



March 17, 2010

Arundeeep Pradhan  
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Association of University Technology Managers  
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Dear Mr. Pradhan,

Following up on our March 10, 2010 letter to which we did not receive a satisfactory reply, we once again reiterate our call on you and AUTM to publicly retract your opposition to the gene patenting recommendations recently made to Secretary of Health and Human Services Kathleen Sebelius. Our concerns are once again stated below.

On February 5, 2010, the United States Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) released a report titled *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*.<sup>1</sup> The report includes recommendations that address the impact of gene patents and licensing practices on clinical and patient access to genetic diagnostic testing.

On the eve of the release of the SACGHS report, you as president of AUTM, jointly with the President of the Biotechnology Industry Organization (BIO) and other members of industry sent a letter to Kathleen Sebelius, Secretary of Health and Human Services, urging her to reject the recommendations outlined in the SACGHS report<sup>2</sup>. On that same day, a representative of AUTM, Dr. Jon Soderstrom, Director of the Office of Cooperative Research at Yale University and immediate past president of AUTM, participated in a BIO-sponsored press conference<sup>3</sup>. We believe that neither the letter of opposition nor the press conference fairly addressed the SACGHS report's conclusions and recommendations. Furthermore, AUTM's stance on this issue is in fundamental conflict with its past policies and its role as an organization representing university technology transfer managers who, as members of the non-profit university community, should represent researchers and the public interest. For the reasons outlined below, we are calling on AUTM to retract its opposition to the SACGHS recommendations and reaffirm that it intends to represent the interests of its university constituents on issues of gene patenting and licensing for diagnostic tests.

The SACGHS task force was commissioned to perform an in-depth assessment of whether, and to what degree, gene patenting and licensing practices affect clinical and patient access to genetic diagnostic testing. The resulting comprehensive and scholarly report incorporates a wide body of evidence, including empirical analysis, commissioned case studies, and extensive expert and public consultations. The report's case studies, in particular, were purposefully sampled to examine a broad range of patenting and licensing practices and to understand what these practices are actually accomplishing for patients.

The report concludes unequivocally that broad gene patent claims and exclusive licensing terms can have adverse effects on the market for genetic diagnostics and on clinical and patient access to genetic testing. SACGHS carefully deliberated a range of policy solutions, and their final recommendations draw directly from the report's conclusions. These recommendations are focused policy reforms tailored to improve

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<sup>1</sup> See the SACGHS final report released Feb 5, 2010. Accessed from [http://oba.od.nih.gov/SACGHS/sacghs\\_documents.html#GHSDOC\\_011](http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011) on March 3, 2010.

<sup>2</sup> [http://bio.org/ip/genepat/documents/SACGHSsign-onletter2-4-2010final\\_000.pdf](http://bio.org/ip/genepat/documents/SACGHSsign-onletter2-4-2010final_000.pdf). Accessed March 3, 2010.

<sup>3</sup> [http://www.bio.org/podcasts/020410\\_NPC.mp3](http://www.bio.org/podcasts/020410_NPC.mp3). Accessed March 3, 2010.

patient access to essential diagnostic services while maintaining the aims of the Bayh-Dole Act and the current U.S. regime of intellectual property and life sciences innovation.

It is unfortunate, then, that the content of the opposition letter and press conference in which AUTM members participated grossly misrepresents the conclusions and recommendations of the SACGHS report. Three erroneous claims were made in the letter and media event, namely:

1. *The proposed policy changes will “undermine the foundations of American life sciences innovation,”<sup>2</sup> by “discourage[ing] investment... undermin[ing] research... and harm[ing] patients.”<sup>3</sup>* This is unwarranted speculation and lacks empirical support. What is more problematic, however, is that there is no distinction in this argument between the limited reforms that SACGHS recommends for genetic diagnostics, and the whole system of intellectual property protection and technology transfer which will certainly remain otherwise intact.
2. *There are no access problems in the first place.* It is stated, for example, that the SACGHS report is “based on claims of a crisis... that does not exist,”<sup>2</sup> and that “the Committee found that access is not harmed.”<sup>3</sup> 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.<sup>4</sup>
3. *The scientific integrity of the SACGHS task force and expert consultants is questionable.* Dr. Jon Soderstrom proposed that the 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.”<sup>3</sup> This type of argument precludes 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. Furthermore, the published committee roster lists a diverse range of experts in the field, including clinicians, researchers, IP law experts and industry representatives. The majority of committee members, including the committee chair, has experience in or has worked alongside industry throughout their careers. In fact, such a diverse group is less likely to have a single-minded, biased “point of view” than a group of opposing industry representatives with a clear financial stake in the status quo.

If indeed AUTM seeks to widely disseminate the fruits of university research, its participation in the opposition to SACGHS raises several questions. First, several studies have found that the majority of patents used in anticompetitive behavior originate from universities.<sup>1</sup> In joining the opposition to SACGHS’ report, is AUTM disavowing any problems with its members’ deals? If these licenses were not problematic, what other justification can AUTM provide, besides perhaps revenues? If these licenses, from AUTM’s standpoint, were in fact problematic, what assurance can it provide that similar mistakes will not be made in the future? Critically, why did AUTM sign on to a statement of dissent rather than suggest alternative solutions?

Moreover, AUTM has previously signed onto policy statements that contradict its current stance on patenting and licensing for genetic diagnostics. For instance, in the 2007 document *In the Public Interest: Nine Points to Consider in Licensing University Technology*, AUTM endorsed the following principles:<sup>5</sup>

- The right for all universities, non-profit companies, and government organizations to practice university-licensed technologies (Point 1)
- Limited use of exclusive licenses, including shielding healthcare providers and researchers from infringement liability (Point 2)
- Broad access to university research tools (Point 5)

<sup>4</sup> 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](http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011) on March 3, 2010.

<sup>5</sup> See [http://www.autm.net/Nine\\_Points\\_to\\_Consider.htm](http://www.autm.net/Nine_Points_to_Consider.htm). Accessed March 10, 2010.



- Careful use of enforcement actions<sup>6</sup> (Point 6)

Similarly, AUTM signed on to the 2009 *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies* (SPS).<sup>7</sup> The SPS affirmed the role of universities and their technology managers in “developing and disseminating [their] technologies for the public good,” and acknowledged that “intellectual property should not become a barrier” to access. Yet when the SACGHS recommended limited liability exemptions to protect researchers and improve patient access, AUTM was opposed.

It is regrettable that AUTM has chosen to solely align itself with a particular industry lobby group rather than also take into account the views and needs of scientists, healthcare providers, and patient groups as presented by an independent government task force – not to mention the non-profit mission of the universities which employ many of its members. This is not the first time, however, AUTM has brought into question the independence of the organization from industry. During the 2008 WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation, and Intellectual Property negotiations, AUTM issued a concerning statement that seemed to imply that WHO should not explore innovative mechanisms to improve access and innovation. Fortunately, AUTM chose to clarify its position on access and innovation by withdrawing its statement.<sup>8</sup>

AUTM has made a commitment to further knowledge and innovation for the public good. Mr. Pradhan, as President of AUTM and signatory of the dissenting letter to Secretary Sebelius, we call on you and AUTM’s Board of Trustees to rectify AUTM’s discordant views on the role of university technology transfer and provide clear support for patenting and licensing gene-based diagnostics in the public interest. Importantly, AUTM must immediately retract its endorsement of the dissent.

Thank you in advance for your consideration of our concerns. We look forward to your response.

Sincerely,

Ethan Guillen  
Executive Director, Universities Allied for Essential Medicines

David Watkins  
MD Candidate (2010), Duke University School of Medicine  
Coordinating Committee Member, Universities Allied for Essential Medicines

CC: AUTM Board of Trustees

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<sup>6</sup> We take the spirit of this recommendation to mean that blatantly anticompetitive behavior by licensees, such as has been found with exclusive licensees mentioned in the SACGHS report, is inconsistent with the intent of the university-developed innovations.

<sup>7</sup> See <http://www.autm.net/Content/NavigationMenu/TechTransfer/GlobalHealth/statementofprinciples.pdf>. Accessed March 10, 2010.

<sup>8</sup> See <http://www.genomeweb.com/biotechtransferweek/autm-retracts-e-mail-seen-opposing-who-plans-increase-third-world-drug-access>. Accessed March 10, 2010.