

## ***THE ASSOCIATION OF PATHOLOGY CHAIRS***

***www.apcprods.org***

Report to the Intersociety Pathology Council

March 3, 2009

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Governance: The Association of Pathology Chairs has sections for the Chairs of LCME-accredited institutions, and their residency program directors (PRODS), pathology department administrators (PDAS) and course directors (for curricula for the medical school, newly established in 2005). In addition, Chairs of hospital departments and affiliates of LCME-accredited institutions participate.

Leadership: APC's President is Dr. Charles Jennette. Dr. Tristram Parslow is the Secretary-Treasurer. APC is managed in the ASIP office.

Meetings: The APC annual meeting is held each July. The theme currently varies over a three-year cycle from practice and management (the theme in 2006) to undergraduate medical education (the theme in 2007) to graduate medical education (the theme in 2008). The 2009 meeting will be in Seattle, Washington from July 15-17 and the theme will be practice and management. In addition, regional meetings are held each year in the Fall/Winter for the Northeast, Southeast, and West/Mid-West groups.

APCREG: In 2003, APC established the Research and Education Group (APCREG). In 2005, APCREG issued two 18-month awards of \$25,000 each for projects in pathology education. In 2009, as part of a new 5-year strategic plan, APC will re-evaluate how it can best meet the mission of APCREG.

Pathology Fellowship Guidelines: In 2008, with the cooperation of residency groups within ASCP and CAP, as well as a leadership group within APC, APC created a consensus set of guidelines for accepting pathology fellowship applications and making candidate offers using a standard application and schedule of events. Fellowship directors advertising in the ICPI Directory of Pathology Training Programs were asked to indicate whether they would use the guidelines in their 2010/2011 application process. The new data regarding fellowships using or not using the guidelines will be revealed in the forthcoming ICPI directory.

Public Advocacy: In 2006, APC launched a public advocacy program and established an *ad hoc* committee, which meets monthly to discuss issues of importance within their departments and among other Pathology societies on whose committees they serve. The APC Advocacy Committee views its role as bridging interests throughout the Pathology community and providing academic expertise and leadership to issues, particularly when it is strategically useful to academic Pathology and to Pathology as a whole. The issues currently active on the Committee's agenda: developing Pathology's role in the newly legislated health information technology agenda and in health care reform (medical homes and other models); monitoring regulatory affairs and payment issues (in concert with CAP's Economic Affairs Committee and AMP's Professional Relations and Coding Committees); generating a statement on direct-to-consumer genetic testing; and surveying the APC membership on general practice management and research standards annually. To view the full public report of the APC Advocacy Committee (issued July 2008), please see the attached document.

# ASSOCIATION OF PATHOLOGY CHAIRS

## AD HOC ADVOCACY COMMITTEE

### REPORT OF ACTIVITIES: JULY 2007 – JUNE 2008

**Donald Karcher, M.D., Chair**

Over the past twelve months, the APC Ad Hoc Advocacy Committee conducted a total of eleven meetings (one at the 2007 summer meeting and ten by conference call). The following are major items and issues addressed by the Committee:

1. **CMS Medically Unlikely Edits (MUEs)**

Throughout the year, the Advocacy Committee continued to closely follow the issue of CMS Medically Unlikely Edits (MUEs), part of CMS's National Correct Coding Initiative (NCCI). Dr. Steve Black-Schaffer, CAP Economic Affairs Committee (EAC) Liaison to the Advocacy Committee, and other Committee members kept the Committee informed of efforts by the CAP and other organizations to challenge the MUE initiative. A major line of defense by the CAP continued to be a recommendation to CMS to form an advisory committee, made up of representatives of the pathology community and other relevant experts, to advise CMS and its subcontractor (Correct Coding Solutions, LLC) on the development and implementation of MUEs. Dr. Black-Schaffer and George Kwass of the CAP met in October with CMS officials, to make a series of recommendations regarding MUEs. Although the meeting seemed to go well, CMS has still not formally accepted the recommendations and has outright rejected formation of an advisory committee. CMS and its subcontractor continue to keep the proposed MUE codes and levels secret, preventing the laboratory community from being able to judge the workability of the edits.

2. **AMA/PPI Practice Expense Survey**

The Committee closely monitored the development and implementation of the AMA/PPI (Physician Practice Information) Practice Expense Survey. This survey was conducted for the AMA by the Gallup Organization, with the data collected to be used by the AMA, CMS, and other national policy makers in setting fee schedules and developing other regulatory policies. A pilot of the survey was conducted during the winter of 2007 and the full survey started in the spring of last year. Dr. Black-Schaffer gave a series of presentations at last year's APC Summer meeting, encouraging academic pathologists and departments to complete the survey. By fall, participation by pathologists overall appeared to be among the highest of any specialty (~10% response rate). Indications are that the trend line for pathology expenses is not looking positive for pathology, but the full survey results are not expected to be released until the end of 2008. The CAP has considered sponsoring its own smaller-scale pathology-focused survey of practice expenses, as a counterpoint to the wide-ranging AMA/Gallup survey.

### 3. **Part A Reimbursement**

The Advocacy Committee joined forces with the Practice and Management (P&M) Committee to study the issue of Part A reimbursement. Working together, the two committees developed a detailed survey instrument to collect appropriate data from academic departments, to inform the issue and provide guidance to chairs in their negotiations for Part A revenue. Before distributing to all APC members, the survey was distributed to members of the P&M Committee and leaders of PDAS for feedback. The feedback received indicated that the survey instrument, as written, was too detailed and would take several hours of work for each department to complete, probably resulting in a low response rate. It was also stated that June is not a good month for most departments to complete such a survey, because of ongoing departmental budget deliberations in preparation for the new academic year. Based on this feedback, it was decided to attempt to get PDAS leaders and P&M Committee members together at the Colorado Springs meeting, to discuss how to proceed. The consensus is that any survey of this type must have the support of PDAS (because, ultimately, department administrators typically complete surveys such as this) and should be designed together with PDAS leaders. It was also decided to seek input from “friendly” hospital administrators, to determine what type of data they would view as supporting a higher Part A payment.

### 4. **SACGHS (Secretary’s Advisory Committee on Genetics, Health, and Society)**

The Advocacy Committee, working closely with the Association for Molecular Pathology (AMP), closely monitored this issue. SACGHS was formed in 2006 by the Secretary of Health and Human Services (HHS) to study the development and use of genetic testing and to make recommendations to the Secretary for possible increased regulation of genetic testing. In March of 2007, the Secretary charged SACGHS to produce a focused report on its findings. A draft SACGHS report was released in November for public comment. In December, both the APC and AMP sent detailed letters to Dr. Reed Tuckson, Chair of SACGHS, outlining concerns and making recommendations. The following were major concerns and/or comments:

- **Definition of a Genetic Test** – The SACGHS report did not properly define a “genetic test”, allowing almost any molecular (e.g. involving DNA, RNA, or protein) analysis to be including in any new regulation.
- **Genetic Tests Are Not Intrinsically Different From Other Laboratory Tests** – The SACGHS report appeared to propose a higher level of oversight for genetic tests than for other laboratory tests, even though these tests are similarly “molecular”, laboratory-developed, complex, and potentially high-risk. It is recognized that genetic tests are potentially more susceptible to misinterpretation and less likely to have other corroborating or confirmatory tests available, but at a technical level these tests are not different from other laboratory tests and should not require more stringent technical and testing personnel standards than other similarly complex tests.
- **Laboratory Personnel Standards** – Pathologists with special training in molecular pathology and more specifically accredited training in Molecular

Genetic Pathology (with co-certification by the ABP and Amer. Board of Medical Genetics) are qualified to oversee the analytical aspects of genetic testing, interpret the results of these tests, and advise on the diagnosis, treatment, and management of patients with genetic disease. Likewise, appropriately trained and experienced laboratory personnel, as defined by CLIA, are qualified to perform the technical aspects of genetic testing.

- Quality Assurance, CLIA, and FDA Regulations – Genetic laboratory practice should not be subject to additional subspecialty accreditation. Current CLIA regulation of genetic testing, similar to all high-complexity laboratory testing, should be adequate to assure quality; additional oversight by the FDA or other regulatory agencies is not necessary. This should not deter expanded proficiency testing programs or improved oversight of direct-to-consumer marketing of clinically dubious “genetic” tests.
- Proficiency Testing – There is support for the proposed expansion of proficiency testing for genetic tests, including expanded availability of proficiency testing materials for rare genetic disorders.
- Clinical Validity – Clinical validity should continue to be determined through use of the peer-reviewed literature, consensus statements by appropriate practice organizations (e.g. CAP and AMP), and collaborative studies by the CDC and other agencies.
- Voluntary Test Registry – It is very important that there to be a detailed registry of genetic tests performed by laboratories and that this registry should be publically accessible (such as the current CLIA-mandated test registry, but made more public); however, this registry should be voluntary, without the need to establish a new mandatory registry system.

The final SACGHS report was released in April and continued to contain some provisions opposed by most of the laboratory community. CAP formed a small coalition, which includes the APC, and has requested a meeting with the Secretary of HHS to discuss the laboratory community’s concerns.

##### 5. **Proposed Changes in the USMLE by the NBME**

The National Board of Medical Examiners (NBME) is in the process of considering changes in the USMLE. The NBME, in concert with the Federation of State Medical Boards (FSMB) and ECFMG, formed the Committee to Evaluate the USMLE Program (CEUP), to look into possible changes in the USMLE, in response to recent changes in medical education and medical practice. Dr. Peter Scoles, Senior Vice President, Assessment Programs, for the NBME, was identified as the contact for comment on this change process. Dr. Jim Crawford, on behalf of the APC, sent a letter to Dr. Scoles expressing concern regarding these possible changes. Drs. Karcher and Crawford attended two separate meetings with Dr. Scoles, the outcome of which was 1) an admission that the basic science community had not been adequately consulted in the earlier stages of this process and 2) a pledge by the NBME to solicit additional input from the basic science community and other stakeholders. As a result, Dr. Scoles is scheduled to attend the Colorado Springs meeting and discuss the change process and receive input from the academic pathology community.

6. **Cytopathology Proficiency Testing**

The Committee closely monitored the ongoing debate dealing with the issue of Federally-mandated cytopathology proficiency testing and participated in discussions regarding the respective positions of the CAP and ASCP. A modified version of H.R. 1237 (the Cytology Proficiency Improvement Act of 2007) was ultimately considered by Congress and members of the Advocacy Committee (e.g. Dr. Dan Remick) were part of a CAP-sponsored team that met with members of Congress to advocate for this legislation and a corresponding Senate Bill.

7. **Increasing Competition from Non-Pathologists and Non-Traditional Pathology Organizations**

The Committee started looking into the issue of competition from non-pathologists and non-traditional pathology organizations. This competition will not only affect revenue generation by more traditional pathology practices, including academic departments, but will clearly compromise the training of house staff and students, as relevant case material is no longer submitted to academic departments, and for the same reason will potentially affect research based on this material. The Committee decided to make this a priority for its 2008-2009 term, with the idea that the issue may be appropriate for a far-reaching discussion at the 2009 APC Summer meeting, the theme of which will be Practice and Management. The Committee will introduce this issue at its meeting in Colorado Springs and solicit thoughts and ideas from attendees at that meeting.

8. **AMA Section on Pathology**

The Committee closely monitored issues under consideration by the AMA Section on Pathology. Dr. Greg Threatte is currently a member of the AMA Section on Pathology and kept the Committee informed of developments. The Advocacy Committee produced a position paper on several of these issues.

9. **AFIP**

The Committee continued to closely monitor the status of the AFIP. The much-awaited GAO report on the AFIP was released, but the conclusion reached in the report was not favorable to maintenance of the AFIP in the Department of Defense. That notwithstanding, the Defense Reauthorization bill passed Congress with language supporting establishment of a Joint Pathology Center in the DoD, which would consist of many key elements of the current AFIP. In June, through the efforts of the AFIP Coalition, of which APC is a member, language was added to the Emergency Supplemental Appropriations Bill to prevent the DoD from spending any funds to disestablish, reorganize, or relocate the AFIP until the Joint Pathology Center is established. Dr. Bill Gardner, Executive Director of the American Registry of Pathology, has been invited to give a report on the status of the AFIP at the Colorado Springs meeting of the Advocacy Committee.

#### 10. **Potential Role for Pathology in the “Medical Homes” Pilot Program**

Dr. Crawford introduced this issue to the Committee. The discussion revolved around the search for a potential role for pathology in the MedPAC-proposed “medical homes” pilot program for primary care. Dr. Crawford noted that he has gotten positive feedback on pursuing this issue from Dr. Jared Schwartz, President of CAP, and the issue is definitely on the mind of the AAMC, based on an AAMC Council meeting he attended. This issue will continue to be pursued by the Committee.

#### 11. **NIH Budget**

Dr. Karcher represented the APC at this year’s annual meeting in June of the National Caucus of Basic Biomedical Science Chairs (NCBBSC). The major agenda item for discussion and for the multiple meetings held on Capitol Hill involving Caucus representatives and Congressional staff members was the NIH budget. There was general consensus that nothing more than a minor budget increase is likely to be approved until at least the “lame duck” period immediately following the upcoming national elections, or possibly even until the new presidential administration takes office and the next Congress is in session. There is, however, considerable optimism that the NIH will get a substantial budget increase under the new administration and Congress. Late in June, language was added to the Science Package in the Supplemental Appropriations Bill that would provide \$150 million in additional funds for the NIH and \$62.5 million for the National Academy of Sciences. Dr. Karcher will maintain this issue as a regular item on the Committee’s agenda.