Office of the General Counsel Washington, DC 20201

September 17, 2010

MEMORANDUM FOR HAROLD E. VARMUS, M.D.

FROM: EDGAR M. SWINDELL

Associate General Counsel for Ethics Designated Agency Ethics Official

SUBJECT: Waiver under E.O. 13490 and Authorization under 5 C.F.R. § 2635.502

The purpose of this memorandum is to provide a limited waiver of the restrictions in Section 1, Paragraph 2, of Executive Order 13490 (the Ethics Pledge or E.O.), and a limited authorization, pursuant to 5 C.F.R. § 2635.502(d), to permit your participation in certain, limited, particular matters involving specific parties that involve your former employer, Memorial Sloan-Kettering Cancer Center (MSKCC). The purpose of this limited waiver is solely to permit you to continue to conduct cancer research in your official capacity as Director of the National Cancer Institute in collaboration with your former employer, MSKCC. This waiver is being issued because of the great potential public benefit of your continued collaborative research with your former employer, MSKCC. This limited waiver and limited authorization will allow you to carry out effectively your duties as the Director of the National Cancer Institute (NCI), a component of the National Institutes of Health (NIH) within the Department of Health and Human Services (HHS).

I. Background Regarding Your Appointment

You have been appointed to serve as NCI Director. NCI leads the efforts of the National Cancer Program and the NIH to reduce dramatically the burden of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers.

You were previously the President and Chief Executive Officer of MSKCC, a cancer treatment and research institution founded in New York in 1884. MSKCC is an NCI-designated cancer center that is funded through a competitive grant process based on its ability to demonstrate scientific excellence and the capability to integrate a diversity of research approaches to focus on the problem of cancer.

Throughout your scientific career, including your prior tenure as the Director of the NIH from 1993 until the end of 1999, as well as your years at MSKCC, you have maintained a research laboratory. Through these laboratories you have continued your research into the molecular mechanisms and genetic bases of cancer, building on your earlier work that resulted in your selection as a co-recipient of the 1989 Nobel Prize in Physiology or Medicine, the 2001 National Medal of Science, and other significant honors. You plan to continue this important work in an

Page 2 – Harold E. Varmus, M.D.

NIH intramural laboratory under the scientific, managerial, and administrative authority of the leadership of the National Human Genome Research Institute (NHGRI), another of the institutes and centers that comprise the NIH, as part of your official duties as NCI Director.

As a result of your prior position at MSKCC, MSKCC meets the definition of "former employer" for purposes of Section 1, Paragraph 2, of the Ethics Pledge. In addition, you have a "covered relationship" with MSKCC for purposes of 5 C.F.R § 2635.502. Without a limited waiver of Section 1, Paragraph 2, of the Ethics Pledge and a limited authorization under 5 C.F.R § 2635.502, you will be prohibited from participating in particular matters involving your official research in which MSKCC is a party or represents a party.

For two years following your appointment, the Ethics Pledge prohibits your participation in any particular matter involving specific parties that is directly and substantially related to your former employer MSKCC. See E.O. 13490, § 1, ¶ 2. Absent a waiver, this restriction would effectively preclude your conferring with MSKCC researchers about projects you led during your MSKCC employment that are now being pursued by other MSKCC researchers, and continuing your ongoing projects that will transition into the NIH intramural laboratory. Similarly, without a waiver, you would be prohibited from engaging in any collegial conversation or collaborative research with an MSKCC investigator, even where such communication or research might lead to a demonstrable public health benefit.

Because the transition and operation of your laboratory will require communication and collaboration with MSKCC, you requested a limited waiver of Section 1, Paragraph 2, of the Ethics Pledge with respect to your former employer on the basis that a limited waiver would be in the public interest. You have also requested a 5 C.F.R § 2635.502(d) authorization with respect to your former employer on the basis that the interest of the Government in the employee's participation outweighs any concern that a reasonable person may question the integrity of the Government's programs and operations.

II. Ethics Commitments by Employees in the Executive Branch – E.O. 13490

Background Regarding Ethics Pledge

The Ethics Pledge provides that a political appointee will not, for a period of two years from the date of appointment, participate in any particular matter involving specific parties that is directly and substantially related to the appointee's former employer or former clients, including regulations and contracts. See E.O. 13490, § 1, ¶ 2. The reference to "regulations," which normally are considered particular matters of general applicability rather than particular matters involving specific parties, encompasses only those rules that have a special or distinct effect on the identified party other than as part of a class. The E.O. defines "former employer" to include any person for whom the appointee was employed within the two years prior to the date of his appointment.

Section 3 of the E.O. provides for waiver of the recusal provisions; and as the HHS Designated Agency Ethics Official (DAEO), I exercise that waiver authority in consultation with the Office

of the Counsel to the President. See Office of Government Ethics Memorandum Re: Authorizations Pursuant to Section 3 of Executive Order 13490, DO-09-008 (Feb. 23, 2009). The standard for waiving the restriction in the Ethics Pledge is that the literal application of the restriction is inconsistent with the purposes of the restriction, or that it be in the public interest to grant the waiver. See E.O. 13490, § 3(a). The E.O. states that "the public interest shall include, but not be limited to, exigent circumstances relating to national security or to the economy." Id., § 3(b).

Limited Waiver of Section 1, Paragraph 2 of the Ethics Pledge

I hereby determine that it directly serves the public interest that you be able to participate fully and actively in your official capacity as NCI Director in scientific research in the fight against cancer, given your commitment to the advancement of science in the United States, your significant and extensive achievements in the field, and the interest of the American people in ensuring that highly-qualified experts continue to search for clues that will lead to better prevention and treatment of human illness and suffering.

Accordingly, pursuant to E.O. 13490, § 3(a), I waive the restriction in E.O. 13490, § 1, ¶ 2, solely to allow your participation as an intramural investigator in the scientific aspects of particular matters involving specific parties that directly and substantially relate to your former employer MSKCC subject to the limitations set forth below.

In order to ensure that the cancer research and collaboration described above may proceed without impediment, this waiver authorizes you to participate as part of your official duties as NCI Director as an intramural investigator within the intramural research program of the NHGRI in particular matters involving specific parties that directly and substantially relate to MSKCC, including where this entity is a party to the matter, represents a party to the matter, is a participant, or a contributor, either individually or as part of a group. Subject to the limitations described below, you may engage fully in your research-related duties as an intramural researcher, including consultation, collaboration, or other active participation as an investigator or supervisor of others engaged in the actual conduct of research projects, and the presentation or publication of research findings, directly or indirectly involving MSKCC researchers.

Limited Application of this Waiver

You may not participate in any meetings or conversations with MSKCC, other than those you may have in the course of the research and research-related activities of an intramural investigator in your official capacity. However, you may participate in meetings or have communications with MSKCC about particular matters of general applicability or regarding policies that do not constitute particular matters provided the meeting or communication is "open to all interested parties." See OGE Memorandum DO-09-011 (March 26, 2009).

You may not participate in the management and administration of the programs and operations of the NCI, including the National Cancer Program and other programs of the institute described at Title IV, Part C, Subpart 1 of the Public Health Service Act, 42 U.S.C. §§ 285-285a-9, that

relate to particular matters involving specific parties, such as contracts, grants, audits, investigations, disputes, litigation, administrative appeals, and similar transactions or proceedings involving MSKCC as an identified party. In relation to grants and contracts, in particular, your obligation to recuse extends to both investigator-initiated applications submitted by MSKCC and Requests for Applications (RFAs) in response to which MSKCC submits an application.

You may not participate directly or indirectly, formally or informally, in any aspect of the peer review process, the agency decision to make or deny an award, the administration of an award, extension or renewal requests, or site visits or other reviews undertaken as part of the award oversight process where MSKCC is or represents a party, is a participant, or a contributor, either individually or as part of a group.

You have agreed to divest permanently any intellectual property rights associated with discoveries made during your MSKCC tenure, and you have confirmed that you will retain no continuing financial ties to MSKCC. Additionally, any intellectual property rights developed through your research while you are serving as NCI Director will be subject to the Federal Technology Transfer Act, ¹ and owned by the Federal Government.

While you may work on government-funded projects and research, you may not be named or identified as Principal Investigator, co-investigator, or equivalent on any request for grants or funds in which MSKCC is a collaborator from any Federal Government agency.

Your intramural research laboratory will be housed at and supervised by NHGRI. NHGRI is not under your supervision or authority. You may not participate in budgetary determinations made by NHGRI regarding your laboratory.

III. Impartiality in Performing Official Duties – 5 C.F.R. § 2635.502

The Standards of Ethical Conduct for Employees of the Executive Branch require an employee to take appropriate steps to avoid an appearance of any lack of impartiality in the performance of the employee's official duties. 5 C.F.R. § 2635.502(a). Under section 502, when an employee knows that a person with whom he has a "covered relationship" is a party or represents a party to a specific party matter, the employee should not participate in the matter without informing an agency official and receiving authorization to participate. An employee has a "covered relationship" under this section with any entity for which the employee has, within the last year served, *inter alia*, as an employee. 5 C.F.R. § 2635.502(b)(1)(iv).

The development of statutory proposals, regulations, and policies, absent a special or distinct effect on an entity other than as part of a class, are considered particular matters of general applicability to which section 502 is inapplicable. However, governmental decisions to hold and participate in meetings or otherwise afford similar opportunities for communication with

¹ 15 U.S.C. Chapter 63 and Executive Order 10096 implemented through 45 C.F.R. Part 7.

Page 5 – Harold E. Varmus, M.D.

identified external entities may themselves be classified as "specific party" matters even if the subject matter of the discussion involves generally applicable policy issues.

As the HHS DAEO, I hereby also provide a corresponding authorization pursuant to 5 C.F.R. § 2635.502(d) for the same reasons and with the same limitations as described above regarding the waiver of Section 1, Paragraph 2, of Executive Order 13490.

IV. Conclusion

Matters from which you must recuse will be referred to the NIH Deputy Director for Extramural Research for disposition. Your disqualification from duties in connection with particular matters that are not covered by this waiver and authorization is not expected to impair materially your ability to perform the duties of your position. In connection with particular matters involving MSKCC as a party or the representative of a party, you will not engage in official duties other than those normally within the scope and authority of an NHGRI intramural investigator, as described above, and will abide by all NIH budgetary, managerial, and procedural controls on the collaboration of intramural scientists and NIH institute and center directors with non-federal institutions while also considering and undertaking appropriate collaborative research projects with institutions other than MSKCC.

Pursuant to a policy directive implemented at the NIH, any assertions or allegations of scientific misconduct or grants management issues between NCI and MSKCC arising from any of the NIH-funded projects on which you worked during the term of your MSKCC employment shall be referred to and processed by the NIH Office of Extramural Research.

This limited waiver and authorization does not affect your obligation otherwise to comply with other provisions of the Ethics Pledge and with all other Standards of Ethical Conduct for Employees of the Executive Branch and agency supplemental rules.