

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Office of Research Integrity,

Petitioner

v.

Philippe Bois, Ph.D.

Docket No. C-10-436

Decision No. CR2366

Date: May 16, 2011

AMENDED DECISION DISMISSING HEARING REQUEST

Petitioner, the Office of Research Integrity (ORI), charges that Respondent, Philippe Bois, Ph.D., falsified data and the results of experiments and published his handiwork in two scientific journals. For these actions, ORI proposes to debar him for three years from eligibility for federal contracts.

Respondent Bois timely requested a hearing to challenge ORI's actions. ORI moves to dismiss his hearing request, arguing that it fails to create a genuine dispute of material fact, as required by 42 C.F.R. § 93.503(a). I agree, and, for the reasons discussed below, I dismiss Respondent Bois' hearing request.

I. Background

Statutory and Regulatory Background. ORI has broad authority to investigate allegations of research misconduct. Congress created ORI as an independent entity specifically authorized to investigate allegations of research misconduct "in connection with projects for which funds have been made available" and to take other actions, including imposing remedies "with respect to such misconduct." 42 U.S.C. § 289b(c)(1), (3), and (4).

The statute directs the agency to define, by regulation, the term “research misconduct.” 42 U.S.C. § 289b(a)(3)(A). When Respondent Bois’ questionable conduct commenced, ORI’s implementing regulations were found at 42 C.F.R. Part 50, and they defined “misconduct in science” as “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.” The definition specifically excluded “honest error” and “honest differences in interpretations or judgments of data.” 42 C.F.R. § 50.102.

Effective June 15, 2005, which was prior to the publication of Respondent’s problematic articles, ORI replaced Part 50 with more comprehensive regulations, titled “Public Health Service Policies on Research Misconduct,” 42 C.F.R. Part 93. Those provisions define “research misconduct” as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” 42 C.F.R. § 93.103. “Fabrication” means “making up data or results and recording or reporting them.” 42 C.F.R. § 93.103(a). “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.” 42 C.F.R. § 93.103(b). Research misconduct does not include honest error or differences of opinion. 42 C.F.R. § 93.103(d).

Beyond defining “misconduct in science,” the Part 50 regulations offer little specific guidance as to the evidentiary standards I should apply here. However, Part 93 is more enlightening. To find research misconduct under the current regulations, 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. 42 C.F.R. § 93.104.

The new rules apply prospectively. 70 *Fed. Reg.* 28,370, 28,380 (May 17, 2005). I apply the definition of research misconduct in effect at the time the misconduct occurred, which means here that, for some of the alleged misconduct, I would apply Part 50, and for some of the alleged misconduct, I would apply Part 93. However, I find that, in publishing incomplete and inaccurate articles, Respondent Bois committed serious scientific misconduct. Because the articles were published after June 15, 2005, and because the act of publishing them more than warrants the three-year debarment, I could affirm the proposed debarment without regard to the Part 50 regulations. In any event, the two definitions of misconduct are consistent, and, as the discussion below shows, because Respondent Bois’ pre-June 15, 2005 conduct seriously deviated from practices “accepted within the scientific community,” he was then guilty of “misconduct in science” under 42 C.F.R. § 50.102.

Respondent filed his hearing request after June 15, 2005, so these proceedings are governed by 42 C.F.R. Part 93. 70 *Fed. Reg.* at 28,380. Under those rules, an individual may contest ORI findings of research misconduct – including any debarment or

suspension action – by requesting a hearing within 30 days of receiving ORI’s charge letter. 42 C.F.R. § 93.501(a). However, ORI’s regulations dictate the form of the request and strictly limit my authority to grant a respondent the requested hearing. A hearing request *must* specifically deny each finding of research misconduct set forth in the charge letter and each basis for that finding, or the finding and/or basis for the finding are considered admitted. 42 C.F.R. § 93.503(b). It must also:

- 1) Admit or deny each finding of research misconduct and each factual assertion made in support of the finding;
- 2) Accept or challenge each proposed [Department of Health and Human Services] administrative action;
- 3) Provide detailed, substantive reasons for each denial or challenge;
- 4) Identify any legal issues or defenses that respondent intends to raise during the proceeding; and
- 5) Identify any mitigating factors that the respondent intends to prove.

42 C.F.R. § 93.501(c). I am directed to grant a hearing request *only* if the respondent raises a genuine dispute over facts material to the findings of research misconduct. A general denial or “assertion of error for each finding of research misconduct . . . is not sufficient to establish a genuine dispute.” 42 C.F.R. § 93.503(a). I *must* dismiss a hearing request if the respondent does not raise a genuine dispute over facts or law “material to the findings of research misconduct and any administrative actions,” or does not “raise any issue which may properly be addressed in a hearing.” 42 C.F.R. § 93.504(a)(2), (3).

Factual and Procedural Background. In this case, from 1999 through 2004, Respondent Bois was a postdoctoral fellow, working in the laboratory of Dr. Gerard Grosveld in the Department of Genetics and Tumor Biology at St. Jude Children’s Research Hospital in Memphis, Tennessee. In 2004, he transferred to the lab of Dr. John Cleveland, Department of Biochemistry, also at St. Jude’s, where he remained until April 2006, when he left for reasons unrelated to any of the issues before me. ORI Jur. Ex. 5; Resp. Opp. at 30.

ORI proposes a three-year debarment based on two instances of alleged scientific misconduct. ORI charges that Respondent Bois knowingly, intentionally, or recklessly fabricated and falsified data that he reported in two papers, for which he was the principal author:

- “FOXO1a Acts as a Selective Tumor Suppressor in Alveolar Rhabdomyosarcoma,” by Philippe R.J. Bois, Kamel Izeradjene, Peter J. Houghton, John L. Cleveland, Janet A. Houghton, and Gerard C. Grosveld, published in *The Journal of Cell Biology* (JCB), Vol. 170 No. 6, September 12, 2005, pages 903-12 (subsequently retracted). ORI Mot. Dis. Ex. 1; and
- “Structural Dynamics of α -Actinin-Vinculin Interactions,” by Philippe R.J. Bois, Robert A. Borgon, Clemens Vornrhein, and Tina IZard, which was published in *Molecular and Cellular Biology* (MCB), Vol. 25, No. 14, July 2005, pages 6112-22 (corrected August 2007). ORI Mot. Dis. Ex. 2.

I previously ruled that ORI has jurisdiction over the allegations of research misconduct set forth in its charge letter. Ruling on Jurisdiction (Oct. 27, 2010).

ORI has filed a motion to dismiss (ORI M/Dismiss), and Respondent Bois responded with a Memorandum in Opposition to ORI’s motion (Resp. Opp.). ORI then filed a reply to Respondent’s memorandum (ORI Reply). The parties have also submitted proposed exhibits. With his hearing request, Respondent submitted nine exhibits, marked A-I (Resp. Exs. A-I). With its motion, ORI submitted 17 exhibits (ORI Exs. 1-17), and, with its reply, ORI submitted three additional exhibits (ORI Reply Exs. 1-3).

II. Discussion

A. Because Respondent Bois has not raised a genuine dispute over facts material to the findings of research misconduct, I may not grant his hearing request. 42 C.F.R. § 93.503(a).¹

1. Undisputed evidence establishes that Respondent Bois departed significantly from “accepted practices of the relevant research community,” when he published articles that did not completely and accurately represent the research findings.

As a threshold matter, Respondent Bois has not disputed that he was the principal author of the articles in question.² He also admits that he made errors in his research and in reporting his research. Resp. Opp. at 2-3 (Respondent concedes “errors in the research

¹ My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

² I discuss below Respondent Bois’ baffling claim that, although undeniably the principal author of the July 2005 MCB article, he had little to no knowledge of, or involvement in, the experiments discussed therein.

and reporting of research” which “were not corrected prior to the publication of the two articles,” and that “he is responsible for some of those errors.”); Resp. Opp. at 8 (Respondent “promptly and openly admitted . . . that he made a mistake in his research as it related to the JCB”); Resp. Opp. at 12 (“With respect to the JCB, . . . the research . . . was flawed.”); Resp. Opp. at 48 (“[T]here is no dispute that an error was made.”); Resp. Opp. at 61 (“[Respondent] admits that he had neglected the particular result from the February 9, 2003 experiment”); Hearing Request at 11-12, ¶ 10; Hearing Request at 20, ¶ 25; Resp. Opp. at 125 (“[Respondent] . . . admits that there was an error in the MCB 2005.”); Hearing Request at 34-35, ¶ 55.

Nor has Respondent challenged ORI’s assertions that the “accepted practices of the relevant research community” require experimental controls and repetitions of scientific experiments. ORI M/Dismiss at 5-6; ORI Ex. 4 (“Repeating a science experiment is an important step to verify that your results are consistent and not just an accident.”).

So the questions are: in conducting the research, did Respondent Bois “seriously deviate” from accepted practices within the scientific community; and, in publishing the admittedly flawed articles, did Respondent Bois “intentionally, knowingly, or recklessly” depart significantly from these practices.

JCB article. Here, with respect to the alleged misconduct that culminated in the publication of the JCB article, ORI charges that Respondent Bois conducted two experiments (in February and December 2003) involving the effect of a protein (FOXO1a) on certain types of childhood tumors. He deviated from accepted practices because he did not report the results of his February experiment (which did not support his hypothesis). The December experiment purportedly supported his hypothesis, but he deviated from accepted practices in conducting and reporting that experiment.

Specifically, ORI alleges the following facts, which – with limited exceptions that are not material – Respondent has either conceded or has not explicitly denied:

- While working in Dr. Grosveld’s laboratory, Respondent studied certain types of malignant tumors found in children. In February 2003 and December 2003, Respondent conducted experiments involving a protein identified as FOXO1a. Charge Letter ¶¶ 7, 12; Hearing Request at 10-11;
- Respondent Bois hypothesized that FOXO1a suppressed tumors. ORI M/Dismiss at 5; *see* Charge Letter ¶¶ 7, 9.

Respondent Bois agrees but accuses ORI of overlooking or ignoring the context and background of his experiments. He claims that, based on his and Dr. Grosveld’s earlier experiments, he “had every reason to believe that the FOXO tumor suppressor protein was expressed in cell lines.” *See* Resp. Opp. at 33, *see*

also 24-25, 27. Respondent Bois provides no details about these earlier experiments, which were not mentioned in his publication. He neither disputes nor explains why investigators saw evidence of only the February and December experiments. Nor has he claimed that anyone ever replicated his purported earlier successes.³

Nevertheless, accepting as true his claim that some earlier experiments supported his hypothesis does not alter the only conclusion that can be drawn from the undisputed facts: Respondent Bois committed scientific misconduct by omitting from his publication the contrary results. *See* 42 C.F.R. § 93.103(b) (“Falsification” includes “omitting data or results such that the research is not accurately represented . . .”). Indeed, accepting his claim as true highlights the significance of the February 2003 experiment – which purportedly yielded (to him) a surprising, if undesirable result – and made it all the more important that he adhere rigorously to accepted research practices, and that he include *all* of his purportedly contradictory results in his published article.

- Respondent’s February 2003 experiment indicated that FOXO1a did *not* suppress tumors. Charge Letter ¶¶ 13, 18. In his hearing request, Respondent Bois agrees that the February 2003 results were “in contradiction to the results” he and Dr. Grosveld “had obtained previously in analyzing cell lines” (and thus were inconsistent with his hypothesis). “Accordingly,” and in view of other demands on his time, “the experimental process came to a standstill,” and he “postponed further work on this specific experimental line of inquiry.” Resp. Opp. at 32; Hearing Request at 11.

In his opposition memorandum, Respondent Bois deviates from the position articulated in his hearing request. He implicitly concedes that the February 2003 experiment did not support his hypothesis but characterizes the results as “inconclusive” rather than “in contradiction.” He suggests that, because they were inconclusive, he forgot about them: they “did not register when he moved forward with the research 11 months later.” Resp. Opp. Br. at 27. Of course, if I were weighing the evidence, such inconsistent claims would likely undermine his credibility. However, neither scenario justifies his publishing results without ensuring that all of his data was accurately reported.

³ Respondent elsewhere claims that his work in this area never involved more than one or two experiments, a claim that is consistent with the investigators’ findings, but seems inconsistent with his claim that his earlier (2002) experiments supported his hypothesis. *See* Resp. Opp. at 36. Of course, *Respondent’s* offering inconsistent versions of events does not create a dispute of material fact that would entitle him to a hearing under 42 C.F.R. § 93.503(a).

- Respondent Bois maintained the data from his February 2003 experiment in his laboratory records. Charge Letter ¶ 13;
- In December 2003, while still working in Dr. Grosveld's laboratory, Respondent Bois conducted a second experiment, which, he claimed, supported his hypothesis that FOXO1a suppressed tumors. However, no existing laboratory notes or records support this conclusion, and the laboratory was unable to reproduce Respondent Bois' results. Charge Letter ¶¶ 15, 28. The parties agree that the data underlying the December 2003 experiment (if any) and Respondent Bois' conclusions were wrong. Charge Letter ¶¶ 17, 18; *see* Resp. Opp. at 12; ORI M/Dismiss at 11;
- The December 2003 experiment included no "control"; accepted standards of conduct for scientific research require that scientific experiments include a control to which the experiment's results can be compared. Charge Letter ¶ 14;
- Respondent Bois did not repeat the December 2003 experiment to verify its purported results; accepted standards of conduct for scientific research also require that scientific experiments be repeated. Charge Letter ¶¶ 23, 24, 28; Resp. Opp. at 67;
- In September 2005, JCB published Respondent's article, in which he claimed that his research supported the hypothesis that FOXO1a suppressed tumors;
- The JCB article included Figure 1A from the December 2003 experiment, which purported to show, falsely, that FOXO1a suppressed tumors. Respondent concedes the error in the figure but asserts that his article did not include other errors. Charge Letter ¶¶ 9, 18, 16, 19, 20; Hearing Request at 11; Resp. Opp. at 34, 43. In making this claim, he does not seem to consider that his failure to include the results of his February experiment was also an error;
- On or about May 7, 2007, JCB published a complete retraction of the JCB 2005 paper. The retraction said that Figure 1A was not correct and that, because the paper's (incorrect) conclusion was based on a faulty assumption having to do with the absence of FOXO1a protein in primary tumors, the publication was forced to retract the paper in its entirety. Charge Letter ¶ 17; Hearing Request at 15; Resp. Opp. at 44.

Thus, the undisputed evidence establishes that Respondent Bois did not mention the results of the February experiment in the JCB article. Even accepting that, as he claims, he genuinely forgot about it when he was writing up the results of his December study, his failure to review all of his lab notes before reporting the results was certainly reckless.

That he has not had access to his notes since leaving the Grosveld lab does not excuse him, because he initially drafted the article that eventually became his publication while he was still there. In his hearing request, he concedes that the manuscript was submitted to another publication in the Spring of 2004, well before he left Dr. Grosveld's lab, and to yet another publication in September 2004, just after he left. Charge Letter ¶ 22; Hearing Request at 18. Further, he concedes that he composed the problematic Figure 1A while still at Dr. Grosveld's lab. His computer contained multiple versions of the figure, generated before and after his departure. Charge Letter ¶¶ 21-22; ORI M/Dismiss at 22-23; Resp. Opp. at 49-50, 51.

In any event, because he did not include a control in his December 2003 experiment, and he did not repeat the experiment, Respondent Bois seriously deviated from accepted practices in the relevant research community. Respondent did not challenge this conclusion, which was contained in ORI's charge letter. Charge Letter ¶ 30; Hearing Request at 23; Resp. Opp. at 72. Although he claims, generally, that his errors were unintentional, he offers no specific reasons for his deviations, from which I must conclude that he knowingly and intentionally failed to include a control and failed to repeat the experiment. *See* 42 C.F.R. § 93.503(b).

Respondent Bois therefore committed scientific misconduct in conducting and reporting the December experiment, in publishing false data in Figure 1A, and in failing to report the results of the February experiment.

MCB article. With respect to the alleged misconduct that culminated in the publication of the MCB article, ORI alleges the following undisputed facts and argues that they also establish that Respondent Bois committed scientific misconduct:

- After leaving the Grosveld lab, Respondent Bois took a position as a postdoctoral fellow at Dr. John Cleveland's lab. Respondent Bois also assisted his wife, Tina IZARD, Ph.D., "in the presentation of the figure that became Figure 4B," that was included in the MCB article. Charge Letter ¶ 31; Hearing Request at 23-24; Resp. Opp. at 74-75;
- On January 7, 2005, Robert Borgon, a graduate student, working in Dr. IZARD's laboratory, responded to a request from Dr. IZARD, the laboratory's principal investigator (P.I.), by emailing P.I. IZARD and Respondent Bois scanned images of a single-stained gel (Figure 4B), which served as an experimental control. Charge Letter ¶ 43; ORI Ex. 8 at 3. P.I. IZARD asked for the images because the MCB article was still in manuscript form, and one of its reviewers had specifically asked to see additional underlying support for the article's hypothesis. Charge Letter ¶¶ 35, 36, 43;

- On February 11, 2005, at 11:43 a.m. P.I. Izard sent an e-mail to Respondent Bois, in which she wrote: “Dearest[,] can you please create a figure to show that papain doe not affect the peptides? Thanks[,] Tina” She did not copy the graduate student. Charge Letter ¶ 43; ORI Ex. 8 at 3;
- Thereafter, Respondent Bois sent e-mails to P.I. Izard that progressively altered the scanned image. He wrote “Et voila!” (“and here it is!”), when he sent what became the “final” image. Charge Letter ¶ 43; ORI Ex. 8 at 4; ORI Ex. 9;
- In the meantime, Graduate Student Borgon sent Respondent Bois an e-mail with a scanned image of a double-stained gel, although he apparently included an error in his description. ORI Ex. 8 at 7. Nevertheless, the error was of no consequence since Respondent rejected the slide as “too dirty for a figure,” advising Graduate Student Borgon that “This will do,” referring to the altered version that he had already sent to P.I. Izard. Charge Letter ¶ 43; ORI Ex. 8 at 8;
- Figure 4B, which was published with the MCB article, did not accurately depict the results of Graduate Student Borgon’s experiment (which, according to Respondent, was otherwise valid and reproducible). Hearing Request at 25, 34; ORI M/Dismiss at 33-34.

Respondent Bois concedes that he helped to create what ultimately became Figure 4B, but submits what he characterizes as an “alternative chronology” for the creation of that image. Hearing Request at 27-30; Resp. Opp. at 27. His alternative chronology is more of a supplementation, in which he talks about errors purportedly made by Graduate Student Borgon and suggests, without even alluding to a shred of evidence, that Graduate Student Borgon himself engaged in some nefarious conduct.

I agree with ORI that, while Respondent Bois has added a confusing but ultimately irrelevant series of accusations, he has not denied any of ORI’s dispositive factual charges that: on February 11, P.I. Izard asked him to create a figure; he sent her progressively altered versions of that figure, culminating in a final image, sent with the message “Et voila!” and his final, falsified image was included in the published article, for which he took credit as principal author. Even if I agreed that Graduate Student Borgon also acted improperly (which I emphatically do not because I see no evidence of it), that fact would not excuse Respondent’s own misconduct.

Finally, Respondent Bois denies any involvement in the research underlying Figure 4B, except to admit that he was “asked to assist in the presentation of the Figure that ultimately became Figure 4B.” This seems a very peculiar, not to mention unethical, level of involvement for a research article’s first author, and ORI challenges his assertion as “intentionally misleading” and “inconsistent with . . . Respondent’s prior statements.”

Hearing Request at 23, 24; ORI M/Dismiss at 30-31; Resp. Opp. at 76.⁴ Inasmuch as the one false aspect of the article was the altered Figure 4B, which is the only portion of the article to which Respondent admits involvement, my accepting this highly questionable claim as true does not alter my inevitable conclusion that Respondent Bois' manipulation and subsequent publication of Figure 4B constituted scientific misconduct.

2. Respondent's defenses do not raise a genuine dispute over facts or law material to findings of research misconduct.

Without specifying what they are, Respondent Bois repeatedly asserts that he has, in fact, disputed issues of material fact, and provided detailed, substantive reasons for his denials of the facts asserted in ORI's charge letter. Resp. Opp. at 1, 3, 4, 11, 12, 21, 22, 23, 26, 27, 42, 43). But, as the above-discussion establishes, in his general denials of the charges, he has offered few details, and, to the extent that he disputes any specific facts, those facts are not material.

Instead, Respondent has come forward with the following affirmative defenses: 1) Dr. John Cleveland, a co-author of the JCB article who was himself apparently charged with misconduct, opined that Respondent was not guilty of scientific misconduct; 2) ORI has not established that Respondent had a "conscious intent to deceive"; and 3) St. Jude's investigation of him was biased and unfair. None of his arguments raises a genuine dispute material to the findings of research misconduct.

The opinion of Dr. John Cleveland. Respondent Bois argues that statements made by his colleague and co-author, Dr. John Cleveland, create disputes of material fact. Dr. Cleveland acknowledged that "mistakes were made" but opined that Dr. Bois probably did not commit research misconduct. Resp. Opp. at 4; Hearing Request Ex. B. But Dr. Cleveland's opinion is not a "fact"; it is a conclusion, and, by his own admission, a conclusion not supported by his knowledge of any underlying facts. Responding to questions posed by a research integrity officer, Dr. Cleveland volunteered that he was not really in a position to form an opinion; he did not have all the data, never looked at the

⁴ "Only individuals that make substantive intellectual contributions should be listed as authors and the order of authorship should be based on the degree of importance of each author's contribution to the project." *Avoiding Plagiarism, Self-plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing*, <http://ori.hhs.gov/education/products/plagiarism>. Moreover, not only is it unethical for an uninvolved or marginally-involved individual to assume principal authorship, but it suggests additional levels of misconduct. If, in fact, his involvement in and knowledge of the underlying experiments were so limited, Respondent Bois could not legitimately have contributed to the figure's preparation.

notebooks; and he did not know how many experiments were performed. Hearing Request Ex. B at 8.⁵

Respondent's state of mind. Respondent argues that he is not guilty of scientific misconduct because his errors were not the product of a "conscious effort to deceive." In Respondent's view, unless ORI demonstrates that he had a "conscious intent to deceive," he falls within the "honest error" exception to scientific misconduct, 42 C.F.R. §§ 50.102 and 93.103(d). Resp. Opp. at 3, 19. ORI rightly points out that this "conscious effort to deceive" standard is Respondent's own creation and is not found in the statute, regulations, or any other authority. ORI Reply at 11-12.

Moreover, contrary to Respondent's implication, establishing honest error is an affirmative defense, for which *Respondent* bears the burden of going forward and the burden of proving by a preponderance of evidence. 42 C.F.R. § 93.516(b)(2). The drafters of Part 93 (which are the regulations that govern these proceedings) recognized an overlap between a respondent's responsibility to prove an affirmative defense and the agency's responsibility to prove that research misconduct was committed intentionally, knowingly or recklessly. So, as ORI has done here, the agency must show that the research misconduct was intentional, knowing, or reckless.⁶ The drafters explicitly retained "honest error or difference of opinion" as an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. 42 C.F.R. § 93.106; *see 70 Fed. Reg.* at 28,372.

St. Jude's Investigation. Finally, Respondent Bois dedicates a substantial portion of his argument to attacking St. Jude's investigation. However, I have no authority to review St. Jude's procedures or misconduct findings, nor do I review ORI's research misconduct proceedings. Rather, I provide an independent, *de novo* review of ORI's findings and the proposed action. 42 C.F.R. § 93.517(b). Thus, Respondent Bois' multiple complaints about the conduct of those proceedings are irrelevant.

⁵ Again, I find unseemly and disturbing the ease with which these research scientists deny any meaningful involvement in the research that underlay the scientific publications for which they took credit. How can the purported authors of a publication be so ignorant of its formation? And if the named authors are not accountable for the publication's contents, who is?

⁶ Thus, even if I accepted Respondent's suggestion that, under Departmental Appeals Board decisions pre-dating June 15, 2005, reckless departures from accepted practices would not constitute scientific misconduct (which I do not), under Part 93, such rulings are no longer valid.

B. The three-year debarment is commensurate with the seriousness of Respondent Bois' misconduct, and the need to protect public health and safety, to promote the integrity of publically-supported research and the research process, and to conserve public funds.

Because he is guilty of scientific misconduct, Respondent Bois is subject to debarment. Considering that he committed multiple offenses, any one of which would justify a debarment, the three-year period seems minimal. Respondent nevertheless challenges the sanction, arguing that the erroneous articles were inconsequential. Resp. Opp. at 8-9. He argues that the JCB research was "preliminary," a "side project" that never advanced beyond one or two experiments (which seems inconsistent with his claims that his 2002 experiments justified his hypothesis). Resp. Opp. at 36. He characterizes the error in his MCB publication as insignificant. Resp. Opp. at 9.

As with other of ORI's administrative actions, debarment is meant to be remedial, and the penalty should be "commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of [Public Health Service] supported research and research process, and conserve public funds." 42 C.F.R. § 93.408. To achieve these goals, the regulation lists mitigating and aggravating factors that the agency may consider in determining the sanction. However, the regulation grants the agency broad discretion, allowing it to consider "other factors as appropriate" and specifically providing that "[t]he existence or nonexistence of any factor is not determinative." 42 C.F.R. § 93.408.

The listed factors are: a) whether the actions were knowing or intentional or was the conduct reckless; b) was the misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct; c) did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare; d) has the respondent accepted responsibility for the misconduct by admitting the conduct, cooperating with the research misconduct proceedings, demonstrating remorse and awareness of the significance and seriousness of the misconduct; and taking steps to correct or prevent the recurrence of the misconduct; e) does the respondent blame others; f) did he attempt to retaliate; g) is he presently responsible for PHS supported research; and h) other factors appropriate to the circumstances. 42 C.F.R. § 93.408.

First, the undisputed evidence establishes that at least some, if not all, of Respondent's misconduct was knowing and intentional. He deliberately conducted the December 2003 JCB experiment without a control and declined to repeat it, and then published the unverified results in the JCB. He deliberately altered Figure 4B and published it in the MCB.

Second, Respondent Bois was guilty of multiple instances of research misconduct.

Third, although he concedes – as he must – that his publications reflected his errors, Respondent Bois has not accepted any responsibility for his misconduct and has instead attempted, without presenting any credible evidence, to shift the blame to a graduate student.

For these reasons, even without considering the impact of his misconduct, I would affirm the relatively lenient three-year debarment. With respect to the impact of his misconduct, ORI charges that publication of false results in the JCB article was serious because the research involved a serious subject (understanding a soft tissue cancer found most often in children) and used human primary tumor samples derived from children with tumors. Charge Letter ¶ 11. Respondent Bois argues that neither the subject of the research (cancer found most often in children) nor the source of the samples studied makes the falsification serious. He also claims that the errors had little or no impact on public health and welfare because the article was retracted in May 2007. Hearing Request at 12; Resp. Opp. at 35, 36.

That his erroneous publications did not have wider impact is fortuitous, but does not diminish the seriousness of Respondent's misconduct. When scientific research is published, and thus disseminated to the broader scientific community, it moves it into a higher realm of significance. Although Respondent trivializes the fact, others obviously read and relied on his JCB article because, as he concedes, it was cited, if "only" seven times. Resp. Opp. at 9. That it was cited at all means that his colleagues in the scientific world studied and were ultimately misled by its contents, causing further waste of time and resources. I also agree that his use of human tissue samples makes the misconduct more serious.

In light of all of these circumstances, a three-year debarment is a penalty commensurate with Respondent's level of misconduct, and is the minimum necessary to protect public health and safety, promote the integrity of publically-supported research, and to conserve public funds.

III. Conclusion

For all of these reasons, I agree that Respondent Bois has not raised a genuine dispute over facts or law material to the findings of research misconduct. The undisputed evidence establishes that Respondent Bois committed scientific misconduct when he failed to report the results of his February 2003 experiment in his published article, when he published false data in Figure 1A, when he did not include a control for his December 2003 experiment, and when he did not repeat that experiment to verify its results. He committed scientific misconduct when he altered Figure 4B and then published the altered version. A three-year debarment is commensurate with the seriousness of his misconduct and necessary to further the purposes of the statute and regulations governing

scientific research. I therefore dismiss his hearing request pursuant to 42 C.F.R. § 93.504(a)(2), (3).⁷

/s/
Carolyn Cozad Hughes
Administrative Law Judge

⁷ Pursuant to 42 C.F.R. § 93.500(c), the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) only reviews an Administrative Law Judge's (ALJ) "ruling on the merits of the ORI research misconduct" in accordance with 42 C.F.R. § 93.523, "the Administrative Law Judge's ruling." The decision under that section constitutes the final HHS action, unless that ruling results in a recommendation for debarment or suspension. In that instance, the ALJ's ruling constitutes findings of fact for the debaring official.