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Steven Teutsch, M.D., MPH
Chair, Secretary's Advisory Committee
on Genetics, Health, and Society
Department of Health and Human Services
c/o Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 270
Bethesda, MD 20892
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Re: Secretary's Advisory Committee on Genetics, Health, and Society; Request for Public Comment, 74 FR 11730-1

Dear Dr. Teutsch:

It is my pleasure to respond on behalf of the Association of American Medical Colleges to your request for public comments on the *Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*. The AAMC is a not-for-profit association representing all 130 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems; and nearly 90 academic and scientific societies. Our member medical schools and teaching hospitals collectively perform about 60 percent of all extramural research sponsored by the NIH, and are central to genomic research and to the application and refinement of gene-based diagnostic tests within our member health systems. We view these activities, as we view much of the discovery, education, and health care missions of our member institutions, as public goods meriting broad national investment and requiring responsible stewardship as a public trust.

We commend the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and its Task Force on Gene Patents and Licensing Practices, led by Dr. James Evans of the University of North Carolina School of Medicine, for an extraordinarily well researched and thoughtful discussion draft. The detailed and comprehensive case studies of gene-based diagnostic tests and the preliminary population level study, provided as appendices to the draft, represent in themselves major contributions to the body of empirical evidence that should advance policies addressing these complex issues

Preliminary Findings

The preliminary findings of the case studies are consistent with several earlier analyses, including those undertaken by the National Research Council's Committee on Intellectual

Property Rights in Genomic and Protein Research and Innovation in 2006, in which the AAMC also participated. SACGHS has preliminarily concluded from the case studies that (1) gene patents were not necessary to “incentivize” development of many diagnostic tests (as tests have been developed without patent protection), and (2) that gene-based diagnostic tests protected by patents are not markedly different in price or availability than non-patented tests. Thus, neither the “pro” nor “con” sides of the gene patent argument (at least as relates to diagnostic testing) would seem vindicated by these conclusions. As with other technologies, many factors affect the availability and disposition of these tests.

The preliminary findings may in part indicate that even patent holders who exercise exclusive control of the practice of genetic diagnostic tests nevertheless must respond to an array of societal and market demands in making diagnostic tests available. The most viable business models for test services may be those most closely aligned with the public health interests of broad dissemination, independent validation, and diversification. If this proves true, one appropriate response for the public health and academic communities may be to assert continued high standards and expectations of all test providers. SACGHS’ final report should include a stronger synthesis and evaluation of the case studies and the degree to which the community can influence the marketplace as well as the providers of and patent holders to genetic tests.

Policy Options

The AAMC understands that the draft’s policy options are designed to provide a range or “framework” of recommendations, and are not derived directly from the case studies or other evidence. Our comments focus on the extent to which these options seem most appropriate for developing final recommendations.

Option 1: Stakeholder Advocacy. The AAMC strongly supported development of the *NIH’s Best Practices for the Licensing of Genomic Inventions*¹ referenced in Option 1.D, and was an early participant in the development of the white paper, *In the Public Interest: Nine Points to Consider in Licensing of University Technology*. The Association supports efforts under Option 1 to promote these two documents within the stakeholder community, to work with other organizations and forums on issues in implementing and refining these or similar guidelines and principles, and otherwise promoting appropriate norms and standards within the research community. However, SACGHS should appreciate that a key to consensus on the *Nine Points*, and to broad endorsement of the NIH Guidelines, has been the ability to preserve flexibility and options within institutional agreements. Such flexibility in implementation would need to be protected in future collaborations.

Options 2 and 3: Enhancing Transparency, Filling Data Gaps: The AAMC supports efforts to promote transparency in intellectual property rights pertaining to genetic diagnostic tests and the collection of data on elements of licensing agreements, as permissible within confidentiality requirements, under iEdison or other databases.

¹ AAMC letter to Dr. Bonny Harbinger, NIH, Jan. 4, 2005, available at: <http://www.aamc.org/advocacy/library/research/corres/2005/010405.pdf> accessed on May 13, 2009.

Option 4: Federal Efforts to Promote Broad Licensing. The AAMC supports efforts to encourage more limited use of exclusive licensing in genetic diagnostic tests, as consistent with the NIH's *Best Practices* guidelines and the *Nine Points* principles, providing that options for flexibility in institutional agreements are protected, as noted in our comment to Option 1.

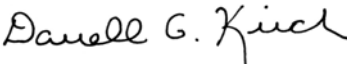
Option 5: Licensing Policies in Federally Funded Research. The AAMC does not at this time support use of the Bayh-Dole Act or reinterpretation of Bayh-Dole to enforce specific licensing policies. The draft recommendations listed under Option 5 seem inconsistent with the spirit of Bayh-Dole, which defers autonomy in patenting and licensing practices to academic institutions receiving federal research funds. Bayh-Dole's specific and well-considered provisions for protection of federal prerogatives and assertion of federal rights are limited, as noted in the draft, to exceptional circumstances or circumstances of national urgency that do not seem supported by the preliminary findings of the case studies or other data as presented.

Option 6: Further Studies of Federal Implementation. The AAMC supports further evaluation and analysis of the impact of intellectual property law on DNA-based inventions and discoveries, as we have supported such studies by the National Academies. An evaluation of Bayh-Dole march-in provisions, also listed under this option, would be broader than issues relating to genetic diagnostic tests and again, does not seem warranted from the preliminary findings of the report.

Options 7 and 8: Revising PTO Policies or Federal Statute: The Association has, on a case-by-case basis, supported changes in PTO procedures (specifically, regarding utility and written-description standards), and in amicus briefs on litigation affecting diagnostic tests or other applications of medical knowledge. However, PTO policies and U.S. Patent Law tend not to focus on narrow areas of invention or application, but apply more broadly. It would be difficult to revise administrative procedures or patent law in ways specific to genetic diagnostic tests, without engendering other consequences that would need to be carefully considered.

In conclusion, the AAMC is grateful to the committee for this opportunity to comment on the public discussion draft and looks forward to participating in future deliberations of the SACGHS. Please contact Susan Ehringhaus (sehringhaus@aamc.org; 202-828-0543) or Stephen Heinig (sheinig@aamc.org; 202-828-0488) with questions about these comments.

Sincerely,


Darrell G. Kirch, M.D.