



U.S. OFFICE OF SPECIAL COUNSEL

1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

December 4, 2007

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-06-0767

Dear Mr. President:

Due to the scientific power of modern cell technology and the opportunity for mischief when taking a person's genetic material, I am forwarding to you a serious matter involving failure to obtain informed consent in a federally funded study of sickle cells in a BABYHUG trial. I received disclosures from Dr. Duane Bonds, a whistleblower at the Department of Health and Human Services (HHS), National Institutes of Health (NIH), National Heart, Lung & Blood Institute (NHLBI), Division of Blood Diseases & Resources (DBDR), Bethesda, Maryland. Dr. Bonds alleged that living cell lines were created for one purpose (Epstein-Barr Virus transformation, or EBV) from the DNA of participants in a contract study at NIH for another purpose (sickle cell issues), in violation of Federal guidelines requiring informed consent for such procedures.

I required the Secretary, HHS, to conduct an investigation into these disclosures pursuant to 5 U.S.C. § 1213(c) and (d). The Secretary, HHS, tasked the Office of Inspector General (OIG) with conducting the investigation. We received the Secretary's report on August 1, 2006. On February 7, 2007, we received a supplemental report from John B. Cronin, Director, Investigative Branch, OIG. Dr. Bonds provided comments on the reports. As required by law, 5 U.S.C. § 1213(e)(3), I am now transmitting to you the reports, together with Dr. Bonds' comments.

As discussed in the attached Analysis of Disclosures, the agency investigation did substantiate the allegation that genetic material was collected from participants in an NIH-funded clinical study, and that it was used to create immortalized cell lines. The investigation revealed that the cell immortalization was neither funded by NIH, nor contemplated formally as a part of the study. The investigation did not substantiate that the investigator knowingly and willingly obtained and used genetic material without informed consent, but rather obtained the genetic material with the mistaken understanding that subjects had consented and that the procedure had been approved. The NHLBI is working with the local study sites to resolve concerns regarding the collection of this material, either through destruction of the samples collected, or by obtaining additional consent from participants.

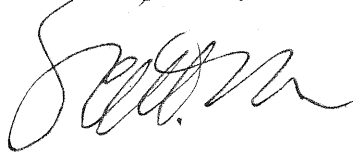
The President

Page 2

I have reviewed the original disclosures, the agency's reports, and Dr. Bonds' comments. Based on that review, I find that the agency's reports contain all of the information required by statute. The statute also requires that I make a determination whether or not the findings of the agency head appear reasonable. In this case, I cannot conclude that all of the findings set forth in the reports appear reasonable, primarily with respect to the conclusion that the contract investigator's actions did not constitute an ethics breach or a violation of federal regulations. Imagine the nefarious uses to which the DNA of unsuspecting subjects of a voluntary study could be put if this kind of cell line immortalization is not treated with greater caution. This time, it was immortalization of cell lines, but at some point, a subject could be unknowingly cloned in a study to which she did not consent. That DNA then could be used for any number of unauthorized purposes.

As required by law, 5 U.S.C. § 1213(e)(3), I have sent copies of the reports and Dr. Bonds' comments to the Chairman of the Senate Committee on Health, Education, Labor, and Pensions, and to the Chairman of the House Committee on Energy and Commerce. I have also filed copies of the reports and Dr. Bonds' comments in our public file and closed the matter.

Respectfully,

A handwritten signature in black ink, appearing to read 'Scott J. Bloch', with a stylized, flowing script.

Scott J. Bloch

Enclosures