

# OSR FOCUS on Legislative Affairs

## A Resource for OSR Representatives



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Tomorrow's Doctors, Tomorrow's Cures

### LabCorp vs. Metabolite

by Robert Hollowell

Though not particularly well publicized within the medical community, the recent case of LabCorp vs. Metabolite has garnered considerable attention and generated buzz among manufacturers of medical products and scholars of patent law. The case was slated for consideration by the U.S. Supreme Court but was dismissed June 22<sup>nd</sup> when the Court ruled 5-3 on a technicality that the previously granted *writ of certiorari*, necessary for the Court to hear the case, had been "improvidently granted." This decision leaves LabCorp's questions concerning the interplay of medical science with patent regulation unresolved; the ramifications of a verdict either way would have the potential to significantly impact the practice of medicine.

The law suit began in 1998 when LabCorp allegedly violated a patent exclusively licensed to Metabolite Laboratories Inc. and Competitive Technologies Inc. when LabCorp stopped paying royalties to the patent holders related to a test for homocystiene levels. At issue is the question of whether LabCorp can correlate elevated homocystiene levels as determined by their own proprietary testing methods with cobalamin or folate deficiency. Further, it has been suggested that if the patent is construed in the manner upheld by the lower courts in Metabolite's favor, it might be a violation of the patent for any physician, seeing an elevated result from a homocystiene level test, to draw the conclusion that the patient may have a vitamin deficiency. See *Labcorp pg 2*

### Interview with Michael J. Murray, MD, PhD

By: Katie Iossi

Michael J. Murray, M.D, Ph.D. is a Professor and Chair of the Department of Anesthesiology at Mayo Clinic Jacksonville. In addition to caring for patients, conducting research, and teaching, he is also an important part of Mayo Clinic's legislative affairs team. Recently I had the chance to pose a few questions on policy and medical students to Dr. Murray. See *Murray Interview pg 3*

### Patient Safety and Quality Improvement Act

By Mike McNeely

On July 9 2005, President Bush signed into law the Patient Safety and Quality Improvement Act. The intent of the law is to establish an anonymous means of reporting medical errors, thereby providing data for analyses of healthcare systems and protocols.

The Patient Safety and Quality Improvement Act was drafted in response to a 1999 report by the Institute of Medicine entitled "To Err is Human." This report asserts that as many as 98,000 unnecessary deaths occur every year as a result of iatrogenic error. See *Patient Safety pg3*

### FOCUS Explainer: Title VII Decoded

By: Robert Hollowell

For medical students, faculty, and others in the academic medical community, among the most concerning aspects of the 2006 and proposed 2007 budgets are the severe rescissions in funding for a group of programs commonly referred to as "Title VII." The 2006 budget cut funding for Title VII programs by over 50% from about 300M to just over 145M. While the president's proposed budget cut all Title VII funding except 10M for Scholarships for Disadvantaged Students, both the House and Senate, perhaps persuaded by strong advocacy on behalf of the AAMC and other stakeholders, have approved slight increases for 2007 from 2006 levels, but far short of 2005 funding. The dramatic volatility in funding for these programs begs the question, what are these Title VII programs? Hopefully, this article will provide you the background necessary to follow the ongoing debate over Title VII funding.

Title VII of the Public Health Service Act (42 U.S.C. 292-295p), in combination with Title VIII which focuses on the nursing workforce in the US, authorizes funding for about 40 programs administered by the Department of Health and Human Services (HHS). In general, these programs promote health education and training through financial assistance for both students and institutions. See *Title VII pg 2*

### **LabCorp** (con't from pg 1)

Briefly, the patent issued to Metabolite protected several claims concerning homocystine level testing including the controversial Claim 13 which reads "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." The federal circuit court found that LabCorp had in fact violated the patent and ordered the company to pay \$5 million in royalties to the patent holders. This ruling was upheld in the appellate court before being dismissed by the Supreme Court on technical grounds, without drawing conclusions on the key issues at hand.

A brief prepared on behalf of the AAMC, AMA, and several other physician groups argued that the Supreme Court should overturn the lower courts by ruling in favor of LabCorp on the basis that the patent issued to Metabolite claims not a process or method, but rather an unpatentable scientific fact or law of nature. The brief further charges that the claim is overbroad citing the interesting precedent of Samuel Morse's patent on the telegraph. In his original patent application, Morse claimed among other developments, "the use of the motive power of the electric or galvanic current, which I call electro-magnetism, *however developed* for marking or printing intelligible characters, signs, or letters, at any distances." This claim was disallowed because it serves not to encourage technological development, as patent laws are intended to do, but rather, to stifle innovation by preventing anyone from using electric current for communication across a distance without Morse's permission. Had Morse's patent been enforced, it would have impeded the technological progress which drove today's telecommunications revolution.

The opinion filed by the three dissenting judges called for the court to reexamine the case to clarify regulations governing the interface between medical science and patent law. Having revealed at least a minority interest in grappling with these issues, the Court can expect to be presented with similar cases in the near future, and may soon provide guidance on what components of medical practice are, in fact, patentable.

To read the dissenting opinion, go to:

[www.supremecourt.us/opinions/05pdf/04-607.pdf](http://www.supremecourt.us/opinions/05pdf/04-607.pdf)

Or to read the AAMC brief:

[www.aamc.org/advocacy/library/research/corres/2005/1223\\_05.pdf](http://www.aamc.org/advocacy/library/research/corres/2005/1223_05.pdf).

### **Title VII** (con't from pg 1)

The majority of the Title VII programs seek to achieve one of three interconnected goals: expanding the supply of primary care health professionals, promoting diversity in the physician workforce, and encouraging distribution to underserved urban or rural areas.

The first set of provisions in this title is devoted to the establishment of institutional need-based student loan programs for students training in allied health professions. In addition to establishing these loans, termed Health Professions Student Loans (HPSL), the legislation authorizes the Loans for Disadvantaged Students (LDS) and Primary Care Loans (PCL) programs by allowing allocation of federal funds to support institutional student loans for students who come from disadvantaged backgrounds or for physicians who promise to practice in primary care for at least 4 years or the life of the loan. These loan programs are self-sustaining once the pool of funds from which loans are granted is established so no federal contributions are necessary on an ongoing basis. Also, while these loans have been less attractive in the recent era of historically low interest rates for Stafford Loans, with the new fixed 6.8% Stafford rates, the PCL and LDS loan programs at medical school may have a resurgence in popularity. One of the proposed title VII cuts would force schools to return the federal portion of any uncommitted loan funds, estimated at \$109M. This recall of funds could impact the ability of schools to expand their programs as options for alternative loan funds change.

The next part of Title VII aims to support programs that improve health professions education for underrepresented minority individuals by providing grants to qualified institutions either as Centers of Excellence (COE) or for specific purposes. COE grant dollars can be allocated to programs which: develop the minority applicant pool, improve programs to support under-represented minority students once enrolled, enhance training of under-represented minority faculty, strengthen cultural competence and minority health curricula, or facilitate research on health issues disproportionately affecting under-represented minority groups. Eligible institutions must have a history of success in serving under-represented minorities and qualify as either an Historically Black University, a Native American or Hispanic COE, or have a proportion of under-represented minorities that is greater than the national average for health professions schools. Additional grants are available for specific programs which support individuals from disadvantaged backgrounds either through educational assistance in preparation for health professions training, scholarships for students in training, and loan repayment programs and faculty fellowships after

completion of training. Grants are authorized for programs which aim to improve the training of all students in addressing health disparities and improving cultural competence.

Addressing the need for enhanced primary care and rural medicine training, the third part of Title VII authorizes funding to support training programs which emphasize the practice or teaching of primary care disciplines for physicians, physician assistants, and dentists. Priority in granting such awards is given to programs with a history of training individuals from disadvantaged background, preparing trainees to care for underserved populations, and producing graduates who remain in primary care fields.

The remainder of the Title VII legislation focuses on interdisciplinary care and geographical workforce distribution. Grant support is made available for the development of Area Health Education Centers (AHEC's) which aim to meet the primary care needs of underserved communities while providing educational and training opportunities. Similarly, to meet the needs of an ageing population, grants are authorized to establish Geriatric Education Centers to provide education and training for health professionals in the field of geriatric medicine. Additional grant programs established include the Quintin Burdick Program for Rural Interdisciplinary Training grants, available for funding innovative interdisciplinary models of rural health delivery, and Allied Health grants to support the training of allied health professionals for service in underserved areas or in fields experiencing personnel shortages.

To continually assess the success of these programs and to foresee future needs in maintaining a stable physician workforce, the Secretary of Health and Human Services is authorized to contract research on workforce infrastructure and the Council on Graduate Medical Education (COGME) is established to function in an advisory role in this ongoing process. Finally, Title VII aims to bolster public health education by granting schools funding to support public health training centers and traineeships for students as well as to promote programs in preventative medicine and health administration.

If you are interested in learning more about programs at your school or in your state that are funded through Title VII, check out the Profiles of Success series at:

[www.aamc.org/advocacy/laborhhs/healthprof/profiles.htm](http://www.aamc.org/advocacy/laborhhs/healthprof/profiles.htm)

Or read about current funding status and AAMC advocacy at:

[www.aamc.org/advocacy/laborhhs/healthprof/start.htm](http://www.aamc.org/advocacy/laborhhs/healthprof/start.htm)

### **Patient Safety** (con't from pg 1)

(A link to a summary of the IOM report is provided below.) The AAMC was among several medical and academic organizations that endorsed the bill.

As directed by the new law, the U.S. Department of Health and Human Services will certify one or more public or private entities as patient safety organizations (PSOs), to be governed by the Agency for Healthcare Research and Quality. These organizations will provide channels through which physicians, medical students, nurses, and other healthcare professionals can report instances of medical error without fear of legal or professional repercussions. Then, in conjunction with the PSOs, HHS will analyze the data and make recommendations based upon any patterns observed.

Involvement in the program is voluntary, and strict privacy measures were incorporated into the final draft of the law, to shield those reporting medical errors. The database established by HHS:

*"Will not be subject to Federal, State or local civil, criminal or administrative subpoena;*

*Will not be subject to discovery in Federal, State or local civil, criminal or administrative proceedings;*

*Cannot be disclosed per the Freedom of Information Act (section 552 of Title 5, United States Code) or any other similar law.*

*Cannot be admitted as evidence or otherwise in civil, criminal or administrative proceedings; or*

*Cannot be used in disciplinary proceedings against a provider."*

For more information on this topic, check out:

U.S. Department of Health and Human Services:

[www.hhs.gov](http://www.hhs.gov)

Agency for Healthcare Research and Quality:

[www.ahrq.gov](http://www.ahrq.gov)

*To Err is Human:*

[www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf](http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf)

### **Murray Interview** (con't from pg 1)

**KI: What is your involvement in legislative affairs and policy work? How did you become involved? How do you balance it with patient care, teaching, and research?**

MM: For 10 years, I was the physician chair of the Mayo Clinic Rochester's Committee for Public Affairs, in Minnesota, but we also monitored and were involved with, legislative activities in Wisconsin and Iowa. I became involved because I had been President of the Minnesota Medical Association and I had been asked by Mayo Clinic

### **Murray Interview** (con't from pg 3)

because of my contacts through the state to become active on the committee. There was recognition that the legislature in Minnesota was increasingly passing laws that were adversely affecting Mayo Clinic and, therefore, a stronger lobbying effort was needed. Balancing my involvement in legislative affairs with patient care, teaching, and research wasn't easy, but I was able to do so, maintaining a busy patient practice, writing textbooks, and conducting NIH-sponsored research. There was never enough time in the day, but because of the importance of the legislative activities, I felt it had to be done. In 1999, I assumed a similar role for our federal affairs activities.

#### **KI: Why is it important for medical students and physicians to be knowledgeable about and involved in policy-making?**

MM: If physicians and physicians-to-be are not involved, then the legislature will pass laws based on other interest groups' best intentions. Lacking a physician response, the legislators may not be aware of the effects of healthcare policy changes on patient care.

#### **KI: As you know, medical students are busy. Do you have advice on how we can work to be knowledgeable about current policy debates and continue to do so as physicians?**

MM: This is a tough one, because my observation is that medical students who are very involved do poorly in medical school. Medical education comes first, but rather than after school going out and throwing a Frisbee, one could at least, at a minimum, monitor newspapers, magazines such as *JAMA (Journal of American Medical Association)*, and again at a minimum, send off a letter to your state representative, congressman, or senator if either the state or federal government is passing legislation that will adversely affect you and your choice of career, or the patients for whom you provide care.

#### **KI: How can medical students and physicians influence policy discussions and actual legislation? Can we make a difference?**

MM: From personal experience, I know we can make a difference. One has to be careful when lobbying legislators not to lecture them nor advocate too much for financial issues, but for what is best for patients.

#### **KI: What do you hope to see happen in the future of the healthcare system?**

MM: I hope patients take more responsibility for their own healthcare and well being, to obtain universal access, with the mechanism to pay for care for all.

### **Supplemental Interview: Dr. Fitzhugh Mullan**

As an additional contribution to this series of interviews with physician-policymakers, Katie Iossi interviewed Dr. Fitzhugh Mullan, a leader in health policy, academic medicine, and community health practice. Dr. Mullan holds appointments in both the School of Medicine and the School of Public Health and Health Services at George Washington University, practices in a community health center in DC, and serves as an editor of *Health Affairs*, a premiere health policy journal. In the interview, he discusses his career from Mississippi to Chicago, New York City, New Mexico, Washington, DC, India, Ghana, and beyond. He also discusses his views of the challenges facing the healthcare system and why he thinks medical students are so important to improving it. In order to include the interview in its entirety, the transcript has been placed on the OSR Web site:

[www.aamc.org/members/osr/mullaninterview.pdf](http://www.aamc.org/members/osr/mullaninterview.pdf)

Check it out!

For questions, please contact:

#### **OSR Legislative Affairs Committee:**

**National Delegate:** Katie Iossi, [katherineiossi@uiowa.edu](mailto:katherineiossi@uiowa.edu)

**Past National Delegate:** Robert Hollowell, [rph6@duke.edu](mailto:rph6@duke.edu)

#### **Regional Delegates:**

**Northeast:** Chris Langhammer, [langhach@umdnj.edu](mailto:langhach@umdnj.edu)

**Central:** Katie Iossi, [katherine-iossi@uiowa.edu](mailto:katherine-iossi@uiowa.edu)

**South:** Bryan Harris, [bryan.d.harris@vanderbilt.edu](mailto:bryan.d.harris@vanderbilt.edu)

**West:** Harlan Gallinger, [harling@u.washington.edu](mailto:harling@u.washington.edu)

#### **OSR STAFF:**

Ally Anderson, OSR Senior Staff Associate,  
[aanderson@aamc.org](mailto:aanderson@aamc.org)

Denine Hales, OSR Administrative Assistant,  
[dhales@aamc.org](mailto:dhales@aamc.org)

Association of American Medical Colleges  
2450 N Street, N.W., Washington, DC 20037-1127

For information on the OSR, visit: [www.aamc.org/osr](http://www.aamc.org/osr)