

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

2018 marks the 25th anniversary of the Academy of Physicians in Clinical Research (APCR). APCR was founded in 1993 as the American Academy of Pharmaceutical Physicians by doctors employed at research-based pharmaceutical companies. Within a few years membership grew to include physicians involved in the development of therapeutic and diagnostic products in academia, in government and at private clinical research sites.

A seat in the American Medical Association (AMA) House of Delegates is AMA's recognition that a specialty society represents a field of medicine with scientific validity. A place in "the House of Medicine" was an early goal for APCR. Delegate status gives the society a voice in healthcare policy. APCR achieved delegate status in 2002 – nine years after it was founded and only one year longer than the minimum required time.

The 2017 Interim Meeting of the AMA House of Delegates (HOD) was held at the Hawaii Convention Center in Honolulu, HI from November 10 through November 14. 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 David O. Barbe, MD, MHA outlined how the AMA advocates on behalf of patients and physicians, using its policy portfolio to shape legislative and regulatory decisions. He summarized AMA's recent achievements in advocating for physicians and patients. Among these achievements:

- Preventing insurance merges that would have weakened the negotiating power of physicians, patients and other stakeholders in the healthcare system.
- Reducing or eliminating prior authorization requirements that consume physician time and reduce patient access to promising therapies.
- Fighting physician burnout and the time crunch by working to improve EHRs, mobile devices, and interoperability.
- Helping physicians to become better educated and better prepared to assist their patients with pain management and addiction.

AMA Executive Vice President (EVP) Jim Madara, MD focused on AMA's Health2047 (<https://health2047.com>) initiative, named for the year in which AMA will celebrate its 200th Anniversary. Health2047 is a Silicon Valley innovation enterprise developing and commercializing healthcare solutions that:

- Enable data liquidity protected by world-class security
- Realign healthcare systems around chronic care
- Produce radical productivity at all levels of care and support
- Facilitate value-based payments

Dr. Madera went on to describe two recent Health2047 Spinoffs:

- The Integrated Health Model Initiative—IHMI for short—an endeavor to create a common data model throughout health care that is unlike anything that exists today. Collaborators include IBM Watson, Intermountain Healthcare, Cerner, and the American Heart Association.
- SwitchCo, Inc. will commercialize a subscriber network for data transport that enables the secure permissions-based sharing of health data among patients, physicians, providers, payers, pharma and other healthcare enterprises.

EXECUTIVE SUMMARY

Issues especially relevant to physicians in clinical research were multiple resolutions on pharmaceutical costs plus discussions of drug importation; health insurance company purchase by pharmacy chains; drug shortages; and the cost of open access for researchers publishing in medical journals. As of January 15, 2018, the complete meeting website is at <https://www.ama-assn.org/hod-interim-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 and clicking on “Find Business Meeting Documents”.

PHARMACEUTICAL COSTS

As previously reported, there were multiple additions to AMA’s policy on drug pricing at the June 2017 meeting of the House of Delegates. At the November 2017 meeting, Resolution 806 (Mandate Transparency by Pharmacy Benefit Managers) from the six New England state delegations proposed that that AMA ask Congress and other appropriate entities to require that there be transparency of drug pricing by pharmacy benefit managers (PBM) to help prevent PBM price manipulation of patient prescription costs. Resolution 806 also proposed that AMA advocate for policy that retail pharmacies and health plans be required to disclose to patients the lowest possible cost of any prescription medication--specifically, any price differential between the price of a drug when using an insurance benefit versus the price of the drug without using that benefit.

Resolution 810 (Pharmacy Benefit Managers and Prescription Drug Affordability) cosponsored by eight medical specialty societies asked that AMA expand its drug pricing advocacy campaign to include and explicitly address the effects and transparency of pharmacy benefit manager

(PBM) practices. Resolution 810 also asked that AMA develop model guidelines for transparency in the rebate system, to include PBM and health plan disclosure to physicians of the contracted cost of medications including discounts and rebates from manufacturers paid back to health plans and PBMs.

Resolution 823 (Unconscionable Generic Drug Pricing) from the Georgia Delegation called for AMA to advocate for national legislation that would prohibit price gouging on off-patent medications where there are fewer than three manufacturers.

At the Reference Committee hearing on these three resolutions, members of the Council on Medical Service and the Council on Legislation supported crafting a new, concise message on prescription drug price transparency. In response, the Reference Committee recommended and the HOD reaffirmed existing policies and adopted several resolves:

That AMA oppose provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price.

That AMA continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.

That AMA develop model state legislation on the development and management of pharmacy benefits.

That AMA advocate for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

That AMA continue implementation of its TruthinRx (<https://truthinrx.org>) grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmaceutical benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.

That AMA report back to the HOD at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign.

Resolution 826 (Improving Affordability of Insulin) from the American Association of Clinical Endocrinologists asked that AMA work with relevant medical specialty societies to convene a summit with participation by patients, clinicians, manufacturers, PBMs, insurers and the appropriate federal representatives to highlight the dramatic increase in insulin costs and identify potential solutions. The HOD reaffirmed AMA's existing policy on drug pricing (H-110.987) in lieu of this resolution.

DRUG IMPORTATION

The Minnesota delegation introduced Resolution 226 (Prescription Drug Importation for Personal Use) asking that AMA support legislation that would allow for the personal purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy, provided such drugs are for personal use and of a limited quantity. At the Reference Committee hearing, there was extensive testimony with unanimous agreement that more flexibility is needed to ensure patients have access to affordable prescription drugs. However, concern was expressed that the in-person personal importation may eventually lead to the same risks as internet-based importation. Also, there should be sufficient resources to ensure that in-person importation is safe and traceable. Given these concerns, the lack of direct policy on in-person importation, and the complex nature of drug importation, the Reference Committee recommended and the House of Delegates agreed that Resolution 226 be referred.

HEALTH INSURANCE COMPANY PURCHASE BY PHARMACY CHAINS

Resolution 234 (Health Insurance Company Purchase by Pharmacy Chains) was an emergency late resolution introduced by the New York State delegation in response to the proposed purchase of Aetna, Inc. by CVS Health Corp. The Resolution asked that AMA object to any purchase of a health insurance plan by any drug store or pharmacy chain and that our AMA work with other stakeholders, including the American Osteopathic Association and specialty colleges, to advocate for protection against such a purchase. AMA has vigorously opposed mergers of two health insurers.

The Reference Committee heard testimony that this proposed merger has unknown impact on physicians and consumers, unknown effect on the health insurance industry when a pharmacy and health insurer merge, and unknown outcome as to whether the CVS/Aetna merger will even be completed. The Reference Committee noted that antitrust is a highly complex and fact intensive issue and that opposing any merger or acquisition without extensive information gathering could hurt AMA's credibility and authority in the antitrust space. The Reference Committee recommended and the HOD agreed that this resolution be referred for decision to the AMA Board of Trustees.

DRUG SHORTAGES

AMA's Council on Science and Public Health issued its eighth report on national drug shortages. The HOD adopted the report adding an additional recommendation to AMA's already extensive policy (H-100.956) on this issue.

Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade

Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.

MEDICAL JOURNALS

As previously reported, at the 2017 Annual Meeting, Resolution 604-A-17 called 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”. The HOD referred the issue to the AMA Board of Trustees for further study.

In Board of Trustees Report 10-I-17, the AMA Board noted that AMA is not in a position to direct or recommend that other medical journal publishers reduce or eliminate their OA fees, especially when fees are a necessary component of OA model journals. Likewise, AMA cannot instruct international research funders to abandon their OA requirements and support only subscription based journals.

The AMA Publishing division investigated the range of OA fees charged by commercial and medical society publishers; the fee charged by The JAMA Network specialty journals falls within this spectrum. The JAMA Network journals require adequate revenue to process, peer review, and publish articles of high quality. As such, current OA fees of \$4,500 to \$5,000 are reasonable, given journal production and hosting expenses. Moreover, AMA continues to offer a no-fee option for authors, while providing the OA option for research funders that require and will pay for OA. The Board recommended that Resolution 604-A-17 not be adopted, but noted that AMA Publishing plans to implement a process for waiving or reducing OA fees when authors are not supported by funders or cannot afford to pay OA fees.

On August 25, 2016, the Federal Trade Commission (FTC) filed a complaint against OMICS Group Inc. and two affiliated companies, alleging that OMICS failed to disclose publishing fees until after submissions were approved for publication and then would not allow researchers to withdraw their articles, invented an Impact Factor and falsely informed authors that their journals are indexed by federal research databases (e.g., PubMed and Medline). The Board of Trustees will continue to monitor the Federal Trade Commission’s actions in relation to predatory publishers and will disseminate the information to AMA members.

PERSONAL NOTES

It is always a great honor to represent the Academy of Physicians in Clinical Research in the AMA House of Delegates. At this meeting, as in past years, I served as a judge for AMA’s annual medical student/resident/fellow research competition.

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 drug products 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 Occupational and Environmental Medicine, the American College of Preventive Medicine, the Aerospace Medical Association, and the American 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. I have been appointed a member of the newly formed SCPM Bylaws Committee.

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 the largest physician organization in the United States and it continues to grow in membership and stature. AMA is a major player 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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