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Fred H. Reinhart  
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May 6, 2009

VIA UPS OVERNIGHT

Mr. Darren Greninger  
National Institutes of Health  
Office of Biotechnology Activities  
6705 Rockledge Drive, Suite 700  
Bethesda, Maryland 2089

RE: Gene Patenting and Licensing Practices and Their Impact on Patient Access to Genetic Tests Draft Report by Secretary's Advisory Committee on Genetics, Health, and Society

Dear Mr. Greninger:

This letter is in response to the solicitation of public comments on the above-referenced draft report. Wayne State University agrees that gene patents and the commercialization of such intellectual property is a complex area. While the research and data collected as part of this report are useful, further investigation and discussion are still required before far reaching policy changes are enacted, especially if such changes are based on anecdotal evidence and outdated technology transfer models.

Wayne State University (WSU) does not believe there is an inherent conflict between commercialization and making innovations readily available to the public. WSU has publically endorsed the *Nine Points to Consider in Licensing University Technology*, a guide for our profession that stresses the importance of the role of universities and research organizations in commercializing innovations, the significance of which is acknowledged in the draft report.

We are concerned that the policy options outlined in chapter five have no connection to the research findings and conclusions of the draft report. The report states, "The draft report also includes policy options. These options do not necessarily correlate with any particular preliminary finding, but rather provide a framework within which to gather public input." We find this a peculiar way to develop policy. We are also concerned that the policy options will be perceived as options that are directly correlated to the research

findings, misleading reviewers to believe that the policy recommendations are based on the results of the research.

Further, because the policy options outlined in the draft report are not based on the conclusions outlined in the chapter immediately preceding, there are issues that warrant highlighting:

1. Licensing university research discoveries is a complex process that requires the flexibility inherent in the Bayh-Dole Act. The elegance of the Bayh-Dole Act is that certain outcomes are expected, i.e. commercialization of university research to benefit the public, but the Act does not dictate the way in which this is to be accomplished. Individual technologies vary widely and Bayh-Dole gives technology managers complete freedom to determine the appropriate pathway to follow in any specific case. The Bayh-Dole Act has worked very well for almost 30 years, and is now widely copied around the world as a best practice for managing university discoveries. It does not require either an Executive Order or Legislative review that would proscribe a particular route for making these developments available to the public. According to the law, a university alone determines which of its inventions should be licensed exclusively or, conversely, nonexclusively. Congress wisely recognized after years of meager commercialization of results arising from the billions of dollars taxpayers invested annually in federal R&D that inventions are most effectively managed by the creating organizations.
2. Requiring regulations for commercialization (patenting and licensing) of genetic tests is not supported by the research findings. Further, university practice has evolved based on the experiences and the collective guidelines provided by NIH and groups such as AUTM that are cited in the study. Most universities and institutions adhere to these guidelines, and there is no credible evidence that new regulations by federal agencies are needed to instruct universities how to effectively manage their inventions under the Bayh-Dole Act.
3. The focus on policy options based on regulatory oversight is also a concern. Because the data and cases analyzed are over a decade old, there seems to be no effort to assess how licensing in this field has evolved, and what current practices are in place that, at a minimum, mitigate these issues and in some cases address them directly. The research findings conclude that intellectual property management issues have not increased the cost of genetic tests, and in only one case, long in the past, did they cause tests to be unavailable for a short period of time.
4. The procedures for governmental use of march-in rights under the Bayh-Dole Act should be the tool of last resort. Even in the cases where the procedures for march-in rights were initiated (CellPro, Norovir and Xalatan), the government established a precedent of extreme caution and would only grant

a march-in in extreme circumstances. In each of these cases, NIH has determined that its exercise of governmental march in rights would stifle commercial development of research and that pricing needs to be addressed by Congress, not NIH. Based on our experience, WSU is concerned that inventors, licensees or entrepreneurs would be loathe to invest the substantial amounts of funding frequently needed to develop and commercialize federally funded inventions because these investments are made with the expectation of exclusive market access for the duration of the patent life. If that exclusivity could be subsequently easily revoked, commercializing entities would be disincentivized.

The issue of gene patenting is very complex, and before any substantial policy changes are considered, the new Secretary of Health and Human Services, along with the U.S. public, must have an opportunity to consider both sides of the issues. It is with this in mind we ask that further data analysis and expert testimony be collected.

On behalf of Wayne State University, thank you for providing me an opportunity to comment on the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society entitled "Gene Patenting and Licensing Practices and Their Impact on Patient Access to Genetic Tests."

Sincerely,

A handwritten signature in cursive script that reads "Fred H. Reinhart".

Fred H. Reinhart

cc. Hilary H. Ratner, Vice President for Research, WSU  
Harvey Hollins, Vice President for Government and Community Affairs, WSU  
James Barbret, Associate Vice President for Research, WSU