

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

IVANA FRECH,

Plaintiff,

v.

**U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,**

Defendants.

Case No. 23-cv-2530 (CRC)

MEMORANDUM OPINION

As a researcher at the University of Utah, Dr. Ivana Frech studied the molecular mechanisms of cellular iron regulation. But in 2011, the Office of Research Integrity (“ORI” or “the Office”), an agency within the Department of Health and Human Services (“HHS” or “the Department”), received allegations that she had manipulated the data underlying a series of research papers that she co-authored. ORI referred the allegations to the University of Utah. Two university committees conducted a thorough investigation, and after uncovering a “pattern of recklessness” in how Dr. Frech reported data across multiple publications, concluded that she committed research misconduct. The University of Utah terminated Dr. Frech’s employment and forwarded the committees’ findings to ORI.

In 2023—ten years after the University of Utah fired Dr. Frech—ORI concluded its own investigation. The Office identified six instances of research misconduct by Dr. Frech across three publications supported by the Department’s Public Health Service (“PHS”). Based on these findings, the HHS Deputy Assistant Secretary for Acquisitions (“the Debarring Official”) debarred Dr. Frech from participating in “covered transactions” for three years. Dr. Frech responded with this lawsuit, alleging that ORI’s misconduct findings and her debarment violated

the Administrative Procedure Act’s (“APA”) prohibition on arbitrary, capricious, or otherwise unlawful agency action. During the course of litigation, the government asked the Court to remand the case so that ORI could reexamine its conclusions. Upon remand, the Office considered additional evidence and concluded that Dr. Frech intentionally “falsified and/or fabricated” the data underlying her research. After considering both aggravating and mitigating factors, the Debarring Official agreed with ORI’s recommendation and retroactively imposed a three-year debarment period, beginning in August 2023.

The matter is now back before this Court, and the parties have filed cross-motions for summary judgment. Once again, Dr. Frech alleges that the Department’s actions violate the APA. For the reasons that follow, the Court will deny Dr. Frech’s motion and grant the government’s cross-motion.

I. Background

A. Regulatory Background

Many research institutions, including the University of Utah, receive funds from PHS to support biomedical and behavioral research. Administrative Record (“AR”) 4820. To qualify for PHS funding, an institution must “[h]ave written policies and procedures for addressing allegations of research misconduct” and “[r]espond to each allegation of research misconduct.” 42 C.F.R. § 93.300(a)–(b) (2005).¹ Federal regulations define “research misconduct” as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” *Id.* § 93.103 (2005). A finding of research misconduct requires a showing that (1) there was “a significant departure from accepted practices of the relevant

¹ For ease of reference, the Court refers to the federal regulations that were in effect on November 6, 2024, the date on which the Debarring Official imposed the three-year debarment period that is currently in effect.

research community”; (2) the misconduct was “committed intentionally, knowingly, or recklessly,” and (3) the allegation of misconduct “be proven by a preponderance of the evidence.” Id. § 93.104 (2005). Honest errors or mere differences of opinion do not amount to research misconduct. Id. § 93.103(d) (2005).

ORI is tasked with ensuring that an institution’s response to allegations of research misconduct complies with the relevant federal regulations. AR 4820; 42 C.F.R. § 93.400(f) (2005). When reviewing research misconduct proceedings, the Office may consider the reports and records prepared by the institution, gather additional evidence, conduct its own analyses, and decide whether research misconduct occurred. 42 C.F.R. § 93.403 (2005). ORI may then “[r]ecommend[] that HHS seek to settle the case” or “propose[] and obtain[] HHS approval of administrative actions.” Id. § 93.404(a) (2005). The administrative actions available to HHS include “retraction of the research record,” prohibiting participation “in any advisory capacity to the PHS,” or “[s]uspension or debarment.” Id. § 93.407(a) (2005).

Federal agencies “use[] the nonprocurement debarment and suspension system to exclude persons who are not presently responsible from Federal programs.” 2 C.F.R. § 180.125(b) (2024). An agency may debar a person for “[a]ny . . . cause that is so serious or compelling in nature that it affects [the person’s] present responsibility.” Id. § 180.800(d) (2024). A debarred person is generally prohibited from participating in “covered transactions,” including grants, scholarships, and fellowships. Id. §§ 180.200, 180.205(c), 180.210, 180.970(a) (2024). Ordinarily, a debarment period “should not exceed three years.” Id. § 180.865(a) (2024).

B. University of Utah Investigation

After receiving her doctoral degree in Italy, Dr. Frech joined the University of Utah as a postdoctoral fellow. AR 59. She worked in Dr. Jerry Kaplan’s laboratory, where she studied

how animal cells regulate iron levels. AR 59, 4922. In 2008, she was appointed as an assistant professor in hematology. AR 59, 620.

In November 2011, ORI received a report that multiple scientific publications co-authored by Dr. Frech and Dr. Kaplan contained data that “appear to have been fraudulently manipulated.” AR 571. Specifically, the complainant alleged that the publications “cut[] and past[ed] altered duplicate images . . . in different contexts.” Id. The director of ORI’s Division of Investigative Oversight forwarded the report to Dr. Jeffrey Botkin, the university’s research integrity officer. AR 606, 4046. Dr. Botkin formed an inquiry committee (the “Inquiry Committee”) shortly thereafter. AR 612.

The Inquiry Committee identified multiple papers by Dr. Frech and Dr. Kaplan that “contain[ed] misrepresentations of the primary results and thus deviate[d] significantly from accepted scientific practice.” AR 615. It also determined that “there was extreme carelessness on the part of Dr. De Domenico in preparing the figures [in the papers] and little oversight from Dr. Kaplan in ensuring that the figures in the papers accurately represented the primary data.”² Id. Notwithstanding this conclusion, the Inquiry Committee “did not uncover evidence of intent to deceive or misrepresent the data from the experiments in question,” and it did not recommend further investigation. Id. Dr. Botkin agreed with the Inquiry Committee’s findings and forwarded the university’s report to ORI in February 2012. AR 620–21.

A few weeks later, Dr. Botkin received a second report of “[a]dditional irregularities,” including “deliberate alterations of images” in at least two publications co-authored by Dr. Frech. AR 634. In light of this new complaint, Dr. Botkin convened a five-member

² Dr. Frech previously went by the name Dr. Ivana De Domenico. The Court will refer to the Plaintiff as Dr. Frech unless it is quoting directly from the administrative record.

investigation committee (the “Investigation Committee”) to review both the reported irregularities and any other publications co-authored by Dr. Frech and Dr. Kaplan. AR 634–35. Dr. Botkin informed ORI that the university was launching a full investigation. AR 707.

The Investigation Committee completed its work in December 2012. AR 962. It determined that the reported irregularities “constitute misrepresentations of the primary data and reflect a serious breakdown in the processes required to ensure that the scientific literature is a faithful record of research results.” Id. The committee also found that (1) the quantity of irregularities “indicates a reckless disregard for the integrity of the research record, as opposed to the occasional lapses that might occur in any laboratory”; (2) the “disregard for integrity extended beyond negligence to instances of intentional falsification . . . and the fabrication of data”; and (3) there was “strong evidence that the research record has been altered so as to hide misconduct or shift responsibility to others.” Id. In total, the Investigation Committee identified irregularities in “over 20” figures across at least ten research papers authored by Dr. Frech. AR 963, 965. Based on this “pattern of recklessness,” the Investigation Committee concluded that Dr. Frech engaged in scientific misconduct and recommended that the University of Utah revoke or decline to renew her appointment as a tenure-track faculty member. AR 966–67.³

Dr. Frech appealed the Investigation Committee’s findings to the University of Utah’s Office of the Academic Senate. AR 3847–49. The President of the Academic Senate formed a consolidated hearing committee panel (the “Hearing Committee”) to hear the appeal.

³ The Investigation Committee “found no evidence that Dr. Kaplan directly contributed to the misrepresentation or manipulation of data.” AR 967. But because of his “failure of appropriate supervision” of Dr. Frech, the committee recommended that the University of Utah relieve him of his senior leadership duties. AR 968.

After a hearing, the Hearing Committee concluded that Dr. Frech “engaged in research misconduct by ‘reckless disregard of accepted practices’ in her area of research.” AR 4045–53. In one paper, the Hearing Committee identified “images that were intentionally manipulated to present false data,” but it could not determine whether the manipulation was done by Dr. Frech specifically. AR 4048. In another, the committee pointed to “several instances of flipped or mislabeled images,” which “show[ed] reckless disregard to [sic] accepted practices.” Id. While the committee determined that “intentional irregularities” could not be attributed to Dr. Frech, it found that “the number and severity of errors in the publications where she is first author show reckless disregard for accepted practices.” AR 4049. It further acknowledged that Dr. Frech’s actions were “part of a larger pattern of complicity in misconduct within the Kaplan laboratories.” AR 4045. The Hearing Committee recommended that Dr. Frech be fired or allowed to resign. AR 4050.

In June 2013, the University of Utah’s president agreed with the Hearing Committee’s findings and terminated Dr. Frech’s employment. AR 4060.

C. ORI’s Initial Misconduct Findings

Shortly after the University of Utah concluded its investigation, Dr. Botkin forwarded the committees’ reports and case files to ORI. AR 1078. ORI acknowledged that it would conduct an independent review of the university’s investigation. See AR 4076. In September 2014, Dr. Frech informed the Office that she “vigorously opposed the accusations made against her” and “continue[d] to maintain that her accusers were incorrect and were motivated by bad faith.” AR 4078. She also asked that, if the Office conducted “any oversight review,” she be allowed to present additional arguments and evidence in her favor. AR 4080.

In 2017, ORI extended a settlement offer to Dr. Frech. AR 4818. Under the terms of the settlement, Dr. Frech would receive supervision and education in lieu of debarment. Id. But if Dr. Frech declined to settle the case, then ORI would “file a charge letter seeking to debar [her] from receiving Federal funds.” Id. Dr. Frech declined the settlement offer.

In July 2023—ten years after the committees’ investigations and nearly six years after the failed settlement negotiations—ORI charged Dr. Frech with research misconduct. AR 4783. The Office found “based on the preponderance of the evidence that [Dr. Frech] intentionally, knowingly, or recklessly falsified and/or fabricated western blot and autoradiogram images related to mechanisms of cellular iron regulation by reusing, relabeling, and manipulating images to falsely report data” in three PHS-supported research papers: a 2008 article published in Developmental Cell (the “2008 Article”), a January 2011 article published in Cell Metabolism (the “January 2011 Article”), and a November 2011 article published in Cell Metabolism (the “November 2011 Article”).⁴ AR 4788–89. The Debarring Official reviewed ORI’s findings and, after evaluating both aggravating and mitigating factors, determined that Dr. Frech’s research misconduct “provide[d] a cause for debarment.” AR 4784, 4802–03. The Debarring Official proposed debarring Dr. Frech for three years, prohibiting her from serving in an advisory capacity to PHS, and recommending that the 2008 Article be retracted.⁵ AR 4803.

The Office’s charge letter to Dr. Frech informed her that she could “contest the ORI findings of research misconduct and proposed HHS administrative actions by requesting an

⁴ A western blot is a technique used to detect and separate different proteins in a sample. The proteins appear as “bands” that can be photographed and assembled to create a figure displaying the results of an experiment. See Mot. Hr’g Tr. 19:7–22:21.

⁵ The January 2011 Article and the November 2011 article were retracted in June 2012. AR 4788.

administrative hearing before an administrative law judge with the HHS Departmental Appeals Board.” AR 4785; see 42 C.F.R. §§ 93.405(a)(3), 93.501(a) (2005). The hearing request had to be in writing and “sent to the [HHS Departmental Appeals Board] or ORI within 30 days of receipt” of the charge letter. AR 4785; see 42 C.F.R. § 93.501(b) (2005). After receiving the charge letter, Dr. Frech’s counsel contacted the Department and asked that “ORI reconsider its decision not to resolve this matter through a mutually agreeable settlement.” AR 4809. But on August 29, 2023, the Office informed Dr. Frech that because she did not request an administrative hearing within 30 days of the charge letter, her three-year debarment became a final HHS administrative action. AR 4812–13; 42 C.F.R. § 93.406 (2005).

D. Procedural History and Voluntary Remand

On the same day that Dr. Frech’s debarment became final, she filed this lawsuit. She alleged that ORI’s misconduct findings and the Debarment Official’s decision violated the APA because the agency actions “were arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, and contrary to law and regulation.” Compl. at 2. In her view, the Department’s actions were arbitrary and capricious because ORI and the Debarment Official (1) reached conclusions about Dr. Frech’s research misconduct that were “contrary” to the findings by the university committees, and (2) failed to adequately show that she acted intentionally, knowingly, or recklessly. Id. ¶¶ 73–74, 82–83. She asked the Court to vacate the HHS actions and order that her name be removed from the federal System for Award Management. Id., Prayer for Relief ¶ 2.

While the litigation was ongoing, Dr. Frech filed a motion for a temporary restraining order or preliminary injunction. She explained that her then-employer, a community hospital in Iowa City, had been purchased by the University of Iowa. Mot. for TRO or Prelim. Inj. at 10.

Because the University of Iowa does not employ debarred individuals, Dr. Frech's employment as a hospital administrator was effectively terminated. Id. Since there was "a limited window of time to lift the debarment and reclaim her job at the community hospital," Dr. Frech sought to enjoin HHS from enforcing her debarment. Id. at 21. After a hearing, the Court denied Dr. Frech's motion. Mot. Hr'g Tr. 42:2–4, 60:17–20. However, the Court cautioned that ORI "may have a bit more explaining to do," and "it may make sense for the government to consider a voluntary remand." Mot. Hr'g Tr. 50:19–20, 60:23–24. The Court highlighted three potential "shortcomings" in ORI's explanation for its debarment decision: first, a lack of detail in the Office's justification of its conclusion that Dr. Frech was personally responsible for an altered figure in one of the articles; second, a failure to grapple with Dr. Frech's argument that the passage of time since the alleged misconduct mitigated any concern that she was not presently responsible; and third, a failure to explain its determination that Dr. Frech "solely planned, initiation, and carried out the wrongdoing," which ran counter to the University of Utah investigation's finding that others were complicit. Mot. Hr'g Tr. 49:5–50:23.

Shortly after the hearing, the government asked the Court to remand the case to HHS so that the Department could reexamine the agency actions at issue. See Joint Status Report (ECF No. 31) at 1. The Court granted this request. Upon remand, Dr. Frech submitted evidence and arguments against her debarment. AR 4822–914.

In November 2024, ORI again concluded that Dr. Frech engaged in research misconduct and recommended a three-year debarment period. AR 4916. The Office specified that Dr. Frech "intentionally and knowingly falsified and/or fabricated" data reported in eight figures across the 2008 Article, the January 2011 Article, and the November 2011 Article. AR 4920–21. Her research misconduct "establishe[d] a lack of trustworthiness and [was] so serious and compelling

in nature that it demonstrate[d] a lack of present responsibility to be a steward of federal funds.” AR 4941. ORI also found that she lacked “present responsibility” because she “continue[d] to deny that she committed knowing and intentional misconduct,” and she “still present[ed] a risk” because she wished to return to her position as a hospital administrator. Id.

The Debarring Official reiterated that Dr. Frech’s research misconduct was “of so serious a nature that a debarment period is necessary to protect the United States Federal Government’s interests.” AR 4953–54. The Debarring Official enumerated the aggravating factors considered in reaching the decision, including the “significant impact” of Dr. Frech’s actions, the scope of the misconduct, the fact that Dr. Frech was solely responsible for the misconduct, her failure to sufficiently accept responsibility, and her desire to return to hospital administration. AR 4950–53. The Debarring Official also identified several mitigating factors, including Dr. Frech’s cooperation with the University of Utah’s investigation, her philanthropic activities, and her character references. AR 4952–54. After considering these factors, the ORI findings, and the administrative record, the Debarring Official debarred Dr. Frech for three years. AR 4953–54. She will remain ineligible until August 2026. AR 4954.

The matter is now back before the Court, and both parties have filed motions for summary judgment. Dr. Frech asserts that the post-remand agency actions “only confirmed [her] longstanding belief that her debarment is punitive, arbitrary, and capricious.” Pl.’s Mot. for Summ. J. at 2. The government counters that the “[t]he Debarring Official’s findings that [Dr.] Frech failed to demonstrate present responsibility, her misconduct is serious and compelling, and she was solely responsible for the misconduct were not arbitrary or capricious.” Defs.’ Cross-Mot. for Summ. J. at 9. The motions are ripe for consideration.

II. Standard of Review

“When evaluating cross motions for summary judgment under the APA, ‘the Rule 56 standard does not apply.’” Scott & White Health Plan v. Becerra, 693 F. Supp. 3d 1, 9 (D.D.C. 2023) (Cooper, J.) (quoting Alfa Int’l Seafood v. Ross, 264 F. Supp. 3d 23, 36 (D.D.C. 2017)). Instead, the Court “sits as an appellate tribunal,” and “[t]he ‘entire case’ on review is a question of law.” Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001). The Court must therefore “limit its review to the ‘administrative record’ and the facts and reasons contained therein to determine whether the agency’s action was ‘consistent with the relevant APA standard of review.’” Pol’y & Rsch., LLC v. HHS, 313 F. Supp. 3d 62, 74 (D.D.C. 2018) (quoting Ho-Chunk, Inc. v. Sessions, 253 F.Supp.3d 303, 307 (D.D.C. 2017)).

Under the APA, courts must “hold unlawful and set aside agency action[s]” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). The “arbitrary and capricious” standard is “a highly deferential one, which presumes the agency’s action[s] to be valid.” Oceana, Inc. v. Ross, 363 F. Supp. 3d 67, 76 (D.D.C. 2019) (Cooper, J) (quoting Env’tl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981)). The Court’s review is “narrow,” and it should not “substitute its judgment for that of the agency.” Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Even if the agency’s decision is of “less than ideal clarity,” the Court may uphold the decision “if the agency’s path may reasonably be discerned.” Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974); see also St. Lawrence Seaway Pilots Ass’n v. U.S. Coast Guard, 357 F. Supp. 3d 30, 35 (D.D.C. 2019) (Cooper, J.); Nat. Res. Def. Council, Inc. v. Coit, 597 F. Supp. 3d 73, 85 (D.D.C. 2022) (Cooper, J.).

Debarment is a “serious” agency action that may only be taken “to protect the public interest”; it may not be used “for the purposes of punishment.” 2 C.F.R. § 180.125(c) (2024); see 42 C.F.R. § 93.408 (2005). “Once a cause for debarment is established,” the “respondent ha[s] the burden of demonstrating to the satisfaction of the debarring official that [she is] presently responsible and that debarment is not necessary.” 2 C.F.R. § 180.855(b) (2024). When evaluating whether a respondent is presently responsible, the debarring official may consider both aggravating and mitigating factors. See 2 C.F.R. §§ 180.845(a), 180.860 (2024); 42 C.F.R. § 93.408 (2005). Some factors are enumerated in the federal regulations, but “[t]he debarring official may consider other factors if appropriate in light of the circumstances of a particular case.” 2 C.F.R. § 180.860 (2024). When evaluating a debarment decision under the “arbitrary and capricious” standard of review, the Court must ensure that there is a “rational connection” between the facts of the case—including any mitigating factors—and the decision to impose debarment. See Canales v. Paulson, No. 06-cv-1330 (GK), 2007 WL 2071709, at *6 (D.D.C. July 16, 2007); see also Campbell v. Schmidt, No. 20-cv-1785 (CRC), 2020 WL 6445874, at *5 (D.D.C. Nov. 3, 2020) (“An agency’s decision to debar a contractor is subject to review under the traditional arbitrary and capricious standard set forth in the APA.” (citation and internal quotation marks omitted)).

III. Analysis

Dr. Frech offers a host of reasons why her debarment violated the APA. Her claims largely fall within two broad categories, although the parties’ arguments often straddle the line between them. First, Dr. Frech contends that her debarment was contrary to law because it was punitive. See 2 C.F.R. § 180.125(c) (2024); 42 C.F.R. § 93.408 (2005). Second, she submits that her debarment was arbitrary and capricious because ORI and the Debarment Official failed

to show that her misconduct was “serious and compelling,” hold others responsible for the same misconduct, or adequately consider several mitigating factors. As explained below, neither set of arguments carries the day.

A. Whether Dr. Frech’s Debarment was Punitive

A key issue throughout the administrative proceedings was whether Dr. Frech knowingly and intentionally engaged in research misconduct. ORI concluded that she “intentionally and knowingly falsified and/or fabricated” data in three publications; Dr. Frech maintains that she only acted recklessly. AR 4921; Pl.’s Mot. for Summ. J. at 18. Now, Dr. Frech claims that the Department is “[p]enalizing” her with debarment because of this “good-faith disagreement.” Pl.’s Mot. for Summ. J. at 18.

As noted above, there are several “mitigating and aggravating factors that the debarring official may consider in determining whether to debar” an individual. 2 C.F.R. § 180.860 (2024). Among these factors is whether the individual “accepted responsibility for the wrongdoing and recognize[d] the seriousness of the misconduct that led to the cause for debarment.” *Id.* § 180.860(g) (2024). While “[t]he existence or nonexistence of any factor . . . is not necessarily determinative of [the individual’s] present responsibility,” *id.* § 180.860 (2024), the Debarring Official may weigh the factors at her discretion, Sloan v. HUD, 231 F.3d 10, 14 (D.C. Cir. 2000); Legion Constr., Inc. v. Gibson, 310 F.R.D. 1, 4 (D.D.C. 2015); Burke v. EPA, 127 F. Supp. 2d 235, 238, 242 (D.D.C. 2001).

When evaluating whether Dr. Frech was presently responsible, ORI observed that she “never took responsibility for her knowing and intentional research misconduct.” AR 4941. She did “express[] regret over the situation,” but she also claimed that “reckless laboratory-wide practices led to the publication of incorrect research images.” *Id.* (quoting AR 4823). ORI

concluded that these statements—made as recently as September 2024—were “far from accepting responsibility for [her] intentional and knowing research misconduct.” Id.

The Debarring Official also considered Dr. Frech’s “failure to sufficiently accept responsibility” when evaluating the aggravating and mitigating factors for debarment. AR 4952. While Dr. Frech “express[ed] remorse” and admitted to making “mistakes,” she maintained that “those mistakes were not intentional or done knowingly.” Id. The Debarring Official concluded that, in light of ORI’s contrary findings, Dr. Frech’s limited concessions were “disingenuous,” and her failure to accept responsibility weighed in favor of debarment. Id.

As the Court noted previously, these conclusions are supported by the record. Mot. Hr’g Tr. 47:25–48:10. Still, Dr. Frech submits that she should not be “penalize[ed]” for her “good-faith disagreement” as to whether she acted knowingly and intentionally. Pl.’s Mot. for Summ. J. at 18. While the Court doesn’t doubt the veracity of her belief, the Department is not punishing her for contesting its findings. Rather, ORI determined that her persistent “fail[ure] to recognize the seriousness of her misconduct” demonstrated a lack of present responsibility. AR 4943. This determination is not punitive, but simply relevant to whether she should be debarred. See Brodie v. HHS, 796 F. Supp. 2d 145, 156 (D.D.C. 2011) (recognizing that whether the plaintiff “expressed remorse or accepted responsibility for his actions” relates to whether “it was in the public interest” to debar him).

As evidence that her debarment was punitive, Dr. Frech contends that her failure to accept responsibility was the Department’s “sole test” for measuring whether she was presently responsible. Pl.’s Mot. for Summ. J. at 15. The record suggests otherwise. In a section titled “Respondent Lacks Present Responsibility,” the amended ORI charge letter cited both her failure to accept responsibility *and* her desire to return to her position at the community hospital, which

“appeared to include responsibilities adjacent to covered transactions.” AR 4941. The Debarring Official agreed, concluding that—among many other aggravating and mitigating factors—Dr. Frech’s intent to return to the hospital “still presents a risk.” AR 4953. So, contrary to Dr. Frech’s suggestion, her failure to accept responsibility was not the *only* basis for concluding that she was not presently responsible.

To be sure, Dr. Frech had “every right to disagree” that she acted knowingly and intelligently. Pl.’s Mot. for Summ. J. at 17. But the Debarring Official also had “every right” to consider her failure to accept responsibility when assessing whether she was presently responsible. See 2 C.F.R. § 180.860 (2024). And critically, it was Dr. Frech’s burden to show that she *was* presently responsible and that debarment was *not* necessary. See id. § 180.855 (2024). Because ORI and the Debarring Official adequately explained why she failed to meet that burden, there is no basis to conclude that her debarment was punitive.

Dr. Frech also faults the Department for failing to “explain[] how it reached a different conclusion than [the University of Utah] regarding [her] scienter.” Pl.’s Mot. for Summ. J. at 20. As she correctly notes, both University of Utah committees concluded only that she acted recklessly. See AR 962 (finding that Dr. Frech showed “a reckless disregard for the integrity of the research record”), 4045 (concluding that Dr. Frech “engaged in research misconduct by ‘reckless disregard of accepted practices’ in her area of research”). The Court previously noted that while ORI was not obligated to accept the committees’ conclusion, see 42 C.F.R. §§ 93.400(a)(7), 93.403(d)–(g) (2005), the Office “may still have a duty to explain the basis for its difference of opinion more fully” on remand, Mot. Hr’g Tr. 50:16–17. ORI did just that, explaining why it found that Dr. Frech acted not just recklessly, but knowingly and intelligently. See, e.g., AR 4927 (considering Dr. Frech’s admission that she “assembled” the manipulated

figure in the 2008 Article while noting that the Hearing Committee “did not address” the admission), 4934 (noting that Dr. Frech was the first author of the November 2011 Article and generated the figure under review), 4936 (same). That conclusion was “within the bounds of reasoned decisionmaking,” and the Court may not “substitute [its] judgment for that of the [Department].” Dep’t of Com. v. New York, 588 U.S. 752, 773 (2019) (citation omitted); see Mot. Hr’g Tr. 45:20–22 (“The record also supports [ORI’s] finding that Dr. Frech committed this misconduct knowingly and intentionally.”).

B. Whether Dr. Frech’s Debarment was Arbitrary and Capricious

Dr. Frech next launches a barrage of attacks on the Department’s debarment decision in her effort to show that it was arbitrary and capricious under the APA. First, the Debarring Official failed to demonstrate that her misconduct was serious and compelling. Second, the Debarring Official arbitrarily debarred her while failing to hold responsible other researchers who committed similar misconduct. Third, the Debarring Official failed to properly consider the significant passage of time between Dr. Frech’s conduct and the decision to debar her. Fourth, Dr. Frech’s conduct since her termination from the University of Utah shows that she is presently responsible. Fifth, the Debarring Official arbitrarily refused to consider other mitigating factors that bear on her present responsibility. This volley falls short.

1. *The “Serious and Compelling” Nature of Dr. Frech’s Conduct*

Dr. Frech first claims that, if her conduct were as “serious and compelling in nature” as ORI suggests, then it would not have waited more than ten years before deciding to debar her. Pl.’s Mot. for Summ. J. at 40 (quoting AR 4803). She also faults ORI for providing “zero explanation” for this delay in administrative action. Id. at 39.

As explained above, an agency may debar a person for “[a]ny . . . cause that is so serious or compelling in nature that it affects [the person’s] present responsibility.” 2 C.F.R.

§ 180.800(d) (2024). In exercising that authority, ORI determined that Dr. Frech’s conduct “establishes a lack of trustworthiness and is so serious and compelling in nature that it demonstrates a lack of present responsibility to be a steward of federal funds.” AR 4941.

Among several other factors, the Office described how Dr. Frech’s research misconduct (1) “had a significant impact on the proposed and reported research record, other researchers, institutions, and the public health or welfare”; (2) “undermines the integrity of the scientific community”; (3) occurred in three PHS-supported papers; and (4) led to the retraction of the two 2011 articles and the recommended retraction of the 2008 Article. AR 4942–43. The Debarring Official then echoed these conclusions in the notice of debarment. AR 4950–51. In light of these findings, it was neither arbitrary nor capricious for the Department to find that Dr. Frech’s misconduct was serious and compelling enough to warrant debarment. See Mot. Hr’g Tr. 47:16–17.

The length of time between Dr. Frech’s actions and her debarment does not suggest otherwise. True, the passage of time may be relevant to whether Dr. Frech was presently responsible. See Mot. Hr’g Tr. 50:3–8 (“[W]hile the Court harbors no doubt that [ORI] was well aware of the timeline when issuing its charge letter and imposing the three-year debarment, [ORI] may have had to explain why this factor did not ameliorate its concerns about Dr. Frech’s present responsibility.”). But the delay does not necessarily reflect the Office’s views on whether her conduct was serious and compelling. Rather, ORI explained that the delay was “[d]ue to the large and growing volume of ORI’s responsibilities relative to its staffing levels.” AR 4944; see also AR 4820–21 (explaining that the Office receives hundreds of allegations per

year but only retains a handful of full-time scientist-investigators on staff). In short, the passage of time relates to her present responsibility, not the severity of her underlying conduct.

2. Misconduct Committed by Other Researchers

Dr. Frech next accuses ORI and the Debarring Official of arbitrarily debarring her while failing to address similar misconduct committed by other researchers. As she notes, the university committees determined that Dr. Kaplan and Dr. Diane Ward, another co-author of the three research papers at issue, had “varying degrees of responsibility” for the irregularities in the western blot images. Pl.’s Mot. for Summ. J. at 32. But while the Department debarred Dr. Frech for her role in the misconduct, it was, in her telling, “entirely dismissive of the accountability of” Dr. Kaplan and Dr. Ward. *Id.* at 33.

The University of Utah formed the Investigation Committee to investigate allegations of research misconduct against Dr. Frech and Dr. Kaplan. *See* AR 962. While that committee’s report focused primarily on Dr. Frech’s “pattern of recklessness” and disregard of accepted scientific practices, AR 966–67, it also evaluated Dr. Kaplan and Dr. Ward’s responsibility. As to Dr. Kaplan, the Investigation Committee “found no evidence that [he] directly contributed to the misrepresentation or manipulation of data.” AR 967. Still, the committee acknowledged that Dr. Kaplan exhibited “a systematic lack of attention to detail” and an “inappropriate and unacceptable distance from primary findings and their reduction to figures and other displays for publication.” *Id.* As to Dr. Ward—who was not a respondent of the investigation—the Investigation Committee noted that she “performed unacknowledged splicing of western blot images, some of which were obvious in the figures.” AR 968. The quantity of errors on Dr. Ward’s part suggested a “lack of attention to detail, failure to examine the raw data, inadequate mentorship in protecting the fidelity of the data, and failure to insist on rigorous and clear

assurance of the integrity of the data.” Id. While committee found no evidence of an “intent to deceive or manipulate data,” it concluded that Dr. Ward shirked her “responsibility to assure the accurate representation of primary data.” Id.; see also AR 965 (noting that for the 2008 Article, the Investigating Committee was “struck by the conspicuous failure of all coauthors, particularly Drs. Ward and Kaplan, to catch and correct [Dr. Frech’s] mistakes before publication”).

After Dr. Frech appealed the Investigation Committee’s findings, she was the sole respondent before the Hearing Committee. AR 4045. Here too, the committee focused primarily on Dr. Frech’s conduct, but it also acknowledged errors by Dr. Kaplan and Dr. Ward. For example, the committee determined that “Dr. Ward was probably responsible for at least one irregularity that was beyond the knowledge base of” Dr. Frech. AR 4047. The Hearing Committee ultimately agreed that there was “complicity in [Dr. Frech’s] misconduct within the laboratory that [went] substantially beyond” her own conduct. AR 4050. However, the Hearing Committee did not conclude that Dr. Kaplan or Dr. Ward intentionally or knowingly engaged in research misconduct, nor did it recommend that any specific action be taken against them. See id.

Dr. Frech first complains that the Department “seems uninterested in exploring Dr. Ward’s ‘sloppiness’ and ‘carelessness’ in the fidelity of data.” Pl.’s Mot. for Summ. J. at 34. But the university committees responded to allegations of research misconduct against Dr. Frech and Dr. Kaplan, not Dr. Ward. And they only made findings of misconduct against Dr. Frech. After the university sent its findings to ORI, the Office conducted an “oversight review” of the university’s investigations and “its own image analysis of [Dr.] Frech’s work.” AR 4925. Because the university investigations centered on Dr. Frech and not Dr. Ward, ORI did not

“arbitrarily single[] out” Dr. Frech by issuing research misconduct findings against her alone. Pl.’s Mot. for Summ. J. at 36.

Dr. Frech next claims that the Debarring Official’s decision to debar Dr. Frech, but not Dr. Kaplan or Dr. Ward, violated the APA because it was “arbitrary.” Id. However, an agency’s decision to *not* initiate debarment proceedings is unreviewable. See Kissner v. Cisneros, 14 F.3d 615, 620 (D.C. Cir. 1994) (citing Heckler v. Chaney, 470 U.S. 821 (1985)). The decision to not bring an enforcement action is within an agency’s “prosecutorial discretion,” so HHS does not need to “demonstrate consistency in exercising its discretion.” Campbell, 2020 WL 6445874, at *11 (quoting Kissner, 14 F.3d at 619 n.5). For that reason, the Court cannot opine on whether the Debarring Official had a “rational basis” for declining to debar Dr. Ward. Pl.’s Mot. for Summ. J. at 35.

Dr. Frech concedes that “an agency’s decision not to investigate is, *in general*, essentially non-reviewable.” Pl.’s Opp. to Defs.’ Cross-Mot. for Summ. J. and Reply to Defs.’ Opp. to Pl.’s Mot. for Summ. J. (“Pl.’s Reply Br.”) at 17. But she claims that this rule does not apply here because the Department’s decision to “do nothing” about Dr. Kaplan or Dr. Ward’s conduct amounts to “an abdication of its regulatory function.” Id. at 16–17 (citing N. Ind. Pub. Serv. Co. v. FERC, 782 F.2d 730, 745–46 (7th Cir. 1986)). To be sure, Chaney suggested that an agency’s decision to forego an enforcement action might be reviewable if “the agency has ‘consciously and expressly adopted a general policy’ that is so extreme as to amount to an abdication of its statutory responsibilities.” 470 U.S. at 833 n.4 (citation omitted); see also Block v. SEC, 50 F.3d 1078, 1082 (D.C. Cir. 1995). Here, however, the record demonstrates that ORI routinely brings debarment proceedings. See AR 4820. Dr. Frech’s citation to a single instance of

nonenforcement is plainly insufficient to trigger this exception. See CREW v. FEC, 892 F.3d 434, 440 n.9 (D.C. Cir. 2018).

Put simply, the Debarring Official’s decision to not debar Dr. Kaplan or Dr. Ward is unreviewable, and it cannot establish that the decision to debar Dr. Frech was arbitrary and capricious.⁶ See Campbell, 2020 WL 6445874, at *11.

3. *The Passage of Time Between Dr. Frech’s Actions and Her Debarment*

Dr. Frech also launches several attacks on how the Department evaluated the time between her research misconduct and the debarment decision. Her initial salvo aims at the length of time itself, as she claims that the Debarring Official “fail[ed] to meaningfully evaluate the passage of time and its impact on [her] present responsibility.” Pl.’s Mot. for Summ. J. at 25.

As both parties acknowledge, ORI issued its research misconduct findings more than ten years after the University of Utah concluded its investigation. In its initial charge letter, ORI did not explicitly consider this ten-year gap as a mitigating factor weighing against debarment. See AR 4802. To be sure, it was not *required* to consider the passage of time, see 2 C.F.R. § 180.860 (2024), but as the Court previously articulated, the Office “may have had to explain why this factor did not ameliorate its concerns about Dr. Frech’s present responsibility,” Mot. Hr’g Tr. 50:6–8. On remand, ORI’s amended charge letter stated that it “considered the length of time elapsed, but found, on balance, that debarment was still appropriate because of countervailing factors discussed in th[e] charge letter, including [Dr. Frech’s] failure, even today, to accept responsibility for and recognize the seriousness of her misconduct.” AR 4944. The Debarring

⁶ In her reply brief, Dr. Frech suggests in passing that the Department’s “failure to investigate Dr. Ward demonstrates [that] the underlying conduct was not serious and compelling.” Pl.’s Reply Br. at 15. However, Dr. Frech waived this argument by failing to raise it in her motion for summary judgment. See Am. President Lines, LLC v. Matson, Inc., 775 F. Supp. 3d 379, 404 (D.D.C. 2025) (Cooper, J.).

Official also “acknowledge[d] the amount of time that passed,” but similarly concluded that debarment was still appropriate in light of several aggravating factors, including her failure to accept responsibility. See AR 4953.

Dr. Frech submits that these explanations are insufficient. She notes that at least two courts in this district set aside a debarment decision because the debarring official failed to consider the length of time that had passed since the respondent’s underlying conduct. In Roemer v. Hoffmann, for example, the court set aside a three-year debarment because the debarring official failed to explain why he “attributed little or no importance” to several mitigating factors, including the length of time since the respondent’s offense, and “what it was about the offense which necessitates, despite these factors, a debarment of three years.” 419 F. Supp. 130, 132 (D.D.C. 1976). And in Canales v. Paulson, the debarring official “acknowledged that [mitigating] factors existed,” including the five years that had passed since the respondent’s offense, but impermissibly “imposed the maximum term of debarment without explaining why he found them unpersuasive.” 2007 WL 2071709, at *6. Dr. Frech says that here too, the Department’s “consideration” of the delay between her conduct and the debarment decision “appears to be nothing more than a box-checking exercise.” Pl.’s Reply Br. at 11.

While the Department’s reasoning might not be as detailed as Dr. Frech (or the Court) would like, it is sufficient under the APA’s deferential standard of review. In Roemer and Canales, the debarring officials provided *no* explanation for why the passage of time did not affect the respondents’ present responsibility. See 419 F. Supp. at 131–32 (debarring official “simply inferred from the nature of the particular offense” that the respondent should be disbarred); 2007 WL 2071709, at *6 (debarring official “did not in any way explain his decision to impose debarment rather than a lesser sanction, given the strength of the mitigating factors”).

Here, by contrast, ORI and the Debarring Official explained that “on balance,” the mitigating effect of any delay was outweighed by specific aggravating factors, including Dr. Frech’s continuing failure to accept responsibility. AR 4944, 4953. This assessment of the passage of time—including the “relative *weight* assigned” to it—is supported by substantial evidence, so the Court cannot conclude that it was arbitrary or capricious. Burke, 127 F. Supp. 2d at 241 (holding that a debarment decision did not violate the APA because it “clearly” indicated that the agency “evaluated each mitigating factor” raised by the respondent, including the “time that has elapsed”).⁷

4. Dr. Frech’s Conduct Since Her Termination from the University of Utah

In addition to the length of time between her research misconduct and the debarment decision, Dr. Frech challenges the Department’s assessment of her conduct during that time. Specifically, she contends that her “positive impact and unblemished record” at another laboratory demonstrates that she is presently responsible. Pl.’s Mot. for Summ. J. at 27.

After the University of Utah terminated Dr. Frech’s employment in June 2013, she “stepped away from science altogether and obtained her MBA.” AR 4824. In 2015, she accepted a position as a research scientist in Dr. Fenghuang Zhan’s laboratory at the University of Iowa. Id. Upon joining the lab, she purportedly agreed to have her work monitored by an internal data monitoring committee. AR 4832–33. Dr. Frech attests that during her four years in

⁷ Dr. Frech also complains that the Department failed to adequately explain why it took ten years for ORI to issue the initial charge letter. See Pl.’s Mot. for Summ. J. at 24–25. While the delay is certainly “regrettable,” Defs.’ Cross-Mot. for Summ. J. at 23, the *reason* for the delay has no bearing on Dr. Frech’s present responsibility. Rather, the length of time itself is “just one factor” among many that “might have spoken” to her present responsibility. Uzelmeier v. HHS, 541 F. Supp. 2d 241, 248 (D.D.C. 2008).

Dr. Zhan’s lab, “no one ever raised a concern with the veracity or accuracy of [her] work, nor did anyone ever question [her] professionalism and integrity.” AR 4854.

In its amended charge letter, ORI questioned Dr. Frech’s characterization of her role in Dr. Zhan’s lab. It first noted that there was no evidence, other than Dr. Frech’s “say so,” that she agreed to a research monitoring plan. AR 4945. The charge letter then identified several instances in which she was purportedly not “transparent about her involvement with federally funded research while working in the Zhan laboratory.” Id. While her alleged lack of candor “underscore[d] her lack of present responsibility,” AR 4946, the Office ultimately concluded that “[e]ven if HHS were to accept the truth” of Dr. Frech’s assertions, that conduct “would not be dispositive, particularly in light of the countervailing factors” weighing in favor of debarment, AR 4944.

Dr. Frech vigorously disputes the Office’s contention that she was not forthcoming about her research activities in Dr. Zhan’s lab. But even accepting the veracity of her claims, she is ultimately asking the Court to reweigh a mitigating factor that ORI already considered. See, e.g., Pl.’s Mot for Summ. J. at 26 (“Dr. Frech’s conduct following her termination from [the University of Utah] is not the behavior of someone with a propensity for acting irresponsibly.”); Pl.’s Reply Br. at 9 (“[T]he Debarring Official refuses to credit Dr. Frech’s unblemished record while at Dr. Zhan’s laboratory as a factor in her present responsibility.”). However, the Office concluded that Dr. Frech’s tenure in Dr. Zhan’s lab—unblemished or not—would not “diminish the appropriateness of her debarment or its length.” AR 4944. Agree or disagree with that determination, it was the product of reasoned decisionmaking and therefore “must be upheld” under the deferential APA standard of review. Burke, 127 F. Supp. 2d at 241 (noting that the Court cannot “substitute [its] judgment for that of agency officials”); Mot. Hr’g Tr. 49:2–4

(concluding that Dr. Frech may “contest” whether she engaged in PHS-funded research in Dr. Zhan’s lab, but “it was her duty to prove that [the Office] erred in failing to consider a mitigating factor”).

5. Consideration of Other Mitigating Factors

In Dr. Frech’s final offensive against the debarment decision, she alleges that the Department arbitrarily discounted mitigating evidence that demonstrated her present responsibility.

After the Court remanded the case to the Department, Dr. Frech submitted testimonials from two of her recent employers. She first quoted a 2018 statement by Dr. Zhan, who reported that Dr. Frech “emphasizes the importance of academic integrity and best lab practices.” AR 4854. She also submitted a letter from the Chief Integrity Officer at the community hospital where she worked, who described Dr. Frech as “uphold[ing] the highest integrity, morals, and ethical character.” AR 4841. In response to this evidence, the Debarring Official “commend[ed] Dr. Frech’s contributions to the community and acknowledge[d] the character references presented.” AR 4953. However, the Debarring Official noted that these testimonials were not “relevant to the underlying debarment cause and wrongdoing at issue, which is research misconduct.” Id. The Debarring Official then concluded that she did “not find that any of these activities and character references, or purported good conduct, are appropriate to diminish Dr. Frech’s period of debarment or its length.” Id.

Dr. Frech homes in on the Debarring Official’s description of this evidence as not “relevant.” In her view, “[t]here is simply no credible way [the Department] can spin” the character references “as unrelated to Dr. Frech’s present responsibility.” Pl.’s Mot. for Summ. J. at 38.

This argument mischaracterizes the Debarring Official’s conclusion. To be sure, the language the Debarring Official used was “of less than ideal clarity.” Burke, 127 F. Supp. 2d at 242 (citing Bowman, 419 U.S. at 286). But the Debarring Official did not state that Dr. Frech’s character references were “unrelated” to her present responsibility. Instead, she made two distinct points. First, the references were not “relevant” to the underlying *cause* of Dr. Frech’s debarment: her research misconduct in three scientific papers between 2008 and 2011. AR 4953. Second, the references did not “diminish” the need for or the length of her debarment. Id. That is, the mitigating effect of the character references did not outweigh the aggravating factors—such as the quantity of research misconduct, its effect on the research record, and Dr. Frech’s failure to accept responsibility—in favor of debarment. See AR 4950–53; Mot. Hr’g Tr. 47:18–49:4. Because the Debarring Official adequately considered this mitigating factor, and the reason for rejecting it “may reasonably be discerned,” the Court must uphold the decision. Burke, 127 F. Supp. 2d at 242 (citing Bowman, 419 U.S. at 286).

* * *

After reviewing ORI’s amended charge letter, the Debarring Official’s decision, and the entire administrative record, the Court cannot conclude that the decision to debar Dr. Frech for three years was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. See 5 U.S.C. § 706(2)(A). The Department addressed the Court’s concerns, articulated “a rational connection between the facts found and the choice made,” provided “substantial evidence” supporting its decision, and made no “clear error in judgment.” Kisser, 14 F.3d at 619 (citations omitted).

Still, it is worth noting the limits of the Court’s opinion. The Court is not stating that it would have reached the same conclusion as the Debarring Official. See State Farm, 463 U.S. at

43 (noting that the Court “is not to substitute its judgment for that of the agency”). The Court is not justifying the Department’s ten-year delay in issuing its debarment decision. See Defs.’

Cross-Mot. for Summ. J. at 23 (noting that “[t]he Office could have done a better job to keep this matter moving . . . and will endeavor to do so in the future”). And the Court does not doubt that Dr. Frech may make meaningful contributions to the scientific community in the future. Instead, the Court simply adheres to the “highly deferential” standard of review under the APA. Kisser, 14 F.3d at 618.⁸

IV. Conclusion

For the foregoing reasons, the Court will deny Plaintiff’s Motion for Summary Judgment and grant Defendants’ Cross-Motion for Summary Judgment. A separate Order shall accompany this memorandum opinion.

CHRISTOPHER R. COOPER
United States District Judge

Date: December 12, 2025

⁸ Because the Court concludes that the Department’s decision to debar Dr. Frech did not violate the APA, it does not address the remaining elements for permanent injunctive relief. The Court also declines to opine on the government’s belated argument that the Privacy Act precludes relief under the APA in this case.