

AN OVERVIEW OF THE RESEARCH MISCONDUCT PROCESS AND AN ANALYSIS OF THE APPROPRIATE BURDEN OF PROOF

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INTRODUCTION

The number of research misconduct cases faced by institutions has increased substantially over recent years.¹ The proffered explanations for this increase range from greater pressure on scientists to publish quickly to there simply being more emphasis in identifying research misconduct.²

1. The Office of Research Integrity (ORI) is a component of the Office of the Assistant Secretary for Health in the Office of the Secretary, within the U.S. Department of Health and Human Services (HHS). The ORI's mission includes research misconduct investigations. The ORI's Annual Report for 2012 states as follows:

In 2012, the 6,714 funded institutions reported 323 allegations, inquiries, or investigations. The count in year 2012 is a record of what institutions submitted in their 2011 Annual Report, which is submitted to ORI in 2012. . . .; From all sources, ORI received 423 allegations in 2012, an increase of 56 percent over the 240 allegations handled in 2011, and well above the 1992-2007 average of 198; [The Division of Investigative Oversight's] review process involved opening 41 new cases, closing 35, and carrying 45 cases into 2013. The number of open cases was the highest number in 16 years. ***In 2012, ORI made findings of research misconduct in 40 percent of the cases (14/29). In contrast, the historical average of this finding is 36 percent; Administrative actions imposed on those who committed research misconduct included: debarred 6 respondents for a varying number of years, prohibited 14 from working as advisors, and required 9 to be supervised in any PHS-supported research activity. OFFICE OF RESEARCH INTEGRITY, 2012 ANNUAL REPORT.

See also, Dr. Jim Kroll, Director, Research Integrity and Administrative Investigations Unit, NATIONAL SCIENCE FOUNDATION OFFICE OF INSPECTOR GENERAL, *NSF OIG: Stories from the Case Files* ("Kroll Presentation"), available at <http://www.slideserve.com/poppy/nsf-oig-stories-from-the-case-files-national-science-foundation-office-of-the-inspector-general> (contains statistics on NSF's research misconduct investigations). To assist the reader, there is an appendix setting forth the most common abbreviations used in this article.

2. A 2015 article in Science News noted that researchers are facing unprecedented funding challenges that put "scientist under extreme pressure to publish quickly and often." According to the article "[t]hose pressures may lead researchers to publish results before proper vetting or to keep hush about experiments that didn't pan out." Tina Hesman Saey, *Repeat Performance: Too Many Studies, When Replicated, Fail to Pass Muster*, 187 SCIENCE NEWS 21 (Jan. 24, 2015). In a PowerPoint presentation at the INORMS 2014 CONCURRENT SESSIONS, the presenters answered the question of why there is an increase in research misconduct cases at NSF by setting forth the following: "We have become better at catching it. Increased

“Research misconduct” is broadly defined to mean fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. For purposes of that definition: (a) “fabrication” is making up data or results and recording or reporting them;³ (b) “falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record;⁴ and (c) “plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.⁵ Research misconduct does not include honest error or differences of opinion.⁶

This article discusses the administrative process in research misconduct cases pursuant to regulations adopted by the Department of Health and Human Services (HHS) and by the National Science Foundation (NSF). It also analyzes key legal terms and discusses the burden of proof applied in research misconduct cases with a focus on those instances where HHS or NSF seek to debar the researcher from future government contracts or grants.

Consider the following simplified example.⁷

Dr. White was the principal investigator on Project X. Dr. Black was a post-doctoral researcher working with Dr. White. Dr. White’s team ran three complex and expensive experiments to test a particular hypothesis—Experiment 1, Experiment 2 and Experiment 3. Experiments 1 and 3 were consistent with the

competition for limited resources; Technology makes it easier to cheat and to catch a cheat. High profile cases increase awareness. RCR training increases awareness. Government interaction with research communities raise awareness of our role in handling RM allegations.” NATIONAL SCIENCE FOUNDATION, OFFICE OF THE INSPECTOR GENERAL RESEARCH INTEGRITY AND ADMINISTRATIVE INVESTIGATIONS DIVISION, *Navigating the Research Misconduct Process: Observations from the U.S. National Science Foundation OIG* (2016), available at tmcstrategies.net/wp-content/uploads/2016/04/NSF-OIG-Presentation.pptx.

3. See, e.g., *Case Summary: Chen, Li*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/chenli> (last visited May 29, 2016).

4. See, e.g., *Case Summary: Bijan, Ahvazi*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/content/case-summary-ahvazi-bijan> (last visited May 29, 2016).

5. See, e.g., 20 OFFICE OF RESEARCH INTEGRITY NEWSLETTER 1, 7 (2011), available at https://ori.hhs.gov/images/ddblock/dec_vol20_no1.pdf. More information on plagiarism can be found at 26 *Guidelines at a Glance on Avoiding Plagiarism*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/plagiarism-0> (last visited May 29, 2016).

6. 42 CFR § 93.103 (2015); 45 CFR § 689.1(a) (2015).

7. Use of the hypothetical is not intended to suggest that HHS or NSF would seek debarment in such a case. To the contrary, a review of HHS and NSF debarment cases indicates that the agencies seek debarment only when the evidence of misconduct is significantly stronger. Nevertheless, under the current regulations, nothing would preclude the agencies from seeking debarment even under the facts of the hypothetical.

hypothesis although the results of the experiments were not identical. The results of Experiment 2 were inconsistent with the hypothesis. Dr. White determined that Experiment 2 was flawed in some undetermined way. He decided not to repeat Experiment 2 because he felt it would be an unnecessary cost and unduly delay the publication of his report. Dr. Black, on the other hand, felt that Dr. White's decision not to repeat Experiment 2 was a mistake and he expressed his opinion to Dr. White. During the course of the project, Dr. White required Dr. Black to change statistical assumptions relating to certain tests and, as result of such changes, the results more strongly supported Dr. White's hypothesis than would otherwise have been the case. Dr. Black expressed his view to Dr. White that the manipulation of the assumptions could cause the report to not accurately represent the research record. Dr. White explained to Dr. Black why he felt the modifications were statistically justified based upon his experience. Dr. White determined that it was not worth the time and expense to retain a statistical expert to validate his decision. Eventually Dr. White published his report without reference to Experiment 2 or a discussion of the statistical assumptions challenged by Dr. Black. In Dr. Black's view, Dr. White's decisions were a significant departure from accepted practices.

The fact pattern here would seem to be one where the objective evidence is not completely clear as to whether Dr. White's decisions were appropriate. In the past, Dr. Black may have simply kept quiet as to Dr. White's report, accepting the dispute as merely an academic disagreement and one in which he should defer to Dr. White as the principal investigator. But today, with the greater emphasis being placed on research misconduct, Dr. Black may very well have felt warranted in filing a complaint with his institution asserting that Dr. White acted inappropriately.

Assuming Dr. Black filed a complaint against Dr. White, there would potentially begin a long and expensive process whereby the institution would investigate Dr. White's conduct and decision-making. Ultimately, the institution would have to make a judgment as to whether Dr. White acted inappropriately in excluding Experiment 2.⁸ It would also have to

8. See Dov Greenbaum, *Research Fraud: Methods For Dealing With An Issue That Negatively Impacts Society's View Of Science*, 10 COLUM. SCI. & TECH. L. REV. 61 (2009). Dr. Greenbaum noted the following:

Additionally, experienced scientists might drop outliers in their data or add in fudge factors, relying not on scientific rigor but on honed hunches, justifying the disposal of those points as spurious. Again, dropping data points without scientific justification may border on falsification of data, or not. The gut reaction, acceptable in many other areas of life, might be necessary when researching uncharted corners of science.

Id. See also, Raymond De Vries, Melissa S. Anderson, & Brian C. Martinson, *Normal Misbehavior: Scientists Talk about the Ethics of Research*, 1 J. EMPIRICAL RES. ON

determine if Dr. White's changes in his statistical assumptions constituted the falsification of data. To some degree, the institution's decision would depend upon the investigating committee's view of the credibility of Dr. White and Dr. Black and the communications between them.

As described below, after the institution completed its investigation and made its decision, its report would then be evaluated by the appropriate agency (typically HHS or NSF), which might undertake its own investigation and would make its own determination as to whether Dr. White's decisions constituted research misconduct. If Dr. White were found to have engaged in research misconduct, he could be debarred from receiving future government grants or contracts.

Under current regulations of HHS and NSF, the "preponderance of the evidence" standard would be applied to Dr. White's case. In other words, whether Dr. White would be found to have engaged in research misconduct would depend upon whether the factfinders determined that it was more likely than not that his decisions constituted research misconduct. As some courts have held, preponderance of the evidence means 50% of the evidence and "a feather."⁹ Thus, in the foregoing hypothetical, Dr. White's

HUM. RES. ETHICS 43, 45 (2006) (cited by Dr. Greenbaum) which quotes a researcher as follows:

One gray area that I am fascinated by . . . is culling data based on your 'experience' . . . [T]here was one real famous episode in our field . . . [where] it was clear that some of the results had just been thrown out . . . [When] queried [the researchers] . . . said, 'Well we have been doing this for 20 years, we know when we've got a spurious result . . . ' [When that happens] . . . [d]o you go back and double check it or do you just throw it out . . . [and] do you tell everybody you threw it out? I wonder how much of that goes on?

Id. See also, Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305, 333-34 (1995). Professor Burk stated:

The discord between the scientific and legal approaches to misconduct is well illustrated by the efforts of federal agencies to settle upon a proper definition of "misconduct." . . . The division between misconduct and legitimate science may be difficult to distinguish, and not even a mens res requirement such as "deliberate falsification" is sufficient to adequately distinguish the two. For example, consider the problem of selective reporting of data. The scientific report is by no means a stenographic or historical description of the research completed, nor is it meant to be. The scientist chooses carefully and deliberately what aspects of his research deserve to be reported. In doing so, he exercises the creativity that lies at the heart of science. . . . The essence of scientific genius is the ability to choose what ought to be left out.

Id.

9. *Colon v. Sec. Dept. Health and Human Services*, 2007 WL 268781 (Fed. Cl. 2007) (the preponderance of the evidence means "50% and a feather."). See also, *United States v. Restrepo*, 946 F.2d 654, 661 (9th Cir.1991) (Norris, J., dissenting), (en banc), cert. denied, 503 U.S. 961 (1992) (noting that preponderance standard "allows a fact to be considered true if the factfinder is convinced that the fact is more probably true than not, or to put it differently, if the factfinder decides there is a 50%-plus chance

future career may rest on that “feather.”¹⁰ If, on the other hand, the standard of proof were “clear and convincing” evidence—the traditional common law standard in fraud cases—the factfinders would be required to have a much greater degree of certainty in their conclusion before finding that Dr. White engaged in research misconduct.¹¹

This article acknowledges the strong public interest in research integrity. But, it suggests that there are constitutional arguments supporting the contention that the clear and convincing standard of proof (rather than the preponderance standard) is required in cases such as Dr. White’s, at least when the agencies seek to debar a researcher. And while the article concludes that the application of the preponderance standard is likely constitutional, it argues that the HHS and NSF’s regulations may nevertheless be invalid under the Administrative Procedures Act (“APA”).¹² It further suggests that, regardless of the legality of the current regulations, HHS and NSF should undertake rulemaking to evaluate whether the clear and convincing standard should be applied in research misconduct cases, especially where debarment is the proposed remedy.¹³

PART ONE

Part One of this article discusses the primary facts that must be established to support a finding of research misconduct, the applicable standard of proof, and the allocation of the burden of proof between the parties.

that it is true”). Comment Note, *Instructions Defining Term “Preponderance or Weight of Evidence*, 93 A.L.R. 155 (originally published in 1934).

10. Roger Wood, *Scientific Misconduct – The High Cost of Competition*, INFOEDGE (Sept. 8, 2014), <http://researchadministrationdigest.com/high-cost-competition-scientific-misconduct/> (“The impact on individual researcher’s careers is more significant, with most – but not all – researchers found to have engaged in misconduct by the DHHS Office of Research Integrity experiencing a “severe decline in research productivity.”). Andrew M. Stern et al., *Financial Costs and Personal Consequences of Research Misconduct Resulting in Retracted Publications*, ELIFE (Aug. 14, 2014), <https://elifesciences.org/content/3/e02956> (“We found that in most cases, authors experienced a significant fall in productivity following a finding of misconduct”).

11. *Speiser v. Randall*, 357 U.S. 513, 526 (1958) (“the possibility of mistaken factfinding [is] inherent in all litigation”); *Addington v. Texas*, 441 U.S. 418, 423 (1979) (It is because of the possibility of mistakes, the standard of proof “serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.”).

12. 5 U.S.C. § 706(2)(B) (2012).

13. *Id.*

A. What Evidence Is Required To Show Misconduct In Administrative Actions?

Under the regulations adopted by HHS and by NSF, the following evidence is required to establish research misconduct: (a) there must be a significant departure from accepted practices of the relevant research community, (b) the misconduct must be committed intentionally, knowingly, or recklessly; and (c) the allegation must be proven by a preponderance of the evidence.¹⁴

One threshold question is the meaning of “significant departure from accepted practices of the relevant research community.” The phrase is not defined in the HHS or NSF regulations. However, the limited judicial precedent discussing similar terminology suggests that it means more than a departure that could be explained by mere negligence. Rather, it is a degree of departure that in and of itself might suggest a fraudulent intent.¹⁵ Applying the foregoing to Dr. White’s situation, the question would be whether his decisions relating to Experiment 2 and the modifications of his statistical assumptions were, even if incorrect, significantly at odds with the normative practices of his field.

14. 42 CFR § 93.104 (2015); 45 CFR § 689.3(c) (2015). The NSF Regulations defines “research” to include proposals submitted to NSF in all fields of science, engineering, mathematics, and education and results from such proposals. 45 CFR § 689.1(a)(4) (2015). See also, *Public Health Service (PHS) Policies on Research Misconduct – 42 CFR Part 93 – June 2005*, U.S. DEPT. OF HEALTH & HUMAN SERVICES, THE OFF. OF RES. INTEGRITY, http://ori.hhs.gov/FR_Doc_05-9643 (last visited May 30, 2016) (hereinafter referred to as the “PHS Regulations”); NATIONAL SCIENCE FOUNDATION, *Part 689—Research Misconduct, available at* http://www.nsf.gov/oig/_pdf/cfr/45-CFR-689.pdf (hereinafter referred to as the “NSF Regulation”).

15. See *Collignon v. Milwaukee County*, 163 F.3d 982 (7th Cir. 1998); *Williams v. City of New York*, 508 F.2d 356 (2d Cir. 1974). When HHS adopted its current regulations, it noted that it was changing “serious deviation” to “significant departure” from the standards of the relevant research community. It expressed the following in explanation of this change:

We propose to revise slightly the burden for establishing research misconduct in three ways: First, in keeping with the OSTP policy, the proposed regulation would require that the FFP be a “significant departure” from accepted practices as opposed to ORI’s current standard of “serious deviation.” As discussed in the OSTP policy statement, the phrase “significant departure” intends to make clear that behavior alleged to invoke research misconduct should be assessed in the context of practices generally accepted by the relevant research community. As the current definition requires a serious deviation from practices generally accepted in the particular scientific community, we do not anticipate that this change in phraseology would alter the burden of proving or disproving research misconduct in any significant way. However, we specifically ask for comments on this issue.

Public Health Service Policies on Research Misconduct, 69 Fed. Reg. 20778, 20780 (Apr. 16, 2004).

A second question is whether the terms “intentional” and “knowingly” mean that the researcher must intend to deceive or simply intends to do an act that constitutes a significant departure from accepted practices of the relevant research community. In the 1993 case of Mikulas Popovic, M.D., PH.D.,¹⁶ before what was then the Research Integrity Adjudications Panel of HHS, the panel indicated that there must be an affirmative intent to deceive (i.e., mens rea). ORI vehemently argued that this decision was in error.¹⁷

Under the current regulations, the importance of the researcher’s state of mind is somewhat unclear. HHS’s initial proposed regulation provided that the researcher had the burden of proving “honest error” as an affirmative defense. HHS received a number of objections contending that HHS and institutions should have the burden of proving the absence of “honest error.” HHS rejected this argument, reasoning that the Office of Science and Technology Policy’s Federal Policy on Research Misconduct (OSTP)¹⁸ (on which the HHS Regulations were based), excluded honest error from the definition of research misconduct. Nevertheless, both HHS and NSF agree that the terms “misconduct or misconduct in science” do not include honest error or honest differences in interpretations or judgments of data.¹⁹

Thus, to the extent the term “honest error” can be interpreted to mean “an absence of fraudulent motive” neither HHS nor NSF are required to prove a fraudulent intent in order to make out a prima facie case. Instead, it is up to the researcher to try to convince the factfinder that he/she made an “honest error”. Thus, going back to Dr. White’s situation, it would be the view of HHS and NSF that the agencies (and Dr. White’s institution) are not required to determine Dr. White’s intent in making the decisions challenged by Dr. Black. Rather, the burden of proof would be on Dr. White to convince the factfinders that his decisions relating to Experiment

16. Mikulas Popovic, DAB 1446 (1993), available at <http://www.hhs.gov/dab/decisions/dab1446.html> (The decision was under the 1989 HHS regulations that were superseded by the current regulations.).

17. OFFICE OF RESEARCH INTEGRITY, 2(1) ORI NEWSLETTER 1 (Dec. 1993), available at http://ori.hhs.gov/images/ddblock/vol2_no1.pdf. For a discussion of early cases before the DAB see Alan R. Price, *Research Misconduct And Its Federal Regulation: The Origin And History Of The Office Of Research Integrity*, 20 ACCOUNTABILITY IN RES. 291, fn. 8 (2013), available at <http://www.tandfonline.com/doi/pdf/10.1080/08989621.2013.822238#.UkunjZ0o5eU> (hereinafter referred to as “Price Article”). The author of the Price Article, Alan Price, was from 1987 to 2006 an employee of the Federal Government, serving as a senior official of the Office of Scientific Integrity (1989-1992) and later the ORI (1992-2006).

18. *Federal Research Misconduct Policy*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/federal-research-misconduct-policy> (last visited May 30, 2016) (hereinafter the “OSTP Policy”). For an interesting article on the history of the Office of Research Integrity of HHS see Price, *supra* note 17.

19. 42 CFR § 93.103 (2015); 49 CFR § 689.1(a) (2015).

2 and his statistical modifications constituted “honest error” if the factfinders otherwise conclude there was research misconduct. But regardless of who has the burden of proof on the issue, the honest error concept suggests that, at least to some degree, the researcher’s state of mind is a factor that must be considered in determining whether he/she acted intentionally or knowingly in engaging in the challenged conduct.²⁰

Nevertheless, HHS continues to emphasize that “honest error is not included in the definition of research misconduct,” which suggests that it does not consider intent a component of research misconduct.²¹ As noted by HHS, this view is supported by the OSTP Policy, which states in its Preamble:

Issue: Despite general support for the rationale for the phrase “does not include honest error or honest differences of opinion,” several comments requested various clarifications.

Response: This phrase is intended to clarify that simple errors or mere differences of judgment or opinion do not constitute research misconduct. The phrase does not create a separate element of proof. Institutions and agencies are not required to disprove possible “honest error or differences of opinion.”

Issue: Several comments requested clarification regarding the level of intent that is required to be shown in order to reach a finding of research misconduct.

Response: Under the policy, three elements must be met in order to establish a finding of research misconduct. One of these elements is a showing that the subject had the requisite level of intent to commit the misconduct. The intent element is satisfied by showing that the misconduct was committed “intentionally, or knowingly, or recklessly.” Only one of these needs to be demonstrated in order to satisfy this element of a research misconduct finding.²²

Of course, the term “reckless”—which is an independent basis for finding research misconduct—suggests something other than a requirement of “a mental state embracing intent to deceive, manipulate, or defraud” (i.e., scienter).²³ The 1989 federal regulation governing research

20. For an article critical of the agencies’ approach to the issue of honest errors, see Jacqueline D. Wright Bonilla, *Illusory Protections for Those Accused of Scientific Research Misconduct: Need for Reform*, 16 J. TECH. L. & POL’Y 107 (2011).

21. *Update on the Philippe Bois Research Misconduct Case*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/blog/update-philippe-bois-research-misconduct-case> (last visited May 30, 2016).

22. See OSTP Policy, *supra* note 18.

23. See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n. 12 (1976) for the

misconduct did not expressly include the term “recklessness.” When those regulations were replaced in 2005,²⁴ HHS expanded the level of intent from “beyond an intentional and knowing standard to include recklessness.”²⁵ Therefore, the remaining question is what the term “recklessness” means if honest error is a defense to a claim of research misconduct.

Although the term “recklessly” is not defined in the regulations, it has been characterized in judicial opinions as an extreme version of ordinary negligence²⁶ or gross negligence plus.²⁷ On the other hand, courts have recognized that “the definition of ‘reckless behavior’ should not be a liberal one lest any discernible distinction between ‘scienter’ and ‘negligence’ be obliterated.”²⁸ Nevertheless, it is fair to assume that by the addition of the term “recklessly” to the regulations, the agencies intend to put the burden of proof on the researcher to show that he/she was not indifferent to the truth whenever the researcher asserts a lack of fraudulent intent.²⁹ This

definition of “scienter.” The False Claims Act, 31 U.S.C. § 3729(a)(2) (2012), discussed *infra*, expressly does not require an intent to defraud. The FCA imposes upon individuals and contractors receiving public funds ‘some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek,’ and to ‘preclude ‘ostrich’ type situations where an individual has ‘buried his head in the sand’ and failed to make any inquiry that would have revealed the false claim.” United States ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 438 (S.D.N.Y. 1999) (quoting S. Rep. No. 99-345 at 20–21, reprinted in 1986 U.S.C.C.A.N. 5266, 5285-86). However, as argued below, the fact that scienter is not required under the FCA is not necessarily dispositive of the issue in research misconduct cases both because “honest error” is an affirmative defense in such proceedings and because the context and nature of scientific disputes are demonstrably different from those in the straight commercial context applicable to most FCA cases.

24. 42 C.F.R. § 93.104(b) (2015).

25. 69 Fed. Reg. 20780 (Apr. 16, 2004) (“consistent with the OSTP policy, the level of intent would be expanded beyond an intentional and knowing standard to include recklessness”). See Plaintiff’s Trial Motion, Memorandum and Affidavit, Brodie v. Dept. of Health and Human Services, 2010 WL 3416349 (D.D.C.) for a detailed discussion about the change from the 1989 to the 2005 standard; see also court’s opinion in Brodie v. Dept. of Health and Human Services Brodie, 715 F. Supp. 2d 747 (D.D.C. 2010).

26. Gulf Grp. Gen. Enter. Co. W.L.L. v. United States, 114 Fed. Cl. 258, 315 (2013); United States Ex Rel. K & R Ltd. P’ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983 (D.C. Cir. 2008).

27. Riley Constr. Co. v. United States, 65 Fed. Cl. 264, 270 (2005).

28. Sanders v. John Nuveen & Co. 554 F.2d 790, 793 (7th Cir. 1977). Recklessness is distinct from innocent mistakes, negligence, and the common errors a scientist may make. But, it does encompass the refusal to learn of information which an individual, in the exercise of prudent judgment, should have discovered. See, e.g., United States ex rel. Bettis v. Odebrecht Contractors of California, Inc., 297 F. Supp. 2d 272, 277 (D.D.C. 2004); U.S. ex rel. Bettis v. Odebrecht Contractors of Cal., Inc., 393 F.3d 1321 (D.C. Cir. 2005) (citing *Hindo v. Univ. of Health Sciences The Chicago Med. Sch.*, 65 F.3d 608, 613-14 (7th Cir.1995), cert. denied, 116 S. Ct. 915 (1996); United States ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1420-21 (9th Cir. 1992)).

29. See Dr. Rameshwar K. Sharma, Dec. No. 1431, 1993 WL 742551 (HHS Dept. App. Bd. 1993).

position would be consistent with the agencies' view that "honest error" is in the nature of an affirmative defense. Thus, going to back to the hypothetical regarding Dr. White, the burden of proof would be on him to show that he was not demonstrating an indifference to the truth by excluding Experiment 2 or by not bringing in an outside statistical expert after Dr. Black challenged him on the modifications of his statistical assumptions.

To date, courts and administrative judges in research misconduct cases seem to have relied on a finding of "recklessness" as an alternative basis for their holdings when the researcher asserted honest error but there was significant evidence of misconduct.³⁰ This approach allows the factfinder to state that even if it were to credit the researcher's argument that his/her actions were unintentional, there was at least recklessness sufficient to warrant a finding of research misconduct.³¹

B. What is the Burden of Proof?

Section 93.106 of the HHS Regulations states:

Evidentiary standards. The following evidentiary standards apply to findings made under this part. Standard of proof. An institutional or HHS finding of research misconduct must be

30. See, e.g., *Bois v. Dept. of Health and Human Services*, Civil Action No. 11-1563 (ABJ) (D.D.C. 2012).

31. According to Dr. Price, "that in the eight years since the revised HHS regulation went into effect (June 2005, to date in 2013), ORI has not made a finding of misconduct committed "recklessly." Price, *supra* note 17, at 16. Dr. Price states the following as to the use of the "recklessness" standard:

Some institutions have tried to make such findings for reckless misconduct. However, in the author's experience as an expert consultant for seven years, there is a danger in institutions using the "reckless" standard too loosely. For example, the author has seen investigation committees and officials propose or make findings of research misconduct for a professor being a poor mentor—or for failing to do forensic image analysis on figures for publication (when the professors had trusted a graduate student or postdoctoral fellow to publish the same raw-data figure that they had showed to the professor earlier).

The author notes that, in the prior decade, two distinguished, nationally-prominent professors had missed such manipulation of images by their graduate students or postdoctoral fellows (until it was detected by others during manuscript review by a journal or after the publication process); these professors were praised for making rapid public retractions of the falsified research publications (ORI findings against Urban under Hood, 1995; ORI findings against Kumar under Hood, 1996; and ORI findings against Hajra under Collins, 1997). No one ever publically accused these professors of being "responsible for the research misconduct" that was committed by their graduate students or postdoctoral fellows. *Id.* at 16 n. 12.

proved by a preponderance of the evidence.³²

And Section 689.3 of the NSF Regulations states as follows:

(d) For those cases governed by the debarment and suspension regulations, the standards of proof contained in the debarment and suspension regulations shall control. Otherwise, NSF will take no final action under this section without a finding of misconduct supported by a preponderance of the relevant evidence.³³

Both agencies also apply the preponderance of evidence standard in debarment proceedings resulting from findings of research misconduct.³⁴ Accordingly, the institutions,³⁵ the agencies, the ALJ (in the case of HHS proceedings), and the debarment officials all may find research misconduct if they conclude that a preponderance of the evidence supports that conclusion.

Whether the preponderance of the evidence standard is the correct one was addressed in the Federal Register notice promulgating the final OSTP Research Misconduct Policy.³⁶ OSTP stated the following in response to the question: “Shouldn’t the burden of proof be more stringent, e.g., require “clear and convincing evidence” to support a finding of research misconduct?”:

While much is at stake for a researcher accused of research misconduct, even more is at stake for the public when a researcher commits research misconduct. Since “preponderance of the evidence” is the uniform standard of proof for establishing culpability in most civil fraud cases and many federal administrative proceedings, including debarment, there is no basis for raising the bar for proof in misconduct cases which have such a potentially broad public impact. It is recognized that non-

32. 42 C.F.R. § 93.106 (2015).

33. 45 C.F.R. § 689.3 (2015); Dr. Brett M. Baker, NATIONAL SCIENCE FOUNDATION, OFFICE OF INSPECTOR General, *2014 Suspension and Debarment Workshop* (Mar. 28, 2014), available at https://www.nsf.gov/oig/outreach/presentations/2014suspdebar/pres/panel_4b_s&d_resulting_from_audits_&_inspections.pdf.

34. 45 C.F.R. § 76.850 (2015) (HHS) (“What is the standard of proof in a debarment action? (a) In any debarment action, we must establish the cause for debarment by a preponderance of the evidence. (b) If the proposed debarment is based upon a conviction or civil judgment, the standard of proof is met.”); 45 CFR § 620.314(c)(1)(c)(1) (2015) (“Standard of proof. In any debarment action, the cause for debarment must be established by a preponderance of the evidence. Where the proposed debarment is based upon a conviction or civil judgment, the standard shall be deemed to have been met.”).

35. An institution may use a higher standard for its own investigation but is required to use preponderance of the evidence in reporting to ORI or NSF. 67 Fed. Reg. 11936 (Mar. 18, 2002).

36. 65 Fed. Reg. 76260 (Dec. 6, 2000).

Federal research institutions have the discretion to apply a higher standard of proof in their internal misconduct proceedings. However, when their standard differs from that of the Federal government, research institutions must report their findings to the appropriate Federal agency under the applicable Federal government standard, i.e., preponderance.³⁷

Two parts of the foregoing statement stand out. First, there is the assertion that the actual harm to the researcher wrongly found to have committed research misconduct is outweighed by the potential harm to the public which might occur if a researcher is mistakenly found not to have committed research misconduct. However, the OSTP does not provide any support for this proposition. Rather, the OSTP seems to have assumed that simply because a researcher is not found to have committed “research misconduct,” (i) his/her research will be published, (ii) that such research will go unchallenged if already published, or (iii) that such researcher will still obtain future federal grants or contracts. None of these assumptions, however, are necessarily correct.

Given the heightened level of scrutiny and analysis inherent in a “research misconduct” proceeding, any flaws in the research that were the basis for the action will prevent any questionable findings from being published regardless of the outcome of the case. Similarly, if the work is already published, there will in all likelihood be counter publications challenging the flawed research. In addition, the flaws found in the research can be considered by the government in making future contract or grant awards even absent a finding that the researcher committed “research misconduct.” In other words, the public interest may be vindicated by the facts revealed in the research misconduct proceedings regardless of the standard of proof. And, to the extent there is a possible harm to the public interest that would result from the lower standard, it would occur only in the very rare case where a researcher would have prevailed under the clear and convincing standard but lost under the preponderance standard (and, to date, most reported cases suggest that the outcome of contested research misconduct cases would have been the same under either standard).

The second questionable statement is the OSTP’s assertion that the preponderance of the evidence is the uniform standard of proof for establishing culpability in most civil fraud cases. As discussed in detail below, that assertion is incorrect.³⁸ In both state and federal courts

37. *Id.* at 76262 (emphasis added).

38. *See*, Roy G. Spece & Carol Bernstein, *Investigating Scientific Misconduct: What Is Scientific Misconduct, Who Has To (Dis)Prove It, And To What Level Of Certainty?*, 26 *MED. & LAW* 493 (2007) (“There is no support for the OSTP’s statement that “preponderance of the evidence’ is the uniform standard for establishing culpability in most civil fraud cases.” It is quite common for various jurisdictions to

applying common law, clear and convincing evidence is the majority rule for finding civil fraud absent a statute mandating a different standard.³⁹ And as to the statement's reference to the preponderance of the evidence standard being applied in other proceedings, there is no discussion of the unique circumstances of scientific researchers.

The standard of proof issue was also addressed as part of the rulemaking at NSF in 2002, where the agency stated:

One of the commenters also expressed concern over the preponderance of evidence standard of proof for a finding of research misconduct. The commenter expressed concern that this standard will increase the risk of a false finding of research misconduct, and recommended a higher standard of proof such as "clear and convincing evidence" or "beyond a reasonable doubt."

The Federal policy adopted the preponderance of evidence standard. In the preamble to the Federal policy, OSTP noted that this is the uniform standard of proof for most civil fraud cases and most Federal administrative proceedings, including debarment. (65 FR 76262). Awardee institutions have the discretion to apply a higher standard of proof in their internal misconduct proceedings. However, if a higher standard is used, and the awardee institution wishes for NSF to defer to its investigation, the awardee institution should also evaluate whether the allegation is proven by a preponderance of evidence.⁴⁰

To the extent NSF relied upon the OSTP's statement that the preponderance standard is the uniform standard of proof for most civil fraud cases, NSF's position is erroneous and, as discussed below, is a factor in considering the validity of the NSF's regulation on this point under the Administrative Procedure Act.

As to HHS, there appears to have been no discussion in the record as to why the agency adopted the preponderance standard as opposed to the clear and convincing standard.⁴¹ Presumably, HHS merely continued the policy

require that civil fraud be established by "clear and convincing evidence." The OSTP's comments do not represent objective reasoning, but bureaucratic embrace of an easy path to convictions regardless of their fairness.").

39. *Id.*

40. 67 Fed. Reg. 11936, 11936 (Mar. 18, 2002).

41. ORI stated the following regarding the preponderance standard but this statement was well before the adoption of the current regulations:

PREPONDERANCE RECOMMENDED AS STANDARD OF PROOF
Preponderance of the evidence, rather than clear and convincing, is the standard of proof recommended by the HHS Review Group on Research Misconduct and Research Integrity for determining whether research misconduct has occurred in PHS-supported research. The standard is consistent with government-wide debarment and suspension regulations and

adopted by OSTP. However, statements by HHS suggest that it adopted the preponderance rule because that standard is applied in typical debarment proceedings brought by federal agencies against commercial entities where the goal is to ensure that the government conducts “business only with responsible persons”.⁴² But even this rationale does not address the particular circumstances of a scientific researcher (as opposed to a commercial business) and whether a higher burden of proof is warranted

the proposed common Federal procedures for responding to allegations of research misconduct. See the ORI web site. “Debarment and other sanctions are taken to protect the public’s and the Federal Government’s interests, not for purposes of punishment,” the Review Group report stated. “The debarment regulations appropriately adopt an evidentiary standard of preponderance of the evidence, the usual standard of proof in civil actions.” The more rigorous standard, clear and convincing, was considered by the Review Group because of significant reputational interests at stake for scientists found to have engaged in research misconduct, but was not recommended. “Because the government’s purpose in imposing debarment or other sanctions is to protect its interest in conducting business only with responsible persons, the Review Group concluded that the application of a more demanding evidentiary standard before sanctions for research misconduct could be imposed would not adequately serve the government interest,” the Review Group report stated. Consistent with prior ORI policy, institutions may apply a different standard of evidence in making internal decisions on misconduct, but must apply the preponderance standard in reporting cases to ORI. OFFICE OF RESEARCH INTEGRITY, 8(1) ORI NEWSLETTER 1, 13–14 (Dec. 1999), *available at* http://ori.hhs.gov/images/ddblock/vol8_no1.pdf.

As to the statement’s suggestion that the preponderance of the evidence standard is not required because the purpose of debarment is not punishment, it ignores that the label given to a government-initiated proceeding is not dispositive if the proceeding results in significant harm to the individual. *Santosky v. Kramer*, 455 U.S. 745, 757 (1982) (“Notwithstanding ‘the state’s civil labels and good intentions,’” the Court has deemed this level of certainty necessary to preserve fundamental fairness in a variety of government-initiated proceedings that threaten the individual involved with ‘a significant deprivation of liberty’ or ‘stigma.’) (first quoting *In re Winship*, 397 U.S. 358, 365–366 (1970); then quoting *Addington v. Texas*, 441 U.S. 418, 425 (1979).)

42. See, *Spece & Bernstein*, *supra* note 38. In his article, Dr. Price, states: However, it became clear in the 1990s (and remains clear in 2013) to the author and other scientists in OSI/ORI who review institutional reports of scientific and research misconduct, that institutional committees and officials are often uncomfortable using such a low standard of proof. Given the serious impact on reputations and careers from allegations and findings of misconduct in science, they appeared to prefer using some level that is closer to a “clear and convincing standard” or to a “beyond a reasonable doubt standard” (generally without so stating in the investigation reports and notification letters to ORI). ORI even found that one major public university in Maryland had formally adopted in the early 1990s a “beyond a shadow of a doubt” standard, which is a literary (not a legal) standard. Price, *supra* note 17, at 17, fn. 13.

given the stigma attached to a finding of research misconduct⁴³ and the long-term impact on the researcher's career.⁴⁴

Although doing no better than NSF in describing its rationale for the preponderance standard, the HHS regulations go further than those issued by NSF by stating the following on the burden of proof:

- (a) The institution or HHS has the burden of proof for making a finding of research misconduct.
- (b) The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
- (c) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised.⁴⁵
- (d) In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of

43. *Addington*, 441 U.S. at 425–26 (higher standard of proof required due to stigma associated with adverse factual finding); see *In re Winship*, 397 U.S. at 374 (Harlan, J., concurring).

44. The Supreme Court has consistently held that the right to pursue one's chosen occupation is a fundamental personal freedom guaranteed by the Constitution that cannot be denied by the Government without due process. See, e.g., *Yick Wo v. Hopkins*, 118 U.S. 356, 374 (1886); *Truax v. Raich*, 239 U.S. 33, 44 (1915); *Hampton v. Mow Sun Wong*, 426 U.S. 88, 102 n.23 (1976). Moreover, the Court has long recognized that "exclusion from any of the professions or any of the ordinary avocations of life for past conduct can be regarded in no other light than as punishment for such conduct." *Ex parte Garland*, 71 U.S. 333, 377 (1866). Thus, to the extent a finding of research misconduct will effectively end a researcher career, it is a valid question as to whether HHS should have provided more of an explanation for its decision to use the preponderance of the evidence standard than merely referring to the practice in traditional debarment proceedings against commercial entities. See *Addington*, 441 U.S. at 423 (1979) ("The function of a standard of proof, as that concept is embodied in the Due Process Clause and in the realm of factfinding, is to 'instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.'").

45. Honest error would be an example of an affirmative defense. See, *Office of Research Integrity v. Bois*, 2011 WL 2164169 (H.H.S.).

honest error or difference of opinion presented by the respondent.

- (e) The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.⁴⁶

PART TWO

Part Two of this article provides an overview of the investigatory and adjudicatory process of research misconduct cases. It broadly describes the NSF procedures and some of the differences between those procedures and the procedures used by HHS. It then illustrates how the process works by discussing two research cases that were litigated in Federal District Court.

A. What Are The Administrative Procedures Applicable To Research Misconduct Cases?

The NSF's Office of Inspector General ("OIG")⁴⁷ is responsible for investigating research misconduct cases at NSF. At HHS, it is the Office of Research Integrity⁴⁸ ("ORI") that is responsible for investigating research misconduct complaints.⁴⁹

In December 2012, NSF's Office of Inspector General issued a "Dear Colleague" letter (the "DCL"), which described NSF's processes for investigating research misconduct claims pursuant to the agency's

46. 42 CFR § 93.106 (2015).

47. *Office of Inspector General*, NATIONAL SCIENCE FOUNDATION, <http://www.nsf.gov/oig/> (last visited June 1, 2016).

48. OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/> (last visited June 1, 2016).

49. Both the OIG and the ORI make publically available presentations on the research misconduct process. *See, e.g., Presentations*, NATIONAL SCIENCE FOUNDATION, https://www.nsf.gov/oig/outreach/presentations/srafau2003_files/v3_document.htm (last visited June 1, 2016); Brett M. Baker, Assistant Inspector General for Audit Office of Inspector General, PowerPoint Presentation at the National Science Foundation Regional Grants Conference (Oct. 7, 2014), *available at* http://www.nsf.gov/bfa/dias/policy/outreach/grantsconf/oig_oct14.pdf.

Many research institutions make publically available descriptions of their procedures for investigating research misconduct claims. *See, e.g., Research Integrity*, CLEMSON UNIVERSITY, <http://www.clemson.edu/research/compliance/integrity.html> (last visited June 1, 2016); *Procedures for Dealing with Issues of Professional Misconduct*, JOHN HOPKINS MEDICINE, http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/professional_misconduct.html (last visited June 1, 2016).

regulations.⁵⁰ The following description is from that letter. ORI's regulations set forth a similar procedure, but include much more detail.

As set forth in the DCL, the investigation process begins when a complainant reports allegations to the OIG or to his/her institutional official. When an institution becomes aware of substantive allegations of NSF-related misconduct, it must notify the OIG. When reporting allegations, the DCL states that complainants are to inform OIG rather than a program office. If program officers become aware of allegations of misconduct, the allegations must be referred for to the OIG for assessment.⁵¹

When OIG receives an allegation, it determines whether the complaint meets the agency's definition of research misconduct and whether the alleged research misconduct is connected with an NSF activity. It is insufficient for the alleged research misconduct to have occurred in an institution receiving NSF funds.⁵² If OIG determines that NSF has jurisdiction, then the OIG will conduct an initial inquiry on whether an allegation has sufficient substance to warrant an investigation.⁵³

As described in the DCL, the first communication with the subject researcher will be a letter from OIG that: (a) states that OIG has received an allegation about the individual and describes the allegation; (b) requests information about the allegation that assists OIG's understanding and assessment; (c) informs the individual that OIG is conducting an inquiry, and that the office has not yet notified the individual's institution; (d) informs the subject of his or her rights under NSF's research misconduct regulation and the Privacy Act⁵⁴; and (e) establishes a deadline by which OIG expects a reply.⁵⁵

If OIG receives a satisfactory explanation in response to its initial letter, it will declare the matter closed and inform both the researcher and the original complainant. On the other hand, if OIG is not satisfied with the researcher's explanation, it usually refers the allegation to the subject's institution for investigation.⁵⁶ When an institution conducts the investigation, which is typically the case, NSF will usually defer its own

50. National Science Foundation, Office of Inspector General, Dear Colleague Letter (Dec. 1, 2012), *available at* https://www.nsf.gov/oig/_pdf/dearcolleague.pdf (hereinafter "DCL").

51. *Id.* at 1–2.

52. If the OIG lacks jurisdiction, it may forward the allegation to the appropriate agency or institutional official for resolution. *Id.*

53. *Id.*

54. 5 U.S.C. § 5552(a) (2012).

55. 45 C.F.R. § 689.5 (2015).

56. DCL, *supra* note 50, at 2.

inquiry until the institution has completed its proceeding and provided its inquiry report.⁵⁷

If the institution agrees to conduct the investigation, OIG will write a letter to the institution's research misconduct official describing the results of OIG's initial inquiry, including the allegation and the researcher's response.⁵⁸ The institution's investigation constitutes a formal development, examination, and evaluation of relevant facts to determine whether research misconduct has occurred. If the institution determines that research misconduct has occurred, it is required to assess its gravity and to propose appropriate action.⁵⁹

According to the DCL, an institution is allowed 180 days to conduct an investigation and report its findings to OIG:

- (a) The report must include: a description of the allegation(s) investigated (including any additional allegation(s) discovered in the course of the investigation); (b) the *curriculum vita* for each individual responsible for conducting the investigation; (c) the methods and procedures used to gather information and evaluate the allegation; (d) a summary of the records compiled; (e) a statement of the findings with the reasoning and specific evidence supporting those conclusions; and (f) a description and explanation of any actions recommended and/or imposed by the institution.⁶⁰

The OIG will review each investigation report for accuracy and completeness in deciding whether to accept the institution's conclusions. The OIG can accept an institution's report in whole or in part, request additional information, or initiate its own independent investigation.⁶¹

If OIG concludes that research misconduct *did not* occur, it will close the case and notify the subject and the complainant.⁶² If OIG concludes research misconduct *did* occur, it develops its own investigation report. The report includes recommended actions for NSF management. It offers the subject an opportunity to respond to a draft version of OIG's report.⁶³ The researcher's comments or rebuttals

57. *Id.*

58. In a small number of cases where, for example, the OIG believes there is unmanageable conflict of interests, the OIG will not refer an investigation to the institution. In these instances, the OIG immediately proceeds with its own investigation. *Id.* at 2.

59. 45 C.F.R. § 689.4 (2015).

60. DCL, *supra* note 50, at 2–3.

61. 45 C.F.R. § 689.6 (2015).

62. DCL, *supra* note 50, at 3.

63. *Id.*; 45 C.F.R. § 689.9 (2015).

receive full consideration and may lead to a revision of the investigation report before it is submitted to NSF's Deputy Director for adjudication.⁶⁴ As stated in the DCL, OIG does not make findings or take actions, but rather makes recommendations to NSF's Deputy Director for findings and actions.⁶⁵

When NSF's investigation report is complete, OIG sends it to the Deputy Director of NSF for adjudication (unless OIG has recommended debarment, in which case the matter will be referred to the debarring official).⁶⁶ If the Deputy Director finds that research misconduct has occurred and decides to take action, NSF will provide a notice of the proposed action and information about appeal rights directly to the individual or institution involved.⁶⁷ The Deputy Director's decision can be appealed to the Director of NSF.⁶⁸

As described in the DCL, if NSF finds that research misconduct did occur, it may take action to protect the interests of the federal government (in addition to any action the institution may take). Actions that NSF management can take fall into three non-exhaustive categories. First, NSF can send a letter of reprimand to the individual or institution involved, can set conditions on NSF awards that affect the individual or institution involved, or can require special certifications or assurances of compliance. Second, NSF can place restrictions on activities or expenditures under present and future awards. Third, NSF can suspend or terminate an active award, or can initiate an action to debar an individual or institution from receiving awards from any agency of the federal government, and from working under any other federal awards.⁶⁹ To date, debarment and suspensions have generally been limited to individuals, and not institutions.⁷⁰

B. ORI's Procedures

HHS's Office of Research Integrity has issued regulations, which provide much more detail than the NSF procedures described above.⁷¹ In

64. DCL, *supra* note 50, at 4.

65. *Id.* at 3; 45 C.F.R. § 689.9 (2015).

66. 45 C.F.R. §689.9(c)(1) (2015) ("In cases in which debarment is considered by OIG to be an appropriate disposition, the case will be referred to the debarring official pursuant to 45 CFR part 620 and the procedures of 45 CFR part 620 will be followed, but: The debarring official will be either the Deputy Director, or an official designated by the Deputy Director.").

67. *Id.*

68. 45 C.F.R. § 689.10 (2015).

69. 45 C.F.R. § 689.3 (2015).

70. *Handling Misconduct - Inquiry Issues*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/ori-responses-issues#12> (last visited June 5, 2016).

71. 42 C.F.R. Parts 50 and 93 (2015).

addition, ORI has prepared a detailed sample policy of procedures for responding to research misconduct allegations.⁷² However, in broad terms, the process followed by ORI is similar to that at NSF.⁷³

One key difference at HHS is that the researcher has the right to seek a hearing before an Administrative Law Judge. Under the ORI Regulations, should ORI review an institution's investigation report and determine that research misconduct has occurred, it will typically attempt to negotiate with the researcher a Voluntary Exclusion Agreement (VEA), in which the respondent accepts the imposition of administrative actions.⁷⁴ If such an agreement is not reached, ORI will make a formal finding of research misconduct and typically recommend administrative actions to the HHS Assistant Secretary for Health (ASH). Under the HHS Regulations, the ASH makes the final HHS decision on the imposition of administrative actions after reviewing the recommendations made by ORI (except when the administrative actions include debarment or suspension). The ASH may accept, modify, or reject the administrative actions recommended by ORI. If the ASH accepts the recommendations, ORI sends the respondent a copy of the final ORI report and a notification letter (the "Charge Letter") that describes the proposed administrative actions to be taken against the researcher. ORI also provides notice of the researcher's right to request a hearing before the HHS Departmental Appeals Board ("DAB"). If a hearing is not requested, the research misconduct finding and administrative actions of the ASH become final.⁷⁵

72. See e.g., OFFICE OF RESEARCH INTEGRITY, *Sample Policy & Procedures for Responding to Research Misconduct Allegations*, available at <http://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf>.

73. See Kroll Presentation, *supra* note 1 (discussion of the differences between the HHS and NSF processes). Susan J. Garfinkel, Holley Thames Lutz, & Linda Youngman, *Misconduct: How Did We Get in this Mess and How Can We Avoid it in the Future?*, 2009 AHILA-SEM (2009) (an overview of the HHS procedures).

74. Jacqueline Bonilla, *Illusory Protections For Those Accused Of Scientific Research Misconduct: Need For Reform*, 16 J. TECH. L. & POL'Y, 107, 115–16 (2011): One might think a researcher can "appeal" a purely institutional determination to the ORI, but this is not the case. As it turns out, regardless of what the ORI ultimately decides to do (and even if it determines that no research misconduct took place), once an institution makes a finding of research misconduct on its own, that finding, and any imposed sanctions, can stand on a permanent basis. Researchers may have no avenue, via the ORI or any other agency, to initiate an objective review of an institution's adverse decision, or to otherwise "reverse" the decision or institutional sanctions.

75. Dr. Price states as follows regarding the ALJ Appeal process:

As noted by former PHS Counsel, turned defense attorney, Charrow (2010), this appeal system at HHS can be challenging to the appellant: First, as a practical matter, few if any scientists will have the resources to seek full review by the DAB. . . . Second, recent changes in the regulations have made an appeal to the DAB less attractive. . . access to an appeal [hearing] is no longer automatic. To qualify you must now specify those aspects of the ORI

If the researcher requests a DAB hearing, it is conducted by an Administrative Law Judge (ALJ), who may consult one or more technical or scientific experts. During the hearing, the researcher may be represented by counsel, file motions and pleadings, participate in case-related conferences held by the ALJ, request discovery, stipulate to facts or law, present and cross examine witnesses, submit evidence, make legal arguments, and submit briefs. Decisions of the DAB are available on Westlaw.

The decision by the ALJ may be reviewed by the ASH except when debarment and suspension is involved, in which case the decision will be reviewed by the debarring official. The ALJ ruling becomes final if the ASH does not indicate an intent to review the decision within 30 days. If the ALJ rules in favor of the researcher and the ASH approves the ruling, the misconduct finding will be overturned and/or the proposed administrative actions will not take effect. Whatever the outcome, a final notification letter is sent to the institution where the investigation was conducted and to the current employing institution if the researcher has relocated.⁷⁶

finding that are factually incorrect and why they are incorrect. Even if you were to prevail at the DAB, the ALJ decision is no longer a true ruling as in the past, but now constitutes a recommended decision to the Assistant Secretary for Health. Since 1996, no ORI/PHS findings of research misconduct have been overruled by the DAB. Since 2005 (to date in 2013), in response to four such appeals, no formal hearings have been held by the ALJs, who have upheld the ORI/PHS findings and recommended administrative actions. Price, *supra* note 17 at 18 (quotations and citations omitted).

Dr. Price further states:

[I]n the eight years under the revised HHS regulation (from June 2005 to date in 2013), the HHS ALJs have granted no formal hearings for such appeals; they have found the appellants have not yet raised issues that would require further adjudication. The author notes that some defense attorneys have expressed the opinion that the revised HHS/ORI regulation has turned the process for appeal of ORI findings – with notice of proposed PHS findings by ORI often after one or several years of review within ORI following an institutional investigation finding—from “scientific debates with ORI” into “legal arguments with ALJs,” making appeals untenable. Price, *supra* note 17 at 18 n. 16.

76. The fundamental fairness of this process has been challenged. See Bonilla, *supra* note 74 at 115–116:

[I]f an institution makes a questionable finding of research misconduct, for example, based on dubious evidence, bias of guilt or personal grudge, or even a mistake, is there any recourse for affected scientists? One must consider that federal regulations have set up misconduct proceedings to be adversarial; that is, it is the accused researcher versus the investigating institution and the people it chooses to represent it. Especially after spending significant time and money to “prove” its case, institutions often have a vested interest in making a negative finding in order to justify bringing the case in the first instance, and to show “zero tolerance” for misconduct in a global sense.

C. Debarment

As noted above, at the conclusion of the misconduct investigation, ORI at HHS and the OIG at NSF can recommend that the subject of a research misconduct complaint be debarred.⁷⁷ Generally, government-wide, debarred persons are prohibited from participating in any federal nonprocurement or procurement (contract) transactions.⁷⁸ Thus, as recognized by the courts, debarment directs the power and prestige of the

Moreover, an institution can easily make negative findings in light of, for example: (1) the institution's low burden to prove research misconduct, that is, a preponderance of the evidence; (2) the fact that the definition of research misconduct includes conduct committed "recklessly," not just "intentionally" or "knowingly"; and (3) respondents have the burden to prove affirmative defenses, such as good faith or difference of opinion. Thus, accused scientists sit in the dangerous position of being investigated, evaluated, and judged by the same entity, often involving many of the same people throughout the process, where an institution can easily make a devastating finding. *Id.*

77. Both agencies have presentations on the web on the debarment process. *See e.g.*, Scott J. Moore, Investigative Scientist, NATIONAL SCIENCE FOUNDATION OFFICE OF INSPECTOR GENERAL, *Navigating NSF Regulatory Requirements for Responsible Research*, (Apr. 14-15, 2016), available at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0ahUKewi-h9WksJTNAhVBQSYKHbTqBAEQFggjMAE&url=http%3A%2F%2Fori.hhs.gov%2Fmeetings%2F2016%2Fslides%2FSCOTT%2520MOORE%2FDefinitions%2520and%2520Requirements.ppt&usq=AFQjCNE6hBPz3mgi4_YOwluDY7bfPUs0eg&sig2=10zqbHGlcUTa4txZUutjvw&bvm=bv.123664746,d.eWE; COUNCIL OF THE INSPECTORS GENERAL FOR INTEGRITY AND EFFICEINCY AND INTERAGENCY SUSPENSION AND DEBARMENT COMMITTEE, *Suspension and Debarment: Basic Concept, Rules, and Process* (Mar. 28, 2014), available at https://www.nsf.gov/oig/outreach/presentations/2014suspdebar/pres/panel_1_primer_on_suspension_and_debarment.pdf.

78. The ORI website states the following as to "debarment":

Who can be debarred? Both individuals and entities may be subject to debarment. In the area of grant and cooperative agreement supported research, this includes anyone who participates in the research: the principal investigators, researchers, contractors, students, and technical and support staff. To date, all ORI debarments have involved individuals, not institutions or other entities. What types of nonprocurement transactions are barred? With some exceptions, because debarments are government-wide, debarred persons may not participate in any Federal nonprocurement or procurement (contract) transactions. Nonprocurement transactions include, but are not limited to, grants, cooperative agreements, subsidies, contracts, subcontracts, scholarships, fellowships, loans, and other forms of Federal funding. . . .**How long is a debarment? The usual term is three years. However, debarments may be for longer periods depending on the seriousness of the debarred person's actions and any aggravating or mitigating circumstances. *Handling Misconduct - Inquiry Issues*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/ori-responses-issues#12> (last visited June 5, 2016).

government at a particular person and has a serious impact on that person's life and career.⁷⁹

The actual decision to debar the researcher is made by the respective agencies' debarment official. At NSF the debarment official is NSF's Deputy Director (or his/her designee)⁸⁰ and at HHS it is the Deputy Assistant Secretary for Office of Grants and Acquisition.⁸¹ The debarring official may debar the researcher for violations such as willful failure to perform in accordance with the terms of one or more contracts, a history of failure to perform, or unsatisfactory performance of one or more contracts.⁸² Consistent with the agencies' position as to the other aspects

79. *Canales v. Paulson*, 2007 WL 2071709 (D.D.C. July 16, 2007), at 10 (quoting *Gonzalez v. Freeman*, 334 F.2d 570, 578 (D.C. Cir. 1964)).

80. 48 C.F.R. § 2509.403 (2015).

81. See, *Office of the Assistant Secretary for Financial Resources Functional Statement*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *Office of the Assistant Secretary for Financial Resources Functional Statement*, <http://www.hhs.gov/about/agencies/asfr/functional-statement/index.html> (last visited June 11, 2016) ("The Deputy Assistant Secretary for OGAPA serves as HHS's suspension and debarment Official"). As to when additional proceedings are or are not necessary 45 C.F.R. § 76.314 states:

(a) *No additional proceedings necessary*. In actions based upon a conviction or civil judgment, or in which there is no genuine dispute over material facts, the debarring official shall make a decision on the basis of all the information in the administrative record, including any submission made by the respondent. The decision shall be made within 45 days after receipt of any information and argument submitted by the respondent, unless the debarring official extends this period for good cause. (b) *Additional proceedings necessary*. (1) In actions in which additional proceedings are necessary to determine disputed material facts, written findings of fact shall be prepared. The debarring official shall base the decision on the facts as found, together with any information and argument submitted by the respondent and any other information in the administrative record. (2) The debarring official may refer disputed material facts to another official for findings of fact. The debarring official may reject any such findings, in whole or in part, only after specifically determining them to be arbitrary and capricious or clearly erroneous. (3) The debarring official's decision shall be made after the conclusion of the proceedings with respect to disputed facts. *Id.*

82. 42 C.F.R. § 93.408 states:

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative: (a) Knowing, intentional, or reckless. Were the respondent's actions knowing or intentional or was the conduct reckless? (b) Pattern. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct? (c) Impact. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health

of the research misconduct process, the burden of proof in debarment proceedings is “preponderance of the evidence”.⁸³ Generally, NSF and HHS may debar a researcher for any cause of so serious or compelling a nature that it affects his or her present responsibility.⁸⁴ A researcher who is debarred (or suspended) may seek judicial review of the debarment under the Administrative Procedure Act.⁸⁵

ORI’s website contains summaries of its research misconduct cases.⁸⁶ There is also a PHS Administrative Action Report on the ORI’s website which includes a chart of individuals who currently have administrative actions imposed against them by ORI, the ASH and/or HHS.⁸⁷ According to that chart, dated January 19, 2015, sixteen individuals listed on the chart were debarred. Three of the debarments were for life. NSF provides

or welfare? (d) Acceptance of responsibility. Has the respondent accepted responsibility for the misconduct by—(1) Admitting the conduct; (2) Cooperating with the research misconduct proceedings; (3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and (4) Taking steps to correct or prevent the recurrence of the research misconduct. (e) Failure to accept responsibility. Does the respondent blame others rather than accepting responsibility for the actions? (f) Retaliation. Did the respondent retaliate against complainants, witnesses, committee members, or other persons? (g) Present responsibility. Is the respondent presently responsible to conduct PHS supported research? (h) Other factors. Other factors appropriate to the circumstances of a particular case. *Id.*

At HHS, if a hearing has been held before an ALJ, and the ALJ had recommended debarment, the ASH is required to serve a copy of the ALJ’s decision on the HHS debaring official, and the ALJ’s decision would constitute findings of fact to the debaring official. The debaring official has the discretion to reject the ALJ’s findings of fact, in whole or in part, but “only after specifically determining them to be arbitrary, capricious or clearly erroneous.” 2 C.F.R. § 180.845(c). The debaring official’s decision is the final HHS decision concerning the administrative action of debarment. 42 C.F.R. § 93.523(c).

83. 45 C.F.R. § 76.314 states:

(c) *Standard of proof.* (1) In any debarment action, the cause for debarment must be established by a preponderance of the evidence. Where the proposed debarment is based upon a conviction or civil judgment, the standard shall be deemed to have been met. (2) *Burden of proof.* The burden of proof is on the agency proposing debarment.”

84. 45 C.F.R. § 76.800 (2004). The term “present responsibility” is not defined in the regulations. However, present responsibility is typically determined based upon consideration of the factors listed in note 83, *supra*.

85. 5 U.S.C. § 706(2)(B) (2012).

86. *See, Case Summaries*, OFFICE OF RESEARCH INTEGRITY, http://ori.hhs.gov/case_summary (last visited June 5, 2016).

87. OFFICE OF RESEARCH INTEGRITY, *PHS Administrative Action Report*, available at http://ori.hhs.gov/ORI_PHS_alert.html.

information on its research misconduct cases in its Semiannual Reports to Congress. Those reports are accessible on NSF's website.⁸⁸

D. The Bois and Brodie Cases

A review of two research misconduct cases litigated in federal court both illustrate the procedures described above and put in context the burden of proof issue discussed in Part III below.

The more recent of the two cases is *Bois v. U.S. Department of Health and Human Services*.⁸⁹ From 1999 through 2006, Dr. Philippe Bois was a Postdoctoral Fellow at St. Jude Children's Research Center.⁹⁰ On February 1, 2006, senior leadership of St. Jude Children's Research Hospital was informed of several allegations of research misconduct by Dr. Bois concerning five images found in three separate articles.⁹¹ A seven member investigation committee evaluated the allegations of data falsification and fabrication.⁹² The investigation committee met ten times. The committee also interviewed ten people, reviewed the research notebooks of Dr. Bois and his co-author and reviewed selected documents taken from Dr. Bois and his co-author's hard drive.⁹³

In its final report St. Jude found, by unanimous decision of the Investigation Committee, that Dr. Bois intentionally engaged in research misconduct with respect to the falsification or fabrication of two of the figures contained in two separate articles— FOXO1a Acts as a Selective Tumor Suppressor in Alveolar Rhabdomyosarcoma, (the "JCB article") and the "Structural Dynamics of α -Actinin-Vinculin Interactions" (the "MCB article").⁹⁴ As to the JCB article, there were two issues: (i) failing to report the results from a test (the "February test") that were inconsistent with Dr. Bois' hypothesis and (ii) reporting on the results ("Figure 1") of a second test (the "December test") when that experiment lacked a control and

88. *Reports and Publications*, NATIONAL SCIENCE FOUNDATION, <http://www.nsf.gov/oig/pubs.jsp> (last visited June 5, 2016).

89. Civil Action No. 11-1563 (ABJ) (DC March 2, 2012), available at http://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_11-cv-01563/pdf/USCOURTS-dcd-1_11-cv-01563-0.pdf.

90. The facts set forth are as those as set forth in the Defendant's Opposition To Plaintiff's Motion For Preliminary Injunction And Memorandum In Support Of Defendant's Motion For Summary Judgment in the civil action in the District Court for the District of Columbia (hereinafter "Defendant's Opposition"). Defendant's Motion for Summary Judgment and Opposition to Plaintiff's Motion for Preliminary Injunction, *Bois v. United States Dep't of Health and Human Services*, No. 11-cv-1563 (D.D.C. Oct. 4, 2011).

91. *Id.* at 6.

92. *Id.* at 7-8.

93. *Id.* at page 7-8.

94. The St. Jude Committee concluded that there was insufficient evidence to support a finding of research misconduct as to a number of other allegations.

allegedly did not in fact produce the reported results. As to the MCB article, the issue was whether an image (“Figure 4B”) was wrongfully manipulated to reflect the result that Dr. Bois wanted.

St. Jude’s investigation report was transmitted to ORI, which undertook its own review and conducted its only analysis of the charges. Ultimately, ORI sent Dr. Bois a 17-page Charging Letter notifying him that ORI “made two (2) findings of research misconduct” against him; and that based on the evidence it had gathered, it had concluded that Dr. Bois “knowingly, intentionally or recklessly fabricated and falsified data reported in two papers.”⁹⁵ In the same letter, ORI notified Dr. Bois that the debarring official proposed debarring him for a period of three years “from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government.”⁹⁶ The letter also informed him that he could contest the findings and debarment proposal by requesting an administrative hearing before an ALJ with the DAB.⁹⁷

Dr. Bois filed a response to ORI’s Charge Letter in the form of a Request for a Hearing. In his hearing request, he admitted some, but denied most, of the allegations contained in ORI’s Charge Letter.⁹⁸ ORI ultimately filed a motion to dismiss Dr. Bois’ request for a hearing, arguing that the undisputed facts showed that Dr. Bois had intentionally, knowingly or recklessly engaged in researched misconduct. As noted by the ALJ, “I must find, by a preponderance of the evidence, that Respondent Bois ‘intentionally, knowingly, or recklessly’ significantly departed from accepted practices of the relevant research community.”⁹⁹ The ALJ ultimately granted ORI’s motion, determining that a hearing was not necessary.¹⁰⁰ The ALJ determined that a 3-year debarment was the “minimum necessary to protect public health and safety, promote integrity of publically-supported research, and to conserve public funds.”¹⁰¹ In fact, the ALJ stated that “[c]onsidering that [Dr. Bois] committed multiple

95. Bois v. U.S. Department of Health and Human Services, Civil Action No. 11-1563, 3 (ABJ) (D.C. March 2, 2012), available at http://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_11-cv-01563/pdf/USCOURTS-dcd-1_11-cv-01563-0.pdf.

96. *Id.*

97. *Id.*

98. Defendants Opposition, *supra* note 90, at 8-9.

99. Office of Research Integrity v. Bois, DAB No. CR2366 (2011), 2011 WL 2164169 (H.H.S.) at 1.

100. *Id.* at 11-12.

101. *Id.* at 12.

offenses, any one of which would justify a debarment, the three-year period seems minimal.”¹⁰²

Dr. Bois brought suit in the District Court for the District of Columbia alleging, in part, that the ALJ’s decision was arbitrary, capricious, an abuse of discretion, not in accordance with the law, and contrary to Dr. Bois’ constitutional rights, and that the ALJ failed to observe proper procedures, in violation of the APA because the ALJ failed to consider material facts raised by Dr. Bois in his hearing request.¹⁰³

The court issued a Memorandum Opinion upholding the ALJ’s finding of research misconduct in connection with Dr. Bois’s work on the JCB article. As stated by the court:

Finally, there is a question as to whether the factual allegation [Dr. Bois’s explanation of why he did not include the results from the February test and the reporting of the December Test even though it lacked a control and allegedly did not in fact produce the reported result] even if it were true, is material: the claimed results do not necessarily cure the problem that a representation was made in the article that a particular experiment performed at a particular point in December yielded results that it did not in fact yield, and that a figure – found on Dr. Bois’s computer – was created and included in a scientific publication, which falsely depicted those results. Even after the ALJ considered the evidence that Dr. Bois proffers here, and even though she dismissed his argument in part as implausible, she also found that his failure to review his lab notebooks before reporting the results of the December test was sufficient to support a finding of reckless research misconduct *on its own*.

According to the ALJ the required level of deference, the Court therefore cannot find that it was arbitrary and capricious to deny the hearing request on the grounds that plaintiff failed to raise a genuine dispute over facts material to the finding of research misconduct in the JCB article.¹⁰⁴

However, the court reversed and remanded the matter back to the ALJ for a hearing in connection with the allegations of research misconduct in connection with the MCB article. The court reasoned that Dr. Bois had produced at least minimal evidence to suggest a possibility that he relied upon the representations of a co-worker in creating the figure at issue and that therefore Dr. Bois was entitled to a

102. *Id.* at 11.

103. *See Bois v. U.S. Department of Health and Human Services*, Civil Action No. 11-1563, 5 (ABJ) (D.C. March 2, 2012).

104. *Id.* at 18.

hearing on that point. As stated by the court:

So, according the ALJ some deference, the Court finds that while it may not have been unreasonable for the ALJ to conclude that the evidence was sufficient for ORI to meet its burden of proving misconduct by a preponderance of the evidence, Dr. Bois made factual allegations in support of his defense that were specific enough to warrant a hearing. . . This is not intended to suggest that ORI will not be able to meet its burden at a hearing; it just means that there should be a hearing.¹⁰⁵

The court made clear, however, that its “ruling should not be read as any sort of exoneration, and it does not purport to address the merits of Dr. Bois’s case; rather, it is simply a determination that Dr. Bois must have the opportunity to present his highly factual defense, which may or may not withstand cross-examination and any rebuttal evidence ORI elects to present.”¹⁰⁶

After the court’s ruling, HHS moved for reconsideration. While that motion was pending, “Dr. Bois and HHS reached a settlement whereby Dr. Bois denied that he committed research misconduct but agreed not to further appeal ORI’s findings of research misconduct for the falsification of the two figures in *MCB* and *JCB*. He further agreed to have his research supervised for a period of three years.”¹⁰⁷

The other research misconduct case to be litigated in federal court was *Brodie v. United States Department of Health And Human Services*.¹⁰⁸ Dr. Brodie was a Research Assistant Professor and Director of the Retrovirus Pathogenesis and Molecular Virology Laboratories at the University of Washington. In these positions, Dr. Brodie submitted grant applications, published scientific articles, and conducted presentations. In 2002, the university initiated an investigation into whether Dr. Brodie had submitted false or fabricated images in his grant applications, articles, and

105. *Id.* at 27.

106. *Id.* at 7.

107. *Update on Philippe Bois Research Misconduct Case*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/blog/update-philippe-bois-research-misconduct-case> (last visited June 5, 2016).

108. 796 F. Supp. 2d 145 (D.D.C. 2011). There are multiple court decisions relating to the claims of Dr. Brodie. The first published opinion was by Judge Friedman denying Dr. Brodie’s motion for preliminary injunction. *Brodie v. United States Department of Health and Human Services*, Civil Action No. 2010-0544 (D.C. 2010) available at <https://www.courtlistener.com/opinion/2665829/brodie-v-united-states-department-of-health-and-hu/>. The second opinion (the one discussed in the text) was by Judge Boasberg and is reported at 796 F.Supp.2d 145 (D.D.C. 2011). Dr. Brodie subsequently brought an action against HHS and various official, which the courts held were precluded on the grounds of res judicata and collateral estoppel. 951 F.Supp.2d 108 (D.D.C. 2013) affirmed 2014 WL 211222 (D.C. Cir. 2014).

presentations.¹⁰⁹ The university later concluded that Dr. Brodie had submitted or presented materials that contained images that he had knowingly and intentionally falsified or fabricated. As a result, the university banned Dr. Brodie from future employment at the university.¹¹⁰

Based on the findings of the university and additional analysis conducted by ORI in its oversight review, “ORI made fifteen findings of research misconduct based on evidence that Dr. Brodie knowingly and intentionally fabricated and falsified data reported in nine PHS grant applications and progress reports and several published papers, manuscripts, and PowerPoint presentations.”¹¹¹ ORI issued a Charge Letter enumerating the above findings of research misconduct and proposing HHS administrative actions. Dr. Brodie subsequently requested a hearing before an Administrative Law Judge. Ultimately, “the ALJ issued a recommended decision to the HHS Assistant Secretary for Health (ASH) granting summary disposition to ORI. The ALJ also stated that Dr. Brodie committed scientific misconduct on multiple occasions and that its extent amply justified debarment for a period of seven (7) years.”¹¹² The matter was then referred to HHS’s debarring official.

Dr. Brodie submitted to the HHS debarring official documents supporting his contention that she should reject the ALJ’s recommended decision. He also requested a meeting with the debarring official. However, the HHS debarring official determined that Dr. Brodie had been afforded an opportunity to contest ORI’s findings of scientific misconduct in accordance with HHS’s regulations and that the issues in Dr. Brodie’s opposition to the ALJ’s recommended decision did not raise a genuine dispute over facts material to the recommended debarment. The HHS debarring official also denied Dr. Brodie’s request to make an oral presentation and issued a notice of debarment.¹¹³ Dr. Brodie then brought suit in the District Court for the District of Columbia alleging that the ALJ erred in determining by summary disposition both that Dr. Brodie acted improperly and that a seven-year debarment was appropriate.

In ruling against Dr. Brodie, the District Court stated:

Plaintiff’s last challenge to the ALJ’s determination that he committed research misconduct focuses on the sufficiency of the evidence for each of the fifteen findings. Plaintiff claims that the ALJ erred in granting summary disposition because there were material facts in dispute for each finding. In so arguing, Plaintiff

109. *CASE SUMMARY: BRODIE, SCOTT, J.*, OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov/content/case-summary-brodie-scott-j> (last visited June 5, 2016).

110. *Brodie*, 796 F. Supp. 2d at 148.

111. *Id.*

112. *Id.*

113. *Id.*

points to evidence that was not before the ALJ because it was not timely submitted. It is axiomatic that this Court must judge the arbitrary and capricious nature of the ALJ's decision on the evidence that he had before him at the time of his decision.

Plaintiff contends that his late evidence, including a personal affidavit, should have been considered because he would have had the opportunity to testify at a hearing. Plaintiff fails to explain, even if that is the case, why he did not submit this evidence as required by the ALJ's scheduling order or as part of his opposition to summary disposition before the ALJ. As Plaintiff failed to avail himself of either of these opportunities, this Court cannot properly consider the untimely evidence in deciding whether a dispute of material fact existed.

Having reviewed the evidence that the ALJ did consider, the Court cannot find that its holding on each of the acts of misconduct was not [sic] arbitrary or capricious. The ALJ's findings on intent, moreover, were reasonable given the overwhelming evidence of fabrication and falsification. The ALJ's decision makes clear that he "examine[d] the relevant data and articulate[d] a satisfactory explanation for [the Agency's] action including a rational connection between the facts found and the choice made." As such, the Court concludes that the ALJ's findings should be upheld.¹¹⁴

114. *Id.* at 155 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Dr. Brodie argued before the District Court that the ALJ erred in applying a preponderance-of-the-evidence standard to the debarment proceedings. He contended—as discussed in Part Three of this article—that the Fifth Amendment requires the more stringent clear and convincing standard in proceedings that impose a seven-year debarment. In refusing to address this argument, however, the District Court stated: "Yet Plaintiff never raised this issue before the administrative agency, and he offers no reason why this Court should consider it now. 'Arguments that are not raised before an administrative agency cannot be raised, for the first time, to the reviewing court.'" *Id.* at 157 (citing *Stephens v. Dep't of Labor*, 571 F. Supp. 2d 186, 190 n. 4 (D.D.C.2008)).

In upholding the seven year debarment, the court reasoned:

Here, the ALJ determined that it was in the public interest to debar Plaintiff from receiving federal funds for seven years. He wrote, "I have considered [the seven-year ban] in light of the undisputed facts relating to the seriousness of [Plaintiff's] misconduct and the aggravating and mitigating factors governing the length of debarment that are set forth at 42 C.F.R. § 93.408." The ALJ found that the instances of Plaintiff's misconduct were "extremely serious," "numerous," and "striking." He determined that the misconduct had a "substantial impact" on several grant applications and journal articles . . . He considered and rejected as irrelevant, moreover, the fact that some of Plaintiff's current colleagues considered him to be honest. All of this led to the ALJ's determination that Plaintiff "is manifestly untrustworthy to receive, utilize, or distribute federal funds." . . . It is clear from his decision, therefore,

Bois and *Brodie* likely represent the most hotly litigated research misconduct cases in recent years (other than those that were prosecuted as criminal violations).¹¹⁵ What stands out in both instances is the degree to which the factual record was so well developed. But what also stands out is that the administrative and judicial decisions suggest that in neither case would a higher standard of proof (clear and convincing evidence) have made a difference in the outcome. In other words, as to either case, at either the administrative or judicial level, the opinions suggest that the decision maker would have recommended debarment even if the standard of proof had been clear and convincing evidence rather than simply a preponderance. This conclusion is significant because it may suggest that in most cases the evidence of research misconduct will be sufficiently clear that the burden of proof will not make a difference in the outcome. And, if that suggestion is correct, it raises the issue addressed in Part III of this article as to who should bear the risk of a wrong decision being reached in the rare close case (like Dr. White in the hypothetical)—the researcher or the ORI/OIG—especially given the fact that the alleged flaws in the research will become publicly available as part of the proceedings (thereby protecting the public interest) even if there is no finding of actual research misconduct by the researcher (and the de facto imposition of the stigma associated with that conclusion).

PART THREE

The question raised in this Part of this article is whether the Due Process Clause requires use of the clear and convincing evidence standard or, in the alternative, whether HHS and NSF should adopt such a standard

that the ALJ considered both aggravating and mitigating factors in determining that it was in the public interest to debar Plaintiff for seven years. *Id.* Plaintiff has thus failed to demonstrate that the ALJ's recommendation was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. As such, the Court will grant summary judgment for Defendants on this issue. *Id.* at 156 (citations omitted).

115. See, SHAW, EXAMPLES OF CRIMINAL ACTIONS FOR RESEARCH FRAUD AND MISCONDUCT included as exhibit in Government Enforcement for Research Fraud and Misconduct 20100926 AHLA-SEM 35 (2010). Available on Westlaw. The most representative criminal case in this area is Eric Poehlman (D. Vt.) No. 05-cr-00038 (6/29/06). Poehlman was a professor of medicine at the Univ. of Vermont Medical School. GOVERNMENT ENFORCEMENT FOR RESEARCH FRAUD AND MISCONDUCT 20100926 AHLA-SEM 35 (2010). The government brought suit under 18 U.S.C. § 1001 (making false statement to a governmental agency) alleging that Poehlman fabricated research data presented in seventeen grant applications and that he presented false data in research and academic papers. Ultimately, Poehlman agreed to criminal, civil, and administrative settlement. Including imprisonment for 12 months and a day and 100 hours of community service following release. *Id.* See also, SHAW, GOVERNMENT ENFORCEMENT FOR RESEARCH FRAUD AND MISCONDUCT, 20120625 AHLA-SEM 42 (2012) and Burk, *Research Misconduct: Deviance, Due Process, And The Disestablishment Of Science*, 3 GEO. MASON INDEP. L. REV. 305, 323 (1995).

on their own at least in the circumstances when they are seeking to debar an individual or institution for research misconduct. The conclusion reached is that the courts will likely hold the “preponderance of the evidence” standard to be sufficient for Due Process purposes given decisions in analogous contexts rejecting the argument that “clear and convincing” evidence is required (such as in cases involving physician licensing and lawyer debarment). However, this Part also concludes that the NSF and HHS regulations adopting the preponderance of evidence standard may be invalid under the Administrative Procedures Act. It suggests that, at a minimum, the agencies should undertake rulemaking on this issue based upon: (i) the rationale of Supreme Court cases which have held that the preponderance of the evidence standard can violate Due Process in certain circumstances, (ii) the agencies’ mistaken belief that the common law rule is that fraud must be proven by the preponderance of the evidence, and (iii) the failure of the agencies to perform any meaningful analysis of the type suggested by Supreme Court precedent in this area.

A. Does the Due Process Clause Require the Application of the Clear and Convincing Standard?

A threshold issue is whether an individual’s due process rights can be violated if a court or administrative agency applies too low of a standard of proof. In *Addington v. Texas*,¹¹⁶ the Supreme Court unequivocally held yes. At issue in *Addington* was the proper burden of proof to be applied in involuntary commitment proceedings. In holding that due process required the application of the clear and convincing standard, the Court reasoned that such a standard is required when the individual interests at stake are both “particularly important” and involve more than mere loss of money.

The *Addington* Court noted, “the function of a standard of proof, as that concept is embodied in the Due Process Clause and in the realm of factfinding, is to ‘instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.’”¹¹⁷ As stated by the Court, “[t]he standard serves to allocate the risk of error between the

116. 441 U.S. 418 (1979).

117. *Id.* (quoting *In re Winship*, 397 U.S. 358, 370, (1970) (Harlan, J., concurring)). In *In Re Winship*, the Court held that a civil proceeding to have a child declared a juvenile delinquent required the beyond a reasonable doubt standard of proof. According to the Court the private interest was exposure of the juvenile “[t]o a complete loss of his personal liberty through a state-imposed confinement away from his home, family, and friends [and] a delinquency determination, to some extent at least, stigmatizes a youth in that it is by definition bottomed on a finding that the accused committed a crime.” *Winship*, 397 U.S. at 374.

litigants and to indicate the relative importance attached to the ultimate decision.”¹¹⁸

In reaching this result, the Court noted that “[g]enerally speaking, the evolution of this area of the law has produced across a continuum three standards or levels of proof for different types of cases.”¹¹⁹ It then discussed each of the standards as follows:

Preponderance of the evidence:

At one end of the spectrum is the typical civil case involving a monetary dispute between private parties. Since society has a minimal concern with the outcome of such private suits, plaintiff’s burden of proof is a mere preponderance of the evidence. The litigants thus share the risk of error in roughly equal fashion.¹²⁰

Beyond a reasonable doubt:

In a criminal case, on the other hand, the interests of the defendant are of such magnitude that historically and without any explicit constitutional requirement they have been protected by standards of proof designed to exclude as nearly as possible the likelihood of an erroneous judgment. In the administration of criminal justice, our society imposes almost the entire risk of error upon itself. This is accomplished by requiring under the Due Process Clause that the state prove the guilt of an accused beyond a reasonable doubt.¹²¹

Clear and convincing:

The intermediate standard, which usually employs some combination of the words ‘clear,’ ‘cogent,’ ‘unequivocal,’ and ‘convincing,’ is less commonly used, but nonetheless ‘is no stranger to the civil law.’ One typical use of the standard is in civil cases involving allegations of fraud or some other quasi-criminal wrongdoing by the defendant. The interests at stake in those cases are deemed to be more substantial than mere loss of money and some jurisdictions accordingly reduce the risk to the defendant of having his reputation tarnished erroneously by increasing the plaintiff’s burden of proof. Similarly, this Court has used the ‘clear, unequivocal and convincing’ standard of proof to protect particularly important individual interests in various civil cases.¹²²

118. *Addington*, 441 U.S. at 423.

119. *Id.*

120. *Id.*

121. *Id.* at 424.

122. *Id.* (citing *Woodby v. INS*, 385 U.S. 276, 285, (deportation); *Chaunt v. United States*, 364 U.S. 350, 353, (1960) (denaturalization); *Schneiderman v. United States*,

The Court recognized that even if the particular standard of proof catchwords do not always make a great difference in a particular case, adopting a standard of proof is more than an empty semantic exercise. According to the Court, the standard of proof reflects the value society places on individual liberty.¹²³

B. Use of Clear and Convincing Standard in Fraud Cases

As noted by the Supreme Court in *Addington* (and contrary to the statement of OSTP in its Federal Register notice promulgating the final OSTP Research Misconduct Policy), the clear and convincing standard was historically employed in civil cases involving allegations of fraud or some other quasi-criminal wrongdoing by the defendant.¹²⁴ The rationale behind this higher standard was that the individual interest at stake in those cases was deemed to be more substantial than mere loss of money.

The Restatement (Third) of Torts: Liability for Economic Harm, Tentative Draft No. 2 (April 7, 2014), states as follows regarding the common law rule requiring clear and convincing evidence:

Standard of proof. The elements of a tort claim ordinarily must be proven by a preponderance of the evidence, but most courts have required clear and convincing evidence to establish some or all of the elements of fraud.¹²⁵

According to the Restatement, “[a] majority of courts apply the clear-and-convincing standard of proof to all elements of a claim for fraud”¹²⁶ and

320 U.S. 118, 125, 159, (1943) (denaturalization)).

123. *Addington*, 441 U.S. at 425. As discussed *infra* at note 135, empirical studies suggest that the differing standards of proof do in fact make a difference in the outcome of cases.

124. *Id.* *Lalone v. United States*, 164 U.S. 255, 257–58 (1896) (the standard of “mere preponderance of evidence” is “not sufficient to warrant a finding of fraud, and will not sustain a judgment based on such finding”); *United States v. Iron Silver Mining Co.*, 128 U.S. 673, 677 (1888) (“for fraud . . . the testimony . . . must be clear, unequivocal and convincing . . .”); *Schneiderman v. United States*, 320 U.S. 118, 120–21, 125 (1943), (a civil fraud action “needs more than a bare preponderance of the evidence to prevail.” The “evidence must be clear, unequivocal and convincing.”); *see also*, *Baumgartner v. United States*, 322 U.S. 665, 671 (1944) (proof of civil fraud must be “clear, unequivocal and convincing”); *Nowak v. United States*, 356 U.S. 660, 663 (1958) (fraud requires proof by “clear, unequivocal and convincing evidence”).

125. RESTATEMENT (THIRD) OF TORTS: LIAB. FOR ECON. HARM § 9 TD No 2 (2014) (comment e).

126. *Id.* at comment f (citing *Elcon Constr., Inc. v. E. Washington Univ.*, 273 P.3d 965 (Wash. 2012); *Estate of Alden v. Dee*, 35 A.3d 950 (Vt. 2011); *Bank Ctr. v. Wiest*, 793 N.W.2d 172 (N.D. 2010); *Flegles, Inc. v. TruServ Corp.*, 289 S.W.3d 544 (Ky. 2009); *Bowman v. Presley*, 212 P.3d 1210 (Okla. 2009); *Kelly v. VinZant*, 197 P.3d 803 (Kan. 2008); *Wells Fargo Bank v. Arizona Laborers, Teamsters & Cement Masons Local No. 395 Pension Trust Fund*, 38 P.3d 12 (Ariz. 2002); *Langman v. Alumni Ass’n of University of Virginia*, 442 S.E.2d 669 (Va. 1994); *Hercules & Co., Ltd. v. Shama*

these courts tend to express the rationale that fraud imputes venality and corruption to the person charged with it.¹²⁷

When the federal courts have been required to resolve the correct standard of proof in fraud cases as a matter of federal law, they have often held that, in the absence of a statute or rule, the clear and convincing standard should be applied.¹²⁸

C. What Is The Meaning of Clear and Convincing?

Given that due process requires the clear and convincing standard to be applied in certain contexts, the next question is exactly what does the term mean other than a standard of proof that falls between the preponderance and beyond a reasonable doubt.

As stated by the Supreme Court in *Cruzan by Cruzan v. Director, Missouri Department of Health*,¹²⁹ clear and convincing evidence is that weight of proof which “produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable [the factfinder] to come to a clear conviction, without hesitancy, of the truth of the precise facts [of the case].”¹³⁰

Restaurant Corp., 566 A.2d 31 (D.C.1989)). There are, however, some cases requiring proof by a preponderance of the evidence with respect to claims of fraud. *See, e.g.*, *Bomar v. Moser*, 251 S.W.3d 234 (Ark. 2007); *State by Humphrey v. Alpine Air Products, Inc.*, 500 N.W.2d 788 (Minn. 1993); *Wieczorek v. H & H Builders, Inc.*, 475 So. 2d 227 (Fla. 1985).

127. *Gibson v. Smith*, 422 S.W.2d 321 (Mo. 1968).

128. *Ty Inc. v. Softbelly's, Inc.* 517 F.3d 494 (7th Cir. 2008) (distinguishing between the standard of proof in fraud cases at common law and those under Federal statutes). The Seventh Circuit in *Ty, Inc.* also relied upon *Barr Rubber Products Co. v. Sun Rubber Co.*, 425 F.2d 1114 (2d Cir. 1990). In *Barr* the Second Circuit held: “there is ample authority of long standing that to substantiate charges of fraud or of undue influence, at least in actions seeking the recovery of monies paid or the rescission or cancellation of contracts, a litigant must present ‘clear and convincing proof.’” The Second Circuit cited: *United States v. American Bell Telephone Co.*, 167 U.S. 224, 241 (1897); *Lalone v. United States*, 164 U.S. 255, 257 (1896) (“the rule is of long standing and is of universal application, that the evidence tending to prove . . . fraud . . . must be clear and satisfactory.”); *United States v. Maxwell Land-Grant Co.*, 121 U.S. 325, 381, (1887); *Atlantic Delaine Co. v. James*, 94 U.S. 207, 214 (1876); *McDonnell v. General News Bureau, Inc.*, 93 F.2d 898, 901 (3d Cir. 1937); *New York Life Ins. Co. v. Kwetkauskas*, 63 F.2d 890 (3rd Cir.), cert. denied, 289 U.S. 762 (1933); *Bowen v. B. F. Goodrich Co.*, 36 F.2d 306, 308 (6th Cir. 1929); *United States v. Hays*, 35 F.2d 948 (10th Cir. 1929).

129. 497 U.S. 261, 285 fn 11 (1990).

130. *Id.* at 285. Given this definition of “clear and convincing,” it should be readily apparent how much more difficult it would be to find research misconduct in cases like *Dr. White's* in the hypothetical if the clear and convincing standard were applied rather than preponderance of the evidence.

Similarly, the Court suggested in *Colorado v. New Mexico*¹³¹ that, in contrast to the “preponderance standard”, the “clear and convincing” standard requires the trier of fact to reach an abiding conviction that the truth of a factual contention is “highly probable.”¹³²

While the proof must be of a heavier weight than merely the greater weight of the credible evidence, it does not require the evidence be unequivocal or undisputed.¹³³

Empirical studies support the instinctive conclusion that results will vary in close cases depending upon whether the burden of proof is a preponderance or clear and convincing evidence.¹³⁴ The most recent of these studies was prepared by David L. Schwartz and Christopher B. Seaman. Professors Schwartz and Seaman based their study on the Supreme Court’s decision in *Microsoft Corp. v. i4i Ltd. Partnership*¹³⁵ in which the Court unanimously affirmed the U.S. Court of Appeals for the Federal Circuit’s longstanding interpretation that patent invalidity must be proven “by clear and convincing evidence.” Using a patent scenario, Professors Schwartz and Seaman ran numerous experiments in which

131. 467 U.S. 310 (1984).

132. *Id.* at 316. An excellent discussion on the differences between the “preponderance of evidence” and “clear and convincing standard” can be found in F. Vars, *Toward A General Theory Of Standards Of Proof*, 60 CATH. U. L. REV. 1 (2010).

133. *See*, *In re Medrano*, 956 F.2d 101, 102 (5th Cir.1992) (Clear and convincing evidence is “that weight of proof which ‘produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable the fact finder to come to a clear conviction, without hesitancy, of the truth of the precise facts’ of the case.”); *Hobson v. Eaton*, 399 F.2d 781, 784, n.4 (6th Cir. 1968) (“Clear and convincing evidence is “that measure of degree of proof which will produce in the mind of the trier of facts a firm belief or conviction as to the allegations sought to be established. It is intermediate, being more than a mere preponderance, but not to the extent of such certainty as is required beyond a reasonable doubt as in criminal cases. It does not mean clear and unequivocal.”); *Kaszuk v. Bakery and Confectionary Union*, 638 F. Supp. 365, 374 (N.D. IL 1984) (Clear and convincing does not mean evidence which unequivocally proves a point, or dispels all reasonable doubt; rather, to the extent that the phrase is susceptible of precise definition it is best described as evidence which produces in the mind of the trier of fact an abiding conviction that the truth of the factual contentions are highly probable); *see also*, *In re Martin*, 538 N.W.2d 399 (Mich. 1995); *Moran v. Fairley*, 919 So. 2d 969, 975 (Miss. Ct. App. 2005); *Castellano v. Bitkower*, 346 N.W.2d 249 (Neb. 1984); *Estate of Schmidt v. Derenia*, 822 N.E.2d 401, 405 (Ohio Ct. App. 2004); *Spartan Radiocasting, Inc. v. Peeler*, 478 S.E.2d 282, 283 n. 4 (S.C. 1996); and *Middleton v. Johnston*, 273 S.E.2d 800, 803 (Va. 1981).

134. D. Schwartz and C. Seaman, *Standards Of Proof In Civil Litigation: An Experiment From Patent Law*, 26 HARV. J.L. & TECH 429 (2013) (finding that here were significant differences in mock jurors’ decisions between the clear and convincing condition and the preponderance in the patent law context). For examples of other scholarly works on the clear and convincing standard, *see, e.g.*, Vance, *The Clear And Convincing Evidence Standard In Texas: A Critique*, 48 BAYLOR L. REV. 391 (1996).

135. 564 U.S. 91 (2011).

jurors' participated in mock trials and were giving jury instructions with different standards of proof. Professors Schwartz and Seaman noted that previous studies had found that standards of proof matter in jurors' decision making, but that none of the studies directly compared the clear and convincing standard with the preponderance standard.¹³⁶ Their experiments suggested that jurors are, in fact, sensitive to these two standards of proof and may reach different decisions based upon which standard they are asked to apply.

D. Mathews v. Eldridge Three-Part Test

While *Addington* held that due process could require a particular burden of proof be used in a proceeding, it was the Court's decision in *Mathews v. Eldridge*,¹³⁷ that established a three-part test for analyzing due process procedural claims. In *Mathews*, the Court held that due process did not require an evidentiary hearing before revocation of disability benefits. In reaching this result, the Court held that the following three factors must be considered in determining whether a judicial or administrative procedure violates due process: (a) "the private interest that will be affected by the official action;" (b) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards;" and (c) "the government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."¹³⁸ After *Mathews*, most courts addressing the appropriate standard of proof in judicial or administrative proceedings have applied this three-part test.¹³⁹

136. Schwartz and Seaman, *supra* note 134, at 468. For example, Professors Schwartz and Seaman noted that in the early 1980s, C.M.A. McCauliff conducted a survey of all active, senior, and retired federal judges regarding the level of certainty, on a scale of 0%-100%, required by nine phrases treated as standards of proof. As stated by Professors Schwartz and Seaman, "[McCauliff's] results generally paralleled the judges' responses in the Simon & Mahan study. For preponderance of the evidence, the overwhelming majority of judges (154 of 175) equated this standard with a probability of 50% or 60%, with an average probability of 55.3%. For beyond a reasonable doubt, nearly all judges (160 of 171) rated this standard between 80% to 100% probability, with an average probability of 90.3%. Finally, for the clear and convincing evidence standard, the majority of judges (111 of 170) rated this standard as 70% to 80% probability, with an average probability of 75.0%." *Id.* at 439 (citations omitted).

137. 424 U.S. 319, (1976).

138. *Id.* at 335.

139. See, e.g., *Eaves v. Bd. of Med. Exam'rs*, 467 N.W.2d 234, 237 (Iowa 1991); *Rucker v. Michigan Bd. of Med.*, 360 N.W.2d 154, 155 (Mich. Ct. App. 1984); *Anonymous v. State Bd. of Med. Exam'rs*, 496 S.E.2d 17, 19-20 (S.C. 1998); *Gandhi v. Med. Examining Bd.*, 483 N.W.2d 295, 298-300 (Wisc. Ct. App. 1992).

E. Impact of *Steadman v. SEC*

The Supreme Court case most often cited on the issue of what standard of proof to apply in civil administrative decisions is *Steadman v. S.E.C.*¹⁴⁰ In *Steadman*, the Court addressed the standard of proof required in disciplinary proceedings before the Securities and Exchange Commission (“SEC”). Applying the preponderance of the evidence standard, the SEC had debarred Steadman. On appeal, the Court of Appeals for the District of Columbia Circuit held that when the SEC chooses to order the most drastic remedies at its disposal, it was required to apply the clear and convincing standard.¹⁴¹ The Supreme Court reversed the DC Circuit, reasoning that Congress intended the preponderance of evidence standard be applied in SEC disciplinary proceedings. In reaching this result, the Supreme Court stated:

Where Congress has not prescribed the degree of proof which must be adduced by the proponent of a rule or order to carry its burden of persuasion in an administrative proceeding, this Court has felt at liberty to prescribe the standard, for “[i]t is the kind of question which has traditionally been left to the judiciary to resolve.” *Woodby v. INS*, 385 U.S. 276, 284, 87 S.Ct. 483, 487, 17 L.Ed.2d 362 (1966). However, where Congress has spoken, we have deferred to “the traditional powers of Congress to prescribe rules of evidence and standards of proof in the federal courts” absent countervailing constitutional constraints. *Vance v. Terrazas*, 444 U.S. 252, 265, 100 S.Ct. 540, 548, 62 L.Ed.2d 540 (1980). For Commission disciplinary proceedings initiated pursuant to 15 U.S.C. § 80a-9(b) and § 80b-3(f), we conclude that Congress has spoken, and has said that the preponderance-of-the-evidence standard should be applied.¹⁴²

Importantly, however, the Court specifically noted that the “petitioner [made] no claim that the federal constitution require[d] application of a clear-and convincing-evidence standard.”¹⁴³ Thus, the Court did not address whether the Federal Constitution required a clear and convincing standard in disciplinary proceedings before an administrative agency.

The dissenters in *Steadman*, citing *Addington* and evaluating the three factors cited in *Mathews*, would have addressed the Federal Constitutional requirements and would have held that that SEC was required to apply the clear and convincing standard. As stated by Justice Powell, with whom Justice Stewart joined, in dissenting:

140. 450 U.S. 91 (1981).

141. *Steadman v. SEC*, 603 F.2d 1126 (D.C. Cir. 1979).

142. *Id.* at 96.

143. *Id.* at 97, n. 15.

[I]n the absence of any specific demonstration of congress' purpose, we should not assume that congress intended the SEC to apply a lower standard of proof than the prevailing common-law standard for similar allegations. With all respect, it seems to me that the court's decision today lacks the sensitivity that traditionally has marked our review of the government's imposition upon citizens of severe penalties and permanent stigma.¹⁴⁴

The dissent supported its conclusion by citing numerous cases for the proposition that, at common law, it was plain that allegations of fraud had to be proved by clear and convincing evidence.¹⁴⁵

For a number of reasons, reliance on *Steadman* is misplaced as a basis for rejecting a constitutional challenge to a claim that a court or administrative body used an impermissibly low standard of proof. First, the majority and dissenters in *Steadman* agreed that the petitioner in that case did not pursue a constitutional challenge before the Court. Second, the fact that the majority relied so heavily on what it perceived as Congressional intent, and given that such intent is not a factor under *Mathews*, it is clear that the Court in *Steadman* was not analyzing the petitioner's claim as a question of constitutional due process. And third, if use of the clear and convincing standard is required by the Due Process Clause in particular circumstances (as held in *Addington*), Congress would not have the authority to require a lesser standard, regardless of Congressional intent. Accordingly, *Steadman* is not dispositive of the issue of whether the "clear and convincing" standard may be constitutionally required in "research misconduct" cases.

F. Stigma To Defendant Requiring Clear And Convincing Evidence

In *Santosky v. Kramer*¹⁴⁶ the Supreme Court indicated that the potential stigma to a defendant may require use of the clear and convincing evidence standard in appropriate circumstance. The *Santosky* Court held that before a state may sever completely and irrevocably the rights of parents in their natural child, due process requires that the state support its allegations by at least clear and convincing evidence. In reaching this conclusion, the Court reasoned:

This Court has mandated an intermediate standard of proof—"clear and convincing evidence"—when the individual interests at stake in a state proceeding are both "particularly important"

144. *Id.* at 106 (Powell, dissenting).

145. *Id.* at 105 (citing, *Woodby v. INS*, 385 U.S. 276, 285, n. 18 (1966); *Weininger v. Metro. Fire Ins. Co.*, 195 N.E. 420, 426 (1935); *Bank of Pocahontas v. Ferimer*, 170 S.E. 591, 592 (1933); *Bowe v. Gage*, 106 N.W. 1074, 1076 (1906)).

146. 455 U.S. 745, 756-57 (1982).

and “more substantial than mere loss of money.” Notwithstanding “the state’s ‘civil labels and good intentions,’” the Court has deemed this level of certainty necessary to preserve fundamental fairness in a variety of government-initiated proceedings that threaten the individual involved with “a significant deprivation of liberty” or “stigma.”¹⁴⁷

Courts have long recognized that the potential stigma to a person wrongfully accused of serious misconduct warrants extra protections. As stated by the United States Court of Appeals for the First Circuit over a century ago in *Troeder v. Lorsch*:¹⁴⁸

When a person is charged with all the elements which constitute a heinous crime, although it be only on a civil issue, it shocks the judicial mind to refuse to give him the benefit of the usual presumption of innocence unless the adverse proofs are so far satisfactory as to be convincing.¹⁴⁹

There is an obvious stigma associated with a finding of research misconduct. Nevertheless, the importance of this consideration in determining whether the Constitution requires application of the clear and convincing standard in such cases is undercut by federal court decisions generally limiting the category of cases in which the potential “stigma” to the defendant warrants a higher standard of proof. For example, in *Sedima, S.P.R.L., v. Imrex Company, Inc.*,¹⁵⁰ a civil RICO case, the Supreme Court held that there is no requirement that a civil action by a private party can proceed only against a defendant who has already been convicted of a predicate act or of a RICO violation. The Court of Appeals below had reached a different result based on the fear that any other construction would raise severe constitutional questions, as it “would provide civil remedies for offenses criminal in nature, stigmatize defendants with the appellation ‘racketeer,’ authorize the award of damages which are clearly punitive, including attorney’s fees, and constitute a civil remedy aimed in

147. *Id.* at 757 (citations omitted).

148. 150 Fed. 710, 714 (1st Cir. 1906).

149. *Id.* In Burk, *Research Misconduct: Deviance, Due Process, And The Disestablishment Of Science*, 3 GEO. MASON INDEPENDENT L. Rev. 305 (1995), Professor Burk stated: “But far more is at stake in a misconduct investigation than the meaning of some new data or the correctness of an empirical model—the rights, reputation, and livelihood of an individual hang in the balance. These are not matters of science, but matters of law. Science can wait until better data become available; law must decide now. Science can focus on accuracy and precision; law must frequently sacrifice these values for equity and expedience. Scientific dialogue has its place in the pages of learned journals or the symposia of a learned society, but it is a poor model for the investigative procedures of a federal agency, with all the legal consequences such an investigation entails.” *Id.* at 328 (citations omitted).

150. 473 U.S. 479 (1985).

part to avoid the constitutional protections of the criminal law.”¹⁵¹ In rejecting this concern, the Supreme Court stated:

We do not view the statute as being so close to the constitutional edge. As noted above, the fact that conduct can result in both criminal liability and treble damages does not mean that there is not a bona fide civil action. The familiar provisions for both criminal liability and treble damages under the antitrust laws indicate as much. Nor are attorney’s fees “clearly punitive.” As for stigma, a civil RICO proceeding leaves no greater stain than do a number of other civil proceedings. Furthermore, requiring conviction of the predicate acts would not protect against an unfair imposition of the “racketeer” label. If there is a problem with thus stigmatizing a garden variety defrauder by means of a civil action, it is not reduced by making certain that the defendant is guilty of *fraud* beyond a reasonable doubt. Finally, to the extent an action under § 1964(c) might be considered quasi-criminal, requiring protections normally applicable only to criminal proceedings, the solution is to provide those protections, not to ensure that they were previously afforded by requiring prior convictions.¹⁵²

Similarly state courts have held that stigma alone is insufficient to require an administrative agency to apply the clear and convincing standard where there is a countervailing public interest—at least in the context of professional disciplinary proceedings.¹⁵³

G. Federal Precedent On Disqualification Of Attorneys In Federal Court

One area of Federal authority that supports the use of the clear and convincing standard can be found in cases dealing with the debarment of attorneys in federal courts. In *In re Ruffalo*,¹⁵⁴ the Supreme Court reversed a disbarment order entered by the Sixth Circuit on the ground that the Ohio Board of Commissioners on Grievances and Discipline failed to provide fair notice of the charges leveled against the attorney. In reaching this result the Court held:

151. 741 F.2d 482, 500 fn. 49 (2d Cir. 1984), rev’d, 473 U.S. 479 (1985).

152. *Sedima*, 473 U.S. at 492 (citations omitted).

153. *See, e.g.* Tsirelman v. Daines, 19 F. Supp. 3d 438, 2014 WL 1930355 (E.D.N.Y. 2014); Eaves v. Bd. of Med. Exam’rs, 467 N.W.2d 234, 237 (Iowa 1991); Rucker v. Michigan Bd. of Med., 360 N.W.2d 154, 155 (1984); Anonymous v. State Bd. of Med. Exam’rs, 496 S.E.2d 17, 19-20 (1998); Gandhi v. Med. Examining Bd., 483 N.W.2d 295, 298-300 (Ct. App.1992).

154. 390 U.S. 544, (1968).

Disbarment, designed to protect the public, is a punishment or penalty imposed on the lawyer. He is accordingly entitled to procedural due process, which includes fair notice of the charge.¹⁵⁵

The Court characterized disbarment actions as “adversary proceedings of a quasi-criminal nature.”¹⁵⁶

Although the Supreme Court in *Ruffalo* did not address the standard of proof,¹⁵⁷ many Federal Courts of Appeals have held that clear and convincing evidence is required in proceedings to disbar an attorney from a Federal Court.¹⁵⁸ For example, *In re Medrano*¹⁵⁹ the Fifth Circuit held:

A disbarment proceeding is adversarial and quasi-criminal in nature and the moving party bears the burden of proving all elements of a violation. The notice of the allegations and the debarment proceeding must satisfy the requirements of procedural due process. A federal court may disbar an attorney only upon

155. *Id.* at 550 (citations omitted).

156. *Id.* at 551.

157. *See*, *In Matter of Friedman*, 1996 WL 705322 (E.D.N.Y. 1996) (The Supreme Court did not reach the issue of the standard of proof to be applied in attorney debarment proceedings).

158. *See, e.g.*, *In re Liotti*, 667 F.3d 419, 426 (4th Cir. 2011); *In re Lebbos*, 2007 WL 7540984 (9th Cir. 2007); *Crowe v. Smith*, 261 F.3d 558, 563 (5th Cir. 2001); *In re Ryder*, 381 F.2d 713, 714–15 (4th Cir. 1967) (per curiam). Courts have also required clear-and-convincing evidence for the imposition of attorneys’ fees as a sanction. *See Autorama Corp. v. Stewart*, 802 F.2d 1284, 1287–1288 (10th Cir. 1986); *Weinberger v. Kendrick*, 698 F.2d 61, 80 (2d Cir. 1982). And a number of circuits have held that clear-and-convincing evidence is required before a court can grant a dismissal under its inherent powers to sanction. *See, e.g.*, *Shepherd v. American Broadcasting Cos., Inc.*, 62 F.3d 1469, 1476 (D.C. Cir. 1995); *Aoude v. Mobil Oil Corp.*, 892 F.2d 1115, 1118 (1st Cir. 1989); *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 538 F.2d 180, 195 (8th Cir. 1976); *see also Ford v. Fogarty Van Lines, Inc.*, 780 F.2d 1582, 1583 (11th Cir. 1986) (per curiam); *Pardee v. Stock*, 712 F.2d 1290, 1292 (8th Cir. 1983); *Titus v. Mercedes Benz of N. America*, 695 F.2d 746, 749 (3d Cir. 1982); *Graves v. Kaiser Aluminum & Chemical Co.*, 528 F.2d 1360, 1361 (5th Cir. 1976).

159. 956 F.2d 101 (5th Cir. 1992). Even though Federal courts have applied the “clear and convincing standard” to disbarment of attorneys from their own courts, they have been unwilling to force state courts to apply the higher standard. As stated in *In re Barach*, 540 F.3d 82 (1st Cir. 2008):

We understand the importance of a lawyer’s right to practice law and agree that, once granted, that right cannot be taken away in an arbitrary or capricious manner. Yet the Due Process Clause is flexible, and reasonable minds can differ as to the need for elevated levels of proof in particular situations. Viewed in this light, the use of a preponderance of the evidence standard in bar disciplinary proceedings does not offend due process. After all, many types of important property rights typically rest, in contested proceedings, on proof by preponderant evidence. [citations omitted] . . . Although there is something to be said on policy grounds for requiring a more sturdy quantum of proof, the use of a preponderance standard is not so arbitrary or irrational as to render state disciplinary proceedings that use it fundamentally unfair. *Id.* at 86–87.

presentation of clear and convincing evidence sufficient to support the finding of one or more violations warranting this extreme sanction.¹⁶⁰

And, in *In re Charges of Judicial Misconduct*,¹⁶¹ the United States Court of Appeals for the District of Columbia Circuit noted the following in a case regarding a complaint of misconduct by a Federal Judge:

In the analogous context of attorney disciplinary proceedings, the American Bar Association's Model Rules and most state and federal jurisdictions that have addressed the question require complainants (or disciplinary counsel) to establish misconduct by clear and convincing evidence. . .¹⁶²

It is important to note, however, that generally the federal courts in this context have not relied upon *Mathews* to conclude that the clear and convincing standard should be applied. Rather, the courts rely upon a limitation in their own inherent power to discipline attorneys who practice before them.¹⁶³

160. 956 F.2d 101, 102 (5th Cir. 1992) (citations omitted). *See* *In re Bird*, 353 F.3d 636, 641 (8th Cir. 2003); *Razatos v. Colorado Supreme Court*, 746 F.2d 1429, 1436 (10th Cir. 1994); *In re Bell South*, 334 F.3d 941, 963 (11th Cir. 2003); *Jaskiewicz v. Mossinghoff*, 822 F.2d 1053, 1058 (Fed. Cir. 1987); *In re Halperin*, 139 F.2d 361, 361 (D.C. Cir. 1943); *In re Fisher*, 179 F.2d 361, 370 (7th Cir. 1950) (“the charges must be sustained by clear and convincing proof and the misconduct must be shown to have been fraudulent and the result of improper motives, and the proof must show intent”); *see also* *In re Sheridan*, 362 F.3d 96, 111 at fn.18 (1st Cir. 2004); *In re Fallin*, 255 F.3d 195, 197 (4th Cir. 2001); *In re Crayton*, 192 B.R. 970, 975 (9th Cir. BAP 1996).

161. 769 F.3d 762 (D.C. Cir. 2014).

162. *Id. at 767*. *See, e.g.*, *Sealed Appellant 1 v. Sealed Appellee 1*, 211 F.3d 252, 254–55 (5th Cir.2000); *In re Oladiran*, No. 10–0025, 2010 WL 3775074, at *7 (D. Ariz. Sept. 21, 2010); *In re Levine*, 675 F. Supp. 1312, 1318 & n. 4 (M.D. Fla.1986); *In re Jaques*, 972 F. Supp. 1070, 1079 (E.D. Tex.1997); *In re Placid Oil*, 158 B.R. 404, 413 (N.D. Tex.1993); *In re Ryder*, 263 F. Supp. 360, 361 (E.D. Va.1967). The DC Circuit noted, however, that a number of states do apply the preponderance of the evidence standard. *See, e.g.*, *In re Crews*, 159 S.W.3d 355, 358 (Mo. 2005) (en banc); *In re Capoccia*, 59 N.Y.2d 549, 551, 466 N.Y.S.2d 268, 453 N.E.2d 497 (1983).

163. *See, e.g.*, *In re Grodner*, 2014 WL 5510994 (5th Cir. 2014). It should also be noted that in *Chambers v. NASCO, Inc.*, 501 U.S. 32, 46 (1991) the Supreme Court recognized that awards of attorneys' fees for bad faith conduct serve the same punitive and compensatory purposes as fines imposed for civil contempt and, as a result, as a result, courts generally require clear and convincing evidence of misconduct before imposing attorneys' fees under their inherent power. *See, e.g.*, *Washington–Baltimore Newspaper Guild, Local 35 v. The Washington Post Co.*, 626 F.2d 1029, 1031 (D.C. Cir. 1980).

Outside the attorney disciplinary context, Federal Courts have held that entering a default judgment as a sanction for misconduct in litigation requires clear and convincing evidence. *See, e.g.*, *Sheppard v. American Broadcasting Co.*, 62 F.3d 1469 (D.C. Cir. 1995) (“A heightened standard of proof is particularly appropriate because most inherent power sanctions, including default judgments, are fundamentally punitive. Our judicial system has a cherished tradition of using a heightened standard of proof to guard against the erroneous imposition of criminal punishments and analogous deprivations of liberty, property, or reputation.”)

H. Loss of Professional or Other License

At the state level, the most analogous decisions to research misconduct debarment are those dealing with the standard of proof for taking a license away from a professional (*e.g.*, physician, attorney) or other service provider. There are a few decisions in this context that have held that the clear and convincing standard must be applied.¹⁶⁴ Several other decisions have applied the preponderance of the evidence standard in the absence of a constitutional challenge.¹⁶⁵ However, the vast majority of decisions hold that the clear and convincing standard is not required by either the Federal Constitution or particular state constitution.¹⁶⁶ It is this last category of cases that most strongly suggest that most courts would not find the clear and convincing standard constitutionally required in research misconduct cases, even ones resulting in debarment.

*Tsirelman v. Daines*¹⁶⁷ is representative of recent cases involving state licenses. In that case, a physician whose license had been revoked brought an action in Federal District Court against the New York Department of

Federal courts have also consistently held that in order to substantiate charges of fraud seeking rescission or cancellation of contracts, a litigant must present clear and convincing proof contracts. See, *e.g.*, *Centex Construction Co. v. James*, 374 F.2d 921 (8th Cir. 1967). But, these holding simply reflect the common law rule as opposed to a requirement of due process.

164. See, *e.g.*, *Painter v. Abels*, 998 P.2d 931 (Wyo. 2000) (physician); *Johnson v. Bd. Of Governors of Registered Dentists*, 913 P.2d 1339, 1345 (Okla.1996); *Mississippi State Bd. Of Nursing v. Wilson*, 624 So.2d 485 (Miss.1993); *Devous v. Wyoming State Bd. Of Med. Examiners*, 845 P.2d 408 (Wyo. 1993); *Davis v. Wright*, 503 N.W.2d 814 (1993) (Psychiatrist); *Ettinger v. Bd. of Med. Quality Assurance*, 135 Cal.App.3d 853 (Ct. App.1982).

165. See, *e.g.*, *Golan v. Sobol*, 195 A.D.2d 634, (3d Dept.1993) (Doctor); *Matter of The Disciplinary Action against the Dentist License of Wang*, 441 N.W.2d 488 (Minn. 1989) (Dentist); *Ferguson v. Hamrick*, 388 So.2d 981 (Ala. 1980) (Doctor); *In Re Kincheloe*, 157 S.E.2d 833 (1967) (Doctor); *Texas State Board of Medical Examiners v. Haynes*, 388 S.W.2d 258 (Tex. Civ. App.1965) (Doctor).

166. See, *e.g.*, *Swiller v. Commissioner of Public Health & Addiction Serv.*, 1995 W.L. 611754 (Conn. 1995) (Chiropractor); *Sobel v. Bd. Of Pharmacy*, 882 P.2d 606 (1994) (Pharmacist); *Pickett v. Utah Dept. Of Commerce*, 858 P.2d 187 (Utah Ct. App. 1993) (Pharmacist); *Petition of Grimm*, 635 A.2d 456 (1993) (Psychologist); *Gandhi v. Med. Examining Bd.*, 483 N.W.2d 295 (1992); *Eaves v. Bd. Of Med. Examiners*, 467 N.W.2d 234 (Iowa 1991) (Physician); *Johnson v. Arkansas Bd. Of Examiners of Psychology*, 305 Ark. 451, 808 S.W.2d 766 (1991) (Psychologist); *Lyness v. Commonwealth, State Bd. Of Medicine*, 561 A.2d 362 (1989) (Physician); *Foster v. Bd. Of Dentistry*, 714 P.2d 580 (1986) (Dentist); *Thangavelu v. Dept. of Licensing & Regulation*, 386 N.W.2d 584 (1986) (Physician); *Matter Of Proposed Disciplinary Action Against Dentist License Of Roger W. Schultz*, 375 N.W.2d 509 (Minn. Ct. App.1985) (Dentist); *Rucker v. Michigan Bd. Of Med.* 360 N.W.2d 154 (1984) (Physician); *In Re Polk*, 449 A.2d 7 (1982) (Physician); *Sherman v. Commission On Licensure To Practice The Healing Art*, 407 A.2d 595 (D.C. Ct. App.1979) (Physician).

167. 19 F.Supp.3d 438, 2014 WL 1930355 (E.D.N.Y. 2014), *aff'd*, — F.3d —, 2015 WL 4491766 (2d Cir. 2015).

Health and others claiming that the application of the preponderance of the evidence standard in his disciplinary hearing failed to comport with the requirements of due process. The defendants moved to dismiss. In rejecting the physician's argument, the District Court first noted that "[t]he federal and New York courts that have considered the issue have all determined that the preponderance of the evidence standard of proof comports with due process in medical disciplinary proceedings"¹⁶⁸ and that "[t]he highest courts of several other jurisdictions have similarly rejected calls for a higher standard of proof."¹⁶⁹ It then applied the *Mathews*' factors to the issue of the revocation of the physician's license.¹⁷⁰

The District Court in *Tsirelman* conceded that, as to the first *Mathews* factor (the private interest), "physicians have an important private interest in their medical license."¹⁷¹ But, the court noted that the physicians' interest in practicing medicine was short of the private interest involved in the cases where the Supreme Court held that the clear and convincing standard was required.¹⁷² According to the court, that interest must be balanced against the need for ethical medical practices protecting the public. As to the second *Mathews*' factor (the governmental interest at stake), the court concluded that without question, New York has an

168. See, e.g., *Chalasanani v. Daines*, 2011 WL 4465564 (E.D.N.Y. 2011) report and recommendation adopted, 10-CV-1978, 2011 WL 4465408 (E.D.N.Y. 2011); *In re Gould v. Bd. of Regents of Univ. of State of N.Y.*, 478 N.Y.S.2d 129, 130 (3d Dep't 1984); *Giffone v. De Buono*, 693 N.Y.S.2d 691, 694 (3d Dep't 1999).

169. See, e.g., *Sherman v. Comm'n on Licensure to Practice the Healing Art*, 407 A.2d 595, 601 (D.C.App.1979); *Petition of Grimm*, 138 N.H. 42, 635 A.2d 456, 461 (1993); *In re Polk*, 90 N.J. 550, 449 A.2d 7 (N.J. 1982); *N.D. State Bd. of Med. Examiners v. Hsu*, 726 N.W.2d 216, 230 (N.D. 2007).

170. *Tsirelman*, 19 F. Supp. 3d at 449-50 ("In determining the proper standard of proof, the three factors set forth in *Mathews v. Eldridge* must be considered: (1) "the private interest that will be affected by the official action;" (2) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail;" and (3) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards." (quoting *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976))).

171. *Tsirelman*, 19 F. Supp. 3d at 450 ("As plaintiff asserts, the loss of a professional license is a serious matter for the license holder. It represents the loss of a livelihood and a career."). See also *RRI Realty Corp. v. Inc. Vill. of Southampton*, 870 F.2d 911, 917 n. 4 (2d Cir. 1989) ("plaintiffs denied licenses required for pursuing a particular occupation . . . have a liberty interest in earning a livelihood and are normally not required to show an entitlement to the license they seek in order to state a claim").

172. As stated by the court: "The private interest at issue here does not quite rise to the level at which the Supreme Court has held a clear and convincing standard of evidence to be constitutionally required. *Tsirelman*, 19 F. Supp. 3d at 453 (citing *Addington v. Texas*, 441 U.S. 418, 425 (1979) (civil commitment); *Woodby v. INS*, 385 U.S. 276, 285 (1966) (deportation); *Chaunt v. United States*, 364 U.S. 350, 353 (1960) (denaturalization); *Schneiderman v. United States*, 320 U.S. 118, 125 (1943) (denaturalization)).

important state interest in protecting the health of its citizens by regulating the practice of medicine within its borders.¹⁷³ Finally, as to the third *Mathews*' factor (an undue risk of error) the court concluded that given the judicial-like process of the state's physician misconduct hearing, there was no undue risk of error sufficient to create a constitutionally required clear and convincing standard.

The plaintiff in *Tsirelman* stressed that medical disciplinary proceedings based primarily on fraud are unique in that they threaten the charged individual with "stigma" as well as the deprivation of an important private interest, necessitating clear and convincing evidence.¹⁷⁴ But, the District Court rejected that argument based on the Supreme Court precedent discussed above where the Court held that the preponderance of the evidence standard comported with due process in federal administrative proceedings involving the commission of fraud¹⁷⁵ as well as similar New York cases¹⁷⁶ and cases in other jurisdictions finding the "stigma"

173. *Selkin v. State Bd. for Prof'l Med. Conduct*, 63 F. Supp. 2d 397, 402 (S.D.N.Y. 1999); *Doe v. Connecticut*, 75 F.3d 81, 85 (2d Cir. 1996); *Blake v. Lang*, 669 F. Supp. 584, 589 (S.D.N.Y. 1987); *Middlesex County Ethics Committee v. Garden State Bar Ass'n*, 457 U.S. 423 (1982); *see also Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 (1975) ("We recognize that the States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions.").

174. The plaintiff relied on *Santosky* and cases applying the clear and convincing standard in common law fraud cases. *See, e.g., Ty Inc. v. Softbelly's, Inc.*, 517 F.3d 494, 499 (7th Cir. 2008) (noting "in the absence of a statute or rule," traditional common law or equitable principles dictate that fraud must be proved by clear and convincing evidence).

175. *See, e.g., Steadman v. S.E.C.*, 450 U.S. 91 (1981) (upholding use of preponderance standard in SEC hearing involving antifraud provisions of securities law). The court noted that Congress and the Supreme Court have repeatedly applied the preponderance standard under federal fraud statutes. *Tsirelman*, 19 F. Supp. 3d at 450 (citing *Herman & MacLean v. Huddleston*, 459 U.S. 375, 389 (1983) (applying preponderance standard to civil enforcement of antifraud provisions of securities law); *Grogan v. Garner*, 498 U.S. 279, 288 (1991) (holding Congress chose the preponderance standard for substantive causes of action for fraud (collecting cases and statutes)); *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 491 (1985) (suggesting preponderance standard applies to civil actions under RICO).

176. The court cited the following New York State cases upholding the preponderance of the evidence standard in medical disciplinary proceedings involved charges of fraudulent misconduct: *Matter of Bazin v. Novello*, 754 N.Y.S.2d 446 (3d Dep't 2003) (physician charged with misconduct including fraudulent billing of insurance companies); *Matter of Giffone v. DeBuono*, 693 N.Y.S.2d 691 (3d Dep't 1999) (charging physician with improper touching under guise of providing legitimate medical treatment). The court also noted that in disciplinary proceedings against attorneys involving allegations of fraud, the Court of Appeals for the Second Circuit held that the preponderance standard provides adequate due process. *See, e.g., In re Theodore Friedman*, 51 F.3d 20, 22 (2d Cir. 1995) (upholding preponderance standard where attorney was charged with knowingly making false affidavit); *In re Friedman*,

insufficient to require a higher standard of proof.¹⁷⁷ Thus, the court held: “In light of the compelling government interest and the procedural safeguards provided to the physicians, the preponderance of the evidence standard is constitutionally adequate in physician misconduct proceedings based primarily on fraud.”¹⁷⁸

In affirming the local court’s decision in *Tsirelman*, the Second Circuit reasoned that physicians have an important, but not compelling, property interest in their medical licenses and a liberty interest in pursuing their chosen profession;¹⁷⁹ the preponderance standard “fairly distributes the risk of error” between the state and the physician;¹⁸⁰ and the countervailing governmental interest is strong. The State, on behalf of the public, has a

1996 WL 705322, at *7 (E.D.N.Y. 1996) (upholding preponderance standard where attorney was charged with instructing witness to give false testimony).

177. The court noted that the preponderance standard had been upheld in the following cases involving other stigmatizing state actions. *See, e.g.*, *Valmonte v. Bane*, 18 F.3d 992, 994 (2d Cir. 1994) (maintenance and publication of names on central registry of suspected child abusers); *Petition of Grimm*, 635 A.2d 456 (N.H. 1993) (physician disciplinary proceedings involving sexual relations with patient); *Gandhi v. State of Wisconsin Med. Bd.*, 307, 483 N.W.2d 295 (Wis. Ct. App. 1992) (physician disciplinary proceeding involving inappropriate touching). *Tsirelman*, 19 F. Supp. 3d at 451-52.

178. *Tsirelman*, 19 F. Supp. 3d at 452.

179. *Tsirelman v. Daines*, 794 F.3d 310, 315 (2d Cir. 2015). The Second Circuit cited: *Donk v. Miller*, 365 F.3d 159, 163 (2d Cir. 2004); *RRI Realty Corp. v. Inc. Vill. of Southampton*, 870 F.2d 911, 917, n. 4 (2d Cir.1989). The Court of Appeals reasoned that: “if a physician loses his license, he remains free to pursue other employment and otherwise participate in life’s activities. For this reason, we find a physician’s interest in his license to be less compelling than those interests that the Supreme Court has determined require clear and convincing proof before the state can effect a deprivation.” *Tsirelman*, 794 F.3d at 315. *Tsirelman* had argued that a physician’s interest in a fraud-based medical disciplinary hearing is more substantial than in other disciplinary proceedings because the resulting reputational harm can extend beyond the medical field. In concluding that this distinction was unpersuasive, the Second Circuit stated:

A license revocation based on medical incompetence, sexual impropriety, or another serious charge would also tend to taint a physician’s other future endeavors. In any event, even if we accepted *Tsirelman*’s argument that physicians have a greater interest in fraud-based revocation proceedings, that interest still does not rise to the fundamental level that requires the application of a heightened standard of proof as a matter of federal due process. *Id.*

180. The Second Circuit reasoned that:

[T]he corresponding consequences of error to the physician and the state in a fraud-based license revocation are roughly equivalent. If a doctor’s license is erroneously revoked, he should be, but is not, allowed to practice medicine. If a doctor’s license is erroneously maintained, he should not be, but is, allowed to continue to practice. Thus, the “social disutility” of each potential outcome is about the same, and it is not in general more serious for a license to be erroneously revoked than to be erroneously maintained. *Tsirelman*, 794 F.3d at 315.

substantial interest in revoking the licenses of doctors who engage in fraud or are otherwise found to be unfit to practice medicine.¹⁸¹

A second representative case in this area is *Jones v. Connecticut Medical Examining Bd.*,¹⁸² in which the Supreme Court of Connecticut held that use of the preponderance of the evidence standard in a physician disciplinary proceeding does not offend a physician's due process rights. In reaching this result, the state supreme court relied upon its prior decision in *Goldstar Medical Services, Inc. v. Department of Social Services*,¹⁸³ in which it had concluded that the preponderance standard is the default rule applicable in federal administrative proceedings, including those in which sanctions include the potential loss of a professional license.¹⁸⁴ The

181. The court of appeals acknowledged a physician's interest in maintaining his license, but concluded that "the State has at least as substantial an interest in protecting the public, and the cost of error is about the same. Thus, we find no constitutional basis for exempting fraud-based medical disciplinary proceedings from the traditional powers of state legislatures to prescribe standards of proof in state proceedings." *Id.* at 316.

182. 72 A.3d 1034 (2013). Among the findings of the Connecticut Medical Examining Bd. against Dr. Jones were that he violated the standard of care with respect to his treatment of child patients (1) by prescribing an antibiotic to a patient he did not know and had never examined; (2) prescribing antibiotics for nearly one year without repeat examinations and without any arrangement with another physician to monitor the patient for the side effects of long-term antibiotic therapy; and (3) diagnosing a disease in two children patients when the exposure risk was extremely low, the medical history was nonspecific, the signs and symptoms were non-specific, and the laboratory tests were negative. *Id.* at 1037.

183. 955 A.2d 15 (Conn. 2008). The administrative proceeding at issue in *Goldstar* was before the Connecticut Commissioner of Social Services (commissioner). *See id.* at 798. Using the preponderance of the evidence standard, the commissioner found that the plaintiffs, who were Medicaid providers, had committed fraud and therefore suspended them from the Medicaid program and ordered restitution. *See id.* at 798–99, 818. The Connecticut Supreme Court in *Goldstar* rejected the plaintiffs' argument that the standard of proof should have been clear and convincing evidence, concluding instead that, "[i]n the absence of state legislation prescribing an applicable standard of proof . . . the preponderance of the evidence standard is the appropriate standard of proof in administrative proceedings. . . ." *Id.* at 821. The Federal standard was relevant to the Connecticut Court, in part, because Medicaid is a cooperative program between the states and the Federal government.

184. The Connecticut Supreme Court in *Goldstar* stated as follows:

We begin by noting that, in this state, proof by preponderance of the evidence is the "ordinary civil standard of proof. . . ." The plaintiffs accurately state, however, that the clear and convincing standard is the appropriate standard of proof in *common-law* fraud cases.

In federal administrative proceedings, the preponderance of the evidence standard is applicable, even when the issue is the commission of fraud. The United States Supreme Court has held that the preponderance of the evidence standard traditionally applies in administrative cases in the absence of a legislative directive to the contrary. *Goldstar*, 955 A.2d at 33–34 (citations omitted).

physician in *Jones* argued, however, that the Supreme Court's decisions in *Mathews* and *Addington* required the clear and convincing standard.¹⁸⁵ In rejecting this argument, the Connecticut Supreme Court concluded that the *Mathews* test warranted the application of the preponderance of the evidence standard.¹⁸⁶ It said:

As stated by the court in *Jones*:

Although the United States Supreme Court has not yet considered whether, under the *Mathews* framework, the federal constitution mandates a higher standard of proof in physician disciplinary proceedings, a majority of our sister states has concluded that the preponderance of the evidence standard satisfies the requirements of due process in such cases. Applying the *Mathews* test in the present case, we agree with the majority of our sister jurisdictions that the use of the preponderance of the evidence standard in a physician disciplinary proceeding does not offend a physician's due process rights. With respect to the first *Mathews* factor, we are mindful of the plaintiff's important property interest in his medical license, the deprivation of which, the plaintiff claims,

185. The plaintiff in *Jones* also cited *Nguyen v. Dept. of Health*, 29 P.3d 689 (Wash. 2001), cert. denied sub nom; *Washington Medical Quality Assurance Comm' v. Nguyen*, 535 U.S. 904 (2002). *Jones v. Connecticut Medical Examining Bd.*, 72 A.3d 1034 (2013). In rejecting the plaintiff's reliance on the Supreme Court cases, holding that a clear and convincing standard was required, the Washington court stated:

The United States Supreme Court "has mandated an intermediate standard of proof—clear and convincing evidence—when the individual interests at stake in a state proceeding are both particularly important and more substantial than mere loss of money. . . . [T]he [c]ourt has deemed this level of certainty necessary to preserve fundamental fairness in a variety of government-initiated proceedings that threaten the individual involved with a significant deprivation of liberty or stigma." "[I]n any given proceeding, the minimum standard of proof tolerated by the due process requirement reflects not only the weight of the private and public interests affected, but also a societal judgment about how the risk of error should be distributed between the litigants."

Jones, 72 A.3d 1034, 1042 fn. 6 (quoting *Santosky v. Kramer*, 454 U.S. 745, 755–57 (1982)).

186. The court stated:

As the United States Supreme Court has explained, [p]rocedural due process imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the [d]ue [p]rocess [c]lause of the [f]ifth or [f]ourteenth [a]mendment. [D]ue process is flexible and calls for such procedural protections as the particular situation demands. The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner, and, specifically, to be heard before being condemned to suffer grievous loss of any kind, even though it may not involve the stigma and hardships of a criminal conviction. . . .

Jones, 72 A.3d at 1040 (quoting *Mathews v. Eldridge*, 424 U.S. 319, 332–333 (1976); *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972)) (quotations omitted).

could both preclude him from practicing medicine and subject him to social stigma. Nonetheless, this interest does not rise to the level of those for which the United States Supreme Court has concluded that due process mandates the application of the clear and convincing evidence standard rather than the preponderance of the evidence standard Regarding the risk of erroneous deprivation, the second factor under the *Mathews* framework, we agree with the board that the procedures adequately protect against an unacceptable risk of error. Turning to the final *Mathews* factor, we are persuaded that the governmental interest weighs in favor of maintaining the preponderance of the evidence standard because a heightened standard of proof necessarily renders it more difficult for the state to protect the public from unsafe medical practitioners.***Weighing these three factors, we are not persuaded that the constitution requires a heightened standard of proof when a physician's license is imperiled in an administrative proceeding before the board. We therefore decline the plaintiff's invitation to judicially impose the heightened standard of proof imposed by a minority of our sister states.¹⁸⁷

Another recent noteworthy case is *Olympic Healthcare Services II LLC v. Department of Social & Health Services*,¹⁸⁸ a decision by the Court of Appeals of Washington. The case involved the revocation of the license of an operator of an adult family home. What is interesting about the case is the Court of Appeals' discussion of three earlier Washington Supreme Court cases, *Nguyen v. Department of Health Medical Quality Assurance Commission*,¹⁸⁹ *Ongom v. Department of Health, Office of Professional Standards*¹⁹⁰, and *Hardee v. Dep't of Soc. & Health Servs.*,¹⁹¹. In *Nguyen* the state supreme court applied the three-part *Mathews* test to conclude that due process required proof by clear and convincing evidence to revoke a

187. The Jones Court found unpersuasive the plaintiff's argument that the disciplinary procedures to which attorneys are subjected should have some bearing on the appropriate disciplinary procedures applied to physicians. According to the court the plaintiff's argument fails to recognize that attorney discipline, unlike physician discipline, is overseen by the Judicial Branch. *Jones*, 72 A.3d at 1044. *See also*, *Statewide Grievance Committee v. Rozbicki*, 558 A.2d 986 (1989) (noting that regulation of attorney conduct is "within the court's inherent authority" and that statewide grievance committee is authorized "to act as an arm of the court in fulfilling this responsibility").

188. 304 P.3d 491 (Wash. Ct. App. 2013).

189. 29 P.3d 689 (Wash. 2001), *cert. denied*, 535 U.S. 904 (2002).

190. 148 P.3d 1029 (Wash. 2006), *overruled by Hardee*, 256 P.3d 339 (Wash. 2011).

191. 256 P.3d 339 (Wash. 2011).

professional license.¹⁹² In *Ongom* the state supreme court held that revocation of state registration as a nursing assistant was indistinguishable from revocation of a medical license and, thus, due process required proof by clear and convincing evidence. And, in *Hardee* the Washington Supreme Court overruled *Ongom*, reasoning that there was a distinction between professional and other licenses. In reaching this result, the court in *Hardee* focused on the time, expense, and education invested in obtaining the licensing. The court identified three factors that distinguished a home child care license from a professional license: (1) the license adheres to the facility and not the individual provider, (2) the state agency can revoke the license for the misconduct of someone other than the provider, and (3) obtaining a license only requires completion of state approved training. Based on *Hardee*, the Washington Court of Appeals in *Olympia* held that the preponderance of the evidence standard was appropriate for revocation of an adult family home license.¹⁹³

I. Burden of Proof Under Federal Contract Statutes

Most claims of fraud relating to government contracts involve one or more of the following statutes: the False Claims Act (FCA)¹⁹⁴, Contract Disputes Act (CDA)¹⁹⁵ Fraud Provision and Forfeiture of Fraudulent Claims Act (FFCA).¹⁹⁶

To establish that a plaintiff is liable under the False Claims Act, the government must show that: (1) the contractor presented a claim for payment, (2) the claim was false or fraudulent, (3) the contractor knew that the claim was false or fraudulent, and (4) the government suffered damages because of the false or fraudulent claim.¹⁹⁷ For purposes of the FCA, the terms “knowing” and “knowingly” mean: (A) that a person, with respect to information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) that no proof of specific intent to defraud is required.¹⁹⁸ However, there must be a

192. As noted above, the decision in *Hardee* represents the minority view. It was based primarily on the court’s reasoning that an individual has a “profound” interest in his or her professional license. Most courts hold that such personal interest is insufficient to warrant application of the clear and convincing standard.

193. *Hardee*, 304 P.3d 491 (Wash. Ct. App. 2013).

194. 31 U.S.C. § 3729 (2000).

195. 41 U.S.C. § 604 (2000).

196. 28 U.S.C. § 2514 (2000).

197. *See, e.g.*, *Young-Montenay, Inc. v. United States*, 15 F.3d 1040, 1043 (Fed. Cir. 1994).

198. 31 U.S.C. § 3729(b). *See, e.g.*, *Ulysses Inc. v. United States*, 117 Fed. Cl. 772 (2014).

showing by the government of more than innocent mistake or mere negligence.¹⁹⁹

The FCA specifically provides that the government need only prove the elements of a FCA claim by a preponderance of the evidence.²⁰⁰ Arguments have been made challenging this standard.²⁰¹ But, to date, there have been no significant judicial decisions addressing the issue.²⁰²

Under the Contract Disputes Act (CDA), if a contractor is unable to support any part of his claim and it is determined that such inability is attributable to a misrepresentation of fact or fraud on the part of the contractor, then the contractor is liable to the government for an amount

199. *UMC Elec. Co. v. United States*, 43 Fed. Cl. 776, 795 (1999); *Comm. Contractors Inc. v. United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998); *Wang v. FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992).

200. 31 U.S.C. § 3731(C) (2000).

201. Eric Askanase, *Qui Tam And The False Claims Act: Criminal Punishment In Civil Disguise*, 70 DEF. COUNS. J. 472 (2003):

In discussion on the 1986 amendments to the FCA, it was clearly expressed that the FCA's burden of proof was to be broadened precisely because courts had found that FCA cases often required "specific intent" and "clear and convincing, even unequivocal, evidence." The framers of the FCA, in contending that it was a traditional civil case, argued for the traditional civil burden: preponderance of the evidence, precisely because they feared the move courts had been making to put more stringent burdens of proof. As a result of the 1986 amendments, "preponderance of the evidence" is the current standard under 31 U.S.C. § 3731(c).

There are circumstances in which the FCA is acts like a criminal, rather than civil, statute. It is punitive and exposed to double jeopardy and double jeopardy challenges. In light of the recent rulings [] that the FCA acts enough like a criminal statute to trigger the traditional criminal defenses of double jeopardy and excessive fines, a simple conjecture is possible: if the FCA acts enough like a criminal statute to concern the Supreme Court with its implications for excessive fines and double jeopardy, its burden of proof should reflect not the lightest civil burden but one closer to a criminal statute. But that is for the courts to decide. *Id.* at 483 (citations omitted).

202. There have been a number of FCA claims regarding research misconduct. *See United States Ex Rel. Jones v. Brigham and Women's Hospital*, 678 F.3d 72 (1st Cir. 2012); *U.S. v. Univ. Of Med.*, 2010 WL 4116966 (D.N.J.); *United States Ex Rel. Gober v. Univ. Of Alabama at Birmingham*, No. 01-CU-00877-VEH (N.D. Ala. settled Apr. 14, 2005) (settlement agreement available at <https://www.justice.gov/sites/default/files/civil/legacy/2014/04/18/Univ.Ala.%202005.pdf>); *United States Ex Rel. Long v. Mayo Foundation*, No. CV02-522-ADM/SRN (D. Minn. settled May 26, 2005) (settlement agreement available at <https://www.justice.gov/sites/default/files/civil/legacy/2014/04/18/MayoClinic%202005.pdf>). The elements of making out a FCA claim are not the same as those under the NSF and HHS regulations regarding research misconduct. For an analysis of FCA claims in the research misconduct context, see Brief of Defendants-Appellees, *United States Ex Rel. Jones v. Brigham and Women's Hospital*, 2011 WL 2309192. As to the evidentiary role that the investigative reports of ORI and OIG can have in an FCA case, see, *U.S. ex rel. Milam v. Regents of University of California*, 912 F. Supp. 868 (D. Md. 1995).

For a discussion of FCA cases involving research misconduct see, B. Stanković, *Pulp Fiction: Reflections on Scientific Misconduct*, 2004 WIS. L. REV. 975 (2004).

equal to such unsupported part of the claim in addition to all costs to the government attributable to the cost of reviewing said part of his claim.²⁰³ While the CDA does not provide a standard of proof, the United States Court of Appeals for the Federal Circuit has applied the preponderance of evidence standard to claims brought under the CDA's fraud provision.²⁰⁴

Finally, under the Fraud Provision and Forfeiture of Fraudulent Claims Act (FFCA), a claim against the United States shall be forfeited by any person who fraudulently submits a false claim to the government.²⁰⁵ The Federal Circuit has held that, to prevail on a claim alleging fraud under the FFCA, the government is required to establish by clear and convincing evidence that the contractor knew that its submitted claims were false, and that it intended to defraud the government by submitting those claims.²⁰⁶ The distinction between the application of the preponderance of the evidence standard in the FCA (which expressly states that the preponderance of the evidence standard applies) and the clear and convincing standard in the FFCA appears to be solely based on the different language of the two statutes.²⁰⁷

J. Does Due Process Require The Clear And Convincing Standard To Be Applied At Least In Circumstances When ORI Or OIG May Seek To Debar A Researcher Based On Research Misconduct?

Applying the foregoing to the research misconduct context, it is clear under *Addington* and *Mathews* that there are circumstances under which the

203. 41 U.S.C. § 604 (2000).

204. See *Grand Acadian, Inc. v. United States*, 105 Fed. Cl. 447, 457–58 (2012); *Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1362 (Fed. Cir. 1998).

205. 28 U.S.C. § 2514 (2000).

206. See, *Ulysses, Inc. v. United States* 117 Fed. Cl. 772 (2014); *Alcatec, LLC v. U.S.*, 100 Fed. Cl. 502, 517 (2012). In *Chapman Law Firm, LPA v. United States*, 113 Fed. Cl. 555, 610-611 (Fed. Cl. 2013) the court stated:

Under the statute, “the government must establish by clear and convincing evidence that the contractor knew that its submitted claims were false, and that it intended to defraud the government by submitting those claims.” Mere negligence, inconsistency, or discrepancies are not actionable under the Special Plea in Fraud statute. The United States Court of Appeals for the Federal Circuit has described the clear and convincing evidence standard as follows: “A requirement of proof by clear and convincing evidence imposes a heavier burden upon a litigant than that imposed by requiring proof by preponderant evidence but a somewhat lighter burden than that imposed by requiring proof beyond a reasonable doubt. Clear and convincing evidence has been described as evidence which produces in the mind of the trier of fact an abiding conviction that the truth of a factual contention is highly probable.”

Id. (quoting *Daewoo Eng'g & Constr. Co. v. United States*, 557 F.3d 1332, 1341 (Fed. Cir. 2009); *Alcatec, LLC v. United States*, 100 Fed. Cl. 502, 517 (2011); *Am-Pro Prot. Agency, Inc. v. United States*, 281 F.3d 1234, 1240 (Fed. Cir. 2002) (internal quotations omitted)).

207. See, *Alcatec, LLC v. U.S.* 100 Fed. Cl. 502 (Fed. Cir. 2011) (discussing different burdens of proof under FCA and FFCA based upon statutory language).

Due Process Clause might require an agency or court to apply a clear and convincing standard of proof before taking an adverse action against a private person. What is less clear is exactly where the line is drawn between those circumstances requiring clear and convincing evidence and those for which a preponderance of the evidence will suffice. The argument has been made that the debarring of a researcher for misconduct fits within the category of cases that constitutionally requires application of the clear and convincing standard.²⁰⁸ As demonstrated above, however, the strength of such an argument is far from clear. In fact, the precedent strongly suggests that the Constitution does not require HHS and NSF to apply the “clear and convincing” standard in research misconduct.

Nevertheless, the precedent also supports the conclusion that HHS and NSF should have more fully evaluated whether there are circumstances where the clear and convincing standard can or should be applied while still ensuring that the public interest is adequately protected. It may very well be that those agencies can articulate why the public interests outweigh the countervailing due process concerns and justify use of the preponderance standard. But, to date, they have not adequately done so.

There is undoubtedly a possibility of mistake when there are factual disputes relating to research misconduct.²⁰⁹ As the Supreme Court noted in *Addington*, the purpose of the standard of proof is “to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.”²¹⁰ And, as also recognized by the Court in *Addington*, there are circumstances where an “individual should not be asked to share equally with society the risk of error.”²¹¹ That is especially true “when the possible injury to the individual is significantly greater than

208. See Trial Motion, Memorandum and Affidavit, *Brodie v. Dep’t. of Health and Human Services*, 2010 WL 3416349 (D.D.C.) in which the Plaintiff stated:

The Fifth Amendment protects several rights of citizenship, including the right not to be deprived of liberty without due process of law, an interest that encompasses the right to be free from official stigmatization. The core requirements of due process are notice and the opportunity to be heard. The Court of Appeals for the District of Columbia Circuit has recognized that “debarment is a form of punishment which stigmatizes the target.” The Court of Appeals further recognized that such stigmatization is “a blow to a protected ‘liberty’ interest, which, of course, triggers an inquiry as to whether the process it has been afforded is adequate.”*Id.* (quoting *Fischer v. Resolution Trust Corp.*, 59 F.3d 1344, 1349 (D.C. Cir. 1995)). See also *Trifax v. District of Columbia*, 314 F.3d 641, 643 (D.C. Cir. 2003) (“Because this liberty concept protects corporations as well as individuals, formally debarring a corporation from government contract bidding constitutes a deprivation of liberty that triggers the procedural guarantees of the Due Process Clause.”).

209. See *Speiser v. Randall*, 357 U.S. 513, 526 (1958).

210. *Addington*, 441 U.S. at 423.

211. *Id.* at 427.

any possible harm to the state.”²¹² Of course, the purpose of the three-factor *Mathews* test is to balance those factors to determine the appropriate balance of the risk of error.

There is no indication that HHS or NSF did the balancing required by *Mathews* in adopting the preponderance standard. Moreover, if the agencies were to undertake such an analysis, there are arguments to support the conclusion that the “clear and convincing” standard is appropriate.

As to *Mathews*’ first factor—“the private interest that will be affected by the official action”—the Supreme Court has consistently recognized the importance of allowing a person to pursue his or her chosen career.²¹³ And while debarment may or may not be permanent, a finding of research fraud by HHS or NSF will, for all practical purposes, either end or substantially limit the ability of a researcher to pursue an academic career. In addition, irrespective of an agencies’ characterization of the purpose of debarment, it cannot be viewed as a decision by the relevant federal agency to punish the researcher for his conduct.²¹⁴ And, as the Court suggested in *In Re Ruffalo*, the punishment is being imposed in what is essentially a quasi-criminal proceeding.²¹⁵

Similarly, the decision to debar a researcher subjects the researcher to the type social stigma that the Court suggested in *Santosky*²¹⁶ warrants application of the clear and convincing standard. This reasoning is implicit in *Addington* where the Court noted that the clear and convincing standard of proof is applied in civil cases involving allegations of fraud or some other quasi-criminal wrongdoing by the defendant in part because “[t]he interests at stake in those cases are deemed to be more substantial than mere loss of money” but directly impact the reputation of the alleged wrongdoer.²¹⁷

As to *Mathews*’ second factor—“the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards”—the institutional proceedings generally will not have all the procedural safeguards that would apply in the judicial context. Moreover, the cases where the standard of proof can be expected to make a difference are likely to be the more complicated proceedings where additional procedural safeguards may be of more importance.

212. *Id.*

213. *See, e.g.*, *Yick Wo v. Hopkins*, 118 U.S. 356, 374 (1886); *Truax v. Raich*, 239 U.S. 33, 44 (1915); *Hampton v. Mow Sun Wong*, 426 U.S. 88, 102 n.23 (1976).

214. *See Woodby v. Immigration Service*, 385 U.S. 276, 285 (1966) (simply calling a proceeding remedial does not justify by itself applying the preponderance of the evidence standard).

215. *In re Ruffalo*, 390 U.S. 544, 550 (1968).

216. *Santosky v. Kramer*, 455 U.S. 745, 757 (1982).

217. *Addington v. Texas*, 441 U.S. 418, 424 (1979).

And as to *Mathews*' third factor—"the government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail"—there is no reason to believe that an institution or an agency will do any less (or more) of an investigation depending on the standard of proof. Presumably, regardless of the standard, the institution and the agencies will do what is required to determine the true facts underlying the challenged research. And, if the result of applying the clear and convincing standard does result in a more thorough investigation, that would seem to be a positive public benefit that would outweigh any extra administrative burden.

Moreover, by the time a research misconduct case reaches a debarment official (that is, after completion of the institution's and agencies' proceedings), the evidence that is necessary for a decision has been compiled. Thus, the main impact of applying the higher standard of proof is to serve to impress upon the debarment official the importance of the decision and thereby perhaps reduce the chances that an erroneous decision will be made with tremendous impact on the researcher.²¹⁸

To the extent the courts have held that the preponderance of the evidence standard is necessary to protect the public interest in the state licensing context, there is a distinction between taking away a license from a physician or lawyer and debarring a researcher. There is an obvious immediate risk of harm to individual members of the public if an unqualified physician is allowed to treat patients (or an attorney is allowed to practice) that is absent in the researcher context. At the time of the debarment proceeding, the researcher's work will typically have been thoroughly reviewed and, where appropriate, modified. And, in those instances where the debarment proceeding occurs after the publication of the research, presumably any needed retractions or corrections to that work can occur independent of a proceeding at which the ultimate issue is whether the researcher should be debarred (that is, the validity of the research can be questioned in multiple forums apart from the debarment proceeding).

And as to the possibility of future misconduct by a researcher, any researcher who has been the subject of a proceeding that resulted in a recommendation of debarment will have his/her work highly scrutinized going forward regardless of the conclusion of the debarment official.²¹⁹

218. *Id.* at 426–27.

219. For example, nothing would preclude a debarment official from stating his or her conclusion that the research was significantly flawed and still conclude that there was not clear and convincing evidence of research misconduct. Presumably, the debarment official could even state that he or she would have imposed debarment under the preponderance standard.

One might argue that the punishment of debarment deters researchers from engaging in

The foregoing is not intended to suggest that there is no public harm if a researcher is wrongly found not to have engaged in research misconduct. Clearly there is a public interest in making sure that all researchers act with the highest integrity. But, HHS and NSF should consider whether that public interest can be vindicated without the need for having a researcher's career depend on fifty percent of the evidence and "a feather." At a minimum, the agencies should thoughtfully consider whether—in the rare close case—the harm to the individual researcher who is wrongly debarred under the preponderance of evidence standard outweighs the potential public harm which may occur should a researcher who did engage in misconduct escapes debarment under the clear and convincing standard. It is noteworthy in this regard that cases such as *Brodie* and *Bois* suggest that application of the clear and convincing standard may only rarely affect the outcome.

K. Did HHS And NSF's Violate the APA In Adopting the Preponderance Of The Evidence Standard?

As noted, HHS and NSF adopted the preponderance of the evidence standard both for the determination as to whether research misconduct occurred and for the decision of the debarment official as to whether to impose debarment as a sanction. The question this raises is whether the agencies' adoption of the preponderance standard violated the Administrative Procedures Act.

Under the APA, a court is required to set aside an agency regulation that is contrary to a constitutional right.²²⁰ Therefore, a court could theoretically hold that the HHS and NSF regulations applying the preponderance of the evidence standard to research misconduct are invalid under this provision by application of the *Mathews*' test. Alternatively, a court may set aside even a constitutional regulation if the court concludes that the regulation is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."²²¹ Under this provision, a researcher, educational institution, or other organization with standing could challenge the regulations of HHS and NSF.

misconduct. While it seems reasonable that such is the case, the mere fact that a researcher may be subject to a debarment proceeding—regardless of the standard of proof—would seem to create determent enough.

220. 5 U.S.C. § 706(2)(B).

221. 5 U.S.C. § 706(2)(A); *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359 (1998) (holding that § 706(2)(a) governs substantive review of agency's interpretation of its own regulations); *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144 (1991) (reviewing agency's interpretation of regulations for "reasonableness"); *Edwards v. Califano*, 619 F.2d 865, 868 (10th Cir.1980) (holding that acknowledged deference to agency's interpretation of own regulation does not preclude review under § 706(2)(A)).

It is well established that courts are generally required to give deference to an agency's interpretations of the statutes that the agency administers.²²² However, there are a number of arguments as to why deference should not be required as to HHS's and NSF's adoption of the preponderance standard. First, the agency deference rule has been held not to apply to questions of law and the proper standard of proof in research misconduct cases would seem to be a legal issue.²²³ Second, when an agency's interpretation of its own regulation is based not on its expertise in a particular field, but on general common law principles, it is not entitled to great deference.²²⁴ In this case, the agencies relied, in part, upon the erroneous assumption that the common law standard in fraud cases was preponderance of the evidence, when in fact, the common law rule is clear and convincing.²²⁵ It also relied upon the standard rule applicable to commercial debarment cases without considering the different circumstances of a scientific researcher. And while HHS and NSF have expertise relating to the importance of public confidence in scientific research, they have no particular expertise in balancing considerations of due process. Third, an agency's failure to consider an important aspect of a problem is "arbitrary and capricious" under the APA.²²⁶ In this instance, the record does not reflect any meaningful consideration of the factors, which would support use of the clear and convincing standard (i.e., the *Mathews* factors). Fourth, an agency's failure to articulate a satisfactory explanation for its conclusions may make its decision arbitrary and capricious, and as noted above,²²⁷ neither HHS nor NSF set forth any

222. See *Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984).

223. See *Wolfe v. Barnhart*, 446 F.3d 1096, 1100 (10th Cir.2006); *Artesian Indus., Inc. v. Dep't of Health and Human Servs.*, 646 F. Supp. 1004, 1006 (D.D.C.1986).

224. See, e.g., *Bd. of County Commissioners v. Isaac*, 18 F.3d 1492, 1497 (10th Cir. 1994) ("An agency's interpretation of its own regulation is not entitled to great deference if it is based on general common law principles rather than the agency's expertise. . . ."); *Mission Group Kansas, Inc. v. Riley*, 146 F.3d 775 (10th Cir. 1998); *Bambidele v. Immigration & Naturalization Service*, 99 F.3d 557, 561 (3d Cir. 1996) (little deference is owed when the dispute involves a legal issue that is not within the agency's particular expertise, such as the interpretation of a statute of limitations); *Edwards v. Califano*, 619 F.2d 865 (10th Cir. 1980) (an agency's interpretation of its own regulation, which is not based on expertise in its particular field but is rather based on general common law principles, is not entitled to great deference); *Jicarilla Apache Tribe v. Federal Energy Regulatory Comm'n*, 578 F.2d 289, 292–93 (10th Cir.1978).

225. *Supra* text at note 124.

226. See *Motor Vehicle Mfrs. Ass'n V. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983).

227. *Id.* at 43.

meaningful analysis as to why the public interest could not be protected by application of the clear and convincing standard.²²⁸

Accordingly, even if the clear and convincing standard is not constitutionally mandated (and it likely is not), a reasonable argument could be made that the agencies' adoption of the preponderance of the evidence standard violated the APA based on:

- (i) the arguments set forth above supporting the conclusion that application of the clear and convincing standard would comport more with due process than the preponderance standard (even in not constitutionally mandated);
- (ii) the fact that OSTP and NSF wrongfully stated in their rulemaking process that the uniform standard of proof in fraud cases is preponderance of the evidence, and
- (iii) the apparent lack of any meaningful analysis during the agencies' rulemaking of the *Mathews*' factors and whether a higher standard of proof should be applied to research misconduct cases in light of the unique circumstances of a scientific researcher.

L. New rulemaking by HHS and NSF.

Rather than HHS and NSF being faced with a legal challenge to their regulations in the absence of a full consideration of the correct standard of proof, the agencies should initiate rulemaking on their own to consider whether application of the preponderance of the evidence standard is appropriate in all circumstances. Should the agencies choose not to initiate such rulemaking, then interested parties should petition the agencies to open rulemaking on this issue pursuant to 5 U.S.C. § 553 which provides that "each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."²²⁹ Should the agencies deny such a petition, that denial can be appealed to the courts.²³⁰

CONCLUSION

The NSF and HHS have adopted procedures which allow for the creation of a reasonably complete evidentiary record for determining whether research misconduct has occurred.²³¹ Researchers have an

228. See *Securitypoint Holdings, Inc. v. Transportation Sec. Admin.* 769 F.3d 1184, 2014 WL 5432132 (D.C. Cir. 2014).

229. 5 USC § 553(e); Sean Croston, *The Petition is Mightier than the Sword: Rediscovering an Old Weapon in the Battles over "Regulation Through Guidance,"* 63 ADMIN. L. REV. 381 (2011); Reeve T. Bull, *Building a Framework for Governance: Retrospective Review and Rulemaking Petitions,* 67 ADMIN. L. REV. 265 (2015).

230. 5 USC §§ 702, 706; *Auer v. Robbins*, 519 U.S. 452 (1997).

231. For articles representative of the view that the procedures adopted by HHS and NSF are fundamentally unfair to researchers see, Jacqueline Bonilla, *Illusory*

opportunity to rebut allegations, and, given how few cases are actually litigated before the DAB and in the courts, it may be fair to assume that in the majority of cases the underlying facts are ultimately not significantly contested. Nevertheless, there are certainly cases which are the result of honest error by the researcher. There will also be cases, such as the hypothetical involving Dr. White, where the evidence is less than clear. And, it would be naïve to believe that there will not be instances where a researcher will be the subject of a malicious complaint or intentional sabotage. In such cases, it is a fair question whether the agencies should be able to impose substantial harm to a researcher's career based merely on a preponderance of the evidence. As shown above, there are legitimate arguments that can be made that due process requires a higher burden of proof. But, even if not constitutionally required, the issue is one that has not been fully vetted and warrants future discussion as part of the rulemaking process.

APPENDIX

Key Agency Abbreviations

| | |
|------|---|
| ASH | Assistant Secretary for Health (of HHS) |
| DAB | Departmental Appeals Board (of HHS) |
| HHS | U.S. Department of Health and Human Services |
| NSF | National Science Foundation |
| OIG | Office of Inspector General of National Science Foundation |
| ORI | Office of Research Integrity (a division of HHS) |
| OSTP | Office of Science and Technology Policy |
| PHS | Public Health Service of HHS |

Other Abbreviations

| | |
|------|--|
| ALJ | Administrative Law Judge |
| APA | Administrative Procedures Act |
| CDA | Contract Disputes Act |
| DCL | Dear Colleague Letter (of HHS) |
| FCA | False Claims Act |
| FFCA | Fraud Provision and Forfeiture of Fraudulent Claims Act |
| RICO | Racketeer Influenced and Corrupt Organizations Act |
| SEC | Securities Exchange Commission |
| VEA | Voluntary Exclusion Agreement |