

**AMA HOUSE OF DELEGATES
APCR DELEGATE'S REPORT
JUNE 14, 2017**

The Annual Meeting of the American Medical Association (AMA) House of Delegates (HOD) was held at the Hyatt Regency Chicago Hotel in Chicago, IL from June 10 through June 14. 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) remains the only one for which pharmaceutical and medical device research is the primary focus.

At the opening Session, AMA President Andy Gurman, MD emphasized AMA's role as an advocate for maintaining the coverage gained through the Affordable Care Act (ACA). He emphasized the AMA's policies are moored in science, research and evidence. He noted the need to stabilize the marketplace and make meaningful health insurance more affordable and accessible for everyone. He spoke forcefully about AMA's advocacy for medical students currently in this country under the Deferred Action for Childhood Arrivals (DACA) program.

AMA Executive Vice President (EVP) Jim Madara reminded the Delegates that 2017 marks AMA's 170th Anniversary. He spoke about Health2047 (<https://health2047.com>), named for the year in which AMA will celebrate its 200th Anniversary. Health 2047 is developing products aimed at improving the health system with the overarching goal of relieving administrative burdens and returning one hour to each physician's working day. Dr. Madera reported continuing progress on AMA's three strategic focus area: 1. Improving professional satisfaction and practice sustainability; 2. Creating the medical School of the future; and 3. Improving health outcomes for patients with pre-diabetes and hypertension.

EXECUTIVE SUMMARY

Issues especially relevant to physicians in clinical research were multiple resolutions on pharmaceutical costs plus discussions of a private researcher certification program; the AMA's Opioid Task Force; and the cost of publishing open access articles in scientific journals. The House of Delegates reaffirmed the principle that the First Amendment applies to scientific knowledge, data and research. As of July 29, 2017, the complete meeting website is at <https://www.ama-assn.org/hod-annual-overview>. 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 "Find Business Meeting Documents".

Major issues for the broader physician community include:

- The implementation of MACRA (Medicare and CHIP Reauthorization Act) More information is at <https://www.ama-assn.org/search/ama-assn/MACRA>;
- the decline in the number of physician owned practices (now less the half);
- the implementation of Maintenance of Certification (MOC) as a requirement for hospital staff membership;
- the increasing administrative burden on practice such as the delays while waiting for prior authorizations;
- The merger of insurance giants continues to create health care market dominating entities The AMA's amicus brief filed with the U.S. Court of Appeals for the District of Columbia helped block the merger of Anthem with Cigna (<https://wire.ama-assn.org/ama-news/appeals-court-upholds-decision-blocking-anthem-cigna-merger>).

PHARMACEUTICAL COSTS

The last major revision to AMA's policy on drug pricing was at the November 2015 meeting of the House of Delegates. At this meeting, Resolution 207 (Sky Rocketing Drug Prices) from the State of Washington asked that AMA strongly advocate for policies, regulations and legislation that protect patients from sky rocketing exorbitant prices for previously affordable drugs; and that AMA advocate for an "out of pocket" maximum dollar amount for total drug costs for our patients not to exceed \$500 per month. Resolution 207 did not result in any new policy but it did result in a general reaffirmation of existing policy.

Resolution 223 from the California Delegation asked that AMA support legislation to prohibit costs for Direct-to-Consumer advertising of prescription medications, medical devices, and controlled drugs to be considered deductible business expenses for tax purposes. This is already AMA policy and that policy was reaffirmed.

In addition, at this meeting, there were multiple resolutions asking for new AMA policies on pharmaceutical costs. Each was heard in Reference Committee B (Legislation) and each was considered separately.

The Resident and Fellow Section introduced Resolution 201 (Improving Drug Affordability) calling for legislation requiring pharmaceutical manufacturers to disclose specific costs related to the marketing of drugs, to give public notice before raising drug prices, to allow the federal government to "address price gouging", and to prioritize review of generic drug applications where there is a drug shortage.

Although testimony was overwhelmingly supportive of AMA doing more on drug pricing issues, the Delegates were against advocating for a specific list of industry cost disclosures. FDA already prioritizes review of generic drug applications where there is a drug shortage. In response to a separate resolution from the Louisiana delegation heard in a different reference committee, the HOD reaffirmed existing AMA policy which is in general opposition to price controls.

In response to Resolution 201, the HOD adopted the following new policy:

AMA supports drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase.

AMA supports legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients.

AMA support the expedited review of generic drug applications and prioritize review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.

The HOD also adopted Resolution 203 (AMA to Support Pharmaceutical Pricing Negotiation in the US) from the Missouri Delegation: AMA prioritizes its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Resolution 219 (Integration of Drug Price Information into Electronic Medical Records) from the Medical Student Section asked that AMA support incorporation of estimated patient out of pocket drug costs into electronic medical records and that AMA collaborate with stakeholders to help make this happen. Although there was testimony questioning the feasibility of doing this, other testimony stated that real-time benefit checks are already being incorporated into some EMRs. The resolution was referred for further study.

Resolution 236 sponsored by all six New England states was adopted resulting in a Directive to take Action that AMA advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer's suggested retail price of those drugs.

RESEARCHER CERTIFICATION

The Florida delegation introduced a resolution asking that AMA study an investigator certification offered by a private Florida-based organization (<https://about.citiprogram.org/en/homepage>). The resolution questioned both the cost and the usefulness of the program. No testimony was offered, but the resolution sparked a

discussion regarding the need for ethics training and certification of investigators. The resolution was referred.

FREE SPEECH APPLIES TO SCIENTIFIC KNOWLEDGE

The Maryland delegation introduced Resolution 228 (Free Speech Applies to Scientific Knowledge). The HOD adopted a Directive to Take Action affirming this principle: “AMA [will] advocate that scientific knowledge, data, and research will continue to be protected and freely disseminated in accordance with the U.S. First Amendment.”

SCIENCE AND TECHNOLOGY RESOLUTIONS

The American Academy of Pain Medicine introduced Resolution 511 (Future of Pain Medicine) asking that 1) AMA convene a task force from organized medicine to discuss medicine’s response to the public health crisis of undertreated and mistreated pain; 2) this task force explore and make recommendations for augmenting medical education designed to educate healthcare providers on how to help patients suffering from pain with evidence-based treatment options; 3) this task force discuss strategies that may prevent or mitigate acute pain, educate physicians about these strategies, and suggest research to study if these strategies prevent the development of chronic pain; and 4) this task force involve many primary care, medical and surgical specialties that are involved in providing pain care.

AMA already has an Opioid Task Force working to reduce opioid-related harm, promote evidence-based pain management practices and policies, reduce stigma, and increase access to treatment for opioid use disorder. Testimony highlighted the need for efforts to improve education on pain management, as well as training and payment reforms to increase access to non-pharmacologic and multimodal strategies for pain management. The Reference Committee strongly supported Resolution 511 with the understanding that, as an AMA-convened Federation-based effort, additional decision-making will be needed on how to best implement a coordinated approach. The Resolution was adopted following extensive supportive testimony.

Resolution 509 sponsored by the Medical Student Section asked that AMA study the safety, efficacy, and potential uses of wearable devices within clinical medicine and clinical research. Resolution 512 from the Illinois Delegation asked that AMA study the need for FDA regulation of dietary supplements. The HOD considered both resolutions to be reaffirmation of existing AMA policy.

MEDICAL JOURNALS

The Pennsylvania Delegation introduced Resolution 604 calling on AMA to investigate the impact of the high costs of open access (OA) publication practices on the dissemination of

research and “to make recommendations to correct the imbalance of knowledge suppression that may occur because of financial limitations”.

Many US and EU research funders require that findings from research supported by their grants be published with open access. OA articles are available to readers without payment of subscription or site license fees. OA is supported by Article Processing Charges (APCs), which help cover costs to review, edit, process, distribute, and host the articles. These fees are typically between \$3,000 and \$5,000 per article.

Scholarly society journals such as JAMA® and the New England Journal of Medicine traditionally have not offered or charged APCs in exchange for OA. All original research articles published in JAMA® are made free to everyone after six months. However, with the launch of JAMA Oncology® in 2015, AMA began to offer an OA option to authors whose research funders required that they use OA. The JAMA Network® OA fees are \$4500 to \$5000 per article. For this reason, JAMA Oncology® is called a “hybrid” journal, as authors may choose either an OA model or a conventional subscription model for their submission. This model recognizes the needs and limited resources of independent researchers and authors but also appears to balance the demands of funders, changing markets, and business practices. The hybrid model was extended to JAMA Cardiology®, which was launched in 2016, and subsequently to all of AMA’s specialty journals across The JAMA Network® on April 1, 2017.

AMA has clear policy on editorial independence, affirming “JAMA® and The JAMA Network® journals have full editorial independence”. The Reference Committee also noted that AMA is not able to direct or recommend that other medical journal publishers reduce or eliminate their OA article fees, nor can our AMA instruct international research funders to abandon their OA requirements and support only subscription-based journals. The HOD referred the issue to the AMA Board of Trustees for further study.

Resolution 605, introduced by the Illinois Delegation, called upon AMA to adopt policy that its AMA-sponsored medical journals develop a means to convey the proper pronunciation of all new pharmaceutical names. The Reference Committee was reminded again that JAMA® and The JAMA Network® have full editorial independence and Resolution 605 was not adopted.

PERSONAL NOTES

It is always a great honor to represent the Academy of Physicians in Clinical Research in the AMA House of Delegates.

I continue to chair the AMA hosted United States Adopted Names (USAN) Council (https://en.wikipedia.org/wiki/United_States_Adopted_Name) which assigns the nonproprietary (generic) names for the active ingredients in all drugs marketed in the US. AMA will continue to staff the USAN Council. 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.

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, 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.

I had the good fortune to be seated between American Gastroenterological Association Delegate Peter Kaufman and AMA Trustee Barbara McAneny when Dr. McAneny was announced as the new AMA President-Elect. I am indebted to Dr. Kaufman for snapping the photo that accompanies this article.

APCR's Policy Manager Ryan J. Essegian, Esq. attended the meeting with me and provided invaluable assistance.

CONCLUSION

AMA has experienced four straight years of membership growth and is becoming increasingly important in creating the future of medicine. Issues relating to drug research, development, availability, pricing, and promotion have become a focus for the House of Delegates (HOD) Within the HOD, 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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AMA Delegate and Past President

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