

**AMA HOUSE OF DELEGATES
APCR DELEGATE'S REPORT
JUNE 13, 2018**

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 9 through June 13. Once again, 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 Executive Vice President (EVP) Jim Madara reported another consecutive year of AMA membership growth. He spoke about Health2047 (<https://health2047.com>), named for the year in which AMA will celebrate its 200th Anniversary. Health2047 Inc is AMA's Silicon Valley business formation and commercialization enterprise focused on developing solutions for US healthcare's four biggest problem areas: data liquidity, chronic care, productivity, security, and payments. Dr. Madera once again 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.

U.S. Surgeon General Jerome Adams, MD, MPH joined the AMA 20 years ago as a student at the Indiana University School of Medicine. He is a long-time member of the HOD. At this meeting, he served as the Delegate for the US public Health Service. On Monday, June 11, he spoke on the need to remove the stigma associated with substance-use disorder, increase access to medication-assisted treatment, and to widen the availability of opioid overdose antidote naloxone (<https://wire.ama-assn.org/delivering-care/surgeon-general-ama-look-upstream-prevent-nation-s-ills>).

EXECUTIVE SUMMARY

Issues especially relevant to physicians in clinical research were multiple resolutions on pharmaceutical costs plus discussion of researcher education programs; new AMA guidance for physicians on access to investigational therapy; items regarding FDA advisory committees, drug shortages, and AMA policy on biosimilar interchangeability pathways; and the launch of a new AMA open access scientific journal. The House of Delegates adopted Board of Trustees Report 46 granting APCR (and other organizations) continuing representation in the House of Delegates through 2022. As of July 16, 2018, 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:

- **AMA seeks to boost affordability, competition in ACA marketplaces**
Nearly 12 million people obtained coverage through the Affordable Care Act (ACA) exchanges this year. The HOD adopted policies aiming to improve the exchanges.
- **Health care AI holds promise, but physicians’ perspective needed**
In its first time addressing the topic of “augmented intelligence,” the HOD laid out a road map for health care AI to ensure quality and protect patient rights.
- **Physicians adopt plan to combat pay gap in medicine**
Reports show pay disparities among male and female physicians after accounting for other factors. The AMA will advocate a wide array of measures to address the issue.
- **AMA puts its organizational muster behind health equity push**
Physicians define “health equity” as optimal health for all. The move is aimed at eliminating disparities affecting racial and ethnic minorities and other populations.
- **Precision medicine should have its play in new pay models**
The tailored approach to delivering care should be incorporated into alternative payment models, the HOD says.

PHARMACEUTICAL COSTS

The HOD adopted a recommendation of Board of Trustees Report 14 that AMA collaborate with other interested stakeholders to develop and implement a strategic plan for improving the availability and accessibility of real-time prescription cost information at the point of care.

Resolutions 217 (Reforming the Orphan Drug Act) introduced by the Medical Student Section, 227 (An Optional National Prescription Drug Formulary) introduced by the Florida delegation, and 238 (Reform of Pharmaceutical Pricing: Negotiated Payment Schedules) introduced by the Illinois Delegation were combined for discussion. All three Resolutions were referred.

- Testimony on Resolution 217 brought out that incentives provided by the Orphan Drug Act (ODA) are needed to support innovation in drug development for rare diseases. However, there are congressional concerns with and public reports on drug developers’ potential manipulation of the ODA incentives that are not consistent with the original intent of the ODA and may be driving higher drug costs and increased sales.

- Testimony on Resolution 228 suggested that a national formulary would not promote innovation and competition and could substantially limit patient access to medically necessary options.
- Testimony on Resolution 238 pointed out that modifying various provisions of the Food, Drug, and Cosmetic Act as well as other federal laws such as the Social Security Act and the U.S. Patent Act in order to institute the replacement of time-specific patent protections with negotiated payment schedules and indefinite exclusivity for FDA-approved drugs in the Medicare Part D Program could limit patient access to clinically necessary alternative options and depress innovation while interjecting significant confusion and complexity in the patent system and the FDA regulatory regime.

Council on Medical Service Report 7 recommended that AMA encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate; disseminate model state legislation to promote increased drug price and cost transparency and to prohibit “clawbacks” and standard gag clauses in contracts between pharmacies and pharmacy benefit managers (PBMs) that bar pharmacists from telling consumers about less expensive options for purchasing their medication; provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency; support physician education regarding drug price and cost transparency and challenges patients may encounter at the pharmacy point-of-sale; support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies and the appropriate use of regular human insulin and neutral protamine Hagedorn (NPH) insulin.

The American Association of Clinical Endocrinologists testified that newer insulin is superior to older insulin because of decreased incidence of hypoglycemia, which is particularly important for elderly patients. In response to this testimony, the HOD deleted the recommendation regarding the use of regular and NPH insulin. The remaining recommendations of the report were adopted.

RESEARCHER EDUCATION

At the 2017 Annual Meeting of the HOD, the Florida delegation introduced a resolution asking that AMA study an investigator certification offered by a private Florida-based organization. The resolution resulted in Board of Trustees (BOT) Report 26 reviewing some of the programs available for educating the research community about human subjects protections and citing examples of relevant policies at Institutions that carry out federally funded research, as well as professional journals that publish the findings of research with human subjects. A copy of the report is attached. The HOD accepted the BOT recommendation that AMA continue to support

efforts to improve protections for human subjects of biomedical and behavioral research and advocate for change as opportunities arise.

NEW GUIDANCE FOR PHYSICIANS ON EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES

The House of Delegates adopted Council on Ethical and Judicial Affairs (CEJA) Report 4 providing new guidance for physicians on expanded access to investigational therapies. In response to the shortage of FDA-approved therapies for certain life-threatening illnesses, the “expanded access” program was created to allow patients to access investigational therapies outside of a clinical trial. In 2009, the FDA created regulations to outline the parameters for how terminally ill patients can apply for expanded access. The report noted that applications for expanded access have grown steadily since its inception, with about 99.7% of the 11,000 applications between 2005 and 2014 being approved. CEJA further recognizes that there are ethical issues associated with expanded access, most notably that of informed consent. CEJA also discusses the financial and equity issues with the costs associated with expanded access, as well as public health ramifications, as expanded access may adversely affect successful completion of clinical trials. The report proposed guidance to physicians whose patients request expanded access to an investigational therapy.

Our Reference Committee heard testimony largely supportive of CEJA Report 4, as well as that the report is relevant in light of the newly-signed “Right to Try Act of 2017.” Testimony noted that this report provides helpful guidance to physicians treating patients with serious, life-threatening illnesses for whom standard therapies have not been effective. The concern was raised that the report places problematic responsibilities on front-line physicians rather than researchers, but alternate testimony pointed out that the recommendations in the report give physicians the right to decline support for patients seeking investigational therapies, and that responsibility does fall on the investigators. Our Reference Committee considered this concern, but agreed that the report does not place unfair responsibilities on the physician.

The new guidance is spelled out in its entirety in the attached copy of CEJA Report 4.

FDA ADVISORY COMMITTEES

Resolution 226 (FDA Conflict of Interest) introduced by the Medical Student Section asked that AMA advocate both that FDA place a greater emphasis on a candidate’s conflict of interest when selecting members for advisory committees and that FDA reduce the number of conflict of interest waivers granted to Advisory Committee candidates. The Resolution was referred following testimony on the floor of the HOD that challenges may exist to find qualified individuals without conflicts.

DRUG SHORTAGES

Council on Scientific Affairs and Public Health (CSAPH) Report 2 was an update on drug shortages. The report noted that in late 2017, major hurricanes struck Puerto Rico which houses significant infrastructure for manufacturing critical pharmaceutical and other medical products. The FDA has issued multiple statements regarding the situation in Puerto Rico and has undertaken extensive efforts to avoid exacerbating critical drug shortages.

The report concluded that although recent natural disasters have increased the number of drug shortages only slightly, shortages of basic products such as saline and small-volume parenteral solutions, and their containers, are significantly impacting the health care system by affecting patient care, increasing the potential for drug errors, and influencing the manner in which health care teams function. Information and discussion at an ASHP-convened roundtable on current issues regarding drug shortages illuminated additional relevant policy considerations such as manufacturer transparency regarding production location and the cause(s) of shortages; quality of outsourcer compounding facilities; and the potential inclusion of vital drug manufacturing sites as critical infrastructure.

HOD adoption of the recommendations of this added several new items to existing AMA policy on drug shortages:

- AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug shortages.
- AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
- AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
- AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.
- AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.

BIOSIMILAR INTERCHANGEABILITY PATHWAY

Resolution 523 (Biosimilar Interchangeability Pathways) was cosponsored by 10 specialty societies. In response the HOD adopted two new policies:

- AMA will strongly support the rigorous pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug;
- AMA will request the FDA to finalize the biosimilars interchangeability pathway outlined in its draft guidance “Considerations in Demonstrating Interchangeability with a Reference Product” with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients.

NEW AMA MEDICAL JOURNAL

AMA is the world’s largest private medical publisher. The inaugural issue of *JAMA Network Open*[™] was published in time for this year’s annual meeting of the HOD. The open-access journal is the 13th journal in the JAMA Network[™] and the third journal launched by AMA in the last three years. *JAMA Oncology* was launched in 2015, followed by *JAMA Cardiology* in 2016.

The journal is intended to be an international platform for investigators around the world, moving away from the U.S.-centric focus of so many journals. It will feature health content from more than 40 medical and health subject areas, with new articles published each Friday. JAMA Network Open will follow the same peer review, editorial and publishing standards as do the other JAMA Network journals.

APCR DELEGATE STATUS RENEWED

Based on APCR (and other organizations) meeting requirements for the number and percentage of organization members who belong to AMA, the House of Delegates adopted Board of Trustees Report 46 granting APCR (and other organizations) continuing representation in the House of Delegates through 2022. Kudos to APCR staff for completing the required paperwork!

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 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 Aerospace Medical Association, the American Association of Public Health Physicians, the American College of Occupational and Environmental Medicine, the American College of Preventive Medicine, the American Academy of Insurance Medicine, the American College of Medical Quality, the Society of Addiction Medicine, and the Association of State and Territorial Health Officials. 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.

For this meeting, I was appointed by the Speaker and Deputy Speaker as Chair of the Reference Committee on Amendments to Constitution and Bylaws (C&B). As Chair of C&B, it was my privilege to preside over debates on a broad range of issues and the crafting of the our Committee's report (<https://www.ama-assn.org/sites/default/files/media-browser/public/hod/a18-refcomm-conby-annotated.pdf>).

CONCLUSION

AMA has experienced five 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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