United States Court of Appeals
for the District of Columbia Circuit

No. 16-5238

Dr. SCOTT J. BRODIE
Appellant,

v.

THOMAS E. PRICE
in his official capacity as Secretary of
the Dep't of Health and Human Services et al.,
Appellees.

Appeal from Order of Dismissal
of the U.S. District Court for the District of Columbia

APPELLANT'S BRIEF

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Certificate as to Parties, Rulings, & Related Cases

1. Parties. Appellant, who was the plaintiff below, is Dr. Scott J. Brodie. The appellees, who were defendants below, are Thomas E. Price (formerly Sylvia Burwell) in his official capacity as Secretary of the Department of Health and Human Services; Kathy Partin (formerly David Wright) in her capacity as the Director of the Office of Research Integrity of the Department of Health and Human Services; Andrea Brandon (formerly Nancy Gunderson) in her capacity as Deputy Assistant Secretary of the Office of Grants and Acquisition Policy and Accountability of the Department of Health and Human Services; and the United States Department of Health and Human Services. There are no amici or intervenors in this matter.

2. Ruling Under Review. The ruling under review is the order and memorandum of District Judge James E. Boasberg dated June 13, 2016. *Brodie v. Burwell et al.*, 15-DC-00322 (Dkt. 30). *See* App.276-306.

3. Related Cases. The case on review has not previously been before this Court or any other court. The district court, however, deemed the matters addressed herein to have been barred by the doctrines of issue and claim preclusion based on the district court's prior rulings in *Brodie v. U.S. Dep't of Health & Human Services*, 796 F. Supp. 145 (D.D.C. 2011) and *Brodie v. U.S. Dep't of Health & Human Services*, 951 F. Supp. 2d 108 (D.D.C. 2013), *summ. aff'd*, 2014 WL 21222 (D.C. Cir 2014). This appeal squarely challenges the district court's ruling and its reliance on the doctrines of issue and claim preclusion.

I, Michael R. Schneider, counsel for the appellant, Dr. Scott J. Brodie, hereby certify that the above is true and accurate to the best of my knowledge and belief.

/s/*Michael R. Schneider*
Michael R. Schneider
D.C. Circuit No. 59847

Table of Contents

Table of Authorities

Cases

Statutes

Other Authorities

Rules

Regulations

Constitutional Provisions

Treatises

Glossary

ALJ	Administrative Law Judge who presided over the Office of Research Integrity proceedings.
DAB	Departmental Appeals Board.
HHS	The United States Department of Health and Human Services.
NIH	The National Institutes of Health.
ORI	The Office of Research Integrity of the United States Department of Health and Human Services.
OSI	The Office of Scientific Integrity at the University of Washington.
PHS	The Public Health Service of the United States Department of Health and Human Services.
PI	Principal Investigators are the lead researchers for grants issued by the National Institutes of Health to universities and other research institutions.
SB Home	Scott Brodie's Home computer that University of Washington officials mistaken claimed was the computer Brodie regularly used at his home.
SB Laptop	Scott Brodie's Laptop computer that he used to transport data between his laboratory and his residence.
SB Residence	Scott Brodie's Residence computer that he had been using regularly at his home but that was in the shop for repairs when the University of Washington initiated its investigation and which appears to have never been sequestered.
UCIRO	University Complaint and Investigation Office at the University of Washington.
UW	The University of Washington.

UWIP	The University of Washington's Inquiry Panel that first examined the allegations of research misconduct against Brodie.
UWIC	The University of Washington's Investigation Committee, which presided over the second phase of the university's process.

Reason Why Oral Argument Should Be Heard

Oral argument would assist this Court in resolving extremely important issues concerning the destruction or spoliation of evidence and the doctrines of res judicata and collateral estoppel in the context of administrative law.

Jurisdictional Statement

The district court dismissed Brodie's complaint and entered judgment on June 13, 2016. Brodie filed a timely notice of appeal on August 10, 2016.

The district court had jurisdiction under 28 U.S.C. §1331 since Brodie's lawsuit was a "civil action[ ] arising under the Constitution [and] laws ... of the United States, to wit, the Fifth Amendment of the United States Constitution, the Administrative Procedure Act, 5 U.S.C. §§551-706, and the regulations of the Public Health Service of the United States Department of Health and Human Services, 42 C.F.R. parts 50 and 93.

This Court has jurisdiction under 28 U.S.C. §1291 because this is an appeal from a "final decision[ ]" of a federal district court.

Issues Presented

1. The APA Claim. Res judicata and collateral estoppel bar the relitigation of claims and issues that were or could have been previously litigated, but only if the litigants have had a "a full and fair opportunity" to do so. A full and fair opportunity to litigate does not exist where a litigant has been deprived of evidence and information that would "materially affect the outcome of the case." Under the Administrative Procedure Act, final agency actions, including decisions not to reopen proceedings, that were premised on misrepresentations or fraud must be set aside if "arbitrary and capricious." Here, Brodie presented the agency with newly discovered evidence that his original data and image files were deleted while the investigation was under way; that Brodie, university and agency investigators, the presiding Administrative Law Judge, and the agency's debarring official were not provided with Brodie's original data and image files and were never informed that this was so, even though university administrators were aware of it; and that this newly discovered evidence was plainly material to the outcome. Did the District Court err as a matter of law in finding that Brodie nonetheless had a full and fair opportunity to litigate his claims and in granting the defendants' motion for dismissal or summary judgment on res judicata and collateral estoppel grounds?

2. The Due Process Claim. Respondents in scientific-research-misconduct proceedings have a due process liberty or property interest in remaining free from unwarranted debarment that prevents them from pursuing their chosen careers and from the stigmatization associated with debarment. Consistent with the PHS regulations, constitutional due process requires that an agency considering debarment provide respondents with notice and an opportunity to be heard that includes a right of access to the relevant evidence necessary to permit them a full and fair opportunity to rebut the allegations against them. Where new evidence shows that this opportunity was not provided due to the destruction of critical evidence and the withholding of information about this destruction from respondents and the agency decisionmakers, due process requires that the agency reopen the proceedings. Here, Brodie presented the agency with newly discovered evidence that his original data and image files were deleted while the investigation was under way and that neither he nor the prior decisionmakers, including the district judges who presided over his two prior lawsuits, were ever provided with this critical evidence. Did the District Court err as a matter of law in ruling that Brodie was barred by res judicata from litigating his claim that the defendants violated his due process rights by refusing to reopen the proceedings in light of the new evidence of the deletion, manipulation, concealment and withholding of critical evidence?

Statement of the Facts and Prior Proceedings

1. The background.

The appellant, Dr. Scott J. Brodie, is a molecular pathologist who joined the University of Washington ("UW") in 1995.[1] In 2000, Brodie was named a Research Assistant Professor in UW's Department of Laboratory Medicine and the Director of its Retrovirus and Molecular Virology Laboratories.[2] From 1999 to 2002, Brodie conducted biomedical research in the highly competitive field of human herpesvirus and retrovirus pathogenesis.[3]

Brodie's research involved taking samples from HIV-infected lymphoid tissues from lymph nodes and other lymphoid organs.[4] The tissues were processed, sectioned, stained with antibodies or molecular probes, placed under a high-powered compound microscope with an attached film camera, and multiple non-digital photographs of each tissue section were taken.[5] Lab technicians then transposed onto the cardboard borders of the films the date, the patient's

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[1]App.11-12, ¶¶3, 8.

[2]App.12, ¶8. *See* App.193-195, ¶¶1-14.

[3]App.12, ¶8.

[4]*See* Mem. in Opp'n to Mot. to Dismiss or for Summ. J., at 6 (Dkt. 24). *See also* App.208-209, ¶82.

[5]*Id. See* App.209, ¶83.

identifying information, the anatomic origin of the tissue sample, and the nature of the procedure, and these films were subsequently digitized.[6]

2. The university's inquiry and investigation.

Sometime in 2002 — one of the Principal Investigators ("PIs") with whom Brodie shared lab space and who had been a collaborator, coauthor and competitor — accused Brodie of having falsified or fabricated data and images based on research conducted between 1999 and 2000.[7] In September 2002, UW initiated a research-misconduct inquiry as required by the Public Health Service Regulations.[8]

Over the course of its inquiry and investigation, UW claimed to have seized over 50 computers and hard drives,[9] including three computers that later become the focus of the case: (1) SB Home, a desktop computer seized from Brodie's home on the first day of UW's inquiry, that had been shared by others in Brodie's lab but was recently borrowed by Brodie while his actual residence computer ("SB Residence") was in a UW shop for repairs;[10] (2) SB Laptop, a laptop computer seized but never properly sequestered or inventoried, that Brodie used for traveling and transporting data between his laboratory and home;[11] and (3) SB Residence, a

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[6] *Id. See* App.208-209, ¶82.
[7] App.12, ¶9.
[8] App.12, ¶10.
[9] App.14, ¶15-16.
[10] App.14-16, ¶¶17-19, 23.
[11] App.15, ¶20. This laptop was the subject of the prior lawsuit. *See Brodie v. U.S. Dep't of Health & Human Services,* 951 F. Supp. 2d 108 (D.D.C. 2013),

desktop computer seized but never properly inventoried or returned to Brodie, that had been used by Brodie as the primary repository of his original data and images, lab notes, drafts grant applications, and communications with colleagues, but which was being repaired at a UW facility at the time that UW's inquiry began.[12] Brodie told UW investigators at the very outset that SB Residence was his "principal computer"; that he was "its sole and exclusive user"; and that it contained "all of his raw data" as well as his "draft presentations, manuscripts, and other publications."[13]

Throughout the UW investigation, Brodie made repeated requests for access to his original computer files, data, and images, but neither SB Residence nor its contents were ever returned to him.[14] It was not until newly discovered evidence became available in 2013 that Brodie learned that the material on SB Residence had not been properly secured; that UW investigators provided him with copies of, at most, only a small portion of his original data, images, and other files; that some of the discovery he and the UWIC received included a "compilation CD" containing files cherry-picked by James Mullins, one of Brodie's collaborators and accusers, that had been stripped of metadata and that looked similar to many of the

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summ. aff'd 2014 WL 21222 (D.C. Cir. 2014) ("*Brodie II*"), annexed at App.184-91.

[12]App.15-16, ¶¶21-22. *See* App.193-94 (¶¶5, 9, 13); 216, 221.

[13]App.15-16, ¶22.

[14]App.10, ¶24, 194-204, ¶¶20, 22,24, 52, 63, 68, 71.

data and image files on SB Residence but which, in fact, originated from computers used by Brodie's collaborators and competitors; that, while the UWIC investigation was still pending, files on SB Residence had been deleted by lab technicians associated with Brodie's competitors; and that, even though UW administrators and attorneys were aware of these systemic problems, neither Brodie, nor the UW inquiry panel ("UWIP"), nor the UW investigative committee ("UWIC") were ever made aware that the data, images, and other files on which their decisions rested did not originate from Brodie's actual residence computer, SB Residence.[15]

In December 2003, after conducting an investigation based on an incomplete and misleading collection of data and image files, the UWIC found that Brodie had committed 15 instances of research misconduct and banned him from future employment at UW.[16] UW sent its final report and supporting materials to the Office of Research Integrity ("ORI"), which is an office of the Department of Health and Human Services ("HHS") charged with conducting its own independent assessment.[17]

[15]App.12-13, 15-17, 24 (¶¶11, 22, 26, 48); App.43-44, 50-56, 58-62, 186; App.194, 196-197, 205-207 (¶¶7, 21-25, 27, 31, 71, 72); *See also* App.216-221, 236-237 (Exs. at SJB 00162-64, 00169-70, 00190-91, 00205-10, 00250, 00276, 00561).

[16]App.17, ¶27.

[17]App.18, ¶28.

3. The ORI proceedings.

ORI subsequently conducted its own oversight assessment based on what we now know to be the incomplete and misleading collection of data and image files provided by UW.[18] On September 17, 2008, over four years after UW had transmitted its records, ORI filed a charge letter alleging that Brodie had published or caused to be published 15 images that had been mislabeled or improperly manipulated, or that were otherwise based on falsified or fabricated data, and notifying him of HHS's intent to debar him for seven years.[19]

On October 16, 2008, Brodie moved for an evidentiary hearing, and the case was assigned to an Administrative Law Judge ("ALJ").[20] Brodie again requested discovery of "[a]ny and all documentation for portable/travel or home computers" containing his original data and source files.[21] Brodie — still unaware that the original data and image files on SB Residence had been deleted and that the discovery provided him originated from SB Home or other laboratory computers and from a compilation of files generated by Mullins, his sometime collaborator and accuser — was told that he had already received all of his data.[22]

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[18] App.24-26, ¶¶48-52.

[19] App.18, ¶32.

[20] App.19 ¶33.

[21] App.14, ¶24; AR2 02876-96. UW never produced a complete inventory of the items it had sequestered. *See* App.196-197, 213, ¶¶27-28, 97.

[22] App.150. *See also* App.205-207, ¶71.

Following discovery, ORI moved for summary disposition. On January 12, 2010, the ALJ issued a recommended decision granting ORI summary disposition.[23] The ALJ — who was himself unaware that Brodie's original data and image files on SB Residence had been deleted by lab technicians associated with one of Brodie's competitors; that much of the evidence before him originated from SB Home or other shared laboratory computers, and not from Brodie's actual home computer; and that Brodie had not, in fact, been provided access to his original data and image files — broadly discredited Brodie's complaints that he had been denied adequate discovery and found that Brodie's claims that he had not been provided with access to his original data were "false"; that Brodie was "manifestly untrustworthy"; that Brodie must have knowingly and intentionally published, caused to be published, or attempted to publish 15 false or fabricated images which he knew or should have known were false or fabricated; and that the pattern of misconduct warranted a punitive seven-year debarment.[24] While the ALJ held Brodie responsible for publishing the images, his decision ignored or dismissed evidence that Brodie's collaborators and competitors had "carefully" reviewed the data and images with Brodie before the data and images were submitted for

[23]App.141. *See also* App.19, ¶37.

[24]*See* App.27, ¶¶48-54; App.141-142, 146-151. *See also* App.140 (ALJ discrediting Brodie's claim that he "lack[ed] sufficient information" to properly respond to the detailed allegations against him and that "all of Brodie's responses were 'based on memory and on the UW summary document.' (ALJ Rec. at 10).").

publication; that many of the images that were included in documents were created, signed, dated, and published, not by Brodie, but by his collaborators; and that even for experienced researchers, it was virtually impossible at high levels of magnification to visually distinguish from which organ a slice of lymphoid tissue originated.[25]

4. Gunderson's decision adopting the ALJ's recommendations.

On March 18, 2010, defendant Nancy Gunderson, HHS's debarring official,[26] issued a final action, notifying Brodie that she had accepted the ALJ's recommendations, including the seven-year debarment.[27]

5. Brodie's filing of *Brodie I*, claiming, *inter alia*, that the agency violated his due-process rights by employing the new preponderance of the evidence standard and by denying him an evidentiary hearing.

On April 2, 2010, Brodie filed a lawsuit against the defendants seeking to enjoin his debarment on the grounds that the ALJ violated Brodie's Fifth Amendment due-process rights and the Public Health Service ("PHS") regulations by denying him an evidentiary hearing and by employing a preponderance-of-the-

[25]*See* App.24-27, ¶¶48-54; 147. *See also* App.208-09,212, ¶82-90; App.218, 223, 235. *See also* Exhs. to Brodie Aff. at SJB 00181-89, 00192, 00269-71, 00296-98, 00343, 00399, 00408, 00707-08, 00731-32).

[26]Andrea Brandon has since replaced Gunderson as the Deputy Assistant Secretary of the Office of Grants and Acquisition Policy and Accountability of the Department of Health and Human Services.

[27]App.19, ¶37. Brodie filed a motion in the district court for a preliminary injunction but that motion was denied. *See* App.177-83.

evidence standard rather than the clear-and-convincing-evidence standard in effect at the time the UW and ORI investigations were initiated; that UW violated his Fourth Amendment rights by conducting a warrantless search and seizure; and that Gunderson's decision was unsupported by sufficient evidence and was arbitrary and capricious pursuant to the Administrative Procedure Act ("APA").[28] On July 12, 2011, the district court rejected Brodie's claims and granted summary judgment on the grounds that the ALJ did not act in an arbitrary and capricious manner and did not otherwise violate the APA, the PHS regulations, or Brodie constitutional rights.[29] Based on the evidence then available, the judge found that the ALJ's finding that Brodie would be liable for research misconduct simply by virtue of having published the problematic images, even if others had created the images, was not arbitrary and capricious.[30]

6. Brodie's petition to reopen the proceedings based on the agency's failure to provide him access to SB laptop, and the filing of *Brodie II*.

On November 3, 2011, Brodie filed a petition asking the ALJ to reopen the proceedings on the additional ground that ORI had violated *Brady v. Maryland,* 373 U.S. 83 (1963), by failing to provide him with access to files on SB Laptop, arguing that he recently learned that an ORI attorney had stated at a compliance

[28]App.19, ¶38. *See* A.169-83.
[29]App.20, ¶39; 177-83.
[30]App.182.

conference that ORI had had access to SB Laptop during its investigation, when it had previously told Brodie that it did not. ORI responded that its counsel had misspoken and that ORI had never received SB Laptop from UW.[31] The ALJ and Gunderson denied Brodie's request to reopen the proceedings.[32]

On July 10, 2012, Brodie filed a second lawsuit against the defendants for failing to reopen the proceedings in light of the new evidence about SB Laptop.[33] As the judge explained, the complaint contained "three counts, all based on the claim that HHS violated *Brady [v. Maryland]* by not securing and producing Dr. Brodie laptop from [UW] during the debarment proceedings."[34] On June 27, 2013, the district court granted the defendants summary judgment on the grounds that *Brady v. Maryland* did not apply to civil debarment proceedings; that Brodie could have, but "did not[,] raise the issue of the missing laptop before the ALJ or the court in *Brodie II*"; that "neither party can point to any information that was derived from the laptop as the basis of ORI's allegations of misconduct"; that the ALJ had found that Brodie would be liable for research misconduct simply because he had published or caused to be published the problematic images, even if others had created or altered them; and that Brodie's second lawsuit was thus barred by

[31]App.20, ¶40.
[32]App.20, ¶41.
[33]App.20, ¶42.
[34]App.184-186 (*Brodie II* District Court opinion).

res judicata and collateral estoppel.[35] Brodie appealed, and in January 2014, this Court issued a summary affirmance.[36]

7. Brodie's public records requests produced newly discovered evidence of the deletion, manipulation, concealment, and withholding of critical evidence during the pendency of the investigation.

In 2008, Brodie began making Washington State public-records requests.[37] In April 2013, after failing to produce the critical material Brodie had initially requested, UW began producing emails and other internal UW documents showing that SB Residence was never properly imaged or inventoried; that researchers and lab technicians associated with Brodie's competitors and accusers had knowingly deleted data on SB Residence while the UWIC investigation was still pending; that the files on SB Residence were never turned over to Brodie as discovery; that the discovery that was given him included a compilation CD containing files generated by Brodie's collaborators and competitors that had been stripped of metadata so that they did not identify whether the files originated from SB Residence, SB Home, or some other shared laboratory computer; and that UW administrators and investigators were aware of the deletion, manipulation, and concealment of this key

[35]App.184-86, 192-93.
[36]App.192 ("*Brodie II*" Court of Appeals' summary affirmance).
[37]App.21, ¶43.

evidence but never revealed it to Brodie, the UWIC, ORI, the ALJ, or HHS's debarring official.[38]

8. Brodie's petition to reopen the proceedings in light of the newly discovered evidence, Gunderson's rejection of that petition, and Brodie's filing of the instant lawsuit.

On April 3, and on May 5, 2014, armed with the newly discovered evidence from the UW public-records requests, Brodie sent two letters to the agency requesting that Gunderson reopen the debarment proceedings.[39] On May 7 and May 15, 2014, Gunderson sent two letters refusing to reopen the proceedings on the ground that Brodie's submissions, "even if taken as true" would not "lead [her] to alter [her] prior conclusions."[40] On May 28, 2014, Brodie sent Gunderson an additional letter pointing out the many ways in which the newly discovered evidence showed that the ALJ's findings and that her decision not to reopen the proceedings were fundamentally flawed, and requesting an explanation of her refusal to reopen the proceedings.[41] On August 5, 2014, Gunderson responded by listing the prior proceedings in Brodie's case and by asserting that "[t]he ALJ's

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[38]*See* App.12-13, 21-26 (¶¶11, 44-52); App.43-44, 50-62. *See also* App.196-207, ¶¶27, 32, 34-39, 43, 47, 50, 51, 56, 57, 63, 68, 71,72, 75, 76; App.218, 221, 223-224, 233-234, 237. *See also* Exs. to Brodie Aff. at SJB 00190-91, 00251-52, 00266-68, 00269-73, 00280-83, 00292, 00300, 00537-46, 00692-95, 00726-28). It is also now clear that the district judges in *Brodie I* and *II* were not aware of this newly discovered evidence.

[39]*See* App.27, ¶56; App.40-84.

[40]App.27, ¶57; App.85-86.

[41]App.87-94.

decision that [Brodie] engaged in multiple acts of research misconduct provide[d] cause for [his] debarment" and that none of the information he had provided in his May 28th letter "persuade[d] [her] to alter [her] conclusions."[42] Gunderson's letter did not mention any of the newly discovered evidence presented by Brodie in his April 3rd or May 5th letters. Nor did it explain whether and how she considered Brodie's newly discovered evidence.

On March 4, 2015, Brodie filed the instant complaint, asserting that Gunderson's failure to reopen the debarment proceedings should be "h[e]ld unlawful and set aside" because that decision, in light of the newly discovered evidence of the deletion, manipulation, concealment, and withholding of critical evidence, was "arbitrary and capricious," "not in accordance with law," and "without observance of procedure required by law" under the APA and the PHS regulations, and because the proceedings were conducted "contrary to" Brodie's Fifth Amendment right to due process of law.[43] On December 1, 2015, the defendants filed a motion to dismiss or, in the alternative, for summary judgment.[44]

[42]App.27, ¶57; App.95-96.
[43]App.28-33, ¶¶ 59-86.
[44]*See* Dkt.20.

9. The district court's decision granting the defendants' motion to dismiss or for summary judgment.

On June 13, 2016, the district judge granted the defendants' motion to dismiss or for summary judgment. The judge acknowledged that *Brodie III* presented "new" evidence of "the deletion of some information from SB Residence," but concluded that Brodie had been "familiar with both the contents on SB Residence and the allegations of research misconduct being investigated"; that he had "known from the beginning of this saga whether that computer contained material and potentially exculpatory evidence"; that he failed to compel production during the administrative proceeding; and that he somehow could have but failed to raise the issue in his first lawsuit.[45] The judge further concluded that even though the instant lawsuit was based on newly discovered evidence, Brodie's new claims, including his due-process claim, were "the same" as those that had been previously brought or that "could have been brought" in his previous complaints, and were thus barred by res judicata, and that Brodie's new issues were "the same" as those previously litigated since the district court in *Brodie I* had ruled that any new evidence would be "immaterial" to his culpability, and that these new issue were thus barred by collateral estoppel.[46]

[45]Mem. in Opp'n to Mot. to Dismiss or for Summ. J. at 12,14-15.
[46]App.1-7; 288-93.

With respect to Brodie's due-process claim (Count III), the judge found that since Brodie began to learn in April 2013 that files on SB Residence had been deleted, he "could have raised" the due-process issue with regard to the deleted files in *Brodie II*, which was still awaiting a final ruling by the district court; that Brodie has either "abandon[ed]" his Count III constitutional-due-process claim or has failed to provide a sufficiently "robust defense" of that claim in his opposition to the defendants' motion to dismiss; and that, since Brodie had "a full and fair opportunity to litigate" this claim in his previous lawsuits, res judicata justified granting summary judgment for the defendants.[47]

10. The docketing of this appeal and this Court's denial of the defendants' summary judgment motion.

This appeal was timely noticed, and on September 30, 2016, the defendants filed a motion for summary affirmance, but on January 18, 2017, this Court (per Henderson, Brown and Pillard, JJ.) issued an order denying that motion and directing that the matter be fully briefed.

[47]App.303-05.

Summary of the Argument

1. The APA Claim. Res judicata and collateral estoppel bar the relitigation of claims and issues that were or could have been previously litigated, but only if the litigants had a "a full and fair opportunity" to do so. A full and fair opportunity to litigate does not exist where a litigant has been deprived of evidence and information that would "materially affect the outcome of the case." Under the Administrative Procedure Act, final agency actions, including decisions not to reopen proceedings, that are premised on misrepresentations or fraud must be set aside if "arbitrary and capricious."

Here, Brodie presented the agency with newly discovered evidence that his original data and image files were deleted while the investigation was under way; that Brodie, university and agency investigators, the presiding ALJ, and the agency's debarring official were not provided with Brodie's original data and image files and were never informed that this was so; and that this newly discovered evidence was material because it would have undermined, or at least mitigated, the ALJ's and Gunderson's pervasive assumptions: that Brodie had lied about not having had access to his original data and image files and that everything he stated was therefore "manifestly untrustworthy"; that the files reviewed by ORI and the ALJ came from Brodie's actual "home computer," when in fact they did not; and that Brodie's purported failure to "come to grips" with the allegations and

properly defend himself against them was not the result of his lack of access to his original data and image files. In addition, the newly discovered evidence would have permitted Brodie to demonstrate that had he had access to his original data and to his emails and communications with his collaborators, he would have been able to demonstrate that his own data and images were all properly labeled; that the tissue samples and microscopic slides actually supported the claims made in the publication; that he had reviewed most or all of the images in question with his collaborators and competitors; that any labeling or other problems with any of the images were likely due to mistakes made not by Brodie but by his collaborators and competitors; and that any problems with the images were the result of "honest error or honest differences in interpretation or judgments of data," and not of intentional, knowing, or reckless misconduct.

Under the circumstances, Brodie did not have a "full and fair opportunity to litigate" the issues previously and the doctrines of res judicata and collateral estoppel should not be invoked to bar the litigation of his claim that the agency's refusal to re-open the proceedings in light of the newly discovered evidence was arbitrary and capricious. *See post* at 20-44.

2. The Due Process Claim. Respondents in scientific-research-misconduct proceedings have a due process liberty or property interest in remaining free from unwarranted debarments that prevent them from pursuing their chosen careers and

from the stigmatization associated with debarment. Consistent with the PHS regulations, constitutional due process requires that the agency provide respondents with notice and an opportunity to be heard that includes a right of access to the evidence needed to give them a full and fair opportunity to rebut the allegations and findings against them. Where new evidence shows that this opportunity was not provided due to the destruction of critical evidence and the withholding of information about this destruction from respondents and the agency decisionmakers, due process requires that the agency reopen the proceedings.

Here, Brodie presented the agency with newly discovered evidence that his original data and image files were deleted while the investigation was under way and that neither he nor any of the prior decisionmakers, including the agency's debarring official and the district judges who presided over his two prior lawsuits, were ever provided with this critical evidence.

Under the circumstances, the District Court erred as a matter of law in ruling that due process did not require the agency to reopen the proceedings and that the claims and issues in the instant lawsuit were barred by res judicata. Contrary to the judge's conclusions, Brodie raised these issues in his complaint and opposition to the defendants' motion to dismiss or for summary judgment. In addition, Brodie's due-process claim was not and could not have been litigated in his prior lawsuits because it was based on new evidence not previously available. *See post* at 44-53.

Argument

1. The judge erred in dismissing Brodie's APA claim (Count I) on res judicata and collateral estoppel grounds because the newly discovered evidence of the deletion, manipulation, concealment, and withholding of evidence shows that the agency's refusal to reopen the proceedings was arbitrary and capricious and that Brodie never had "a full and fair opportunity to litigate" that claim.

A. The statutory and regulatory framework.

In 1993, Congress created ORI as an office within HHS to oversee investigations of scientific research misconduct pursuant to regulations to be issued by the Secretary of HHS.[48] Congress directed that those regulations define "research misconduct"; ensure that institutions receiving federal funds develop an "administrative process to monitor the institution's administrative process and investigations," "review reports of research misconduct," and establish a process at ORI to review research-misconduct allegations, conduct its own investigations, and take appropriate remedial action.[49] Pursuant to this directive, the HHS Secretary promulgated PHS regulations governing research misconduct.

The regulations in effect at the time of UW's investigation[50] required that institutions receiving federal funds "establish uniform policies and procedures for

[48] *See* 42 U.S.C. §289b(a)(1), (a)(2),(b)-(e).

[49] *Id.*

[50] 42 C.F.R. Part 50, Subpart A. As of June 16, 2005, these regulations were replaced by 42 C.F.R. Part 93. The university proceedings were conducted under

investigating and reporting instances of alleged or apparent" scientific research misconduct.[51] Those regulations defined "misconduct in science" as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research."[52] The regulations specifically excluded "honest error or honest differences in interpretations or judgments of data."[53]

Institutions receiving federal funds were (and are) required to conduct a two-part process. First, institutions receiving misconduct allegations were required to conduct an "inquiry" to determine whether an "investigation" was "warranted" and to file a written report containing a statement of the evidence reviewed, a summary of relevant witness interviews, and a statement of conclusions.[54]

Second, if warranted, institutions were required to undertake an "investigation" that would include "examination of all documentation," including

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42 C.F.R. Part 50 and ORI decided to apply the old definition of scientific misconduct, while applying Part 93 to its investigation and hearing process. *See* ORI Charge Letter at 2 (citing 70 Fed. Reg. 28370, 28380).

[51]42 C.F.R. §§50.101, 50.103.

[52]42 C.F.R. §50.102.

[53]*Id.* Under the new rule effective as of June 16, 2005, "research misconduct" is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." 42 C.F.R. §93.103. Proof of research misconduct now requires a showing by "a preponderance of the evidence" of "a significant departure from accepted practices of the relevant research community" that is "committed intentionally, knowingly, or recklessly." 42 C.F.R. §93.104.

[54]*See* 42 C.F.R. §50.103(d)(1).

"relevant research data and proposals, publications, correspondence, and memoranda of telephone calls"; conducting, "interviews ... of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations"; making transcribed summaries of those interviews "part of the investigatory file"; "[s]ecuring necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence"; giving the respondent an opportunity to review and comment on "[i]mposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated"; notifying ORI of "the final outcome of the investigation"; and "[p]reparing," "maintaining," and providing to ORI "the documentation to substantiate the investigation's findings."[55] The regulations also required that the institutions conduct a full and fair investigation of all allegations,[56] and that they

[55]42 C.F.R. §50.103(d)(7),(8),(10)-(15). *See id.* at §93.307(e)-(f). Consistent with these requirements, the new 2005 regulations specifically obligate institutions to conduct a "thorough and sufficiently documented" investigation, including "examination of all research records and evidence relevant to reaching a decision on the merits of the allegations," *id.* at §93.310(e), interviewing all relevant witnesses, *id.* at §93.310 (g), and "[p]ursu[ing] diligently all significant issues and leads," *id.* at §93.310 (h). Regardless of whether the investigation concludes that research misconduct occurred, the report, its findings and conclusions, all the relevant evidence, and any information about actions taken or pending by the institution must be forwarded to ORI. *See id.* at §93.315. The new regulations also require that institutions "[t]ake reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable." 42 C.F.R. §93.310(f).

[56]42 C.F.R. §50.103. *See also* 42 CFR §93.310.

"comply with [their] own administrative process."[57] For UW, this meant, that all "[f]aculty, staff, and students [we]re required to release to the OSI [UW's Office of Scientific Integrity] and UCIRO [the University Complaint and Investigation Office] all original databooks, records, laboratory notes, and/or other materials that are determined to be necessary" and that the OSI and the UCIRO were "responsible for the safe keeping of the records in their custody."[58]

Upon receipt of the institution's report, ORI is obligated to review the information to determine whether the investigation was performed "with sufficient objectivity, thoroughness and competence."[59] The regulations permit ORI to "request clarification or additional information" and authorize it "to perform its own investigation" and "impose sanctions of its own" if "appropriate."[60]

New PHS regulations effective June 16, 2005, provide that with regard to matters pending at the time the new rules came into effect, the new procedural requirements would be "applicable to the institution's subsequent steps in that proceeding," but that "the definition of research misconduct that was in effect at

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[57]42 C.F.R. §50.103(a) (2);

[58]UW Executive Order 61. The PHS regulations now specifically require that institutions obtain all relevant research records, "promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner." 42 C.F.R. §93.305(a). *See also* 42 C.F.R. §93.307(b); 42 C.F.R. §93.310 (d).

[59]42 C.F.R. §§50.105(a)(6).

[60]42 C.F.R. §50.106 (a)(6) & (7). *See also* 42 C.F.R. §§93.403-.404.

the time the misconduct occurred would apply."[61] Since most of ORI's investigative process occurred after June 16, 2005, the new regulations found at 42 C.F.R. Part 93 were applicable to the actions of ORI, the ALJ, and HHS's debarring official.

Under the new regulations, once ORI has received the institution's final investigation report and the related investigatory materials, ORI is required to conduct its own independent assessment of the allegations and make its own independent findings.[62] ORI has the authority to obtain materials from any source additional to those reviewed by the institution, and may supplement the evidence and develop its own analysis.[63] The new regulations specifically require that the institution "provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews,"[64] and that all relevant records be maintained by the institution for seven years.[65] If misconduct is found, ORI may also recommend administrative actions, ranging from a reprimand to government-wide debarment for varying periods of time.[66]

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[61] 70 Fed. Reg. 28370, 28380 (2005).
[62] *See* 42 C.F.R. §93.403-.404.
[63] *See* 42 C.F.R. §93.403(d)-(e).
[64] 42 C.F.R. §93.313(h).
[65] 42 C.F.R. §93.317(d).
[66] *See* 42 C.F.R. §93.407(a).

If ORI makes findings of misconduct and recommends sanctions, the regulations give respondents the right to appeal those findings and sanctions to an ALJ of the Departmental Appeals Board ("DAB"), who is to conduct a de novo review of ORI's actions.[67] If the respondent requests a hearing, the agency is required to provide him with a full evidentiary hearing before the ALJ.[68]

After the hearing, the ALJ issues a "recommended decision" to HHS's Assistant Secretary for Health, recommending whether to affirm, modify, or reject ORI's findings and recommended sanction.[69] The Assistant Secretary then determines whether the ALJ's recommended findings are "clearly erroneous" or whether the decision is, in whole or in part, "arbitrary or capricious,"[70] and the matter is referred to the agency's debarring official, the Deputy Assistant Secretary of the Office of Grants and Acquisition Policy and Accountability, who issues the agency's "final decision."[71]

The reopening of administrative proceedings is warranted if "newly discovered material evidence" presented to the debarring official indicates that the agency's original decision was based on "erroneous factual assumptions," "fraud,"

[67] *See* 42 C.F.R. §§93.500(b), 93.517(b).
[68] *See* 42 C.F.R. §§93.501-.523; 69 Fed. Reg. at 20,783 (Apr. 2004).
[69] *See* 42 C.F.R.§93.523(b).
[70] *See id.*
[71] *See* 42 C.F.R. §93.522.

or some other misrepresentation that requires such a reopening.[72] The debarring official's original debarment decision as well as her decision whether to reopen a proceeding are both considered final agency actions subject to federal-court review under the APA.[73]

B. The standard of judicial review under the APA.

Under the APA, the courts must "hold unlawful and set aside agency actions, findings, and conclusions that are arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law," or that are "contrary to [a respondent's] constitutional right" under the Fifth Amendment to a fair due-process hearing, or that are "without observance of procedure required by law."[74]

While "the focal point for judicial review should be the administrative record already in existence,"[75] the courts may consider evidence not included in the administrative record to ascertain whether the agency considered all factors relevant to its decision.[76] At a minimum, the agency must have considered relevant

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[72]*See* 2 C.F.R. §§180.875, 180.880(a). *See Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1361 (Fed. Cir. 2008); *Elkem Metals, Com. v. United States*, 193 F. Supp. 2d 1314, 1321 (Ct. Int'l Trade 2002); *Alberta Gas Chemicals, Ltd. v. Celanese Corp.*, 650 F.2d 9, 13 (2d Cir. 1981).

[73]*See* 5 U.S.C. §701-706. *See also Tokyo Kikai*, 529 F.3d at 1361 (citing 5 U.S.C. §706(2)(a); *Macktal v. Chao*, 286 F.3d 822, 826 (5th Cir. 2002)).

[74]5 U.S.C. §706(2)(A)-(D).

[75]*Camp v. Pitts*, 411 U.S. 138, 142 (1973). *See Florida Power & Light Co. v. Lorion*, 470 U.S. 729,743-44 (1985).

[76]*See IMS, P.C. v. Alvarez*, 129 F.3d 618, 623-34 (D.C. Cir. 1997) (citing *James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1094 (D.C. Cir. 1996), *citing*

data and articulated an explanation establishing a "rational connection between the facts found and the choice made."[77] An agency action is arbitrary or capricious if the agency has relied on factors which Congress has not intended it to consider, has entirely failed to consider an important aspect of the problem, has offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[78]

C. The standards of appellate review.

This Court reviews a district court's orders granting a motion to dismiss under Rule 12 of the Federal Rules of Civil Procedure and a motion for summary judgment under Rule 56, de novo.[79] So long as the complaint has pled sufficient "factual content that allows the court to draw the reasonable inferences that the defendant is liable for the misconduct alleged,"[80] this Court, must "treat the

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Environmental Defense Fund, Inc. v. Costle, 657 F.2d 275, 285 (D.C. Cir. 1981), *citing Asarco v. U.S. Environmental Protection Agency*, 616 F.2d 1153, 1160 (D.C.Cir.1980)).

[77]*Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986) (internal quotation marks and citation omitted). *See also Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C.Cir.1993) ("The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result.").

[78]*See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[79]*See Rudder v. Williams*, 666 F.3d 790, 794 (D.C.Cir.2012); *Potter v. District of Columbia*, 558 F.3d 542, 547 (D.C.Cir.2009).

[80]*Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

complaint's factual allegations as true,"[81] and must grant the plaintiff "the benefit of all inferences that can be derived from the facts alleged."[82]

In reviewing claims denied on summary judgment under Rule 56(c), the Court, viewing the evidence in the light most favorable to the non-moving party,[83] ordinarily affirms only if "there is no genuine issue as to any material fact [and] the moving party is entitled to judgment as a matter of law."[84] But in reviewing a district court's review of a final agency action under the APA, the Rule 56 standard does not ordinarily apply because "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record" — supplemented by any facts needed to show that the agency's "explanation for its decision runs counter to the evidence"[85] — "permitted the agency to make the decision it did."[86]

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[81] *Gilvin v. Fire*, 259 F.3d 749, 756 (D.C.Cir.2001).

[82] *Hettinga v. United States*, 677 F.3d 471, 476 (D.C. Cir. 2012) (quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C.Cir.1979)).

[83] *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C.Cir.2006) (citing *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 150 (2000)).

[84] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986) (citing Fed. R. Civ. P. 56(c)(2)).

[85] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43.

[86] *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89-90 (D.D.C.2006) (*quoting Occidental Eng'g. Co. v. INS*, 753 F.2d 766, 769 (9th Cir.1985) (internal quotation marks omitted)). *See also Richards v. INS*, 554 F.2d 1173, 1177 & n. 28 (D.C.Cir.1977); *Charter Operators of Alaska v. Blank*, 844 F.Supp.2d 122, 126–27 (D.D.C.2012); *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C.2011).

D. The law governing res judicata, collateral estoppel, and the misrepresentation, deletion, manipulation, and concealment of evidence.

The doctrine of res judicata encompasses two subsidiary doctrines, "claim preclusion" (res judicata, proper) and "issue preclusion" (collateral estoppel).[87] As the Supreme Court explained in *Taylor v. Sturgell*:

> Under the doctrine of claim preclusion, a final judgment forecloses "successive litigation of the very same claim, whether or not relitigation of the claim raises the same issues as the earlier suit." *New Hampshire v. Maine*, 532 U.S. 742, 748 (2001). Issue preclusion, in contrast, bars "successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment," even if the issue recurs in the context of a different claim. *Id.*, at 748–749. By "preclud[ing] parties from contesting matters that they have had a full and fair opportunity to litigate," these two doctrines protect against "the expense and vexation attending multiple lawsuits, conserv[e] judicial resources, and foste[r] reliance on judicial action by minimizing the possibility of inconsistent decisions." *Montana v. United States*, 440 U.S. 147, 153–154 (1979).[88]

Under the doctrine of claim preclusion, "a judgment on the merits in a prior suit bars a second suit involving the same parties or their privies based on the same cause of action,"[89] so long as the issues "were or could have been raised in that action."[90] The doctrine of claim preclusion does not bar the second cause of action,

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[87] *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008).

[88] *Id.* at 892.

[89] *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 n. 5 (1979), cited in *Drake v. F.A.A.*, 291 F.3d 59, 66 (D.C. Cir. 2002) (emphasis added).

[90] *Drake*, 291 F.3d at 66 (citing *Allen v. McCurry*, 449 U.S. 90, 94 (1980) (emphasis added)).

however, where the second or subsequent suit raises claims that are not "identical" or that qualitatively differ from the prior action or that center on a different "nucleus of fact," or where the claims raised in the second suit could that not have been raised in the prior litigation.[91]

Under the doctrine of issue preclusion, "the general rule is that "[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim."[92] For issue preclusion to apply, the issue raised in the second or subsequent lawsuit must be "identical" to the issue raised in the prior lawsuit.[93]

In both cases, the claims or issues previously raised must be "identical" and the party against whom preclusion is sought must have had "a full and fair opportunity to litigate" the claim or issue in the prior action.[94] So, for example,

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[91]*See Drake,* 291 F.3d at 66. *See also, I.A.M. Nat. Pension Fund, Ben. Plan A v. Industrial Gear Mfg. Co.,* 723 F.2d 944 (D.C. Cir. 1983).

[92]*B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1303 (2015); Restatement (Second) of Judgments §27 (1982) at 250 (1980); *see also id.,* §28 at 273).

[93]*Otherson v. Department of Justice, I.N.S.,* 711 F.2d 267, 273 (D.C. Cir. 1983).

[94]*See Youngin's Auto Body v. D.C.,* 775 F. Supp. 2d 1, 5 (D.D.C. 2011) (citing *Allen v. McCurry,* 449 U.S. at 94). *See also Jones v. Kirchner,* 835 F.3d 74, 82 (D.C. Cir. 2016), *cert. denied,* No. 16-901, 2017 WL 236822 (U.S. Mar. 20, 2017) (quoting *Prosise v. Haring,* 667 F.2d 1133, 1141 (4th Cir. 1981), *affirmed* 462 U.S. 306 (1983)) ("[A]mong the most critical guarantees of fairness in applying collateral estoppel" ... "is the guarantee that the party to be estopped had

where a plaintiff can show that he was misled by a defendant's false representation or concealment of evidence which caused the plaintiff to sue on less than the entire claim in the first action, the court will not permit the defendant to rely on claim preclusion should the plaintiff sue on the remainder of the claim in a second action.[95]

In determining whether the defendant had a full and fair opportunity to litigate the claim or issue in the prior action, the courts will consider whether a plaintiff asserting res judicata had previously concealed from the defendant "information that would materially affect the outcome of the case," even if the defendant claims that "the information was not concealed but rather only recently became available."[96] This is because the doctrine of res judicata "does not bar a litigant from doing in the present what he had no opportunity to do in the past."[97]

There is, moreover, "little disagreement" that an agency, itself, "has the inherent power to order reconsideration when its initial determination was tainted

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not only a full and fair opportunity but an adequate incentive to litigate to the hilt the issues in question.").

[95]*See* Restatement (Second) of Judgments §27 (1982); Robert C. Casad & Kevin M. Clermont, *Res Judicata: A Handbook on Its Theory, Doctrine, and Practice* 237 (2001).

[96]Restatement (Second) of Judgments §28. *See also* Steven J. Madrid, "Annexation of the Jury's Role in Res Judicata Disputes: The Silent Migration from Question of Fact to Question of Law," 98 Cornell L. Rev. 463, 468-70 (2013).

[97]*Drake*, 291 F.3d at 66-67.

by fraud" or "misrepresent[ations]";[98] that an agency decision that is premised on such fraud or misrepresentations can be challenged under the APA's "substantial evidence" and "arbitrary and capricious tests";[99] and that, in some cases, punitive sanctions can be imposed on the parties.[100]

E. Res judicata and collateral estoppel do not bar the instant lawsuit because the newly discovered evidence shows that Brodie did not have a "full and fair opportunity to litigate" the issues previously and because the new evidence was material as it fundamentally undermined the integrity of the underlying proceedings.

Gunderson's refusal to reopen the debarment proceedings constituted a "final decision" of the agency and is subject to judicial review. As discussed above, the newly discovered evidence showed that researchers associated with Brodie's competitors and accusers knowingly deleted data on SB Residence while the UWIC investigation was still pending; that SB Residence was never properly

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[98] *See* Daniel Bress, Note, Administrative Reconsideration, 91 Va. L. Rev. 1737 (2005) (citing *Elkem Metals Co.*, 193 F. Supp. 2d at 1321, for the proposition that "where the first adjudication was tainted by misrepresentation, courts have said reconsideration is justified to prevent fraud from being perpetrated on the agency").

[99] *See Belville Ming Co. v. United States*, 999 F.2d 989, 1001-02 (6th Cir. 1993); *Chen v. D.C.*, 839 F. Supp. 2d 7, 12-13 (D.D.C. 2011); *Residential Funding Corp. v. DeGeorge Fin. Corp.*, 306 F.3d 99, 107 (2d Cir. 2002). *See also Kirkendall v. Dep't of the Army*, 573 F.3d 1318, 1325–27 (Fed.Cir. 2009) (finding evidence spoliation where agency destroyed relevant documents in violation its own document retention program and petitioner made a "compelling case" that his effort to prove his case was hampered by the destruction of the documents).

[100] *See United States v. Bunty*, 617 F. Supp. 2d 359 (E.D.PA. 2008).

imaged or inventoried; that most if not all of the files on SB Residence were never turned over to Brodie as discovery; that the discovery provided to Brodie included files generated by Brodie's collaborators and competitors that had been stripped of metadata and thus did not identify whether the files originated from SB Residence, SB Home, or some other laboratory computer; and that UW administrators and investigators were aware of the deletion, manipulation, concealment, and withholding of key evidence but never revealed it to Brodie, the UWIC, ORI, the ALJ, or the agency's debarring official.[101]

In asking Gunderson to reopen the proceedings, Brodie made her aware of both this newly discovered evidence and of the fact that this caused the ALJ to issue a recommended decision that was thoroughly unreliable, tainted by misrepresentations, and profoundly arbitrary and capricious.[102] Gunderson's explanation for her refusal to reopen the proceedings, which failed to address any of the newly discovered evidence ran "counter to" the newly discovered evidence and was inadequate. Because the newly discovered evidence had previously been concealed and withheld from Brodie and from all of the key decisionmakers in this case — including from the ALJ, Gunderson, and the district court in the two prior

[101] *See* App.12-13, 21-26, ¶¶11; App. 44-52, 43, 44, 50-62; App.196-207, ¶¶27, 32, 34-39, 43, 47, 50, 51, 56, 57, 63, 68, 71, 72, 75, 76; App. 227-232, 234 (Exs. to Brodie Aff. at SJB 00161-67, 00190-91, 00251-52, 00266-68, 00273, 00292, 00542-50, 00557-60, 00683, 00696-99); AR 2879-96.

[102] *See* App.40-84.

lawsuits — Brodie has never had "a full and fair opportunity to litigate" this issue previously, and neither res judicata nor collateral estoppel should be invoked to bar this complaint. Under the circumstances, Gunderson's failure to reopen the debarment proceedings was "arbitrary and capricious," "not in accordance with law," "contrary to [Brodie's] constitutional right" to due process, and "without observance of procedure required by law," and should thus be "h[e]ld unlawful and set aside."[103]

The district judge treated Count I as seeking alternative relief from either "the ALJ's 2010 debarment decision" or from Gunderson's "recent refusal to reopen the debarment proceedings."[104] The judge then proceeded to arrive at two distinct conclusions, first that res judicata bars Brodie's attack on the ALJ's "debarment decision,"[105] and second that collateral estoppel bars Brodie's attack on Gunderson's 2014 refusal to reopen the proceedings.[106]

But this is, as the complaint suggests, a false dichotomy.[107] Gunderson's refusal to reopen the proceedings was based on her finding that the newly discovered evidence "does not raise any arguments that, even if taken as true, would lead [her] to alter her prior conclusions," and this finding was, in turn,

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[103]*See* 5 U.S.C. §706(2)(A)-(D).
[104]*See* App.289.
[105]App.289-91.
[106]App.300.
[107]*See also* App.28-30, ¶¶ 60, 67-70.

plainly based on the ALJ's 2010 finding that Brodie had "engaged in multiple acts of research misconduct" that warranted the seven-year debarment.[108]

The judges conclusion that res judicata bars Brodie's Count I claim is based on his conclusion that Brodie "knew all along that SB Residence 'contained all of [his] lab notes, original data, drafts of grants and communications with colleagues'"; that Brodie knew that "SB Residence was in the University's possession at the time of the investigation"; that Brodie failed to compel production of SB Residence; and that he "could have argued" in *Brodie I*, but failed to do so that the ALJ's decision was arbitrary and capricious because the ALJ "did not consider the evidence stored on SB Residence."[109] This is wrong for several reasons.

First, the new evidence now shows that Brodie could not have understood whether files that he had been provided as discovery included his SB Residence files since most, if not all, of the files he had been provided had not been properly imaged and inventoried and had been stripped of metadata and file path names, and since UW, ORI, and the ALJ repeatedly kept asserting — falsely, as it turns out —

[108]*See* App.85-86, 95-96. In addition, the ALJ does not have the power to make a debarment decision but merely to recommend findings and an agency action to the agency's debarring official, who is the one authorized to make the debarment decision.

[109]*See* App.287, 290-91.

that all of Brodie's original files had been produced.[110] As this Court has recognized, res judicata "does not bar a litigant from doing in the present what he had no opportunity to do in the past."[111]

Second, Brodie repeatedly requested access to all of his original data, including to the data and image files on his home computers (which would have included both SB Residence and SB Laptop), throughout the entire process, starting days after the raid on his lab when he explained to UW administrators that his real home computer was in the repair shop; to the various stages of UW's inquiry and investigative process, when he repeatedly requested the return of his raw data, original source materials, and computer files; through ORI's oversight review process when he made similar demands for his data and computer files; and finally before the ALJ, when Brodie's counsel moved for discovery of all data and computer files, including all films, slides, notebooks, inventories, documentation of computers and hard drives seized from Brodie and the lab, and other all source documents for the images and figures at issue.[112] Brodie should not be faulted for having relied on the representations of UW and ORI investigators that all of his

[110]*See* App.150. *See also* App.205-207, ¶71.

[111]*Drake*, 291 F.3d at 66-67. *See also I.A.M. Nat. Pension Fund, Ben. Plan A*, 723 F.2d 944.

[112]*See* App.14,16-19, 23, ¶¶24, 47(g); *See also* App.196-197, 213, ¶¶27-30, 97; AR2 02876-96.

original data had been produced, especially when he was not in a position to understand whether these representations were accurate.

Third, any more targeted efforts to obtain discovery of his home computer files would have been futile since UW administrators never properly imaged and inventoried his SB Residence files, and since most, if not all, of the files on SB Residence had been deleted during the pendency of the investigation.

Fourth, Brodie's complaint does not — as the defendants suggested and as the district judge apparently assumed — focus exclusively on the fact that Brodie was deprived of access to his SB Residence files. Rather, the newly discovered evidence shows that neither Brodie nor prior decisionmakers were ever made aware that Brodie's chief accuser, James Mullins, provided UW administrators with a compilation of images from his own computer and from lab computers to which many others had access; that UW administrators collaborated with Mullins in stripping this critical source material of metadata that would have identified the source of the files; that UW also misplaced and failed to preserve tissue samples, microscopic slides, photographic prints, Kodachrome slides, lab and study notebooks, many of which simply "disappeared" during the investigation; that the computer files that the UWIC had ordered UW administrators to produce were never provided to Brodie; and that none of the prior decisionmakers, including the UWIC, ORI, the ALJ, the debarring official, and the district judges in *Brodie I* and

Brodie II, were ever made aware of any of this critical information.[113] Until the newly discovered evidence emerged, Brodie had no opportunity to fully and fairly litigate the issue by showing "that the ALJ's decision was arbitrary and capricious because the ALJ did not consider the evidence stored on SB Residence."[114]

While the judge acknowledged that Brodie could not have challenged in *Brodie I* and *Brodie II* Gunderson's 2014 decision not to reopen the proceedings since the prior lawsuits predated Gunderson's decision,[115] the judge found that the issues raised in Count I were nonetheless barred by collateral estoppel (issue preclusion) because the district court in *Brodie I* and *Brodie II* had previously concluded that the ALJ had found it "irrelevant" that "others may have shared computers or actually done the manipulations that [Brodie] falsely represented as products of his research"; that even if it were "assum[ed] that [Brodie] personally created none of the false images and data," he "was the person who published the false information" and "[e]ither... published information that he knew to be false or fabricated, or he published it with indifference to the truth of its contents"; and that this claim "would require a relitigation of *Brodie I's* legal conclusion that the

[113]*See* App.12-26, ¶¶11, 22, 26,48; App.43-45; 49-62; App.194-207, ¶¶7, 21-22, 27, 29-32, 38, 43, 45, 47, 48, 50-53, 57-58, 71; App. 218, 221, 223-24, 230, 233-34, 235-75. *See also* Exs. to Brodie Aff. at SJB 00251-52, 00267-68, 00273, 00519, 00541-42, 00550, 00560.

[114]*See* App.287, 289-91.

[115]App.292.

evidence on the computer is immaterial."[116] But in light of the nature and extent of the newly discovered evidence, this conclusion, too, misses the mark.

First, the newly discovered evidence clearly shows that despite the ALJ's findings to the contrary, Brodie was never given access to the most significant cache of his original data and images, and thus cannot thus be said to have had "a full and fair opportunity to litigate" the Count I issues in those prior proceedings. Based on this alone, the doctrine of collateral estoppel should not be invoked to bar Brodie's Count I averments.[117]

Second, the ALJ's decision is largely premised on his assumption that the data and image files that he and ORI had reviewed were from Brodie's home computers. Indeed, the ALJ's report is littered with well over four dozen references to "his [Brodie's] computer." [118] But this assumption was wrong.

Third, the ALJ's conclusion that Brodie never "c[a]me to grips with ORI's precise allegations that certain figures, images or other information published or submitted by [Brodie] were materially false" is premised on the ALJ's assumption

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[116]App.293, 296, 297, 306.

[117]*See Kirchner*, 835 F.3d at 82. *See also Allen*, 449 U.S. at 95 ("But one general limitation the Court has repeatedly recognized is that the concept of collateral estoppel cannot apply when the party against whom the earlier decision is asserted did not have a 'full and fair opportunity' to litigate that issue in the earlier case.").

[118]*See* App.141-168.

that Brodie was lying about having been denied access to critical information, including his original data, and that Brodie's assertion that he was "hamstrung" in his ability to frame responsive answers to the allegations without access to his original data was "a red herring."[119] We now know, however, that the ALJ's assumptions, were not only false and but exude an odor of herring, themselves. It is unlikely that the ALJ's wholesale discrediting of Brodie — whom the ALJ found to be "manifestly untrustworthy" and a bit of a conspiracy theorist, did not taint every aspect of the ALJ's recommended decision, including his materiality finding, especially since Brodie's concerns were ultimately validated over a decade after the UW investigation.

Fourth, it is hard to imagine that the ALJ's recommended findings would not have differed significantly had he known that UW investigators never properly imaged and inventoried SB Residence, and that the data and image files on which he based his decision came primarily from compilation CDs and from the computers of Brodie's collaborators and accusers. As an experienced ORI investigator has explained, to determine whether published papers constitute evidence of research misconduct, a fact finder "would need direct access to the

[119] *See* App.150.

original data, and a fact-finding process that would require a fuller review by the institution."[120]

Fifth, had the original data, including the files on SB Residence, been available, they could have shown that Brodie and his staff actually performed all of the experiments he claimed to have performed; that Brodie's own work was correctly labeled; that the tissue samples and microscopic slides actually supported the claims made in his manuscripts, PowerPoint presentations, and grant applications; and that if there were any labeling problems, they were likely due to mistakes made by Brodie's competitors or their lab technicians, all of whom had a financial stake in Brodie's ouster from UW and in taking over both his multimillion dollar federal grants and his huge storehouse of data.

Sixth, even if the ALJ's conclusion that Brodie had some role in a number of questionable images that had been published in various manuscripts, grant applications, or PowerPoint presentations, it would still be necessary to understand who had created or altered the images; who had prepared the final version of the images for publication or submission; and whether anyone had reviewed those images before final preparation and submission with Brodie and his coauthors, and if so, who and what was communicated to him,[121] especially since there was

[120]*See* App.26, ¶53. *See also* App.208, ¶80 & Exs. at SJB 00080, 00150.

[121]The ALJ, himself, found that at least two of the images in question were not submitted by Brodie but rather by one of his collaborators. *See also* App.161,

evidence that Brodie's collaborators and coauthors had reviewed the images with him before the images were submitted and subsequently used some of the images in question in their own grant applications. While scientists like Brodie should certainly do their best to check and recheck the work of collaborators and those they hire to assist them, this is the exception rather than the rule since researchers, especially PIs who work with collaborators, "need to be able to trust the reports of other researchers, else they'd have to build all the knowledge themselves."[122]

Seventh, this information about who created, prepared, and reviewed the files would also have been directly relevant to whether any problems with these images were the result of "honest error or honest differences in interpretation or judgments of data," and not of intentional, knowing, or reckless misconduct.[123]

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164. *See also* App.87-88 (Brodie letter to Gunderson stating the he "should have been able to present 'his research' as evidence of what he knew to be true and to show exactly what 'he' sent to others," including his collaborators and principal accusers, Dr. James Mullins and Dr. James Mittler).

[122]*See, e.g.*, Janet D. Stemwedel, "Building Knowledge in Science Requires Trust and Accountability," Forbes, Jun 25, 2015.

[123]*See* 42 C.F.R. §50.102 ("honest error or honest differences in interpretation or judgments of data" does not constitute research misconduct). *See* 42 C.F.R. §93.103(d). *See also Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir.1992) ("Proof of one's mistakes or inabilities is not evidence that one is a cheat.... Without more, the common failings of engineers and other scientists are not culpable under the Act.... The phrase "known to be false" ... does not mean "scientifically untrue"; it means "a lie." The Act is concerned with ferreting out "wrongdoing," not scientific errors.... What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.").

Such an inquiry would have been especially necessary here given that the images of lymphoid tissues, when photographed at high levels of magnification, could not readily have been visually distinguished from one another and given that multiple photographs of adjacent sections of the same tissue were routinely taken.[124]

Even if it is true that the newly discovered evidence might require the courts to "make legal or factual determinations contrary to those it already affirmed in *Brodie I*," the equitable doctrine of collateral estoppel should not be invoked to prevent a determination whether a prior adjudication "was tainted by misrepresentation" requiring the re-opening the case "to prevent fraud from being perpetrated on the agency."[125] This is because "[c]ollateral estoppel is an equitable doctrine controlled by the principles of fairness to both parties," and that it should not be invoked to "work any unfairness."[126]

Under the circumstances, Brodie did not have a "full and fair opportunity to litigate" the issues previously, and the doctrines of res judicata and collateral estoppel should not be invoked to bar the litigation of his claim that the agency

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[124]*See* App.211, ¶82.

[125]*See* Bress, Note, Administrative Reconsideration, 91 Virg. L. Rev. 1737 (citing *Elkem Metals Co.*, 193 F. Supp. 2d at 1321). *See also Belville Ming Co.*, 999 F.2d at 1001-02; *Chen*, 839 F. Supp. 2d at 12-13; *Residential Funding Corp.*, 306 F.3d at 107.

[126]*See Jack Faucett Associates v. American Telephone & Telegraph*, 744 F.2d 118, 125 (D.C. Cir. 1984), cert. denied, 469 U.S. 1196 (1985).

refusal to re-open the proceedings in light of the newly discovered evidence was arbitrary and capricious.

2. The judge erred in dismissing Brodie's constitutional-due-process claim (Count III) on res judicata grounds because the newly discovered evidence shows that the agency's refusal to reopen the proceedings violated Brodie's due-process right to evidence that would have permitted him to rebut the allegations against him and that Brodie did not have "a full and fair opportunity to litigate" that claim.

A. The law governing due process.

The Due Process Clause of the Fifth Amendment provides that "[n]o person shall be ... deprived of life, liberty, or property, without due process of law."[127] After first determining "whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty,'" the court will "then consider whether the procedures used by the government in effecting the deprivation 'comport with due process.'"[128]

As this Court has long recognized, "'the right to hold specific private employment and to follow a chosen profession free from unreasonable governmental interference comes within the 'liberty' and 'property'"' interests

[127]U.S. Const. amend. V.

[128]*Ralls Corp. v. Committee on Foreign Inv. in U.S.*, 758 F.3d 296, 315 (D.C. Cir. 2014) (quoting *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999)).

protected by the Fifth Amendment."[129] "[W]hen the government formally debars an individual from certain work or implements broadly preclusive criteria that prevent pursuit of a chosen career, there is a cognizable 'deprivation of liberty that triggers the procedural guarantees of the Due Process Clause.'"[130] This Court has also recognized that "debarment is a form of punishment which stigmatizes the target,"[131] and delivers "a blow" to the individual's "protected 'liberty' interest, which, of course, triggers an inquiry as to whether the process it has been afforded is adequate."[132]

In determining what process is due, the courts routinely look to three factors:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the [g]overnment's interest, including the function involved and the fiscal and

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[129] *Abdelfattah v. U.S. Dept. of Homeland Sec.*, 787 F.3d 524, 538 (D.C. Cir. 2014) (quoting *Greene v. McElroy*, 360 U.S. 474, 492 (1959)). *See also Kartseva v. Dep't of State*, 37 F.3d 1524, 1529 (D.C.Cir.1994) (recognizing a constitutional "right to follow a chosen trade or profession").

[130] *Abdelfattah*, 787 F.3d at 538 (quoting *Trifax Corp. v. Dist. of Columbia*, 314 F.3d 641, 643–44 (D.C.Cir.2003)).

[131] *Fischer v. Resolution Trust Corp.*, 59 F.3d 1344, 1349 (D.C. Cir. 1995) (citing *Old Dominion Dairy Products, Inc. v. Secretary of Defense*, 631 F.2d 953, 962-63 (D.C. Cir. 1980)).

[132] *Fischer*, 59 F.3d at1349; *Trifax*, 314 F.3d at 643. *See also, United States v. Edwards*, 777 F. Supp. 2d 985, 998 (E.D.N.C. 2011); *Nguyen v. Wash. Dept. of Health Med. Quality Assurance Comm.*, 29 P.3d 689, 694 (Wash. 2001) (citation omitted).

> administrative burdens that the additional or substitute procedural requirement would entail.[133]

Due process ordinarily requires, at a minimum, notice of the proposed official action and "the opportunity to be heard at a meaningful time and in a meaningful manner."[134] This "notice and hearing" requirement has been interpreted to require access to the evidence that is necessary to permit a respondent a full and fair opportunity to rebut or mitigate the charges against him.[135] This requirement is consistent with the specific requirements of the PHS regulations, themselves, which provide a meaningful guide as to what process respondents are due in this kind of inquiry.[136]

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[133]*Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

[134]*Id.* at 348 (citing *Joint Anti–Fascist Refugee Committee v. McGrath*, 341 U.S. 123, 171–172 (1951) (Frankfurter, J., concurring)).

[135]*See Greene*, 360 U.S. at 496 (citing the "immutable" revocation-of-security-clearance case that "the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue"); *Ralls Corp.*, 758 F.3d at 318 ("recogniz[ing] that the right to know the factual basis for the action and the opportunity to rebut the evidence supporting that action are essential components of due process"); *Gray Panthers v. Schweiker*, 652 F.2d 146, 172 (D.C. Cir. 1980) (holding that claimants with Medicare reimbursement claims under $100 dollars were entitled to "core requirements of due process," which include "adequate notice of why the benefit is being denied and a genuine opportunity to explain why it should not be"). *See also McDaniels v. Flick*, 59 F.3d 446, 457 (3d Cir.1995).

[136]*See Doe v. Gates*, 981 F.2d 1316, 1320 (D.C.Cir.1993) (quoting *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972) ("A property or liberty interest ... can be derived from 'statutes, regulations, ordinances, or existing rules or understandings ... that secure certain benefits and that support claims of entitlement to those benefits'").

As Brodie's complaint alleged, under the PHS regulations, UW was required to "retain[] and examin[e] the original databooks or other laboratory materials to ensure the accuracy of the original record";[137] "ensure that all evidence relevant to a potential debarment was properly secured, accounted for, and maintained";[138] give Brodie copies of or access to his original research records;[139] inform him if the underlying evidence against him had been deleted, manipulated, or withheld from the decisionmakers;[140] and "conduct a full and fair review of all the evidence relating to a claim of scientific misconduct, including reopening the investigation and rescinding debarment where new and material evidence becomes available."[141]

B. The standard of review.

This Court reviews de novo the district court's dismissal and granting of summary judgment based on its determination that the procedures employed by an agency comported with Due Process.[142]

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[137]App.30, ¶73 (citations omitted).
[138]App.31, ¶77 (citing 45 C.F.R. §74.53(1)).
[139]App.30, ¶73 (citing 42 C.F.R. §93.305).
[140]App.31, ¶78 (citing 42 C.F.R. §93.516(b)(1)).
[141]App.31, ¶76 (citing 2 C.F.R. §§180.765-880).
[142]*See Malladi Drugs & Pharmaceuticals, Ltd. v. Tandy Eyeglasses*, 552 F.3d 885, 889 (D.C. Cir. 2009). *See also Johnson v. Executive Office for U.S. Attorneys*, 310 F.3d 771 (D.C. Cir. 2002).

C. Brodie amply stated a procedural-due-process claim in his complaint and in his opposition to the defendants' motion to dismiss or for summary judgment.

Here, Brodie clearly had a substantial liberty or property interest in protecting his livelihood from debarment and his reputation from permanent stigmatization. The defendants' failure to provide Brodie with the relevant evidence necessary to permit him a full and fair opportunity to rebut or mitigate the charges against him and to ensure him a fair and reasonable factfinding process based on a review of the original data and images, and not on some bastardized compilation of files from Brodie's competitors and from shared laboratory computers, ran an enormous risk of erroneously depriving Brodie of his substantial interests. While the agency had an interest in avoiding unnecessary fiscal and administrative burdens in overseeing the investigation and in reaching an accurate result, those interests could have been fully satisfied had they adhered to the procedures that the PHS regulations required them to adhere to. In light of the newly discovered evidence, due process required the agency to give Brodie an opportunity to reopen the proceedings so that he could show that he had never been given access to the critical evidence needed to rebut the charges and that the agency decisionmakers, themselves, had also been deprived of that evidence.

The district judge's conclusion that Brodie failed to adequately allege that he had a liberty or property interest in access to SB Residence and to an agency

review that was properly based on his original data and images, and that he "abandon[ed]" his Count III due-process claim or failed to provide a sufficiently "robust defense" does not withstand scrutiny. In his complaint, Brodie specifically alleged that he had been debarred for seven years; that "the destruction of data during a federally mandated investigation by investigators ... irreparably damaged his reputation in the scientific community and the government's perception of his trustworthiness for receiving and administering federal funds, and ultimately affected his capacity for continued employment as a skilled medical researcher";[143] that he had "a protected liberty and property interest in the preservation of data favorable to him" and "a due process right to a fair, unbiased, and impartial institutional and administrative proceeding that included his right of access to favorable and exculpatory evidence that would have permitted him to have mounted a full and fair defense"; that the "spoliation of evidence and the failure to obtain and consider the relevant research records, and to provide those records to Dr. Brodie deprived [him] of his right not to be deprived of liberty or property without due process law as guaranteed by the Fifth Amendment"; and that "[t]he defendants' failure to advise Dr. Brodie of the spoliation of critical evidence, their failure to provide him a hearing to address the destruction of evidence favorable to him, and their failure to reopen the administrative and

[143]App.19, 32-33 (¶¶37, 80-81, 85).

debarment proceedings upon learning of the spoliation of this critical evidence violated Dr. Brodie's constitutional right to due process of law."[144]

In addition, in his opposition to the defendants' motion to dismiss, Brodie explained that "debarment is a form of punishment which stigmatizes the target," ... and delivers "a blow" to the individual's "protected 'liberty' interest, which, of course, triggers an inquiry as to whether the process it has been afforded is adequate";[145] and that "the agency's decision to sanction [him] so harshly with a seven-year debarment, coupled with the public dissemination of information so injurious to [his] personal and professional reputation, has been severely stigmatizing to him and has caused him irreparable injury to his scientific career, his livelihood, and his personal reputation," especially "[g]iven the shameful lack of adequate process."[146] Even if not artfully crafted, Brodie adequately asserted that he had due-process liberty and property interests that have been recognized by this Court; that the newly discovered evidence showed that the deletion, manipulation, and withholding of critical evidence violated his rights of access to exculpatory evidence and a fair hearing; and that he has never evinced an intent to abandon this claim.

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[144]App.32-32, ¶¶81-85.

[145]Mem. in Opp'n to Mot. to Dismiss or for Summ. J., at 39 (citing *Fischer*, 59 F.3d at 1349, and other cases).

[146]*Id.* at 39-40. *See also id.* at 30, 31, 34, 38.

D. Brodie could not have previously raised his due process claim without the newly discovered evidence that he had been debarred based on proceedings in which all parties, including himself, the ALJ, the debarring official, and the court in Brodie I and II, had been deprived of Brodie's original data and images.

The District Court judge also concluded that "[e]ven if the spoliation-of-evidence issue 'involves some new facts that were not in included in *Brodie I* or *Brodie II*, Brodie's due-process claim is barred by res judicata because *Brodie II* was "still pending" in April 2013 when the newly discovered evidence began to emerge,[147] and because Brodie "could have raised" the due-process claim generally in his previous lawsuits.[148] The judge's conclusions do not stand up to scrutiny.

First, as noted above in Point I, Brodie could not have raised the due-process claim until he began receiving, organizing, and making sense of the newly discovered evidence for the same reasons stated above — that the deletion, manipulation, and withholding of Brodie's original data and images prevented him from having had "full and fair opportunity to litigate" the qualitatively new due-process claim raised in this complaint.

Second, while it is true that *Brodie II* was still pending in April 2013 when Brodie began to receive the newly discovered evidence, Brodie would have first

[147] App.304-05.
[148] App.303-05.

been required under the doctrine of administrative exhaustion to present the new evidence and make his due process claim before the agency's debarring official before raising the claim in the district court.

Third, by April 2013, the issues in *Brodie II* had already been fully briefed, the period for amending the *Brodie II* complaint "as a matter of course" had long since passed, and the parties were simply awaiting a decision from the court.[149] Given that the gravamen of the *Brodie II* complaint was the deprivation of access to SB Laptop, it is far from clear that the district court would have permitted Brodie to amend and enlarge the complaint to address the new issues relating to a different computer raised by the new evidence.

Under the circumstances, the District Court erred as a matter of law in ruling that due process did not require the agency to reopen the proceedings and that Brodie's Count III due-process claims was barred by res judicata.

[149] *See Brodie II*, D.D.C. No. 12-1136, Docket Sheet (showing that after extensive briefing by the parties, the final motion — the defendants' motion to file a surreply — was filed, with leave of the court, on February 28, 2013, and the court's memorandum and order granting the defendants' motion for summary judgment was issued on June 27, 2013). *See also* Fed. R. Civ. P. 15(a)(1).

Conclusion

For all of the above-stated reasons, the district judge erred in dismissing the complaint and granting summary judgment because Brodie has never had the requisite "full and fair opportunity to litigate" the qualitatively new claims and new issues he raises in his complaint.[150] This Court should therefore vacate the judge's order and remand to the district court to allow Brodie an opportunity to prove his case.

Respectfully submitted,
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[150] *See Youngin's Auto Body*, 775 F. Supp. 2d at 5 (citing *Allen*, 449 U.S. at 94).

Addendum Table of Contents

Administrative Procedure Act, 5 U.S.C. §701
This chapter applies, according to the provisions thereof, except to the extent that -

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law

(b) For the purpose of this chapter -

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include -

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; chapter 2 of title 41; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix; and

(2) "person", "rule", "order", "license", "sanction", "relief", and "agency action" have the meanings given them by section 551 of this title

5 U.S.C. §702
A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages

and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein

(1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or

(2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought

5 U.S.C. §703
The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. If no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement

5 U.S.C. §704
Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or

determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority

5 U.S.C. §705
When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings

5 U.S.C. §706
To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall -

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be -

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

2 C.F.R. §180.875
As a debarred person you may ask the debarring official to reconsider the debarment decision or to reduce the time period or scope of the debarment. However, you must put your request in writing and support it with documentation.

2 C.F.R. §180.880
The debarring official may reduce or terminate your debarment based on—

(a) Newly discovered material evidence;

(b) A reversal of the conviction or civil judgment upon which your debarment was based;

(c) A bona fide change in ownership or management;

(d) Elimination of other causes for which the debarment was imposed; or

(e) Other reasons the debarring official finds appropriate.

42 C.F.R. §50.101
This subpart applies to each entity which applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act. It requires each such entity to establish uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act. This subpart does not supersede and is not intended to set up an alternative to established procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

42 C.F.R. §50.102
As used in this subpart:

Act means the Public Health Service Act, as amended, (42 U.S.C. 201 et seq.).

Inquiry means information gathering and initial factfinding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Institution means the public or private entity or organization (including federal, state, and other agencies) that is applying for financial assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or noncompeting. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

OSI means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

OSIR means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for

dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.

PHS means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

42 C.F.R. §50.103

(a) Assurances. Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant:

(1) Has established an administrative process, that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with its own administrative process and the requirements of this Subpart.

(b) Annual Submission. An applicant or recipient institution shall make an annual submission to the OSI as follows:

(1) The institution's assurance shall be submitted to the OSI, on a form prescribed by the Secretary, as soon as possible after November 8, 1989, but no later than January 1, 1990, and updated annually thereafter on a date specified by OSI. Copies of the form may be requested through the Director, OSI.

(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.

(c) General Criteria. In general, an applicant institution will be considered to be in compliance with its assurance if it:

(1) Establishes, keeps current, and upon request provides the OSIR, the OSI, and other authorized Departmental officials the policies and procedures required by this subpart.

(2) Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(4) Informs, in accordance with this subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

(d) Inquiries, Investigations, and Reporting—Specific Requirements. Each applicant's policies and procedures must provide for:

(1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(4) Notifying the Director, OSI, in accordance with §50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in §50.104(b) exist.

(5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department's Office of Inspector General.

(6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

(7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

(8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(10) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.

(12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(15) Notifying the OSI of the final outcome of the investigation.

42 C.F.R. §50.104

(a)(1) An institution's decision to initiate an investigation must be reported in writing to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

(2) An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

(3) Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under §50.103(d), a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

(4) The final report submitted to the OSI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have

engaged in misconduct, as well as a description of any sanctions taken by the institution.

(5) If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

42 C.F.R. §50.105
Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

42 C.F.R. §93.103
Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

42 C.F.R. §93.104
A finding of research misconduct made under this part requires that -

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

42 C.F.R. §93.305
An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains adequate records for a research misconduct proceeding. The institution must -

(a) Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;

(b) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;

(c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and

(d) Maintain the research records and evidence as required by §93.317.

42 C.F.R. §93.307
(a)*Criteria warranting an inquiry*. An inquiry is warranted if the allegation -

(1) Falls within the definition of research misconduct under this part;

(2) Is within §93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b)*Notice to respondent and custody of research records*. At the time of or before beginning an inquiry, an institution must make a good faith effort to

notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

(c)*Review of evidence.* The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.

(d)*Criteria warranting an investigation.* An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is -

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in §93.102; and

(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

(e)*Inquiry report.* The institution must prepare a written report that meets the requirements of this section and §93.309.

(f)*Opportunity to comment.* The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.

(g)*Time for completion.* The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry

record must include documentation of the reasons for exceeding the 60-day period.

42 C.F.R. §93.310
Institutions conducting research misconduct investigations must:

(a)*Time.* Begin the investigation within 30 days after determining that an investigation is warranted.

(b)*Notice to ORI.* Notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of §93.307 and §93.309.

(c)*Notice to the respondent.* Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.

(d)*Custody of the records.* To the extent they have not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Whenever possible, the institution must take custody of the records -

(1) Before or at the time the institution notifies the respondent; and

(2) Whenever additional items become known or relevant to the investigation.

(e)*Documentation.* Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.

(f)*Ensuring a fair investigation.* Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.

(g)*Interviews.* Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.

(h)*Pursue leads.* Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

42 C.F.R. §93.313
The final institutional investigation report must be in writing and include:

(a)*Allegations.* Describe the nature of the allegations of research misconduct.

(b)*PHS support.* Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c)*Institutional charge.* Describe the specific allegations of research misconduct for consideration in the investigation.

(d)*Policies and procedures.* If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.

(e)*Research records and evidence.* Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.

(f)*Statement of findings.* For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so -

(1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;

(2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;

(3) Identify the specific PHS support;

(4) Identify whether any publications need correction or retraction;

(5) Identify the person(s) responsible for the misconduct; and

(6) List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.

(g)*Comments.* Include and consider any comments made by the respondent and complainant on the draft investigation report.

(h)*Maintain and provide records.* Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

42 C.F.R. §93.315
The institution must give ORI the following:

(a)*Investigation Report.* Include a copy of the report, all attachments, and any appeals.

(b)*Final institutional action*. State whether the institution found research misconduct, and if so, who committed the misconduct.

(c)*Findings.* State whether the institution accepts the investigation's findings.

(d)*Institutional administrative actions.* Describe any pending or completed administrative actions against the respondent.

42 C.F.R. §93.317
(a)*Definition of records of research misconduct proceedings.* As used in this section, the term “records of research misconduct proceedings” includes:

(1) The records that the institution secures for the proceeding pursuant to §§93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

(2) The documentation of the determination of irrelevant or duplicate records;

(3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by §93.309(d);

(4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to §93.310(g); and

(5) The complete record of any institutional appeal covered by §93.314.

(b)*Maintenance of record.* Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.

(c)*Provision for HHS custody.* On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

42 C.F.R. §93.403
ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may -

(a) Determine whether there is HHS jurisdiction under this part;

(b) Consider any reports, institutional findings, research records, and evidence;

(c) Determine if the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions;

(d) Obtain additional information or materials from the institution, the respondent, complainants, or other persons or sources;

(e) Conduct additional analyses and develop evidence;

(f) Decide whether research misconduct occurred, and if so who committed it;

(g) Make appropriate research misconduct findings and propose HHS administrative actions; and

(h) Take any other actions necessary to complete HHS' review.

42 C.F.R. §93.407
(a) In response to a research misconduct proceeding, HHS may impose HHS administrative actions that include but are not limited to:

(1) Clarification, correction, or retraction of the research record.

(2) Letters of reprimand.

(3) Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.

(4) Suspension or termination of a PHS grant, contract, or cooperative agreement.

(5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.

(6) Special review of all requests for PHS funding.

(7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.

(8) Certification of attribution or authenticity in all requests for support and reports to the PHS.

(9) No participation in any advisory capacity to the PHS.

(10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.

(11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.

(b) In connection with findings of research misconduct, HHS also may seek to recover PHS funds spent in support of the activities that involved research misconduct.

(c) Any authorized HHS component may impose, administer, or enforce HHS administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, the Office of Inspector General, the PHS funding component, and the debarring official.

42 C.F.R. §93.500

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.

(b) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an administrative hearing before an Administrative Law Judge (ALJ) affiliated with the HHS DAB, when -

(1) ORI has made a finding of research misconduct against a respondent; and

(2) The respondent has been notified of those findings and any proposed HHS administrative actions, including debarment or suspension, in accordance with this part.

(c) The ALJ's ruling on the merits of the ORI research misconduct findings and the HHS administrative actions is subject to review by the Assistant Secretary for Health in accordance with §93.523. The decision made under that section is the final HHS action, unless that decision results in a recommendation for debarment or suspension. In that case, the decision under §93.523 shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c).

(d) Where a proposed debarment or suspension action is based upon an ORI finding of research misconduct, the procedures in this part provide the notification, opportunity to contest, and fact-finding required under the HHS debarment and suspension regulations at 45 CFR part 76, subparts H and G, respectively, and 48 CFR Subparts 9.4 and 309.4.

42 C.F.R. §93.516

(a)*Standard of proof.* The standard of proof is the preponderance of the evidence.

(b)*Burden of proof.*

(1) ORI bears the burden of proving the findings of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where ORI establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether ORI has carried the burden of proof imposed by this part, the ALJ shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) ORI bears the burden of proving that the proposed HHS administrative actions are reasonable under the circumstances of the case. The respondent has the burden of going forward with and proving by a

evidence any mitigating factors that are relevant to a decision to impose HHS administrative actions following a research misconduct proceeding.

42 C.F.R. §93.517

(a) The ALJ will conduct an in-person hearing to decide if the respondent committed research misconduct and if the HHS administrative actions, including any debarment or suspension actions, are appropriate.

(b) The ALJ provides an independent de novo review of the ORI findings of research misconduct and the proposed HHS administrative actions. The ALJ does not review the institution's procedures or misconduct findings or ORI's research misconduct proceedings.

(c) A hearing under this subpart is not limited to specific findings and evidence set forth in the charge letter or the respondent's request for hearing. Additional evidence and information may be offered by either party during its case-in-chief unless the offered evidence is -

(1) Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

(2) Otherwise inadmissible under §§93.515 or 93.519.

(3) Not offered within the times or terms of §§93.512 and 93.513.

(d) ORI proceeds first in its presentation of evidence at the hearing.

(e) After both parties have presented their cases-in-chief, the parties may offer rebuttal evidence even if not exchanged earlier under §§93.512 and 93.513.

(f) Except as provided in §93.518(c), the parties may appear at the hearing in person or by an attorney of record in the proceeding.

(g) The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. However, even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses.

42 C.F.R. §93.522

(a) After the hearing and under a schedule set by the ALJ , the parties may file post-hearing briefs, and the ALJ may allow the parties to file reply briefs.

(b) The parties may include proposed findings of fact and conclusions of law in their post-hearing briefs.

42 C.F.R. §93.523

(a) The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within 60 days after the last submission by the parties in the case. If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties, the Assistant Secretary for Health and the debarring official, if debarment or suspension is under review. The ALJ shall serve a copy of the ruling upon the parties and the Assistant Secretary for Health.

(b) The ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may review the ALJ's recommended decision and modify or reject it in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. The Assistant Secretary for Health shall notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. If that notification is not provided within the 30-day period, the ALJ's recommended decision shall become final. An ALJ decision that becomes final in that manner or a decision by the Assistant Secretary for Health modifying or rejecting the ALJ's recommended decision in whole or in part is the final HHS action, unless debarment or suspension is an administrative action recommended in the decision.

(c) If a decision under § 93.523(b) results in a recommendation for debarment or suspension, the Assistant Secretary for Health shall serve a copy of the decision upon the debarring official and the decision shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c). The decision of the debarring official on debarment or suspension is the final HHS decision on those administrative actions.

Certificate of Compliance

I, Michael R. Schneider, hereby certify that the foregoing brief was prepared in a 14-point, proportionately spaced Times New Roman serif font, that the brief contains under 12,800 words in compliance with Federal Rules of Appellate Procedure 32(g)(1)) and Circuit Rule 32(e)(1).

/s/*Michael R. Schneider*
Michael R. Schneider

Certificate of Service

I, Michael R. Schneider, hereby certify that I have served the foregoing document on all counsel of record by electronic filing via this Court's CM/ECF system.

/s/*Michael R. Schneider*
Michael R. Schneider

Dated: April 14, 2017