UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Danville Division

The United States of America, *ex rel.* Joseph M. Thomas, Bringing this Action on Behalf of the United States of America,

Plaintiff,

v.

Duke University,
Duke University Health System, Inc.
William M. Foster, Ph.D.,
and
Erin N. Potts-Kant,

Defendants.

Note: This is now case No. 1:17-cv-256 in the U.S. D.C. M.D. N.C.

Civil Action No. 4:13-cv-00017

RELATOR THOMAS'S COMBINED OPPOSITION TO DUKE AND DUHS'S MOTION TO DISMISS AND FOSTER'S MOTION TO DISMISS

Relator Joseph M. Thomas ("Thomas" or "Relator"), by counsel, submits this brief in opposition to Defendants Duke University, Inc. ("Duke") and Duke University Health System, Inc.'s ("DUHS") motion to dismiss the Amended Complaint (Dkt. No. 72), as well as Defendant William M. Foster, Ph.D.'s ("Foster") motion to dismiss (Dkt. No. 73).[1] For the reasons that follow, the Court should deny the motions.

I. INTRODUCTION

This case is about massive grant fraud and institutional malfeasance, which caused over a hundred million dollars of taxpayer funds to be wrongfully obtained and wasted. The scale and

[1] Given their close substantive overlap, and in the interest of judicial economy, Thomas is responding jointly to these two motions. Defendant Erin N. Potts-Kant ("Potts-Kant") also filed a motion to dismiss (Dkt. No. 70), which will be opposed separately. Unless context dictates otherwise, this Opposition will collectively refer to Duke, DUHS, and Foster as "Defendants."

scope of this fraud is difficult to fathom. For over ***eight years***, experimental results—data critical to, and paid for by, pulmonary research grant funding—were wholly made up, deliberately falsified, and/or intentionally not performed as reported. Multiplying this fraud, the laboratory that produced this fraudulent data operated as a "core" facility, conducting experiments not only throughout Duke, but for other research institutions as well.

This core lab, known as the "Foster Lab," was named after Foster, its director. Potts-Kant worked for Foster, and actually falsified and fabricated the experimental results. Both Foster and Potts-Kant were employed by Duke and/or DUHS.

But this vast fraud is not limited to the conduct of Foster and Potts-Kant. Express warnings were made, and red flags readily apparent. Many other researchers and principal investigators were complicit, either consciously or through their own reckless and/or deliberately ignorant actions and omissions. At a minimum, ***no one***—not Foster nor any other principal investigator, supervisor, or researcher—reviewed the raw data produced by Potts-Kant for almost a decade. Instead, at best, all involved chose to blindly use Potts-Kant's "too good to be true" results, again and again, reaping the personal and professional benefits that they made possible.

The fraud, however, reaches beyond even the conduct of multiple individuals; it was also caused by and reflects the "toxic environment" within Duke and DUHS. Not only was the institution rocked by other research misconduct scandals during the same period, but its actions after unquestionably having actual knowledge in Spring 2013 evidences a culture of concealment that, independent of the Foster Lab research fraud, results in False Claims Act ("FCA") liability.

Defendants continue to try and avoid responsibility now, but their motions are without merit. They are flawed both in law and fact, misstating legal standards, ignoring well-pleaded facts and their reasonable inferences, and conflating the Amended Complaint's distinct claims.

For example, Defendants fail to independently address the presentment element, disregarding **Exhibit C** (Dkt. No. 25-11) and **Exhibit C-1's** (Dkt. No. 25-12) detailed spreadsheets of the specific false claims at issue—identified by grant number, year, amount paid, funding agency, recipient institution, and even principal investigator. They also apply the wrong falsity standard. Contrary to Defendants' arguments, *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013) does ***not*** require that representative false claims be alleged. Instead, *Nathan* holds that alleging a fraud scheme with particularity suffices as well, provided that it leads to the plausible inference that false claims were actually made. In any event, Thomas meets either *Nathan* benchmark, having alleged both a pervasive fraud that necessarily led to the submission of false claims, as well as specific examples of false claims.

Defendants' ancillary grounds fare no better. FCA materiality and scienter are plainly alleged. Counts IV and V plead false certification claims for violation of Duke's institutional assurance status. And DUHS is liable to the extent that Foster, Potts-Kant, and others acted as DUHS employees or agents.

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At bottom, Defendants' primary argument is that it is not reasonable and plausible that fraudulent data and results were included in grant applications and progress reports, when such data and results were: (i) necessary to receive grant funding; (ii) paid for by grant funding; and (iii) required to be reported in grant applications and progress reports. In the words of the Fourth Circuit, this contention "stretch[es] the imagination." *Nathan*, 707 F.3d at 457. The motions to dismiss should be denied.

II. STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss is a vehicle which may test a relator's allegations of fraud under Rule 9(b). *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783 n.5 (4th Cir. 1999) ("*Harrison I*"). Rule 9(b) requires that "a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Rule 9(b) applies only with respect to the FCA's fraud element. *Nathan*, 707 F.3d at 455. There is no heightened pleading standard for knowledge, which "may be alleged generally" under Rule 8. *Id.*; Fed. R. Civ. P. 9(b); *Ashcroft v. Iqbal*, 556 U.S. 662, 686-87 (2009).

While detailed factual allegations are not required, to satisfy Rule 8, a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The court, however, should deny a motion to dismiss if the complaint "state[s] a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Such facial plausibility requires allegations of "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

The Fourth Circuit has cautioned against undertaking a "mechanical" analysis requiring direct proof of each element of a claim. *Robertson v. Sea Pines Real Estate Cos.*, 679 F.3d 278, 287 (4th Cir. 2012).[2] In other words:

> *Iqbal* and *Twombly* do not require a plaintiff to prove his case in the complaint. The requirement [of Rule 8] is tempered by the recognition that a plaintiff may only have so much information at his disposal at the outset. A complaint need not 'make a case' against a defendant or *forecast evidence* sufficient to *prove* an element of the claim. It need only *allege facts* sufficient to *state* elements of the claim.

[2] Duke and DUHS rely on *Robertson*. Duke and DUHS Mem. in Sup. of their MTD (Dkt. No. 74) (hereinafter "Duke Br.") at 7.

Id. at 291 (quotations omitted). Therefore, "evaluating the sufficiency of a complaint is a 'context-specific task that requires the reviewing court to draw' not only 'on its judicial experience,' but also on 'common sense.'" *Id.* at 287 (quoting *Iqbal*, 556 U.S. at 679).

The movant may not ignore facts alleged in the complaint; rather, all properly pled facts and reasonable inferences therefrom, must be taken as true and in the light most favorable to the plaintiff. *See Trs. of Hackberry Baptist Church v. Womack*, 62 F. Supp. 3d 523, 526 (W.D. Va. 2014) ("In determining facial plausibility, the court must accept all factual allegations in the complaint as true."); *Vassar v. Ross*, No. 4:14cv00056, 2015 U.S. Dist. LEXIS 76736, at *15, n.8 (W.D. Va. June 15, 2015) ("all reasonable inferences must be made in favor of Plaintiff[] and [his] allegations"); *Nathan*, 707 F.3d at 455 (the court "must view the facts alleged in the light most favorable to the plaintiff").

In addition to the operative complaint, on a motion to dismiss the court should consider attached exhibits, integral documents incorporated by reference, and those matters of which the court may take judicial notice. *Walker v. Serv. Corp. Int'l*, No. 4:10CV00048, 2011 U.S. Dist. LEXIS 39856, at *10-11 (W.D. Va. Apr. 12, 2011).

"A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Harrison I*, 176 F.3d at 784.

III. BACKGROUND

A. Summary of Relevant Facts

1. The federal grant process.

a. Research institutions rely on grants to fund medical research.

Federal grants are the lifeblood for research institutions like Duke. Given, however, the many research needs and the many qualified applicants, the grant process is highly competitive; only the most deserving research studies are awarded scarce federal dollars.[3]

Institutions initially seek grant funding through an application, which describes the proposed research project and includes supporting preliminary studies, experimental data, and other research results.[4] But a successful grant application does not guarantee subsequent funding years. Rather, continued grant funding is dependent on meritorious annual progress reports, which—as the name indicates—detail the research accomplishments to date, plans for the future, and progress towards the previously stated research goals.[5]

Principal investigators (like Foster) are the institutional agents that apply for funding through grant applications and progress reports.[6] These grant documents—as well as the comprehensive Institutional Assurance and Annual Report—include certifications as to their accuracy and completeness, as well as compliance with applicable policies and research regulations. These certifications are a condition of grant approval and grant funding.[7]

b. Publications are central to grant research and funding.

Medical research is an iterative process, with today's research serving as the foundation

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[3] Am. Compl., ¶¶ 2, 56, 58.
[4] *Id.*, ¶¶ 150, 217, 342(a).
[5] *Id.*, ¶¶ 95-98, 103-105, 119-22, 217.
[6] *Id.*, ¶ 29.
[7] *Id.*, ¶¶ 4, 88-101, 115-116.

for that of tomorrow.[8] This is particularly true for federally funded research, where the true purpose is not for the grant recipient to benefit, but the public. To facilitate this, and to allow other researchers to build upon and refine previously funded work, "[r]esearch results must therefore be communicated to the medical and scientific community. Typically, this is done through journal publications."[9]

Journal publications are thus the "primary conduit" to advancement for researchers and institutions.[10] This includes using publications to help to obtain grants, which tangibly "fund the costs of research, including salaries, institutional support, and infrastructure."[11] "The more publications, and the more noteworthy the results, the more advancement and benefit."[12] This grant-research-publication cycle is self-perpetuating: grants fund research, the most important research results are published, and the published research results are then reported in grant documents—progress reports to continue funding and applications to seek new funding.[13]

To justify proposed research, grant applications must include supporting preliminary data, research results, and experiments in the application's "Research Plan" and "Project Narrative" sections. In discussing the proposed research plan and/or project, the supporting material often includes substantive discussion of related journal publications. Any publications discussed must then also be cited in the application's "Bibliography and References Cited/Progress Report Publication List" section.[14]

As for progress reports, these "inform the NIH of the grantee's accomplishments,

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[8] *Id.*, ¶ 131.
[9] *Id.*, ¶ 132. *See also id.*, ¶ 108.
[10] *Id.*, ¶¶ 133-36
[11] *Id.*, ¶ 134.
[12] *Id.*, ¶ 136.
[13] *Id.*, ¶¶ 6, 133-36.
[14] *Id.*, ¶¶ 102, 150, 342, 364.

including publications and inventions resulting from the award, personnel and location changes, budget updates, and other information pertaining to the grantee's use of funds."[15] Grantee institutions "must provide complete references to the publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively."[16] Final progress reports "summarize the grantee's accomplishments, ***identify significant results (positive or negative)***, and list publications resulting from the grant."[17] Per express NIH policy, "[a]ll research results that are funded by the NIH and accepted for publication by a peer-reviewed journal must be made available to the public no later than 12 months after publication."[18] This public access requirement has been in place since April 2008.[19]

Just as grants must identify resulting publications, publications likewise identify the grants that funded their research results. This is specifically alleged for the publications identified in the Amended Complaint[20] and its **Exhibit E** (Dkt. No. 25-15), as well as shown on the face of the publications attached as **Exhibit B** to the Amended Complaint (Dkt. Nos. 25-4 to 25-10).

In summary, there is a tight integration among research results, publications, and grant funding, with "the publication of articles and papers [being] central to the NIH and EPA grant

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[15] Am. Compl., ¶ 94.

[16] *Id.*, ¶ 103. *See also id.*, ¶ 104 ("For non-competing continuation progress reports, the grantee institution must report publications resulting directly from the grant. If the grantee has no publications to report, it must include such a statement."), ¶ 121 (EPA progress reports must report all resulting publications).

[17] *Id.* ¶ 98 (emphasis added). *See also id.*, ¶ 105 (final progress reports "must include a list of significant results (positive or negative), and a list of resulting publications"), ¶ 122 (EPA final progress reports must report all publications).

[18] *Id.* ¶ 106.

[19] *Id. See also id.* ¶ 121 (EPA website displays list of all publications and presentations arising from a grant).

[20] *Id.*, ¶¶ 165, 170, 176, 182,187, 193, 199, 205, 211.

systems."[21]

c. Funding agencies require protections against research fraud.

While the public good is the ultimate purpose of grant funding, it must be achieved through the work of grant recipients. But because those same individuals and institutions personally benefit so much by grant funding, fraud is always a risk.[22] Recognizing this temptation, funding agencies place strict conditions on grant recipients—an integrated set of requirements, policies, certifications, and assurances for institutions to prevent and respond appropriately to research misconduct and fraud.[23]

As threshold matters, "[n]o NIH grant funds can be used to disseminate information that is deliberately false or misleading."[24] And "[t]he grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project."[25] Grantees are also subject to the research misconduct regulations found in 42 C.F.R. Part 93 (the "Regulations").[26]

"The Regulations establish an institution's '***affirmative duty*** to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct.'"[27] In any inquiry or investigation into allegations of research misconduct, an institution is obligated to report ***both*** the

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[21] *Id.*, ¶ 215. *See also id.*, ¶ 216.

[22] *Id.*, ¶ 137. These benefits are personal and professional, tangible and intangible. They include financial gain and job security, as well as increased reputation and professional esteem. *Id.*, ¶¶ 133-36.

[23] *Id.*, ¶ 60. In addition, every grant award—through its "indirect costs"—pays for compliance with government "regulations, including fostering an environment of research integrity and dealing forthrightly with allegations of research misconduct." *Id.*, ¶ 57.

[24] *Id.*, ¶ 61. *See also id.*, ¶¶ 123-30 (discussing the EPA Research Misconduct Policy).

[25] *Id.*, ¶ 62.

[26] *Id.*

[27] *Id.*, ¶ 66 (quoting 42 C.F.R. § 93.100(b) (emphasis added).)

affected grants and affected publications to the Office of Research Integrity ("ORI").[28]

Institutions must also have an active "assurance" to be eligible for grant funding.[29] An assurance is established each time a grant application or separate assurance form—*i.e.*, the Institutional Assurance and Annual Report—is submitted. To maintain its assurance status, a grantee institution must submit the required forms and otherwise comply with the Regulations.[30] The Regulations require that "institutions 'foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.'"[31] Institutions also must establish and comply with their research misconduct policies that meet the Regulations' requirements.[32]

Duke adopted the "Duke University Policy and Procedures Governing Misconduct in Research" (the "Duke Policy") to comply with its assurance obligations.[33] The Duke Policy emphasizes the fundamental importance of research integrity—particularly in collaborative research—and the shared responsibility for preventing and reporting research misconduct. For example, the Duke Policy states that:

> Duke University strives to foster an atmosphere of honesty and trust in which pursuit of knowledge can occur. ***Integrity of research forms the foundation of respect among scholars and students and between the academic world and the public***. All members of the university community share responsibility for maintaining this climate of trust.[34]

According to the Duke Policy, responsibility to prevent research misconduct and ensure

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[28] *Id.*, ¶¶ 75-82.

[29] *Id.*, ¶ 68.

[30] *Id.*, ¶¶ 69, 73-74.

[31] *Id.*, ¶ 67 (quoting 42 C.F.R. § 93.412(a).). *See also id.*, ¶¶ 70-72.

[32] *Id.*, ¶¶ 70-72.

[33] *Id.*, ¶¶ 139-40, 146. The Duke Policy was effective November 1995 and revised in January 2007, and is part of the Duke Faculty Handbook. *Id.*, ¶ 140.

[34] *Id.*, ¶ 141 (emphasis added).

research integrity begins with principal investigators, who "must bear primary responsibility for ensuring the integrity of collaborative research performed under their supervision whether by faculty or non-faculty."[35] This responsibility, however, is shared with "department and division chairpersons, and center directors," who, along with principal investigators, "are expected to ***make periodic and reasonable inquiries concerning the integrity of the activities conducted under their supervision***."[36] Anyone having reason to believe that a researcher has committed misconduct must report this, in writing, to the appropriate official.[37]

As an additional research integrity safeguard, institutions must make multiple certifications related to the request for and proposed use of grant funds.[38] For example, on an application, the institution certifies that: (i) it can provide appropriate oversight; (ii) it "agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application;" (iii) it complies or intends to comply with all applicable policies, certifications and assurances referenced in the application instructions; and (iv) that all information provided is true, complete, and accurate.[39]

2. *For close to a decade, the "core" Foster Lab produced fraudulent data, research results paid for by and used to obtain dozens of grants.*

The Foster Lab generated fraudulent data on every *flexi*Vent or multiplex experiment purportedly run by Potts-Kant.[40] Her supervisors—including, but not limited to Foster—were complicit, either intentionally or by their extreme recklessness or willful ignorance. The fraud scheme perpetuated itself in an almost decade-long vicious cycle: fraudulent data led to more

[35] *Id.*, ¶ 143.

[36] *Id.*, ¶ 143 (emphasis added).

[37] *Id.*, ¶ 144.

[38] *Id.*, ¶ 88. These express certifications are set forth in the Amended Complaint (*see id.*, ¶¶ 88-101, 115-16), and are not detailed in full again here.

[39] *Id.*, ¶¶ 89-91.

[40] *Id.*, ¶¶ 154, 233.

grant funding, and grant funding paid for more fraudulent data. The same fraudulent results funded by and used to obtain grant funding were also included in publications, for which Potts-Kant and Foster were co-authors.[41]

The Foster Lab operated as a "core" laboratory, meaning that it was an experimental hub throughout Duke and for other research institutions.[42] In 2005, as a 25-year-old, Potts-Kant began working in the Foster Lab as an employee of Duke and/or DUHS. Foster was Potts-Kant's direct supervisor, ran the Foster Lab, and was an employee and/or agent of Duke and/or DUHS.[43] Foster was held out by Duke and DUHS (and Foster himself) as a one of the world's leading authorities on pulmonary research, specifically experiments involving mice.[44] Potts-Kant was also supervised by other principal investigators and researchers for whom she "performed" experiments.

Potts-Kant's did her experimental work on two machines—the "*flexi*Vent" and "multiplex."[45] The *flexi*Vent measures pulmonary function by force-ventilating a mouse, while the multiplex analyzes samples of biological material.[46] "The airway physiology and inflammation data resulting from experiments performed on the *flexi*Vent and multiplex machines is ***fundamental in current pulmonary research studies***."[47] Moreover, "research results and related publications [are] ***fundamental*** to the grant system, and reported in grant applications and progress reports to secure funding."[48] Accordingly, "[i]t is unlikely that the

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[41] *Id.*, ¶¶ 5-6, 159-60.
[42] *Id.*, ¶¶ 5, 27.
[43] *Id.*, ¶¶ 21, 22, 24, 313.
[44] *Id.*, ¶¶ 25, 334.
[45] *Id.*, ¶¶ 147, 149. The multiplex is also known as "Luminex" or "Bio-Plex" machine. *Id.*
[46] *Id.*, ¶¶ 148-49.
[47] *Id.*, ¶ 150 (emphasis added).
[48] *Id.*, ¶ 315 (emphasis added).

NIH would award any significant grant funding for pulmonology research that does not include preliminary studies based on *flexi*Vent and/or multiplex experiments."[49]

a. Potts-Kant committed research fraud on every project.

Potts-Kant's work was suspect from the beginning. Coordinating with Potts-Kant's hire, the Foster Lab bought the *flexi*Vent purchase to replace the APTI machine, older equipment that performed the same type of measurement. But Potts-Kant never produced *flexi*Vent results consistent with prior APTI results, a discrepancy that was dismissed by Foster and others.[50]

Ultimately, "Potts-Kant committed research misconduct and fraud on nearly every experiment or project with which she was involved," from 2005 to March 2013.[51] This fraud took three primary forms.[52] *First*, Potts-Kant often would not run the purported experiment at all. Instead, she would make-up data out of whole cloth, and then report these fabricated results. *Second*, Potts-Kant would conduct an experiment, but then intentionally manipulate the results. To do this, Potts-Kant would download raw data from the *flexi*Vent or multiplex machines, change the data in Excel, and then report the falsified Excel data. *Third*, Potts-Kant would intentionally not run the experiments as reported, and then report falsified data.[53]

Through these methods, "Potts-Kant was able to generate fraudulent research results that: (i) supported researchers' hypotheses; (ii) were statistically significant; and/or (iii) purported to have been consistently 'replicated.'"[54] As explained above, this fraud was to the personal advancement and benefit of not only Potts-Kant, but also Foster, Duke, DUHS, and other

[49] *Id.*, ¶ 150.

[50] *Id.*, ¶¶ 151-52.

[51] *Id.*, ¶¶ 154, 229. In March 2013, Potts-Kant was placed on administrative leave due to a separate embezzlement fraud. *Id.*, ¶¶ 7, 227-29.

[52] The last two forms of the fraud often occurred in tandem, *i.e.*, experiments were knowingly run incorrectly, and then Potts-Kant intentionally manipulated the results.

[53] *Id.*, ¶¶ 4, 64(a), 64(b), 156-57.

[54] *Id.*, ¶ 158.

principal investigators.[55] For example, because of these fraudulent results, Potts-Kant and Foster became co-authors on over 38 journal publications, all of which report falsified and/or fabricated data.[56] In turn, these publications identify the grants that funded their research, research that was fraudulent.[57]

b. False claims were presented to the government.

Grant funds were not only used to publish the Foster Lab's fraudulent results; the Foster Lab's fraudulent results were also used in grant applications and progress reports to receive grant funds.[58] These are claims for money under the FCA.[59]

As previously discussed, preliminary data and results are critical for grant applications, and for pulmonary grants, include experimental results from the *flexi*Vent and multiplex machines. Research results, along with resulting publications, must be reported in grant progress reports to receive continued funding. Journals publish and communicate significant research results, and these publications identify their funding grants. Thus, "[t]he interaction among grant applications, grant progress reports, and publications establish that Duke University made the same false reports of research results to the NIH and the EPA as were made in the publications funded by NIH and EPA grants."[60]

For example, Foster and Potts-Kant authored publication PMID 22502799, "Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/-

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[55] *Id.*

[56] *Id.*, ¶¶ 159-60. *See also id.*, ¶¶ 162-213; Am. Compl. **Exs. B & E.** This co-authorship was a Foster Lab requirement to perform experiments for other researchers. *Id.*, ¶¶ 27-28.

[57] *See, e.g., id.*, ¶¶ 165, 170, 176, 182,187, 193, 199, 205, 211. *See also* Am. Compl. **Exs. B & E.**

[58] *Id.*, ¶¶ 5, 155, 214.

[59] *See, e.g., id.*, ¶¶ 348-49. Duke and DUHS admit this. Duke Br. at 11 (referring to a "claim for payment, *e.g.*, a grant application or progress report"). So too does Foster. Foster Mem. in Sup. of his MTD, Dkt. No. 75, (hereinafter, "Foster Br.") at 7 (grant applications and progress reports are FCA claims).

[60] *Id.*, ¶ 218.

mice," which was written in 2011 and published in the *Journal of Allergy and Clinical Immunology* in early 2012 (the "Mast Cell Paper").[61] The *flexi*Vent data reported in Figures 3A, 3B, 4C and 6A of the Mast Cell Paper is fraudulent.[62] The Mast Cell Paper states that it was supported by NIH grants, including "PO1-AI81672 to J.R.W., M.K. and W.M.F."[63] The "PO1-AI81672" identifier refers to a specific funding grant (hereinafter, the "SP-A Grant"), "W.M.F." refers to Foster, and "M.K." refers to Dr. Monica Kraft. The requirement that "results" and "accomplishments" must be reported in progress reports provides the compelling inference that the Mast Cell Paper's fraudulent data was also reported in the SP-A Grant progress reports.

Accordingly, Thomas alleges as follows:

> 219. Due to the sequence of grant applications, grant progress reports, and publications, Duke University made the same reports of false and/or fabricated research results to the NIH, in grant applications and progress reports, described in paragraphs **(162, 166, 171, 177, 183, 188, 194, 200, 206)** above and as described in paragraphs **(1, 6, 11, 17, 23, 28, 31, 36, 41, 47, 52, 60, 65, 72, 77, 82, 87, 92, 97, 102, 107, 112, 118, 123, 128, 133, 138)** of **Exhibit E** as were made in the publications funded by those NIH grants, that are listed in **Exhibits C** and **C-1**.
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> . . .
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> 222. Duke University applied for and received at least 49 grants, totalling over $82,776,000 that were directly premised on and/or arose from the research misconduct and fraud of Potts-Kant and/or the Foster Lab, including false reports of research results in grant

[61] *Id.*, ¶ 206. The Amended Complaint contains an error and mistakenly states that the Mast Cell Paper was accepted for publication on January 17, 2013. *Id.*, ¶ 210. As evidenced by the article itself (attached as part of **Exhibit B** to the Amended Complaint, Dkt. No. 25-5, Pageid#: 1374-1385) and shown below, it was actually written in 2011, accepted for publication on March 1, 2012, and published online on April 12, 2012:

> Received for publication July 18, 2011; revised February 21, 2012; accepted for publication March 1, 2012.
> Available online April 12, 2012.

[62] Am. Compl., ¶¶ 207-10.

[63] Am. Compl., Ex. B (Pageid#: 1374).

> progress reports, as described below. ***These grants are identified in the attached as*** **Exhibit C**.
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> 223. In addition to those grants made to Duke University listed in **Exhibit C**, the NIH made 15 multi-year grants to grantee institutions other than Duke University, totalling over $120,910,000, which were premised on and/or arose from the research misconduct and fraud of Potts-Kant and/or the Foster Lab. ***These grants are identified in the attached*** **Exhibit C-1**. In many instances, the grantee institutions assigned experimental work to be performed at Duke University funded by these grants. In those instances, the grant applications and grant progress reports submitted by the grantee institutions necessarily included the same reports of false and/or fabricated research results that are stated in the publications in **Exhibit B** as described above and in **Exhibit E**.[64]

As indicated in those paragraphs, **Exhibits C** and **C-1** specify the claims at issue by grant number, year, amount, funding agency, recipient institution, and principal investigator. These amounts were actually paid by the United States, due to the systematic research fraud.[65] In addition, Duke made claims for and received grant funds after it was no longer in compliance with its institutional assurances.[66]

Duke also made false certifications in the applications and progress reports for the grants identified in **Exhibit C** to the Amended Complaint, in its Institutional Assurance and Annual Report, and for all grant applications and progress reports after Duke was no longer in compliance with its assurance obligations.[67]

And in connection with the false and/or fraudulent claims, Defendants made or used, or caused to be made or used, false records and statements, including:

> (i) ***false statements of research results*** made in grant applications or grant progress reports; (ii) ***false publications*** reported in the

[64] Am. Compl., ¶¶ 219, 222-23 (bold emphasis in original; italicized and bold emphasis added).
[65] *See, e.g., id.*, ¶¶ 222-23, 356-57.
[66] *See, e.g., id.*, ¶¶ 380-402.
[67] *Id.*, ¶¶ 219, 224-26, 380-402.

grant applications and progress reports; (iii) ***false certifications*** in the grant applications and progress reports; (iv) the ***grant applications and progress reports***, as false records; and (v) ***false certifications*** in the Institutional Assurance and Annual Reports.[68]

c. Foster and other researchers ignored warnings and red flags.

Although Potts-Kant generated the data underlying the false claims for the grants specified in **Exhibits C** and **C-1**, Foster and many individuals are also responsible, as well as Duke and DUHS as institutions.

During Potts-Kant's employment, multiple express warnings were made about her work, warnings that were ignored by Foster and others:

- Dr. Wayne Mitzner, Director of the Respiratory Biology/Lung Disease Program at Johns Hopkins University, questioned the validity of the Foster Lab's data. But without checking the raw data, Foster vigorously defended Potts-Kant and his laboratory.[69]

- Dr. Jamie Cyphert, a researcher with the NIEHS, questioned the Foster Lab's data and requested the *flexi*Vent machine "script" to try and independently replicate the results. The Foster Lab refused this request. In fact, Foster, Potts-Kant, and the Foster Lab refused to share this script with anyone.[70]

- In 2010 or 2011, Dr. Jerry Eu—at the time a principal investigator within the Pulmonary Division—advised Foster and Dr. John Hollingsworth (another Pulmonary Division principal investigator) that he suspected Potts-Kant of falsifying results. "Dr. Eu 'blinded' Potts-Kant to an experiment and confirmed his suspicions, and then told Foster and Dr. Hollingsworth what he had found and they ignored his concerns."[71]

- Charles Giamberandino, a lab research analyst, "raised concerns of possible research misconduct involving Potts-Kant and the Foster Lab during the period between 2010 and 2012. Mr. Giamberardino stated that Potts-Kant should have been 'blinded' from aspects of experiments."[72]

During Potts-Kant's employment, there were obvious red flags about her work that were

[68] *Id.*, ¶ 364.
[69] *Id.*, ¶ 318.
[70] *Id.*, ¶¶ 319-20.
[71] *Id.*, ¶¶ 36, 321.
[72] *Id.*, ¶¶ 43, 322.

ignored by Foster and others:

- Potts-Kant could purportedly process mice through the *flexi*Vent in just three minutes, approximately ***seven times faster*** than Barbara Theriot, Potts-Kant's peer in terms of *flexi*Vent experience who worked in another lab.[73]

- Her results were consistently "too good to be true," meaning that "in too many instances, they supported the stated hypotheses and desired outcome, and/or were statistically significant."[74]

- The large number of publications authored by Potts-Kant, a junior researcher, was highly unusual (as was the spike in Foster's authorship).[75]

During Potts-Kant's employment, Duke, DUHS, and the Pulmonary Division were also going through similar scandals, which should have made Foster and others hyper-attentive to possible data manipulation. Instead, the fraud's continuation—when any researcher or supervisor's simple check of Potts-Kant's raw machine data would have revealed it (assuming they did not already have actual knowledge)—evidences a "toxic environment," one that pushed for more grants and more publications above all else:[76]

The Potti Scandal

- Dr. Anil Potti—a former Duke medical researcher focused on cancer genomics—has been accused of falsifying data from 2006 to until he resigned in 2010.[77]

- The Potti scandal received widespread attention beginning in 2011, not only within the scientific community but also the general news media, including a February 2012 *60 Minutes* program titled "Deception at Duke."[78]

- In 2011, Dr. Robert Califf—then Duke's Vice-Chancellor in Charge of Clinical Research—was quoted in The Economist as saying, "[a]s we evaluated the issues, we had the chance to review our systems and we believe we have identified, and ***are***

[73] *Id.*, ¶¶ 41, 328-30.
[74] *Id.*, ¶ 333.
[75] *Id.*, ¶ 332.
[76] *Id.*, ¶ 300.
[77] *Id.*, ¶¶ 301-302.
[78] *Id.*, ¶¶ 303-308.

implementing, an improved approach."[79]

- In 2015, reflecting back upon the lessons from the Potti scandal, Dr. Califf was quoted as stating that Duke had "learned the importance of high-quality evidence, and ***not just taking somebody's word for it***."[80]

The Sanyal Fraud

- In 2011, a formal finding of research misconduct was issued against Dr. Shamarendra Sanyal, a former postdoctoral scholar within the Pulmonary Division that worked under Dr. Eu.[81]

- ORI found that Dr. Sanyal had falsified data in a grant applications submitted to the NIH and another federal agency.[82]

d. Defendants review the Foster Lab's fraudulent data.

Only after Potts-Kant's separate embezzlement came to light in March 2013, did anyone inquire about the provenance of the Foster Lab's reported data. The review did not distinguish between Foster Lab data reported in publications or grant documents. Instead, these data were reviewed as a single pool, specifically the "Foster Lab data that had been reported in grant applications, grant progress reports, and publications."[83] The review "involved senior administrators within Duke University and/or DUHS,[84] as well as principal investigators and other researchers within the Pulmonary Division."[85] Thomas participated in this review, and he also had many discussions with those more directly involved, including principal investigators Dr. Julie Ledford and Dr. Lorretta Que, among other Pulmonary Division personnel.[86]

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[79] *Id.*, ¶¶ 305-306.

[80] *Id.*, ¶ 308.

[81] *Id.*, ¶ 311, 335-337.

[82] *Id.*, ¶ 312.

[83] *Id.*, ¶ 230.

[84] These senior administrators included: "Donna Cookmeyer, Ph.D., the Research Integrity Officer; Sally A. Kornbluth, Ph.D., the Vice Dean for Basic Science; Mary E. Klotman, M.D., the Chair of the Department of Medicine; and Nancy Andrews, M.D., Ph.D., Dean of the School of Medicine." *Id.*, ¶ 231.

[85] *Id.*, ¶¶ 231-32.

[86] *Id.*, ¶¶ 18, 35, 38, 232-33.

This review confirmed the far-reaching fraud involving grant applications, progress reports, and publications. Thomas has personal knowledge that, based on this review, ***all*** research results reported by Potts-Kant are "either non-existent, falsified, manipulated, unreliable, and/or fraudulent in some manner."[87] Extensive details are provided in the Amended Complaint about the different fraudulent methods, which are summarized here:

- Potts-Kant simply "made-up" many reported results, and there is not any corresponding raw *flexi*Vent or multiplex data.[88] For example:
  - "Ms. Theriot noted that only a few raw data files existed for the Foster Lab's *flexi*Vent experiments."[89]
  - "Dr. Ledford found that there was no raw data at all for the Foster Lab *flexi*Vent experiments from before 2009."[90]
  - Dr. Ledford also "found no raw data files for Dr. Hollingsworth's study of ozone and diesel exhaust exposure."[91]
  - "[Dave] Francisco also noted that raw data files did not exist for two of the six multiplex experiments that he reviewed, and that original data could not be located for the publication designated PMID 22773729."[92]
  - "Dr. Que found that some of Potts-Kant's records did not include 'plate keys' for the experiments she had run.[93]
  - "Mr. Francisco also noticed that plate keys were missing."[94]
  - "The reviewers could not find raw data to support the results reported in PMID 21930959, PMID 22073274, PMID 22773729, PMID 21684833, PMID 21037098, PMID 17993584, and PMID 17878331,"[95] and "[t]hese

[87] *Id*., ¶ 233 ("Thomas understands that ***all*** work completed by Potts-Kant is false, fabricated, and/or fraudulent in some way.") (emphasis added).
[88] *Id*., ¶¶ 234-39.
[89] *Id*., ¶ 235.
[90] *Id*.
[91] *Id*.
[92] *Id*., ¶ 236. Mr. Francisco was a lab analyst, who also worked as Dr. Kraft's lab manager. *Id*., ¶ 42.
[93] *Id*., ¶ 237. "Plate keys are records of multiplex experiments that allow other researchers to confirm and compare reported values." *Id*.
[94] *Id*..
[95] *Id*., ¶ 238.

publications state that the reported research was funded by Grants AI 081672, AI 064789, AI 58161, ES 016126, ES 020426, ES 016166, ES 016347, ES02046, ES016659, ES 11961, ES12717, HL 05009, HL 086887, HL 081825, HL 067021, HL 075307, HL 67281, HL 91335, HL 77291, P50-HL084917, ATS 07-012."[96]

- Dr. Que and Dr. Ledford concluded that "the Foster Lab had never even run the experiments it reported in the first place—Potts-Kant had simply made up the results." For example, Dr. Ledford, "observed that the data reported for Dr. Hollingsworth's epigenetic work involving maternal diesel exposure was entirely made up," and "also noted that Duke University had withdrawn a pending grant application because the underlying data was false."[97]

- "Mr. Francisco identified fabricated multiplex and *flexi*Vent data in connection with the publication PMID 22773729."[98]

- "Ms. Theriot observed that two parts of Figure 2 (the cytokines IL-6 and KC results) in PMID 20543006 were simply 'made up.'"[99]

- Potts-Kant intentionally manipulated the results of experiments she did run.[100] For example:

  - As detailed below, Dr. Ledford concluded that Potts-Kant had "manipulated" data from three experiments that were reported in Figure 6A of the Mast Cell Paper.[101]

  - "Dr. Que observed that Potts-Kant's multiplex data was likely false."[102]

  - "Dr. Ledford identified data that Potts-Kant had falsified," including that she "had lowered the reported resistance values in the 'LPS/NOS' project."[103]

  - "Mr. Francisco identified data that Potts-Kant had manipulated in the interleukin 8 ("IL-8") and TNF-α cytokines results that were significant to the conclusions in PMID 22773729."[104]

  - "Ms. Theriot found that the Foster Lab's airway hyperresponsiveness

[96] *Id.*, ¶ 239.
[97] *Id.*, ¶ 240-41.
[98] *Id.*, ¶ 242.
[99] *Id.*, ¶ 243.
[100] *Id.*, ¶¶ 253-60.
[101] *Id.*, ¶¶ 271-78.
[102] *Id.*, ¶ 254.
[103] *Id.*, ¶ 255.
[104] *Id.*, ¶ 256.

("AHR") results in the diesel particle experiments were 'all bad.'"[105]

- "Ms. Theriot also found that all of the calculations in publication PMID 20348208 were incorrect."[106]

- Potts-Kant intentionally did not conduct experiments correctly or as reported.[107] For example:

  - "[W]hen Dr. Ledford tried to re-run certain experiments, she observed that the ***mice died*** after being administered an antigen but before the experiments could be performed. This shows that administering antigens at the dosage called for and reported by Potts-Kant killed the mice before they could be tested and that any reported results were, therefore, fabricated."[108]

  - "Dr. Ledford also found that Potts-Kant had administered the wrong ozone dose in some of her experiments, and that the data from experiments involving LMP-420, an inhibitor of tumor necrosis factor α ("TNF-α"), for some of her experiments was fraudulent."[109]

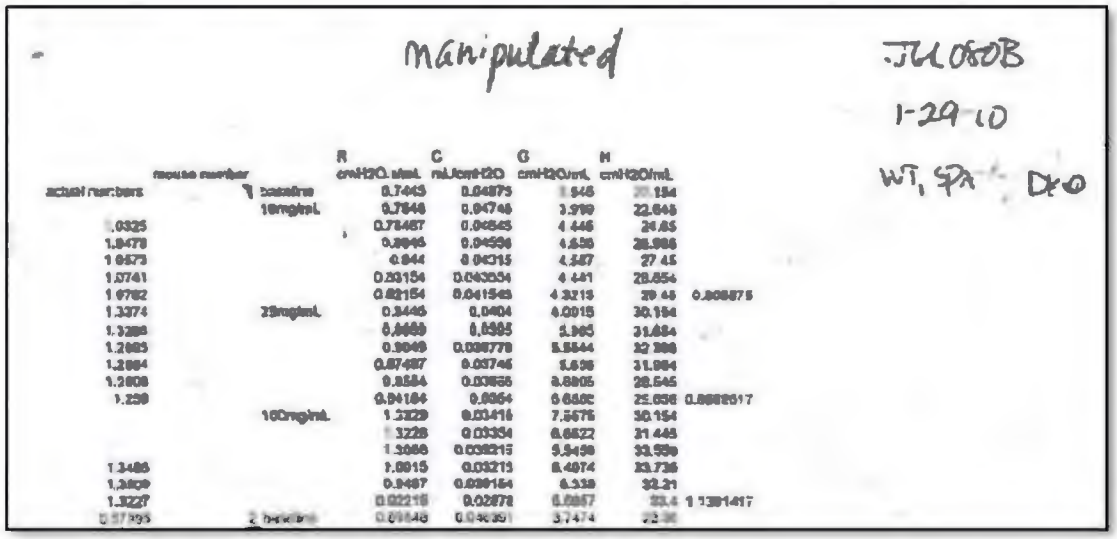
  - "Dr. [Jennifer] Ingram noted that Potts-Kant had not exposed mice to the proper antigens for some studies."[110]

As additional confirmation of the widespread fraud, Duke and/or DUHS were unable to repeat reported Foster Lab results when conducting new experiments, often producing data directly contrary to that reported in grant applications, progress reports, and publications.[111]

Exhibit D to the Amended Complaint (Dkt. No. 25-13) illustrates the institutional review.[112] In those documents, Dr. Ledford identified manipulated *flexi*Vent data related to mast cell research and the SP-A Grant. These documents were created in April 2013, only days after the review began. They are notes and spreadsheets that Dr. Ledford made while comparing the Foster Lab's reported mast cell data with the raw machine data. In Dr. Ledford's own

[105] *Id.*, ¶ 257.
[106] *Id.*, ¶ 258.
[107] *Id.*, ¶¶ 246-52.
[108] *Id.*, ¶ 247 (emphasis added).
[109] *Id.*, ¶ 249
[110] *Id.*, ¶ 250. Dr. Ingram is an assistant research professor, who worked for Dr. Kraft. *Id.*, ¶ 39
[111] *Id.*, ¶¶ 261-268.
[112] This same **Exhibit D** was attached to the original Complaint, filed on May 17, 2013. Dkt. No. 1-12.

handwriting, Potts-Kant's data is "manipulated," as depicted below:[113]



A graph of the actual raw data from three experiments—conducted on November 3, 2009, January 29, 2010, and March 2, 2011—shows high variability, and the absence of any statistically significant difference between the experimental groups.[114] The intentionally manipulated reported data, however, purports to show the opposite: low variability and a high degree of significance between experimental groups.[115] This fraudulent mast cell data was reported in the Mast Cell Paper, specifically as part of Figure 6A.[116] The Mast Cell Paper then reports that the SP-A Grant funded the published research.[117]

As further confirmation, Dr. Ledford and Ms. Theriot re-ran the experiments reported in the Mast Cell Paper, including those reported in Figure 6A, and could not repeat the published results.[118] In fact, "Theriot observed results that were the opposite of what was published."[119]

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[113] *Id.*, ¶ 271-78, 288-89; Dkt. No. 25-13, Pageid#: 1665-66.
[114] *Id.*, ¶¶ 273, 277.
[115] *Id.*, ¶ 277.
[116] *Id.*, ¶¶ 274, 276.
[117] *Id.*, ¶ 211.
[118] *Id.*, ¶ 278.

3. Defendants concealed the research fraud after March 2013 and seek more grant funding using Potts-Kant's data.

Soon after the review began in March 2013, Defendants determined that all Foster Lab data generated by Potts-Kant was falsified and/or fabricated.[120] But despite having actual and specific knowledge of this widespread fraud—knowledge that reached the senior institutional managers and administrators—Defendants acted to conceal the research fraud, rather than make complete and timely disclosures to grant funding agencies and journal publications. This was done to protect the personal and organizational interests of Duke, DUHS, and Foster.[121] Duke and/or DUHS even assigned Foster a leadership role in this review, despite the fact that it examined work produced by his lab.[122] Placing Foster in this conflicted role also violated Duke's obligations under the Regulations.[123]

In April 2013, Dr. Kraft—Chief of the Pulmonary Division—held a lab meeting to discuss the fraud. There, she instructed researchers to communicate about the fraud only in person or over the phone, in order to avoid creating a "paper trail."[124]

In April or May 2013, Duke and/or DUHS created and circulated a "script" with mandated instructions on how to communicate about the situation outside of Duke, *i.e.*, to funding agencies, journals, and co-authors. The script misleadingly stated that there was an "employment situation" that was being reviewed, and was designed to not disclose accurate

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[119] *Id.*, ¶ 278.

[120] *See* Compl., Dkt. No. 1 (filed on May 17, 2013), ¶ 46 ("Relator Thomas has discussed this research fraud with Dr. Ledford, Dr. Que, Charles Giamberardino and other Pulmonary Division personnel. These research personnel have explained to Relator Thomas that upon review of Potts-Kant's research, all such research is either non-existent, falsified, manipulated or fraudulent in some manner."). *See also* Am. Compl., ¶ 233.

[121] *Id.*, ¶¶ 279-80, 297.

[122] *Id.*, ¶ 281.

[123] *Id.*, ¶ 341(h).

[124] *Id.*, ¶¶ 32, 282.

information about the Foster Lab research fraud.[125]

On or about May 7, 2013, Duke's central research administration office told the Pulmonary Division that it did not want things to "snowball," and that any disclosures of the fraud could be avoided if "trends" held up—irrespective of whether research fraud and misconduct had already occurred.[126] Defendants next embarked on a plan to try and accomplish just that. Specifically "in the hopes of ***avoiding such disclosures to the NIH, EPA***, and publications," they sought to repeat experiments and "recalculate" raw machine data, to try and replicate the fraudulent results that had been reported by the Foster Lab.[127] Defendants then acted to avoid and delay issuing retractions, and otherwise not fully and accurately communicate with funding agencies.[128]

On May 17, 2014, Dr. Kraft held a lab-sponsored dinner. By that time, the existence of a "whistleblower" was known, but not Relator Thomas's identity. After the dinner, Dr. Kraft told Thomas and others that despite the whistleblower, "nobody is going to take us down."[129]

Defendants not only failed to fully disclose the research fraud after March 2013; they affirmatively continued to use data generated Potts-Kant to try and obtain grant funding. The SP-A Grant referenced above was a five-year grant that awarded Duke close to $9 million,

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[125] *Id.*, ¶ 285.

[126] *Id.*, ¶ 283.

[127] *Id.*, ¶ 284 (emphasis added). "Recalculating" data means to try and utilize the raw machine data, even when it differed from the data reported from the experiment. *Id.*, ¶ 230. At a minimum, reliance on the raw data under such circumstances would require belief in the integrity of the person that had generated it, *i.e.*, that the experiments had been performed faithfully. Here though, that person was Potts-Kant, the same individual that had intentionally reported fraudulent results and had just been put on leave for a separate embezzlement. Moreover, by that time, Defendants, had actual knowledge that Potts-Kant had not performed the experiments correctly. *Id.*, ¶¶ 246-250.

[128] *Id.*, ¶¶ 279, 283, 286-87.

[129] *Id.*, ¶ 298. Dr. Kraft has subsequently left the Pulmonary Division, along with Foster and many other principal investigators. *Id.*, ¶ 299; Decl. of S. Gibson (Dkt. No. 69-4), ¶¶ 11, 17.

funded in fiscal years 2009-2014.[130] In June 2013, to claim the last year of grant funding, Duke submitted a progress report, which "included research reports based on experiments performed by Potts-Kant and the Foster Lab. This was ***done intentionally***, months after Potts-Kant was placed on leave, with actual knowledge that none of her work was reliable."[131]

Duke then sought try and renew the SP-A Grant, in order to obtain an additional five years of funding. Duke submitted a competing renewal grant application in Fall 2013, which "included research results based on the 'recalculation' of data produced by Potts-Kant."[132] In addition to having actual knowledge that there was no basis to rely on any of Potts-Kant's work, this recalculated data conflicted with repeat experiments performed earlier in 2013.[133]

4. Defendants' fraud was material.

"As described above, experimental results and data from the *flexi*Vent and multiplex are "fundamental in current pulmonary research studies," and critical to grant funding.[134] Certifications in grant documents are a condition of grant approval and funding.[135] And—per the Duke Policy—"integrity of research forms the foundation of respect . . . between the academic world and the public."[136] Accordingly, as alleged in the Amended Complaint, Defendants fraudulent records and statements were "material" for at least the following reasons:

a. They were made in the grant applications, progress reports, and the Institutional Assurance and Annual Report.

b. They were ***required to be included*** in the grant applications, progress reports, and the Institutional Assurance and Annual Report.

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[130] Am. Compl., ¶¶ 288-289; **Ex. C**, Dkt. No. 25-11 at Pageid# 1649.
[131] Am. Compl., ¶ 292.
[132] *Id.*, ¶¶ 293-95.
[133] *Id.*, ¶¶ 292, 296.
[134] *Id.*, ¶¶ 150, 315.
[135] *Id.*, ¶ 101.
[136] *Id.*, ¶ 141.

c. They related to the provision of preliminary data, other research results, and experiments that had allegedly been performed ***as the basis for supporting the proposed research***, and therefore were likely to affect the NIH's and the EPA's funding decisions. Defendants knew that the report of false and/or fabricated preliminary data and other data would ***cause the applications to receive artificially high priority rankings, and be more likely to cause the NIH and the EPA to award the grant***.

d. They falsely reported results of experiments that would, if accurate, ***prove and/or support research hypotheses***.

e. The physiological phenomenon that were the subject of the Foster Lab's false and fabricated research results were ***central to hypotheses asserted in grant applications and discussed in the grant progress reports***. These reported physiological results ***were convincing—but false and fraudulent—evidence that the asserted hypotheses had been proven*** by properly designed and conducted experiments with observed, documented, and reproducible results.

f. They falsely reported results of experiments that would, if accurate, ***support the need for additional research using additional grant funding***.[137]

In addition, without an active institutional assurance, Duke was not eligible for any NIH grant funding.[138]

5. Defendants acted with FCA knowledge.

Duke, DUHS, and Foster acted with FCA "knowledge"[139] or scienter. "At all relevant times," Potts-Kant, Foster, and other principal investigators and researchers were "employees and/or agents of Duke [] and/or DUHS, and acting in the course and scope of their employment

[137] *Id.*, ¶ 342 (emphasis added). *See also id.*, ¶ 101 (certifications a condition of grant funding).

[138] *Id.*, ¶ 68.

[139] For purposes of the FCA, the terms "knowing" and "knowingly" "mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.*, ¶ 48 (quoting 31 U.S.C. § 3729(b)(1)(A)). "No proof of a specific intent to defraud is required to show knowledge." *Id.*, ¶ 48 (citing 31 U.S.C. § 3729(b)(1)(B)).

Unless otherwise specified, use of "know," "knew," "knowing," "knowingly," or "knowledge" refers to this statutory definition, and thus one or more of the ways to establish knowledge under the FCA.

and/or agency."[140] Defendants and Potts-Kant each "knew that research results and related publications were fundamental to the grant system, and reported in grant applications and progress reports to secure grant funding."[141]

As for Potts-Kant, she "knew that the reported research results in question were false and/or fabricated, having generated the results herself."[142] Foster and other principal investigators then either: "(i) failed to review Potts-Kant's data for accuracy; (ii) failed to compare her reported data with the raw data produced and stored by the machines; (iii) failed to appropriately review Potts-Kant's data; or (iv) reviewed Potts-Kant's data and, therefore, would have understood that it was false and/or fabricated."[143]

Assuming that no one ever reviewed Potts-Kant's data, this occurred despite the Duke Policy requirement that principal "investigators, department and division chairpersons, and center directors . . . make periodic and reasonable inquiries concerning the integrity of the activities conducted under their supervision."[144] It also occurred at a time when Foster and others within the Pulmonary Division had made or received warnings about Potts-Kant's work, Duke had purportedly already "learned the importance of high-quality evidence, and not just taking someone's word for it" from the Potti scandal, and another researcher in the Pulmonary Division (Dr. Sanyal) had engaged in grant research fraud.[145]

More specifically, Foster knew that the research results in question were false and/or fabricated for at least the following reasons:

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[140] *Id.*, ¶¶ 313-14

[141] *Id.*, ¶ 315.

[142] *Id.*, ¶ 316.

[143] *Id.*, ¶¶ 335336.

[144] *Id.*, ¶ 143.

[145] *See supra* at III(A)(2)(c).

a. Foster was responsible for designing experiments Potts-Kant conducted, supervising Potts-Kant's actual performance of the experiments, and interpreting the results.

b. The sheer scope, duration, and differing types of Potts-Kant's activities in creating the false data over a period of years indicates that her direct supervisor was involved. These activities included Potts-Kant's failure to perform certain experiments, failure to preserve the raw data from many of the those experiments that she did perform, failure to follow experimental protocols, fabrication of certain research results, and alteration of other research results.

c. The false research results reported in grant applications and grant progress reports, and reported in the publications funded by the grants, were too complex and required too much expertise for Potts-Kant to have developed on her own, given her limited experience and training.

d. Foster failed to supervise Potts-Kant.

e. Raw data did not exist to support some of the reported research results.

f. Foster received warnings about Potts-Kant's work. His failure to follow-up indicates either that: (i) he already understood that the work was fraudulent; or (ii) he acted with reckless disregard and/or was deliberately ignorant to the truth or falsity of Potts Kant's work.

g. The large number of publications that Potts-Kant co-authored.

h. The number of publications that Foster himself co-authored increased dramatically after Potts-Kant was hired.

i. The data reported by Potts-Kant was "too good to be true."

j. Foster refused to provide other researchers with the raw data or *flexi*Vent scripts that would allow other researchers to attempt to replicate or verify the Foster Lab's results when those researchers requested such information.[146]

These facts establishing Foster's knowledge largely overlap with facts establishing other Duke and/or DUHS principal investigators' knowledge, as well as senior executives and

[146] *Id.*, ¶ 339.

managers.[147] In addition, Defendants had "actual and specific knowledge that Potts-Kant's reported research results in question were false and/or fabricated by no later than March 2013."[148] But despite this knowledge, Duke and/or DUHS "refused to disclose to other researchers or the government known problems with the research results reported by Potts-Kant and the Foster Lab."[149] And Duke even continued to use Potts-Kant data in grant applications and progress reports after having actual knowledge that it was false and/or fabricated, including when it submitted the SP-A Grant progress report in June 2013 and the SP-A Grant renewal application that Fall.[150]

B. Claims Asserted in the Amended Complaint

The Amended Complaint asserts five counts under the FCA: (1) false or fraudulent claims in grant applications and progress reports for the grants identified in **Exhibits C** and **C-1** under 31 U.S.C. § 3729(a)(1)(A); (2) false records or statements in grant applications, grant progress reports, and Institutional Assurance and Annual Reports for the grants identified in **Exhibits C** and **C-1** under 31 U.S.C. § 3729(a)(1)(B); (3) reverse false claims for the grants identified in **Exhibit C** under 31 U.S.C. § 3729(a)(1)(G); (4) false or fraudulent claims in grant applications and grant progress reports with respect to Duke's assurance status under 31 U.S.C. § 3729(a)(1)(A); and (5) false records or statements with respect to Duke's assurance status under 31 U.S.C. § 3729(a)(1)(B).

Counts One, Two, and Three are alleged against Defendants and Potts-Kant, and involve grants awarded to Duke and other institutions based on false and fabricated research results. Counts Four and Five are alleged only against the institutional Defendants and are based

[147] *See id.*, ¶ 341. *Compare id.*, ¶ 341 *with id.*, ¶ 339.
[148] *Id.*, ¶ 340.
[149] *Id.*, ¶ 341(j).
[150] *Id.*, ¶¶, 292-96, 341(i).

on false certifications of compliance with the assurances required by NIH regulations.

C. Procedural History

After serving a copy of the original Complaint and a written disclosure on the United States, Thomas filed this action under seal on May 17, 2013.[151] The United States commenced an investigation, receiving multiple extensions of time for good cause shown.[152] On November 13, 2015, Thomas filed the Amended Complaint.[153]

The United States' investigation is ongoing. On August 8, 2016, the United States Attorney for the Western District of Virginia filed a "Notice of the United States that It Is Not Intervening at this Time."[154] It stated that the "Court indicated that the Government must make its intervention decision on or before August 9, 2016, and that no further extensions of time would be granted."[155] Because the "Government's investigation has not been completed," the United States was "not able to decide before the Court's deadline whether to proceed with the action."[156] Accordingly, the United States stated that it was "not intervening ***at this time***."[157] The United States made clear, however, that "the ***Government's investigation will continue***."[158]

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[151] Dkt. No. 1.

[152] *See* 31 U.S.C. § 3730(b)(3).

[153] Dkt. No. 25.

[154] Dkt. No. 35

[155] *Id.*

[156] *Id.*

[157] *Id.* (emphasis added).

[158] *Id.* (emphasis added). Further, the United States requested that should the "Relator or Defendants propose that this action be dismissed, settled, or otherwise discontinued, this Court solicit the written consent of the United States before ruling or granting its approval," pursuant to 31 U.S.C. § 3730(b)(1). *Id.*

IV. ARGUMENT

A. Counts I, II, and III state FCA claims under Rules 8(a), 9(b), and 12(b)(6).

Although all of Defendants' arguments lack legal and factual foundation, falsity is their focus. Defendants disaggregate and repeat falsity arguments in different sections of their briefs, purportedly under Rule 12(b)(6) and then Rule 9(b). None hit their target.

Defendants even try to inject falsity into the presentment inquiry, refusing to independently address this separate FCA element. But Thomas has identified the claims at issue, in the spreadsheets found in **Exhibits C** and **C-1**. There is no question that claims were presented to the Government; in fact, they were actually paid to Duke and other institutions.

Defendants actual falsity arguments fail. As a threshold matter, they apply the wrong legal standard. The governing *Nathan* case does ***not*** require that specific false claims must always be alleged with particularity; a relator can also allege a fraud scheme that necessarily leads to the plausible inference that false claims were made. To base an FCA claim on a fraud scheme, the relator must state his reasons connecting the fraud to the false claims, providing "some indicia of reliability." *Nathan*, 707 F.3d at 456-57.

Thomas meets either *Nathan* falsity standard. An insider, he describes in detail a far-reaching scheme to falsify and fabricate research results to obtain grant funding. There are numerous details and indicia of reliability stated in the Amended Complaint regarding the fraud, including confirming facts communicated to Thomas during Duke and DUHS's own institutional review. Thomas has further identified specific falsity in grant-funded publications, and explained why—given their interconnectedness with grant applications and progress reports—these same fraudulent research results were necessarily reported in false claims. Alternatively, Thomas also specified examples of false claims, namely the June 2013 SP-A Grant progress

report and Fall 2013 SP-A Grant renewal application.

Defendants remaining falsity arguments are without merit. They ignore Thomas's well-pleaded allegations about the intentional fraud, even going so far as to mischaracterize his falsity allegations as "consist[ing] of nothing other than literally true bibliography listings and differences in experimental outcomes," and label contemporaneous statements confirming the fraud as "anecdotal" and "unsubstantiated and conclusory hearsay." Duke Br. at 15, 31, n.14. Defendants also rely on inapposite cases, including summary judgment rulings based on undisputed ***evidence*** that wrongdoing had not occurred.

Duke and DUHS (but not Foster) challenge materiality. There, they wrongly attempt to convert an example of relevant "proof" from the Supreme Court's recent *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016) decision into the purported pleading standard. More fundamentally, they do not credit allegations that the research fraud was "fundamental" and "central" to grants, nor the common-sense notion that research fraud is material to research funding.

Finally, Defendants make passing scienter arguments. But these ignore Thomas's well-pleaded facts describing their knowledge and the bases thereof, including Foster's role in supervising Potts-Kant. In addition, Duke and DUHS fail to acknowledge that, as organizations, their "knowledge" is that of their employees and agents.

1. The claims at issue were presented to the United States.

In contrast to this case, *Nathan* involved an attenuated FCA claim by an employee of a third-party entity. The issue was whether the relator had plausibly alleged that the defendant pharmaceutical company, Takeda Pharmaceuticals ("Takeda"), had caused false claims to be

presented to Medicare and other federal health insurance programs. 707 F.3d at 453.[159] None of the alleged claims would have been presented by Takeda. Instead, the relator claimed that Takeda's improper marketing would have led physicians to prescribe the drug Kapidex to an unspecified number of patients for "off label" uses, which would have then led an unspecified number of those patients to submit government reimbursement requests for off-label Kapidex prescriptions. The relator further alleged that because off-label uses are not federally reimbursable, then any such requests would have constituted false claims. *Id.* at 454-55.

The threshold problem in *Nathan* was the uncertain presentment of claims. As the Fourth Circuit stated, "***[i]mportantly***, to trigger liability under the Act, ***a claim actually must have been submitted*** to the federal government for reimbursement, resulting in 'a call upon the government fisc.'" *Id.* at 454 (quoting *Harrison I*, 176 F.3d at 785) (emphasis added).

The Fourth Circuit did not adopt the relator's proposed standard that it was sufficient to "***only*** allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment." *Id.* at 456 (emphasis added). It reasoned that "liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme. Therefore, when a relator fails to plead ***plausible allegations of presentment***, the relator has not alleged all the elements of a claim under the Act." *Id.* (internal citations omitted) (emphasis added). On the other hand, when the claims at issue—*i.e.*, those presented to the Government—are identified, this "provid[e]s notice to a defendant of its alleged misconduct," one of Rule 9(b)'s purposes. *Id.* at 456. *See also Harrison I*, 176 F.3d at 784 (courts "should hesitate to dismiss a complaint under Rule 9(b)" if "the defendant has been made aware of the particular circumstances for which she will have to

[159] At issue in *Nathan* was an FCA claim only under 31 U.S.C. § 3729(a)(1)(A). 707 F.3d at 453.

prepare a defense at trial").

Here, there are no presentment issues. **Exhibits C** and **C-1** to the Amended Complaint specify the particular grant claims at issue in Counts I, II, and III. The claims are identified with particularity, by the grant identification number, funding agency, year, amount, recipient institution, and principal investigator. These claims were not only presented to the Government through grant applications and progress reports, but were ***actually paid*** to Duke and other institutions.

Defendants purport to acknowledge the distinction between presentment and falsity.[160] Duke and DUHS state that the "essential elements" of an FCA claim are "(1) a claim for payment; (2) falsity; (3) materiality; and (4) knowledge." Duke Br. at 9. Foster provides a similar summary. *See* Foster Br. at 7. Such independent treatment of presentment is consistent with *Nathan*, and demonstrated in the other cases Defendants rely upon. For example, in *United States ex rel. Jallali v. Sun Healthcare Grp.*, No. 12-61011, 2015 U.S. Dist. LEXIS 180383 (S.D. Fla. Sep. 17, 2015), the Florida district court stated "[w]hether submission of the claim or payment by the government are sufficiently established are different questions than whether the scheme has been sufficiently pleaded." *Id.* at *8.[161]

But despite recognizing that presentment and falsity are separate FCA elements, Defendants proceed to collapse falsity into the presentment inquiry (and then go on to make

[160] Use of "falsity" or "false" in the Argument section is often a shorthand for the FCA's "false or fraudulent" claim language. *See* 31 U.S.C. § 3729(a)(1)(A) & (B).

[161] Duke and DUHS incorrectly state that the *Jallali* relator had provided "billing records as exhibits to her complaint." Duke Br. at 14. While this was the relator's self-serving characterization, it was rejected by the court: "Relator argues that the exhibits submitted with the original complaint document 'billing events.' ***They do not.***" *Jallali*, 2015 U.S. Dist. LEXIS 180383, at *14 (internal citation omitted) (emphasis added)). The *Jallali* court further stated that "Relator characterizes the treatment record charts as 'billing entries,' but there is no evidence that claims were submitted to the government based on the procedures or patient visits reflected by these entries." *Id.* at *14. *See also id.*, at *21 ("Relator's affidavit conflates the treatment records with 'billing statements' and does not link Defendants' allegedly improper practices with false claims.").

additional falsity arguments). For example, Duke and DUHS contend that Thomas "has not ple[d] that (1) even one ***false*** claim or certification was presented to the government for payment; (2) any such claim or certification was ***false*** or ***fraudulent***; . . ." Duke Br. at 10 (emphasis added). *See, e.g., id.* at 11-15 (arguing falsity as part of presentment), 25-28 (same). Foster commits the same error. Foster Br. at 7-9.

Defendants injection of falsity into presentment shows the lack of merit to an independent presentment argument. So too does the fact that, in *Nathan* and their other cited cases, the failure to adequately allege the presentment of specific claims was a threshold concern, one that does not exist here.

In short, the Amended Complaint pleads with particularity that the specific claims detailed in **Exhibits C** and **C-1** were not only made, but paid.

2. The claims presented were false or fraudulent.

Having identified the claims at issue in **Exhibits C** and **C-1**, the next issue is the falsity of those claims. Thomas has alleged the falsity element with Rule 9(b) particularity and under either standard set forth in *Nathan*.

a. *Nathan* holds that there are two ways to plead false claims.

Nathan does not require that specific false claims be alleged with particularity. In addition, the falsity element is satisfied if a fraud scheme, as alleged and reasonably inferred, would necessarily have led to false claims.

The Fourth Circuit stated its holding as follows: "we hold that when a defendant's actions, as alleged and as reasonably inferred from the allegations *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Nathan*, 707

F.3d at 457 (emphasis in original). Accordingly, if, on the other hand, a fraud scheme necessarily led to the submission of false claims, then specific false claims do ***not*** need to be alleged with particularity. *Id.* The Fourth Circuit made this very point in the opinion's next paragraph, "emphasiz[ing]" that its holding "does not foreclose claims under the Act when a relator ***plausibly pleads*** that specific, identifiable claims actually were presented to the government for payment," and that such allegations "must be evaluated on a case-specific basis." *Id.* at 458 (emphasis added).

A review of how the Fourth Circuit arrived at its holding confirms that alleging a fraud scheme with particularity can satisfy Rule 9(b), even in the absence of alleging specific false claims with particularity. *Nathan's* analysis began with *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002), stating that:

> We agree with the Eleventh Circuit's observation that the particularity requirement of Rule 9(b) "does not permit a False Claims Act plaintiff merely to ***describe a private scheme in detail*** but then to allege simply and ***without any stated reason*** for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government."

Nathan, 707 F.3d at 456-57 (quoting *Clausen*, 290 F.3d at 1311) (emphasis added). Rather than unadorned allegations of falsity, "Rule 9(b) requires that '***some indicia of reliability***' must be provided in the complaint to support the allegation that an actual false claim was presented to the government." *Id.* at 457 (quoting *Clausen*, 290 F.3d at 1311) (emphasis added).[162]

The Fourth Circuit then referenced cases where "courts have held that the requirements of Rule 9(b) can be satisfied in the absence of particularized allegations of specific false claims."

[162] In 2014, citing and quoting *Clausen*, the 11th Circuit stated that "there is no per se rule that an FCA complaint must provide exact billing data or attach a representative sample claim." *United States ex rel. Mastej v. Health Mgmt. Assocs.*, 591 Fed. Appx 693, 704, 2014 U.S. App. LEXIS 20921 (11th Cir. 2014). Rather, given the 11th Circuit's "nuanced, case-by-case approach, other means are available to present the required indicia of reliability that a false claim was actually submitted." *Id.*

Nathan, 707 F.3d at 457. It reasoned that these were consistent with *Clausen's* "stated reason" and "some indicia of reliability" standards, provided that "specific allegations of the ***defendant's fraudulent conduct*** necessarily led to the ***plausible inference that false claims were presented to the government***." *Id.* (emphasis added).

The Fourth Circuit's primary example of a case fitting within the *Nathan* framework was *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009). *Id.* Summarizing *Grubbs*, the Fourth Circuit stated that given the specific allegations about the "services that were recorded by the physicians but never were provided, such allegations constituted 'more than probable, nigh likely, circumstantial evidence that the doctors' fraudulent records caused the hospital's billing system in due course to present fraudulent claims to the Government.'" *Id.* (quoting *Grubbs,* 565 F.3d at 192). The Fourth Circuit continued that "[a]ccordingly, the [*Grubbs*] court further concluded that it would '***stretch the imagination***' for the doctors to continually record services that were not provided, but 'to deviate from the regular billing track at the last moment so that the recorded, but unprovided services never get billed.'" *Id.* (quoting *Grubbs*, 565 F.3d at 192) (emphasis added).[163] *See also Grubbs*, 565 F.3d at 190 ("hold[ing] that to plead with particularity the circumstances constituting fraud for a False Claim Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with ***reliable indicia*** that lead to a strong inference that claims were actually submitted") (emphasis added).

The Fourth Circuit stated that it was "[a]pplying these principles" by its holding. *Nathan*,

[163] *Nathan* also cited *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010) with approval, where, as recounted by the Fourth Circuit, the "Tenth Circuit held that 'claims under the [False Claims Act] need only show the ***specifics of a fraudulent scheme*** and provide an adequate basis for a ***reasonable inference*** that false claims were submitted as part of that scheme.'" *Nathan*, 707 F.3d at 457, n.6 (quoting *Lemmon*, 614 F.3d at 1172) (emphasis added).

707 F.3d at 457. And at the opinion's conclusion, the Fourth Circuit returned again to *Grubbs*. It contrasted the *Nathan* relator's "inherently speculative in nature" allegations with "cases such as *Grubbs*," stating that its relator's "claim does not involve an integrated scheme in which presentment of a claim for payment was a necessary result." *Nathan*, 707 F.3d at 461.

A recent Fourth Circuit district court decision—*United States ex rel. Michaels v. Agape Senior Cmty. Inc.*, No. 0:12-cv-03466, 2014 U.S. Dist. LEXIS 41943 (D.S.C. March 28, 2014)—correctly applied *Nathan* to a healthcare fraud case:

> The court understands the holding in *Nathan* to allow for a relator to satisfy the specificity requirements of Rule 9(b) by alleging "specific false claims actually . . . presented to the government for payment." *Nathan*, 707 F.3d 451, 457-58. However, a relator may also satisfy the *Nathan* standard by ***alleging a reasonable inference that false claims were necessarily submitted to the government.***

Michaels, 2014 U.S. Dist. LEXIS 41943, at *5 (emphasis added). The court then evaluated both *Nathan* standards, and concluded that the "[r]elators have met their burden to survive Defendant's Motion to Dismiss." *Id.* at *7.

b. The Amended Complaint satisfies the *Nathan* falsity standards.

i. Claims presented were necessarily false due to Defendants' fraud.

Thomas, a Duke insider, has described with particularity an integrated fraud that necessarily leads to the plausible inference that the claims presented (as detailed in **Exhibits C** and **C-1**) were false. *Nathan*, 707 F.3d at 457, 461. He further has provided the "stated reason[s]" for why the claims were false, as well as multiple "indicia of reliability." *Id.* at 457.

As detailed in the Amended Complaint and summarized above, ***all*** of Potts-Kant's reported experimental results were intentionally falsified, fabricated, or are fraudulent. The fraud scheme reported data that (i) supported researchers' hypotheses, (ii) were statistically

significant, and/or (iii) purported to have been consistently 'replicated.'" Through this fraud, the Foster Lab produced fraudulent data that formed the basis for grant applications, grant progress reports, and publications. Thus, the fraud allowed Duke and other institutions to receive the grant funding specified in **Exhibits C** and **C-1**, and for the affected researchers to publish journal articles. The fraud's scope is massive, given its almost decade-long run, and the fact that the Foster Lab was a hub for mice experiments throughout Duke and other research institutions. *See supra* at III(A)(2).

From this fraud, Thomas alleges that the grant applications and progress reports that underlie the payments specified in **Exhibits C** and **C-1** were false claims, and provides multiple reasons and indicia of reliability:

First, is the interconnectedness and identity—mandated by grant instructions and regulations, and then applied in practice—between grants, research, and published research results. Grant applications must include supporting preliminary data and research results in the "Research Plan" and/or "Project Narrative" sections. Any publications discussed must also be cited in the application's bibliography/references cited section. Similarly, progress reports must inform the funding agency about the grantee's accomplishments and results (positive or negative), and report all publications funded by the grant. All such publications must then be made available to the public, which are the "primary conduit" by which researchers communicate significant results. *See supra* at III(A)(1). In other words, published research results are central to the grant system. They help make grants possible, grants fund more research, significant research results are published, which then leads to more grant funding.

Here, Thomas alleges that research results reported in publications and research results reported in grant documents arise from the same pool of data. He has specified false and/or

fabricated data in dozens of publications co-authored by Potts-Kant and/or Foster. These publications identify the grants that funded this fraudulent research. These grants, including the amounts claimed and paid by the Government, are then identified in **Exhibits C** and **C-1**. *See supra* at III(A)(2)(a)-(b).

Given the above framework, it is a reasonable and plausible inference that the claims identified in **Exhibits C** and **C-1** were false, because fraudulent research results reported in publications would also have been reported in those grant applications and progress reports. For example, the Mast Cell Paper was funded by the SP-A Grant. The Mast Cell Paper reports Figure 6A as a research result. Figure 6A includes fraudulent data from three experiments, the last of which was performed on March 2, 2011. *See supra* at 23. Therefore, Duke would have reported the Figure 6A research result in SP-A Grant progress reports, beginning in 2011. Likewise, Duke would have reported the fraudulent mast cell research as a basis for the SP-A Grant renewal application submitted in Fall 2013.[164]

This is only common-sense. Not every research result is published. If a research result is significant enough to publish in a scientific journal, then the same result would be significant enough to report in grant documents. In fact, to contend otherwise, "stretch[es] the imagination." *Nathan*, 707 F.3d at 457.

Second, Thomas was working within Duke when Defendants determined that the body of Foster Lab data underlying grant applications, progress reports, and publications was fraudulent. In March 2013, Defendants undertook a review of Potts-Kant's reported results. This review was comprehensive, examining an undifferentiated pool of data—results reported in grant

[164] Foster's main counter-argument is based on an error. *See* Foster Br. at 8-9. The "article" referenced there is the Mast Cell Paper, which was written in 2011 and published in 2012, not 2013 as the text of the Amended Complaint mistakenly alleged. *See supra* at 15, n.61.

applications, progress reports, and publications. Thomas has personal knowledge that the principal investigators and researchers involved quickly concluded that all of Potts-Kant's data was fraudulent, and he detailed the three primary (and often overlapping) ways that Potts-Kant reported fraudulent research results. Thomas states the basis for his knowledge, including in **Exhibit D**, where Dr. Ledford—in her own handwriting—confirms Potts-Kant's "manipulated" data reported in the Mast Cell Paper. *See supra* at III(A)(2)(d).

Further, despite having actual knowledge that the Foster Lab's reported data was fraudulent, Defendants embarked on a campaign of concealment from funding agencies and journals. This was to preserve their personal and institutional interests, including to continue grant funding, seek more grant funding, and avoid their obligation to repay grants. *See supra* at III(A)(3). This is significant—that Defendants intentionally sought to avoid disclosures to funding agencies and journals alike evidences the fact that the data fraud affected grants and publications in the same way.

Finally, the grant applications and progress reports also include certifications as to their accuracy and completeness, as well as their compliance with applicable policies and research regulations.[165] Thus, independent of whether the fraudulent research results identified in the publications were also reported in these grant documents, the certifications were false statements, as grant funds were used to "disseminate information that is deliberately false or misleading" through the publications. *See* Am. Compl., ¶ 61. These false certifications also render their

[165] Duke and DUHS's separate certification arguments with respect to Counts I, II, and III miss the mark entirely. *See* Duke Br. at 28-29. The affected grants are identified with particularity in **Exhibits C** and **C-1**, as each underlying application and progress report contain false certifications, including violations of the express certification language specifically alleged. *See supra* at III(A)(1)(c). The certifications were made by Duke as an institution, which is the "person" that submitted the certification. Am. Compl., ¶ 88 ("In connection with grant funding, ***an institution makes certifications*** related to its request for, and proposed use of, federal funds.") (emphasis added). Further, the Amended Complaint paragraphs cited in footnote 13 are limited to Counts IV and V, and thus do not apply to Counts I-III. Duke Br. at 28, n.13 (quoting Am. Compl., ¶¶ 382, 395-96).

associated claims false under 31 U.S.C. § 3729(a)(1)(A) and (B).[166]

ii. Thomas has alleged examples of specific false claims.

Although Defendants' fraud scheme necessarily led to false claims, Thomas also meets *Nathan*'s alternative standard by alleging "specific false claims." *Nathan*, 707 F.3d at 457. This standard does not rigidly require that bills must be attached to the complaint, but rather that the false claim examples be alleged with particularity. Such flexibility only makes sense, as a bill itself does not identify a fraud. *Grubbs*, 565 F.3d at 190 ("Standing alone, raw bills—even with numbers, dates, and amounts—are not fraud without an underlying scheme to submit the bills . . . . It is the scheme in which particular circumstances constituting fraud may be found that make it highly likely the fraud was consummated through the presentment of false bills.")

In June 2013—based on specific information learned during the investigation into the Foster Lab data—Duke submitted a progress report for the SP-A Grant "that included research reports based on experiments performed by Potts-Kant and the Foster Lab." Am. Compl., ¶ 292. This was a false claim for the SP-A Grant's last year of funding, made "with actual knowledge that none of [Potts-Kant's] work was reliable." *Id.*

Later that Fall, Duke sought to renew the SP-A Grant for another five years. It submitted a competitive renewal grant application, which "included research results based on the 'recalculation' of data produced by Potts-Kant." *Id.*, ¶¶ 293-95. This too was a false claim. At the time, not only did Duke have actual knowledge that there was no basis to rely on any of Potts-Kant's work, but that the recalculated data also conflicted with repeat experiments conducted earlier in 2013. *Id.*, ¶¶ 292, 296.

These specific false claims are alleged with particularity, describing their "time, place,

[166] After obtaining actual knowledge of the widespread fraud, Defendants also had an obligation to repay the ill-gotten grant funds under 31 U.S.C. § 3729(a)(1)(G). But instead, they sought to conceal the fraud.

and contents," and who submitted the claims. *Nathan*, 707 F.3d at 455-56. They both involve the SP-A Grant, identified as Grant ID P01AI081672. The claims were made in the SP-A Grant progress report submitted by Duke in June 2013 to obtain funding for the Grant's final year, and in a renewal application submitted by Duke in Fall 2013 to try and claim an additional five-years of funding. Both submissions used raw *flexi*Vent or multiplex machine data generated by Potts-Kant; this is the specific data that was false.

iii. Denying the motion is consistent with the purpose of Nathan and Rule 9(b).

An overarching lesson from *Nathan* and its cited cases is that Rule 9(b) is not a "gotcha" pleading bar, nor a "straitjacket" applied to FCA cases in a mechanical fashion. *See, e.g.*, *Grubb*s, 565 F.3d at 190 ("In sum, the 'time, place, contents and identity' standard is not a straitjacket for Rule 9(b). Rather, the Rule is content specific and flexible and must remain so to achieve the remedial purposes of the False Claims Act."). Instead, Rule 9(b) requires careful, case-by-case analysis of the facts alleged and their reasonable inferences. If a complaint reveals that the FCA claims have merit, then the case should proceed.

Nathan's approach is consistent with Rule 9(b)'s four general purposes: (1) ensuring the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of; (2) protecting defendants from frivolous suits; (3) eliminating fraud actions in which all the facts are learned after the discovery; and (4) protecting defendants from harm to their good will and reputation. *Harrison I*, 176 F.3d at 784.

Here, Defendants know the specifics of the fraudulent conduct that they must defend against with respect to Counts I-III: false or fabricated *flexi*Vent or multiplex research results, generated by Potts-Kant, reported in the applications and progress reports for grants identified in **Exhibits C** and **C-1**. The Amended Complaint's detailed factual allegations establish that its

claims are not frivolous and that Thomas does not seek to learn "all the facts" during discovery. Accordingly, any harm to Defendants' reputations from the litigation would not be unwarranted.

In short, *Nathan* and Rule 9(b) are not designed to protect and insulate those that perpetrate fraud, and moving this case forward is consistent with their purposes.

c. Defendants' falsity arguments fail.

i. Defendants assert the wrong legal standard.

As an initial matter, Defendants frame their falsity arguments by the wrong standard. On Page 1 of their brief, Duke and DUHS state that "[u]nder ***well-settled Fourth Circuit case law***, Relator was required to identify the specifics of representative, false claim." Duke Br. at 1 (emphasis added). They then double-down on the error by stating that "[w]hile Rule 9(b) does not require a relator to identify all false claims, it does require the relator to identify 'some representative claims.' Without the identification of such representative claims, a relator's FCA complaint must be dismissed." *Id.* at 9 (citations omitted). The support offered for this sweeping proposition, however, is not a Fourth Circuit decision, but a non-binding case from the Eastern District of Virginia, *Virginia ex rel. Hunter Labs., LLC v. Quest Diagnostics, Inc.*, No. 1:13CV1129, 2014 U.S. Dist. LEXIS 69023 (E.D. Va. May 13, 2014), which involved the Virginia Fraud Against Taxpayers Act, not the FCA. *Id.* at *2.

Later, in a footnote, Duke and DUHS at least try to hedge, stating "the Fourth Circuit has not expressly addressed the question of whether representative claims must be actually identified in a relator's complaint to meet the 9(b) pleading standard." Duke Br. at 25, n.10. But even then, in the text of the same page, they once again misstate the legal standard: "it is not enough in the Fourth Circuit to merely allege the details of a fraudulent scheme without particularly

pleading that the defendant presented a false claim to the government." *Id.* at 25.[167]

As explained above, *Nathan* does ***not*** require pleading specific false claims (a standard that Thomas meets in any event). Rather, *Nathan* is also satisfied if a fraud scheme necessarily leads to the plausible inference that false claims were made. This is plain from *Nathan*'s express holding, as well as its entire legal analysis. *Nathan*, 707 F.3d at 455-58, 461.[168] *See also United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015) (interpreting *Nathan* as "requiring only 'some indicia of reliability' that a false claim had been presented to the government") (quoting *Nathan*, 707 F.3d at 457); *Michaels*, 2014 U.S. Dist. LEXIS 41943, at *5 (agreeing with the Solicitor General's conclusion that in *Nathan*, the Fourth Circuit "declined to adopt a per se rule requiring relators to plead specific false claims," and holding that "a relator may also satisfy the *Nathan* standard by alleging a reasonable inference that false claims were necessarily submitted to the government").

ii. Thomas provides the connection between Defendants' fraud scheme and the false claims.

Defendants argue that Thomas failed to plead the "link" between the fraud scheme and the claims for payment, primarily relying on *United States v. Kernan Hosp.*, 880 F. Supp. 2d 676 (D. Md. 2012).[169] Duke Br. at 25-28; Foster Br. at 13. As an initial matter, *Kernan Hospital*, a Maryland case, was decided in 2012, ***before*** *Nathan*, and is thus of little relevance.[170] But

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[167] Foster makes the same mistake, repeatedly misstating *Nathan's* holding. *See, e.g.*, Foster Br. at 2 ("The Amended Complaint therefore runs afoul of the ***well-established law in the Fourth Circuit*** that a Relator set out with specific detail the facts surrounding the presentment of a false claim to the government.") (emphasis added), 15 ("Under well-established law in this Circuit . . . .").

[168] Thus, there was no need for the *Quest Diagnostics* court to have speculated (incorrectly) about what *Nathan* "suggests." *See Quest Diagnostics*, 2014 U.S. Dist LEXIS 69023, at *18-19.

[169] The ultimate problem in *Kernan Hospital* was that the complaint "generally does not provide enough information for Kernan to identify which claims the Government contends were false." *Kernan Hospital*, 880 F. Supp. 2d at 688. This concern is not present here, given **Exhibits C** and **C-1**'s detailed spreadsheets of the claims at issue.

[170] Neither is *United States ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522 (D. Md. 2006),

Defendants' contentions based on *Kernan Hospital* are also wrong substantively.

The "link" described in *Kernan Hospital* is the same "some indicia of reliability" concept from *Clausen*, which *Nathan* relied upon in holding that a fraud scheme—even without specific false claims—is sufficient if there is a plausible inference that the fraud resulted in false claims. To wit, *Kernan Hospital* first quotes this language from *Clausen* and then discusses a subsequent Eleventh Circuit case—*United States ex. rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006)—that applied *Clausen*'s standard. *Kernan Hospital*, 880 F. Supp. 2d at 687.

According to *Kernan Hospital*, in *Atkin*s the "Eleventh Circuit affirmed the district court's dismissal because 'the complaint fail[ed] [R]ule 9(b) for want of sufficient indicia of reliability to support the assertion that the defendants submitted false claims.'" *Id.* (quoting *Atkins*, 470 F.3d at 1358-59). *Kernan Hospital* then quotes *Atkins* further, stating that the deficiency was the "summary conclu[sion]" that the fraud scheme led to false claims, rather than providing "link" between the two. *Id.*[171]

As they did with *Nathan*, Defendants misapply *Kernan Hospital*, contending that the missing "link" here is Thomas's "fail[ure] to allege even one specific claim for payment that was actually submitted to the Government." Duke Br. at 26.[172] But as demonstrated above, the "link" discussed in *Kernan Hospital* is the same "indicia of reliability" or "stated reason" that *Nathan* requires to state an FCA claim based on a fraud scheme. Thomas easily meets this

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which Foster cited without substantive explanation (Foster Br. at 13), and was decided seven years prior to *Nathan*.

[171] The other pre-*Nathan* case cited by Duke and DUHS on this point reached a similar result. *See* Duke Br. at 27. In *United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, No. 3:07cv290, 2011 U.S. Dist. LEXIS 3055 (E.D. Va. Jan. 12, 2011), the district court found that to plead a fraudulent scheme with particularity, "in addition to alleging particular details of a scheme to submit false claims, the complaint must also contain 'reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* at *62 (quoting *Grubbs*, 565 F.3d at 190).

[172] As discussed above, Thomas did plead two specific claims for payment—the June 2013 SP-A Grant progress report and Fall 2013 SP-A Grant renewal application.

standard. *See supra* at IV(A)(2)(b)(i).

iii. Defendants misstate or ignore Thomas's allegations.

On a motion to dismiss, factual allegations cannot be ignored. To the contrary, all facts and their reasonable inferences must be taken and true and interpreted in the light most favorable to the plaintiff. Defendants do not adhere to this requirement.

This is perhaps best illustrated by the superficial treatment that the Amended Complaint—71 pages, with 345 paragraphs of factual allegations—receives in both briefs. Duke and DUHS present the "Facts" in a page and a half, with most space devoted to the parties' backgrounds. They then address "Relator's Allegations" in under two-pages, with only argumentative and skeletal references to any facts. Duke Br. at 2-6. Foster offers a "nutshell" summary in his introduction, followed by less than three pages devoted to the facts. Foster Br. at 1-5. In the argument sections, Defendants consistently ignore and mischaracterize facts, and also fail to appreciate the details and differences between Counts I, II, and III.

For example, Duke and DUHS inaccurately state that the "only allegation" made in support of Count III's reverse false claims is that "Defendants 'knowingly and improperly sought to avoid or decrease their obligations to pay money to the Government.'" Duke Br. at 14, n.7 (quoting Am. Compl., ¶ 344). This ignores the concealment facts alleged after the March 2013 investigation. Am. Compl., ¶¶ 279-99.

Defendants also try to give the impression that the only connection between (i) grant applications and progress reports and (ii) research results in publications, is the grant documents' reference to publications in a "bibliography." *See* Duke Br. at 12-13, 15-16; Foster Br. at 9-10.[173] This is incorrect. The justification for the proposed research must be stated in an

[173] This is accomplished by repetitive use of "bibliography," ignoring fact allegations about what is

application's substantive "Research Plan" and/or "Project Narrative" section, and the grant's "accomplishments," and "results" in progress reports. Publications discussed in the grant documents or those funded by the grant must, ***in addition***, then be reported in a bibliography or publication list. Am. Compl., ¶¶ 94, 98, 102-105, 150, 342, 364. *See also supra* at 7-8.

iv. Defendants' reliance on Milam is misplaced.

Applying the inaccurate "bibliography" short-hand, Defendants argue that a citation to a publication in a grant application or progress report "is not a false statement as a matter of law, even if the publication itself contains allegedly false or fabricated data." Duke Br. at 15. *See also* Foster Br. at 10-11. This broad claim rests on a solitary Maryland case from over 20 years ago—*United States ex rel. Milam v. Regents of the Univ. of Cal.*, 912 F. Supp. 868 (D. Md. 1995)—which was decided on summary judgment, not a motion to dismiss.[174]

This procedural context is important. At the outset, the *Milam* court stated that "[t]he essence of the dispute between the parties is reflected in the different ways they characterize the events of the past thirteen years: relator sees this as a case of scientific misconduct and intentional fraud, while defendants view the case as a scientific dispute." 912 F. Supp. at 874. The court then decided this fundamental issue, based on the evidence adduced: "[a]t most, the Court is presented with a legitimate scientific dispute, not a fraud case." *Id.* at 886.

The lack of proof thus drove the court's decision. The evidence showed that the relator's

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included in grant applications and progress reports, and even by excising language from the fact paragraphs that are quoted. *Compare* Duke Br. at 12 and Foster Br. 9 ("¶ 102 '(In a grant application the institution must provide a bibliography of any references cited'") *with* Am. Compl., ¶ 102 ("In a grant application, the institution must provide a bibliography of any references cited ***in the 'Research Plan' and/or 'Project Narrative' section***.") (emphasis added); *compare* Duke Br. at 13 and Foster Br. 10 ("¶ 105 ('In a final progress report, the grantee institution must include . . . a list of resulting publications.'") *with* Am. Compl., ¶ 105 ("In a final progress report, the grantee institution must include ***a list of significant results (positive or negative), and*** a list of resulting publications.") (emphasis added).

[174] Although a motion for judgment on the pleadings was also pending, the *Milam* court denied that as moot and only considered the summary judgment motions. *Milam*, 912 F. Supp. 868, 873-74, 891.

claim was not based on intentional data manipulation nor fabrication. *See, e.g.*, *id.* at 886 ("Not one deposition states that data was juggled or manipulated."). Instead, it largely rested on the failure to be able to replicate experimental studies, even though she had changed the original methodology by "add[ing] a rinse step." *Id.* at 876-77, 879. The relator's employer, UCSF, conducted an inquiry but concluded that "no fraud" had occurred. *Id.* at 878. ORI then reviewed this inquiry and a related one from another institution, but "did not find sufficient evidence to warrant a further investigation." *Id.* at 879-80.[175] Here, the case is at the pleading stage, where all of Thomas's factual allegations must be taken as true. And unlike in *Milam*, no institutional or ORI review has found that fraud and misconduct did not occur.

Milam's stale statements about publication citations in grant documents are also inapplicable to the present case. In *Milam*, unlike here, there was no claim that false articles were funded by the grants in question. It also is unclear what the grant application instructions, progress report instructions, or the research misconduct regulations required at that time. The experiments and articles in question stretched back over the "thirteen years" ***before*** the 1995 decision (*id.* at 874), occurring primarily in the 1980s. *See generally id.* at 874-79. Despite this opaqueness about grant policies and practices back in the 1980s, there is at least one critical difference now: NIH funded publications must be made publicly available. This became an NIH requirement in April 2008, well after *Milam*, and demonstrates the fundamental interconnectedness between grants and publications that exists today. *See* Am. Compl., ¶ 106.

The limited rationale expressed by *Milam* is also infirm. The court drew from a check-kiting case, where depositing a check when there were insufficient funds was not a "false

[175] The ORI report was not given preclusive effect, but the court did consider it on summary judgment, stating that "it would be hard to conceive of a more probative piece of evidence." *Milam*, 912 F. Supp. 880.

statement," because "technically speaking, a check is not a factual assertion at all, and cannot be characterized as 'true' or 'false.'" *Milam*, 912 F. Supp. at 883 (quoting *Williams v. United States*, 458 U.S. 279, 284 (1982)). That analogy fails in this context. Citing a publication in a grant application or progress report is a representation that those results (i) support the need for the proposed research (in the case of an application) or (ii) were paid for by the grant and justify continued funding (in the case of a progress report). *See supra* at III(A)(1)(b)-(c). Those "assertions" are false if a publication's data or results were intentionally fraudulent, whether the publication's fraudulent data or results were reproduced in the text of the grant documents (which Thomas alleges occurred) and/or incorporated through a citation.[176]

v. This case is not about scientific differences.

Duke and DUHS also try to reinvent the Amended Complaint as alleging FCA claims based on mere "scientific judgments," "[d]ifferences of [s]cientific [o]pinions," or "differences in experimental outcomes." Duke Br. at 15-17.[177] This argument finds no support in Thomas's well-pleaded facts, nor in the sole case cited.

As discussed above, the data reported by Potts-Kant was wholly made-up, deliberately manipulated, or obtained through knowingly improper methods. *See supra* at III(A)(2)(a). This is not a case about differences in opinions, judgments, or outcomes. It is about intentional fraud, a black-and-white question, at the cost of hundreds of millions of dollars.

Duke and DUHS try to root their argument in the fact that, after they discovered that all of Potts-Kant reported results were fraudulent, attempts to repeat certain experiments failed to replicate her reported results (and often were directly opposite). Duke Br. at 16-17. But these

[176] *Milam* would also have no application to Thomas's false certification claims.

[177] Foster does not make this argument directly in his motion.

facts represent additional ***confirmation*** of the widespread fraud, not its foundation.[178]

United States ex rel. Hill v. Univ. of Med. and Dentistry of N.J., 448 F. Appx. 314 (3d Cir. 2011), a summary judgment decision, does not support Duke and DUHS's argument. The *Hill* relator based her claim on a purported failure to follow proper scientific protocol. *Id.* at 315-16. Her institution, UMDNJ, conducted an inquiry and concluded that "there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation." *Id.* at 315 (quotation omitted). The relator next pursued her claims with ORI, which—after a review and independent analysis—"issued a report concluding there was insufficient evidence to warrant further investigation." *Id.* (quotation omitted). She then filed a second claim, but UMDNJ concluded that "there was no cause to credit the allegations as the proffered statistics alone were insufficient to warrant further investigation." *Id.* at 316.

With respect to the relator's FCA claim on summary judgment, the *Hill* district court "found that plaintiff failed to produce evidence [that] the data was false." *Id.* at 316. The Third Circuit agreed, as the district court's finding mirrored "three independent reviews" by "[t]he relevant scientific bodies" that had all "found insufficient evidence of scientific misconduct." *Id.*

Here, Thomas's falsity allegations must be taken as true. Further, Thomas's claims are about black-and-white issues of intentional fraud (not scientific disagreements or protocols), and no scientific body has found insufficient evidence of scientific misconduct.

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[178] Duke and DUHS imply that for the 22 grants listed in Paragraph 270, their sole falsity basis is that the reported results could not be replicated. Duke Br. at 17, n.8. But that is not inaccurate. For example, the first grant listed—AI081672 (the SP-A Grant)—is implicated by the "manipulated" mast cell data attached as **Exhibit D**, as well as by specific allegations about the lack of raw data (Am. Compl., ¶ 239), the failure to run experiments (*id.*, ¶ 245), the intentional manipulation of data (*id.*, ¶ 260), and the failure to conduct experiments as reported (*id.*, ¶ 252). And more broadly speaking, based upon Duke and/or DUHS's review of Potts-Kant data "***all*** work completed by Potts-Kant is false, fabricated, and/or fraudulent in some way." *Id.*, ¶ 233 (emphasis added).

vi. Thomas alleges falsity with specificity.

Defendants' final falsity claim is that Thomas failed to plead falsity with enough specificity. Duke Br. at 29-32; Foster Br. at 14-16. Their argument is largely duplicative of prior ones, and thus subsumed in the above discussion of *Nathan*.

To add, Duke and DUHS advance a hyper-technical pleading standard, where alleging a false claim with particularity means alleging not only that a figure is false, but what individual experiments made up the figure, and how those experiments contributed to the falsity. Duke Br. at 30-31. No legal support is given for these extreme requirements—which would impose a heavy burden of proof, not pleading—save a generic statement that falsity must be objective. But that objectivity standard is easily met here. As discussed above, Potts-Kant's reported results were made-up, intentionally manipulated, or knowingly not performed as reported.[179]

Duke and DUHS also ask the Court to disregard all facts that Thomas learned from his discussions with principal investigators and researchers during their review of the fraudulent data. *Id.* at 31, n.14. According to Duke and DUHS, these statements are "anecdotal" and "unsubstantiated and conclusory hearsay," therefore entitled to no weight. *Id.* They also criticize Thomas for filing his original complaint "approximately six weeks after Potts-Kant's termination," which they claim makes any statements "unconfirmed," "premature," and lacking

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[179] The example highlighted by Duke and DUHS is a curious choice. They criticize the Amended Complaint's statement that "Potts-Kant falsified and/or fabricated the data" in PMID 21037098—"Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide"—specifically "Figures 1C, 2C, 4C, and 5C." Br. at 31 (quoting Am. Compl., ¶¶ 172-73). But roughly four months after the Amended Complaint was filed, this same article—authored by Potts-Kant, Foster, and others—was "corrected" by *The Journal of Immunology*, including by the retraction of the ***exact same*** Figures. *See* **Exhibit 1** ("We hereby retract Figs. 1C, 2C, 4C, and 5C from the published article").

Thomas requests that the Court take judicial notice of **Exhibit 1**, as its accuracy cannot reasonably be questioned, and it represents Defendants' admissions. Fed. R. Evid. 201(b)(2); *Lovegrove v. Brock & Scott*, No. 2:16cv418, 2017 U.S. Dist. LEXIS 7140, at *8 (E.D. Va. Jan. 17, 2017) ("The court may take judicial notice of public court records and ***parties' admissions*** even if they are attached only to the motion to dismiss.") (emphasis added).

in Rule 9(b) "specificity." *Id.* No support is provided for these remarkable assertions.

First, the motion to dismiss stage tests matters of pleading, not proof. All facts alleged must be taken as true, and this is not the time to make evidentiary objections such as "hearsay."[180] *Second*, contemporaneous statements from the principal investigators and researchers directly involved in the original studies and review is textbook and compelling evidence of fraud, particularly given the institutional concealment that was taking place at the same time. *Third*, the fact that Thomas could file this lawsuit so soon after Potts-Kant's termination not only underscores that the widespread nature of the fraud was quickly understood, but that Duke and/or DUHS then attempted to conceal it from the outside world.[181]

For his part, Foster briefly references two cases—*United States ex rel. Rector v. Bon Secours Richmond Health Corp.*, No. 3:11-CV-38, 2014 U.S. Dist. LEXIS 52161 (E.D. Va. Apr. 14, 2014) and *United States ex rel. Hagood v. Riverside Healthcare Ass'n, Inc.*, No. 4:11cv109, 2015 U.S. Dist. LEXIS 37134 (E.D. Va. Mar. 23, 2015). Foster Br. at 16. Both cases, in fact,

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[180] In any event, statements by Duke and/or DUHS employees and agents would be excluded from hearsay as party-admissions. Fed. Evid. R. 801(d)(2).

[181] This is exemplified by how long it took Defendants to publicly acknowledge the fraudulent data in the Mast Cell Paper. In April 2013, Dr. Ledford confirmed that "manipulated" data had been reported in Figure 6A. Am. Compl., ¶¶ 271-78 & **Exhibit D**. On November 21, 2015 (over two-and-a-half years later), the *Journal of Allergy and Clinical Immunology* issued an online correction to the Mast Cell Paper which was published in hard-copy form in January 2016. The correction is signed by the original authors (all from the Duke University Medical Center), including Foster and Potts-Kant, as well as Dr. Ledford.

The Mast Cell Paper correction states that the authors had "recently become aware of potential discrepancies" in the reported data and machine-generated raw data. They had commenced an investigation, and found that the "SE" (*i.e.*, standard error) in the raw data was greater than published, and that they "could not verify that the mice were alive during the duration of the methacholine challenge." When performing the experiments again, the results did not repeat. Accordingly, the authors were "excluding the findings presented in Figs 3, A and B; 4, C; and 6, A," because they "believe the *flexi*Vent data are unreliable." These are the ***exact same*** Figures that the Amended Complaint alleges are fraudulent in the Mast Cell Paper. Am. Compl., ¶¶ 207, 209 (stating that "Figures 3A and 3B, Figure 4C, and Figure 6A (*flexi*Vent)" were fraudulent).

The Mast Cell Paper correction is attached as **Exhibit 2**. Thomas requests that the Court take judicial notice, as its accuracy cannot reasonably be questioned, and it represents admissions by Defendants. *See supra* at 53, n.179

support Thomas's overall legal analysis, as they confirm that *Nathan* provides for alternative FCA pleading standards. *Hagood*, 2015 U.S. Dist. LEXIS 37134, at *26-27 ("[T]he sufficiency of Relators' presentment allegations turns on whether the 'specific allegations of [Defendants'] fraudulent conduct necessarily le[ad] to the plausible inference that false claims were presented to the government.'") (quoting *Nathan*, 707 F.3d at 457-58); *Rector*, 2014 U.S. Dist. LEXIS 52161, at *22-23, 29 (similar). *Rector* and *Hagood* found that their relators did not meet the fraud scheme standard because, unlike here, the arguments lacked indicia of reliability. Those relators certainly had not specified the claims at issue, as Thomas has in **Exhibits C** and **C-1**.

3. Fraudulent research results are material to the Government's grant funding decision.

Duke and DUHS also challenge the materiality of their fraudulent conduct.[182] The FCA defines "material" as "having a ***natural tendency*** to influence, or ***be capable*** of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4) (emphasis added). In *Escobar*, the Supreme explained that the FCA's materiality requirement had common law roots, and that "[u]nder any understanding of the concept, materiality look[s] to the ***effect on the likely or actual behavior*** of the recipient of the alleged misrepresentation." 136 S.Ct. at 2002 (emphasis added) (quotation omitted).[183] Looking at both tort law and contract law, the Court next described two circumstances in which a misrepresentation would be material: (1) when a reasonable person would attach importance to the matter in determining a choice of action; or (2) when the defendant knows or has reason to know that the recipient of the representation attaches

[182] Foster does not make this argument directly in his motion.

[183] The term "material" is only found in the text of 31 U.S.C. § 3729(a)(1)(B) & (G), ***not*** 31 U.S.C. § 3729(a)(1)(A). Although the Supreme Court in *Escobar* expressly did not decide whether materiality for a 31 U.S.C. § 3729(a)(1)(A) claim is governed by the statutory definition or the common law (136 S.Ct. at 2002), given the reasoning expressed there, Thomas will apply a single materiality standard based on both.

importance to the matter (even if a reasonable person would not). *Id.* at 2002-03.

The Supreme Court then discussed the kind of factors that would be relevant in establishing materiality, emphasizing that there were not bright-line rules:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-04. *See also id.* at 2001 ("materiality cannot rest on 'a single fact or occurrence as always determinative'") (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)); *United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 109 (1st Cir. 2016) (on remand, stating that the Supreme Court's decision "makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive").

Here, the Amended Complaint's well-pleaded facts establish that Defendants' fraud was material. *First*, although "not automatically dispositive," that grant applications and progress reports require research results to be reported, and all "certifications are a condition of grant approval and grant funding" (*see supra* at III(A)(1)(c)), is significant "proof" of their materiality. *Escobar*, 136 S.Ct. at 2003.[184]

[184] In FCA cases decided before *Escobar*, courts repeatedly held that false statements and certifications in

Second, "data resulting from experiments performed on the *flexi*Vent and multiplex machines is ***fundamental*** in current pulmonary research studies" and "***central*** to the hypotheses asserted in grant applications and discussed in grant progress reports." Am. Compl., ¶¶ 150, 342(e) (emphasis added). Without such data "[i]t is ***unlikely*** that the NIH would award any significant grant funding for pulmonology research." *Id.*, ¶ 150 (emphasis added). *See also id.*, ¶ 315 ("research results and related publications [are] ***fundamental*** to the grant system, and reported in grant applications and progress reports to secure grant funding") (emphasis added), ¶ 342(c)-(f) (the fraudulent research results caused applications "to receive artificially high priority rankings," made it "more likely" that grants would be awarded, and were related directly to "research hypotheses" and the purported need to fund propose/additional research). Given this data's importance, Defendants' fraud had a natural tendency to influence or was capable of influencing the Government's funding decision; in fact, this was the fraud's likely effect. Further, the critical importance of research data is not in dispute; per the Duke Policy, "integrity

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grant applications and progress reports were material. *See United States ex. rel. Feldman v. van Gorp*, 697 F.3d 78, 97 (2nd Cir. 2012) (affirming relator jury verdict in case involving false statements in progress reports, concluding that the "facts were more than sufficient to allow a reasonable jury to conclude that had the facts been disclosed they would have had a natural tendency to influence, or would have been capable of influencing, the decision to renew the grant and pay money to the defendants pursuant to it"); *United States ex. rel. Jones v. Brigham & Women's Hospital*, 678 F.3d 72, 93-95 (1st Cir. 2012) (vacating summary judgment for the defendant and holding that false preliminary research results in grant application could have had a natural tendency to influence grant reviewers); *United States ex. rel. Longhi v Lithium Power Technologies, Inc.*, 575 F.3d 458, 471-72 (5th Cir. 2009) (affirming summary judgment for the government, holding that false statements in grant applications were material); *United States ex. rel. Kozak v. Chabad-Lubavitch, Inc.*, No. 2:10-cv-01056, 2015 U.S. Dist. LEXIS 65187, at *25 (E.D. Ca. May 11, 2015) (granting summary judgment for Government in grant case holding: "[b]ecause both the NSG Program grant applications and the drawdown requests expressly required compliance with the applicable financial management standards and because as indicated above those requirements were undisputedly not satisfied, the false certifications made by Chabad were unquestionably material"); *United States ex. rel. Resnick v. Weill Medical College of Cornell University*, No. 04 Civ. 3088, 2010 U.S. Dist. LEXIS 11019, at *19 (S.D.N.Y. Jan. 21, 2010) (denying motion to dismiss in NIH grant case: "[a] strong inference can be drawn that statements in the annual reports were material to the Government's funding decisions based on Resnick's description of the regulatory requirements, and her allegations regarding the misapplication of grant funds"); *United States ex. rel. Anti-Discrimination Center of Metro New York, Inc. v. Westchester County*, 668 F.Supp. 2d 548, 568-70 (S.D.N.Y. 2009) (rejecting grantee argument that false certifications to HUD to support housing grants were not material).

of research forms the foundation of respect . . . between the academic world and the public." *Id.*, ¶ 141.

Third, Duke and DUHS sought to conceal the research fraud from funding agencies after having actual knowledge by no later than March 2013. This intentional cover-up further evidences the fraud's materiality to grant funding. *See, e.g., United States ex rel. Badr v. Triple Canopy*, 775 F.3d 628, 638 (4th Cir. 2015) ("Triple Canopy's actions in covering up the guards' failure to satisfy the marksmanship requirement suggests its materiality"), *vacated and remanded by* 2016 U.S. LEXIS 4163 (U.S. Jun. 27, 2016).[185]

For their part, Duke and DUHS ignore the specific facts described above. They characterize the Amended Complaint as only "mak[ing] conclusory allegations and bare bones assertions with respect to the materiality element." Duke Br. at 18. In support of this incorrect statement, Duke and DUHS quote a portion of Paragraph 342's first sentence (*see id.* at 18), but then make no reference to its next—"***[f]or example***, such false statements and records were material ***because:***"—which proceeds to detail ***six*** specific reasons that Defendants' fraud was material. *See* Am. Compl., ¶ 342(a)-(f) (emphasis added).

Duke and DUHS also misread *Escobar*, and instead fashion a materiality standard of their own making. According to Duke and DUHS, Thomas was required to "allege plausible facts that the government ***routinely withholds payment*** for failing to comply with . . . the numerous federal regulations and grant policy statements cited by Relator underlying the two alleged certifications."[186] Duke Br. at 19 (emphasis in original). *See also id.* at 20 (stating that Thomas

[185] The Supreme Court vacated and remanded *Triple Canopy*, for further consideration in light of *Escobar*. The Fourth Circuit reheard *Triple Canopy* on January 26, 2017.

[186] As illustrated by this passage, Duke and DUHS confine most of their arguments to Thomas's certification claims, rather than addressing materiality more broadly. Thomas also does not understand their reference to "two" certifications.

failed to allege that the Government "automatically withhold[s] payment," which is required "to plead materiality in accordance with the Supreme Court's guidance in *Escobar*"). In fact, the Supreme Court held that while "proof" that the Government typically refuses payment for noncompliance is relevant to the materiality inquiry, it is in no way required. *Escobar*, 136 S.Ct. at 2003.[187]

Duke and DUHS's other cases do not help their argument either. *United States v. Sanford–Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) is a summary judgment decision, where the undisputed evidence established a lack of materiality. *Id.* at 447 (the relator had "offered no evidence" that the Government's payment decision would likely have been different if it had known about the alleged noncompliance, and to the contrary, "the subsidizing agency and other federal agencies in this case have already examined SBC multiple times over and concluded that neither administrative penalties nor termination was warranted") (quotation omitted).

Unlike the relator in *United States ex rel. Southeastern Carpenters Reg'l Council v. Fulton Cnty*, No. 1:14cv4071, 2016 U.S. Dist. LEXIS 103054, at *21-22 (N.D. Ga. Aug. 5, 2016), Thomas expressly alleges that the fraud was "central" and "fundamental" to grant funding. Am. Compl., ¶¶ 150, 315, 342(e).[188] Likewise, contrary to the parenthetical Duke quotes from *United States ex rel. Lee v. N. Adult Daily Health Care Ctr.*, No. 13CV4933, 2016 U.S. Dist. LEXIS 121136, at *37-38 (E.D.N.Y. Sept. 7, 2016), Thomas specifically alleges that

[187] Nor is there any merit to Duke and DUHS's suggestion that a relator must allege that any non-compliance mandated a refusal to pay, rather than having a "likely" effect on the payment decision. *United States ex rel. Hedley v. Abhe & Svoboda, Inc.*, No. RDB-14-2935, 2016 U.S. Dist. LEXIS 99367, at *22-23 (D. Md. July 29, 2016) (rejecting the defendants' materiality argument that sought to impose a burden of "proof" rather than pleading, and finding that it was not necessary to use imperative term like "shall" for non-compliance because the FCA "commands only that the false statements be 'capable' of influencing the government action").

[188] In *Fulton County*, the relators only claimed that the requirements were a condition of their contract, and did "not allege other facts establishing materiality." *Fulton County*, 2016 U.S. Dist. LEXIS 103054, at *22.

Defendants' fraud "likely" affected the Government's payment decision, and/or "had a natural tendency to influence, or be capable of influencing" it, and then provided his specific reasons. Am. Compl., ¶¶ 150, 342.

Finally, basic common-sense dictates that Duke and DUHS's argument must fail. In essence, they contend that intentional research fraud—including making up and manipulating research results—is not material to the Government's decision to fund research. As put recently by a post-*Escobar* court, this type of "argument is meritless because it requires leaving common sense at the door." *United States ex rel. Beauchamp v. Academi Training Ctr., Inc.*, No. 1:11cv371, 2016 U.S. Dist. LEXIS 166267, at *13-15 (E.D. Va. Nov. 30, 2016) (holding that "relators have alleged sufficient facts to support the common-sense proposition" that an "inability to shoot straight . . . likely would have influenced the government's decision" to pay under a contract where the personnel were protecting U.S. officials in a high-risk warzone).

4. Duke and DUHS's knowledge is thoroughly alleged under Rule 8(a).

Duke and DUHS also make a short scienter argument. Duke Br. at 22. They contend that there are not allegations that they—as institutions—had "knowledge"[189] that the grant documents in question contained false research results or certifications. *Id.* This argument ignores that, as a condition of funding, they agreed to be "responsible for the actions of its employees and other research collaborators, including third parties, involved in the project." Am. Compl., ¶ 62. This alone is dispositive. Moreover, as a matter of law, an organization can only obtain knowledge through its employees, and its employees' knowledge is likewise imputed

[189] As discussed above, under the FCA, to have acted "knowingly" means "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Further, "no proof of specific intent to defraud" is required to show knowledge. 31 U.S.C. § 3729(b)(1)(B)). *See, e.g., United States v. Savannah River Nuclear Solutions, LLC*, No. 1:16cv825, 2016 U.S. Dist. LEXIS 168067, at *54 (D.S.C. Dec. 6, 2016).

to the organization.

In *Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003) ("*Harrison II*"), the Fourth Circuit rejected defendant Westinghouse's argument that there is a "single actor" requirement in false certification cases, *i.e.*, that "a single employee must know both the wrongful conduct and the certification requirement." *Id.* at 919. In this context, the Fourth Circuit held that the appropriate organizational scienter inquiry was "whether there was ***at least one Westinghouse employee*** who knew or should have known that [Westinghouse's subcontractor] was submitting a bid seeking government funds and that this bid was tainted." *Id.* (emphasis added).

Harrison II's "at least one employee" test has been adopted and applied by district courts both within and outside of the Fourth Circuit. For example, in *United States v. Fadul*, No. DKC 11-0385, 2013 U.S. Dist. LEXIS 27909 (D. Md. Feb. 28, 2013), the district court cited *Harrison II* for the proposition that the "[g]overnment must prove an entity's scienter by demonstrating that a particular employee or officer acted knowingly. That employee or officer need not be the same individual who submits the false claims." *Id.* at 29 (citation omitted) (emphasis added).[190]

Harrison II is also consistent with how courts from around the country have addressed the issue of FCA corporate knowledge for employees acting within the scope of their employment. *See, e.g.*, *United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747-78 (7th Cir. 2013) ("Corporations such as [the defendant] 'know' what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do

[190] *See also United States v. Kaman Precision Prods.*, No. 6:09cv-1911, 2011 U.S. Dist. LEXIS 97263 at *15, n.14 (M.D. Fla. Aug. 30, 2011) (citing *Harrison II* for the proposition that corporate scienter can be established by "showing that at least one employee knew or should have known that a false statement was being submitted to secure government funds"); *Laymon v. Bombardier Trans. (Holdings) USA, Inc.*, No. 05-169, 2009 U.S. Dist. LEXIS 24403, at *39 (W.D. Pa. Mar. 23, 2009) (same); *United States ex rel. Fago v. M&T Mortg. Corp.*, 518 F. Supp. 2d 108, 123-24 (D.D.C. 2007) (same).

something about that knowledge."); *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir. 2012) ("We have long held that corporate defendants may be subject to FCA liability when the alleged misrepresentations are made while the employee is acting within the scope of his or her employment"); *Grand Union Co. v. United States*, 696 F.2d 888, 890-91 (11th Cir. 1983) (imputing the knowledge of check-out cashiers to the employer grocery store);[191] *United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977) ("a corporation will be liable for violations of the False Claims Act if its employees were acting within the scope of their authority and for the purpose of benefiting the corporation"); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 239 (D.P.R. 2000) ("An employer will not be able to escape liability by proving its ignorance of an employee's false statement. The employee's knowledge that a claim is false will be imputed to his or her employer.").

Here, the fraud benefitted Duke and DUHS, as well as Potts-Kant, Foster, and others. As Potts-Kant was Duke and/or DUHS's employee and/or agent acting in the course and scope of her employment and/or agency, her knowledge is imputed to Duke and/or DUHS. For the same reason, the knowledge of Foster and other principal investigator's and researchers is imputed to Duke and/or DUHS. *See* Am. Compl., ¶¶ 21-22, 24, 158, 313-14.

Duke and DUHS also claim that Thomas did not allege "that Potts-Kant, or any other Defendant, knew that certain false research results or false certifications were included in specific grant applications or progress reports submitted to the government." Duke Br. at 22. This is incorrect. Thomas alleged that "Defendants each knew that research results and related publications were fundamental to the grant system, and reported in grant applications and progress reports to secure grant funding," and that Potts-Kant knew that the reported research

[191] In *Harrison II*, the Fourth Circuit cited *Grand Union* with approval. *Harrison II*, 352 F.3d at 920, n.12.

results in question were false and/or fabricated, having generated the results herself." Am. Compl., ¶¶ 315-16. Likewise, "Foster, Duke [], and DUHS knew that the reported research results in question were false and/or fabricated," for the many reasons detailed in the Amended Complaint. *See supra* at III(A)(5).

5. Foster's knowledge is thoroughly alleged under Rule 8(a).

In his scienter argument, Foster does ***not*** challenge that the Amended Complaint sufficiently alleges his FCA knowledge that Potts-Kant committed fraud on every research project for the Foster Lab. Foster Br. at 12 (stating that the "Amended Complaint here contains multiple allegations that Foster should have been aware of Potts-Kant's alleged research fraud" and then quoting Paragraph 339 as an example—"Foster knew that the reported research results were false and/or fabricated for ***reasons that include*** . . ."). Nor could he, given the extensive allegations about his knowledge of the fraud. *See supra* at III(A)(5).[192]

Instead, Foster contends that the Amended Complaint lacks "factual allegations that [he] was aware that any grant applications or progress reports contained false statements, or that any certifications regarding them were false." Foster Br. at 12. This is almost the identical argument made by Duke and DUHS, and is incorrect for similar reasons, as Foster's knowledge is in fact alleged. *See supra* at III(A)(5) & IV(A)(4); Am. Compl., ¶¶ 315, 317.

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[192] When reciting the Amended Complaint's ***facts*** (in a light most favorable to Thomas), Foster asserts that Thomas did not state how his supervision was deficient and that allegations about his knowledge of Potts-Kant's fraud are "speculative." Foster Br. at 5. As indicated above, however, Foster does not advance these contentions in his argument, instead conceding that his knowledge of Potts-Kant's fraudulent research was sufficiently alleged. In any event, such contentions would be without merit. *See supra* at III(A)(5).

And to reiterate, Thomas alleges that, ***at best***, Foster—Potts-Kant's direct supervisor—never reviewed her raw machine data for over eight years, which is patently unreasonable and also in violation of the Duke Policy. Am. Compl., ¶¶ 143, 335. On the other hand, if Foster did review Potts-Kant's raw data, then he would have had actual knowledge of the research fraud prior to March 2013. *Id.*, ¶ 335 (iv). Thomas in no way forecloses the reasonable possibility that Foster was actively involved in the fraud. *See generally id.*, ¶ 339.

In addition, given Foster's position, his knowledge about the research fraud, and the Amended Complaint's extensive allegations about the grant system, the only reasonable inference is that Foster likewise knew that the grant applications and progress reports contained false statements. In other words, if Foster knew that Potts-Kant's research results were false, it necessarily follows that he knew they would be reported in grant documents to obtain and maintain grant funding. The converse proposition advanced by Foster requires him—a world-renowned scientist, the Foster Lab director, Potts-Kant's supervisor, and the ***principal investigator for multiple grants identified in Exhibit C***—to be wholly ignorant of the fact that Potts-Kant's false research would be reported in grant applications and progress reports. Such an inference goes beyond unreasonable, it would be absurd.[193]

B. Counts IV and V sufficiently plead false certification claims.

By March 2013 or soon thereafter,[194] Duke and/or DUHS senior managers, administrators, and principal investigators knew that all the Foster Lab's data generated by Potts-Kant was falsified and/or fabricated. *See* Am. Compl., ¶¶ 227-78. The institutional decisions (i) to conceal the research fraud, rather than disclose it to grant funding agencies, journal publications, and other researchers, and (ii) to continue reporting the false data in grant applications and progress reports, such as the June 2013 progress report and Fall 2013 renewal application for the SP-A Grant, violated Duke's assurances necessary to receive grant funding. *Id.*, ¶¶ 67-74, 279-99, 344-45, 383-86, 388. These assurances include the duties to foster an

[193] In this vein, *United States ex rel. Decesare v. Americare in Home Nursing*, 757 F. Supp. 2d 573 (E.D. Va. 2010) is of no help to Foster given the extensive facts alleged in the Amended Complaint about his knowledge and their reasonable inferences.

[194] Counts IV and V allege false certification liability for calendar years from 2007 to 2015. Am. Compl., ¶¶ 382, 389-390, 395, 400-401. While the ultimate proof at trial may establish an earlier trigger date for Duke and DUHS's liability based on knowing institutional violations of Duke's regulatory assurances, Thomas will focus on the time period of March 2013 and thereafter for purposes of this brief.

environment that promotes responsible research, discourages research misconduct, deals forthrightly and promptly with possible allegations or evidence of research misconduct; and to otherwise comply with the Regulations. *Id.*, ¶¶ 67, 69-72, 75-82, 344-45, 383-86, 388.

From that point forward—when Duke failed to disclose its violations, but instead certified compliance with its assurances and the Regulations in grant applications and progress reports presented to NIH, and in Institutional Assurance and Annual Reports submitted to ORI—Duke's certifications were false. Counts IV and V allege liability against Duke and DUHS for false claims and false records based on these false certifications. *Id.*, ¶¶ 382, 387, 395-96.

Courts have almost universally recognized the validity of FCA liability premised upon false certifications of regulatory compliance. *See, e.g., United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 379-80, 383-84 (4th Cir. 2015) (false certifications of compliance with Anti-Kickback Statute form basis for FCA liability); *Savannah River Nuclear Solutions*, 2016 U.S. Dist. LEXIS 168067, at *9-12, *26-31 (false certifications of compliance with Department of Energy regulations form basis for FCA liability); *United States v. Univ. of Phx.*, 461 F.3d 1166, 1168-70 (9th Cir. 2006) (false certifications of compliance with educational regulations form basis for FCA liability).

Duke and DUHS argue that Thomas failed to plead the two conditions required for implied false certification liability under *Escobar*. Duke Br. at 23. As to the express false certifications, they argue that Thomas did not allege any grant applications or progress reports that contained false certifications, or the falsity and materiality of any such certifications. *See id.* at 25. Duke and DUHS's arguments are without merit, primarily because they misconstrue the FCA claims in Counts IV and V.

For FCA liability to attach for an implied false certification, the claim must "not merely request payment," but also must make "specific representations about the goods or services provided." *Escobar*, 136 S. Ct. at 2001. In each grant application, progress report, and Institutional Assurance and Annual Report that Duke submitted to the Government, it executed a certification of compliance. *See* Am. Compl., ¶¶ 89-100. Those certifications were Duke's ***implied and express representations*** that it was complying with its assurances and the Regulations.

The second condition for implied false certification liability requires that "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 136 S. Ct. at 2001. After March 2013, when Duke was violating its assurances and the Regulations, its failure to disclose its noncompliance rendered its representations— its certifications of compliance—false.

Thus, to the extent Counts IV and V assert FCA liability for implied false certifications, the well-pleaded facts are sufficient to satisfy the *Escobar* conditions for such liability.

Unlike the claims in Counts I, II, and III of the Amended Complaint, the wrongful conduct—*i.e.*, the fraud—at the center of Counts IV and V is Duke and DUHS's concealment of the Foster Lab fraud and continued use of fraudulent data to seek additional grant funding. Those institutional decisions violated Duke's assurances and the Regulations. When Duke falsely certified its compliance in grant applications and progress reports presented to NIH after March 2013, the subsequently awarded grant funds to Duke were specific payments connected to Duke and DUHS's fraud and Duke's false certifications. Duke's failure to disclose its noncompliance with its assurances and the Regulations connected the wrongful conduct to claims for payment. Thus, Thomas pled factual allegations with sufficient plausibility and

particularity to identify the grant applications, progress reports, and Institutional Assurance and Annual Reports that contained the certifications (*i.e.*, those Duke submitted after March 2013), the certifications' falsity, and the fraud that made them false.

Duke and DUHS, nevertheless, argue that Thomas did not identify specific grants applications, progress reports, and Institutional Assurance and Annual Reports that contained express false certifications. The well-pleaded facts show that ***every*** certification of compliance that Duke executed and submitted to NIH and ORI after March 2013 was false. In such a context, nothing more is required. *See Decesare*, 757 F. Supp. 2d at 582-83 (holding that "the relator had alleged facts "to show that *every* certification submitted" by a particular defendant was false) (emphasis in original); *Drakeford*, 792 F.3d at 386 (holding that each Medicare form asking for reimbursement for a prohibited referral constituted a separate false claim under the FCA). It should be no mystery to Duke and DUHS as to the conduct they must defend—false certifications in grant applications, progress reports, and Institutional Assurance and Annual Reports, after the institutional decision to conceal the Foster Lab fraud and to continue to report the Foster Lab's fraudulent data. *See Decesare*, 757 F. Supp. 2d at 583.

As to materiality, to receive NIH grant funds, Duke, like every grant recipient, must comply with its assurances and the Regulations, and certify its ongoing compliance in grant applications, progress reports, and Institutional Assurance and Annual Reports. 42 C.F.R. §§ 93.301(b), 93.302(b). That the certifications are required as a condition of payment together with their purpose—to protect limited grant funds and guard against research fraud—signifies their importance to NIH's grant-funding decisions, and illustrates their materiality under *Escobar* as discussed above. *See supra* at III(A)(1)(c) & III(A)(4).

Thus, the well-pleaded facts in Counts IV and V sufficiently identify the grant applications, progress reports, and Institutional Assurance and Annual Reports that contained implied and express certifications, the falsity of the certifications, and their materiality.[195]

C. The Amended Complaint states claims against DUHS.

DUHS misapprehends the basis of Thomas's claims against it. DUHS argues that the Amended Complaint fails to state claims, because DUHS was not the grantee of the affected grants. *See* Duke Br. at 32-35.

This argument fails because the Amended Complaint alleges that DUHS, through its agents and employees, ***caused*** false claims to be submitted under § 3729(a)(1)(A) (Count I), ***caused*** false records to be made or used in connection with false claims under § 3729(a)(1)(B) (Count II), and ***caused*** false records and statements to be made concealing an obligation to pay money to the government under § 3729(a)(1)(G) (Count III).

The Amended Complaint describes the intertwined relationship between DUHS and Duke, and as it relates to Potts-Kant, Foster, and others. *See, e.g.*, Am. Compl., ¶¶ 20-22, 24, 279-81, 284, 344. Given the close relationship between Duke and DUHS, including cross-appointments and shared employment activities, it is a reasonable inference that Potts-Kant, Foster, and other Duke researchers and managers were acting, at various times, on behalf of DUHS as well as Duke, or perhaps sometimes even only on behalf of DUHS.

[195] With regard to scienter, Duke and DUHS mention false certifications only once. They argue Thomas did not plead that any defendant knew the false certifications were included in grant applications or progress reports. *See* Br. at 22. If Duke and DUHS are referring to the false certifications alleged in Counts IV and V, the argument in Section IV(A)(4) of this brief answers their argument and demonstrates that it has no merit, because *Harrison II's* "at least one employee" test is satisfied. When Duke and DUHS's administrators, senior managers, and principal investigators decided to conceal Duke's fraudulent research and to continue to use the Foster Lab's fraudulent data, they knew Duke's subsequent certifications of compliance with its regulatory assurances were false.

If DUHS is not included as a Defendant, then Duke may subsequently attempt to argue that it is not responsible for the actions of DUHS employees or agents. The Amended Complaint states claims against DUHS, which should remain a Defendant.

V. CONCLUSION

For the reasons stated above, Relator Thomas respectfully requests that the Court deny the Defendants' motions to dismiss the Amended Complaint.[196]

Respectfully submitted this 6th day of February, 2017.

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[196] Should the Court disagree, any dismissal should be without prejudice and Thomas will request leave to file a Second Amended Complaint. A "court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). This is liberal standard—"leave to amend should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or amendment would be futile." *Baird v. Fed. Home Mortg. Corp.*, No. 3:15CV00041, 2016 U.S. Dist. LEXIS 41938, at *25 (W.D. Va. Mar. 29, 2016) (quotation omitted).

Further, "leave to amend is almost always allowed to cure deficiencies in pleading fraud." *Rector*, 2014 U.S. Dist. LEXIS 52161, at *44 (quotation omitted). Thomas's investigation into Duke's fraud has continued, and he possesses significant additional information related to his claims. Contrary to Defendants' wholly speculative statements on brief, amendment would not be futile. Although Thomas has amended his complaint once, this was before service or unsealing. Thus, Defendants' motions are the first time that any party has purported to identify any deficiencies, which Thomas should have an opportunity to address if the Court determines that they have merit. *See Hagood*, 2015 U.S. Dist. LEXIS 37134, at *50-51 (in dismissing without prejudice, the court rejected a futility argument when the amended complaint had been filed while the case was still under seal, because "this is not a case in which Relators had notice of any deficiencies in the First Amended Complaint prior to the resolution of the instant motion").

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of February, 2017, a true and correct copy of the foregoing was filed electronically with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to counsel of record in this matter, and by email and U.S. Mail upon the following parties: