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OFFICE OF THE ATTORNEY GENERAL

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LITIGATION BUREAU

July 26, 2022

**Via ECF**

Hon. Frederic Block  
United States District Judge  
Eastern District of New York  
225 Cadman Plaza East  
Brooklyn, New York 11201

Re: ***Blain v. State University of New York Downstate Medical Center, et al.***  
**22-cv-3022 (FB)**

Your Honor:

This Office represents Defendants the State University of New York (“SUNY”), sued herein as State University of New York Downstate Medical Center (“SUNY Downstate”),<sup>1</sup> Vitaly Citovsky, Richard Gronostajski, Frank Middleton, and David Christini in the above-referenced matter. I write to advise the Court that Plaintiff has repeatedly initiated communications with the National Institutes of Health (“NIH”) regarding the grants at issue in this lawsuit and, as a result, NIH has requested a response from SUNY. For the reasons described below, SUNY intends to submit the requested response to NIH by July 28, 2022.

As the Court is aware, Plaintiff brings this action alleging numerous claims, including gender discrimination and retaliation under various statutes. In particular, Plaintiff challenges actions taken by SUNY in connection with an investigation into accusations of Plaintiff’s misconduct in research funded by grants from federal agencies, including NIH.

On May 23, 2022, Plaintiff moved for a preliminary injunction, which Defendants opposed. *See* ECF Nos. 5, 14-16. Following initial briefing, the Court held a three-day hearing, and deferred ruling until the parties completed briefing on the issues raised in Plaintiff’s motion. Pursuant to the current schedule, that briefing is expected to conclude on September 30, 2022. *See* Docket Entry Dated July 13, 2022. In the meantime, the Court has instructed the parties to maintain the status quo, and for there to be “No further action about the journal, patent, or

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<sup>1</sup> As a subdivision of SUNY, SUNY Downstate is not a legally-cognizable entity separate from SUNY, the sole appropriate institutional defendant. *See* N.Y. Educ. Law §§ 351-352; *Pemrick v. Stracher*, 2007 WL 1876504, at \*1, n. 1 (E.D.N.Y. June 28, 2007), *aff’d* 331 Fed. App’x 17 (2d Cir. 2009).

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anything like that.” *See* Tr. p. 538. Yet, while Plaintiff pressed the Court to preclude Defendants from taking any action with respect to Plaintiff, Plaintiff has taken her own affirmative actions in an attempt to alter the status quo.

Specifically, on June 27, 2022, Plaintiff’s counsel initiated communication with NIH, claiming that SUNY made various misrepresentations, and requesting “an opportunity to submit a more detailed description of these events in support of Dr. Blain’s reinstatement as PI on the grants.” *See* Ex. A. On June 30, 2022, NIH responded, stating:

While NIH’s discussions about the grant will be with the recipient institution (SUNY Downstate), you are welcome to send us information in writing at any time. If you wish to submit information, such as a more detailed description and relevant supporting documents, you may provide the information via email or through a shared Box folder. The material that you send us will in turn inform our dialogue with the recipient institution (SUNY Downstate). Please note that we may share the materials you give us with the institution.

*See* Ex. B. Approximately two weeks later, after the hearing concluded, Plaintiff’s counsel sent NIH a ten-page letter (with fifteen exhibits), replete with out-of-context quotes from the transcript of the hearing, misrepresentations of the testimony, and mischaracterizations of Your Honor’s statements. *See* Ex. C (July 12 Letter, without exhibits). NIH then sent a follow-up email to SUNY with various questions, and requested a response by July 28, 2022. *See* Ex. D.

While the Court has not issued any order or specific directive precluding SUNY’s communications with NIH concerning the grants at issue,<sup>2</sup> out of an abundance of caution, SUNY has refrained from taking any specific action with respect to Plaintiff’s prior role on the grant to avoid altering the status quo. However, Plaintiff has not felt similarly constrained, and has indeed taken steps in an attempt to alter the status quo. Now, due to Plaintiff’s own actions, NIH has reached out to SUNY with specific questions concerning Plaintiff, and has requested a response. For multiple reasons, SUNY must respond to NIH’s request.

First, SUNY must maintain its working relationship with NIH. There are numerous SUNY Downstate researchers working on NIH-funded grants; SUNY Downstate’s research portfolio for the fiscal year 2022 totaled over \$24 million in NIH funding. This funding is critical to supporting scientific research and furthering the goals of SUNY Downstate and its faculty, as well as the larger SUNY system. SUNY has a longstanding relationship with NIH and has a strong institutional interest in maintaining that relationship and preserving future funding opportunities.<sup>3</sup> If SUNY is seen as an uncooperative partner, it may lose funding opportunities, which would be detrimental to researchers, the SUNY system, and the community at large.

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<sup>2</sup> Indeed, the Court seemed to recognize that the actions taken with respect to the NIH grant were unrelated to Plaintiff’s gender, and thus not actionable. *See* Tr. p. 543.

<sup>3</sup> As Dr. Christini testified, SUNY has “very large institutional – interests with the NIH.” Tr. p. 484.

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Simply put, SUNY has a duty to reply to NIH and cooperate as its research partner and funding recipient. SUNY cannot allow Plaintiff to put forward its one-sided and self-serving position, without the opportunity to respond. Nor can SUNY ignore a direct inquiry from its grant partner. This is demonstrated by the NIH Grants Policy Statement, which includes provisions on information sharing, monitoring, and record access,<sup>4</sup> as well as the NIH's Notice of Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH.<sup>5</sup>

Second, NIH explicitly told Plaintiff that any submissions she made would “inform [its] dialogue with the recipient institution (SUNY Downstate).” *See* Ex. B. Thus, Plaintiff was on notice that any submission she made to NIH would likely lead to further communications between SUNY and NIH about the topics raised in that submission. Plaintiff subsequently went forward and sent NIH a comprehensive submission, knowing that it would prompt NIH to engage in a dialogue with SUNY about Plaintiff and her removal from the grants at issue. Thus, Plaintiff cannot now try to preclude such communications, which she had been advised would be a consequence of her actions.

Third, as Defendants have already demonstrated, any request that the Court enjoin Defendants from communicating about Plaintiff's research misconduct is improper. ECF No. 15, pp. 16-18. As the Second Circuit has made clear, such a prohibition is an unconstitutional prior restraint, in violation of the First Amendment. *See id.* (citing cases). “Prior restraints of future speech are particularly dangerous because of the difficulty courts face in designing an order that does not chill protected speech.” *Bihari v. Gross*, 119 F. Supp. 2d 309, 325 (S.D.N.Y. 2000). Any uncertainty in a court's directive can blur the lines between permissible free speech and enjoined speech. *See Metro. Opera Ass'n, Inc. v. Loc. 100, Hotel Emps. & Rest. Emps. Int'l Union*, 239 F.3d 172, 174 (2d Cir. 2001) (vacating an injunction as “impermissibly vague” and finding it presented serious questions under the First Amendment and libel law where it failed to provide the defendant with adequate notice of what conduct was being enjoined); *Latino Officers Ass'n, N.Y., Inc. v. City of N.Y.*, 196 F.3d 458, 465 (2d Cir. 1999) (“The danger of a prior restraint, as opposed to ex post disciplinary action, is precisely that making predictions ex ante as to what restrictions on speech will ultimately be found permissible is hazardous and may chill protected speech.”). Thus, in circumstances like those here, Defendants should not be precluded from speaking about Plaintiff with third parties.<sup>6</sup> *See, e.g., McLaughlin v. New York*, 784 F. Supp. 961, 977 (N.D.N.Y. 1992) (refusing to enjoin defendant's “blacklisting” of former

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<sup>4</sup> *See, e.g.,* [https://grants.nih.gov/grants/policy/nihgps/html5/toc\\_test\\_417.htm](https://grants.nih.gov/grants/policy/nihgps/html5/toc_test_417.htm), at Parts 8.3 (Management Systems and Procedures); 8.4 (Monitoring); 8.4.2 (Record Retention and Access).

<sup>5</sup> *See* <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html#:~:text=NOT%2DOD%2D19%2D020,Research%20Misconduct%20to%20the%20NIH&text=The%20NIH%20strives%20to%20exemplify,in%20the%20conduct%20of%20science.>

<sup>6</sup> Indeed, the Court already referenced the difficulty in fashioning the relief sought by Plaintiff here. *See* Tr. 447 (“I don't know what kind of preliminary injunction relief I can grant here. It's kind of not so clear.”).





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June 27, 2022

**Via Email**

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Director  
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[norman.sharpless@nih.gov](mailto:norman.sharpless@nih.gov)

Michael S. Lauer, M.D.  
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Dear Drs. Sharpless and Lauer:

We represent Dr. Stacy Blain, the former Principal Investigator (“PI”) on grants R21 CA252585 and R01 CA249667, for which the awardee institution is SUNY Downstate Medical Center (“SUNY Downstate”). We understand that on April 12, 2022, after SUNY Downstate removed Dr. Blain as PI on grant R01 CA249667, Dr. Blain’s attorney, Paul Thaler, submitted a letter to you and Dr. Lauer replied that NIH’s “communications going forward will be exclusively with the recipient organization (in this case SUNY Downstate Medical Center).” We write to respectfully request that NIH reconsider its decision to communicate exclusively with SUNY Downstate about this matter.

Dr. Blain has sued SUNY Downstate, alleging that it has long discriminated and retaliated against her based on her gender. One such retaliatory act was removing Dr. Blain as the PI on NIH grants. Before we filed suit, SUNY Downstate claimed that NIH had “mandated” Dr. Blain’s removal, in writing. We asked for a copy of the letter, and SUNY Downstate refused. We now understand why.

Although SUNY Downstate intimated that NIH’s directive came as a result of SUNY Downstate’s finding of research misconduct, we now know that is untrue. We know this because, during our nascent litigation, we demanded a copy of any NIH correspondence, which SUNY Downstate finally produced last Thursday, June 23, 2022. An NIH letter, dated January 25, 2022, shows that SUNY Downstate was misleading NIH about what occurred.

From the letter, NIH demanded Dr. Blain’s removal—not because of the weak research misconduct finding—but rather because SUNY Downstate had “informed [NIH] that Dr. Stacy Blain is in violation of [its] policies” and had “stated that in the course of a misconduct investigation, ‘she declined multiple requests to review the notebooks and identify the data that she asserts supports the figures in the manuscript and was, therefore, in violation of SUNY

Downstate’s policy.” SUNY Downstate did not want Dr. Blain to know this because it is patently false, and demonstrably so.<sup>1</sup>

Dr. Blain cooperated fully with the investigation, including by attending interviews and providing all the notebooks with relevant data that were available to her. Indeed, by contrast, several other scientists—who were also co-first authors on the relevant papers—refused to be interviewed.

Nevertheless, SUNY Downstate claims that Dr. Blain was uncooperative. Why? Because, during the investigation, SUNY Downstate demanded that she set aside her work and conduct a detailed and extensive analysis of data, some of which no longer existed given that some of the allegations dated back more than 15 years. Consistent with the federal regulations, Dr. Blain declined to do the Investigation Committee’s work for them. *See* 42 CFR § 93.310 (describing an institution’s responsibilities when conducting research misconduct investigations). When she so declined, SUNY Downstate claimed that she was in violation of its “cooperation” policy. However, SUNY Downstate’s Policy merely requires that a faculty member such as Dr. Blain must “cooperate with [SUNY Downstate] officials in the review of allegations and the conduct of inquiries and investigations” and must “provide evidence relevant to research misconduct allegations.” *See* SUNY Downstate Research Misconduct Policy and Procedure at § 1. Dr. Blain met these obligations by cooperating with sequestration, identifying the relevant lab notebooks and the lab members who had identified the data, responding to multiple requests from the Inquiry and Investigation Committees, and participating in interviews during both the inquiry and the investigation.

It should be noted that SUNY Downstate itself violated its own policies in various ways during this pre-ordained “investigation.” We are more than happy to make a detailed presentation on these violations.

Dr. Blain’s decision to refrain from conducting this work does not make her uncooperative nor is it a violation of SUNY Downstate’s policy. We seriously doubt SUNY Downstate could find a single example of having taken this position with any other faculty member in the past. She has no obligation to do as SUNY Downstate requested. Rather, SUNY Downstate’s research misconduct policy plainly states that the investigation committee (not Dr. Blain, the respondent of the investigation) “is responsible for conducting a thorough examination of all facts and evidence relevant to the investigation to determine, based on a preponderance of evidence, whether research misconduct has occurred . . . .” *See* SUNY Downstate Research Misconduct Policy and Procedure at § 6.9.

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<sup>1</sup> In fact, SUNY Downstate’s response to NIH’s letter, dated February 22, 2022, *admits* that NIH directed Dr. Blain’s removal “based *solely* on the policy violation[.]” Bizarrely, SUNY Downstate further claims in that letter that without having made its baseless research misconduct findings, it would not have sought to remove Dr. Blain as a PI due to the purported policy violation. Given that ORI’s oversight review remains pending, it is premature for any federal action such as removing Dr. Blain from grants based on the institutional findings. This further demonstrates that SUNY Downstate engaged in a rush to judgement to take actions designed at harming Dr. Blain’s reputation and career for a misleading “violation” that it admits it would not typically seek to punish in this manner.

Given SUNY Downstate's misrepresentation of the central fact that led to NIH's request for the designation of a new PI, we request an opportunity to submit a more detailed description of these events in support of Dr. Blain's reinstatement as PI on the grants.

Sincerely,

/s/ Jim Walden

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cc: Michelle G. Bulls ([bullsmg@mail.nih.gov](mailto:bullsmg@mail.nih.gov)), Director of the Office of Policy for Extramural Research Administration, National Institutes of Health



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

Date: June 30, 2022

To: Jim Walden, Esq.  
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From: Michael S. Lauer, MD  
NIH Deputy Director for Extramural Research  
Director, NIH Office of Extramural Research

Re: Your letter of June 27, 2022 re: Dr. Stacy Blain

Dear Mr. Walden:

Thank you for your letter in which you indicate that Dr. Blain cooperated fully with the investigation and that SUNY Downstate violated its own policies. You requested an opportunity to provide a more detailed description of the events in question.

While NIH's discussions about the grant will be with the recipient institution (SUNY Downstate), you are welcome to send us information in writing at any time. If you wish to submit information, such as a more detailed description and relevant supporting documents, you may provide the information via email or through a shared Box folder. The material that you send us will in turn inform our dialogue with the recipient institution (SUNY Downstate). Please note that we may share the materials you give us with the institution.

Sincerely yours,

Michael S Lauer, MD  
NIH Deputy Director for Extramural Research





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July 12, 2022

**Via Email**

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National Institutes of Health  
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Dear Dr. Lauer:

Thank you for the opportunity to provide more information about Dr. Stacy Blain's removal as principal investigator ("PI") on two grants, R01 CA249667 and R21 CA252585, for which SUNY Downstate Medical Center ("SUNY") is the awardee institution.

**EXECUTIVE SUMMARY**

Between June 29 and July 1, 2022, a Federal District Court in Brooklyn, New York heard evidence in connection with Dr. Blain's motion for a preliminary injunction (the "Hearing") to stop SUNY from continuing its wrongful and intentional campaign to destroy her career.

As detailed below, U.S. District Court Judge Frederic Block, having heard testimony from 11 witnesses, expressed grave concern over SUNY's biased investigation and baseless declaration that Dr. Blain violated a cooperation requirement in SUNY's Research Misconduct Policy (the "Cooperation Policy"). *See* Research Misconduct Policy § 1 ("All faculty . . . will cooperate with the DMC officials in the review of allegations and the conduct of inquiries and investigations.").

SUNY tried to absolve itself of responsibility for removing Dr. Blain from her grants by blaming the National Institutes of Health ("NIH")—and you, Dr. Lauer, in particular—for having made the determination that Dr. Blain had violated SUNY's Cooperation Policy. Only when challenged on cross examination was SUNY forced to concede that NIH made no such determination. Instead, NIH directed SUNY to re-assign the PI role only based on SUNY's (flawed) determination of Dr. Blain's noncooperation.

More broadly, the evidence at the Hearing revealed SUNY's determination of noncooperation to be unfounded and unprecedented and, worse, exposed its underlying investigation as biased and meritless.

**I. SUNY's Selective Disclosures to NIH and ORI are Part of a Pattern of Gender Bias**

**A. Dr. Blain Became a Renowned Cancer Researcher Despite SUNY's Persistent Discrimination**

In or about 2002, Dr. Blain joined the faculty of SUNY as a tenure-track Assistant Professor with a joint appointment in its Cell Biology and Pediatrics departments. Since that time, she has encountered a workplace hostile to her due to her gender, including by underpaying her

relative to her male colleagues and obstructing her tenure eligibility. Despite the obstacles that SUNY threw in her way, Dr. Blain has become a leading cancer researcher. In particular, the assay that Dr. Blain developed will help ensure that cancer patients receive only effective treatments, and the p27-targeting cancer-treating drug that Dr. Blain invented—IpY—will potentially open the door to a brand-new form of cancer treatment.

No one disagrees that Dr. Blain’s research is groundbreaking. Indeed, Judge Block praised Dr. Blain during the Hearing as, among many other accolades, “a terrific researcher” and an “outstanding scientist.” Hearing Tr. 203:2-5; 451:7-24. Even Dr. Janice Brissette, who replaced Dr. Blain as PI on one of the grants, recognized that Dr. Blain’s work was “so important” and “critical to continue.” Hearing Tr. 451:11-12. Scientists outside of SUNY also agreed that Dr. Blain’s work has a very real potential of revolutionizing cancer treatment. *See, e.g.*, Hearing Tr. 116:7-12.

Despite Dr. Blain’s many accomplishments and important work, SUNY continues to discriminate and retaliate against her. After listening to days of evidence during the Hearing, Judge Block agreed that SUNY has treated Dr. Blain very unfairly. He said, among other things, that she “ha[s] been treated shabbily,” Hearing Tr. 203:1-5, has “suffered greatly because of this,” Hearing Tr. 343:22-344:5, and that SUNY’s conduct “bothers [him] as a judge,” Hearing Tr. 346:25-347:4. Its discriminatory and retaliatory actions include, beginning in 2019, conducting a grossly unfair and pretextual investigation of research misconduct allegations against her.

## **B. SUNY Ignored a Prior Investigation and Mised ORI**

As you are aware, SUNY and ORI received a complaint from “Claire Francis” on June 4, 2019, claiming that certain Western Blot diagrams (the “Subject Diagrams”) were falsified. In a letter to SUNY on July 17, 2019, ORI directed SUNY to either investigate the matter or, if SUNY “ha[d] already conducted an inquiry or review of this matter,” to “send [ORI] a copy of the report of the findings” (the “ORI Letter”). SUNY commenced an investigation without disclosing to ORI a prior year-long investigation concerning the exact same data.

Three years earlier, in about March 2016, SUNY itself received an identical complaint about the same data. In that matter, a male graduate student in Dr. Blain’s lab, Priyank Patel, was accused of data falsification by another student. Dr. Mark Stewart, the then-Interim Provost<sup>1</sup>, convened a committee to investigate the circumstances of the underlying data, consistent with SUNY’s policies. Indeed, the record revealed that Dr. Stewart specifically considered SUNY’s Research Misconduct Policy during his investigation and followed appropriate steps.

Every research misconduct investigation under SUNY’s Research Misconduct Policy starts with an “assessment” of the allegations, and, at the Hearing, a SUNY witness conceded that Dr. Stewart had convened an “assessment committee.” *See* Hearing Tr. 464:3-7. Over the course of this year-long investigation, Dr. Miriam Feuerman and the assessment committee (comprised of Dr. William Chirico and Dr. Lorin Weiner) reviewed all of the relevant back-up data, interviewed

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<sup>1</sup> In directing this investigation of alleged data falsification, Dr. Stewart was also essentially acting as the Institutional Official responsible for the research misconduct proceedings.

the accused student and the complainant, and eventually determined that the data was not fabricated and did not constitute research misconduct. As a result, Dr. Stewart documented the assessment committee's findings, documented necessary corrective actions, and closed the matter without any disciplinary action against the male graduate student (the "Stewart Report").

When SUNY received the ORI Letter in 2019, it should have immediately produced the Stewart Report as being responsive to ORI's request for "the report of the findings" of any prior "review or inquiry" into the subject matter. It did not.<sup>2</sup> Nor did SUNY reveal to ORI that Dr. Patel's thesis committee reviewed the data carefully and not only cleared him to graduate, but also lauded his work, "commend[ing] [him] on the amount of fascinating and important work [he has] accomplished" and "appreciat[ing] [his] well-organized and concise presentation, and [his] thoughtful, serious, and mature approach to the science, which was also wonderfully showcased in [his] thesis Discussion" (the "Thesis Review").<sup>3</sup>

Although beyond the scope of this letter, we would be pleased to provide a longer explanation of how the decision to withhold the Stewart Report and Thesis Review from NIH and ORI—which SUNY would have never done to a male professor—fits into a broader pattern of gender discrimination against Dr. Blain. For present purposes, it is enough to note the Hearing testimony about SUNY's completely biased and pretextual investigation, and the Court's incredulity over its abject unfairness to Dr. Blain, including the baseless and unprecedented determination that she failed to cooperate under SUNY's Cooperation Policy. Although we enclose the entire record of the Hearing for your review, a few examples make the point efficiently:

- **The Investigation Committee's determination of data falsification was wrong and unsupported:** Dr. Andrew Koff, one of the world's leading molecular cell biologists and a leading cancer researcher, testified that the Investigation Committee's central determination—that the Subject Diagrams were falsified—was incorrect and unfounded. Hearing Tr. 54:14-16. After hearing Dr. Koff and other witnesses express similar views, Judge Block stated, "I've heard outstanding people testify that she's done nothing wrong . . . it just seems ludicrous to me. But, in any event, she's outstanding, you agree, and it would be great if we had her continue PI services; right?" Hearing Tr. 452:21-453:3.
- **Inquiry Committee members lied to witnesses:** Despite the fact that ORI has yet to make any research misconduct determination, Inquiry Committee members (who also served on the Investigation Committee) told a witness that ORI "analyzed th[e] paper and did find that exactly the same bands . . . were cut and pasted to mean two different

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<sup>2</sup> Over time, SUNY has provided various excuses for failing to produce the Stewart Report to ORI. At the Hearing, however, a SUNY witness finally conceded that someone in leadership intentionally directed the staff not to disclose it. Hearing Tr. 373:22-374:6 (SUNY's witness testifying that "the decision not to tell ORI" about the 2016 investigation was "an institutional leadership decision"). Although we will explore this issue further in discovery, we believe this decision—for which we have been unable to find a precedent—was rooted in gender animus.

<sup>3</sup> The thesis committee included Dr. Janice Brissette. In her testimony, she confirmed that the Thesis Review did not reveal any falsification of the Subject Diagrams.

things,” which was “almost by definition research misconduct.” *See* Dr. Stewart Inquiry Tr. at 6:5-8. Another Inquiry Committee member told a witness that ORI found Dr. Blain had falsified data “with premeditation.” *See* Dr. Roman Inquiry Tr. at 22:20-23. Judge Block agreed that the Inquiry Committee’s comments to the witnesses were “confusing at the very least.” Hearing Tr. 403:25-404:4.

- **The Committees refused to consider exculpatory evidence:** The Committees refused to interview witnesses favorable to Dr. Blain and refused to include exculpatory evidence elicited through the investigation in either of their reports. Although we could provide a fuller description of all the blatant cherry-picking, three examples suffice here to make the point:
  - The Inquiry Committee sought to interview Dr. Brissette, who reviewed the Subject Diagrams as part of the Thesis Review. When the Inquiry Committee tried to schedule the interview, Dr. Brissette wrote in an email: “[o]verall, I never noticed anything that suggested misconduct on the part of Priyank or Stacy” and that Dr. Blain was a “hands-on” manager. Hearing Tr. 456:4-15. After seeing this perspective in an email, the Committees neither interviewed Dr. Brissette nor included her exculpatory perspective in any of their reports.
  - During the investigation, Dr. Katrina Nguyen and Dr. Cindy Gomez both provided strong exculpatory testimony regarding Dr. Blain—but the Investigation Committee did not include any of their evidence in the final investigation report (the “Investigation Report”).
  - Dr. Susan Gottesman and Dr. Jonathan Somma worked closely with Dr. Blain and her graduate students during the relevant period. Although they would have attested to her scientific rigor and adherence to strict standards, the Committees failed to interview them (and refused Dr. Blain’s request that they interview Dr. Gottesman specifically).

Judge Block questioned the integrity of the investigation given these omissions, stating, “Do you think it would be fair, unbiased and objective to leave out the testimony of prominent people who testified that there is no wrongdoing . . . ?” Hearing Tr. 428:10-12. Understanding that both SUNY’s President and ORI needed to review the Investigation Report—and either accept or reject its findings—the Judge questioned why the report failed to “explain the plusses and the minuses so that an even, fair investigation would give the people who are making the ultimate determination a nice balance of the key and relevant evidence.” Hearing Tr. 426:23-427:2. The Judge was even more blunt, saying: “[the Investigation Report] could have said that we’ve had very prominent people say that she did nothing wrong, . . . right? It didn’t do that.” Hearing Tr. 426:11-16. The witness was forced to agree. *Id.*

- **SUNY’s prior Institutional Official testified that SUNY’s allegation concerning lack of cooperation was unprecedented:** Dr. Richard Coico, the prior Institutional Official at SUNY responsible for research misconduct matters, testified that (a) he had never before heard of SUNY holding a faculty member responsible for “reckless” research misconduct for failing to spot problems in a graduate student’s work, (b) the Cooperation Policy requires only that a respondent cooperate in the sequestration of

data, which is then made available to the investigators, and provide truthful information during requested interviews, and (c) the Cooperation Policy does not require a respondent to do the Committee's work for it. *See* Hearing Tr. 99:21-101:5. On this basis, Dr. Coico, having reviewed the Investigation Report, opined that its conclusions were wrong, as he saw "no evidence of misconduct as defined by NIH" and that any errors with the data did not constitute research misconduct. Hearing Tr. 101:6-16.

- **Judge Block dismissed a SUNY witness for trying to mislead him:** SUNY called its Assistant Vice President for Employee & Labor Relations, presumably to explain that no imminent employment disciplinary actions would occur. However, that witness proved to be highly evasive when Judge Block posed questions during her direct examination. As the Judge was attempting to discern the exact allegations that could be the proper subject of disciplinary proceedings (we argued that the research misconduct allegation was time-barred under a collective bargaining agreement), the witness refused to answer. Growing increasingly frustrated by her obvious evasions, Judge Block dismissed her from the witness stand and accused SUNY's counsel of "trying to pull the wool over [his] eyes" with "mystery charges." Hearing Tr. 314:11-23. In the middle of her *direct examination*, the Judge cut off further testimony, saying, "I do not want to have to listen to [the witness' testimony] . . . . She cannot tell me anything." Hearing Tr. 313:18-21.

In sum, SUNY resolved to re-investigate the same data it had fully investigated in 2016, deciding to conceal the earlier report. SUNY convened a three-person Inquiry Committee that tried to strongarm witnesses with false statements and yet found no new evidence. But it still recommended a full investigation. Then, these three men compromised the majority of the Investigation Committee, which (a) used unscientific methods to find falsification in the Subject Diagrams, (b) lacking any actual evidence to show Dr. Blain's awareness of these alleged falsifications, relied on speculation and false assumptions to determine, essentially, that she must have known of them,<sup>4</sup> and (c) in so doing, ignored compelling exculpatory evidence, all to find Dr. Blain guilty of falsifying the same data for which SUNY had cleared a male graduate student. Because SUNY knew the research misconduct charges were too old for disciplinary proceedings under the collective bargaining agreement, and too weak to stick in any event, it contrived a policy violation for "failure to cooperate" based on Dr. Blain's decision—which was, in turn, based on her counsel's advice—not to perform work the Investigation Committee itself was charged with performing. Judge Block has not yet made formal findings of fact, or issued his decision, but we believe these are the key take-aways from the testimony adduced at the Hearing.

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<sup>4</sup> One of the Investigation Committee's key bases for finding that Dr. Blain must have known of the falsifications is that those falsifications were so obvious that they "would be readily apparent to any cell biologist." Investigation Report, at 14. This phrase was controverted again and again at the Hearing, including by SUNY's own witnesses. *See, e.g.*, Hearing Tr. 465:15-23 (Dr. Brissette agreeing that "Any cell biologist who does this kind of work would recognize that the data in Priyank Patel's diagrams is fabricated" is "a false statement").

## II. SUNY Used the Dishonest Investigation Report to Mislead NIH and Remove Dr. Blain as Principal Investigator

On the heels of the grossly flawed Investigation Report, but before ORI has concluded its review of the allegations, SUNY sought to remove Dr. Blain as PI from her grants and used the NIH as a strawman to conceal its intentions. This was improper and in violation of federal research misconduct policy, which provides that allegations of research misconduct against a scientist do not bring their research to a halt. *See* Executive Office of the President; Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy, 65 Fed. Reg. 76,260 (Dec. 6, 2000) (“Safeguards for subjects give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons.”) (emphasis added). This is especially true when accomplished scientists “[a]damantly disagree” with the Committee’s initial findings, *see* Hearing Tr. 54:16, and when the underlying science has been repeatedly confirmed in independent laboratories, *see* Hearing Tr. 65:21 (“Scientists will trust the science.”).

SUNY’s consistent position before and during the Hearing—that is, until sharp questioning by Judge Block—was that NIH forced it to remove Dr. Blain from her grants. As SUNY tried to defend this as more information emerged, it changed the story. At first, SUNY stated that NIH forced SUNY to remove her for committing research misconduct. When this version was undermined, SUNY pivoted, saying that NIH made a finding that Dr. Blain violated SUNY’s Cooperation Policy and, on that basis, demanded her removal as PI. After sticking to this story during his direct examination, SUNY’s witness was forced to correct the record in response to cross examination, including by Judge Block: that NIH’s directive was only a reaction to SUNY’s determination that Dr. Blain had violated the Cooperation Policy.

Although we could provide much more detail, a high-level timeline of the story’s evolution is as follows.

On or about February 15, 2022, Michael Vernick, one of SUNY’s lawyers, notified Dr. Blain’s counsel that SUNY had shared excerpts of the Investigation Report with NIH and, as a result, NIH instructed SUNY to either replace Dr. Blain as the PI on the grants or bilaterally terminate the grants. In substance, Mr. Vernick conveyed that NIH’s decision was based on SUNY’s findings of research misconduct.

Although Mr. Vernick’s words were somewhat ambiguous and carefully chosen, on June 29, 2022, another lawyer acting for SUNY, Clement Colucci, was much more direct in his opening statement. Explaining why SUNY had no choice but to remove Dr. Blain, Mr. Colucci said: “[NIH] said to us, we have a problem here. We can’t have somebody who’s, somebody who has been found guilty of research misconduct running any of our grants.” Hearing Tr. 32:9-19.

Then, on July 1, 2022, SUNY called Shoshana Milstein, SUNY’s Vice President of Compliance and Audit Services, as a witness. She first testified that NIH’s decision was “based upon information -- right or wrong -- that was sent up to them by [SUNY].” Hearing Tr. 354:12-

19. She claimed that NIH's decision was "quite surprising" and that SUNY "pushed back" by telling NIH that "putting the research misconduct issue aside, if someone just violated our policies and procedures, we would not remove them from the grant," but SUNY's push back was unsuccessful because "Dr. Lauer was very [adamant] that this was the direction he wanted us to go in." Hearing Tr. 354:21-355:5.

Later that day, SUNY called Dr. David Christini, SUNY's Senior Vice President for Research, as a witness, apparently to explain the evolution of SUNY's story between the Vernick/Colucci version to the Milstein version. His explanation was clear, and he repeated it a number of times in response to Judge Block's questions during his direct examination. He blamed NIH—and, in particular, you, Dr. Lauer—as having concluded, pursuant to your oversight authority, that Dr. Blain had failed to cooperate, requiring her removal. *See* Hearing Tr. 481:3-13.

This story fell apart on cross examination, much to Judge Block's consternation. Dr. Christini walked back his statement:

Q Doctor, I think you testified before we took our break that NIH made a finding that Dr. Blain didn't cooperate; is that right?

A No, that's -- if I said that, I misspoke. NIH honed in on our investigation -- Investigative Committee's finding that Dr. Blain didn't cooperate.

Hearing Tr. 520:5-10. Judge Block cut to the quick, since he recalled Dr. Christini's testimony vividly:

**[Y]ou told me [Dr. Blain was removed] because [NIH] said she failed to cooperate and that [she] violated a very important policy and that was really the basic reason why NIH told you, you got to stop all this. You testified to that.**

Hearing Tr. 520:15-20 (emphasis added). Dr. Christini sheepishly replied: "That was their reasoning in the entirety they gave us." Hearing Tr. 520:21-22. He attempted to deny that he had, moments before, stated that NIH made a finding of noncooperation—leading us immediately to ask the Court to have Dr. Christini's prior testimony read back to him. Hearing Tr. 521:7-17.

Judge Block, returning to Dr. Christini's prior testimony, stated: "[Y]ou said that NIH terminated this program because she did not cooperate. **You told me that.**" Hearing Tr. 521:18-22 (emphasis added). In response, Dr. Christini finally conceded, in relevant part: "[T]hat [was] based on our finding." Hearing Tr. 521:23-25.

Quite obviously, we were not part of any discussions between SUNY and NIH during the relevant period. Based on our consultations with Paul Thaler, Dr. Blain's counsel in the SUNY investigation and the pending ORI review, we understand the way in which the process is supposed to work in his experience. Based on that general understanding, we found it difficult to believe that NIH was invested in—or "adamant" about, as Mrs. Milstein put it—Dr. Blain's removal as PI in these circumstances.

But what we know, without doubt, is that SUNY lied during the Hearing to obfuscate its malintent toward Dr. Blain and the actions it took against her. It first argued unambiguously that NIH ordered her removal based on research misconduct. Confronted with evidence that exposed that story as false, SUNY then claimed NIH made a determination of noncooperation, directing Dr. Blain's removal based on its own finding. That story, likewise, was exposed as fable.

SUNY's explanation kept changing because it wanted to cover its tracks. It knew that its conclusion that Dr. Blain had been uncooperative was ridiculous and, therefore, removing Dr. Blain as PI on that basis was utterly indefensible. As described below, Dr. Blain was fully cooperative. Knowing this, SUNY strenuously tried to portray itself as having its hands tied and to blame NIH for the decision. However, after the truth came out, Judge Block summed it up simply: "the information was sent to [NIH] by you folks. They said, okay, we're going to take this action. That's what they did." Hearing Tr. 531:18-21. Judge Block expressed significant skepticism of SUNY's determination that Dr. Blain had been uncooperative and pressed Dr. Christini for evidence that supported it. *See* Hearing Tr. 529:2-530:23. He could not provide it. *Id.*

### **III. Contrary to SUNY's Assertion, Dr. Blain Fully Cooperated with the Investigation**

Dr. Blain did not violate the Cooperation Policy and, thus, should not have been replaced as PI. She fully cooperated with the inquiry and investigation, as she had done during the 2016 investigation. Among other things, Dr. Blain: (1) returned from vacation early to assist with the sequestering of the relevant documents; (2) provided all the relevant notebooks and documents in her possession to the Investigation Committee; and (3) sat for two interviews—one during the inquiry stage and the other during the investigation stage—and provided truthful answers to the questions posed to her. As Dr. Coico testified, these actions satisfied SUNY's Cooperation Policy. *See* Hearing Tr. at 99:23-100:14. Indeed, in the Inquiry Committee's final report (the "Inquiry Report"), it concluded that the witnesses it interviewed—including Dr. Blain—were "highly cooperative." Inquiry Report, at 5.

The Investigation Report, however, unjustifiably reversed the Inquiry Report's earlier finding that Dr. Blain was "highly cooperative" and claimed, instead, that she had been uncooperative. It asserted that "the Committee requested on multiple occasions that Dr. Blain identify what she contended were the raw data for the questionable figures, specifically for the 2008 MCB paper" and "Dr. Blain declined multiple requests to review the notebooks and identify the data that she asserts supports the figures in the manuscript[.]" Investigation Report, at 8. These requests by the Investigation Committee were, essentially, requests that Dr. Blain do the Investigation Committee's job on its behalf. Section 6.10 of SUNY's Research Misconduct Policy states unequivocally that the Investigation Committee, not a respondent such as Dr. Blain, is responsible for the "[e]xamination of evidence, including review of all relevant documentation[.]" As Dr. Coico testified, the Cooperation Policy does not require that a respondent do the Committee's work for it. Hearing Tr. 100:10-12. Therefore, Dr. Blain's decision to decline the Investigation Committee's request—which she made based on the advice of her highly experienced counsel—cannot serve as a basis for a finding that she violated the Cooperation Policy.



Moreover, the Investigation Committee knew that its request was patently unreasonable, and aspects of it were literally impossible. A member of the Investigation Committee admitted during a July 2020 interview of Dr. Blain that “there was no way physically that we would obtain those primary data from the collection of endless data that [Dr. Blain] supplied.” Dr. Blain Investigation Tr. 48:22-24. Moreover, some of the data no longer existed, including because SUNY allowed one co-author (who was responsible for some of the Subject Diagrams) to take her data when she left SUNY, but she did not maintain it. *See* Dr. Blain Investigation Tr. 33:16-18 (Investigation Committee member noting that the co-author “was allowed to take [the original film] with her.”). Indeed, the primary focus of the Investigation Committee’s request was on a 2008 paper, for which the underlying data was generated between 2003 and 2008. *See* Investigation Report, at 8 (“Accordingly, the Committee requested on multiple occasions that Dr. Blain identify what she contended were the raw data for the questionable figures, *specifically for the 2008 MCB paper.*”) (emphasis added). Under the applicable record retention policies,<sup>5</sup> Dr. Blain had no obligation to maintain such old data, even if it had stayed in her lab. Thus, the Investigation Committee erected a strawman: even though there was “no way” for the five-member Committee to complete the task, it demanded that Dr. Blain do it.

Given that Dr. Blain was fully cooperative with the Committees and did not violate the Cooperation Policy, she should never have been removed as PI on the grants and, we respectfully suggest, should be restored now, pending the ORI review.

#### **IV. Dr. Blain’s Removal from the Grant Has Had Significant Negative Effects on the Grant’s Projects**

Dr. Blain’s removal from her position as PI on the grants has caused a series of negative developments on the grant’s projects.

No one at SUNY could lead Dr. Blain’s grants more effectively than Dr. Blain because Dr. Blain has dedicated her life to this particular research. SUNY chose to assign the R01 CA249667 grant to Dr. Brissette, who is uniquely unqualified. Although Dr. Brissette is highly credentialed and a successful research scientist, she does not have comparable experience to Dr. Blain. In response to Judge Block’s own questions, Dr. Brissette was also forced to concede that it would “be of value if Dr. Blain was still there doing the great work” on the grant because Dr. Blain is “an outstanding scientist.” Hearing Tr. 451:7-10.

Indeed, when other participants of the grant’s project learned of Dr. Blain’s removal as PI and the replacement by Dr. Brissette, they withdrew from participation. Two such former participants are Dr. Susan Gottesman and Dr. Jonathan Somma, both of whom had been working with Dr. Blain and on the development of the assay funded by the grant for ten and seven years, respectively. Hearing Tr. 109:15-16 (Dr. Gottesman stating that she has worked with Dr. Blain for over ten years); 186:13-18 (Dr. Somma stating that he has worked on the grant-funded project

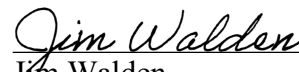
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<sup>5</sup> *See* State University of New York Records Retention and Disposition Schedule, Academic Affairs & Instruction (Feb. 2010) (available at <https://system.suny.edu/media/suny/content-assets/documents/compliance/info-management/records/Academic-Affairs-Schedule.pdf>) (requiring research files to be retained for 3 years after the research has concluded).

since 2015). A majority of the technicians working on the grant project also withdrew after Dr. Blain's removal. *See* Hearing Tr. 119:20-22. Additionally, Mount Sinai and other institutions that provided essential materials to the project and informed the investigators of patient response withdrew. Hearing Tr. 118:12-22.

In sum, Dr. Blain's removal as PI on the grants has had disastrous consequences on the underlying cancer research. Her removal was premised on SUNY's lie that Dr. Blain violated its Cooperation Policy. Dr. Blain's removal not only wastes NIH extramural research funding (because SUNY replaced her with an unqualified PI, resulting in key participants in the project quitting), it also wastes Dr. Blain's efforts that should be dedicated to developing a revolutionary drug for cancer patients. As Judge Block stated, the drug that Dr. Blain is developing is "an important drug," especially for people in "life-threatening situations" who would "want to get that drug as quickly as possible." Hearing Tr. 50:25-51:10. SUNY's misconduct threatens one of the key goals of NIH, which is to "improve the health of the Nation by conducting and supporting research in the causes, diagnosis, prevention, and cure of human diseases[.]"<sup>6</sup> The Office of Extramural Research—tasked with ensuring the integrity of, and compliance with, applicable laws, regulations, and policies that govern NIH extramural research funding—cannot allow SUNY to continue its campaign to destroy Dr. Blain's career and vitally important work. We respectfully request that you reconsider her removal from the grants.

Sincerely,

  
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<sup>6</sup> National Institutes of Health, Missions and Goals (available at: <https://www.nih.gov/about-nih/what-we-do/mission-goals>).

**From:** Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>  
**Date:** Monday, July 18, 2022 at 1:58 PM  
**To:** David Christini <David.Christini@downstate.edu>  
**Cc:** Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>, Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>, Valdez, Patricia (NIH/OD) [E] <patricia.valdez@nih.gov>, Compliance Review <ComplianceReview@mail.nih.gov>, Ring, Christine (NIH/OD) [E] <christine.ring@nih.gov>  
**Subject:** [EXTERNAL] Dr. Stacy Blain (grants R21 CA252585 and R01 CA249667)

## External email

*Do not click links, open attachments or provide your User ID or Password if the sender is unknown.*

Dear Dr. Christini

We received this letter and accompanying documents from Mr. James Waldman, an attorney representing Dr. Stacy Blain.

After you have read through these materials, please let me know:

- Does SUNY Downstate continue to believe, as stated in its Final Investigation Report, that Dr. Blain was uncooperative with the scientific misconduct investigation and therefore violated University policy?
- Does SUNY Downstate believe that she is still being uncooperative and in violation of University policy?

I would appreciate a written response within the next 10 days.

Best, Mike

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