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Dr. Bonnie Harbinger
Office of Technology Transfer
National Institutes of Health
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Rockville, MD 20852
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RE: Comments on Proposed Best Practices for the Licensing of Genomic Inventions

Dear Dr. Harbinger,

The Association for Molecular Pathology (AMP) would like to provide comments on the proposed “Best Practices for the Licensing of Genomic Inventions,” published in the Federal Register Vol. 69, No. 223, on Friday, November 19, 2004. We support non-exclusive licensing whenever possible since restrictive licensing requirements have serious negative effects on the healthcare available to patients. While AMP commends the efforts required to develop best practice guidelines, the proposed recommendations for the licensing of genomic inventions are limited with respect to two critical issues for clinical laboratories: (1) they do not include patent infringement lawsuit protection for the medical use of genetic information by healthcare providers, and (2) they do not address the cost of royalty payments for molecular diagnostic tests, for which current reimbursement is not adequate to pay for even the cost of testing.

As background, AMP is an international not-for-profit educational society representing over one thousand physicians, doctoral scientists, medical technologists and other professionals who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity, AMP members are involved in every aspect of molecular diagnostic testing, including administration and interpretation of molecular diagnostic tests, research and development, education and regulatory issues. Since its inception ten years ago, AMP has provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

As clinician scientists, AMP members are characteristically at the forefront of clinical implementation of recent advances in molecular medicine, and we fully agree with the assertion that “patent protection rarely should be sought” when “further research and development investment is not required.” The evident testing by multiple clinical laboratories would seem ample evidence that “further development investment” is infrequently essential to the expeditious development of such inventions into clinical diagnostic tests. Clinical laboratories offering molecular diagnostic testing services frequently are discouraged and limited by burdensome licensing and patent enforcement practices. These practices are contradictory to AMP’s goal and, we believe, NIH’s intent. Hence, AMP would urge PHS to consider the singular importance and impact of the proposed best practice guidelines for clinical molecular diagnostic testing.

Many clinical laboratories are experiencing patent enforcement for molecular tests they perform. Researchers discover genetic variations associated with a specific disease, and file for patent protection prior to publication of the discovery. The publication of a genetic variation associated with a disease allows the translation of the

sequence information into diagnostic tests in CLIA-licensed laboratories using prior art, even before the patent is issued. Once the patent is issued, clinical laboratories performing the test in support of medical practice receive notification of patent infringement and the need to obtain a license or stop performing the test. This process disrupts clinical services to patients and medical practice.

Many licensing and enforcement obstacles have, and continue to be, experienced by healthcare providers, particularly those who practice molecular diagnostics. These obstacles run the full range from non-royalty bearing licensing, to licensing with conditions restricting the practice of medicine, to costly royalty-bearing licensing, to outright requirement to cease and desist specific genetic testing due to exclusive license enforcement. Patent enforcement involves a wide range of diseases, including Charcot-Marie-Tooth Type 1a, Apolipoprotein E genotyping for Alzheimer Disease, *BRC1* testing for breast cancer, Canavan Disease, B and T cell antigen receptor analysis for leukemias and lymphomas, and Spinocerebellar Ataxia Type 1. Research has demonstrated that the impact of gene patents is of broad significance in the molecular diagnostic community, with approximately 25% of laboratories being required to discontinue performing one or more tests, and 50% of laboratories deciding not to offer specific tests covered by patents (Merz *et al.*, *Nature* 2002; **415**:577-579.; Cho *et al.*, *J Mol Diagn* 2003; 5:3-8). This limitation of medical practice or additional cost for testing that is not covered by Medicare at a level appropriate to the cost of testing has a growing negative impact on the integration of genetics and genomics into medical practice. The combination of these factors has a deleterious effect on patient care in the U.S. The proposal states that one of its purposes is to maximize access to inventions in order to improve the health of the American people. We believe that the proposal does not alleviate the current negative impact of gene patents on molecular diagnostics, with resultant negative consequences for the healthcare of Americans.

To alleviate the overly burdensome restrictions inherent in the proposed best practice guidelines, we recommend the following considerations:

1. Address the need for protection from litigation for healthcare providers (laboratory professionals as well as clinicians) regarding the medical use of genetic information.
2. Recommend compulsory non-exclusive licensing at a reasonable royalty rate, since the majority of limitations on medical practice are from the enforcement of exclusive licenses. Options for language to address the royalty costs include recommending a reasonable royalty fee that takes into account the corresponding reimbursement level or, for not-for-profit healthcare provider institutions, an outright waiver of royalty fees.

We welcome the opportunity for dialog on these points which we believe would further strengthen the recommendations for the public good. AMP is available for further discussions and information. Please feel free to contact me, as President of the Society at (303) 864-5468 or lovell.mark@tchden.org, or the Chair of AMP's Professional Relations Committee, Debra G.B. Leonard, M.D., Ph.D. at (212) 746-2041 or dgl2001@med.cornell.edu.

Thank you very much for your consideration of this very important issue.

Sincerely,



Mark A. Lovell, M.D.
President