AMA HOUSE OF DELEGATES
APCR DELEGATE'S REPORT
JUNE 10, 2015

The Annual Meeting of the American Medical Association (AMA) House of Delegates (HOD) was held in at the Hyatt Regency Chicago Hotel in Chicago, IL from June 6 through June 10. As usual, resolutions and reports regarding pharmaceuticals and medical devices were a significant part of the meeting agenda. Among more than 120 national medical specialty societies (and more than 50 state and territorial medical societies) represented in the AMA House of Delegates our Academy of Physicians in Clinical Research (APCR) is the only one for which pharmaceutical and medical device research is the primary focus.

Outgoing AMA President Bob Wah announced that AMA membership has increased for the fourth straight year.

AMA Executive Vice President (EVP) Jim Madara is a former Dean of the Medical School at the University of Chicago. He highlighted AMA's partnership with 11 medical schools to create the medical school of the future. Examples he cited were work with the University of Oregon to develop a combined specialty in medicine and informatics as well as work with Vanderbilt to build an electronic "home" for each medical student's portfolio. This home includes: competency-based assessments, experience logs, written reflections, coach-guided summaries and student-generated learning goals.

EXECUTIVE SUMMARY

Issues relevant to physicians in clinical research include a proposed revision of the AMA *Code of Medical* Ethics, a Council on Ethical and Judicial Affairs (CEJA) report proposing guidance on the use of drug samples, an update on Maintenance of Certification (MOC), and a proposed new tax on profits on drugs developed from government funded research. As of today, the complete meeting website is at http://www.ama-assn.org/go/annual2015. Final actions on each item are available as part of the annotated Reference Committee reports, which can be seen by going to the meeting website, clicking on "Reports and Resolutions", and then clicking "proceed" on the following screen. Also available on the meeting website are the AMA EVP's report highlighting accomplishments on AMA's three major initiatives (patient outcomes, medical education, and physician practice sustainability).

REVISION OF AMA *CODE OF MEDICAL ETHICS*

AMA's Council on Ethical and Judicial Affairs (CEJA) has been working on a modernized AMA *Code of Medical Ethics* since 2008. The revised *Code* had been presented to the House of Delegates (HOD) at the November 2014 interim meeting. There were only minimal comments

on the chapter addressing Research & Innovation. Most of the concern was about the chapters regarding Patient-Physician Relationships and Consent, Communication & Decision Making.

At the November 2014 meeting, the HOD referred the revisions back to CEJA asking for an additional comment period. The new issue that emerged most clearly was that the language of the draft modernized Code was open to potential misinterpretation that could have adverse consequences for physicians. Responding to comments received online, CEJA attempted to clarify the intended meaning of the terms *must*, *should* and *may*.

At this June 2015 meeting, the HOD Testimony focused largely on the process of how the House of Delegates has been asked to review and decide on this report. There was concern regarding the logistics of using the online forum to view the report, the inability to discuss specific changes at a reference committee, and the volume of the report. The HOD referred the report back to CEJA suggesting a special reference committee dedicated to the *Code* modernization at the November 2015 meeting.

A copy of the chapter addressing Research & Innovation with a crosswalk to the current *Code* is available from your AMA delegate.

DRUG SAMPLES

Council on Ethical and Judicial Affairs (CEJA) Report 2 once again examined the benefits and challenges of prescribing and dispensing sample medications. Testimony indicated confusion about the interpretation of the report as written and those testifying were greatly concerned that the report would limit their ability to dispense prescription samples to patients. Some thought the report made dispensing prescription samples unethical. Other testimony interpreted the report to forbid prescription samples to those who could afford the full prescription, which would restrict the ability of the physician to use a prescription sample as a test trial for patients. Due to the amount of confusion in interpreting the report, it was referred back to CEJA. (Unlike recommendations in reports from other AMA Councils, recommendations from CEJA cannot be amended on the floor of the House of Delegates (HOD). Recommendations in CEJA reports must be adopted or referred back to CEJA.)

UPDATE ON MAINTENANCE OF CERTIFICATION

Council on Medical Education (CME) Report 2 provided a comprehensive update on Maintenance of Certification (MOC). AMA policy reinforces the need for ongoing learning and practice improvement, and the MOC program is based on sound theoretical rationale. However, there have been differences of opinion about the efficacy of MOC implementation in improving physician care and patient outcomes. Continuous study of its evidence will be important in identifying improvements to the program, especially to be able to keep pace with advances in clinical practice, technology, and assessment.

AMA efforts with the American Board of Medical Specialties (ABMS) and its member boards to improve MOC are highlighted in this report. For example, the ABMS Multi-specialty MOC Portfolio Approval Program, which provides a streamlined approach for hospitals and health care organizations to support physician involvement in quality improvement (QI) initiatives, allows physicians from multiple specialties to receive credit in their programs for MOC. This report also provides examples of ABMS member boards' work to identify learning redundancies and streamline processes to reduce overall costs.

This report reviews how the specialty boards are working with medical specialty societies to develop educational curricula and provide resources to support physician professional development. The report also includes a summary of how the member boards are providing a mechanism for identifying continuing medical education and QI activities and resources that also satisfy other national, state, and private-sector QI and reporting activities.

At a separate meeting sponsored by the Council on Medical Education, ABMS President Margaret Nora, MD, JD, MBA announced that ABMS has formed a Task Force on Maintenance of Certification for "Physician Executives" and a separate Task Force on Maintenance of Certification for "Physician Researchers".

PHARMACEUTICAL PACKING AND ABUSE DETERRENT FORMULATIONS

The House of Delegates adopted new policy supporting research into, and development of, into novel and affordable pharmaceutical packaging for dispensed medications, as well as abuse deterrent formulations in attempts to increase ease of use, improve patient adherence compliance, and decrease the abuse potential for misuse and abuse of controlled substances.

PROPOSED TAX ON PROFITS FROM DRUGS FROM GOVERNMENT FUNDED RESEARCH

The Delegates accepted a recommendation from Reference Committee E (Science and Technology) that Resolution 526 – "Recycling Pharmaceutical Profits to NIH Funding" be referred for decision to the AMA Board of Trustees. Resolution 526 asked that AMA support the concept that pharmaceutical companies that can be shown to have profited from intellectual property publicly funded by the American taxpayer, should provide for a share of that profit from pharmaceuticals whose research can be attributed to the National Institutes of Health (NIH), and that those funds be made available as supplemental appropriations to support and grow biomedical research at NIH. Testimony at the Reference Committee emphasized inadequate funding of NIH, the fact that many pharmaceutical companies have benefitted from tax payer-funded scientific findings, and that some of the profits gained by such companies should be used to help fund the NIH. Testimony also noted that the resolution failed to recognize the complementary roles of NIH and industry and disregarded the critical role that investments by industry play in transforming scientific findings from basic research into research and development pipelines and potential new medicines. Furthermore, in cases where federal research agencies' or federally funded institutions' translational research results in patents, they are able to retain ownership and obtain royalties for patented inventions via

licensing to the private sector. Some sentiment was expressed for reaffirming current AMA policies related to NIH funding. Given the complex issues involved and whether this is a specific approach that AMA should endorse, the Reference Committee recommended referral for decision.

ADDRESSING RECREATIONAL MISUSE AND DIVERSION OF CONTROLLED SUBSTANCES

The House of Delegates adopted a Directive that AMA, in conjunction with other Federation members, and key public and private stakeholders, and pharmaceutical manufacturers, pursue and intensify collaborative efforts involving a public health approach in order to: 1) reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications; 2) increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and 3) reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction.

DRUG EXPIRATION DATES

The AMA had preexisting policy that urges the United States Pharmacopeia (USP), to determine whether lengthening of expiration dates will provide clinical and/or economic benefits or risks for patients and, if this is the case, to conduct longer stability testing on their drug products. At this meeting, the HOD adopted additional policy that urges the FDA to work with the pharmaceutical industry and the USP to develop a schedule for the review and re-evaluation of expiration dates of prescription and over-the-counter drug products.

PERSONAL NOTES

It is a great honor to represent the Academy of Physicians in Clinical Research in the AMA House of Delegates. Especially gratifying to me is the increase in the number of medical students who now attend the AMA meeting. My own medical school (Johns Hopkins) participates actively.

At the 2015 Annual Meeting, I had the additional honor of serving as Chair of Reference Committee D (Public Health).

The AMA will continue to staff the United States Adopted Names (USAN) Council, which assigns the generic names for the active ingredients in all drug products marketed in the United States (http://en.wikipedia.org/wiki/United_States_Adopted_Name). AMA cosponsors the USAN Council along with the US Pharmacopeia (USP) and the American Pharmacists Association (APhA). The FDA has a liaison member. USAN Council activities are supported by user fees from sponsors applying for names and from the sale of print and electronic data bases. Former APCR Board of Trustees member Judith Jones and I are the only two physicians among the five Council members. I was elected Chairman of the USAN Council in January 2012. Both of us have been reappointed to serve on the USAN Council through the end of 2015.

At the AMA, APCR is a member of the Section Council on Preventive Medicine (SCPM). Other SCPM members include the American Association of Public Health Physicians, the American College of Preventive Medicine and the Aerospace Medical Association, and the Society of Addiction Medicine. Representative of the US military services, the US Public Health Service and the US Department of Veterans Affairs also attend our Section Council meetings.

The AMA Delegation from MedChi – The Maryland State Medical Society provides me with important backup and logistic support at meetings of the AMA House of Delegates. I am a life member of MedChi and I have represented MedChi in the US Pharmacopeial Convention since 2008.

CONCLUSION

AMA is experiencing membership growth for the fourth straight year and is becoming increasingly important in creating the future of medicine. Within the AMA House of Delegates, APCR is the only voice focused on clinical research.

Please feel free to call upon me if I can answer any questions.

Thanks!

Peter

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