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US Department of Health and Human Services

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[Federal Register: January 23, 2009 (Volume 74, Number 14)]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

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SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Luk Van Parijs, PhD, Harvard Medical School, Brigham and Women's Hospital, California Institute of Technology, and Massachusetts Institute of Technology: Based on the reports of separate investigations conducted by Harvard Medical School (HMS)/Brigham and Women's Hospital (BWH), California Institute of Technology (CalTech), and Massachusetts Institute of Technology (MIT) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Luk Van Parijs, former Graduate Student, Department of Pathology, HMS, former Research Fellow and Instructor of Pathology, BWH, former Postdoctoral Fellow, Department of Biology, CalTech, and former Associate Professor, Department of Biology, Center for Cancer Research, MIT, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants U19 AI56900, R21 AI49897, R01 AI42100, P01 AI35297, R37 AI25022, R01 AI32531, National Cancer Institute, NIH, grant R01 CA51462, and National Institute of Environmental Health Sciences (NIEHS), NIH, grant P30 ES02109, and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM57931.

PHS found that Respondent engaged in scientific misconduct by including false data in NIAID, NIH, grant applications R01 AI54519-01A1, R01 AI54973-01, and R01 AI54973-01A1, NCI, NIH, grant application 2P30 CA14051-34, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant application R21 DK69277-01. Specifically, PHS found that Respondent engaged in scientific misconduct by including false data in seven published papers, three submitted papers (with two earlier versions submitted for one of these), one submitted book chapter, and multiple presentations as follows:

1. While at HMS/BWH, Dr. Luk Van Parijs falsified the expression of IFN- γ and KJ-126 in flow cytometry dot plots for the immunized, naive, tolerized and tolerized + IL-12 experimental groups in Figure 4, JEM 186:1119-1128, 1997, by using the same non-stained cell population in the lower left quadrant to falsely represent CD4+ T cells negative for IFN- γ and KJ-126 in each experimental group.
2. That Dr. Luk Van Parijs falsified the expression of different proteins in flow cytometry dot plots in Figure 1, Immunity, 8:265-274, 1998, in Figure 1C, Immunity, 11:281-288, September 1999, and in Figure 5, Immunity 11:763-770, December 1999, by using portions of the same dot plot to represent different cell populations expressing different proteins. Specifically:
 - a. While at HMS/BWH, Dr. Van Parijs used portions of the same dot plot to represent T cell populations expressing the 3A9 T cell receptor and CD4+ (top panel) or CD8+ (bottom panel) in 3A9+ (wild type), in 3A9/lpr (Fas-), or in 3A9/gld (FasL-) transgenic mice in Figure 1, Immunity 1998, where:
 - i. The CD4/3A9 dot plots for the 3A9+ and 3A9/gld transgenic mice were the same, and the 3A9+ dot plot was a subset of the 3A9/lpr dot plot;
 - ii. The CD8/3A9 dot plots for the 3A9+ and 3A9/lpr transgenic mice were the same in the lower left and lower right quadrants, and the 3A9/gld dot plot was a subset of the wild type dot plot
 - b. While at CalTech, Dr. Van Parijs used portions of the same dot plot to represent the expression of hIL-2R β and GFP in T cells infected with WT or Δ 355+8F IL-2R mutant in Figure 1C, Immunity, September 1999, where the Δ 355+8F dot plot was a subset of the WT dot plot

c. While at CalTech, Dr. Van Parijs used portions of the same dot plot to represent the expression of B220 and IgM in infected (GFP+) and not infected (GFP-) spleen cells isolated from reconstituted mice in Figure 5, *Immunity*, December 1999, where the Infected (GFP+) dot plot for control mice was a subset of the Not Infected (GFP-) dot plot for FLIP mice.

3. While at MIT, Dr. Luk Van Parijs falsely claimed in the text of *RNA Interference Technology* (Cambridge University Press, July 2004) and in Figure 2 of *Nature Genetics* 33:401-406 (2003) that experiments depicting the functional silencing of genes in hematopoietic stem cells (HSCs) and in non-cycling dendritic cells by lentiviral-mediated RNAi were performed, when they were not. Specifically, in *Nature Genetics*:

a. Figure 2b falsely showed the transduction of bone marrow-derived dendritic cells infected with pLL3.7 Bim by flow cytometry, and knockdown of Bim expression by Western blot

b. Figure 2d falsely showed the efficiency of pLL3.7 CD8 lentiviral infection in HSCs by flow cytometry for GFP expression (left panel), and falsely showed stable gene expression in progeny by flow cytometry for GFP expression in spleen cells from chimeras derived from infected HSCs (right panel)

c. Figure 2e falsely showed the reduction of CD8+ T cells in spleen cells from chimeras derived from pLL3.7 CD8 infected HSCs (right panel) and controls (left panel).

4. While at MIT, Dr. Luk Van Parijs falsified figures in grant applications submitted to the National Institutes of Health (NIH), a presentation in 2003, and Figure 6A, *Immunity* 19:243-255 (2003), by falsely claiming that the image in the figure represented an immunoprecipitation assay for Ras-GTP and a Western blot for total Ras protein, when it actually represented a Western blot for Bcl-2 and [beta]-actin in T cells, previously published as Figure 5C, *J. Immunol.*, 168:597-603 (2002).

Dr. Van Parijs also admitted to falsification or fabrication of data in multiple submitted manuscripts, grant applications submitted to NIH, and presentations as follows.

5. While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations and submitted manuscripts in 2004, he falsely claimed that the bifunctional lentiviral vectors, U6-shRNA-rat insulin promoter (RIP)-Myc had been made, when they had not, and that transgenic mice carrying these lentiviral vectors with shRNA silencing Bim or Pten proteins in pancreatic cells showed accelerated tumorigenesis and death.

6. While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations in 2003 and 2004 and in grant application R21 DK69277-01 submitted to NIH in 2003, he falsely claimed that the number of CD8+ T cells and the incidence of diabetes was reduced by silencing CD8 expression with the pLL3.7 CD8 lentivirus in non-obese diabetic (NOD) transgenic mice, when the NOD transgenic mice data did not exist.

7. While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations, submitted manuscripts, and grant applications submitted to NIH in 2004, he falsely claimed that transgenic mice had been generated with the mono-functional lentiviral vectors with c-Myc, Ras or Akt under the control of the CD4 promoter, when they had not, and that transgenic mice had been generated with the bi-functional lentiviral vectors with CD4-c-Myc, Ras or Akt- and U6-shRNAs targeting luciferase, Bcl-2, or Bim proteins, when they had not. The effect of these misrepresentations was the reported false conclusion that a cytokine-stimulated proto-oncogene network regulated CD4+ T-cell survival and responses to foreign and self antigens.

8. While at MIT, Dr. Luk Van Parijs admitted that in presentations and submitted manuscripts in 2004, he falsely claimed that mice injected with plasmids carrying shRNAs for Bcl-2, Akt1 and Akt2, complexed to polyethylene imine (PEI) showed a significant reduction in c-myc-induced tumor growth, when the experiments had not been done.

9. While at MIT, Dr. Luk Van Parijs admitted that in presentations in 2004, he falsely claimed that shRNAs designed using algorithms developed in 2004 were more effective to silence target genes than the shRNAs designed with algorithms in 2002.

10. While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations, submitted manuscripts, a grant application submitted to NIH, and in the text of *Current Opinions in Molec. Therapeutics*, 6:136, 2004, he falsely claimed that an in vivo RNAi screen was developed to identify genes in cytokine and apoptosis pathways that accelerated or suppressed Myc-induced tumorigenesis in lethally irradiated mice, by using bi-functional lentiviral vectors that expressed c-Myc under control of the CMV enhancer-[beta]-actin promoter (CAG) and U6-driven shRNAs designed to silence 168 selected genes, when the experiments had not been done.

11. While at MIT, Dr. Luk Van Parijs admitted that in a submitted manuscript in 2004 and a grant application submitted to NIH in 2003, he falsely claimed that with the use of retroviral vectors with Bim and activated Ras, Akt or Myc, he showed that the IL-2-stimulated activation of proto-oncogene pathways functioned to promote the survival of T cells following antigen encounter by regulating Bim and Bcl-2 pathways, when the experiments that were performed were inconclusive.

Dr. Van Parijs has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of five (5) years, beginning on December 22, 2008:

(1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR Part 376 et seq.) of OMB Guidelines to Agencies on Government wide Debarment and Suspension (2 CFR, Part 180); and

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

Dated: January 14, 2009.
Chris B. Pascal,
Director, Office of Research Integrity.
[FR Doc. E9-1453 Filed 1-22-09; 8:45 am]
BILLING CODE 4150-31-P

Page last updated on December 6, 2009

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Case Summary - Scott J. Brodie

[Federal Register: May 5, 2010 (Volume 75, Number 86)]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Misconduct in Science

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that on March 18, 2010, the Department of Health and Human Services (HHS) Debarring Official, on behalf of the Secretary of HHS, issued a final notice of debarment based on the misconduct in science findings of the Office of Research Integrity (ORI) in the following case:

Scott J. Brodie, DVM, Ph.D., University of Washington: Based on the findings in an investigation report by the University of Washington (UW) and additional analysis conducted by ORI in its oversight review, ORI found that Scott J. Brodie, DVM, Ph.D., former Research Assistant Professor, Department of Laboratory Medicine, and Director of the UW Retrovirology Pathogenesis Laboratory, UW, committed misconduct in science (scientific misconduct) in research supported by or reported in the following U.S. Public Health Service (PHS) grant applications:

- 1 P01 HD40540-01 (National Institute of Child Health and Human Development [NICHD], National Institutes of Health [NIH])
- 5 P01 HD40540-02 (NICHD, NIH)
- 1 P01 AI057005-01 (National Institute of Allergy and Infectious Diseases [NIAID], NIH)
- 1 R01 DE014149-01 (National Institute of Dental and Craniofacial Research [NIDCR], NIH)
- 2 U01 AI41535-05 (NIAID, NIH)
- 1 R01 HL072631-01 (National Heart, Lung, and Blood Institute [NHLBI], NIH)
- 1 R01 (U01) AI054334-01 (NIAID, NIH)
- 1 R01 DE014827-01 (NIDCR, NIH)
- 1 R01 AI051954-01 (NIAID, NIH).

Specifically, ORI made fifteen findings of misconduct in science 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. The fifteen findings are as follows:

1. Respondent knowingly and intentionally falsified a figure that was presented in manuscripts submitted to the Journal of Experimental Medicine and the Journal of Virology and in several PowerPoint presentations that purported to represent rectal mucosal leukocytes in some instances and lymph nodes in other instances.
2. Respondent knowingly and intentionally falsified portions of a three-paneled figure included in several manuscript submissions, PowerPoint presentations, and grant applications.
3. Respondent knowingly and intentionally falsified a figure included as Figure 1N in American Journal of Pathology 54:1453-1464, 1999, three NIH grant applications, and several PowerPoint presentations.
4. Respondent knowingly and intentionally falsified a figure that was published as an insert within Figure 1K in American Journal of Pathology 54:1453, 1999 and included the figure in a number of NIH grant applications.
5. Respondent knowingly and intentionally falsified a figure representing a panel of four green fluorescent cells and included it as a figure in several grant applications claiming that each cell had been subjected to different treatments when three of the cells came from a single image.
6. Respondent knowingly and intentionally falsified an image included as Figure 5A in a paper published in the Journal of Clinical Investigations 105:1407, 2000 and submitted to various journals and included in different grant applications.
7. Respondent knowingly and intentionally falsified a figure appearing as Figure 3.III.A, inset, in a manuscript submitted to Science entitled "A persistent reservoir of HIV-1 in pulmonary macrophages" and as figures in various grant applications and PowerPoint presentations.

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8. Respondent knowingly and intentionally falsified multiple versions of a figure depicting green and red fluorescent cells used as Figures 3.III.H and I in a manuscript submitted to Science, as Figures 6C and 6D of NIDCR, NIH, grant application 1 R01 DE14827-01, as Figures C.2.1 1H and C.2.11I of NHLBI, NIH, grant application 1 R01 HL072631- 01, and in PowerPoint presentations.

9. Respondent knowingly and intentionally falsified a figure, labeled as Figure 9E in NIDCR, NIH, grant application 1 R01 DE014827-01 and in various other grant applications and PowerPoint presentations.

10. Respondent knowingly and intentionally falsified the bottom half of Figure C.2.5 of NHLBI, NIH, grant application 1 R01 HL072631-01 by using the same image twice, labeling it once as being treated for 2 hours with lipopolysaccharide (LPS) and the second as being treated for 12 hours with LPS. Respondent also used a second image twice, labeling it once as "no LPS" and the second time as "24 hours with LPS."

11. Respondent knowingly and intentionally falsified a figure that purports to represent viral decay in rectal mucosa and included the figure as a slide in two PowerPoint presentations and three NIH grant applications.

12. Respondent knowingly and intentionally falsified: (a) A histopathology figure that was described in a paper published in the Journal of Infectious Diseases 83:1466, 2001, as inguinal lymph nodes from an untreated AIDS patient using in situ PCR to show the presence of HIV-1 cells when it was actually from a tissue expressing the neomycin marker; (b) the gel images resembling Figures 2A and C, which Respondent claimed to be based on lymph node cells, although he reported the gel images elsewhere to represent results from rectal tissue; and (c) various versions of these blots that Respondent reported elsewhere and labeled differently with respect to the copy numbers detected and as detecting DNA in some instance and RNA in others.

13. Respondent knowingly and intentionally falsified Figures 2DI and 2DII included in a paper published in the Journal of Leukocyte Biology 68:351-359, 2000.

14. Respondent knowingly and intentionally falsified Figure 4, Panels A and B, in NIDCR, NIH, grant application 1 R01 DE014827-01 by manipulating the source images.

15. Respondent knowingly and intentionally falsified a number of figures and made false statements in the text of NIAID, NIH, grant application 1 R01 AI051954-01 submitted jointly with a colleague by relabeling figures based on research carried out with HIV-1 or HIV-2 and identifying the figures and text as research conducted with ovine lentivirus (OvLV).

ORI issued a charge letter enumerating the above findings of misconduct in science and proposing HHS administrative actions. Dr. Brodie subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. In January 2009, the ALJ issued a ruling holding that there were no triable issues challenging ORI's findings that there were materially false statements, images, and other data in the relevant publications, presentations, and grant applications. However, the ALJ held that Dr. Brodie raised triable issues about his intent to commit scientific misconduct and the reasonableness of the proposed debarment of seven (7) years.

On January 12, 2010, 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. Pursuant to 42 CFR 93.523(c), the ASH forwarded the ALJ's recommended decision to the HHS Debarment Official, which constituted the findings of fact required under 2 CFR parts 180 and 376.

On February 1, 2010, Dr. Brodie submitted a letter to the HHS Debarment Official with attachments to request that the ALJ's recommended decision be rejected as a whole. On February 26, 2010, Dr. Brodie submitted a letter requesting the opportunity to meet with the HHS Debarment Official to orally present the reasons supporting his request that the ALJ's recommended decision be rejected. However, the HHS Debarment Official determined that Dr. Brodie had been afforded an opportunity to contest ORI's findings of scientific misconduct in accordance with 42 CFR part 93, subpart E. Given the findings of facts in this case, the HHS Debarment Official determined that the issues in his presentation in opposition to the ALJ's recommended decision did not raise a genuine dispute over facts material to the recommended debarment. Accordingly, the HHS Debarment Official also denied Dr. Brodie's request to make an oral presentation and issued a notice of debarment to begin on March 18, 2010, and end on March 17, 2017. On March 23, 2010, Dr. Brodie submitted a letter requesting a postponement of the effective date of the debarment. This request was denied by the Debarment Official on April 6, 2010.

Thus, the misconduct in science findings set forth above became effective, and the following administrative actions have been implemented for a period of seven (7) years, beginning on March 18, 2010:

(1) Dr. Brodie has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to the Department of Health and Human Service's Implementation (2 CFR part 376 et seq.) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180; and

(2) Dr. Brodie is prohibited from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,
Director, Division of Investigative Oversight, Office of Research Integrity.
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Case Summary - Meleik Goodwill

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Office of the Secretary
 Findings of Research Misconduct
 AGENCY: Office of the Secretary, HHS.
 ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Meleik Goodwill, Ph.D., Wadsworth Center, N.Y.S. Department of Health: Based on the Wadsworth Center report and the oversight review conducted by the Office of Research Integrity (ORI), the U.S. Public Health Service (PHS) found that Meleik Goodwill, Ph.D., former postdoctoral fellow, Wadsworth Center, N.Y.S. Department of Health, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R21 ES013269-02.

Specifically, PHS found that the Respondent engaged in research misconduct by the fabrication of data for growth curves presented in Figure 1 in the 2007 Journal of Neuroimmunology article (Goodwill, M.K., Lawrence, D.A., & Seegal, R.F. "Polychlorinated biphenyls induce proinflammatory cytokine release and dopaminergic dysfunction: Protection in interleukin-6 knockout mice." Journal of Neuroimmunology 183(1-2):125-132, 2007), and by the use of composite images of Western- blot bands from unrelated experiments done in 2005 that were falsely labeled as if from different experiments to construct Figure 4A in the 2007 Journal of Neuroimmunology article. Figure 4B of the article also was falsified by use of identical sets of number for different treatments. The 2007 Journal of Neuroimmunology article was retracted in J. Neuroimmunol. 197(1):197, 2008.

Dr. Goodwill has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on January 21, 2011:

- (1) That any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS- supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;
- (2) That any institution employing her submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-funded research in which she was involved, a certification to ORI that the data provided are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report; and
- (3) To exclude herself voluntarily from service in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,
 Director, Division of Investigative Oversight, Office of Research Integrity.
 [FR Doc. 2011-2975 Filed 2-9-11; 8:45 am]
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