



March 17th, 2010

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius,

Universities Allied for Essential Medicines (UAEM) is a non-profit coalition of students at over 60 research institutions in the United States, Canada and Europe. We write to commend the *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* which was recently released by the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and to encourage you to adopt SACGHS's recommendations. We would also like to express our concern about the fervent opposition by industry trade groups and university technology managers to the committee's recommendations.

The purpose of the SACGHS task force was to determine if, and to what degree, contemporary patenting and licensing practices affect patient and clinical access to genetic diagnostic testing. The task force is to be lauded for executing a comprehensive, objective, scholarly report that incorporates a wide body of evidence, including empirical analyses, case studies, and comparisons with other US and international policies. The report's case studies, in particular, were carefully chosen to examine a broad range of patenting and licensing practices and understand what these practices actually accomplish for patients.

As the report details, broad patent claims and exclusive licensing terms can have adverse effects on the market for genetic diagnostics. While it is frequently contended that such practices are necessary to induce private investment to develop testing, in no case studied was an exclusive licensee first to the market with a genetic test. Furthermore, in many cases (e.g. hemochromatosis, Alzheimer's disease, breast and ovarian cancer, spinocerebellar ataxia, and long-QT syndrome), patent enforcement led to withdrawal of some laboratories – many of which were based at universities – from the marketplace. Extensive anticompetitive behavior by some firms actually “cleared” the market, such that the exclusive licensee became a sole provider (e.g. Alzheimer's disease, spinocerebellar ataxia, breast and ovarian cancer). In the case of long-QT syndrome, where treatment can depend on genetic subtype, there was no test on the market in between 2002-2004 due to patent enforcement, and only one provider (PGxHealth) from 2004-2009. In 2009 another firm (GeneDx) entered the market by securing countervailing exclusive rights not held by PGxHealth.

These behaviors have had direct effects on patient and clinical access to genetic testing. While an exclusive license does not necessarily lead to unfair test prices, a sole provider scenario interacts negatively with pre-existing reimbursement structures: patients covered by an insurer or health plan that does not have an agreement with the sole provider have no alternative place to get testing. Furthermore, monopoly scenarios set a standard of care, based on patent status instead of clinical expertise, and can hinder quality control/improvement¹ and patient access to “second opinion” testing² which are essential aspects of modern medicine.

Genetic testing for cystic fibrosis is a salutary counter-example to these unfortunate situations, as is detailed in the SACGHS report. The University of Michigan, Johns Hopkins University and the Hospital for Sick

¹ Walsh T, Casadei S, Coats KH et al. Spectrum of BRCA1, BRCA2, CHEK2, and TP53 in families at high risk of breast cancer. *Journal of the American Medical Association*. 2006;295:1379-88.

² National Research Council (2006). Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation, and public health. Washington, DC. National Academies Press.

Children in Toronto, Canada all issued non-exclusive licenses for testing of this condition. Subsequently, a robust, competitive marketplace has evolved to offer high-quality testing that is widely available and affordable to patients.

While patenting and licensing practices are certainly not the only factors affecting access to genetic testing, it is clear that exclusive licensing is integral to many of the problems detailed in the SACGHS report. Licensing in this way incentivizes a particular type of anticompetitive business model for which patients and potential business competitors have little legal recourse. To address this problem, the SACGHS recommended a limited statutory exemption from liability for anyone wanting to use gene patents for diagnostic testing. While this exemption is one of several possible solutions, the committee felt that it was a tailored solution to a problem specific to the unique market dynamics around genetic diagnostics. UAEM supports such an exemption and believes it complements US patent law by allowing market competition to work for patients' benefit. In addition, given universities' commitment to the public good, we ask you to explore mechanisms that will strongly incentivize, or if possible, oblige universities to consider the primacy of patient access and not only revenue when they license gene patents related to diagnostics.

In addition to identifying these current problems, the SACGHS task force found considerable concern by stakeholders in the field that contemporary patenting and licensing practices will threaten future innovation in genetic diagnostics. Currently, scientists can be held liable for using patented genes in their research. Moreover, the future of diagnostic testing will clearly involve robust methods of whole genome analysis.³ Broad gene-by-gene claims on DNA sequences and detection methods will clearly be infringed. When rights to the genome are fragmented, both research and diagnostic testing are threatened. Indeed, the SACGHS report and prior studies have documented cases in which medically relevant patient results are not reported to patients, due to exclusive licensing of gene patents.⁴ To address these concerns, the SACGHS recommendations include a limited statutory exemption from liability for anyone using patented genes for research. The report emphasized that this statutory exemption "is designed to permit research that can generate insights into disease, genetic tests, and therapeutics."⁵ Our organization supports such a research exemption and believes it allows clinicians to use genetic advances in the pursuit of patient care and researchers to pursue scientific inquiry freely – consistent with the US Constitution's stated aim of the patent system to "promote progress in science and the useful arts."⁶

In our organization's work exploring the impact of university licensing decisions on national and global access to health innovations, we have found a dearth of data to address our research questions. This is due to the lack of both appropriate metrics and transparency in university licensing agreements. Our experience is mirrored by other researchers exploring the relationship between patents, innovation and access.⁷ Access to appropriate empirical data is essential to inform future policy debates and decisions regarding gene patents. We support the ideas outlined in SACGHS Recommendation #3, which proposes greater public disclosure of licensing information, including field of use and scope, to open the way for innovation. Therefore, we urge you to adopt and implement the necessary measures to increase transparency in licensing of gene-based patents, particularly those resulting from federally funded research at academic institutions.

³ Lifton, R.P. Individual Genomes on the Horizon. *New England Journal of Medicine*, 2010: Mar 10 (Epub).

⁴ Huys I, Berthels N, Matthijs G, van Overwalle G. Legal uncertainty in the area of genetic diagnostic testing. *Nature Biotechnology*. 2009;27:903-9.

⁵ Please see the SACGHS final report released Feb 5, 2010, p. 90. Accessed from http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011 on March 13, 2010.

⁶ Eisenberg RS. Patents and the progress of science: exclusive rights and experimental use. *University of Chicago Law Review*. 1989;56:1025.

⁷ Toward a New Era of Intellectual Property: From Confrontation to Negotiation. A Report by The International Expert Group On Biotechnology, Innovation And Intellectual Property. Montreal: The Innovation Partnership, 2008, available at www.theinnovationpartnership.org



Madame Secretary, we are also quite concerned about the opposition to this report by industry trade groups and university technology managers. On February 4, members of the Biotechnology Industry Organization (BIO), along with representatives from the Association of University Technology Managers (AUTM) jointly sent you a letter of dissent⁸ and held a press conference sponsored by BIO,⁹ which pre-empted the public release of the SACGHS report and engaged in tactics that, we believe, misrepresent its conclusions and recommendations.

First, the dissenting organizations assert that the proposed policy changes will “undermine the foundations of American life sciences innovation.”⁸ James Greenwood, President of BIO, began his press conference with the bold statement that the SACGHS recommendations would “discourage investment... undermine research... and harm patients.”⁹ Not only is his argument unwarranted speculation, but Mr. Greenwood and his panelists also failed to clarify that the recommended liability exemptions are limited to genetic diagnostics, and that they in fact have no implications whatsoever for any other area of the intellectual property system. In keeping with Mr. Greenwood’s selective use of the facts, Brian Stanton later misquoted SACGHS Recommendation #1, leaving out the clause limiting the liability exemption to genetic diagnostics.⁹ At no point in the press conference did Dr. Stanton or another panelist mention that the exemption would, by design, have no impact whatsoever on therapeutic applications of gene patents. Indeed, they repeatedly implied the opposite. We reiterate that the SACGHS recommendations will in no way undo the Bayh-Dole Act and related legislation. They are tailored to research and development in the narrow field of genetic diagnostics, and we believe their enactment will stimulate commerce and preserve a competitive marketplace that will better ensure timely access and innovation of quality diagnostics.

Second, and more fundamentally, the aforementioned letter of dissent and press conference fail to acknowledge that there are any access problems in the first place. Claims have repeatedly been made that the recommendations are “based on claims of a crisis... that does not exist,”⁸ and that “the Committee found that access is not harmed.”⁹ These claims blatantly contradict the findings of the report and the accompanying public comments, including the tacit admission by the Committee’s own dissenting voices.¹⁰ Such claims also appeal to the “status quo” in a manner redolent of the opposition to the current healthcare reform legislation. While BIO members are important stakeholders in the health sector, they are also the most prominent financial beneficiaries from the status quo, in which access and innovation for the public good are suffering.

Third, and more practically, the dissenting organizations have called into question the scientific integrity of the Task Force and their expert consultants. For instance, Jon Soderstrom, Managing Director of the Yale University Office of Research and immediate past president of AUTM, maintained that the SACGHS case studies were “not selected by any objective, fair-minded, or even random basis, but [were] essentially hand-selected, frankly, by folks who had a point of view.”⁹ Lines of attack such as these undermine any reasonable discussion of scientific evidence and policy solutions. By all accounts, the case studies were purposefully sampled by the commissioned researchers and the SACGHS members to shed light on the intellectual property arena surrounding genetic diagnostic testing. With regard to accusations of biased membership, the published committee roster lists a diverse range of experts in the field, including clinicians, researchers, IP law experts and industry representatives. The majority, including the committee chair, has had experience in or has worked alongside industry throughout their careers.

The involvement of AUTM representative in the opposition to the SACGHS report calls into question whom they view as their true constituents and beneficiaries. On March 10, we wrote to AUTM to express the concerns that we have raised above. We also reminded them that their stance on this issue contradicts their

⁸ http://bio.org/ip/genepat/documents/SACGHSsign-onletter2-4-2010final_000.pdf. Accessed March 3, 2010.

⁹ http://www.bio.org/podcasts/020410_NPC.mp3. Accessed March 3, 2010.

¹⁰ Please see the SACGHS final report released Feb 5, 2010, lines 3676, 3684, 3698-9, and 3716. Accessed from http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011 on March 3, 2010.

endorsement of several policy statements on patenting and licensing practices – including the document *In the Public Interest: Nine Points to Consider in Licensing University Technology*¹¹ (2007) and the *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies*¹² (2009). These policy statements stress the importance of limiting non-exclusive licensing, ensuring broad access to research tools (which would include patented genes), and developing and disseminating technologies with primacy placed on the “public good.” AUTM needs to resolve this cognitive dissonance and reassure the public that they are acting in the broad interest of the public good, rather than the narrow interests of the biotechnology industry.

In conclusion, we urge the Department of Health and Human Services to continue moving forward to incorporate the SACGHS recommendations incrementally into a series of agency and statutory reforms. It is our hope that these reforms will preserve the system of knowledge-sharing that has allowed America – built largely on research performed at our stellar research universities – to be a leader in biotechnology innovation and, more importantly, that such reforms will lead to better transfer of innovations to patients.

Sincerely,

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¹¹ http://www.autm.net/Nine_Points_to_Consider.htm. Accessed March 10, 2010.

¹² <http://www.autm.net/Content/NavigationMenu/TechTransfer/GlobalHealth/statementofprinciples.pdf>. Accessed March 10, 2010.