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Mr. Darren Greninger
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Drive, Suite 700
Bethesda, Maryland 20892

Subject: Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) Public Consultation Draft Report (the "Report") on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests

Dear Mr. Greninger:

The Council on Governmental Relations (COGR) is an association of more than 175 U.S. research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research and other sponsored activities conducted at its member institutions. The Association of American Universities (AAU) is an association of 60 leading public and private U.S. research institutions. AAU focuses on issues important to research intensive universities, such as funding for research, research policy issues, and graduate education. Our associations have been awaiting issuance of the draft Report with great interest, given its profound implications both for the public and for our member institutions.

COGR, AAU and their member institutions appreciate the opportunity to provide comments on the issues, findings and policy options discussed in this important Report. We particularly appreciate the Committee's recognition that public input is needed as to whether there is indeed a need for change and on the appropriateness, feasibility and implications of the policy options presented prior to finalizing specific recommendations. We fully agree that the SACGHS needs more information and perspectives before coming to conclusions about whether changes are needed in Federal laws, policies or programs to address the issues discussed in the Report.

In the discussion that follows, we express some general concerns with the draft Report. We also discuss the policy options more specifically.

Principal Concerns

We have three principal concerns about the draft Report:

1. **Lack of support for Policy Options**. The policy options in the draft Report are not supported by the Report's Findings and Conclusions **(our concern here cannot be overstated)**;

2. **Lack of understanding that licensing is a complex process requiring substantial flexibility.** There is little or no recognition of the complexity of the licensing process, the critical role of industry, the need for flexibility in addressing case-specific challenges, or the fact that analysis of historical patenting and licensing transactions may be lagging indicators of current practices; and

3. **Too much focus on regulation without consideration of possible incentives**. The policy options assume that greater federal control and regulation over licensing polices and practices would facilitate access, but do not consider whether incentives might have a greater impact than burdensome federal compliance requirements.

1. Lack of Support for Policy Options. COGR and AAU's primary concern is the glaring disconnect between the policy options discussed in Chapter V of the Report and the key findings. The Report notes that the SACGHS "found little in the way of broad or consistent evidence that indicates either positive or negative effects of gene patents on patient access to diagnostic tests." Given this and the lack of any clear finding that licensing practices affect the cost or availability of genetic tests or impact innovation, **there appears no firm basis in the Report for the policy options that follow**. Virtually all of the Case Studies contain vague, conditional and sometimes inconclusive statements about the effect of patenting or licensing practices on the availability of genetic tests for particular medical conditions. Speculative statements about possible future effects or risks are not a sound basis for setting forth options that would result in potentially far-reaching changes in public policy. Moreover, these changes could have substantial unintended consequences and negatively impact the ability of academic institutions to engage industry in the commercial development of promising university technologies for the public benefit.

Other Commentary - We note that others have expressed similar concerns about the Report. An editorial accompanying a commentary on the Report in the March 26, 2009 issue of Nature points out that few of the concerns about exclusive rights to gene patents have been borne out and that "genetic tests from companies with exclusive rights are no more expensive or harder to access than those offered by various providers under non-exclusive license." It also highlights the fact that the Report disclosed little to no irreparable harm to genetic diagnostics from patenting.

Further, a March 25 article in the "Patent Docs" blog notes that the Nature commentary acknowledges that the SACGHS Report disclosed little to no "irreparable" harm to genetic diagnostics from patenting, but the authors assert that "neither have [patents] proven greatly advantageous." At best, the authors' own research "detect[ed] no pervasive effects of patenting that consistently help or hinder clinical access to genetic testing." The blog article comments that this "is consistent with the overwhelming majority of studies showing that the anti-commons (effects) aren't tragic after all". The article concludes "what weakening the patent system will do is make it less likely that the fundamental research done at universities (where researchers are indeed not motivated by

patent concerns) will be translated into useful genetic diagnostic tests. There is enormous expense required to convert the genetic observations made in a laboratory into a validated diagnostic test that physicians can rely upon in making diagnostic and therapeutic decisions." (see http://www.patentdocs.org/2009/03/genetic-diagnostic-testing-the-anticommons-revisited.html).

Earlier Reports - These findings are not new. Rather, they are consistent with an earlier report of the Organisation for Economic Co-Operation and Development (OECD). Based on a workshop held seven years ago, the OECD report concluded that "The patentability of genetic inventions is not fundamentally in question among the users of the system, be they from the public or private sectors or from the medical establishment" and "The available evidence does not suggest a systematic breakdown in the licensing of genetic inventions. The few examples used to illustrate theoretical economic and legal concerns related to the potential for the over-fragmentation of patent rights, blocking patents, uncertainty due to dependency and abusive monopoly positions appear anecdotal and are not supported by existing economic studies." (See "Genetic Inventions, Intellectual Property Rights and Licensing Practices," OECD 2002).

In a 2006 report the National Academy of Science (NAS) Committee on Intellectual Property Rights in Genomic and Proteomic Research and Innovation reached similar conclusions with regard to access to genetic inventions for research purposes. While noting the potential for the landscape for genomic and proteomic patents to become more burdensome over time, as the SACGHS report cites the NAS Committee found that "access to patented inventions or information inputs into biomedical research rarely impose a significant burden for biomedical researchers." (See "Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health" (available at http://books.nap.edu/catalog/11487.html). In our view the **Key Findings and Preliminary Conclusions** in the SACGHS Report provide further confirmation that the situation fundamentally has not changed since these earlier reports. The final Report should reflect this.

Finally, the SACGHS Report contains much discussion of the Case Studies but little or no discussion of the Population Level Study of DNA Patents (Appendix 2). The Timeline Analysis in that study concluded "These results suggest that automatic and default nonexclusivity could have a cost, especially given the apparent impossibility of *a priori* identifying groups of patents "needing" to be licensed nonexclusively because they are certain or likely to be associated with clinical diagnostic tests of genetic origin. Given the apparent impossibility of identifying patents "needing" to be licensed nonexclusively, and the potential unintended removal of incentives where they could be beneficial, nuanced exclusivity with prudent diligence is an attractive policy option."

It is troubling that the discussion of Policy Options ignores this finding.

2. **Lack of understanding that licensing is a complex process requiring substantial flexibility.** In the area of genetic diagnostics, while some medical practitioners may have the lab resources necessary to perform such tests, many do not. Industry involvement may be necessary to make such services or diagnostic kits available in numbers that universities simply cannot achieve. Further, industry processes may result in more consistency from one test to the next. However, the reality is that, for any given university technology, it is highly unlikely that companies will line up to take a license, exclusive or otherwise. A patent is simply one factor in their decision of whether to invest in development of a product. In the area of genetic diagnostics, the cost/benefit tradeoff is made much more difficult by the involvement of and constraints imposed by third-party payers. Universities must therefore balance a tremendous number of potentially conflicting factors in order to successfully partner with a company that will invest the necessary resources in order to bring an embryonic university technology to the marketplace.

It is critical that universities retain the flexibility to appropriately balance these multiple licensing issues and to explore creative solutions to emerging problems. Many of the recommendations in the Report, however, are directed toward holding universities accountable to quasi-standards, leaving no ability to address case-specific and compelling circumstances. In addition, the Case Studies discussed in the Report reflect strategies and decisions made years ago, despite the fact that this is an environment of rapid evolution in both patent law and licensing practices. As such, they may not be accurate representations of current and evolving norms.

3. Too much focus on federal regulation without consideration of possible incentives. Many of the policy options discussed are directed toward imposing reporting and compliance requirements on universities and their licensees. Increasing administrative burdens of this kind should only be done when justified by compelling need or benefit. It might be useful instead to find some means of encouraging good behavior through incentives rather than (or in addition to) threats.

One of the strengths of the US patent system and of technology transfer practices is that they evolve and self regulate as a new technology matures. When the first patent applications for genetic sequences were filed, the sequence was unknown and non obvious. The standards for patentability for this technology have since been raised, and a mere sequence is no longer considered to be novel or nonobvious. For example, we note that the Federal Circuit has significantly raised the bar for obviousness for gene patents in the recent decision *In re Kubin.* We question the need for further government regulation to promote what is already occurring through the mechanisms currently in place. In addition, academic technology transfer practices evolve to adapt to a changing landscape. For example, after a few companies asserted IP that they had licensed from an academic institution against other academic institutions, universities began reserving rights not only to be able to practice their own inventions, but to allow other non-profit research institutions to do so as well. This has evolved into standard practice in the academic community.

In the remainder of our comments we discuss the specific policy options identified in the draft Report and end with some suggestions for the consideration of the SACGHS.

Potential Policy Options for Public Consideration (Chapter V)

1. Advocacy Efforts by Key Stakeholders to Ensure Access

We do not disagree in principle with the usefulness of a set of principles and guidance documents that engage stakeholders. However, we are concerned that these efforts might prematurely move in the direction of rigid requirements or regulation, and would therefore suggest that several important qualifications be made.

Greater focus is needed as to the purpose and objectives of the forum proposed in section **I.C**. of the Report. Convening this group under federal auspices with a primary focus on developing strategies increases the likelihood of it devolving into a regulatory group. Rather than focusing on developing strategies, it would be more productive for such a group instead to focus on establishing a very broad dialogue among all stakeholders, including industry, whose needs and perspectives are critical, and without whom the fruits of university research might never be available to patients. It is also interesting to note that the Report is bereft of industry perspectives in this area.

With regard to section **1.D**., we have similar concerns. While the Association of University Technology Managers (AUTM) has endorsed the *Nine Points* document (as have COGR and AAU), in fact the *Nine Points* was developed by an *ad hoc* group of experienced university technology transfer practitioners. The document was intended primarily to raise the awareness of other technology transfer professionals and encourage them "to the extent appropriate… to bear in mind the concepts" articulated in the document with respect to certain potentially controversial issues, and to seek creative solutions. Despite the clear purpose of the document, the Report inappropriately advocates the **adherence** to the principles reflected in the *Nine Points* **as a formal compliance tool**. However, the document was clearly not intended to be prescriptive or used as a set of compliance standards. Moreover, as discussed above, flexibility is required to address the unique and often conflicting licensing issues and to push the boundaries of conventional technology transfer. It also is worth pointing out that the *Nine Points* document specifically recognizes and discusses the need for flexibility in licensing genomic diagnostic tests.

2. Enhancing Transparency in Patents and Licensing

We agree with the concept of transparency. However, the experience of our member institutions is that our industry partners typically are reluctant to release or authorize release of certain license information, as recommended in sections **2.A.** and **B**. of the Report. In addition, section **2.C**. appears cumbersome and would likely be difficult to implement in practice. These are areas where industry input would be useful.

3. Filling Data Gaps

We also agree in principle with the desirability of obtaining more data on gene patenting and licensing arrangements related to genetic tests, especially before implementing any kind of far-reaching public policy. However, some of this information in section **3.C.** of the Report may be considered proprietary by our industry licensees, as it would give their competitors insight into the direction of their businesses. Our institutions cannot be put in a position of divulging the proprietary information of their licensees. Also, while COGR assisted NIH in the development of the iEdison invention reporting system, we are reluctant to endorse proposals that would increase the reporting burden without a clear demonstration of the need and objectives of such reporting. In fact, some of the suggested data elements may be very difficult, if not impossible, to capture.

4. Federal Efforts to Promote Broad Licensing and Patient Access

While we again agree in principle with taking steps to foster patient access, the Report provides no basis for the options discussed in this session. It does not demonstrate any clear need for the federal government to have a role in this area. Instead, it proceeds on the premise that "the public sector frequently looks to the actions of the Federal Government for guidance." To the contrary, the Report findings indicate that current strategies and practices are working well in facilitating patient access overall. Successful approaches to any emerging issue are evolutionary and require a high degree of flexibility to find effective and creative solutions. Experience has shown that calls for the federal government to "encourage" or "promote" often lead to regulations and compliance requirements that do not provide the needed flexibility. The options discussed in this session appear to reflect particular agendas rather than having basis in empirical evidence of need.

These concerns are reinforced by the discussion of the NIH *Best Practices* in section **4.A**. and the *Nine Points* document in section **4.B**., which implies that both documents should be promoted by the federal government. Our concerns with such treatment of the *Best Practices* are noted in the discussion of **5.A**. and **5.B**. below. And as noted in the discussion of **1.D**. above, the *Nine Points* document was not intended as a set of compliance standards. Federal government "encouragement" of their use easily could morph into something more prescriptive.

5. Licensing Policies Governing Federally Funded Research to Facilitate Access

We have very serious concerns about the policy options discussed in this section. **5.C.** suggests that the Secretary of HHS request an Executive Order that would clarify authority under the Bayh-Dole Act (the "Act") for HHS to impose a nonexclusive license presumption for any genetic diagnostic invention. This presumption would be an award term and condition for HHS (NIH) funding. In our view, this is contrary to the intent of the Bayh-Dole Act. It also would unnecessarily involve HHS/NIH in individual institution licensing decisions, and perhaps implies a reversion to the unworkable case-by-case petition approach that generally existed prior to Bayh-Dole. We have serious doubts about whether the

HHS/NIH is equipped to make such determinations. Finally, the conclusion that agencies must impose access requirements does not reflect an understanding of the complexities involved in bringing a technology to market, particularly a complex market such as this one.

The Act purposefully shifted responsibility for development of federally funded technologies from federal funding agencies to the institutions that receive federal funding. These institutions have the most direct knowledge of the technology and far greater ability to determine how to most effectively achieve practical application of the technology for public benefit. They also are able to involve the inventor in working directly with the licensee, which has proven to be an important factor in achieving successful development. It may be more beneficial in certain cases to grant exclusive or co-exclusive licenses in a specified field given the early-stage nature of these technologies and the need to attract the substantial investments necessary to fund further development to achieve commercial application. A presumption of non-exclusivity as an award requirement will certainly hinder the development of some technologies and is antithetical to the basic premise of the Act which recognizes that federal funding recipients are in the best position to determine how to achieve utilization and public benefit. Undermining this key concept is likely to have unintended consequences and would set an unfortunate precedent that threatens the ability of universities to effectively partner with industry to achieve the goals of the Act. Our concerns are not theoretical but rather based on real world experiences. We are aware, for example of several cases where licensees have terminated or declined licenses from our institutions for genetic diagnostics specifically because of the lack of exclusivity. (It is also worth noting that an exclusive license can be useful as a means of driving broad availability, since it gives the licensor the opportunity to impose wide distribution as a diligence requirement.).

We also have serious concerns about the suggestions in section **5. A. and B**. of the Report that: 1) NIH should explore making compliance with the NIH *Best Practices for the Licensing of Genomic Inventions* a condition of grant awards; and 2) HHS should issue an Executive Order clarifying that the goals of Bayh-Dole are best fulfilled in the context of genetic diagnostic tests in a manner reflected in the *Best Practices*.

COGR has repeatedly expressed the view to NIH that certain aspects of the *Best Practices* are inconsistent with the Bayh-Dole Act and inappropriate as compliance standards. In fact, the *Federal Register* Notice on the *Best Practices* (69 *FR* 67747) specifically disclaimed the intent for them to constitute additional regulations, guidelines or award conditions for any NIH contract or grant. Moreover, like the *Nine Points* document, the *Best Practices* document itself states that it "clearly and specifically articulates that the recommendations are not intended to constitute additional regulations, guidelines, or conditions of award for any contract or grant." Making any set of best practices a compliance condition raises issues of mandates and auditable prescriptive regulations, with the concomitant accountability and reporting requirements, as the discussion in the Report recognizes.

A specific example of our concern with the utilization of *Best Practices* as a compliance tool is the implication that patent protection should not be sought and exclusive licenses not be

used unless significant private sector research and development investment is required to develop and make a genomic invention widely available. As discussed previously, there are a number of reasons why universities may provide exclusive rights to particular inventions. Moreover, this again raises issues of consistency with Bayh-Dole as does the suggestion that non-exclusive licensing should be pursued as a best practice. As noted above, determining the optimal strategy for transferring genomic inventions at early stages of technology development is problematic.

6. Study Federal Implementation of Intellectual Property Laws

While we certainly support the idea of conducting further studies before taking action, we note that the Government Accountability Office (GAO), prompted in part by concerns about gene diagnostics, currently is engaged in the study discussed in section **6. B.** The study is expected to be released by this summer. If this recommendation is pursued, SACGHS should seek to assure that clear value would be added by an additional HHS study.

7. Improving and Clarifying US Patent and Trademark Office (PTO) Policy

We have no objection to HHS providing PTO with advice on technological developments related to patenting of genetic diagnostics, and with guidelines to assist PTO examiners in evaluating applications in this area. We note that the NAS Committee made a similar recommendation.

8. Options Related to Statutory Change

As with the other options, the Report fails to establish a need for the possible statutory changes discussed. Options such as denying injunctive relief in certain situations or creating exemptions for patent infringement liability for certain individuals are extreme changes to current law which should be based on compelling justification. The Report fails to provide this.

Chapter III. NIH's Technology Transfer and Data Sharing Polices

Finally, clarification of some of the points discussed in **Chapter III** under **NIH's Technology Transfer and Data Sharing Policies** also is needed. The Report discusses suggestions of the scholars cited that the Act's "exceptional circumstances" provisions are too burdensome and therefore a deterrent for NIH and other agencies to invoke the procedure. This assertion does not square with the experience of our member institutions. To the contrary, we have seen a dramatic growth in such determinations of exceptional circumstances ("DEC's) by the NIH to restrict invention title, and that these tend to be of broader scope than is necessary to accomplish the stated purpose. Further, they have often taken the form of informal or quasi-determinations that do not follow NIH's stated procedures. In some cases individual NIH programs or institutes simply have discouraged or prohibited patenting with no regard for the formal NIH or Bayh-Dole requirements.

Additionally, the discussion of march-in rights inappropriately blurs the clear distinction between march-in rights, which do not affect title to inventions, and exceptional circumstance determinations, which often do. The statement that the administrative obligations to march-in "are sufficiently cumbersome that NIH has never exercised these rights" likewise is not factually correct. Although NIH ultimately did not exercise march-in, in fact, NIH has considered three march-in petitions under Bayh-Dole and its stated reasons for denying them had nothing to do with cumbersome administrative obligations.

Conclusion

It is critically important that all proposed policy modifications be based on real evidence that patenting and licensing practices are affecting the cost or availability of genetic tests or impacting innovation. This is clearly not the case here. We therefore strongly support the idea of continuing to gather data before making any policy recommendations, and rethinking the connections between the data and the recommendations so that any future proposals are clearly necessary and limit the risk of negative unintended consequences.

Successful transfer of a nascent university technology into a product that is available for the public benefit is a collaborative effort that requires the participation of industry. Our experience shows that additional proscriptions are likely to decrease industry participation in this process. Any decrease in the participation of industry will result in fewer developments reaching the marketplace for the public benefit. We therefore strongly recommend that SACGHS seek input from industry as an important stakeholder in the technology transfer process. In addition, it could be helpful to identify some means of incentivizing industry to make gene diagnostics broadly available – a "carrot" instead of or in addition to any regulatory "sticks."

We appreciate the fact that the SACGHS and its predecessor have been studying factors affecting the adequacy and availability of genetic diagnostic tests for some time. This is an extremely important area of public policy where ongoing review and advice from experts is critical. We share the Committee's goal of fostering and promoting patient access to these important technologies while avoiding detrimental policy changes. For these reasons it also is critically important to avoid basing public policy recommendations on speculative linkages or personal belief systems that are not firmly grounded in empirical facts. Unfortunately the Report does not provide compelling evidence to support potential policy recommendations. We urge the SACGHS to reconsider the appropriateness of developing recommendations in the policy areas identified, pending development of a far more robust set of findings and conclusions that would provide the necessary basis for consideration of such options.

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