Resolution 925 asks that our American Medical Association advocate for the National Board of Physicians and Surgeons to be recognized as an alternative to ABMS boards for recertification for physicians nationally.

Your Reference Committee heard mixed testimony that reflected differences of opinion on this complex item. Testimony supported lifelong learning and the need to keep current with advances in clinical practice, technology, and assessment. Our AMA has adopted extensive policy on maintenance of certification (MOC) that reinforces the need for ongoing learning and practice improvement and supports the principles of MOC. There was concern that the pathway to board recertification through the American Board of Medical Specialties (ABMS) and its specialty boards is costly and time consuming and diverts physicians from their focus on active patient care. In addition, there was also concern expressed about the lack of evidence to support the assertion that specialty organizations, such as the American College of Cardiology, had plans to develop alternative pathways to board recertification, as noted in lines 8 through 11 of the Resolution. The Council on Medical Education closely monitors the development and implementation of maintenance of certification standards and reports back to the HOD annually. Given the complexity of the issues presented, this item may benefit from a study of alternative mechanisms. Further, your Reference Committee believes that the study called for in the first Resolve of Resolution 924 should be completed before supporting alternative pathways to recertification, as called for in the second Resolve of Resolution 924 and Resolution 925. For these reasons, your Reference Committee recommends that only the first Resolve of Resolution 924 be adopted in lieu of Resolution 925.

(18) RESOLUTION 927 - SHOULD DRUG ADS BE BANNED?

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following Substitute Resolution 927 be adopted.

BAN DIRECT-TO-CONSUMER ADVERTISEMENTS OF PRESCRIPTION DRUGS AND IMPLANTABLE MEDICAL DEVICES

RESOLVED, that our American Medical Association support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.

RESOLVED, that Policy H-105.988 be rescinded.

HOD ACTION: First Resolve of Substitute Resolution 927 adopted, second Resolve of Substitute Resolution referred for decision.

Resolution 927 asks that our American Medical Association 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.

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 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. Your Reference Committee agrees.

Policy to be rescinded:

H-105.988 Direct-to-Consumer (DTC) Advertising of Prescription Drugs and Implantable Devices

It is the policy of our AMA: 1. That our AMA considers acceptable only those product-specific DTC advertisements that satisfy the following guidelines: (a) The advertisement should be indication-specific and enhance consumer education about both the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used. (b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug’s or device’s approval for marketing. (c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products. (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended. (e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable. (f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient. (g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition. (h) In general, product-specific DTC advertisements should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care profession...
professionals in DTC advertisements, a disclaimer should be prominently displayed. (i) The use of actual health care professionals, either practicing or retired, in DTC to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement. (j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved. (k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.

2. That our AMA opposes product-specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.

3. That the FDA review and pre-approve all DTC advertisements for prescription drug or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.

4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTC.

5. That DTC advertisements for newly approved prescription drug or implantable medical device products not be run until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTC for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product’s sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.

6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTC advertisements.

7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTC, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.

8. That our AMA supports the concept that when companies engage in DTC, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.

9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-specific DTC and with the Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion E-5.015 and to adhere to the ethical guidance provided in that Opinion.

10. That the Congress should request the Agency for Healthcare Research and Quality (AHRQ) to perform periodic evidence-based reviews of DTC in the United States to determine the impact of DTC on health outcomes and the public health. If DTC is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTC regulation or, if necessary, to prohibit DTC in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.

11. That our AMA continues to monitor DTC, including new research findings, and work with the FDA and the pharmaceutical and
medical device industries to make policy changes regarding DTC, as necessary. 12.
That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e.,
advertisements that discuss a disease, disorder, or condition and advise consumers to
see their physicians, but do not mention a drug or implantable medical device or other
medical product and are not regulated by the FDA). (BOT Rep. 38 and Sub. Res. 513,
A-99; Reaffirmed: CMS Rep. 9, Amended: Res. 509, and Reaffirmation I-99; Appendix
& Reaffirmed: Sub. Res. 503, A-01; Reaffirmed: Res. 522, A-02; Reaffirmed: Res. 914, I-
02; Reaffirmed: Sub. Res. 504, A-03; Reaffirmation A-04; Reaffirmation A-05; Modified:
BOT Rep. 9, A-06; Reaffirmed in lieu of Res. 514, A-07)

(19) RESOLUTION 901 - ACCESS TO MENTAL HEALTH
CARE FOR MEDICAL TRAINEES

RESOLUTION 913 - MENTAL HEALTH SERVICES FOR
MEDICAL STAFF

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends
that Resolutions 901 and 913 be referred.

HOD ACTION: Resolutions 901 and 913 referred.

Resolution 901 asks that our American Medical Association 1.) support the provision of
on-campus mental health care in medical schools and residency programs that goes
beyond supportive counseling; and 2.) encourage ongoing and future initiatives by
medical schools and residency programs to provide urgent and emergent access for all
medical trainees to psychiatrists that could include an in-house board-certified
psychiatrist.
Resolution 913 asks that our American Medical Association encourage health systems,
hospitals, and medical schools to offer physicians and medical students access to
confidential and comprehensive mental health services not affiliated with their place of
employment.

For both Resolution 901 and 913, your Reference Committee heard testimony that
emphasized the importance of making confidential and comprehensive mental health
services available to medical students, and resident and fellow physicians. It was noted
that Liaison Committee on Medical Education (LCME) accreditation standards require
medical schools to provide medical services at sites in reasonable proximity to the
locations of their required educational experiences, and that the LCME collects data on
access to psychiatric services and student satisfaction with mental health services. It
was also noted that this item is consistent with the work being done by the Accreditation
Council for Graduate Medical Education (ACGME) to support trainee well-being, through
such efforts as the ACGME Clinical Learning Environment Review process. There was
concern expressed during testimony about providing students and residents access to
in-house psychiatrists for urgent and emergent care. It was noted that a psychiatrist
located in reasonable proximity to training sites would be the most appropriate caregiver
so that students and residents would not be obligated to receive care from a physician
who is involved in their academic assessment and advancement. Other factors related to
OSHA standards and occupational health care regulations also need to be considered,