

Dated: January 16, 2009.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. E9-1510 Filed 1-22-09; 8:45 am]

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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.

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 β -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- β -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]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date: February 25, 2009, 9 a.m.-3 p.m. February 26, 2009, 10 a.m.-4 p.m.

Place: Hubert Humphrey Building, 200 Independence Avenue, SW., Room 505A, Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day the Committee will hear updates from the Department, the HHS Data Council, the Center for Medicare and Medicaid Services, as well as update on the transition to the new administration. There will also be an ONC update on the NHIN Conference. In the afternoon there will be a speaker on de-identification of health data from the Center for Democracy and Technology.

On the morning of the second day there will be a briefing on international terminology and an update on Health Statistics for the 21st Century. There will also be an update from NCHS Board of Scientific Counselors and an overview of emerging and innovative sources of health data.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions can be scheduled for late in the afternoon of the first day and second day and in the morning prior to the full Committee meeting on the second day. Agendas for these breakout sessions will be posted on the NCVHS website (URL below) when available.

For Further Information Contact:

Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: January 12, 2009.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10273]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.