	$ 63.57	$ 89.95	2.45	$ 79.19
ePatch® 3-year Useful Life / Software Mid Tier / Software 5-Year Useful Life	$ 71.25	1.99	$ 64.09	$ 90.78	2.48	$ 79.86
ePatch® 3-year Useful Life / Software High Tier / Software 5-Year Useful Life	$ 72.44	2.02	$ 65.05	$ 92.32	2.51	$ 81.11
ePatch® 5-year Useful Life / Software Low Tier / Software 5-Year Useful Life	$ 64.68	1.82	$ 58.78	$ 78.08	2.16	$ 69.60
ePatch® 5-year Useful Life / Software Mid Tier / Software 5-Year Useful Life	$ 65.32	1.84	$ 59.30	$ 78.91	2.18	$ 70.27
ePatch® 5-year Useful Life / Software High Tier / Software 5-Year Useful Life	$ 66.51	1.87	$ 60.26	$ 80.45	2.22	$ 71.52
ScottCare® novi+™						
novi+™ 2-Year / Include software as Direct (2-year)	$100.15	2.71	$ 87.43	$139.77	3.70	$ 119.44
novi+™ 2-Year / Include software as Direct (5-year)	$ 96.03	2.61	$ 84.10	$134.44	3.57	$ 115.13
novi+™ 2-Year / Exclude software from Directs	$ 92.08	2.51	$ 80.91	$129.32	3.44	$ 111.00
novi+™ 5-Year / Include software as Direct (2-year)	$ 81.14	2.23	$ 72.07	$101.75	2.75	$ 88.72
novi+™ 5-Year / Include software as Direct (5-year)	$ 77.02	2.13	$ 68.75	$ 96.42	2.62	$ 84.42
novi+™ 5-Year / Exclude software from Directs	$ 73.07	2.03	$ 65.55	$ 91.30	2.49	$ 80.28
Cardea SOLO™						
Cardiac Insight Studies: $147.88 Supply	$191.94	5.01	$ 161.58	na	na	na
GSA Advantage: $167.11	$211.17	5.49	$ 177.12	na	na	na

93. The table illustrates that the PE rates for comparable ECG monitoring devices are consistent with the PE rates of the Zio XT once improper indirect costs are removed from iRhythm's total costs.

4. Statements of Other Parties

94. MCDA was not the only party to take issue with the proposed reimbursement rates, the actual direct costs to produce AECG devices, iRhythm's failure to provide traditional invoice data, or iRhythm's assertions of product superiority.

95. As outlined in MCDA's report to CMS, MCDA reviewed an interview with a current senior executive at a large extended wear ECG monitoring company, who expressed surprise that the Proposed Rule overlooked standard methodology and instead used an irrelevant proxy input that resulted in an inflated reimbursement rate. Significantly, the senior executive did not expect any other ECG monitoring companies to deviate from iRhythm's strategy and actually provide CMS with a traditional invoice because doing so would decrease reimbursement.

96. Another senior executive at one of iRhythm's competitors stated that the production costs for each AECG device were less than $50, and would decrease over time as demand scaled upwards. The senior executive also pointed out that the software utilized by other manufacturers was comparable to iRhythm's. The senior executive emphasized that his company's ECG monitoring device—produced at less than $50 per unit—was superior to the Zio XT, as it allowed customers to own and control the data, as opposed to the Zio XT which requires doctors to request reports after iRhythm's cardiac technicians scan and analyze the data.

5. Economic Distortions and Adverse Consequences

97. After identifying the true direct costs of the Zio XT, MCDA discussed the economic distortions and adverse consequences that would result if CMS finalized the inflated reimbursement rates from the Proposed Rule. Most notably, MCDA delineated how "CMS would be creating a significant economic distortion that can be exploited by providers and suppliers to generate remarkably high profits. [The Proposed Rule] sets up a dangerous environment of perverse economic incentives that can and likely will be exploited – most likely legally – at the detriment of taxpayers, the benefit of physicians and suppliers, and without any clear benefit to patients." *See* October 5, 2020 MCDA Report, at p. 42.

98. MCDA reviewed interviews with senior executives at iRhythm's competitors, who stated that the exponential increase in reimbursement rates for the Zio XT would create an incentive for AECG

manufacturers to adopt at least four different abusive tactics if adopted in the Final Rule:

a. AECG providers simply generate incremental profits from the inflated reimbursement rates, costing Medicare and taxpayers exponentially more money;

b. Dominant AECG providers like iRhythm spend aggressively on direct-to-consumer sales and marketing to promote products regardless of clinical necessity, thereby generating greater profits at the expense of Medicare and taxpayers;

c. AECG providers spend aggressively on sales and marketing in an effort to induce physicians to prescribe the devices, and then increase the charge to physicians to cover the increased sales and marketing efforts, thereby increasing profits at the expense of Medicare and taxpayers; and

d. AECG providers engage in fraud and abuse by encouraging the use of AECG devices, even without cause or need, to capitalize on the inflated reimbursement rates at the expense of Medicare and taxpayers.

99. Consequently, MCDA urged CMS not to adopt the initially proposed inflated PE rates in the Final Rule.

E. iRhythm Fails to Contest the Core Findings of the MCDA Report

100. On October 5, 2020, iRhythm filed a 3-page perfunctory response comment intended to prevent both investors and the CMS from appreciating the facts raised by MCDA in its report. *See* October 5, 2020 iRhythm Comment to CMS, available at https://www.regulations.gov/comment/CMS-2020-0088-30888.

101. iRhythm's October 5, 2020 comment falsely claimed that the Zio XT was entitled to an inflated rate because it provided the benefits of a longer duration of service and analyzed more clinical data than the other devices, including BioTelemetry's ePatch. This claim was false because the ePatch also provides up to 14 days of continuous monitoring and has virtually the same features as the Zio XT.

102. The October 5, 2020 comment also stressed that the only studies used to craft the recommendations by healthcare experts involved iRhythm's Zio XT, and no other AECG devices. iRhythm argued that this fact, combined with the fact that the Zio XT constituted 97% of all Medicare billing for AECG devices, meant that CMS should disregard the evidence provided by MCDA concerning the actual invoice data of BioTelemetry's ePatch.

103. As a result, iRhythm urged CMS to adopt the inflated reimbursement rate in the Final Rule.

F. The Final Rule for 2021

104. On December 1, 2020, CMS released the Final Rule that established payment policies, payment rates and provisions for AECG monitoring and other medical services for calendar year 2021. In the Final

Rule, CMS again emphasized that it did not receive any traditional invoices to support the inflated reimbursement rates initially proposed for AECG devices, and that CMS requires "an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item." External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 85 Fed. Reg. 84632 (Dec. 28, 2020). CMS also stressed that while it was aware of arguments from iRhythm and other manufacturers regarding how data from an AECG device is uploaded for the healthcare provider's use, "we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice." *Id.* Because Zio XT accounted for the majority of the Medicare-reimbursed market, these statements directly reflected iRhythm's failure to provide required documentation.

105. In the Final Rule, CMS acknowledged the severe criticisms contained in MCDA's October 5, 2020 Report, and found that "[g]iven the conflicting information and assertions provided by commenters, we are unable to identify accurate national pricing" for devices such as the Zio XT. CMS again welcomed the submission of additional invoices or other pricing information to determine accurate pricing for the AECG devices. It also refused to establish pricing based on using the neurostimulator as a proxy price "pending additional information." *Id.* at 84633-34. While CMS maintained Category I CPT codes for AECG devices, allowing those services to be provided and billed to Medicare patients, it again delegated pricing for those codes to the regional MACs for

calendar year 2021. Hence, Novitas remained responsible for determining the reimbursement rates for the Zio XT.

106. On this news, iRhythm's stock price declined by over 20% from its previous day's closing price of $240.64 to close at $192.21 on December 2, 2020. The Company's stock price declined again on December 3, 2020 to close at $184.50, and again declined on December 4, 2020 to close at $180.80.

107. Within two weeks of the Final Rule's release, King abruptly retired as the Company's President and CEO. On January 12, 2021, Coyle became the Company's CEO.

G. The December 30, 2020 MCDA Report

108. On December 30, 2020, after CMS delegated the decision to set reimbursement rates back to the MACs for 2021, MCDA circulated another report that directly addressed and refuted the arguments made by iRhythm in its October 5, 2020 comment.

109. MCDA addressed iRhythm's claims that the existing reimbursement methodology was inappropriate for a vertically integrated company like iRhythm, and did not fully consider the alleged high clinical value of the Zio XT. Additionally, MCDA presented an updated simulation of the PFS rates, which it originally produced in the October 5, 2020 Report to establish what the true reimbursement rates should be, recalculated using 2021 PFS Final Rule data and methodology.

1. The Appropriateness of the Standard Methodology

110. With respect to iRhythm's claim that "clinical value" itself justified above-cost reimbursement rates,

MCDA emphasized that nothing in the Social Security Act permitted "clinical value" to be taken into account when setting PE rates, which are instead largely based on the actual cost of the device itself plus a standardized amount for indirect costs designed to prevent providers from recouping impermissible costs based on their own subjective opinions.

111. MCDA then rebutted iRhythm's false contention that vertical integration justified high reimbursement rates. MCDA pointed out how, even with data limitations due to vertical integration, CMS could use invoice data from comparable AECG devices, such as BioTelemetry's ePatch, which were identified and discussed in MCDA's October 5, 2020 Report.

112. MCDA noted that CMS grappled with a similar issue in 2008 concerning direct inputs for vertically integrated providers of cardiac monitoring services, which demonstrated that a manufacturer's claim that accurate invoicing could not be provided because of vertical integration would not prevent CMS from faithfully applying its reimbursement methodology in the Final Rule. The 2008 situation that MCDA referenced involved LifeWatch Services, Inc. ("LifeWatch") and CardioNet, Inc. ("CardioNet"), and is outlined in Section M(1) below. *See* ¶¶184-188. Like iRhythm, LifeWatch and CardioNet argued that the benefits of their 24/7 remote cardiac monitoring services could not be accurately captured due to their unique business structures, and as a result, the PE rates did not reflect their proper relative costs. After careful consideration, CMS rejected these arguments and applied its standard methodology, identifying direct cost inputs despite the manufacturers' claim

that vertical integration made such inputs unmeasurable.

113. With respect to iRhythm's claim that high operating costs justified high reimbursement rates, MCDA demonstrated that its actual operating costs attributable to the Zio XT were, in fact, low after stripping out prohibited indirect costs attributable to SG&A expenses and R&D expenses that iRhythm had improperly sought to fold into the reimbursement rate. MCDA also showed that iRhythm's actual direct costs closely match the direct costs of BioTelemetry's ePatch, for which an invoice was available and examined by MCDA.

114. Finally, MCDA directly addressed iRhythm's misleading claim that the cost of specialized analytical software was unaccounted for in the standard reimbursement methodology. MCDA responded that the cost of the software was already accounted for under the standard methodology in other services and could be accounted for in the standard reimbursement methodology for 932X2 and 932X6. As MCDA showed, even if iRhythm declined to provide invoices detailing analytical costs, the direct cost could be derived either by backing out other improperly-included costs like SG&A expenses and R&D expenses, or estimated by reference to comparable costs of the analytical software for BioTelemetry's ePatch, which MCDA estimated was between $3.95 and $9.95 per service. MCDA further highlighted that if iRhythm's purported software and "deep learning" algorithm related costs were baked into the inflated reimbursement rates from the Proposed Rule, the actual cost of that component would range between $830,000 to $1,070,000 *in total (not per unit*). Notably, the highest cost of software

in the entire CMS fee schedule, which is for a highly-advanced Electrophysiology, Pulmonary Vein Processing Software that performs full high-resolution 3-D mapping of the heart, allows fly-through exploration of the digital representation of the heart, and automatically identifies and measures the size of different parts of the heart is only $109,774 *in total (not per unit*).

115. Consequently, in order for iRhythm's specialized analytical software to justify the inflated PE rates of CMS' Proposed Rule, it would need CMS to allow costs more than seven times the highest cost for any software in the entire CMS fee schedule. As a result, MCDA demonstrated that iRhythm's argument that its analytical software justified inflated PE rates was false.

2. MCDA's Rebuttal to iRhythm

116. MCDA also refuted iRhythm's false claim that the BioTelemetry ePatch was a poor comparison to the Zio XT, showing that both the length and the clinical yields of the two devices are likely similar. iRhythm had previously stated falsely that BioTelemetry's ePatch does not provide up to 14 days of monitoring. *See* October 5, 2020 iRhythm Comment to CMS, at p. 2.

117. MCDA further observed that the quantity of clinical studies is categorically "irrelevant" to the calculation of direct costs, which requires the best possible *invoice or cost data* to make a determination.

118. MCDA also criticized the "running theme through iRhythm's assertions .... That, because they were the only extended external ECG provider who actively participated in the RUC process, and that the

RUC therefore used information supplied by iRhythm to review, that CMS should ignore the information for other major products that have validly billed and will continue to validly bill under these codes." *See* December 30, 2020 MCDA Report, at p. 19, available at https://www.mcdaintel.com/post/mcda-second-report-on-extended-external-ecg-payment-policy. As MCDA emphasized, CMS is required under its established processes to specify accurate direct inputs for national reimbursement irrespective of who engaged with the RUC process, and thus should consider information from other AECG providers as relevant.

3. Updated Physician Fee Schedule PE Rate Simulation

119. Building upon its prior analysis of PE rates for Zio XT and similar devices, MCDA examined four scenarios:

a. Rates under the Proposed Rule;

b. The Proposed Rule's rates that excluded iRhythm's SG&A costs from the patch supply input cost;

c. The Proposed Rule's rates that excluded iRhythm's SG&A and R&D costs; and

d. MCDA's main summary recommendation based on the direct costs of the BioTelemetry ePatch 2.0

120. MCDA found that adjusting inflated references used initially for the Proposed Rule, which did not strip out prohibited SG&A and R&D costs, the rates would be $76.28 (7-day) and $87.33 (15-day). As

MCDA noted, these adjustments resulted in a final cost in line with comparable calculations based upon BioTelemetry's actual invoices, which resulted in rates of $67.23 (7-day) and $94.78 (15-day).

121. The following chart illustrates MCDA's updated findings:

	Global Code				Scanning Analysis & Report Code			
	CMS 2021 Proposal (incl SG&A and R&D)	CMS 2021 Proposal excl SG&A incl R&D	CMS 2021 Proposal excl SG&A and R&D	MCDA Main Recommendation	CMS 2021 Proposal (incl SG&A and R&D)	CMS 2021 Proposal excl SG&A incl R&D	CMS 2021 Proposal excl SG&A and R&D	MCDA Main Recommendation
>48 Hour - 7 Day Service: Global = 93241 / Scanning Analysis & Report = 93243								
Work RVU	0.50	0.50	0.50	0.50	-	-	-	-
MP RVU	0.07	0.07	0.07	0.07	0.02	0.02	0.02	0.02
Direct Costs - Patch	$ 413.24	$ 105.18	$ 41.17	$ 30.02	$ 413.24	$ 105.18	$ 41.17	$ 30.02
Direct Costs - Total	$ 469.86	$ 161.80	$ 97.79	$ 86.64	$ 457.15	$ 149.09	$ 85.08	$ 73.93
PFS Rate - 2021	$ 414.17	$ 164.01	$ 112.03	$ 102.97	$ 378.43	$ 128.26	$ 76.28	*$ 67.23*
PFS Rate - 2020	$ 433.20	$ 172.64	$ 118.50	$ 109.07	$ 394.25	$ 133.68	$ 79.54	$ 70.11
PFS Rate - 2019	$ 442.10	$ 175.60	$ 120.22	$ 110.58	$ 403.07	$ 136.57	$ 81.19	$ 71.55
PFS Rate - 2018	$ 456.64	$ 180.72	$ 123.39	$ 113.40	$ 417.18	$ 141.26	$ 83.93	$ 73.94
PFS Rate - 2017	$ 452.69	$ 179.25	$ 122.43	$ 112.53	$ 413.44	$ 139.99	$ 83.18	$ 73.28
PFS Rate - 2016	$ 459.40	$ 181.58	$ 123.85	$ 113.80	$ 419.99	$ 142.17	$ 84.44	$ 74.38
PFS Rate - 2015	$ 464.06	$ 183.44	$ 125.14	$ 114.98	$ 424.34	$ 143.72	$ 85.41	$ 75.25
>7 Day - 15 Day Service: Global = 93245 / Scanning Analysis & Report = 93247								
Work RVU	0.55	0.55	0.55	0.55	-	-	-	-
MP RVU	0.08	0.08	0.08	0.08	0.03	0.03	0.03	0.03
Direct Costs - Patch	$ 413.24	$ 105.18	$ 41.17	$ 50.34	$ 413.24	$ 105.18	$ 41.17	$ 50.34
Direct Costs - Total	$ 480.68	$ 172.62	$ 108.61	$ 117.78	$ 467.97	$ 159.91	$ 95.90	$ 105.07
PFS Rate - 2021	$ 427.38	$ 177.22	$ 125.23	$ 132.68	$ 389.48	$ 139.32	$ 87.33	*$ 94.78*
PFS Rate - 2020	$ 447.16	$ 186.59	$ 132.45	$ 140.21	$ 405.79	$ 145.23	$ 91.08	$ 98.84
PFS Rate - 2019	$ 456.25	$ 189.75	$ 134.37	$ 142.30	$ 414.83	$ 148.33	$ 92.95	$ 100.88
PFS Rate - 2018	$ 471.16	$ 195.24	$ 137.91	$ 146.12	$ 429.31	$ 153.39	$ 96.06	$ 104.27
PFS Rate - 2017	$ 467.09	$ 193.65	$ 136.83	$ 144.97	$ 425.46	$ 152.01	$ 95.20	$ 103.34
PFS Rate - 2016	$ 473.97	$ 196.15	$ 138.42	$ 146.69	$ 432.18	$ 154.36	$ 96.63	$ 104.90
PFS Rate - 2015	$ 478.80	$ 198.18	$ 139.87	$ 148.23	$ 436.68	$ 156.06	$ 97.76	$ 106.11

H. Independent Expert Review Corroborates and Bolsters the MCDA Reports' Findings

122. Dr. Freeman is a board-certified ophthalmologist specializing in ophthalmic plastic and reconstructive surgery who is also a Certified Coding Specialist and a Certified Professional Medical Auditor. He holds a Bachelor of Science from the College of Engineering at Cornell University, an

M.D. from the University of Michigan Medical School, and an M.B.A. from the University of Central Florida.

123. Dr. Freeman has previously served as an expert witness for both plaintiffs and defendants in disputes that concern Medicare reimbursement rates, auditing, compliance, and CPT codes. He also has served as a member of the AMA's CPT Advisory Committee since 2004 and serves as the Chair of both the Coding and Third-Party Reimbursement Committee of the American Society of Ophthalmic Plastic and Reconstructive Surgery and the Third-Party Liaison Committee of the Florida Society of Ophthalmology.

124. Lead Plaintiff retained Dr. Freeman as a consultant to review and analyze the pertinent facts of this case, including the reimbursement rates identified in CMS' Proposed Rule and the Final Rule, the information provided to CMS during the notice-and-comment period, including both MCDA Reports and iRhythm's response seeking to justify inflated reimbursement rates, facts uncovered in the Delaware Litigation between Bardy and Hill-Rom, and other information relevant to the claims in this Action.

125. After analyzing all relevant facts, including the invoice data that Mr. Muller analyzed and discussed in his detailed Reports, Dr. Freeman concurred with the essential findings and conclusions of MCDA's Reports. Specifically, Dr. Freeman agreed that BioTelemetry's ePatch 2.0 is the most appropriate comparator to the Zio XT, and that the proxy input utilized in the Proposed Rule is not an equivalent comparator. Dr. Freeman further noted an absence of compelling evidence to demonstrate

similarities between the Zio XT and the neurostimulator, and, in fact, concluded that the direct cost of an implanted sacral neurostimulator is in actuality significantly higher than that for an AECG device. Dr. Freeman agreed with the MCDA's Reports' conclusion that the Zio XT and ePatch 2.0 are largely comparable.

126. Dr. Freeman also rejected iRhythm's false claim that the clinical value and health benefits of the Zio XT could be used to substantiate inflated reimbursement rates under CMS' cost methodology. While clinical value and health benefits may be relevant to whether a device should be covered by Medicare, he emphasized that clinical value is *irrelevant* to the task of setting PE rates, which are specified in the Social Security Act, and are based on the relative practice expense resources involved in furnishing the service or group of services.

127. Dr. Freeman also reviewed relevant evidence and expert testimony that came to light through the unredacted record in the Delaware Litigation between Bardy and Hill-Rom. *See* Section M(2), ¶¶189-197. Dr. Freeman noted that expert and fact witness testimony in that action indicated that the actual, direct cost of AECG devices is, in fact, trending downwards.

128. Moreover, Dr. Freeman concurred with MCDA's conclusion that the reimbursements rates were previously inflated because iRhythm provided claims data to the RUC and the MAC that improperly included prohibited indirect costs such as SG&A expenses and R&D expenses as direct costs.

129. Dr. Freeman also stated that MACs beside Novitas have clearly concluded that the rates sought

by iRhythm for valuation codes 93243 and 93247 are excessive. The chart below shows the large discrepancy between the rates set by Novitas before the Proposed Rule was announced and the rates set by other MACs for cardiac monitoring devices:

Medicare Administrative Contractor (MAC) Reimbursement for Zio and Traditional Holter Monitoring, by State

State	MAC	City	0297T	93226	State	MAC	City	0297T	93226
ID	Noridian		$ 33.34	$ 33.34	IL	NGS	Chicago	$ 47.05	$ 38.70
UT	Noridian		$ 34.50	$ 34.50	FL	First Coast		$ 47.20	$ 38.75
KY	CGS		$ 34.95	$ 32.64	CA	Noridian	San Francisco	$ 48.86	$ 48.86
OH	CGS		$ 35.96	$ 34.07	CT	NGS		$ 49.35	$ 41.33
AZ	Noridian		$ 35.99	$ 35.99	MA	NGS	Boston	$ 50.93	$ 43.72
SD	Noridian		$ 36.90	$ 36.90	NY	NGS		$ 51.67	$ 43.96
ND	Noridian		$ 36.95	$ 36.95	WV	Palmetto		$ 171.34	$ 31.97
WY	Noridian		$ 37.08	$ 37.08	AL	Palmetto		$ 183.26	$ 32.89
MT	Noridian		$ 37.35	$ 37.35	TN	Palmetto		$ 185.53	$ 33.31
NV	Noridian		$ 37.71	$ 37.71	SC	Palmetto		$ 187.80	$ 33.72
OR	Noridian	Portland	$ 39.03	$ 39.03	NC	Palmetto		$ 191.59	$ 34.47
IA	WPS		$ 39.25	$ 33.49	VA	Palmetto		$ 201.91	$ 36.57
KS	WPS		$ 39.75	$ 33.71	GA	Palmetto	Atlanta	$ 205.51	$ 37.04
NE	WPS		$ 39.97	$ 33.57	MS	Novitas		$ 267.10	$ 32.11
IN	WPS		$ 40.89	$ 33.92	AR	Novitas		$ 267.99	$ 32.26
AK	Noridian		$ 41.32	$ 41.32	OK	Novitas		$ 269.65	$ 33.10
HA	Noridian		$ 42.35	$ 42.35	NM	Novitas		$ 284.28	$ 34.31
WA	Noridian	Seattle	$ 42.46	$ 42.46	LA	Novitas	New Orleans	$ 304.13	$ 35.97
WI	NGS		$ 42.52	$ 35.30	TX	Novitas	Houston	$ 311.08	$ 37.54
MO	WPS	St. Louis	$ 42.87	$ 35.63	CO	Novitas		$ 312.67	$ 37.80
VT	NGS		$ 44.63	$ 37.53	DE	Novitas		$ 318.85	$ 37.86
MN	NGS		$ 44.71	$ 37.29	PA	Novitas	Philadelphia	$ 336.21	$ 39.98
ME	NGS	Portland	$ 45.37	$ 37.26	MD	Novitas	Baltimore	$ 339.28	$ 40.72
MI	WPS	Detroit	$ 45.72	$ 36.96	NJ	Novitas	North Jersey	$ 365.48	$ 43.71
NH	NGS		$ 46.34	$ 38.79	DC	Novitas	Washington, DC	$ 372.67	$ 44.75
RI	NGS		$ 46.79	$ 38.96					

Source: Medicare Administrative Contractor Fee Schedules, 2019
Note: In states with multiple sub-regions, we used the region with the highest reimbursement rate

130. Finally, Dr. Freeman stated that commercial rates indexed to Medicare decrease if Medicare reimbursement rates decrease. He further stated that commercial rates could fall if assumptions based upon previous Medicare rates do not prove correct.

131. Dr. Freeman's conclusions are corroborated by numerous analysts who reported in 2021 that any cut in the reimbursement rate from CMS or Novitas would also negatively impact commercial rates for the Zio XT because, while not all commercial rates are directly indexed to Medicare rates, commercial rates

are generally priced as a multiple of the Medicare rates.

132. For example, on January 31, 2021, an analyst at Baird Equity Research highlighted that, while commercial rates are negotiated independently of Medicare rates, commercial payors tend to follow Medicare's lead and a cut in reimbursement rates for Medicare would place pressure on the commercial rates as well. Mike Polark, *Seatbelts Should Remain Fastened*, BAIRD EQUITY RESEARCH, January 31, 2021, at 5. Similarly, on February 2, 2021, analysts from Oppenheimer wrote in an analyst report that a cut in the Medicare reimbursement rates would be followed by a similar reduction in commercial rates. Suraj Kalia & Mike Ott, *Expert Call Highlights Gathering Storm on The Story*, OPPENHEIMER, February 2, 2021, at 1.

133. Moreover, Dr. Freeman's conclusions and the commentary from analysts on this topic are substantiated by prior CMS practice. Between 2009 and 2010, a MAC reduced the reimbursement rates for CardioNet's MCOT device, which led to a corresponding decline in commercial reimbursement rates. *See* Mike Polark, *Back to the Future? Revisiting the Mobile Cardiac Telemetry Analog, Again*, Baird Equity Research, April 16, 2021, at 1.

134. Indeed, directly contradicting King's false statements that commercial rates are unaffected by Medicare rates, in a February 25, 2021 earnings call, Coyle admitted that iRhythm was holding rather than processing approximately 90% of 2021 year-to-date Zio XT claims and 50% of those claims were being held because commercial payors had already begun to contemplate renegotiating commercial rates because

Medicare reimbursement rates had been slashed. Coyle also conceded that the rate cut made by Novitas may have a potential "bleed over effect on to the commercial side" of iRhythm's business. On May 6, 2021, Coyle again acknowledged that Medicare rate cuts would impact negotiations with commercial payors, with a particularly negative impact on 2022 if CMS did not establish higher rates, thereby corroborating Dr. Freeman's conclusion.

I. Novitas Slashes Reimbursement Rates

135. Following CMS' delegation of rate-setting to Novitas in the Final Rule, on January 29, 2021, Novitas established calendar year 2021 reimbursement rates for CPT Codes 93241, 93243, 93245 and 93247. Novitas slashed reimbursement rates for the Zio XT from an average of $312 before the Class Period to an average of $77.10 for participating providers, $73.82 for nonparticipating providers and $89.36 for physicians who do not accept Medicare's approved amount as payment in full.

136. Upon the announcement of Novitas' massive rate cut for the Zio XT, the Company's stock price declined by nearly 33% to close at $168.42 on January 29, 2021 from its previous day closing price of $251 on January 28, 2021, on heavy trading volume.

137. Between January 2021 and April 2021, Coyle repeatedly referred to this rate cut as an alleged mistake. According to Coyle, the new rate was similar to a standard ECG monitoring device that provides only 24 to 48 hours of monitoring, and did not take into account iRhythm's more sophisticated device with longer term monitoring for up to 14 days. However, Novitas spoke with Mr. Muller several times during early 2021, and Mr. Muller told Lead

Plaintiff that, based on his impressions from those conversations, Novitas did not make any "mistake," and indicated that Novitas is now sensitive to and conscientious about price. Indeed, even assuming that Coyle's claim had any merit, a traditional ECG monitoring device that provides monitoring for less time is a far better proxy to set pricing than the clinically irrelevant and cost inappropriate neurostimulator that CMS, in fact, rejected in the Final Rule for 2021 after the publication of the October 5, 2020 MCDA Report.

138. On February 25, 2021, the Company announced in a press release that it was unable to provide financial guidance to investors due to "uncertainty" related to reimbursement rates. It also held an earnings conference call on the same day to announce the financial results for the fourth quarter of 2020. On this conference call, Devine and Coyle disclosed that the Company would hold back or not seek reimbursement for approximately 90% of all 2021 year-to-date Zio XT claims, and 50% of that amount related to withheld claims for commercial contracts because, according to Coyle, the Company had not yet reached an agreement and commercial payors had indicated that the Novitas rate cuts were the reason for the failure to reach an agreement.

139. On April 10, 2021, after numerous meetings where iRhythm was afforded the opportunity to identify its objections to the rate set, Novitas modestly revised the reimbursement rates for the Zio XT to approximately $115, a figure that was still over 60% less than what iRhythm reaped before the Class Period, and far less than Defendants' false characterization of Novitas' rate cuts as a mistake had led investors to expect.

140. On this news, the price of the Company's stock again plunged by over 39% to close at $80.36 on April 12, 2021 from its previous day closing price of $132.76 on April 9, 2021.

141. In reaction to this negative news, on April 12, 2021, the Company disclosed that the revised rates would have negatively impacted 2020 Medicare revenue by $41.3 million and would have decreased 2020 total company revenue from $265.2 million to $223.8 million, or a decrease of 15.6%. On a conference call to discuss Novitas' updated rates, Coyle told investors that the Company would discontinue serving Medicare patients, but the Company reversed itself and abandoned the plan to exit the Medicare segment in May 2021. Multiple analysts, including those from Morgan Stanley, BTIG and Oppenheimer, observed that the Novitas rates, unless reversed, would create downward pricing pressure on commercial contracts.

J. Disruptions Continue as the Company's Position Becomes More Precarious

142. On June 1, 2021, Coyle abruptly resigned from his position as CEO as well as a member of the Company's Board of Directors, after less than five months of service. Devine replaced Coyle as the Company's interim CEO.

143. On this news, the Company's stock price declined by nearly 18% to close at $62.77 on June 2, 2021 from its prior closing price of $76.25. Analysts reacted negatively to Coyle's abrupt departure and observed that his resignation signaled his (and the Company's) failure to effectively manage the reimbursement crisis. For example, an analyst from Oppenheimer openly questioned Coyle's self-serving

excuse that he had resigned for "personal reasons," and reiterated that: "[t]he sudden upper management shuffle belies more issues behind the scenes. Remember, the CEO was the 'only' hope investors latched onto to get IRTC out of the reimbursement mess." Suraj Kalia, Mike Ott & Shaymus Contorno, *CEO Resignation So Soon Surprising*, OPPENHEIMER, June 2, 2021, at 1. Similarly, analysts from Morgan Stanley reacted negatively to Coyle's departure, and stated that the resignation "introduces further disruption and incremental uncertainty . . . " and "we do not see a clear path to material reimbursement upside at this time." Cecilia Furlong & Calvin Chu, *CEO Transition Injects Another Layer of Complexity*, MORGAN STANLEY, June 2, 2021, at 1.

K. The Proposed Rule for 2022 is Released

144. On July 13, 2021, CMS released the proposed rule that includes updated payment policies, payment rates, and other provisions for services provided to be effective on or after January 1, 2022.

145. In the proposed rule for calendar year 2022, CMS "remain[ed] concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be." External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 86 Fed. Reg. 39178 (July 23, 2021). CMS again sought public comment and information from all stakeholders regarding "fair and stable pricing for these services." *Id*. at 39179. It again emphasized that relevant information such as actual invoices, a more appropriate proxy input or other pertinent information "would be ideal for us to use in

establishing fair and stable pricing for these services." *Id*. Yet again, CMS stressed that "in the absence of such additional and actionable information (*that is, information that provides further context to information that has already been considered*) we are proposing to maintain contractor pricing for these services." *Id*. (Emphasis added).

146. Defendants told investors that they had met with CMS personnel during the Class Period in early 2021 in an effort to convince the government to set higher, national reimbursement rates and circumvent the adverse decisions from Novitas. To this day, Defendants continue to conceal the specifics of their communications with CMS to investors, but the proposed rule for 2022 now makes clear that CMS was not persuaded by their excuses. As a result of the proposed rule for 2022, iRhythm continues to be stuck with the noninflated rates set by Novitas in April 2021.

147. The market again reacted negatively upon the release of the new proposed rule for 2022. On July 14, 2021, the price of the Company's common stock declined by nearly 9% to close at $53.90 from its previous day closing price of $59.07, on heavy trading volume.

L. Defendants' False and Misleading Statements and Omissions

148. The Class Period begins on August 4, 2020 when Defendants held a conference call to discuss CMS' Proposed Rule for the PFS effective on January 1, 2021. On this conference call, King was directly asked about the lack of an invoice to support the costs of the Zio XT and the clinically irrelevant proxy input

contained in the Proposed Rule, and King provided the following false and misleading response:

> Q: Suraj Kalia
>
> Perfect. So Kevin, help us understand for November when the final rates come out a read of the current proposal. Specifically, they're talking about a crosswalk comparison with percutaneous neurostimulation leads which, by definition, are more resource-intensive. *And they also say that this is not clinically appropriate, but they do not have -- I forget what the words were -- they don't have invoicing for extended patch monitors. When CMS is specifically saying that this is not a clinically appropriate comparator, how confident are you all that this will be maintained in November in the final proposal -- in the final rule and then move on to Jan 1 implementation?*
>
> A: Kevin King
>
> We're very confident in the data that was provided, and we're very confident in the calculation of the RVU. The crosswalk of the supply is a reflection that our business model is not a typical business model in that we are the developer, the manufacturer, the supplier and the provider of the service. So there is no sale of iRhythm to iRhythm. It's just one integrated service. *And so we worked hand-in-hand, as referenced in the CMS note, and we provided over 500,000 invoices to CMS for our service across a wide range of contracted arrangements, commercial carriers, noncommercial carriers, patients have paid out*

> *of pocket, CMS rates and everything, and those were all used.*
>
> At the end of the day, they wanted to find something that was equivalent in supply cost, and they chose this factor of this neurology [chit] or what was described there. The calculation of a PR -- PE RVU is very complicated, involves over 2 dozen steps to calculating that, and there are numerous adjustments, including reductions of direct and indirect costs and a whole variety of assumptions on who utilizes it by specialty such that there's a net reduction. *And I think that calculation was done well, and we'll support it. And I'm confident it's what CMS wanted, and that's where we've got the rates. I'm not concerned about that changing.*

149. The statements identified in Paragraph 148 were materially false and misleading when made because (a) iRhythm did not provide any "invoices" (let alone 500,000) as King falsely claimed, but instead only provided claims data that was inadequate and could not substitute for actual invoices; and (b) the statements omitted the following facts, each of which was necessary to make the statements not misleading under the circumstances in which they were made: (1) the neurostimulator referenced by the analyst that was used as a proxy input or "crosswalk" was used only because it was the closest supply item in price and CMS emphasized that an actual invoice would be required for the Final Rule; (2) the neurostimulator was a grossly inadequate comparator because its actual direct costs are far higher than the Zio XT's; (3) iRhythm's inflated reimbursement proposal included prohibited indirect

costs such as SG&A expenses and R&D expenses; (4) the largest cost component of the Zio XT was the device itself, which was trending downwards and therefore could not substantiate any increase in reimbursement; (5) King was already informed but concealed that Dr. Quinn, an expert on reimbursement rates, coverage decisions and federal rulemaking, had warned iRhythm in 2017 that CMS would be laser focused on breaking down the core costs of the device, CMS would require Defendants to substantiate each component of the costs, and, as a result, the Company would face major challenges with its current reimbursement strategy going forward; and (6) King knew that the rates set by Novitas were an outlier because he led the efforts to negotiate the rates with the MACs, and all the other MACs had refused to match iRhythm's proposal for inflated rates before the Class Period began.

150. On August 6, 2020, iRhythm held an earnings conference call to announce the financial results for the second quarter of 2020. On this earnings conference call, King was specifically asked by an analyst whether the Company would provide CMS with an actual invoice to support the costs and reimbursement rates for the Zio XT, and King made the following materially false and misleading statements in response:

> Q: Suraj Kalia
>
> Got it. Now it's clearer. And Kevin, one last and I'll hop back in queue. *I presume you will be supplying the invoices for various components to CMS before the final reimbursement rule comes out.*
>
> A: Kevin King

> *Sure. As I said on the call, I think it was yesterday, we provided to CMS over 500,000 invoices for our service across contracted, non-contracted, Medicare, self-pay, client bill.* They have full access of all various and sundry types of payments over an extended period of time. *And they have everything they can get from us.*

151. The statements identified in Paragraph 150 were materially false and misleading when made because (a) iRhythm did not provide any "invoices" (let alone 500,000) as King falsely claimed, but instead only provided claims data that was inadequate and could not substitute for actual invoices; and (b) iRhythm had not provided CMS "everything they can get from us," but instead withheld highly critical actual cost data for both its device and its analytics.

152. On the August 6, 2020 earnings conference call, another analyst pointedly asked King whether there was a risk that reimbursement rates could change between the announcements of the Proposed Rule and the Final Rule for 2021 and King made the following materially false and misleading statements in response:

> Q: Gene Mannheimer
>
> Wow. Okay, that's great. Okay. *And another question on, I guess, how things can change between now and December. Historically, does the reimbursement tend to change from the proposed rule to the final rule? And if so, has it veered very much from that proposed rule?*
>
> A: Kevin King

> I think the big factor here, I guess, is the conversion factor that all of the RVUs and the physician payment system get multiplied by to arrive at a price point. And what was proposed in the rule here was about a 10.6% decrease in conversion factor across all categories, not just the code set that we use but for everything. And my guess is that, that is going to be heavily debated. It's a fairly large decrease. And I think in prior years, it's been nowhere near that level. There is a reason for that. And it's my understanding, I'm hoping I'm correct, but physician payment for codes that are called evaluation and management, E&M codes, went up substantially and that CMS is required to operate a balanced budget format, so they can't just pile on more expense.
>
> They have to when something goes up, something else has to go down. And it seems like the best way that they were able to facilitate that was to just drain more water out of the pool through the conversion factor. So my suspicion is in the budgeting process, that's going to be highly debated. *As far as on the code structure side, I the process was so thorough and so complete, I'm hoping that there's not much to change. But of course, there's the comment period. And we'll see what happens.*

153. The statements identified in Paragraph 152 were materially false and misleading when made because (a) King was aware of but concealed that CMS rates often change between proposed and final rules; (b) the rate-setting process was "not thorough and complete," but was instead hindered because

iRhythm failed to provide a complete invoice with a breakdown of costs as required; (c) King was already informed but concealed that Dr. Quinn, an expert on reimbursement rates, coverage decisions and federal rulemaking, had warned iRhythm in 2017 that CMS would be laser focused on breaking down the core costs of the device, CMS would require Defendants to substantiate each component of the costs, and, as a result, the Company would face major challenges with its current reimbursement strategy going forward; (d) King knew that the rates set by Novitas were an outlier because he led the efforts to negotiate the rates with the MACs, and all the other MACs had refused to match iRhythm's proposal for inflated rates before the Class Period began; and (e) because the claims data submitted by the Company to CMS had already been rejected as inadequate before these false statements were made.

154. On August 13, 2020, King participated in the Canaccord Genuity 40th Virtual Annual Growth Conference where an analyst specifically asked about the impact that reimbursement changes would have on the Company's business, and King made the following materially false and misleading statements in response:

> Q: Cecilia Furlong
>
> Great. And I guess, just in the last five-minutes, *I definitely want to touch on reimbursement, kind of an epilogue following the past several years. But can you just touch on the recently proposed codes, changes to reimbursement, and impact on your business?* But then also, just the shift from a single set of codes to two, and what that implies or may

imply about the value proposition of long-term wear monitoring?

A: Kevin King

Sure. Well, that's – decision is nearly behind us, right? The initial ruling was put out by CMS on August 4 and 5. *Look, we believe that the decision was built on a foundation of clinical evidence, that longer term monitoring is superior, and from a diagnostic standpoint, and that it quite often changes medical treatment decisions.*

We have a very long standing collaboration or history of collaboration with medical societies as well as CMS; these played into it. And the decision that came out from a prescribing mix and payor perspective. If we apply those to our 2019 revenues, our 2019 revenues would increase by high single-digits. *And so this is a really favorable ruling, and it was a burden off of our shoulders right now because a lot of people were betting against us or thinking that the risk were high. And I would just reiterate that for the last four years, as I've spoken to you and to many others in your shoes, we've always been confident that our reimbursement rate will be the same or go up. And we believe, it stood the evidence in the fact base that we have.* So we're really, really happy with that. It is an initial ruling, so there's a common period that takes place between now and sometime in early December, before it becomes final.

155. The statements identified in Paragraph 154 were materially false and misleading when made because (a) the decision was not "nearly behind us"

but was instead embroiled in a vigorous debate at the time; (b) the rate decision that CMS indicated was to be made in a final rule was not a matter of "clinical evidence" but rather actual costs, which iRhythm actively concealed by refusing to provide cost invoices as requested by CMS; (c) contrary to King's false statements, the risk of an adverse ruling from CMS remained very high because Defendants had not provided actual invoice data to justify the costs of the Zio XT, and King himself knew of this high risk because he knew about the red flags raised by Dr. Quinn, and led the efforts to negotiate the rates with the MACs, and all the other MACs had refused to match iRhythm's proposal for inflated rates before the Class Period began; and (d) the inflated reimbursement rate was not supported by "evidence in the fact base that we have," and instead was undermined by evidence that the inflated rates in the Proposed Rule included prohibited indirect costs such as SG&A expenses and R&D expenses, and the single biggest cost component of the Zio XT, the device itself, was trending downwards.

156. On November 6, 2020, the Company held an earnings conference call to announce the financial results for the third quarter of 2020. On this conference call, King was directly asked whether anything had changed that would put the reimbursement rates identified in the Proposed Rule at risk, and King made the following materially false and misleading statements in response:

Q: David Lewis

The first would just be any update on the reimbursement process, Kevin, other than the commentary you've already provided sort of in

> *the public domain would be question number one*. And then question number two for me would just be, as you think about -- it's early, but as you think about 2021, I know there's a lot of dynamics moving around from reimbursement from a revenue perspective. But, if you think about the underlying volume of the business, I'm just trying to think about how we should think about sort of '21 over a baseline 2019 and is sort of 25% volume growth for this business, sort of the right structural growth rate that you're seeing? Thanks so much.
>
> A: Kevin King
>
> Yes. Hi, it's Kevin. *Really don't have any other updates on reimbursement than what we said here in the prepared remarks and the comments that we've had since the open period closed. We remain extremely confident in where we sit. We've provided all of the necessary information and feedback, and we're looking very forward to December 1st when the final ruling takes place.*

157. The statements identified in Paragraph 156 were materially false and misleading when made for the same reasons identified in Paragraphs 153 and 155. In addition, King failed to disclose the following facts that made his statements further misleading under the circumstances in which they were made: (a) that the release of MCDA's Report in the notice-and-comment period had put the excessively high reimbursement rates for the Zio XT at risk; and (b) that the Company had failed to dispute MCDA's findings that invoices from iRhythm's direct competitors showed that the Zio XT's actual costs

were far lower than the reimbursement rates the Company wanted CMS to endorse, and the fact that the Company improperly included prohibited indirect costs such as SG&A expenses and R&D expense to support the Proposed Rule's inflated reimbursement rates.

158. On December 1, 2020, CMS released the Final Rule for the PFS effective on January 1, 2021. In the Final Rule, CMS repeatedly emphasized the need for a representative invoice to establish commercial pricing, acknowledged the severe criticisms of the October 5, 2020 MCDA Report, refused to adopt national pricing due to those criticisms, and instead delegated the authority to set reimbursement rates back to Novitas. In response, iRhythm held a conference call on December 2, 2020 to discuss CMS' Final Rule, and King made the following materially false and misleading statements:

> *While we were expecting a national pricing decision, it's very important to note, this is not a rate cut rather a rate increase was not approved and the changes relate to roughly one quarter of our revenue.* We believe a local contracting path is an attractive and familiar option for the company, and leverages the long-standing working relationships we have with several local contractors. *Separate but related, we believe our commercial contract pricing is unaffected, as is our ability to pursue Medicaid contracting and reimbursement for our home enrollment service. And most importantly, the clinical validation that is associated with the Category I codes, the CPT codes remain and we believe this positions us well to improve patient*

access and physician willingness to adopt the technology.

159. Analysts understood these statements to mean that the Company did not expect any downside risk of a rate cut. For example, an analyst report from William Blair published on December 2, 2020 observed that "[m]anagement believes that contractor pricing could remain in place for the next two years at least," and another analyst from J.P. Morgan observed on the same day that "to be clear this isn't a rate cut, but rather a proposed increase isn't confirmed; there's a big difference." Margaret Kaczor, Brandon Vazquez & Maggie Boeye, *Reimbursement Update Adds Back Overhang, but Fundamentals Strong for This Leader in Digital Health*, WILLIAM BLAIR, December 2, 2020, at 2; Robbie Marcus, Allen Gong, Lilia-Celine Lozada & Sarin Murlidar, *Buy the Dip; Reverting to Contractor Pricing Is a Minor Setback and Doesn't Take Better Pricing Off the Table*, J.P. MORGAN, December 1, 2020, at 1.

160. The statements identified in Paragraph 158 were materially false and misleading when made because: (a) CMS' rejection of an unsubstantiated and inflated rate affected (directly and indirectly) *nearly all* of the Company's revenue, not just 25%; (b) commercial contract pricing was not "unaffected"; (c) the local contracting (*i.e.*, rate setting by MACs) path was not "attractive," but was in fact undermined by proof contained in the October 5, 2020 MCDA Report that the inflated reimbursement rates previously under consideration for the Zio XT were grossly inflated; and (d) King's references to "clinical validation" were misleading because clinical value is irrelevant to the task of setting reimbursement rates.

161. After his prepared remarks, King took questions from analysts and was immediately asked if CMS' decision meant that iRhythm was "back to ground zero":

> Q: David Lewis
>
> Okay. And just maybe two more for me. The first one, Kevin is just, the reimbursement made obviously had stemmed for, for years and you can argue even goes back to the pre IPO days. *So, some are got conclude this decision sort of suggests that we're back to square zero, and we're kind of starting over. If based on sort of the RVU information and the proposed rule from CMS and how this process is played out? What would you say to investors, who believe you are kind of back to ground zero? And why is that or is not the case?*
>
> A: Kevin King
>
> *Well, I don't think we're back to ground zero.* I think we've made tremendous progress here. We have a permanent CPT code, codes, code sets that have replaced temporary codes. We have communicated, and it has been supported that evidence generated by iRhythm is superior to other methodologies that have created a new category.
>
> There's widespread acceptance and adoption of the technology, digital technologies including Artificial Intelligence. *I think the challenge is, as I described, CMS has a rather rigid framework that requires precise inputs like an invoice that don't exist in these categories. And it's our job to help them to remodel or to affect*

> *change such that not only iRhythm, but every other digital health company and every other subscription service company and healthcare, can get the benefit of fairly valued remuneration.*
>
> *So, I don't think we're back at ground zero at all, I'm extremely confident. And importantly as I said look, this is not a rate cut. This isn't a price increase per se. And I'm extremely confident of where we are.* Disappointing we didn't get across the finish line on this particular point, but our relationships with AMA, CMS, all of these organizations are good. We intend to continue to collaborate with them and try to push this forward, not only for us, but for the industry.

162. The statements identified in Paragraph 161 were materially false and misleading for the same reasons identified in Paragraph 160. In addition, the statements identified in Paragraph 161 were materially false and misleading when made because (a) CMS' rejection of national pricing and delegation to MACs did, in fact, put iRhythm "back at ground zero"; (b) this effectively *was a rate cut*, as CMS indicated it could not substantiate the inflated rate under consideration, but the Final Rule delegated the rate-setting decision which would determine the extent of the rate cut to MACs like Novitas; (c) actual inputs do exist in those categories of services, as demonstrated by MCDA's examination of an actual invoice from BioTelemetry's ePatch; and (d) the statements omitted to disclose the following facts that were necessary to make the statements not misleading under the circumstances in which they were made: (1) that the data iRhythm submitted to

the RUC and CMS included prohibited indirect costs for SG&A expenses and R&D expenses; and (2) that iRhythm had little incentive to provide an actual invoice because the biggest cost component of the service, the Zio XT device itself, was trending downwards.

163. On the conference call held on December 2, 2020, King was directly asked why Defendants contended that the reimbursement rate would not go down, and King made the following materially false and misleading statements in response:

> Q: Robbie Marcus
>
> Got it. And then, one of the most common questions I've gotten overnight this morning is, what gives you confidence, that when you go back to the MACs really Novitas and Noridian to begin early next year to discuss the rate going forward, that it should be, sort of a status quo with maybe, the bulk case of some upside to or book ended between the CMS rate that was proposed. *What gives you confidence the rate won't go down? And it's really just a price increase wasn't affirmed rather than something of a price cut? Thanks a lot.*
>
> A: Kevin King
>
> *Yes*. I think it comes to the long-standing relationships, where we have with these administration centers or local contractors. In both cases Noridian and Novitas and to some extent Palmetto on the East Coast, these things stand back almost seven years of working relationships.

> I wouldn't say, on a day-to-day basis, but pretty deep. They understand our technologies. Our technologies have been validated. We've been audited by these organizations in the past and we've used the RUC process with Novitas the first go round. *And now we have new data that came out of the initial ruling that we intend to use. So, that gives me confidence that we're going to be -- we're going to be shooting for that for the higher end of where we were. I don't know if we'll get there. I hope we do. But that's certainly where the discussions will begin. And there isn't really a basis for them for lowering if there isn't any new data that would suggest that the price of our service would be less.*

164. The statements identified in Paragraph 163 were materially false and misleading when made because (a) there was, in fact, "new data that would suggest that the price of our service would be less" as outlined in the October 5, 2020 MCDA Report; and (b) there were multiple "bas[e]s for them for lowering" reimbursement rates including that iRhythm added prohibited indirect costs such as SG&A expenses and R&D expenses to inflate the reimbursement rates initially discussed, that the inflated Proposed Rule rate was, in part, influenced by a comparison service that was not, in fact, comparable, and that the actual cost of the Zio XT was, in fact, trending downwards.

165. Another analyst again pointedly asked King whether the setbacks from the Final Rule would impact the rates paid by commercial parties, and King made the following materially false and misleading statements in response:

Q: Kaila Krum

> Hi guys. Thanks for taking our questions. *So, you've mentioned this has a direct impact on about 1/4 of your revenue. How does this impact your relationships with private payers and/or sort of the balance of your revenue base?*
>
> A: Kevin King
>
> Hi, Kaila. Look, *I don't believe it does* and we've commented on this in the past when we described the initial ruling or the benefits of the initial ruling where we said crosswalking the 2019 revenue to the initial ruling would take us up in high single digits, and that was largely CMS. *And we did not believe that the commercial contracts that we have in place would largely be affected mostly because they were already paying higher than where we were and higher than the initial ruling ones. So I'm not overly concerned about that. Many of these contracts are already completed and have been crosswalked to the existing commercial rates that we have.* So, I'm feeling pretty confident about that.

166. The statements identified in Paragraph 165 were materially false and misleading when made because CMS' rejection of an unsubstantiated and inflated rate affected (directly and indirectly) *nearly all* of the Company's revenue, not just 25%, and because commercial contract pricing was at serious risk of a reduction within the next few years as commercial payors renegotiated their contracts as a multiple of the reduced Medicare rate.

167. When asked directly whether the Final Rule would cause greater unpredictability, King

made the following materially false and misleading statements in response:

Q: Kaila Krum

No, you're fine. I just had one final question. *Just in terms of your expectation going into next year does – I mean does this change sort of make the reimbursement process slower or more sort of unpredictable, just would love to get your thoughts on that?*

A: Kevin King

Help me understand a little bit more of that. Going into next year does this make the conversion of the commercial contracts faster or slower? That's your question?

Q: Kaila Krum

So, I guess, I mean, does having to go through sort of the MACs make the reimbursement process slower or more sort of unpredictable versus having the established rate and everything in place. It almost seems like, the ability to be able to go to Novitas and have those discussions is almost like a more of the same. And shouldn't impact the reimbursement process make it slower or unpredictable, but just want to clarify that comment.

A: Kevin King

Yes. As I said earlier, *I don't believe this is going to be a challenging process*. It is going to take some time. And as I said in the prepared remarks, we're going to work on that, and it's going to take a few months. But aside from

> that, I think this should be fairly straightforward conversation. *The data is already available*, the relationships are in place with numerous local carriers, and we'll try to contract with as many as possible to establish the right pricing level. *And I don't -- and it's about a quarter of our business. I don't see any impact to volume. I don't see any impact to commercial contracting rates so aside from the few months to get in line with the local carrier pricing calendars, I don't think this is going to be terribly disrupted to us.*

168. The statements identified in Paragraph 167 were materially false and misleading when made for the same reasons identified in Paragraphs 160, 162, 164, and 166.

169. On February 25, 2021, iRhythm held a conference call to announce the financial results for the fourth quarter of 2020. At this conference call, Coyle, the new CEO of iRhythm, was again directly asked about the lack of a representative invoice that could support higher reimbursement rates, and Coyle made the following materially false and misleading statements in response:

> Q: Suraj Kalia
>
> Got it. Mike, you mentioned about the consortium you met with Novitas, I believe, a couple of weeks ago. Forgive me, if I got that wrong. *The fundamental question, I think so, all of us are trying to figure out, were any invoices provided by any of the participants in this -- in these meetings, that seems to be sort of the hiccup in this whole process that could yield*

tangible results pretty quickly. I'd love to get your comments on that.

A: Michael Coyle

So I think one of the benefits of having the fourth largest producers of the -- or suppliers of the service available. And the four companies who are involved in these discussions represent about 97% of the building under the old temporary code with iRhythm frankly representing about 85% of that. But all of the major players who actually provide the service as called out for the code were there. And all of us were able to identify the key components of being able to successfully deliver that service as inclusive of a patch technology that can reliably provide 14-day data with high patient compliance and is labeled as such by the FDA. That when you start to talk about that length of a period of time for collecting, but is essentially 1.5 million cardiac cycles that then have to be analyzed, doing that in the manual process or with the base Holter-like-software approach simply doesn't work because of the complexity and massive amount of data that's being analyzed. *So having an advanced analytic platform and in our case driven by AI and machine-learned algorithms is critical to being able to have an efficient identification in a sensitive way of where there could be potentially risk -- high risk rhythms in that 14-day code. You may only be looking for five to eight minutes of time over that entire period. It's being able to find it with high sensitivity requires these advanced analytics.*

And then, once those areas of potential risk or -- of concerned parts of the electrogram, you need a team of highly trained individuals who could then look at those data and make conclusions about in our case, 13 different potential arrhythmias that could exist versus what you would typically see with the Holter, which is about four. So the idea of a catch being identified at some cost point that isn't part of a fully integrated system. It isn't going to get you the fundamental report that is what becomes useful for the physician enabled in determining whether there is actionable rhythms there and what that action should be. And obviously, that's where the fully integrated long-term ECG technology comes in. And all of the players in the space would point to the fact that having these fully integrated systems is what's important to be able to get the outcome that the code is looking for.

170. The statements identified in Paragraph 169 were materially false and misleading when made because (a) the alleged advanced "analytic platform" and "machine learned algorithms" that Coyle spoke extensively about are indirect costs that CMS has disallowed for more than a decade; (b) iRhythm could, but chose not to, provide an invoice that broke down these costs; (c) iRhythm sought to recover costs for the hardware and software components that were dramatically out of line with the most complex components reimbursed in past PFSs; (d) the largest component of the cost was the production cost of the Zio XT itself, which was trending downwards before Coyle made these misleading statements; and (e) as confirmed by CW1, Coyle knew, but failed to disclose,

that iRhythm folded inappropriate indirect costs for R&D expenses and SG&A expenses into its proposed reimbursement rates and that the Company could not collect all of its indirect costs for the Zio XT device.

171. On February 26, 2021, iRhythm filed its Annual Report on Form 10-K for the full fiscal year 2020. Defendants Coyle and Devine signed this Annual Report, and it contains their certifications pursuant to the Sarbanes-Oxley Act of 2002. The Annual Report misleadingly discussed hypothetical risks such as: "policy affecting Medicare coverage and reimbursement relative to our Zio service *could* have a material effect on our performance," "[c]hanges to the coverage, method and level of reimbursement for our Zio service *may* affect future revenue," and "changes in public health insurance coverage and CMS reimbursements for the Zio service *could* affect the adoption and profitability of our Zio service." (Emphasis added). Such statements were materially false and misleading when made because many of these risks had *already* materialized, including a massive rate cut initiated by Novitas in January 2021, and Defendants had no legitimate basis to seek inflated reimbursement rates from CMS or the MACs before such false statements were made.

172. On April 10, 2021, following numerous meetings with iRhythm and other industry participants, Novitas revised its reimbursement rates, but still set them over 60% below what they were before the Class Period, effectively devastating the Company's business. In response, Defendants Coyle and Devine held a conference call to discuss Novitas' revised rates. At this conference call, Coyle was asked by an analyst about how the Company could help drive Novitas' rates higher, and Coyle

made the following materially false and misleading statements in response:

> Q: Cecilia Furlong
>
> Great. Thanks for taking my question. I guess just first off curious on just discontinuing service to Medicare, how should we be thinking about the time to fully implement? And how long do you hold Medicare claims as you continue your negotiations with Novitas? *And I guess near-term to what can you see really driving Novitas payment higher?*
>
> A: Michael Coyle
>
> [...] So that will be sort of job one, but then we will be very interested to understand their methodology. *Obviously as I mentioned they haven't spoken to us about how pricing was being established. I think we all know the history here that the difficulty here in the physician area is that basically it's a cost based model. They're assuming a physician in practice buying at arm's length technology and then applying it in their practice and using the invoices associated with those individual purchases to be able to establish fair pricing or fair cost inputs to establish pricing. It's obviously very different for us. And frankly the other providers of fully integrated services in long-term ECG were in fact there is substantial internal investment that has gone in the development of the advanced AI algorithms 750,000 hours of ECG data that are driving our ability to do real-time applications of analysis, the ability to actually have a tiered cardiac technician organization that can basically*

triage simpler to more complex rhythms to be able to very efficiently process which turns out to be 20,000 minutes of ECG data for every record that comes in on a 14-day case.

So, there are significant cost impacts -- inputs that we simply can't provide the invoices for because we're doing them internally and we've obviously tried an alternative methodology here with the rug process to use the arm's length negotiations we have in the commercial pay segment of our market to establish what those commercial payers view as the appropriate value of that overall offering including Medicare advantage, right, which basically has as we showed in public data in the rug process, generally pays $300 for that service.

173. The statements identified in Paragraph 172 were materially false and misleading when made for the same reasons identified in Paragraphs 170. In addition, Coyle's statements were materially misleading because: (a) Novitas had in fact spoken to iRhythm about "how pricing was being established," including a specific warning from the Executive Medical Director at Novitas, Dr. Andrew Bloschichak ("Dr. Bloschichak"), to Coyle that the Company's cost methodology was unacceptable; (b) the statements omitted to disclose that the April 2021 rates set by Novitas closely tracked MCDA's proper methodology, removing inappropriate SG&A and R&D expenses, undermining Coyle's claim that Novitas' approach was "very different" from the costs that should be considered for iRhythm's product; (c) iRhythm had actual knowledge that pricing would be based on actual costs and not clinical outcomes; (d) iRhythm could provide invoices reflecting actual cost

information if it was in its interest to do so, but refused since such invoices would not substantiate the inflated rates it advocated for; (e) the reference to "alternative methodologies" was misleading because Coyle omitted to disclose that iRhythm sought to recoup impermissible SG&A and R&D costs and thus could not possibly justify a price increase; and (f) Coyle omitted to disclose that Dr. Bloschichak told Coyle that Novitas would not consider any "alternative methodologies" unless iRhythm first convinced *all* the other MACs that the alternative was valid and reliable.

174. On the April 12, 2021 conference call to discuss Novitas' revised reimbursement rates, Devine also made the following materially false and misleading statements:

> Q: Margaret Kaczor
>
> Okay. Thanks. Sorry about that. All right. And then -- so let's take this a step further. At this point patient access unfortunately is getting damaged because of the situation that Novitas is creating with this rate that, is there any kind of push that Medicare will try to address it quickly. *And I know you talked about the proposed rule for fiscal '22, but are there other mechanisms that Medicare could have to address this?*
>
> A: Douglas Devine
>
> I think I already mentioned the primary sort of vehicles for us in terms of next steps, the primary one is what you just mentioned which is to use the annual physician schedule work here that has -- that Medicare is in the middle

> of CMS's and middle of -- to actually get these codes revisited for national pricing. And as I said, we have made additional proposals here in terms of how to think about the establishment of value for these particular codes and we are anxious to engage Medicare on that topic. And typically, in the July-August timeframe, they make the decisions about which are going to actually get codes signs of them so we're hoping that will take place here and reasonable near-term.
>
> Absent that or in addition to that obviously we have the opportunity of MAC pricing being established. *We completely are ready to re-engage Novitas as they see fit for expansion of the discussion and we would really like the physician advocacy that I think will be coming into both CMS and Novitas to put us in a position that we're in an opportunity to have MACs being established that works for everyone. And then of course we operate in three jurisdictions under three separate MACs. So we have additional MACs that we can engage and are engaging to actually now move to the next steps to give us multiple if you will shots on goal to get this addressed.*

175. The statements identified in Paragraph 174 were materially false and misleading when made because: (a) they omitted to disclose that months before these statements were made, Dr. Bloschichak of Novitas had expressly warned Coyle that iRhythm's attempt to seek inflated rates that included inappropriate indirect costs was unacceptable and Novitas would not consider any alternative methodology unless iRhythm first

convinced all the other MACs of the appropriateness of that methodology; and (b) therefore, iRhythm did not have "multiple shots" on goal to seek inflated reimbursement rates, but rather faced an uphill battle that was almost certainly bound to fail after the revised rates were released in April 2021.

176. On May 6, 2021, iRhythm held an earnings conference call to announce the financial results for the first quarter of 2021. On this conference call, Coyle was asked about Novitas' reimbursement methodology, and Coyle made the following materially false and misleading statements in response:

> Q: Cecilia Furlong
>
> Great. I guess I wanted to start off with just really what shifted in terms of what Novitas was looking at pre the rates coming on initially versus the conversations you've been able to have with them subsequent to that. Just really what kind of changed in how they were looking at this, what you were able to bring to the table show them now and kind of their acceptance and willingness to move forward?
>
> A: Michael Coyle
>
> So thanks, Celia, for the question. *The methodology that Novitas is using is very much rooted in sort of a pure cost analysis. And it's based really on what they view as direct product costs, which I think, as you know, that is just the start of the story for the Zio service and that there are significant sort of additional expenses that fall into the opex category that come along with things like the bad debt expense that we see*

with patients with the customer service side of actually having patients putting these -- applying the technology in the at-home setting, revenue cycle management investment in terms of processing of claims and dealing with levels of claims rejection. And so what we've tried to do with them is basically identify the costs that they have acknowledged and then to bring into the picture of these other costs that have not been acknowledged, including and very importantly, the costs associated with the development of the deep learned algorithms that are key to being able to do this service from the standpoint that 20,000 minutes of electric cardiogram information cannot be done using traditional Holter approaches and brute force analysis of those waveforms. They've got to be processed in a way that really find the needle in the haystack and then allow the physician to see exactly what arrhythmias are taking place over that time period.

And it's that, of course, benefit that turns what Holter's 24% diagnostic yield into something closer to 97% when you use the Zio system. So that ability to have the patient identified the first time with the appropriate arrhythmias and then allow them to be treated without a lot of waste in the system is what we're kind of pointing them to. *So coming up with alternative methodologies that actually will look not just at those direct product costs, but the broader variable cost that go into providing the service and some of these important investments in technology, software, our 750,000-hour database that actually allows the*

> *deep-learned algorithms to develop and getting some cost allocations associated with that into the analysis. And we're -- this is not a unique issue for us. There are other areas of the physician fee schedule, and I would point to things like clinical diagnostics, genetic testing, where they have very similar issues, where there are very expensive capital investments made both in manufacturing as well as in the R&D activities that need to be reflected in the calculation of the cost*. And there have, in fact, been alternative methodologies that have been generally accepted across the MACs in these areas that we are now suggesting would be appropriate models to relook at. And that's exactly where we are in discussions with them, that we think can take this first step and get us to a more reasonable representation of the true products and providing the service.

177. The statements identified in Paragraph 176 were materially false and misleading for the same reasons identified in Paragraphs 170 and 173.

178. On the May 6, 2021 earnings conference call, Coyle also misleadingly referred to the Company's meetings with Novitas as "constructive," asserted that Novitas showed "openness to discussing an alternative costing model," and made the following additional misleading statements in response to pointed analyst questions:

> Q: Malgorzata Maria Kaczor Andrew
>
> So a couple for me. One, I wanted to shore up some details on the new payment methodology that you shared with Novitas and a few others. So have they reached back out since that

meeting? Or have some of the other MAcs reached out since kind of those original meetings? Are there future meetings on the books or more of a wait-and-see mode? And I guess, if you don't hear by year end, is that the time frame where you think you fully explored all paths? Or could it take longer than that?

A: Michael Coyle

So it has been very interactive in the sense that based on this proposal, I think the Novitas has basically seen this as a viable path for being able to address what they want to get to, which is to make sure, a, the service is available to patients in the Medicare system. They've heard a lot of feedback that is valued very highly, and we would be expecting 250,000 patients in Medicare to be treated or to receive the service this year. *And so they understand sort of the importance of it. And I think they have seen the application of this alternative approach in clinical diagnostics has been very appropriate. And so now the question in their mind will be, is it appropriate to this particular set of codes. And so that is where we sit right now, is not only engaging Novitas in that discussion, but also bringing the MACs who actually were involved in developing these methodologies and who were the original champions of them into support for these particular codes. And that activity is -- meetings are being scheduled -- have been scheduled, will be over the next several weeks, talking to multiple constituents both among the MACs as well as with the CMS.*

179. The statements identified in Paragraph 178 were materially false and misleading when made because Coyle omitted to disclose that (a) Dr. Bloschichak had already told Coyle that iRhythm's methodology to support inflated reimbursements was unacceptable; (b) Novitas' revised rates in April 2021 closely tracked MCDA's methodology, and removed inappropriate indirect costs for R&D expenses and SG&A expenses; (c) Novitas did not consider clinical value to be relevant to the task of setting reimbursement rates; and (d) Dr. Bloschichak had already told Coyle that Novitas would not consider any "alternative approach" unless iRhythm first convinced all the other MACs that the alternative was valid, which was extremely unlikely given that industry experts had already concluded that Novitas was an outlier amongst the MACs and its past, high rates for the Zio XT were a huge red flag.

180. On June 2, 2021, Devine attended the William Blair 41st Growth Stock Conference. At this event, Devine was specifically asked about the Company's outlook on reimbursement rates and any potential impact on commercial contracts due to the Novitas rate cuts, and Devine made the following materially false and misleading statements in response:

> Q: Margaret Kaczor
>
> Fair Enough. Thanks, Doug. Yeah. I guess there is a few things to go down. *Should this signal anything in terms of the outlook for reimbursement, any kind of change in probabilities, whether it's the summer of this year or does that remain the same as it's been? And then kind of a similar question for commercial perspective because Mike was hired*

as the commercial guy. So does this change anything beyond yesterday's plan or January's plan? You guys talked about international launches and so on. So can you still leverage some of those relationships as well?

A: Douglas Devine

Yeah. We're thinking the -- first of all, starting off with the reimbursement, we've -at the earnings release, I think we did -- in Q1 earnings release, we did a very thorough job of outlining our reimbursement strategy. The three-pronged continuing to work with Novitas, working with CMS on national pricing, engaging with other MACs, engaging with often at cost models that we think will be easier for -- may help the decision makers get to this type of decision and understanding our value better.

There has been no change -- there is no substance of news, progress has been good, executing on all the three of those strategies. We continue to take good meetings and have good dialog with multiple MACs and CMS as we go through the process. As we've said before, I mean, every time we take a meeting, we don't consider that. We're not going to get into the tennis match. We don't consider that material information, but I can definitely assure you that everything has stayed on track to our expectation. Since earnings release, we've had a number of meetings with a number of different entities. And this does not in any way reflect the difference in our opinion on what the outcome and what the chances of how we'd be

handicapping the chances of various outcomes in the reimbursement process.

On the commercial process, things have been very stable -- things have been stable. As we highlighted before, we've got about 10% of our payers that are still in negotiations that continues to be the case. We have not seen shift in commercial. And as we said, we do think that the more meeting commercial discussions are really going to be occurring more around the year end and versus we were not expecting to see other commercial negotiation come up and when we our talk track in the Q1 earnings release and hasn't been a change from that in between now and then, we're still forecasting.

181. The statements identified in Paragraph 180 were materially false and misleading when made for the same reasons identified in Paragraphs 166, 170 and 173, and because: (a) "progress" had not been "good"; (b) the Company had not had the claimed "good meetings...and good dialog" with MACs and CMS regarding the Company's attempt to restore inflated pricing as an "alternative" to the standard cost-based approach; (c) the Company could not "execute on all three of those strategies" since Novitas had already declined to consider any alternatives unless all the other MACs endorsed the alternative approach first; and (d) Devine, in fact, withheld "material information" concerning communications with Novitas that are described in detail in Paragraphs 198 through 204.

182. At the William Blair 41st Growth Stock Conference, Devine was also asked whether iRhythm's alternative strategies to seek inflated

reimbursement rates was acceptable under current law, and he made the following materially false and misleading statements in response:

> Q: Margaret Kaczor
>
> Okay. *Got a couple more here in terms of kind of one, do you expect or think your cost effectiveness argument can be accepted by the MACs or CMS under current law?* And then any other greater detail on the use of the strategies for the clinical lab fee scheduled to inform rates under a physician fee schedule?
>
> A: Douglas Devine:
>
> *Well, it's certainly allowable under the law type of questions. As I mentioned, the cost models that we're moving to are ones that have been used by multiple MACs and multiple cost curves. So I think that's the best answer I can give to that point. But we're not reinventing the wheel here, we're not trying to move into unbroken ground. We're trying to leverage best practices and best practices here.* In terms of the outcomes, I think we've talked about it in the earnings release as thoroughly as we can. And I'm confident we're doing the right things, but at the same time as I emphasized before, there the transparency on how the final decisions are made is very limited, and we're going to find out about things at the same time that the rest of you do. We're going to find out the final decision at the same time rest of you do.

183. The statements identified in Paragraph 182 were materially false and misleading when made for

the same reasons identified in Paragraphs 170, 173, 175 and 181, and because (a) existing law did not allow iRhythm to recover impermissible costs for SG&A and R&D expenses; (b) CMS had already deemed technology related expenses as indirect costs in the past; and (c) the Company was, in fact, trying to break new ground with its attempt to seek impermissible, indirect costs from CMS and that fact was clear given what Dr. Bloschichak had told Coyle months before Devine made these misleading statements.

M. Additional Allegations of Scienter

1. CMS' Past Practices Put Defendants on Notice That the Risk of a Rate Cut Was High

184. Industry participants including Defendants knew that iRhythm's attempt to include prohibited, indirect costs for the Zio XT to support inflated reimbursement rates was impermissible, not just from published cost methodology but because it had been tried—and rejected following public notice and comments—a decade before.

185. In 2008, CMS requested comments on a new CPT Code for 2009—code 93229— that covered wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage. This CPT Code related to cardiac monitoring devices provided by LifeWatch and CardioNet.

186. Both LifeWatch and CardioNet argued that CMS' standard pricing methodology was ill-equipped to establish the correct direct costs for their devices

because it did not properly account for the high cost of complex software and hardware that received, analyzed, and stored ECG data from patients. LifeWatch and CardioNet also implored CMS to disregard its standard methodology, and instead allow reimbursement for indirect costs associated with a centralized monitoring system that provides services to multiple patients at once instead of only one specific patient at one time.

187. In the notice-and-comment periods—in a prelude to iRhythm's own arguments a decade later—industry participants argued that the clinical benefits of the device justified higher reimbursement rates, and that CMS' standard cost methodology "does not work for remote cardiac providers whose businesses are structured differently from physicians' practices and, as a result, the RVUs assigned to the services do not reflect their proper relative cost." J. Remote Cardiac Monitoring Services (CPT codes 93012, 93229, 93268, and 93271), 75 Fed. Reg. 73308 (Nov. 29, 2010). Commenters supportive of the industry further argued that the centralized monitoring system at the heart of the devices is inherently different than other indirect expenses that are used to run a practice, and therefore should not be calculated as an indirect cost. *Id*.

188. CMS thoroughly and conclusively rejected these arguments. In the final rules that set payment policies and reimbursement rates for the PFS in 2011 and 2012, CMS repeatedly stated that "we believe it is more appropriate to classify the costs associated with the centralized monitoring equipment, including the *hardware and software, workstation, webserver, and call recording system, as indirect costs* since it is difficult to allocate those costs to services furnished to

individual patients in a manner that adequately reflects the number of patients being tested." J. Remote Cardiac Monitoring Services (CPT codes 93012, 93229, 93268, and 93271), 76 Fed. Reg. 73186 (Nov. 29, 2011) (emphasis added). CMS also rejected deviating from its standard cost methodology and stated that it would be inappropriate to do so based on claims made by a handful of device manufacturers, who furnished only a portion of all cardiac monitoring services. The only item accepted as a direct, reimbursable cost by CMS was the cardiac telemetry monitoring device worn by the patient.

2. Defendants' Scienter is Confirmed in the Delaware Litigation Between Bardy and Hill-Rom

189. On February 28, 2021, iRhythm's law firm of record in this Action filed a Verified Complaint on behalf of iRhythm's competitor, Bardy, against Hill-Rom in the Delaware Court of Chancery seeking to enforce a merger agreement between the two companies. According to the lawsuit, Hill-Rom gave Bardy notice that it would not close the merger because the new Novitas rates in 2021 had devastated Bardy's business and constituted a material adverse event that excused performance. The matter was tried over three days and involved substantial pre-trial and post-trial briefing, deposition testimony of 13 fact witnesses and 5 expert witnesses, and live testimony from 6 fact witnesses and 5 expert witnesses at trial. Much of the testimony focused on iRhythm because it was the largest seller of AECG devices.

190. In a post-trial brief, Bardy's lawyers agreed that "iRhythm's patch has been clinically shown to be

far less reliable than the CAM patch both in terms of missing arrhythmias and misdiagnosing rhythm disorders in healthy patients." *Bardy Diagnostics, Inc. v. Hill-Rom, Inc.*, No. C.A. No. 2021-0175-JRS, Plaintiff's Post-Trial Br. at 6 (Del. Ch. May 26, 2021). In the same brief, Bardy's lawyers concurred that CMS' rate-setting process is "'iterative,' building upon prior analyses and input from stakeholders, who are given multiple opportunities to comment and 'educate' CMS," confirming the value and impact of the MCDA Reports. *Id*. at 13. Bardy relied on testimony to argue that rates initially listed in CMS' proposed rules are not significant because until a final rule is published "you don't know where CMS is ultimately going to land." *Id*. at 17 n.79 (Frank. Tr. 471:14-472:1).

191. Bardy further argued that Hill-Rom had assumed the risk of a rate cut during the notice-and-comment period in 2020 between the Proposed Rule and the Final Rule for calendar year 2021, because it hired a law firm and consultants such as David Parr, who warned that Novitas' pre-Class Period inflated rates were at risk, and projections based on one or two instances of outlier MAC pricing like Novitas' pre-Class Period rates for AECG services were a huge red flag. After the Final Rule for 2021 was announced in December 2020, Mr. Parr again correctly warned that there was a high risk that Novitas' rate structure would move to the mid-range when the CPT codes became permanent. Hill-Rom decided to move forward despite these warnings. However, Hill-Rom did renegotiate the merger price downwards, and linked earnout payments to revenue targets that would change depending on whether the MAC would

cut rates, showing that all the players in the industry understood the risks involved here.

192. Evidence also emerged in this litigation that senior executives at Bardy believed that the industry had only one chance between January 2021 and April 2021 to convince Novitas to raise the rates. Defendants described the communications with Novitas as "constructive" and gave investors the false impression that the MAC was open to hearing the industry's views even after the April 2021 rate cuts, but they did not disclose that the industry believed that there was no hope for an increase after April 2021. *See Bardy Diagnostics, Inc. v. Hill-Rom, Inc.*, No. C.A. No. 2021-0175-JRS, Defendant's Post-Trial Br. at 26 (Del. Ch. May 26, 2021).

193. Expert testimony and internal emails between the most senior executives at Bardy also confirmed that cuts to reimbursement rates would necessarily have a negative impact on contracts with commercial payors as well. For instance, an internal Bardy document acknowledged that commercial payors would renegotiate rates as a multiple of the Medicare rate. *Id.* at 12-15. One witness confirmed the reality that "you don't see the effect [on commercial rates] playing out immediately" and you "would expect the effect to increase over time." *Id.* at 14 (Noether. Tr. 820:3-7). The witness further stated that peer-reviewed economic literature supported "the effect to happen over one to three years." *Id.* (Noether. Tr. 820:7-11).

194. Adi Renbaum, an expert who testified in support of Bardy, and was retained by iRhythm's current law firm that represents it in this Action, admitted that clinical value is relevant only for

determining whether to "establish coverage" or whether Medicare should cover the services at all, and that once coverage is established "public health arguments and clinical benefits of a particular service do not factor into the task of setting a reimbursement rate for that service." *Id.* at 41 (Renbaum. Tr. 344:7-11, 366:20-24). Ms. Renbaum further conceded that CMS sets rates based on the actual "costs incurred by the service providers," and that "the patch devices themselves are the single largest cost component of the CPT codes at issue." *Id.* (Renbaum. Tr. 334:21-335:17, 337:7-10). Ms. Renbaum also admitted that CMS "will not set national pricing for the CPT codes at issue without actual invoices reflecting the cost information for the patch devices themselves." *Id.* at 41-42 (Renbaum. Tr. 337:24-338:17).

195. Hill-Rom also relied on the testimony of a former Medical Director of Novitas, who said that "[p]ublic health arguments and clinical benefits support a coverage policy (ie: why the service is appropriate and reimbursed). They do not factor into the 'mundane' task of pricing or valuing the service which comes from an understanding of how the service is rendered and what cost inputs are used." *Id.* at 43 (Querry. Tr. 218:12-21).

196. In addition, the CFO of Bardy, Mark Querry, testified that the cost of the patch itself was "trending down," corroborating the account of the senior executive quoted in the October 5, 2020 MCDA Report, and demonstrating that the industry had no incentive to produce an invoice at all. *Id.* at 42 (Querry. Tr. 184:15-19).

197. Finally, one of the key issues in the merger litigation was whether Bardy had been

disproportionately impacted by the rate cuts compared to its peers, which would excuse Hill-Rom from completing the transaction. While the parties disputed the facts on this issue, experts on both sides compared whether the financial impact on Bardy was similar to the financial impact on iRhythm, and there was no dispute that both companies would be worthless from the perspective of the sum of all future cashflows if the lower rates persisted. Expert modeling in the merger litigation also revealed that iRhythm's revenues would decline 16% for Medicare payors and 60% if both Medicare payors and commercial payors were included in the calculations, effectively destroying its business if the rate cuts persisted.

3. Confidential Witness Confirms Scienter

198. CW1 was iRhythm's EVP of Payer Relations and Market Access from July 2017 to May 2021. CW1 directly reported to King and then to Coyle during each of their respective tenures as CEO. CW1 has decades of experience working in the digital healthcare industry, including specific expertise in reimbursement rates and interfacing with government agencies, MACs and third-party commercial payors. As the EVP of Payer Relations and Market Access at iRhythm, CW1 led a department that strategized and oversaw the Company's policies and practices for seeking reimbursement from CMS, Novitas and commercial payors, as well as benefit verification and patient financial assistance. CW1 regularly met with and spoke to the Individual Defendants concerning the rates for the Zio XT and the Company's reimbursement strategy.

199. CW1 described CW1's own responsibilities as extremely broad relative to the world of reimbursement and revenue collection, and stated that CW1 did all of the footwork, investigated pertinent issues, and then raised them in strategic discussions that resulted in ultimate decisions made by the Individual Defendants and the Company's Board of Directors. CW1's central role in the Company's reimbursement strategy is confirmed by several other CWs. CW2 was a Revenue Cycle Manager at iRhythm from November 2019 to April 2021. CW2 reported to the Director of Revenue Cycle Services, who reported to CW1. According to CW2, CW1 oversaw the Company's communications with CMS, MACs and commercial payors and participated in negotiations about reimbursement rates. CW3, a former Sales Territory Manager at the Company from September 2017 to May 2020, stated that CW1 and CW1's department led and oversaw reimbursement rate negotiations for the Zio XT. CW4 was a Patient Financial Navigator Manager, whose immediate supervisors reported to CW1. CW4 also confirms that CW1 interfaced with CMS and Novitas concerning reimbursement rates for the Zio XT.

200. CW1 confirmed that, contrary to the misrepresentations Defendants made to investors during the Class Period, the Company did not provide CMS with an "invoice," and made no attempt, at any point, to break down the costs of the various components of the Zio XT, even though the Company knew what the actual costs of each component were. CW1 further confirms that MCDA's analysis is correct, and that iRhythm did, in fact, seek reimbursement for indirect costs, including R&D expenses and SG&A expenses. According to CW1, the

Individual Defendants knew that the proposed rates for the Zio XT included such indirect costs, but nevertheless intended to seek reimbursement for all of the indirect costs from CMS. CW1 further states that the Individual Defendants knew that CMS' standard cost methodology is based on an indirect allocator that standardizes the amount a company can receive in indirect costs, and does not allow companies to simply include all indirect costs, yet disregarded the standard and still sought to collect the full value of the service, including *all* indirect costs.

201. CW1 recalled that, in 2017, years before the Class Period began, iRhythm hired and consulted with Dr. Quinn, an industry expert on reimbursement rates, coverage decisions and federal rulemaking based in Los Angeles, California. In 2017, CW1 met with Dr. Quinn and, like Mr. Parr, Dr. Quinn stated that Novitas' reimbursement rates for the Zio XT were an outlier, and that iRhythm faced serious problems because CMS would be laser focused on breaking down the core costs of the device and would require Defendants to substantiate each component of the costs, and thus the Company would face major challenges with its current reimbursement strategy going forward. CW1 stated that the Individual Defendants disregarded the red flags that Dr. Quinn had raised before the Class Period began because the Company, including the Board of Directors, on which both King and Coyle served during their tenures, was collectively living in denial. CW1 also stated that CW1 relayed the concerns Dr. Quinn had raised with CW1 directly to King, but Defendants simply decided to support the Company's proposal with historical payments for the Zio XT, *i.e.* claims data that the

CMS, in fact, rejected very early on in the Class Period and before many of the misrepresentations were made to investors. CW1 states that Coyle and Devine were also aware, no later than early 2021, of the serious concerns that Dr. Quinn had raised in 2017.

202. In addition, according to CW1, King directly participated in and led the negotiations to seek inflated reimbursement rates from the MACs before the Class Period began, and King failed to convince all the other MACs to match the inflated rates that Novitas alone had endorsed and adopted. Specifically, according to CW1, all the other MACs had refused to adopt the inflated reimbursements rates set by Novitas years before the Class Period began. CW1 stated that Coyle and Devine were also aware, no later than early 2021, that King had failed to convince all the other MACs to adopt inflated reimbursement rates for the Zio XT before the Class Period began.

203. After CMS rejected the Proposed Rule in December 2020 and Novitas began to slash reimbursement rates for the Zio XT in January 2021, CW1 described the internal state of affairs at the Company as frantic. CW1, Coyle and other senior executives at the Company, along with senior executives from iRhythm's competitors, repeatedly met with Novitas to discuss reimbursement rates between January 2021 and April 2021. According to CW1, Coyle also independently met with Dr. Bloschichak, the Executive Medical Director at Novitas since June 2020, to propose higher reimbursement rates for the Zio XT.

204. CW1 asserts that the $115 rate set by Novitas in April 2021 closely tracked MCDA's calculations, removing the indirect costs that iRhythm had folded into its total costs to seek a higher reimbursement rate for the Zio XT. CW1 further confirms that Defendants agreed with Bardy's senior executives that the industry had only one chance to convince Novitas to set a higher reimbursement rate in meetings held between January 2021 and April 2021. This was so, according to CW1, because Dr. Bloschichak told Coyle in February 2021 that iRhythm's proposal was unacceptable, and that Novitas would consider alternative methodologies only if all the other MACs first supported the alternative methodology. Hence, CW1 explains that the rate set by Novitas in April 2021 became immovable because the industry failed to convince all the MACs to agree on a novel and alternative methodology by that time, and Dr. Bloschichak had directly told Coyle that Novitas would not break new ground and deviate from CMS' standard cost methodology in the absence of consensus amongst all the MACs. CW1 knows the details about Coyle's conversations with Dr. Bloschichak because Coyle relayed the specifics of those conversations back to CW1.

205. CW1 also confirms that the reduction in the Medicare rate for the Zio XT would also negatively impact commercial contracts, and that both Coyle and Devine understood this fact at the outset. According to CW1, many commercial payors developed a wait and see approach after the Final Rule was released in December 2020 and Novitas began to substantially reduce reimbursement rates for the Zio XT.

4. That Defendants' Misrepresentations Involved iRhythm's Core Operations Bolsters Scienter

206. Between 95% to 97% of the Company's revenue is derived from the Zio devices, only 10% of which consisted of revenue received from the sale of Zio AT. Hence, the Zio XT is the Company's core product, and it is inconceivable that Defendants would not know about the most significant risk impacting this product even before the Class Period began.

207. There can be no reasonable dispute that reimbursement rates for the Zio XT were critical to the Company's viability throughout the Class Period. Modeling by experts retained in the Delaware Litigation between Bardy and Hill-Rom showed that iRhythm would run out of cash within the next few years if the rates set by Novitas in April 2021 did not change. Expert testimony in the Delaware Litigation further revealed that iRhythm's revenues would decline by 60% for all payors if Novitas or CMS did not increase the rates, effectively delivering a death blow to the Company's future.

208. The reimbursement rates set by CMS or the MAC were also of such critical importance to the Company's short term and long term prospects that it is highly unlikely that the Defendants here would not be aware: (a) of past CMS practice rejecting arguments similar to those they touted to investors; (b) that the cost of the Zio XT device itself was the single largest cost component of the CPT codes; or (c) that the Company was not entitled to inflate reimbursement rates by folding in SG&A and R&D

expenses, even if they declined to produce detailed cost invoices.

5. Defendants Held Themselves out as Knowledgeable About the Regulatory Landscape

209. Defendants' own statements show that they repeatedly held themselves out as extremely knowledgeable about the regulatory landscape, and CMS' and the MACs' cost methodology, rules, and practices. For example, on an August 4, 2020 conference call to discuss the Proposed Rule for 2021, King told investors that the Company "worked hand-in-hand with the various governing bodies, AMA, ACC, HRS, in drafting and constructing that code language. So we were well aware and well informed, and we think this best represents the interest of patients, providers, service providers like ourselves in the industry." At this conference call, King also stated that iRhythm had provided CMS with claims data for the inflated reimbursement rates, which he falsely referred to as "invoices." On August 6, 2020, King told investors that the Company had "collaborated" with "CMS staff" for several years to convince the agency to endorse inflated reimbursement rates. King also discussed how CMS was required to operate a balanced budget format, demonstrating that he was familiar with its rules. On August 13, 2020, King again told investors that "we have a very long standing collaboration or history of collaboration with medical societies as well as CMS."

210. Similarly, Coyle told investors at an earnings conference call held in February 2021 that the Company had already had multiple meetings with Novitas, described the meetings as "very

constructive," and claimed that Novitas was considering the differences between traditional ECG monitoring devices and the Zio XT, including "the increased cost components that go into being able to provide that significant clinical and economic advantage relative to" traditional monitoring devices. Coyle, however, did not disclose that iRhythm had included in the figures it provided Novitas inappropriate, indirect costs from Medicare, that clinical value is irrelevant to reimbursement rates, or that iRhythm had no incentive to provide a proper invoice with a breakdown of costs because the actual cost of the Zio XT was trending downwards. On the earnings conference call held in February 2021, Devine also spoke about the meetings with Novitas, and told investors that the Company emphasized the "cost differential" between traditional ECG monitoring devices and the Zio XT in meetings with Novitas.

211. On the April 12, 2021 conference call to discuss Novitas' revised reimbursement rates, Coyle told investors that the Company was "actively involved" with CMS and had met with CMS in March 2021 to discuss reimbursement rates. On May 6, 2021, Coyle told investors that the Company had again met with Novitas after the revised rates were released in April 2021 and acknowledged that Novitas was laser focused on "cost inputs." Coyle also told investors again that "we continued to pursue national pricing with CMS," and that iRhythm had met with CMS in March 2021.

212. Given Defendants' own statements, it is inconceivable that Defendants would not know, or did not recklessly disregard, that their misleading

statements throughout the Class Period misled investors.

6. iRhythm's Reaction to the MCDA Reports Creates an Additional Inference of Scienter

213. As discussed above, iRhythm was fully aware of and submitted a three-page response to the October 5, 2020 MCDA Report in the notice-and-comment period between the release of the Proposed Rule and the Final Rule in 2020. In this letter, iRhythm did not dispute that it improperly sought reimbursement for prohibited indirect costs, including SG&A expenses and R&D expenses, and did not dispute that it had declined to provide invoice data to CMS that would substantiate a higher rate.

7. King's Insider Sales at Inflated Prices Enhance an Inference of Scienter

214. During the Class Period, King took advantage of iRhythm's artificially inflated stock price and earned approximately $18.816 million from sales of iRhythm common stock on the open market:

King's Class Period Stock Sales[1]:

Date	Shares Disposed	Price	Proceeds
8/12/2020	25,694	$178.7570	$4,592,982
8/12/2020	17,272	$179.5466	$3,101,129

[1] Excluded from these charts are proceeds from shares withheld by iRhythm in order to cover tax withholding obligations.

8/12/2020	3,558	$181.1289	$644,457
8/12/2020	3,102	$181.9863	$564,522
8/12/2020	3,989	$181.7665	$725,067
8/12/2020	6,007	$184.0681	$1,105,697
11/12/2020	2,210	$251.8636	$556,619
11/12/2020	1,796	$252.4287	$453,362
11/12/2020	5,438	$254.4094	$1,383,478
11/12/2020	9,724	$255.1935	$2,481,502
11/12/2020	9,659	$256.1629	$2,474,277
11/12/2020	690	$257.2528	$177,504
11/12/2020	2,152	$258.2600	$555,776
Total	91,291		$18,816,371

215. King sold 124,709 fewer shares of the Company's common stock during the Class Period than in the months preceding the Class Period when he sold 216,000 shares of common stock for proceeds of $20.57 million.

216. King also took advantage of the fact that, while the average price of the Company's common stock before the Class Period was $95.2412, the average price of the Company's common stock increased significantly to $206.1142 as Defendants misled investors repeatedly with their false statements.

LEAD PLAINTIFF'S CLASS ACTION ALLEGATIONS

217. Lead Plaintiff brings this Action as a class action pursuant to Federal Rule of Civil Procedure

23(b)(3) on behalf of all persons or entities that purchased or otherwise acquired iRhythm's common stock between August 4, 2020 and July 13, 2021 (the "Class Period"), both dates inclusive. Excluded from the Class are Defendants, officers, and directors of iRhythm, any entity in which any of the Defendants (alone or in combination with other Defendants) have or had a controlling interest, and any affiliates, family members, legal representatives, heirs, successors or assigns of any of the above.

218. The Class is so numerous that joinder of all members is impracticable. Throughout the Class Period, iRhythm's common stock was actively traded on the NASDAQ under the ticker symbol "IRTC." An average monthly volume of 11.2 million shares traded during the Class Period. Lead Plaintiff believes that there are several hundred if not thousands of members in the proposed Class, with the overwhelming majority of Class members having held shares in a street name. Potential Class members may be identified from records maintained by iRhythm, its transfer agents, and brokers and banks that hold shares beneficially for investors in a street name 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.

219. Lead Plaintiff's claims are typical of the claims of those of the Class, as all Class members were similarly affected by Defendants' wrongful conduct in violation of the federal laws complained of herein.

220. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and

has retained counsel competent and experienced in class action and securities litigation.

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

A. whether iRhythm and the Individual Defendants made false and misleading statements or failed to disclose material information that rendered their Class Period statements misleading;

B. whether the Individual Defendants are control persons of iRhythm for purposes of Section 20(a) of the Exchange Act;

C. whether iRhythm and the Individual Defendants made the misrepresentations or omissions with scienter;

D. whether the federal securities laws were violated by Defendants' acts as alleged herein;

E. whether the prices of iRhythm's securities during the Class Period were artificially inflated because of the Defendants' misconduct complained of herein; and

F. whether the Class has sustained damages with respect to its Exchange Act claims and, if so, what is the proper measure of damages.

222. 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 Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this Action as a class action.

223. With respect to the Exchange Act claims, Lead Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

A. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

B. the omissions and misrepresentations were material;

C. iRhythm's common stock traded in an efficient market;

D. the Company's common stock was liquid and traded with moderate to heavy volume during the Class Period;

E. the Company traded on the NASDAQ, and was covered by multiple analysts;

F. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

G. Lead Plaintiff and other Class members purchased or otherwise acquired iRhythm common stock between the time that the Defendants failed to disclose or misrepresented material facts, and the time that the true facts were disclosed or materialized, without knowledge of the omitted or misrepresented facts.

224. Based upon the foregoing, Lead Plaintiff and other Class members are entitled to a presumption of reliance upon the integrity of the market if they did not actually rely on Defendants' materially false or misleading statements.

225. Alternatively, Lead Plaintiff and the Class members 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 (1972), as Defendants omitted material information in violation of a duty to disclose such information, as detailed above.

COUNT I:

(Against Defendants iRhythm, King, Coyle, and Devine for Violations of Section 10(b) and Rule 10b-5)

226. Lead Plaintiff repeats and realleges the allegations contained in Paragraphs 1 to 225 above as if fully set forth herein.

227. This Count is asserted against iRhythm and each of the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

228. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon the Lead Plaintiff and the other members of the Class; made various untrue statements of material fact and 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; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including the Lead Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of iRhythm common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire iRhythm common stock at artificially inflated prices.

229. Specifically, iRhythm and the Individual Defendants made material misrepresentations and omitted to disclose material information that rendered their statements misleading as particularized in Paragraphs 148 through 183.

230. The Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive the Lead Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to iRhythm and the Individual Defendants. In addition to the facts alleged herein demonstrating a strong inference of scienter, certain information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within these Defendants' knowledge and control. As the senior managers of iRhythm, the Individual Defendants had knowledge of the details of iRhythm's internal affairs that were inconsistent with their public statements.

231. As officers and directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information regarding iRhythm's business, operations, and finances. As a result of the dissemination of the aforementioned false and misleading statements, the market price of iRhythm common stock was artificially inflated throughout the Class Period. Additionally, as a seller of iRhythm common stock during the Class Period, King had a duty to disclose or refrain from trading on iRhythm's artificially inflated stock price.

232. In ignorance of the adverse facts concerning iRhythm's business, operations, and finances, which were concealed by the misrepresentations and omissions alleged herein, Lead Plaintiff and the other members of the Class purchased or otherwise acquired iRhythm common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock or upon statements disseminated by Defendants and were damaged thereby.

233. During the Class Period, iRhythm's common stock was traded on an active and efficient market. Lead Plaintiff and the other members of the Class, directly relying on the materially false and misleading statements described herein, or relying upon the integrity of the market, purchased, or otherwise acquired shares of iRhythm at prices artificially inflated by Defendants' wrongful conduct. Had Lead Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock or would not have purchased or otherwise acquired it at the inflated prices that were paid. At the time of

the purchases or acquisitions by Lead Plaintiff and the Class, the true value of iRhythm's common stock was substantially lower than the prices paid by Lead Plaintiff and the other members of the Class. The market price of iRhythm's common stock declined sharply upon public disclosure of the facts or materialization of the risks alleged herein to the injury of Lead Plaintiff and other Class members.

234. By reason of the conduct alleged herein, iRhythm and the Individual Defendants knowingly or recklessly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

235. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other Class members suffered damages in connection with their respective purchases of the Company's common stock during the Class Period when the risk of Defendants' wrongdoing materialized or upon the disclosure thereof, causing the price of iRhythm common stock to decline. iRhythm and the Individual Defendants are liable for damages in connection with these losses under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II:

(Against Defendants King, Coyle, and Devine for Violations of Section 20(a) of the Exchange Act)

236. Lead Plaintiff repeats and realleges the allegations contained in Paragraphs 1 to 235 above, as if fully set forth herein.

237. During the Class Period, the Individual Defendants participated in the operation and management of iRhythm, and conducted and participated, directly and indirectly, in the conduct of

iRhythm's business affairs. Because of their senior positions, they knew the adverse non-public information that rendered iRhythm's public statements false and misleading.

238. As officers and directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to iRhythm's financial information and results of operations, and to correct promptly any public statements issued by iRhythm, which had become materially false or misleading.

239. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the Company's statements, which iRhythm disseminated in the marketplace during the Class Period concerning iRhythm's financial information and business. King served as the Company's CEO until January 12, 2021, and he was directly involved in the day-to-day management of the Company, including direct communications with analysts and investors in conference calls where he made false and misleading statements identified in Paragraphs 148 through 168. Coyle served as the Company's CEO from January 12, 2021 to June 1, 2021, and similarly managed the Company's day-to-day affairs, including direct communications with analysts and investors where he made the false and misleading statements identified in Paragraphs 169 through 170, Paragraphs 172 through 173, and Paragraphs 176 through 179, and signed the Annual Report that was filed with the SEC and contained the misleading statements identified in Paragraph 171. Devine served as the Company's CFO from June 2020 to June 2021, was involved in its day-to-day to management,

and signed and certified the misleading Annual Report identified in Paragraph 171. Between June 1, 2021, and July 13, 2021, Devine also served as the Company's CEO and made the false and misleading statements in direct response to pointed analyst questions identified in Paragraphs 174 through 175, and Paragraphs 180 through 183.

240. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause iRhythm to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of iRhythm 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 iRhythm's common stock.

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

242. As control persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the primary violations of the Exchange Act committed by iRhythm.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff 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 Lead Plaintiff as the Class Representative;

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

C. Awarding Lead Plaintiff 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.

DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: September 24, 2021

POMERANTZ LLP

By: */s/ Omar Jafri*

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CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2021, a copy of the foregoing was filed electronically via the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's

electronic filing system. Parties may access this filing through the Court's CM/ECF System.

POMERANTZ LLP

By: */s/ Omar Jafri*
Omar Jafri
Lead Counsel