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AMA Delegate's Report 2013

Once again it was my honor to represent APCR at a meeting of the American Medical Association (AMA) House of Delegates (HOD). The Annual Meeting was held in at the Hyatt Regency Hotel in Chicago from June 14 through June 19.

This was my third meeting with a badge labeled with our new name, Academy of Physicians in Clinical Research (APCR). The new name continues to draw favorable comments. (It also continues to put us first in the alphabetical list of medical specialties represented in the AMA House of Delegates.)



[Read the 2012 AMA Delegate's Report](#)

EXECUTIVE SUMMARY

Issues relevant to physicians in clinical research included the imminent implementation of the Physician Payments Sunshine Act plus updated information on drug shortages, pharmacy compounding, biosimilars, and support for prevention and public health. The US Supreme Court has announced decisions in keeping with the previously adopted HOD positions on pay for delay and the patenting of human genes. AMA policy now defines obesity to be a disease even in the absence of complications such as cardiovascular disease and diabetes. Delegates express concerns over the increasing cost of maintaining specialty board certification. AMA Executive Vice President Jim Madara described progress on AMA's five-year strategic plan and reported that AMA membership increased is now on track to increase for the third straight year. As of today, the complete meeting website is at <http://www.ama-assn.org/go/annual2013>. 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.

PHYSICIAN PAYMENTS SUNSHINE ACT

Effective August 1, 2013, drug and device manufacturers are required to report payments ([including payments for clinical research](#)) and items of value given to physicians and teaching hospitals. The Centers for Medicare and Medicaid Services (CMS) will post this data on a publicly available website. These reports are required by the Physician Payments Sunshine Act which was part of the Affordable Care Act (ACA). The initial reporting period covers five months ending on December 31, 2013. Subsequent periods will begin on January 1 and each covers a full calendar year. In January 2014, CMS will launch the physician portal that allows physicians to sign-up to receive notice when their individual consolidated reports are available for review. Manufacturers will report their data to CMS on March 31 of each year. Physicians can use the physician portal to contact a manufacturer if they want to dispute the accuracy of a report.

AMA's summary of the new reporting requirements is available at <http://www.ama-assn.org/resources/doc/washington/sunshine-act-physician-financial-transparency-reports.pdf>. More detailed information from AMA is at www.ama-assn.org/go/sunshine and from CMS at <http://go.cms.gov/openpayments>. A CMS fact sheet for physicians is at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf>. AMA's summary of state "sunshine" laws is at <http://www.ama-assn.org/resources/doc/washington/state-sunshine-laws-chart.pdf>

DRUG SHORTAGES

A new report from the Council on Science and Public Health (CSAPH) noted that, "Some improvement in the number of new shortages affecting 'medically necessary drugs' is apparent although the overall number of shortages remains elevated. The majority of drug shortages are due to manufacturing quality issues, often related to aging infrastructure or production equipment. High market concentration of manufacturers and limited spare production capacity contribute to scenarios promoting drug shortages. Although the exercise of regulatory discretion by the FDA has been beneficial in mitigating individual drug shortages, this approach will not be as effective as company-based improvements in infrastructure, processes, and manufacturing lines. It also may paradoxically delay necessary upgrades if companies are able to temporarily cope from incident to incident with the help of dedicated FDA assistance."

The upcoming Government Accountability Office (GAO) report is designed to shed more light on the real world causes of drug shortages, including market driven and economic variables, and to recommend solutions in light

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of root cause analysis.

PHARMACY COMPOUNDING

A new report from CSAPH followed up on the Resolution on compounding adopted at the last HOD meeting. After considering the report, the delegates amended AMA policy to add that traditional compounding pharmacies must be subject to state board of pharmacy oversight (as well as complying with United States Pharmacopeia-National Formulary (USP-NF) monographs).

AMA will no longer recognize the accreditation program of the Pharmacy Compounding Accreditation Board (PCABTM) and the PCAB Seal of Accreditation. AMA now "supports the view that facilities (other than pharmacies within a health system that serve only other entities within that health system) that compound sterile drug products without receiving a prescription order prior to beginning compounding and introduce such compounded drugs into interstate commerce be recognized as compounding manufacturers subject to FDA oversight and regulation."

BIOSIMILARS

The House revised a resolution calling for AMA to study the safety of biosimilars and voted to revisit the topic of biosimilars and study emerging issues such as the remodeling of pharmacy practice acts, naming conventions, which products might be deemed interchangeable, and what notification requirements should be in place for prescribers to facilitate post-marketing surveillance.

SUPPORT FOR PREVENTION AND PUBLIC HEALTH

At AMA, APCR is a member of the Section Council on Preventive Medicine (SCPM). The House adopted a resolution put forth by the American Association of Public Health Physicians (AAPHR), a fellow SCPM member. This resolution adds specifics to a resolution adopted at the previous HOD meeting opposing policies that aim to cut, divert, or use as an offset, dollars from the Prevention and Public Health Fund for purposes other than those stipulated in the Affordable Care Act of 2010. The new Resolution is a directive for AMA to take action:

To work with Congress and the Administration to prevent further cuts in the funds dedicated under the Affordable Care Act to preserve state and local public health functions and activities to prevent disease;

To recognize a crisis of inadequate public health funding, more intense at the local and state health jurisdiction levels, and encourage all medical societies to work toward restoration of adequate local and state public health function and resources;

In concert with state and local medical societies, continue to support the work of the Centers for Disease Control and Prevention, and the efforts of state and local health departments working to improve community health status, lower the risk of disease and protect the nation against epidemics and other catastrophes.

MAINTENANCE OF CERTIFICATION

The House considered a Council on Medical Education report on Maintenance of Certification (MOC) and multiple resolutions dealing with the time and expense of the MOC process. The Council report was amended to add additional recommendations that:

AMA 1) work with the American Board of Medical Specialties (ABMS) and ABMS specialty boards to continue to examine the evidence supporting the value of specialty board certification and MOC and to determine the continued need for the mandatory high-stakes examination; and 2) work with the ABMS to explore alternatives to the mandatory high-stakes examination.

AMA solicit an independent entity to commission and pay for a study to evaluate the impact that Maintenance of Licensure and MOC requirements have on physicians' practices, including but not limited to: physician workforce, physicians' practice costs, patient outcomes, patient safety and patient access.

PAY FOR DELAY

At its previous meeting, the House adopted a resolution to put AMA on record as supporting federal legislation that makes tactics delaying conversion of medications to generic status, also known as "pay for delay," illegal in the United States.

During this meeting, the US Supreme Court announced its decision In the case of Federal Trade Commission v. Actavis, No. 12-416 (http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf), saying that the Federal Trade Commission (FTC) can sue pharmaceutical companies for potential antitrust violations. FTC contended that a payment to Actavis by Solvay Pharmaceuticals, the holder of a patent on a testosterone gel known as AndroGel, represented an unlawful restraint of trade because it was intended to keep Actavis from producing its generic version of AndroGel for a certain number of years.

SUPPORT OF PUBLIC ACCESS TO GENETIC DATA

The AMA adopted policy that encourages companies, laboratories, researchers and providers to publicly share

data on genetic variants and the clinical significance of those variants through a system that assures patient and provider privacy.

The AMA had previously adopted policy opposed to the patenting of human genes. On the day before the current meeting began, the US Supreme Court announced its decision in *Association for Molecular Pathology et al v. Myriad Genetics, Inc., et al* (http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf). "On the heels of the U.S. Supreme Court decision that genetic information is not patentable, this policy urges collaboration and data sharing with privacy protections to advance genomic medicine," said AMA Board Member Dr. William Kobler. "Genetic analyses done collectively with the ability to compare genetic variants and analysis will allow researchers and health care professionals to more quickly identify and adopt advances in genomic medicine to benefit patients."

COST OF SPECIALTY DRUGS

In response to a Council on Medical Services report on value-based insurance design, the House adopted a modified policy stating:

"Our AMA encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. Consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance..."

OBESITY AS A DISEASE

The AMA adopted policy that recognizes obesity as a disease requiring a range of medical interventions to advance obesity treatment and prevention.

"Recognizing obesity as a disease will help change the way the medical community tackles this complex issue that affects approximately one in three Americans," said AMA board member Patrice Harris, M.D. "The AMA is committed to improving health outcomes and is working to reduce the incidence of cardiovascular disease and type 2 diabetes, which are often linked to obesity."

AMA EXECUTIVE VICE-PRESIDENT'S REPORT

AMA Executive Vice President and CEO James L. Madara, MD reported progress on the three focus areas that were announced at last year's meeting. In the **Improving Health Outcomes initiative**, the AMA has begun work to improve outcomes around cardiovascular disease and type 2 diabetes.

As part of the **Accelerating Change in Medical Education initiative**, 11 schools will receive \$1 million each in funding to implement projects to transform medical education. The **recipients**, were selected after consideration of proposals from 82 percent of the nation's accredited medical schools.

In the focus area to **shape care delivery and payment models**, AMA is in the initial stage of identifying models of care delivery and payment that promote the long-term sustainability of physician practices as well as professional satisfaction with them. Later stages will involve supporting and disseminating those models.

Dr. Madara's speech is available on Utube at: <http://www.ama-assn.org/ams/pub/meeting/highlights-madara-speech.shtml>.

PERSONAL NOTES

The AMA continues to staff the United States Adopted Names (USAN) Council, which assigns the generic names for all drug products marketed in the United States. 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. I was elected Chairman of the USAN Council in January 2012.

Saul Levin, former VP for Science and [Preventive] Medicine, is now the Interim Director of the District of Columbia Department of Health. On August 1, 2013, he will become Medical Director (Chief Executive Officer) of the American Psychiatric Association.

I was honored to serve as Chief Teller for the 2013 Annual meeting. The Chief Teller is responsible for conducting AMA elections.

Gynecologist Robert Wah, MD, a first generation Chinese American, was elected President-Elect. Dr. Wah served more than 23 years on active duty as a captain in the U.S. Navy Medical Corps. He now practices and teaches at the Walter Reed National Military Center in Bethesda, Md., and the National Institutes of Health. A nationally recognized expert in health information technology, Dr. Wah also serves as chief medical officer for Computer Sciences Corporation.

Maya Babu, MD, MBA, a graduate of both Harvard Medical School and Harvard Business School, was elected to the Resident-Fellow position on the AMA Board of Trustees. Dr. Babu is a resident in neurosurgery at the Mayo

Clinic. She has business experience working as an associate in medical devices investment banking at Piper Jaffray and as a business development associate at Medtronic as well as government experience working at CMS.

AMA discontinued providing staff support for the National Task Force on CME Provider/Industry Collaboration effective October 31, 2012 following the annual conference in Baltimore. The Alliance for Continuing Medical Education (ACME) expressed an interest in integrating Task Force activities into its programs, but in early 2013 Task Force members first voted against a formal affiliation with ACME and ultimately voted to disband. I was a member of the Task Force from 1992 until the time of its disbanding.

CONCLUSION

AMA is experiencing membership growth for the third straight year. AMA's focus on three major initiatives (patient outcomes, medical education, and physician practice sustainability) is on track to give organized medicine a leadership role in shaping the future of medicine and clinical research.

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

Thanks!

Peter

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