

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

IVANA FRECH,
771 Highland Park Ave
Coralville, Iowa 52241

Plaintiff,

v.

Civ. No.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, and
XAVIER BECERRA, in his official capacity
as the Secretary of Health and Human Services,
and H. KATRINA BRISBON, in her official
capacity as the Deputy Assistant Secretary for
Acquisitions and Suspension and Debarment
Official of the U.S. Department of Health and
Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

OFFICE OF RESEARCH INTEGRITY, and
SHEILA GARRITY, in her official capacity as the
Director of the Office of Research Integrity, and
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

THE UNITED STATES OF AMERICA,

Serve: Hon. Matthew M. Graves,
U.S. Attorney, District of Columbia
601 D Street, NW
Washington, DC 20001

Hon. Merrick B. Garland, U.S. Attorney General
950 Pennsylvania Avenue NW
Washington, DC 20530

Defendants.

COMPLAINT

This legal action seeks to enjoin the U.S. Department of Health and Human Services's ("HHS") improper findings of research misconduct and debarment of Dr. Ivana Frech ("Dr.

Frech”), previously known as Dr. Ivana De Domenico, a former research scientist who has not been engaged in research funded by Public Health Service (“PHS”) funds for more than ten years. This action seeks to shield Dr. Frech from unjustified findings that she is solely responsible for errors in research published more than a decade ago, from the reputational harm that would follow publication of those findings, and from the purely punitive imposition of debarment against an individual who has, in essence, voluntarily excluded herself from participating in covered transactions for at least ten years; *i.e.*, longer than the period of debarment HHS now seeks to impose.

Absent immediate action to enjoin publication of these improper findings and the accompanying debarment, Dr. Frech will suffer irreparable reputational harm. Indeed, the federal research misconduct regulations require that respondents facing allegations of research misconduct be provided with confidentiality in order to protect their reputations in the absence of any ultimate finding of research misconduct. *See* 42 C.F.R. § 93.108. This requirement inherently recognizes the significant reputational harm that even the mere allegation of research misconduct can cause. That harm is exponentially amplified where HHS itself publishes erroneous findings.

Dr. Frech seeks immediate relief from the unlawful findings and debarment recently imposed on her by Defendant HHS, acting through Defendants the Secretary of Health and Human Services, the Office of Research Integrity (“ORI”), the Director of ORI, and HHS’s Deputy Assistant Secretary for Acquisitions (*i.e.*, its Suspension and Debarment Official (“SDO”)) (collectively referred to as the “HHS”). The HHS’s research misconduct findings and debarment constitute final agency actions that were arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, and contrary to law and regulation, in violation of the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701 *et seq.* Immediate intervention by the Court is needed to

prevent irreparable harm to Dr. Frech, including irreversible damage to her reputation, and the potential for unjustifiable harm to her current career outside of science.

INTRODUCTION AND STATEMENT OF FACTS

1. Dr. Frech (then known as Dr. De Domenico) arrived in Salt Lake City to attend the University of Utah (“UU”) as an exchange student from Italy in 2004. At that time, Dr. Frech joined Dr. Jerry Kaplan’s laboratory, which was managed by Dr. Kaplan’s colleague, Dr. Diane Ward. Dr. Ward was responsible for overseeing the experiments of lab members such as Dr. Frech, writing manuscripts, and generating figures for publication.

2. In or about April 2008, Dr. Frech became a tenure-track assistant professor and independent investigator at UU. Despite leaving Dr. Kaplan’s lab at that time and attempting to redirect her research focus to pursue other lines of research, the lack of senior research presence in Dr. Kaplan’s and Dr. Ward’s lab resulted in Dr. Frech occasionally being asked to guide their technicians on some experiments and, if necessary, to assist in assembling figures for publication. During those times when Dr. Frech assisted in figure assembly, she necessarily relied on the data generated and provided by Drs. Kaplan and Ward’s technicians. Drs. Kaplan and Ward had ultimate responsibility for the final manuscript and figures, which they submitted to journals.

3. In or about October 2011, allegations of research misconduct arose involving multiple papers published from Dr. Kaplan’s lab, for which Dr. Frech is a coauthor. Pursuant to UU’s research misconduct policy and the applicable federal regulations (42 C.F.R. Part 93), UU conducted an inquiry and an investigation into the allegations, which involved research published between 2007 and 2011 (and, therefore, involving data that had been generated even earlier).

4. UU’s inquiry concluded that it “did not uncover evidence of intent to deceive or misrepresent the data from the experiments in question.” Nevertheless, UU determined that an

investigation was necessary and assembled an investigation committee. The investigation reviewed allegations of research misconduct in 11 papers. Nine of these papers included Dr. Kaplan as the senior and corresponding author. One paper, on which Dr. Kaplan is a coauthor, listed Dr. Frech as the senior and corresponding author. And one paper, for which both Dr. Kaplan and Dr. Frech are coauthors, listed Dr. Wesley Sundquist as the senior and corresponding author. Notably, the only paper for which Dr. Frech is the senior and corresponding author is not one of the three papers for which ORI made findings against Dr. Frech.

5. The investigation committee interviewed Dr. Frech three times, with one member (Dr. David Goldenberg) conducting the majority of the questioning. The transcripts from the interviews clearly demonstrate that at least Dr. Goldenberg, and perhaps the entirety of the investigation committee, had already improperly (and erroneously) decided that Dr. Frech was responsible for research misconduct before the interviews began.

6. Unsurprisingly, given the tone of the interviews and conduct of the investigation, the investigation committee's report concluded that Dr. Frech had engaged in research misconduct. The basis for this determination was a purported "pattern of recklessness," which the investigation committee defined as "actions that are marked by lack of proper caution and care with respect to the consequences of the actions, and are therefore negligent and a breach of expected professional responsibility." Furthermore, the investigation committee found that the alleged research misconduct "was committed in reckless disregard of accepted practices."

7. Pursuant to the federal regulations, a finding of research misconduct requires more than a determination that the definition of research misconduct has been met (*i.e.*, by finding fabrication, falsification, or plagiarism). It requires: "(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.” *See* 42 C.F.R. § 93.104 (emphasis added). These requirements are echoed in UU’s research misconduct policy, with the second element altering the lowest level of intent to “reckless disregard of accepted practices.”

8. UU’s description of the levels of intent – and the corresponding determination by the investigation committee – conflate two separate elements of research misconduct. Specifically, UU conflates the need to determine there was a significant departure from accepted practices with the need to determine that a respondent possessed the requisite level of intent to find research misconduct. Additionally, UU’s definition of recklessness includes negligence and a lack of proper caution and care. As a result, UU’s definition of recklessness includes ordinary negligence and mere carelessness, neither of which rises to the level of intent necessary to support a research misconduct finding.

9. Notably, the UU investigation determined that Dr. Frech was not solely responsible for the errors at issue in the allegations, but rather that Dr. Kaplan, Dr. Ward, and others shared responsibility. In fact, the investigation committee recommended that UU “relieve Dr. Kaplan of his senior leadership duties” based on his role in the errors and the “systematic” issues in his lab.

10. Following receipt of the final investigation report in or about December 2012, Dr. Frech appealed UU’s findings and recommendations. A Consolidated Hearing Committee (“CHC”) heard her appeal on April 29, 2013, and issued its report on May 8, 2013 (the “CHC Report”). The CHC Report determined that, although Dr. Frech engaged in research misconduct “based on ‘reckless disregard of accepted practices’[,]” that “[t]here was complicity in this misconduct within the laboratory that goes substantially beyond Dr. De Domenico.” More

specifically, the CHC found that Dr. Kaplan, Dr. Ward, and possibly others also bore responsibility for the errors identified in the allegations. The CHC Report also recommended “further investigation of the laboratory procedures uncovered in this investigation.”

11. Following conclusion of the UU investigation in early 2013, UU sent the records of its inquiry and investigation to ORI for ORI’s oversight review and to determine what findings and actions, if any, should be made by HHS. ORI and HHS have thus been considering this matter for more than 10 full years.

12. In June and July 2013, Dr. Frech sought to ensure that ORI had received the CHC Report along with the rest of the record. On July 1, 2013, Dr. John Dahlberg (then the Director of ORI) contacted UU to ask if ORI received a copy of the CHC Report, noting that he did not believe ORI had yet received it, and requesting a copy be provided to ORI. On the same date, Dr. Frech requested a copy of the record provided to ORI by UU. In or about September 2013, ORI informed Dr. Frech about the records it had received from UU. The CHC Report was not included in the records identified.

13. On or about July 19, 2023, more than a decade after the process at UU concluded, Dr. Frech received a Charge Letter from ORI identifying its findings and administrative actions. Despite the numerous allegations involved in 11 papers at issue during UU’s investigation, ORI made six research misconduct findings with respect to only three papers. None of these involve the paper for which Dr. Frech was the senior and corresponding author.

14. In each of the six findings of research misconduct, ORI states that Dr. Frech acted “intentionally, knowingly, or recklessly” and that she “falsified and/or fabricated” figures in the three papers. ORI also states that “Respondent’s actions were knowing and intentional” and that “Respondent solely planned, initiated, and carried out the wrongdoing.” These conclusions are

not only erroneous, but are also directly contradicted by the evidence, including UU's findings. Additionally, they do not represent a legitimate finding as required by the regulations since they only name all of the possible outcomes, without concluding by a preponderance of the evidence as to a particular finding.

15. In addition to describing ORI's findings, the Charge Letter also informs Dr. Frech that she will be debarred from participation in covered transactions for a three-year period as an administrative action imposed by HHS.

16. Following issuance of the CHC Report in 2013, Dr. Frech's employment at UU was terminated. Since that time, Dr. Frech has voluntarily excluded herself from participation in covered transactions. In other words, the proposed sanction, had it been imposed contemporaneously with UU's findings, would have been satisfied three times over by the time the Charge Letter was prepared.

17. After leaving UU, Dr. Frech returned to school to obtain a MBA and changed her last name from De Domenico to Frech. She then joined Dr. Fenghuang Zhan's lab as a research assistant at the University of Iowa ("UI") on or about September 29, 2015. During her time in Dr. Zhan's lab, none of the research Dr. Frech was involved with was supported by PHS funds. Additionally, Dr. Frech's research activities at UI were subject to oversight and monitoring by Dr. Zhan, Dr. Guido Tricot, and Dr. Zhan's lab manager. At no point have there been any concerns raised regarding Dr. Frech's research beyond the papers investigated by UU. Even if there had been, ORI does not have jurisdiction over research not supported by PHS funds.

18. Dr. Frech has not been engaged in any scientific research activities – PHS-supported or otherwise – since late 2019, when she declined to follow Dr. Zhan to the University of Arkansas. Dr. Frech's last day in Dr. Zhan's lab was on or about December 18, 2019. Dr.

Frech ultimately resigned from UI as of May 1, 2020, when no suitable new position at UI could be identified for her. Since 2020, Dr. Frech has been working as an administrator at a community hospital in Iowa City.

19. Following receipt of ORI's Charge Letter, Dr. Frech requested copies of the exhibits to the Charge Letter, which were not provided concurrently with the Charge Letter itself. Those exhibits were provided on August 10, 2023.

20. Following receipt of the Charge Letter exhibits, beginning on August 15, 2023, Dr. Frech sought in good faith to negotiate with ORI to resolve this matter in a mutually acceptable manner. Through August 18, 2023, Dr. Frech and ORI exchanged correspondence that made it clear that, although Dr. Frech disagreed with and contested ORI's findings, she was willing to reach a settlement. Although ORI rejected the specific proposals by Dr. Frech during this time, it did not foreclose the possibility of reaching an agreement.

21. On August 18, 2023, following ORI's rejection of Dr. Frech's most recent proposal, Dr. Frech, through counsel, informed ORI that she would convey a settlement proposal to ORI the following week. ORI did not respond. Consistent with Dr. Frech's representation, on August 22, 2023, Dr. Frech contacted ORI to engage in further discussion. Only then did ORI respond, taking the position that the deadline to contest ORI's findings had passed and that the findings had therefore become final. Dr. Frech promptly responded, noting that her communications seeking to resolve the matter amicably had made it abundantly clear that she contested the findings.

22. On August 23, 2023, Dr. Frech and ORI exchanged further communications, both via email and telephone. Despite Dr. Frech's shock at being sandbagged by ORI's silence until it asserted the deadline had already passed, ORI insisted that it could neither continue to negotiate

nor could Dr. Frech now request a hearing, despite her communications with ORI detailing her disagreement with the findings.

23. In lieu of requesting a hearing that ORI has repeatedly expressed would be denied, Dr. Frech now brings this action to enjoin ORI's publication of its findings and HHS's debarment of her or, in the alternative, to be heard on the merits of her challenge to the findings and debarment.

24. As shown below, the ORI's findings against and the debarment of Dr. Frech are arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, and contrary to law and regulation, in violation of the APA.

25. Pursuant to the federal regulations, research misconduct is defined as fabrication (making up data or results), falsification (manipulating materials, equipment, or processes, or changing or omitting data or results to misrepresent the research), or plagiarism. *See* 42 C.F.R. § 93.103. Honest error is expressly excluded from the definition of research misconduct. *See id.* Despite the fact that fabrication and falsification are inherently two very different things (data is either fabricated or it is falsified; it cannot reasonably be said to be both), ORI here finds with respect to each image at issue that Dr. Frech "falsified and/or fabricated" the data at issue. By including both of these forms of research misconduct in its findings, ORI is essentially acknowledging that it is unable to determine by a preponderance of the evidence whether any data was made up or altered.

26. Similarly, a finding of research misconduct must be supported by a determination that a respondent possessed one of the requisite levels of intent (*i.e.*, that a respondent acted intentionally, knowingly, or recklessly). *See* 42 C.F.R. § 93.104(b). Here, ORI treats this requirement as a mere box-checking exercise, repeating in mere conclusory fashion for each of

its findings that Dr. Frech acted “intentionally, knowingly, or recklessly” and alternatively stating that Dr. Frech’s “actions were knowing and intentional.” ORI identifies no evidence for increasing the level of intent beyond what UU determined.

27. A preponderance of the evidence available to ORI demonstrates that there were systematic problems in Dr. Kaplan’s lab and that any research misconduct went “substantially beyond Dr. De Domenico.” ORI’s findings that Dr. Frech possessed any intent beyond recklessness and that she “solely planned, initiated, and carried out the wrongdoing” is therefore directly contradicted and unsupported by substantial evidence, arbitrary, capricious, and an abuse of discretion.

28. Although UU’s investigation included Dr. Kaplan as a respondent, ORI’s findings, to date, are solely against Dr. Frech. Despite the fact that Dr. Kaplan was also investigated by UU, the investigation committee expressly noted that it “did not examine any reports on which Dr. De Domenico was not a co-author.” During the CHC hearing, Dr. Frech demonstrated that the same types of errors for which ORI now finds her solely responsible are present in other papers by Dr. Kaplan that Dr. Frech had no role in preparing.

29. Dr. Frech was not the Primary Investigator (“PI”) for the research at issue in ORI’s findings; Dr. Kaplan was. Dr. Frech was first a lab member and later outside the lab, and reliant on other members of Dr. Kaplan’s lab to conduct the experiments and provide her with appropriate data for use in the figures. UU’s findings against Dr. Frech were not based on any evidence that Dr. Frech intentionally, knowingly, or even recklessly engaged in research misconduct. Instead, UU relied primarily on “[t]he number and nature of errors” and finding that “in aggregate” they “deviate[d] from expected scientific practice in a fashion that is reckless.” Under the circumstances described by UU, a finding that Dr. Frech – as opposed to Dr. Kaplan – was even

recklessly responsible for research misconduct is arbitrary, capricious, an abuse of discretion, and unsupported by substantial evidence.

30. The purpose of the federal research misconduct regulations is remedial in nature and is intended to safeguard science while allowing for the rehabilitation of even those scientists who engage in intentional research misconduct. *See, e.g.*, 42 C.F.R. § 93.101(e) (explaining that the purpose of the regulations is to protect public health and safety, promote research integrity, and conserve PHS funds); 42 C.F.R. § 93.408 (expressly stating that “the purpose of HHS administrative actions is remedial”).

31. ORI waited more than 10 years before making findings and taking administrative actions against Dr. Frech. Its refusal to continue engaging in settlement discussions and to proceed with finalizing those findings and actions despite Dr. Frech’s clear disagreement with those findings and actions simply because she did not contest them in the form preferred by ORI within a comparatively very short period of time is arbitrary, capricious, an abuse of discretion, and contrary to law, regulation, and public policy.

32. The very fact that ORI waited for more than 10 years before debarring Dr. Frech further demonstrates that such action is purely punitive, as Dr. Frech has voluntarily excluded herself from PHS-funded research for more than three times the length of the debarment ORI intends to impose. Indeed, Dr. Frech has been employed entirely outside of scientific research (PHS-funded or otherwise) for more than three years now; *i.e.*, for more than the period of debarment ORI and HHS are imposing. Had ORI taken action as recently as seven years after receiving the record from UU, the period of debarment would already be expired.

33. Publication of research misconduct findings is, itself, discretionary – despite ORI’s insistence that it must do so. There is no publication requirement in the federal regulations. The

regulations state only that ORI “may” publish notice of findings. *See* 42 C.F.R. § 93.411 (“When a final HHS action results in a settlement or research misconduct finding, ORI may . . . publish notice of the research misconduct findings”); 42 C.F.R. § 93.414 (“ORI may publish a notice of final agency findings of research misconduct, settlements, and HHS administrative actions . . .”). Where, as here, regulations use permissive language (*i.e.*, “may”) instead of mandatory language (*i.e.*, “must” or “shall”), the regulations do not require the action described. *See, e.g., Lopez v. Davis*, 531 U.S. 230, 241 (2001). All of the research at issue in this matter took place under Dr. Frech’s previous name (*i.e.*, as Dr. De Domenico). Publication of findings identifying Dr. Frech as solely responsible for research misconduct based on research conducted 12 to 16 years ago (or more) is enormously prejudicial, fails to serve the purpose of ORI’s mission of protecting science, and would unduly and unfairly harm Dr. Frech’s reputation and her non-scientific employment. The mere passage of time itself has demonstrated that protection of science has already been achieved here (the goal of the regulations), and there is no future risk to science, because Dr. Frech has voluntarily changed careers.

34. For these and other reasons set forth below, ORI’s research misconduct findings against and debarment of Dr. Frech are arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, and contrary to law and regulation, in violation of the APA.

35. Furthermore, unless this Court enjoins the publication of the erroneous and unlawful findings and debarment, Dr. Frech will sustain imminent irreparable harm to her reputation. Indeed, the federal research misconduct regulations and corresponding institutional policies contain confidentiality requirements for the very purpose of protecting the reputations of respondents in the event that the allegations are wrong. *See, e.g.*, 42 C.F.R. § 93.108 (limiting disclosure of respondents’ identities to those who need to know in order to provide an objective

and fair process); 42 C.F.R. § 93.304(k) (requiring institutions to take steps to restore respondents' reputations in the event no finding of research misconduct is made). If ORI makes its findings public, the harm to Dr. Frech's reputation and her career outside of science will already be done, even if those findings are reversed, as they should be.

36. Accordingly, this Court should: (1) preliminarily enjoin publication of ORI's findings of research misconduct against Dr. Frech and the debarment of Dr. Frech; (2) vacate and set aside the ORI findings and debarment, declaring them null and void and ordering that Dr. Frech's name not be entered into the System for Award Management available at www.sam.gov; (3) permanently enjoin HHS from publishing research misconduct findings against Dr. Frech and from proposing for debarment and debarring Dr. Frech based on the conduct alleged in the Charge Letter; and (4) if the Court is unwilling to grant permanent injunctive relief, Dr. Frech requests that the Court hear and decide Dr. Frech's challenge to the merits of the findings and debarment. We further request that the Court award Dr. Frech her reasonable attorneys' fees, including attorneys' fees under the Equal Access to Justice Act ("EAJA"), 28 U.S.C. § 2412, all costs and expenses, and grant such other relief as the Court deems just and proper.

THE PARTIES, JURISDICTION, AND VENUE

37. Plaintiff Dr. Ivana Frech currently resides in Coralville, Iowa. HHS informed Dr. Frech on August 22, 2023 that its research misconduct findings and debarment action against her are final.

38. Defendant the Department of Health and Human Services is a department of the United States Government and is headquartered at 200 Independence Avenue, S.W., Washington, DC 20201.

39. Defendant Xavier Becerra is the Secretary of Health and Human Services. Mr. Becerra's office is located at 200 Independence Avenue, S.W., Washington, DC 20201.

40. Defendant the Office of Research Integrity, is a component of HHS and acts on behalf of HHS as the office responsible for overseeing and directing Public Health Service ("PHS") research integrity activities. ORI is headquartered at 1101 Wootton Parkway, Suite 240, Rockville, MD 20852.

41. The Director of ORI, Defendant Sheila Garrity, reports to HHS and specifically the Secretary of Health and Human Services. Ms. Garrity's office is located at 1101 Wootton Parkway, Suite 240, Rockville, MD 20852. Along with Ms. H. Katrina Brisbon, Ms. Garrity is the HHS official who issued to Dr. Frech the letter describing HHS's research misconduct findings and administrative actions, including debarment.

42. Defendant H. Katrina Brisbon is HHS's Deputy Assistant Secretary for Acquisitions and Suspension and Debarment Official (a/k/a the "SDO"). HHS regulations delegate to Ms. Brisbon, as the Deputy Assistant Secretary for Acquisitions, the responsibility for overseeing, administering and executing HHS's suspension and debarment program. Ms. Brisbon's office is located at 200 Independence Avenue, S.W., Washington, DC 20201. Along with Ms. Garrity, Ms. Brisbon is the HHS official who issued to Dr. Frech the letter describing HHS's research misconduct findings and administrative actions, including debarment.

43. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action seeks judicial review of, and to set aside, final agency action (the research misconduct findings against and debarment of Dr. Frech) under the Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq.*

44. Venue is proper pursuant to 28 U.S.C. § 1391(b)(2) because this is the District in which a substantial part of the events giving rise to this action occurred. In the alternative, venue is proper pursuant to 28 U.S.C. § 1391(e)(1)(A) and (C) because this is the District in which Defendants HHS, Mr. Becerra, and Ms. Brisbon reside and in which a substantial part of the events giving rise to this action occurred.

APPLICABLE LAW

I. GENERAL OVERVIEW OF RESEARCH MISCONDUCT

45. The federal regulations applicable to PHS-funded research for which ORI has oversight and pursuant to which ORI and HHS make findings and institute administrative actions are found in 42 C.F.R. Part 93. The purpose of these regulations is remedial in nature and is intended to “[p]rotect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.” *See* 42 C.F.R. § 93.101(e). “Any interpretation of this part must further the policy and purpose of the HHS and the Federal government to protect the health and safety of the public, to promote the integrity of research, and to conserve public funds.” *See* 42 C.F.R. § 93.107.

46. Research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” *See* 42 C.F.R. § 93.103. “Fabrication” is defined as “making up data or results and recording or reporting them” whereas “falsification” is defined as “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.” *See id.* at (a) and (b).¹ Honest error is expressly excluded from the definition of research misconduct. *See id.* at (d).

¹ There is neither an allegation of nor any purported finding of plagiarism in this matter.

47. A finding of research misconduct requires more than simply finding that the definition of research misconduct has been met through fabrication, falsification, or plagiarism. Specifically, a finding of research misconduct requires that “(a) [t]here be a significant departure from accepted practices of the relevant research community; and (b) [t]he misconduct be committed intentionally, knowingly, or recklessly; and (c) [t]he allegation be proven by a preponderance of the evidence.” *See* 42 C.F.R. § 93.104. Each of these elements are separate, and each must be met to support a research misconduct finding.

48. ORI does not itself conduct research misconduct inquiries and investigations, instead referring allegations to the relevant institution (or HHS component) where the research was conducted for inquiry and, should one be found warranted, investigation. *See* 42 C.F.R. §§ 93.400(a), 93.402. ORI conducts an oversight review of an institution’s findings and process, and may then make a federal finding of research misconduct and propose HHS administrative actions. *See* 42 C.F.R. §§ 93.400(a)-(c), 93.403. ORI thus relies heavily on the institutional reports and record developed during the institutional inquiry and investigation.

49. Despite the fact that neither UU’s investigation report nor the CHC Report found that Dr. Frech possessed any intent beyond recklessness, ORI perplexingly – and without any basis – alternatively states that Dr. Frech acted “intentionally, knowingly, or recklessly” or that her actions “were knowing and intentional.” The first of these statements, repeated with respect to each and every one of ORI’s findings, abdicates responsibility for finding a single level of intent for each allegation by a preponderance of the evidence in favor of simply checking the box and claiming the intent element of a research misconduct finding has been satisfied. ORI also abandons its burden for determining whether data was made up or altered, by simply claiming with respect to each finding that Dr. Frech “falsified and/or fabricated” data. If ORI

cannot make a determination as to the specific level of intent or the type of research misconduct that Dr. Frech purportedly possessed or engaged in, it cannot plausibly satisfy its burden of making a research misconduct finding by a preponderance of the evidence.

50. Similarly, although both UU's investigation report and the CHC Report determined that there were systematic problems in Dr. Kaplan's lab and identified multiple people who were "complicit" in the errors in the papers, ORI unjustifiably concludes that Dr. Frech "solely planned, initiated, and carried out the wrongdoing." In essence, after more than a decade, ORI has made findings that are less specific than UU's findings, and are indeed contradicted by UU's findings and the available evidence.

51. Dr. Frech is neither the senior nor the corresponding author for any of the three papers for which ORI makes research misconduct findings against Dr. Frech, though she is the first author for two of the publications. For the third of these publications, on which Dr. Frech is one of the middle authors, the CHC Report determined that although the "manipulation does appear to have been intentional, we cannot conclude that it was done by Dr. De Domenico as opposed to an unknown third person." ORI relies entirely on a letter that Dr. Frech sent on or about July 21, 2012 during the UU investigation stating that "a[n] image was generated by me and sent to Dr. Kieffer and Sundquist on March 3, 2008" and that "the duplication came from me." However, Dr. Frech was pressured into writing that letter under threat of losing her employment, and has disclaimed the accuracy of the letter since shortly after sending it. This letter was available to the CHC during its consideration of Dr. Frech's appeal, and the CHC nevertheless concluded that the available evidence could not support a determination that Dr. Frech manipulated the image.

52. Although the publications at issue in the UU investigation spanned the time period from 2007 to 2011, the publications for which ORI makes its findings were published in 2008 and 2011 (both of the papers for which Dr. Frech is the first author). Although Dr. Frech was a member of Dr. Kaplan's lab from 2005 to 2008, she left his lab in 2008. Thus, Dr. Frech was not even a member of the lab at the time the majority of the research at issue in this matter was conducted. Even while a lab member, Dr. Frech did not herself conduct any of the experiments underlying the allegations in this matter.

53. Dr. Frech does not challenge – and has not challenged – the existence of errors in the papers. However, at most points, Dr. Frech was not the person preparing the figures and figures were often changed by other authors or members of Dr. Kaplan's lab at or around the time of manuscript submission while Dr. Frech was in Italy. Because neither UU nor ORI reviewed publications arising from Dr. Kaplan's lab for which Dr. Frech is not a coauthor, Dr. Frech did so, and identified the same sorts of errors in publications by Dr. Kaplan and his colleagues. This demonstrates that the systemic problems in Dr. Kaplan's lab did, in fact, go far beyond Dr. Frech and contradict ORI's finding that she is solely responsible for the errors. Furthermore, available evidence demonstrates that with respect to the majority of ORI's findings, accurate original data were available at the time the figures were generated, thereby further demonstrating that Dr. Frech did not possess a requisite level of intent to engage in research misconduct.

II. GENERAL OVERVIEW OF SUSPENSION AND DEBARMENT

54. Under applicable HHS regulations, debarment means “the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants,

contracts, and cooperative agreements.” 42 CFR § 93.205. Debarment includes both procurement and non-procurement matters.

55. As instructed by the Office of Management and Budget (“OMB”) guidance located at 2 CFR § 180.15, HHS regulations pertaining to non-procurement suspension and debarment matters are implemented at 2 CFR § 376. In short, HHS adopted OMB’s guidance to federal agencies on the government-wide debarment and suspension system for non-procurement programs and activities, thereby giving regulatory effect to that guidance, as supplemented by HHS specific regulations.

56. Under controlling regulations, the purpose of debarment is to protect the public interest by ensuring that the Federal Government conducts business only with responsible persons. Pertinent to this action, the non-procurement debarment and suspension system is used “to exclude from Federal Programs persons who are not *presently* responsible.” 2 CFR § 180.125 (Emphasis added). In recognition of the potentially financially-crippling consequence and irreparable reputational stigma that attaches to a person from being debarred, the regulations permit HHS to only debar a person in order to protect the public interest; HHS cannot use debarment as a means of punishment.

57. HHS carries the burden of proving a cause for debarment exists, which it must demonstrate by a preponderance of the evidence. 2 CFR § 180.850. A preponderance of the evidence “means proof by information that, compared with information opposing it, leads to the conclusion that the fact at issue is more probably true than not.” 2 CFR § 180.990.

58. Federal agencies, such as HHS, may debar a person for a number of causes, to include a cause “so serious and compelling a nature that it affects” a person’s present responsibility.

59. Despite grounds for debarment, the debarring official is not required to take debarment action and may consider mitigating or aggravating factors before rendering a decision whether to debar a person. A non-exhaustive list of these factors is listed at 2 CFR § 180.860 and the debarring official may consider other factors given the circumstances of a particular case.

60. ORI's July 19, 2023 charge letter asserts that Plaintiff intentionally, knowingly, or recklessly engaged in research misconduct that is so serious and compelling in nature that it demonstrates a lack of present responsibility. This statement does not explain which of the three scienters (*i.e.*, intentionally, knowingly, or recklessly) the Plaintiff acted with in carrying out the alleged misconduct. The UU report, which ORI principally relied on, concluded only that the Plaintiff acted "in reckless disregard of accepted practices." Acting intentionally is not the equivalent of acting recklessly and the debarring official fails to explain under which scienter the cause for debarment was considered, the aggravating and mitigating factors that were analyzed, and the length of the Plaintiff's debarment that was evaluated. Indeed, whether the Plaintiff acted recklessly as opposed to intentionally goes to a mitigation factor that the debarring official should have considered. 2 CFR §180.860(f) (the extent to which the person planned, initiated, or carried out the wrongdoing.). This failure renders the debarring official's decision arbitrary and capricious.

61. Repeatedly parroting the scienter elements for the finding of research misconduct is insufficient to establish that research misconduct alone is a cause for debarment. Instead, under applicable regulations the alleged misconduct must be, in its nature, so serious or compelling that it affects the Plaintiff's present responsibility. Other than summarily concluding research misconduct is so serious and compelling as to warrant debarment, the debarring

official's debarment action fails to *explain* why the misconduct alleged here is so serious and compelling, despite more than a decade having passed, as to affect the Plaintiff's present responsibility. Moreover, HHS's failure to take action on information in its possession for more than a decade vitiates the agency's contention that the alleged misconduct is so serious or compelling that the Government's interests must be protected from Plaintiff today. In other words, the failure to act over the course of the last ten years undercuts any notion that the alleged misconduct is material to the issue of Plaintiff's present responsibility.

62. In ORI's findings of research misconduct against the Plaintiff, HHS noted that the agency's debarring official considered the factors found at 2 CFR § 180.860 in determining to debar the Plaintiff and for how long debarment should last. The debarring official's analysis is scant, conclusory, and fails to demonstrate by a preponderance of the evidence that the Plaintiff is not presently responsible under the controlling regulations.

63. For example, the debarring official states that the Plaintiff "solely planned, initiated, and carried out the wrongdoing." There is no evidence in ORI's findings that the Plaintiff "planned" anything, nor does the debarring official's statement cite to any reference in the record supporting such planning. In fact, the UU investigation contradicts that statement, finding that there were systematic problems in Dr. Kaplan's lab and identified multiple people who were "complicit" in the errors in the papers that formed the basis for HHS's debarment action. Moreover, ORI summarily concluded that Plaintiff intentionally, knowingly, *or* recklessly engaged in research misconduct without ever articulating which of these three types of scienter she supposedly carried out the alleged misconduct with. For example, it is not clear how Plaintiff could "recklessly" plan research misconduct and HHS does nothing to explain away this gap in the logic of its theory of culpability.

64. The debarring official similarly concluded that Plaintiff's purported misconduct "had a significant impact on the proposed and reported research record, other researchers, institutions, and the public health or welfare." Again, there is no specific evidence supporting this statement. Instead, HHS made broad, speculative statements that Plaintiff's research findings "would have been considered a significant and exciting finding in the field"; not that it *was* considered by others as a significant and exciting finding.

65. HHS also maintained, with no evidentiary support, that "basic and clinical researchers would and/or did follow up" and that Plaintiff's "fabricated and/or falsified research papers led to [a] waste of valuable time and resources." However, HHS offers no specifics, or even estimates, as to how much time and resources were supposedly wasted due to the Plaintiff's alleged misconduct. And while HHS asserts that the three articles at issue were cited by others in scientific literature 142 times as of April 19, 2023, the agency abjectly fails to explain when those citations occurred, the material to which the literature cited, the scientific literature that cited the questioned material, or the context in which the material was discussed in the literature. Instead, HHS appears to have performed the equivalent of a Google search and determined that the results show some form of reliance on the questioned research by an undefined scientific community. But, as Defendants admit, two of the three articles in question were retracted in 2012 and the agency provides no evidence that anyone in the scientific community relied on any of the erroneous data in these papers within the last decade.

66. HHS also fails to give credit to UU's CHC Report and recommendations issued in May 2013, which found that there "likely was intentional falsification of published data or images but *we could not determine by a preponderance of the evidence that these items were work of Dr. De Domenico.*" In addition, the CHC noted that "there was complicity in this

misconduct within the laboratory that goes substantially beyond Dr. De Domenico.” Yet, HHS provides no explanation as to how ORI’s “oversight review” and “additional analysis” reached a different conclusion than that of the CHC. In fact, ORI does not even cursorily describe what additional analysis it performed to have reached a different conclusion. Nevertheless, ORI concludes that the Plaintiff’s actions were “knowing and intentional” and that she “solely planned, initiated, and carried out the wrongdoing.” There is no evidence that these two statements are accurate.

67. The most glaring gap in the Defendant’s analysis is the lack of any explanation as to how Plaintiff’s alleged conduct from over a decade ago bears on her present responsibility to conduct business with the Government. Rather, HHS’ position seems to be that because the Plaintiff did something wrong 10 years ago, she needs to be debarred now. This is quintessential prohibited punishment on the part of the agency. In the main, HHS has failed to demonstrate that any of its conclusory statements adequately, and legally, support the Plaintiff’s debarment for a lack of present responsibility. Accordingly, the Plaintiff’s debarment is arbitrary, capricious, is not supported by substantial evidence, and violates law and regulation and should be enjoined.

COUNT I

Violation of the Administrative Procedure Act, 5 U.S.C. §701, et seq. (Debarment)

68. The allegations contained in the foregoing paragraphs are incorporated as if fully stated herein.

69. The proposed debarment of Dr. Ivana Frech on July 11, 2023, with the immediate effect of excluding her from conducting business with the government, and notification by ORI

on August 22, 2023 that the Charge Letter's proposed debarment was now final both constitute final agency action, reviewable pursuant to 5 U.S.C § 706.

70. Judicial review of final agency actions is governed by Section 706 of the Administrative Procedure Act. The court may set aside agency actions, findings, or conclusions when they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

71. When conducting a review of agency actions under the APA, the Court considers “whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied on have some basis in the record, and whether the agency considered all relevant factors.” *Uzelmeier v. U.S. Dept. of Health and Human Services*, 541 F.Supp.2d 241, 245 (D.D.C. 2008).

72. HHS has failed to demonstrate by a preponderance of the evidence that Plaintiff intentionally, knowingly, or recklessly engaged in research misconduct so serious or compelling in nature that it affects her present responsibility to conduct business with the government.

73. Federal agencies, such as HHS, may debar a person for a number of causes, to include a cause “so serious and compelling a nature that it affects” a person's present responsibility. HHS is relying on this basis alone to demonstrate Plaintiff's debarment for a period of three years is warranted.

74. The information provided by HHS lacks the factual and legal predicates to support that Plaintiff engaged in conduct so serious and compelling in nature as to warrant her debarment.

75. The record provided by HHS fails to show that the Plaintiff acted intentionally, knowingly, or recklessly with respect to the matters in issue and which form the basis for the

Plaintiff's debarment. In fact, the CHC Report, following its evaluation of UU's investigation determined there "likely was intentional falsification of published data or images but we could not determine by a preponderance of the evidence that these items were work of Dr. De Domenico." The CHC further found that the manipulation of an image "does appear to be intentional," the CHC could not conclude that the Plaintiff was responsible. In sum, the CHC concluded after a fulsome presentation of all information that no intentional irregularities can be assigned to the Plaintiff.

76. HHS's Charge Letter does not explain how it reached a different conclusion as to the same information that was presented to the CHC. Rather, HHS summarily stated that it conducted additional analysis, but did not explain what analysis it performed, how it was performed, when it was performed or in what manner it may have amplified the information previously evaluated by UU. Notably, HHS did not interview or request information from the Plaintiff before issuing the Charge Letter. Instead, HHS simply concluded that the Plaintiff intentionally, knowingly, or recklessly engaged in research misconduct and that she "solely planned, initiated, and carried out the wrongdoing."

77. Therefore, HHS's proposed debarment of the Plaintiff is arbitrary, capricious, an abuse of discretion, and otherwise is not in accordance with the law in violation of the Administrative Procedure Act.

COUNT II

Violation of the Administrative Procedure Act, 5 U.S.C. §701, et seq. (Agency Findings)

78. Dr. Frech incorporates by reference the foregoing paragraphs as if fully stated herein.

79. The Charge Letter describing ORI's findings, coupled with ORI's communications on August 22 and 23, 2023 stating that the findings are now final, constitutes final agency findings reviewable pursuant to 5 U.S.C. § 706.

80. Judicial review of final agency findings is governed by Section 706 of the APA. Under the APA, the court may set aside agency actions, findings, or conclusions as unlawful when they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, or if they are unsupported by substantial evidence. *See Chef Time 1520 LLC v. Small Bus. Admin.*, --- F. Supp. 3d ----, 2022 WL 17820293 at *5 (D.D.C. Dec. 20, 2022).

81. When conducting a review of agency actions under the APA, the Court considers "whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied on have some basis in the record, and whether the agency considered all relevant factors." *Uzelmeier v. U.S. Dept. of Health and Human Services*, 541 F.Supp.2d 241, 245 (D.D.C. 2008).

82. Agency findings or actions may be considered arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, 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." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

83. "Agency fact-finding warrants considerable deference" only if "it is supported by substantial evidence." *Chef Time 1520 LLC*, 2022 WL 17820293 at *5.

84. Defendants have entirely failed to demonstrate by a preponderance of the evidence that Plaintiff intentionally, knowingly, or recklessly engaged in research misconduct, that Plaintiff was solely responsible for the purported misconduct, or which form of research misconduct Plaintiff is responsible for.

85. Defendants' claims that, for each of the research misconduct findings, Plaintiff acted "intentionally, knowingly, or recklessly" and "falsified and/or fabricated" figures demonstrate that Defendants fail to explain their findings, did not consider all relevant factors, have no basis in the record for their findings, are unsupported by substantial evidence, and cannot explain why the findings run counter to the evidence before the agency, including the contrary findings by UU's investigation and the CHC Report.

86. For these reasons and those explained in the foregoing paragraphs, Defendants' research misconduct findings against Plaintiff are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law in violation of the APA.

COUNT III
(INJUNCTIVE RELIEF)

87. Dr. Frech incorporates by reference the foregoing paragraphs as if fully stated herein.

88. Dr. Frech will meet her burden to show that preliminary and permanent injunctive relief is appropriate and necessary in this litigation. Specifically, Dr. Frech will demonstrate that she will prevail on the merits of her claim that the Charge Letter's findings and administrative actions violate the Administrative Procedure Act, that she will suffer irreparable harm to her reputation and career outside of scientific research if the Court withholds preliminary and permanent injunctive relief, that the harm to Dr. Frech outweighs

any harm to the Government, and that granting preliminary and permanent injunctive relief is in the public interest.

89. Dr. Frech is therefore entitled to preliminary and permanent injunctive relief under 5 U.S.C. § 702.

PRAYER FOR RELIEF

WHEREFORE, Dr. Frech respectfully requests that the Court:

1. Preliminarily enjoin ORI and HHS from publishing the Charge Letter's findings and from debaring Dr. Frech, and schedule this matter for resolution on the merits;
2. Vacate and set aside the ORI and HHS findings and debarment, declaring them null and void and order that Dr. Frech's name not be entered into the System for Award Management available at www.sam.gov;
3. Permanently enjoin ORI and HHS from publishing research misconduct findings against Dr. Frech and from proposing for debarment and debaring Dr. Frech based on the conduct alleged in the Charge Letter;
4. If the Court is unwilling to grant permanent injunctive relief, Dr. Frech requests in the alternative that the Court hear and decide Dr. Frech's challenge to the merits of the findings and debarment;
5. Award Dr. Frech her reasonable attorneys' fees, including attorneys' fees under the EAJA and all costs and expenses; and
6. Grant such other relief as the Court deems just and proper.

Dated: August 29, 2023

COHEN SEGLIAS PALLAS GREENHALL & FURMAN PC

By: /s/ Jackson S. Nichols
Jackson S. Nichols (DC Bar 975511)
Stephen D. Tobin (*pro hac vice* motion pending)
Paul E. Simon (DC Bar # 1023006)
(D.D.C. *pro hac vice* motion pending)
900 Seventh Street, NW
Suite 725
Washington, DC 20001
Tel.: (202) 466-4110
Email: jnichols@cohenseglias.com

Attorneys for Plaintiff

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS Ivana Frech (b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF <u>Johnson Co.,</u> (EXCEPT IN U.S. PLAINTIFF CASES)	DEFENDANTS U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES XAVIER BECERRA, OFFICE OF RESEARCH INTEGRITY, SHEILA GARRITY, H. KATRINA BRISBON, The United States of America COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT <u>Washington, DC</u> (IN U.S. PLAINTIFF CASES ONLY) <small>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</small>																								
(c) ATTORNEYS (FIRMNAME, ADDRESS, AND TELEPHONE NUMBER) Jackson S. Nichols, Esq. Cohen Seglias Pallas Greenhall & Furman, PC 900 Seventh Street NW, Suite 725 Washington, DC 20001 (202) 466-4110	ATTORNEYS (IF KNOWN)																								
II. BASIS OF JURISDICTION (PLACE AN x IN ONE BOX ONLY) <div style="display: flex; justify-content: space-between;"> <div style="width:48%;"> <input type="radio"/> 1 U.S. Government Plaintiff </div> <div style="width:48%;"> <input type="radio"/> 3 Federal Question (U.S. Government Not a Party) </div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width:48%;"> <input checked="" type="radio"/> 2 U.S. Government Defendant </div> <div style="width:48%;"> <input type="radio"/> 4 Diversity (Indicate Citizenship of Parties in item III) </div> </div>	III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY! <table style="width:100%; border: none;"> <thead> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> </tr> </thead> <tbody> <tr> <td>Citizen of this State</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td style="text-align: center;"><input checked="" type="radio"/> 1</td> <td>Incorporated or Principal Place of Business in This State</td> <td style="text-align: center;"><input type="radio"/> 4</td> <td style="text-align: center;"><input type="radio"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input checked="" type="radio"/> 2</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td style="text-align: center;"><input type="radio"/> 5</td> <td style="text-align: center;"><input type="radio"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="radio"/> 6</td> <td style="text-align: center;"><input type="radio"/> 6</td> </tr> </tbody> </table>		PTF	DFT		PTF	DFT	Citizen of this State	<input type="radio"/> 1	<input checked="" type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4	Citizen of Another State	<input checked="" type="radio"/> 2	<input type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5	Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6
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IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

<input type="radio"/> A. Antitrust <input type="checkbox"/> 410 Antitrust	<input type="radio"/> B. Personal Injury/Malpractice <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Medical Malpractice <input type="checkbox"/> 365 Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Product Liability	<input type="radio"/> C. Administrative Agency Review <input type="checkbox"/> 151 Medicare Act <u>Social Security</u> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <u>Other Statutes</u> <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 890 Other Statutory Actions (If Administrative Agency is Involved)	<input checked="" type="radio"/> D. Temporary Restraining Order/Preliminary Injunction Any nature of suit from any category may be selected for this category of case assignment. *(If Antitrust, then A governs)*
<input type="radio"/> E. General Civil (Other) OR <input type="radio"/> F. Pro Se General Civil			
<u>Real Property</u> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent, Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property <u>Personal Property</u> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<u>Bankruptcy</u> <input type="checkbox"/> 422 Appeal 27 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <u>Prisoner Petitions</u> <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Conditions <input type="checkbox"/> 560 Civil Detainee – Conditions of Confinement <u>Property Rights</u> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent – Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 (DTSA)	<u>Federal Tax Suits</u> <input type="checkbox"/> 870 Taxes (US plaintiff or defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609 <u>Forfeiture/Penalty</u> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <u>Other Statutes</u> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 430 Banks & Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 462 Naturalization Application	<input type="checkbox"/> 465 Other Immigration Actions <input type="checkbox"/> 470 Racketeer Influenced & Corrupt Organization <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act (TCPA) <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

<input type="radio"/> G. Habeas Corpus/ 2255 <input type="checkbox"/> 530 Habeas Corpus – General <input type="checkbox"/> 510 Motion/Vacate Sentence <input type="checkbox"/> 463 Habeas Corpus – Alien Detainee	<input type="radio"/> H. Employment Discrimination <input type="checkbox"/> 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	<input type="radio"/> I. FOIA/Privacy Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	<input type="radio"/> J. Student Loan <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (excluding veterans)
<input type="radio"/> K. Labor/ERISA (non-employment) <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="radio"/> L. Other Civil Rights (non-employment) <input type="checkbox"/> 441 Voting (if not Voting Rights Act) <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 Americans w/Disabilities – Employment <input type="checkbox"/> 446 Americans w/Disabilities – Other <input type="checkbox"/> 448 Education	<input type="radio"/> M. Contract <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholder's Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="radio"/> N. Three-Judge Court <input type="checkbox"/> 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN
☒ 1 Original Proceeding
 ☐ 2 Removed from State Court
 ☐ 3 Remanded from Appellate Court
 ☐ 4 Reinstated or Reopened
 ☐ 5 Transferred from another district (specify)
 ☐ 6 Multi-district Litigation
 ☐ 7 Appeal to District Judge from Mag. Judge
 ☐ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
 5 U.S.C. § 701, the Administrative Procedure Act - suit to enjoin further action by U.S. government agency

VII. REQUESTED IN COMPLAINT

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$ Injunction

JURY DEMAND:

Check YES only if demanded in complaint
 YES ☐ NO ☐

VIII. RELATED CASE(S) IF ANY

(See instruction)

YES ☐ NO ☒

If yes, please complete related case form

DATE: August 29, 2023

SIGNATURE OF ATTORNEY OF RECORD /s/ Jackson S. Nichols

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil coversheet. These tips coincide with the Roman Numerals on the cover sheet.

- I.** COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.
- III.** CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV.** CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.
- VI.** CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII.** RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

)
)
)
)
)
)
)
)
)
)
)

Civil Action No. _____

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

for the

District of

Plaintiff(s)

V.

Civil Action No.

Defendant(s)

To: *(Defendant's name and address)*

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

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)

Civil Action No. _____

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Civil Action No. _____

Defendant(s)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

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I declare under penalty of perjury that this information is true.

Date: _____

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Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

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Civil Action No. _____

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

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Civil Action No. _____

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: