

AMA HOUSE OF DELEGATES APCR DELEGATE'S REPORT NOVEMBER 17, 2015

The Interim Meeting of the American Medical Association (AMA) House of Delegates (HOD) was held at the Atlanta Marriott Marquis Hotel in Atlanta, GA from November 13 through November 17. 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.

AMA Executive Vice President (EVP) Jim Madara is a former Dean of the Medical School at the University of Chicago. He announced that 21 additional medical schools from more than 100 that applied have been selected to join the 11 founding members of AMA's consortium to create the medical school of the future. A monograph describing the work of the consortium is available at <https://download.ama-assn.org/resources/doc/about-ama/x-pub/ace-monograph-interactive.pdf>.

EXECUTIVE SUMMARY

Issues especially relevant to physicians in clinical research include APCR's own resolution asking AMA's support in securing legislation to cover out of pocket costs for Medicare beneficiaries participating in clinical trials, 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 extensive discussion and revision of AMA's policies on prescription drug pricing including a call for legislation to reduce the exclusivity period for new biologic drugs, an update on Maintenance of Certification (MOC), a call for FDA guidelines on paid endorsements of prescription drugs in social media, an update on the drug shortages and a call for legislation to ban Direct-to-Consumer (DTC) advertising of prescription drugs. As of January 2, 2016 the complete meeting website is at <http://www.ama-assn.org/go/interim2015>. 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).

Major issues for the broader physician community also include:

- Incompatibilities among Electronic Health Records (EHRs) systems resulting in much wasted time and duplication of effort. At the same time Medicare is demanding more and more reports and mandated implementation of ICD-10 is necessitating time-

consuming searches for new, sometimes exotic, codes to describe formerly routine diagnoses;

- The merger of insurance giants continues to create health care market dominating entities;
- Postgraduate medical education (i.e. residencies) funding decreases by HHS and increased rates of physician desertion from practice portend doctor shortage.

OUT OF POCKET COSTS FOR MEDICARE BENEFICIARIES PARTICIPATING IN CLINICAL TRIALS

At this meeting, the APCR sponsored Resolution 813 (Removing Financial Barriers to Participation in Clinical Trials for Medicare Beneficiaries). Our resolution was combined for discussion with Resolution 823 (H.R. 6 – The 21st Century Cures Act). We won support for our Resolution from the Section Council on Preventive Medicine (SCPM) and the Specialty and Service Society (SSS). The House of Delegates accepted the Reference Committee recommendation to refer the matter for decision to the AMA Board of Trustees (BOT). This outcome ensures that the BOT will discuss this important issue in time to take action before the US Senate takes up the 21st Century Cures Act in 2016. Dr. Kenneth Braunstein, a hematologist/oncologist and member of both APCR and the Georgia State Medical Society, helped write both Resolutions, won the support of his state society and helped present the issue to the Section Council on Preventive Medicine (SCPM).

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. This project represents the first thorough review in more than 50 years. The revised *Code* had been presented to the House of Delegates (HOD) at the November 2014 interim meeting and again at the June 2015 annual meeting. There have been 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, and, most recently on the need to be clear that the modernized code provides guidance, not regulation.

For this November 2015 meeting, the Speakers appointed a special Reference Committee on the Modernized Code of Medical Ethics, but once again the HOD referred the revisions back to CEJA asking for an additional call for comments on the AMA website and a rehearing before the special Reference Committee in June 2016.

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 Report 2 describes the responsibility of dispensing samples of prescription medications to maximize benefits for patients and minimize risks and requires physicians to approach the use of samples systematically. It states that physicians will need to implement policies and practices that balance convenience, potential clinical benefits for patients, and the opportunity to enhance access to care for individual patients with the need to ensure that samples are safely managed and dispensed.

Testimony in support of this report was mixed, with many calling for referral. Those in favor of the report's adoption spoke specifically about the use of samples in communities that are medically underserved and disproportionately burdened by health care disparities. Yet, those opposed to adoption stated that the report too severely limits the ability of small practices to dispense samples, while others found the recommendation restricting the provision of samples only within the confines of an established patient-physician relationship to be unrealistic and impractical.

The report 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.) An earlier version of this report had been presented at the June 2015 meeting of the HOD and was also referred back to CEJA.

PHARMACEUTICAL COSTS

Council on Medical Service Report 2 (Pharmaceutical Costs) as presented contained recommendations to improve the affordability of generic drugs, brand-name drugs, and biologics.

Resolution 806 asked that AMA advocate that the appropriate regulatory bodies of the federal government exercise its "march-in-rights" authority under the Bayh-Dole Act to assure the availability of pharmaceuticals at fair and reasonable prices to consumers, and reaffirm AMA policy in support of advocating that Medicare be granted the right to negotiate drug prices with pharmaceutical companies.

Resolution 814 asked that AMA convene a task force of all relevant stakeholders in the development, approval, and cost of prescription drugs, which should include representation from physicians, physician researchers, the pharmaceutical industry, pharmacy benefit managers, insurance payers, the Centers for Medicare & Medicaid Services, the US Food and Drug Administration, hospitals, and patient advocates; generate a grassroots effort to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and helps to put forward solutions to make prescription drugs more affordable for all patients; and report back to the HOD regarding the progress of the drug pricing task force and grassroots effort at the 2016 Interim meeting.

Resolution 817 asked that AMA work diligently and actively with Congress to advance legislation that would allow the Department of Health and Human Services to negotiate with pharmaceutical manufacturers the prices that may be charged for covered Medicare Part D drugs; and seek and actively support measures that would increase transparency in how pharmaceutical companies, pharmacy benefit managers, and health insurance companies determine the costs of prescription medications, including increasing transparency related to any incentives given by drug companies to pharmacy benefit managers or health insurance companies related to the dispensing or promotion of their manufactured drugs.

Following extensive discussion, the HOD adopted as AMA policy the following recommendations:

1. That AMA reaffirm Policy H-155.962, which opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.
2. That AMA reaffirm Policy H-110.988, which supports efforts to ensure fair and appropriate pricing of generic medications.
3. That AMA reaffirm Policy H-110.989, which supports the Federal Trade Commission (FTC) in its efforts to stop "pay for delay" arrangements by pharmaceutical companies and federal legislation that makes tactics delaying conversion of medications to generic status, also known as "pay for delay," illegal in the United States.
4. That AMA reaffirm Policy H-110.992, which states that AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs.
5. That AMA reaffirm Policy D-330.954, which states that AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs, and work toward eliminating Medicare prohibition on drug price negotiation.
6. That AMA encourage Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
7. That AMA encourage Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

8. That AMA monitor the impact of mergers and acquisitions in the pharmaceutical industry.
9. That AMA continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
10. That AMA encourage prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
11. That AMA support legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
12. That AMA support legislation to shorten the exclusivity period for biologics
13. That AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
14. That AMA generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

FDA GUIDELINES FOR PAID ENDORSEMENTS ON SOCIAL MEDIA

The HOD adopted Resolution 209 asking that AMA lobby the Food and Drug Administration (FDA) to update regulations to ensure closer regulation of paid endorsements of drugs or medical devices by individuals on social media, and lobby the FDA to develop guidelines to ensure that compensated parties on social media websites provide information that includes the risks and benefits of specific drugs or medical devices and off-use prescribing in every related social media communication in a manner consistent with advertisement guidelines on traditional media forms.

UPDATES ON MAINTENANCE OF CERTIFICATION

Council on Medical Education Report 2 reviews and consolidates existing American Medical Association (AMA) policy on Maintenance of Certification (MOC), Osteopathic Continuous Certification (OCC) and Maintenance of Licensure (MOL) to ensure that these policies are current and coherent. No attempt was made to modify any existing policy beyond what was necessary for editing for clarity. The newly consolidated policies will be accessible through “Policy Finder” on the AMA website.

Details regarding the new National Board of Medical Examiners Clinical Research ProgramSM, have been posted at <http://www.nbme.org/NewInitiatives/clinicalresearchprogram.html>.

BANNING DIRECT-TO CONSUMER ADS FOR PRESCRIPTION DRUGS

Resolution 927 from the Organized Medical Staff Section asked that AMA convene a taskforce to study issues arising from direct-to-consumer (DTC) advertising of prescription drugs and implantable devices, including, but not limited to, whether DTC advertising is educational for patients as well as the effects of DTC advertising on the patient-physician relationship and healthcare utilization and costs.

The Reference Committee report stated, “Strong supportive testimony was offered on this resolution and many speakers agreed that it was time to revisit this issue. Others believed that sufficient research on the pros and cons of direct-to-consumer advertising (DTCA) already was available, and that convening a task force per se was unnecessary. The United States is only one of two countries in the world (New Zealand) that allows this practice. Ultimately, the goal of advertising is to drive choice and demand for a product, not educate, although some patients may be prompted to visit a physician based on increased awareness of a specific disease mentioned in DTCA. The intersection of DTCA with the cost of drugs is another factor. Testimony also suggested that it was appropriate to support a ban altogether.” The Reference Committee also recommended that existing AMA policy providing guidance for DTC advertising be rescinded.

Your AMA Delegate discussed his own experience as a former Director of the FDA Office in charge of regulating prescription drug advertising and suggested that AMA’s existing policies be retained in case there were constitutional or other obstacles in enacting such a ban (<http://www.fiercepharmamarketing.com/story/just-say-no-drugs-advertising-ama-votes-ban-dtc-ads/2015-11-17>). The delegates voted to seek a ban on DTC advertising of Prescription Drugs, but to refer for decision to the AMA Board of Trustees the question of whether to rescind current AMA policy.

NATIONAL DRUG SHORTAGES UPDATE

Council on Science and Public Health Report 2 provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public

health issue, and recommends amending current AMA policy based on the fact that some previous sections of policy have been implemented or accomplished. The HOD agreed and updated Policy H-100.956 will be posted on the AMA website stating, “Our AMA supports the recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that experience drug shortages.”

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 (more than 750 at the Medical Student Section) who now attend the AMA House of Delegates meeting. My own medical school (Johns Hopkins) participates actively.

At this meeting both Dr. Kenneth Braunstein and I served as judges for the 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 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. Both of us have been reappointed to serve on the USAN Council through the end of 2016.

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 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

Peter H. Rheinstein, M.D., J.D., M.S.

President

Severn Health Solutions

Publisher

www.discoverymedicine.com

410-647-9500 (T)

410-647-6135 (F)

Email: phr@jhu.edu

phr@severnhealthsolutions.com

Linked  profile

www.linkedin.com/in/phrmd