AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (I-16)

Report of Reference Committee K

Paul A. Friedrichs, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Board of Trustees Report 9 - Product-Specific Direct-To-Consumer Advertising of Prescription Drugs
2. Council on Science and Public Health Report 3 - Genome Editing and its Potential Clinical Use
3. Council on Science and Public Health Report 4 - Hormone Therapies: Off-Label Uses and Unapproved Formulations
4. Resolution 903 – Prevention of Newborn Falls in Hospitals
5. Resolution 926 – Establishing and Achieving National Goals to Eliminate Lead Poisoning and Prevent Lead Exposures to Children

RECOMMENDED FOR ADOPTION AS AMENDED

6. Council on Science and Public Health Report 1 - Urine Drug Testing
7. Resolution 902 – Removing Restrictions on Federal Public Health Crisis Research
8. Resolution 904 – Improving Mental Health at Colleges and Universities for Undergraduates
9. Resolution 905 – Chronic Traumatic Encephalopathy (CTE) Awareness
10. Resolution 908 – Faith and Mental Health
11. Resolution 910 – Disparities in Public Education as a Crisis in Public Health and Civil Rights
12. Resolution 911 – Importance of Oral Health in Medical Practice
13. Resolution 912 – Neuropathic Pain Recognized as a Disease
14. Resolution 913 – Improving Genetic Testing and Counseling Services in Hospitals and Healthcare Systems
15. Resolution 914 – Needle / Syringe Disposal
16. Resolution 915 – Women and Alzheimer's Disease
17. Resolution 916 – Women and Pre-Exposure Prophylaxis (PrEP)
18. Resolution 917 – Youth Incarceration in Adult Prisons
19. Resolution 918 – Ensuring Cancer Patient Access to Pain Medication
20. Resolution 919 – Coal-Tar Based Sealcoat Threat to Human Health and the Environment
21. Resolution 924 – AMA Advocacy for Environmental Sustainability and Climate
22. Resolution 925 – Graphic Warning Label on all Cigarette Packages
23. Resolution 927 – The DEA Order to Reduce Opioid Production

RECOMMENDED FOR REFERRAL

24. Resolution 901 – Disclosure of Screening Test Risks and Benefits, Performed Without a Doctor's Order
25. Resolution 906 – Universal Color Scheme for Respiratory Inhalers
26. Resolution 907 – Clinical Implications and Policy Considerations of Cannabis Use

RECOMMENDED FOR REFERRAL FOR DECISION

27. Resolution 909 – Promoting Retrospective and Cohort Studies on Pregnant Women and Their Children

RECOMMENDED FOR NOT ADOPTION

28. Resolution 920 – Haptenation and Hypersensitivity Disorders Communication

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

29. Resolution 928 – Closing the Loop on Pharmaceuticals

Resolutions handled via the Reaffirmation Consent Calendar:

Resolution 921 – Raise the Minimum Age of Legal Access to Tobacco to 24 Years
Resolution 922 – Responsible Parenting and Access to Family Planning
Resolution 923 – Reverse the Onus in the Manufacture and Use of Chemicals

(1) BOARD OF TRUSTEES REPORT 9 - PRODUCT-SPECIFIC DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Board of Trustees Report 9 be adopted and the remainder of the report be filed.

Board of Trustees Report 9 summarizes concerns and findings on the impact of DTCA and whether the AMA should maintain a comprehensive policy on what constitutes acceptable product-specific DTCA. Additionally, this report briefly considers whether establishing policy opposing industry tax credits for DTCA is advisable. The Board of Trustees recommends that the following statements be adopted in lieu of Second Resolve, Resolution 927-1-15 and Resolution 514-A-16:

1) That Policy H-105.988, "Direct-to-Consumer (DTC) Advertising (DTCA) of Prescription Drugs and Implantable Devices," be amended by addition and deletion to read as follows:

It is the policy of our AMA:

1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
2. That until such a ban is in place, ~~1. That our AMA considers acceptable only those~~ our AMA opposes product-claim~~specific~~ DTCA ~~advertisements~~ that does not 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-claim~~specific~~ DTCA ~~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 professionals in DTCA ~~advertisements~~, a disclaimer should be prominently displayed.

(i) The use of actual health care professionals, either practicing or retired, in DTCA 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 DTCA ~~advertisements~~ for prescription drugs 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 DTCA.

5. That DTCA ~~advertisements~~ for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA 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 DTCA ~~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 DTCA, 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 DTCA, 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-claim~~specific~~ DTCA and with the Council on Ethical and Judicial Affairs ~~(CEJA)~~ Ethical Opinion E-~~5.015~~9.6.7 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)~~ or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA 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 DTCA regulation or, if necessary, to prohibit DTCA 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 supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.
12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.
13. 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). (Modify Current HOD Policy)

2) That Policy H-105.986, "Ban Direct-to-Consumer Advertisements of Prescription Drugs and Implantable Devices," be rescinded as it is now incorporated into amended Policy H-105.988.

Limited but supportive testimony was offered on Board of Trustees Report 9. AMA policy supports a ban on product specific direct-to-consumer advertising (DTCA), but given the current First Amendment protections for this practice, a need exists to maintain AMA policy on what constitutes an acceptable DTCA. DTCA that promotes public health, such as those for CDC recommended immunizations, should be considered *a priori* as acceptable.

(2) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 3 - GENOME EDITING AND ITS POTENTIAL CLINICAL USE

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 3 be adopted and the remainder of the report be filed.

Council on Science and Public Health Report 3 was initiated to inform physicians and the House of Delegates about the recent remarkable advances in genome editing and its potential clinical applications in gene therapy, as well as concerns about it and proposals to ensure its responsible use. The Council on Science and Public Health recommends that our AMA 1. encourage continued research into the therapeutic use of genome editing; and 2. encourage continued analysis of potential uses of germline editing and the development of international principles to guide appropriate use.

Unanimously supportive testimony was received on CSAPH Report 3. The Council was thanked for informing the House on the transformative technology of genome editing. Testimony expressed concern for the potential ethical abuses that may arise from genome editing technology, such as choosing "desirable" physical traits. Your Reference Committee agrees with this concern, but points out that the National Academy of Sciences, Engineering and Medicine will be releasing a report late in 2016 that explores ethical concerns and ways to address such concerns, and that the Council's Recommendation 2 urges the development of principles grounded in science and ethics to determine the permissible uses of germline genome editing. Your Reference Committee therefore recommends that Council on Science and Public Health Report 3 be adopted.

(3) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 4 - HORMONE THERAPIES: OFF-LABEL USES AND UNAPPROVED FORMULATIONS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 4 be adopted and the remainder of the report be filed.

Council on Science and Public Health Report 4 is intended to inform physicians about the use of off-label and unapproved uses of hormones, especially compounded hormone therapies. The Council on Science and Public Health recommends the following recommendations be adopted in lieu of Res 512-A-15:

1. That Policy D-120.969 be amended by addition and deletion to read as follows:
   D-120.969 ~~FDA Oversight of Bioidentical~~ Compounded Hormone ~~(BH)~~ Therapy Preparations
   Our AMA ~~will~~: (1) recognizes the term "bioidentical hormone" as a marketing term not grounded in science; use of the term "compounded hormone therapy" is

preferred; (~~1~~2) will urge that renewed attention be devoted to the ~~of the Food and Drug Administration (FDA) to conduct surveys for~~ purity and potency ~~dosage accuracy~~ of ~~all~~ compounded hormone therapy ~~"bioidentical hormone"~~ formulations; (~~2~~3) will urge continued attention to the ~~FDA to require mandatory~~ reporting ~~by drug manufacturers, including compounding pharmacies,~~ of adverse events related to the use of compounded hormone therapies ~~"bioidentical hormones"~~; ~~(3) urge the FDA to create a registry of adverse events related to the use of compounded "bioidentical hormone" preparations~~; (4) recommends that physicians and other prescribers fully inform patients of the potential side effects and risks of the use of compounded hormone replacement therapy; and (5) will request that when drug ingredients with black box warnings are used in compounded products, patients should be informed about the ~~FDA require the inclusion of uniform patient information, such as~~ warnings and precautions associated with the use of such drug ingredients~~, in packaging of compounded "bioidentical hormone" products; and (5) urge the FDA to prohibit the use of the term "bioidentical hormones" unless the preparation has been approved by the FDA.~~

2. Our AMA supports that patients be informed that compounded products are not FDA-approved.
3. That our AMA urge the United States Pharmacopeia to re-examine the validity of the current estriol monograph.

Considerable support was offered for Council on Science and Public Health Report 4. Most of the testimony was on the wisdom of adding a recommendation that would link the use of hormone replacement therapy with a specific deficiency diagnosis, confirmed with laboratory values. Speakers provided evidence based examples where this type of approach was not necessary or not clinically relevant. A request also was made for the AMA to explicitly establish a position that the use of human chorionic gonadotropin for weight loss is inappropriate. This issue was evaluated in the report, but your Reference Committee believes that such a statement in the policy compendium is unnecessary and urges adoption of the report.

(4) RESOLUTION 903 – PREVENTION OF NEWBORN FALLS IN HOSPITALS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 903 be adopted.

Resolution 903 asks that our AMA support implementation of newborn fall prevention plans and post-fall procedures through clinically proven, high-quality, and cost-effective approaches.

Your Reference Committee heard supportive testimony for this item. Newborn falls can result in injury or even death of the newborn and severe emotional distress to the parents and caregiver(s), but falls are preventable. Institutions have taken measures to reduce falls such as awareness and education efforts for expectant parents and hospital/birthing center staff. Some testimony supported the term “drops” since many instances of falls occur when parents or caregivers accidentally drop the infant. However, the term “falls” is the standard terminology in research literature, e.g., infants

falling from furniture when they are not being carried or held. The American Academy of Pediatrics testified that its recently updated guidelines on safe infant sleep include several recommendations that support falls prevention, and requested that those recommendations be explicitly supported in the resolution. However, your Reference Committee believes that the broad nature of the original language is inclusive of all clinically-proven approaches. Therefore, your Reference Committee recommends that Resolution 903 be adopted.

(5) RESOLUTION 926 – ESTABLISHING AND ACHIEVING NATIONAL GOALS TO ELIMINATE LEAD POISONING AND PREVENT LEAD EXPOSURES TO CHILDREN

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 926 be adopted.

Resolution 926 asks that our American Medical Association 1. call on the United States government to establish national goals to: a) ensure that no child has a blood lead level >5 µg/dL (>50 ppb) by 2021, b) eliminate lead exposures to pregnant women and children, so that by 2030, no child would have a blood lead level > 1 µg/dL (10 ppb); and 2. Call on the United States government in all its agencies to pursue the following strategies to achieve this goal: a) adopt health-based standards and action levels for lead that rely on the most up-to-date scientific knowledge to prevent and reduce human exposure to lead, and assure prompt implementation of the strongest available measures to protect pregnant women and children from lead toxicity and neurodevelopmental impairment, b) identify and remediate current and potential new sources of lead exposure (in dust, air, soil, water and consumer products) to protect children before they are exposed, c) continue targeted screening of children to identify those who already have elevated blood lead levels for case management, as well as educational and other services, d) eliminate new sources of lead introduced or released into the environment, which may entail banning or phasing out all remaining uses of lead in products (aviation gas, cosmetics, wheel weights, industrial paints, batteries, lubricants, and other sources), and the export of products containing lead, and setting more protective limits on emissions from battery recyclers and other sources of lead emissions, e) provide a dedicated funding stream to enhance the resources available to identify and eliminate sources of lead exposure, and provide educational, social and clinical services to mitigate the harms of lead toxicity, particularly to protect and improve the lives of children in communities that are disproportionately exposed to lead, and f) establish an independent expert advisory committee to develop a long-term national strategy, including recommendations for funding and implementation, to achieve the national goal of eliminating lead toxicity in pregnant women and children, defined as blood lead levels above 1 µg/dL (10 ppb).

Your Reference Committee heard testimony unanimously supportive of Resolution 926. National goals and standards for addressing elevated blood lead levels in children are included as a part of Healthy People 2020 and have been established based on data from the National Health and Nutrition Examination Survey. Establishing new national goals and pursuing the outlined strategies to achieve these goals should prevent future public health emergencies, like the one experienced in Flint, Michigan. Therefore, your Reference Committee recommends adoption.

(6) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 1 - URINE DRUG TESTING

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that part 2 of Recommendation 1 in Council on Science and Public Health Report 1 be amended by addition on page 13, line 13, to read as follows:

1. That Policy H-95.985, "Drug Screening and Mandatory Drug Testing," be amended by addition and deletion as follows:

2. Results from ~~such~~ drug testing programs can yield accurate evidence of prior exposure to drugs. Drug testing does not provide any information about pattern of use of drugs, dose of drugs taken, ~~abuse of~~ ~~or~~ physical dependence on drugs, the presence or absence of a substance use disorder, or about mental or physical impairments that may result from drug use~~.~~, nor does it provide valid or reliable information about harm or potential risk of harm to children or, by itself, provide indication or proof of child abuse, or neglect or proof of inadequate parenting.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that part 4 of Recommendation 1 in Council on Science and Public Health Report 1 be amended by addition on page 13, line 26 to read as follows:

1. That Policy H-95.985, "Drug Screening and Mandatory Drug Testing," be amended by addition and deletion as follows:

4. Since physicians often are called upon to interpret results, they should be familiar with the disposition characteristics ~~pharmacokinetic properties~~ of the drugs to be tested before interpreting any results. ~~and the use to which the results will be put~~. If interpretation of any given result is outside of the expertise of the physician, assistance from appropriate experts, such as a certified Medical Review Officer, should be pursued. (Modify Current HOD Policy)

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 1 be adopted as amended and the remainder of the report be filed.

Council on Science and Public Health Report 1 was initiated to help promulgate urine drug testing (UDT) as a medical management tool that can be used to better serve patient populations. This report recommends:

1) That Policy H-95.985 be amended by addition and deletion as follows:

Drug ~~Screening and Mandatory Drug~~ Testing

The AMA believes that physicians should be familiar with the strengths and limitations of drug ~~screening~~ testing techniques and programs:

2. Due to the limited specificity of the inexpensive and widely available non-instrumented devices such as point-of-care drug testing devices ~~screening techniques~~, ~~forensically~~ acceptable clinical drug testing programs ~~must~~ should include the ability to access highly specific, analytically acceptable ~~technically more complicated and more expensive~~ confirmation techniques, which ~~unequivocally~~ definitively establish~~es~~ the identities and quantities of drugs, in order to further analyze results from presumptive testing methodologies. Physicians should consider the value of data from non-confirmed preliminary test results, and should not make major clinical decisions without using confirmatory methods to provide assurance about the accuracy of the clinical data.
3. Results from ~~such~~ drug testing programs can yield accurate evidence of prior exposure to drugs. Drug testing does not provide any information about pattern of use of drugs, dose of drugs taken, ~~abuse of~~ ~~or~~ physical dependence on drugs, the presence or absence of a substance use disorder, or about mental or physical impairments that may result from drug use.
4. Before implementing a drug testing program, ~~P~~physicians ~~need to be aware of~~ should: (a) understand the objectives ~~of a drug testing program in which they participate~~ and questions they want to answer with testing; (b) understand the advantages and limitations of the testing technology; (c) be aware of and educated about the drugs chosen for inclusion in the drug test; and (d) ensure that the cost of testing aligns with the expected benefits for their patients. ~~, and they~~ Physicians also should be satisfied that the selection of drugs (analytes) and subjects to be tested as well as ~~and~~ the screening and ~~confirming~~ confirmatory techniques that are used meet the stated objectives.
5. Since physicians often are called upon to interpret results, they should be familiar with the disposition characteristics ~~pharmacokinetic properties~~ of the drugs to be tested before interpreting any results. ~~and the use to which the results will be put~~. If interpretation of any given result is outside of the expertise of the physician, assistance from appropriate experts should be pursued.

2) That our AMA, in conjunction with the AMA Opioid Task Force, develop practical guidance and educational materials to assist physicians with implementing urine drug testing as part of a risk mitigation strategy when opioid analgesics are prescribed for chronic use.

Strong support was offered for Council on Science and Public Health Report 1 as useful guidance for practicing physicians. One speaker noted that the Council may wish, in the future, to address drug testing in patients admitted to the hospital. The Council recommended adding a notation regarding medical review officers in Recommendation 1 and testimony also supported adding information on the inappropriate use of drug testing results to make judgements about pregnant women or parenting. Your Reference Committee recommends that Council on Science and Public Health Report 1 be adopted as amended.

(7) RESOLUTION 902 – REMOVING RESTRICTIONS ON FEDERAL PUBLIC HEALTH CRISIS RESEARCH

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 902 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA oppose efforts to restrict funding or suppress the findings of biomedical and public health research for ~~the purpose of influencing~~ political ~~discourse~~ purposes. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 902 be adopted as amended.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the title of Resolution 902 be changed, to read as follows:

OPPOSE RESTRICTIONS ON PUBLIC HEALTH RESEARCH

Resolution 902 asks that our AMA recognize the importance of timely research and open discourse in combatting public health crises and oppose efforts to restrict funding or suppress the findings of biomedical and public health research for the purpose of influencing political discourse.

Your Reference Committee heard testimony largely supportive of the intent of Resolution 902. While the AMA has extensive policy supporting public health research and condemning inappropriate political influence on funding decisions, this resolution specifically focuses on restricting public health funding. Your Reference Committee agreed with testimony that a minor amendment was needed to clarify the intent of the second Resolve statement. The title was also changed to broaden the focus to all public health research rather than just federal public health crisis research. Therefore, your Reference Committee recommends that Resolution 902 be adopted as amended.

(8) RESOLUTION 904 – IMPROVING MENTAL HEALTH AT COLLEGES AND UNIVERSITIES FOR UNDERGRADUATES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first resolve of Resolution 904 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association support strategies that emphasize de-stigmatization and enable timely and affordable access to ~~accessibility and de-stigmatization as strategies in~~ mental health services for undergraduate and graduate students ~~measures implemented by colleges and universities~~, in order to improve the provision of care and increase its use by those in need (New HOD Policy); and be it further

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second resolve of Resolution 904 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA support colleges and universities in ~~publicizing~~ emphasizing to undergraduate and graduate students and parents the importance, ~~of mental health resources, with an emphasis on the~~ availability, and efficacy of ~~such~~ mental health resources (New HOD Policy); and be it further

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the third resolve of Resolution 904 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA support collaborations of university mental health specialists and local public or private practices and/or health centers in order to provide a larger pool of resources, such that any student is ~~be~~ able to access care in a timely and affordable manner. (New HOD Policy)

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that Resolution 904 be adopted as amended.

RECOMMENDATION E:

Madam Speaker, your Reference Committee recommends that the title of Resolution 904 be changed, to read as follows:

IMPROVING MENTAL HEALTH SERVICES FOR UNDERGRADUATE AND GRADUATE STUDENTS

Resolution 904 asks that our AMA support 1. accessibility and de-stigmatization as strategies in mental health measures implemented by colleges and universities, in order to improve the provision of care and increase its use by those in need; 2. colleges and universities in publicizing the importance of mental health resources, with an emphasis on the availability and efficacy of such resources; and 3. collaborations of university mental health specialists and local health centers in order to provide a larger pool of resources, such that any student be able to access care in a timely and affordable manner.

Your Reference Committee heard unanimously supportive testimony about the importance of accessible mental health services on college and university campuses. An increasing number of students are experiencing disorders such as depression, anxiety, suicidal ideation, alcohol misuse, eating disorders, and self-injury, and mental health centers on campuses have struggled to provide care to all those in need. Amendments were suggested to ensure that parents are aware of the importance of mental health services and their availability for their sons and daughters who are students, and for mechanisms to collaborate with local mental health providers to ensure timely access. Your Reference Committee agrees with the importance of providing mental health services for college and university students, including graduate students, and believes that the recommendation should be adopted with the addition of the suggested amendments and clarifying language.

(9) RESOLUTION 905 – CHRONIC TRAUMATIC ENCEPHALOPATHY (CTE) AWARENESS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 905 be amended by addition and deletion, to read as follows:

~~RESOLVED, That our American Medical Association amend part one of H-470.954 by addition and deletion to read as follows:~~
~~Reduction of Sports-Related Injury and Concussion H-470.954:~~
~~1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged~~

~~consequences.; and (c) promote education for physicians and the public on the detection, treatment and prognosis of chronic traumatic encephalopathy (CTE). (Modify Current HOD Policy); and be it further~~

RESOLVED, That our AMA support ~~work with interested agencies and organizations to advocate for further~~ research into the detection, causes, and prevention ~~and treatments for~~ of injuries along the continuum from subconcussive head impacts to conditions such as chronic traumatic encephalopathy (CTE). (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 905 be adopted as amended.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Policy H-470.954 be reaffirmed.

Resolution 905 asks that our AMA:

1) Amend part one of Policy H-470.954, "Reduction of Sports-Related Injury and Concussion," by addition and deletion to read as follows:
    1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; ~~and~~ (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences~~.~~; and (c) promote education for physicians and the public on the detection, treatment and prognosis of chronic traumatic encephalopathy (CTE); and
2) Work with interested agencies and organizations to advocate for further research into the causes of and treatments for chronic traumatic encephalopathy (CTE).

Your Reference Committee heard testimony in support of maintaining existing policy. Therefore, your Reference Committee recommends reaffirming Policy H-470.954. While there was broad support for increased awareness and research into the causes of chronic traumatic encephalopathy (CTE) and measures to prevent it, others noted that CTE can only be diagnosed post-mortem. Several delegations opposed the amendment called for in Resolve 1 since antemortem detection of CTE is not possible at this time, nor is treatment. Testimony pointed out that radiographic detection methods are improving, and anatomic changes due subconcussive injury may be detectable. Many speakers supported the research called for in Resolve 2. Your Reference Committee concurs that there is value in supporting research on CTE, as well as on the continuum of subconcussive head impacts that may lead to more permanent injury and impairment. It therefore recommends adoption of the second resolve with these amendments.

Policy recommended for reaffirmation:
H-470.954 Reduction of Sports-Related Injury and Concussion

1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences. 2. Our AMA supports the adoption of evidence-based, age-specific guidelines on the evaluation and management of concussion in all athletes for use by physicians, other health professionals, and athletic organizations. 3. Our AMA will work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the ability of physicians to prevent, diagnose, and manage concussions and other sports-related injuries. 4. Our AMA urges appropriate agencies and organizations to support research to: (a) assess the short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span; (b) identify determinants of concussion and other sports-related injuries in pediatric and adult athletes, including how injury thresholds are modified by the number of and time interval between head impacts and concussions; (c) develop and evaluate effective risk reduction measures to prevent or reduce sports-related injuries and concussions and their sequelae across the lifespan; and (d) develop objective biomarkers to improve the identification, management, and prognosis of athletes suffering from concussion to reduce the dependence on self-reporting and inform evidence-based, age-specific guidelines for these patients. CSAPH Rep. 3, A-15

(10) RESOLUTION 908 – FAITH AND MENTAL HEALTH

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following Resolution be <u>adopted in lieu of Resolution 908</u>, to read as follows:

FAITH AND MENTAL HEALTH

RESOLVED, That our American Medical Association support mental health and faith community partnerships that foster improved education and understanding for faith leaders regarding culturally competent, medically accepted, and scientifically proven methods of care for psychiatric and substance use disorders (Directive to Take Action); and be it further

RESOLVED, That our AMA support better understanding on the part of mental health providers of the role of faith in mental health and addiction recovery for some individuals, (Directive to Take Action); and be it further

RESOLVED, That our AMA support efforts of mental health providers to create respectful, collaborative relationships with local religious leaders to improve access to scientifically sound mental health services. (Directive to Take Action)

Resolution 908 asks that our AMA 1. advocate and support mental health and faith community partnerships that will provide a platform for faith leaders to get educated about psychiatric and substance abuse disorders and mental health providers understand the role of faith in recovery; and 2. study and support a partnership to foster respectful, collaborative relationships between psychiatrists, other mental health providers and the faith-based community to improve quality care for individuals and families with mental health and substance abuse problems.

Your Reference Committee heard positive testimony for this resolution. The important role of faith in recovery of some patients was underscored, as well as the need for improvement in access to mental health services. The APA partnered to develop the Mental Health and Faith Community Partnership, a collaboration between psychiatrists and clergy aimed at fostering a dialogue between the two fields, reducing stigma, and accounting for medical and spiritual dimensions as people seek care. The GLMA suggested substitute language that maintained the spirit of the resolution but emphasized medically accepted and scientifically proven mental health services. The resolution sponsors, the IMG Section, concurred with these changes. The ASAM proposed that addiction medicine be called out as a specific mental health service, but your Reference Committee believes it is appropriate to maintain “mental health services” as a more general statement so that it refers to all mental health disorders and services. Your Reference Committee recommends adoption of the substitute language offered by GLMA and supported by the IMG Section.

(11) RESOLUTION 910 – DISPARITIES IN PUBLIC EDUCATION AS A CRISIS IN PUBLIC HEALTH AND CIVIL RIGHTS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 910 be <u>amended by addition</u> to read as follows:

RESOLVED That our AMA issue a call to action to all educational private and public stakeholders to come together to organize and examine, and using any and all available scientific evidence, to propose strategies, regulation and/or legislation to further the access of all children to a quality public education<u>, including early childhood education,</u> as one of the great unmet health and civil rights challenges of the 21st century. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 910 be amended by addition of a third Resolve to read as follows:

RESOLVED, that our AMA acknowledge the role of early childhood brain development in persistent educational and health disparities and encourage public and private stakeholders to work to strengthen and expand programs to support optimal early childhood brain development and school readiness (New HOD Policy); and be it further

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Resolution 910 be adopted as amended.

Resolution 910 asks that our AMA consider continued educational disparities based on ethnicity, race and economic status a detriment to the health of the nation; and issue a call to action to all educational private and public stakeholders to come together to organize and examine, and using any and all available scientific evidence, to propose strategies, regulation and/or legislation to further the access of all children to a quality public education as one of the great unmet health and civil rights challenges of the 21st century.

Your Reference Committee heard testimony unanimously in support of this Resolution. Research has consistently linked educational attainment with health outcomes. Testimony from the AAP highlighted the importance of the role of early childhood education in brain development and an amendment was offered to address this issue. Your Reference Committee agrees that early childhood education is important and therefore, recommends adoption as amended.

(12) RESOLUTION 911 – IMPORTANCE OF ORAL HEALTH IN MEDICAL PRACTICE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first Resolve of Resolution 911 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association recognize the importance of a.) managing oral health, and b.) access to dental care as a part of optimal ~~overall~~ patient care (New HOD Policy); and be it further

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 911 be amended by deletion, to read as follows:

~~RESOLVED, That our AMA support efforts to educate physicians on oral condition screening and management, as well as the consequences of poor oral hygiene on mental and physical health (New HOD Policy); and be it further~~

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the third Resolve of Resolution 911 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA ~~encourage closer~~ explore opportunities for collaboration ~~of physicians~~ with the American Dental Association on a ~~dental providers to provide~~ comprehensive strategy for improving oral health ~~medical~~ care and education for clinicians. (New HOD Policy); ~~and be it further~~

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that the fourth Resolve of Resolution 911 be amended by deletion, to read as follows:

~~RESOLVED, That the AMA support efforts to increase access to oral health services. (New HOD Policy)~~

RECOMMENDATION E:

Madam Speaker, your Reference Committee recommends that Resolution 911 be adopted as amended.

RECOMMENDATION F:

Madam Speaker, your Reference Committee recommends that the title of Resolution 911 be changed to read as follows:

IMPORTANCE OF ORAL HEALTH IN PATIENT CARE

Resolution 911 asks that our AMA 1. recognize the importance of managing oral health as a part of overall patient care; 2. support efforts to educate physicians on oral

condition screening and management, as well as the consequences of poor oral hygiene on mental and physical health; 3. encourage closer collaboration of physicians with dental providers to provide comprehensive medical care; and 4. support efforts to increase access to oral health services.

Testimony highlighted existing evidence of a link between poor oral hygiene, development of periodontal disease, and its relationship with other systemic diseases. Overall patient care, health, and dental health outcomes could be improved by more attention to oral health by physicians and better collaboration between physicians and dentists. The importance of care that "reconnects the mouth to the rest of the body" was underscored. A number of amendments were suggested on topics such as training, effects on reproductive health, and creative mechanisms that practices can implement to promote oral and dental health care. Your Reference Committee believes that in lieu of the many amendments, simplification of the language, emphasizing importance of oral health and access to dental care, and exploring opportunities for collaboration with the American Dental Association to improve oral health care, is called for, and recommends adoption with these amendments.

(13) RESOLUTION 912 – NEUROPATHIC PAIN RECOGNIZED AS A DISEASE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 912 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association recognize neuropathic pain as a distinct pain condition ~~disease state~~ with multiple pathophysiological aspects requiring a range of interventions different from other pain conditions ~~to advance neuropathic pain treatment and prevention~~; and be it further (New HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 912 be amended by the addition of a second Resove, to read as follows:

RESOLVED, That our AMA support efforts to educate patients and physicians and other healthcare providers on the appropriate prevention and treatment of neuropathic pain.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Resolution 912 be adopted as amended.

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that the title of Resolution 912 be changed, to read as follows:

NEUROPATHIC PAIN

Resolution 912 asks that our AMA recognize neuropathic pain as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance neuropathic pain treatment and prevention.

Conflicting opinions were expressed about the validity and wisdom of categorizing neuropathic pain as a disease, although there was general agreement that neuropathic pain must be treated differently than other pain states (e.g., nociceptive, inflammatory). Proponents believe that declaring neuropathic pain as a disease would foster better treatment and reduce the overuse of opioids for the treatment of neuropathic pain symptoms. Opponents strongly expressed the view that any distinctions are "symptom" and not disease-related. One person noted that if neuropathic pain is designated as a disease, it may be used for disability claims. Significant support was offered for an amendment that emphasized neuropathic pain as a distinct pain "condition" in need of specific interventions. The Council on Science and Public Health previously examined this issue in 2010, but did not expressly recommend that neuropathic pain (or maldynia) be considered a disease. Your Reference Committee agrees that it is not appropriate at this time to declare neuropathic pain as a disease.

(14) RESOLUTION 913 – IMPROVING GENETIC TESTING AND COUNSELING SERVICES IN HOSPITALS AND HEALTHCARE SYSTEMS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first Resolve of Resolution 913 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association support appropriate ~~efforts to assess the usage~~ utilization of genetic testing, ~~and need for access to~~ pre- and post-test counseling for patients undergoing genetic testing ~~services~~, and physician preparedness in counseling patients or referring them to ~~board-certified~~ qualified genetics specialists (New HOD Policy); and be it further

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 913 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA support the development and dissemination of ~~encourage efforts to create and disseminate~~ guidelines for best practice standards concerning pre- and post-test genetic counseling ~~for genetic test results~~ (New HOD Policy); and be it further

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the third Resolve of Resolution 913 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA support ~~further~~ research ~~into~~ and open discourse concerning issues in medical genetics, including ~~the~~ genetic specialist workforce levels ~~shortage~~, physician preparedness in the provision of genetic testing and counseling services, and impact of genetic testing ~~results~~ and counseling on patient care and outcomes ~~satisfaction~~. (New HOD Policy)

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that Resolution 913 be adopted as amended.

RECOMMENDATION E:

Madam Speaker, your Reference Committee recommends that the title of Resolution 913 be changed, to read as follows:

IMPROVING GENETIC TESTING AND COUNSELING SERVICES

RECOMMENDATION F:

Madam Speaker, your Reference Committee recommends that Policy H-460.902 be reaffirmed.

Resolution 913 asks that our AMA 1. support efforts to assess the usage of genetic testing and need for counseling services, physician preparedness in counseling patients or referring them to board-certified genetics specialists; 2. encourage efforts to create

and disseminate guidelines for best practice standards concerning counseling for genetic test results; and 3. support further research into and open discourse concerning issues in medical genetics, including the genetic specialist workforce shortage, physician preparedness in the provision of genetic testing and counseling services, and impact of genetic test results and counseling on patient satisfaction.

Your Reference Committee heard mostly supportive testimony for this resolution. Studies have previously noted that a gap exists in genetic testing knowledge and counseling skills among physicians. Testimony pointed out that genetic testing has become progressively more complex. Concern was raised about the recent practices of some insurance companies to restrict genetic test ordering to only patients that have received pre-test counseling from a medical geneticist or genetic counselor. Your Reference Committee believes that the AMA should support efforts to improve appropriate genetic testing and access to counseling services, and recommends amendments to the resolution to make it more direct and clear. Specifically, instead of calling for more assessments of genetic test usage and counseling, your Reference Committee recommends amendments to Resolve 1 that directly support appropriate testing and access to counseling services. It also recommends replacing "board-certified" with "qualified" because testimony underscored that many providers, such as oncologists, are proficient in providing counseling services even though they may not be board-certified in medical genetics or genetic counseling. Your Reference Committee also recommends amendments to Resolves 2 and 3 that support best practice guidelines, and research into issues in medical genetics. In Resolve 3, it offers an amendment supporting research into the impact of testing and counseling on patient care and outcomes, rather than patient satisfaction, since this will contribute to efforts to define the clinical situations in which genetic testing is appropriate. It also recommends a title change to include genetic testing and counseling improvements in all settings. Finally, your Reference Committee recommends reaffirmation of Policy H-460.902, which opposes the practice of insurance companies restricting genetic test ordering to only certain specialists.

Policy recommended for reaffirmation:
H-460.902 Opposition to Genetic Testing Restrictions Based on Specialty
1. Our AMA opposes limiting the ordering of genetic testing based solely on physician specialty or other non-medical care based criteria. 2. Our AMA opposes public and private payers imposing a standard of practice with requirements for utilization of non-affiliated medical specialists or non-physicians prior to ordering genetic testing. 3. Our AMA, working with other interested specialty and component societies, will communicate our opposition to non-medical restrictions to genetic testing to relevant health insurers. 4. Our AMA will continue to support the importance of pre- and post-testing counseling when a patient is considered to be at risk for a hereditary susceptibility for cancer and other diseases by a qualified health professional so that patients have the benefit of informed decision-making regarding genetic testing. Res. 115, A-14

(15) RESOLUTION 914 – NEEDLE / SYRINGE DISPOSAL

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-95.958 be <u>amended</u>, to read as follows:

H-95.958 Syringe and Needle Exchange Programs
Our AMA: (1) encourages communities, especially those with a drug injection use problem, to establish needle exchange programs and physicians to refer their patients to such programs; (2) will initiate and support legislation providing funding for needle exchange programs for injecting drug users; and (3) strongly encourages state medical associations to initiate state legislation modifying drug paraphernalia laws so that injection drug users can purchase and possess needles and syringes without a prescription and needle exchange program employees are protected from prosecution for disseminating syringes. (Res. 231, I-94; Reaffirmed Ref. Cmt. D, I-96; Modified by CSA Rep. 8, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Modified: Res. 203, A-13)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that amended Policy H-95.958 be adopted in lieu of Resolution 914.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Policy H-95.942 be reaffirmed.

Resolution 914 asks that our AMA 1. support the requirement that medical facility needle/syringe disposal devices be as theft-proof and tamper-proof as possible; this requirement could be established by rule or statute; 2 support the requirement that stored used needles/syringes be properly secured so as to discourage theft; 3. support the requirement that theft and tamper-proof containers be placed in public restrooms for the purpose of needle/syringe disposal; an ideal device would crush the syringe as part of the disposal process; and 4. encourage those communities with a significant IV drug abuse population to establish a needle exchange program, since this helps eliminate the demand for used needles/syringes.

Considerable testimony was provided in support of Resolution 914, and the evidence base demonstrating the effectiveness of needle exchange programs in reducing the spread of blood borne infectious diseases among injection drug users. Concerns were expressed about the type of mandates included in this resolution and the cost of implementation given that many needle disposal devices and programs currently exist. Ultimately, the types of disease clusters or local epidemics that prompted this resolution are fostered by a combination of poverty, addiction, lack of public transportation, lack of access to physicians and treatment facilities for substance use disorders, as well as a lack of HIV-related funding, services, and awareness. Stigma that discourages testing and treatment also may contribute. Therefore, your Reference Committee recommends that attention be focused on the development of effective needle exchange programs with continued attention to community needle disposal initiatives.

Policy recommended for reaffirmation:

H-95.942 Safe Disposal of Used Syringes, Needles and Other Sharps in the Community 1. Our AMA recognizes that used sharps in the community pose a public health hazard in diverse ways to workers and to the public. 2. The AMA requests manufacturers of disposable hypodermic needles and syringes to adopt designs to prevent reuse, and to include in the packaging clear directions for their correct disposal. 3. Our AMA continues to support the mission of the Coalition for Safe Community Needle Disposal.

(16) RESOLUTION 915 – WOMEN AND ALZHEIMER'S DISEASE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first Resolve of Resolution 915 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association support increased ~~participate in efforts to raise~~ awareness of the ~~noted~~ sex and gender differences in incidence and etiology of Alzheimer's disease and related dementias (Directive to Take Action); and be it further

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 915 be amended by deletion, to read as follows:

~~RESOLVED, That our AMA make readily available to physicians the relevant guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias (Directive to Take Action); and be it further~~

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the third Resolve of Resolution 915 be amended by deletion, to read as follows:

~~RESOLVED, That our AMA encourage physicians to consider performing regular cognitive testing as a part of wellness visit protocols for older adults, especially patients with increased risk of developing Alzheimer's disease and other forms of dementia, including, but not limited to, female sex, genetics, and cardiovascular co-morbidities (New HOD Policy); and be it further~~

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that the fourth Resolve of Resolution 915 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA encourage increased enrollment in clinical trials of ~~with all~~ appropriate patients with Alzheimer's disease and related dementias, and their families, to better identify sex-differences in incidence and progression and to advance a treatment and cure of Alzheimer's disease and related dementia. (New HOD Policy)

RECOMMENDATION E:

Madam Speaker, your Reference Committee recommends that Resolution 915 be adopted as amended.

RECOMMENDATION F:

Madam Speaker, your Reference Committee recommends that Policy H-25.991 be reaffirmed.

Resolution 915 asks that our AMA 1. participate in efforts to raise awareness of the noted sex and gender differences in incidence and etiology of Alzheimer's disease and related dementias; 2. make readily available to physicians the relevant guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias; 3. encourage physicians to consider performing regular cognitive testing as a part of wellness visit protocols for older adults, especially patients with increased risk of developing Alzheimer's disease and other forms of dementia, including, but not limited to, female sex, genetics, and cardiovascular co-morbidities; and 4. encourage increased enrollment in clinical trials with all appropriate patients with Alzheimer's and related dementias, and their families, to better identify sex-differences in incidence and progression and to advance a treatment and cure of Alzheimer's and related dementia.

Your Reference Committee heard supportive testimony for this resolution. The Women Physicians Section testified that more women than men develop Alzheimer's Disease (AD), that women are more likely than men to progress to cognitive impairment, and have significantly greater deterioration of cognition than men. The need for greater awareness of this sex difference, as well as research into better treatments, was underscored. Your Reference Committee notes that AMA Policy H-25.991 already encourages physicians to make use of clinical guidelines for the diagnosis and treatment of AD and other dementias, addressing Resolve 2. Additionally, the Medicare Annual Wellness Visit includes assessment for cognitive function, and several organizations have guidelines for screening, addressing Resolve 3. Therefore, your Reference Committee recommends that Resolution 915 be adopted with amendments that clarify language in Resolves 1 and 4, and that remove Resolves 2 and 3. It also recommends

reaffirmation of Policy H-25.991 to re-emphasize the appropriate use of guidelines for AD diagnosis and treatment.

Policy recommended for reaffirmation:
H-25.991 Alzheimer's Disease
The AMA encourages: (1) physicians to make appropriate use of guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias; (2) physicians to make available information about community resources to facilitate appropriate and timely referral to supportive caregiver services; (3) studies to determine the comparative cost-effectiveness/cost-benefit of assisted in-home care versus nursing home care for patients with Alzheimer's disease and related disorders; and (4) studies to determine how best to provide stable funding for the long-term care of patients with Alzheimer's disease and other dementing disorders. CSA Rep. 6, I-97 Reaffirmed: CSAPH Rep. 3, A-07

(17) RESOLUTION 916 – WOMEN AND PRE-EXPOSURE PROPHYLAXIS (PrEP)

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-20.985 be amended by addition to read as follows:

H-20.895 Pre-Exposure Prophylaxis for HIV
1. Our AMA will educate physicians and the public about the effective use of pre-exposure prophylaxis for HIV, including use in women and minority populations, and the US PrEP Clinical Practice Guidelines. 2. Our AMA supports the coverage of PrEP in all clinically appropriate circumstances. Res. 106, A-16

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy H-20.985 be adopted as amended in lieu of Resolution 916.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Policies H-20.922 and H-20.904 be reaffirmed.

Resolution 916 asks that our AMA 1. partner with the appropriate organizations to increase community awareness about Pre-exposure prophylaxis (PrEP) by developing a women-focused PrEP education and social marketing campaign aimed at reaching PrEP eligible women in the U.S., particularly women of color; 2. make readily available the current guidelines on Pre-exposure prophylaxis (PrEP) to increase knowledge and skills among family planning and other sexual and reproductive health care providers, particularly in areas with high HIV incidence; 3. encourage residency programs (e.g., Obstetrics and Gynecology, Family Medicine) to train future physicians to offer and

administer HIV prevention services, including Pre-exposure prophylaxis (PrEP), and improve providers' ability to respond holistically to women living with and vulnerable to HIV; 4. encourage relevant organizations to develop training for physicians on HIV prevention services, including Pre-exposure prophylaxis (PrEP);and 5. encourage family planning, sexual health, and primary care providers to facilitate the integration of Pre-exposure prophylaxis (PrEP) services within clinics that serve HIV-vulnerable women and communities highly impacted by HIV.

Your Reference Committee heard testimony regarding the disproportionate number of minority women affected with HIV and the fact that PrEP is being prescribed more often in men than in women. Broad support for access to PrEP for women, especially in minority populations, was offered. Several amendments covering a variety of topics, such as addressing insurance coverage barriers, training, and access to PrEP in transgender individuals were offered. Your Reference Committee appreciates the amendments, but given the widespread support for the foundational concept of PrEP in women, believes that this resolution is best addressed with a simple amendment to Policy H-20.985, which was just adopted at A-16, and supports PrEP for HIV prevention. Your Reference Committee therefore recommends adoption of this amended policy, as well as reaffirmation of existing HIV prevention policy.

Policies recommended for reaffirmation:
H-20.922 HIV/AIDS as a Global Public Health Priority
In view of the urgent need to curtail the transmission of HIV infection in every segment of the population, our AMA: … (4) Encourages cooperative efforts between state and local health agencies, with involvement of state and local medical societies, in the planning and delivery of state and community efforts directed at HIV testing, counseling, prevention, and care. … (6) In coordination with appropriate medical specialty societies, supports addressing the special issues of heterosexual HIV infection, the role of intravenous drugs and HIV infection in women, and initiatives to prevent the spread of HIV infection through prostitutes. …

H-20.904 HIV/AIDS Education and Training
(1) Public Information and Awareness Campaigns…b) Our AMA urges the communications industry, government officials, and the health care communities together to design and direct efforts for more effective and better targeted public awareness and information programs about HIV disease prevention through various public media, especially for those persons at increased risk of HIV infection. … (3) Education and Training Initiatives for Practicing Physicians and Other Health Care Workers. Our AMA supports continued efforts to work with other medical organizations, public health officials, universities, and others to foster the development and/or enhancement of programs to provide comprehensive information and training for primary care physicians, other front-line health workers (specifically including those in addiction treatment and community health centers and correctional facilities), and auxiliaries focusing on basic knowledge of HIV infection, modes of transmission, and recommended risk reduction strategies. …

(18) RESOLUTION 917 – YOUTH INCARCERATION IN ADULT PRISONS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the following resolution be adopted in lieu of Resolution 917, to read as follows:

YOUTH INCARCERATION IN ADULT FACILITIES

RESOLVED, That our American Medical Association support legal reforms to address juveniles (less than 18 years of age) detained or incarcerated in adult facilities, including 1. early intervention and rehabilitation services, 2. appropriate guidelines for parole, and 3. fairness in the expungement and sealing of records. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policies H-60.919, H-60.986, and H-60.922 be reaffirmed.

Resolution 917 asks that our AMA 1. oppose incarceration of children (individuals less than 18 years of age) in adult prisons for non-violent crimes; 2. work with appropriate organizations to address age cutoffs for children (individuals less than 18 years of age) in adult prisons; 3. advocate for elimination of the incarceration of children (individuals less than 18 years of age) in adult prisons for non-violent crimes; 4. advocate for the passage of legislation that addresses reform for children (individuals less than 18 years of age) in adult prisons with respect to developing appropriate guidelines for parole, expungement and sealing of records, and solitary confinement; and 5. support early intervention and rehabilitation for children (individuals less than 18 years of age) that have been incarcerated in adult prisons.

Testimony was overwhelming supportive of the intent of this Resolution. It was noted that our AMA already has a number of existing policies addressing legal and judicial reforms to prevent the incarceration of children in adult prisons or pretrial confinement facilities. These existing policies were developed and informed by the Council on Science and Public Health's report on Juvenile Justice Reform (A-16), which specifically examined this issue. Our AMA also has existing policy on solitary confinement. However, current AMA policy does not address reforms for those children already incarcerated in adult facilities; therefore, your Reference Committee recommends that Resolution 917 be adopted as amended and existing policies on this issue be reaffirmed.

Policies recommended for reaffirmation:
H-60.919 Juvenile Justice System Reform
Our AMA: 1. Supports school discipline policies that permit reasonable discretion and consideration of mitigating circumstances when determining punishments rather than

"zero tolerance" policies that mandate out-of-school suspension, expulsion, or the referral of students to the juvenile or criminal justice system. 2. Encourages continued research to identify programs and policies that are effective in reducing disproportionate minority contact across all decision points within the juvenile justice system. 3. Encourages states to increase the upper age of original juvenile court jurisdiction to at least 17 years of age. 4. Supports reforming laws and policies to reduce the number of youth transferred to adult criminal court. 5. Supports the re-authorization of federal programs for juvenile justice and delinquency prevention, which should include incentives for: (a) community-based alternatives for youth who pose little risk to public safety, (b) reentry and aftercare services to prevent recidivism, (c) policies that promote fairness to reduce disparities, and (d) the development and implementation of gender-responsive, trauma-informed programs and policies across juvenile justice systems. 6. Encourages juvenile justice facilities to adopt and implement policies to prohibit discrimination against youth on the basis of their sexual orientation, gender identity, or gender expression in order to advance the safety and well-being of youth and ensure equal access to treatment and services. 7. Encourages states to suspend rather than terminate Medicaid coverage following arrest and detention in order to facilitate faster reactivation and ensure continuity of health care services upon their return to the community. 8. Encourages Congress to enact legislation prohibiting evictions from public housing based solely on an individual's relationship to a wrongdoer, and encourages the Department of Housing and Urban Development and local public housing agencies to implement policies that support the use of discretion in making housing decisions, including consideration of the juvenile's rehabilitation efforts. CSAPH Rep. 08, A-16.

H-60.986 Health Status of Detained and Incarcerated Youth
Our AMA (1) encourages state and county medical societies to become involved in the provision of adolescent health care within detention and correctional facilities and to work to ensure that these facilities meet minimum national accreditation standards for health care as established by the National Commission on Correctional Health Care; (2) encourages state and county medical societies to work with the administrators of juvenile correctional facilities and with the public officials responsible for these facilities to discourage the following inappropriate practices: (a) the detention and incarceration of youth for reasons related to mental illness; (b) the detention and incarceration of youth in adult jails; and (c) the use of experimental therapies, not supported by scientific evidence, to alter behavior. (3) encourages state medical and psychiatric societies and other mental health professionals to work with the state chapters of the American Academy of Pediatrics and other interested groups to survey the juvenile correctional facilities within their state in order to determine the availability and quality of medical services provided. (4) advocates for increased availability of educational programs by the National Commission on Correctional Health Care and other community organizations to educate adolescents about sexually transmitted diseases, including juveniles in the justice system. (CSA Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Appended: Res. 401, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

H-60.922 Solitary Confinement of Juveniles in Legal Custody
Our AMA: (1) opposes the use of solitary confinement in juvenile correction facilities except for extraordinary circumstances when a juvenile is at acute risk of harm to self or others; (2) opposes the use of solitary confinement of juveniles for disciplinary purposes in correctional facilities; and (3) supports that isolation of juveniles for clinical or therapeutic purposes must be conducted under the supervision of a physician. Res. 3, I 14 Reaffirmed: CSAPH Rep. 08, A-16.

(19) RESOLUTION 918 – ENSURING CANCER PATIENT ACCESS TO PAIN MEDICATION

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first resolve of Resolution 918 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association policy, D-120.947, A More Uniform Approach to Assessing and Treating Patients with Controlled Substances for Pain Relief, be amended by addition as follows:

3. Our AMA will work diligently with the Centers for Disease Control and Prevention and other regulatory agencies to provide increased leeway in the interpretation of the new guidelines for appropriate prescription of opioid medications in long-term care facilities and in the care of patients with cancer and cancer-related pain ~~survivors~~, in much the same way as is being done for hospice and palliative care. (Modify Current HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 918 be adopted as amended.

Resolution 918 asks that our AMA:

1) Amend Policy D-120.947, "A More Uniform Approach to Assessing and Treating Patients with Controlled Substances for Pain Relief," by addition as follows:

    3. Our AMA will work diligently with the Centers for Disease Control and Prevention and other regulatory agencies to provide increased leeway in the interpretation of the new guidelines for appropriate prescription of opioid medications in long-term care facilities and in the care of patients with cancer and cancer survivors, in much the same way as is being done for hospice and palliative care; and

2) Advocate and support advocacy at the state and federal levels against arbitrary prescription limits that restrict access to medically necessary treatment by limiting the dose, amount or days of the first or subsequent prescription for patients with pain related to a cancer or terminal diagnosis.

Although intended to target primary care clinicians, promulgation of the CDC Guidelines on the Use of Opioids for Chronic Pain has changed the clinical practice environment for pain management by influencing state legislation, as well as institutional and payer policies. Testimony highlighted unintended consequences including increasing difficulties experienced by patients, including cancer patients, in need of opioid-based pain management strategies. A need exists for the medical community to ensure that

access to effective, opioid-based pain management is not compromised in these patients. The sponsor of the resolution clarified that the population of interest is really those with cancer-related pain, and not cancer survivors. Accordingly, your Reference Committee recommends that Resolution 918 be adopted as amended.

(20) RESOLUTION 919 – COAL-TAR BASED SEALCOAT THREAT TO HUMAN HEALTH AND THE ENVIRONMENT

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 919 be amended by deletion, to read as follows:

RESOLVED, That our American Medical Association advocate for ~~national~~ legislation to ban the use of pavement sealcoats that contain polycyclic aromatic hydrocarbons (PAH); or requires ~~at least,~~ use of sealcoat products that contain ~~low or no~~ minimal PAH~~, specifically products where the concentration of PAH is less than 1/1000th the concentration in coal-tar sealcoats~~. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 919 be adopted as amended.

Resolution 919 asks that our AMA advocate for national legislation to ban the use of pavement sealcoats that contain polycyclic aromatic hydrocarbons (PAH); or at least, use sealcoat products that contain low or no PAH, specifically products where the concentration of PAH is less than 1/1000th the concentration in coal-tar sealcoats.

Your Reference Committee heard limited, but supportive and compelling testimony addressing the negative health and environmental consequences of polycyclic aromatic hydrocarbons (PAHs). It was noted that numerous state and local jurisdictions have banned PAHs. Your Reference Committee believes that AMA advocacy on this issue should not be limited to federal legislation, and also that the language should be broad and not specify a level that may not be evidence-based. Therefore, your Reference Committee recommends that Resolution 919 be adopted as amended.

(21) RESOLUTION 924 – AMA ADVOCACY FOR ENVIRONMENTAL SUSTAINABILITY AND CLIMATE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first Resolve of Resolution 924 be amended by addition and deletion, to read as follows:

RESOLVED, That our American Medical Association ~~develop a strategy to advocate for governments and other organizations~~ support initiatives to promote environmental sustainability and other efforts to halt global climate change (Directive to Take Action); and be it further

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 924 be amended by deletion, to read as follows:

RESOLVED, That our AMA incorporate principles of environmental sustainability within its ~~institutional mission and~~ business operations (Directive to Take Action); and be it further

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the third Resolve of Resolution 924 be amended by addition and deletion, to read as follows:

RESOLVED, That our AMA ~~offer programs to physicians to assist them~~ support physicians in ~~to~~ adopting programs for environmental sustainability in their practices and ~~to~~ help physicians to share these concepts with their patients and with their communities. (Directive to Take Action)

RECOMMENDATION D:

Madam Speaker, your Reference Committee recommends that Resolution 924 be adopted as amended.

Resolution 924 asks that our AMA 1. develop a strategy to advocate for governments and other organizations to promote environmental sustainability and other efforts to halt global climate change; 2. incorporate principles of environmental sustainability within its institutional mission and business operations; and 3. offer programs to physicians to assist them to adopt environmental sustainability in their practices and to help physicians to share these concepts with their patients and with their communities.

Your Reference Committee heard testimony mostly supportive of Resolution 924. Testimony in opposition noted that our AMA has existing policies and institutional programs that address this resolution. Your Reference Committee agrees that climate change is an important public health issue. However, given the numerous scientific resources that already exist on this issue, including reports developed by the World Health Organization and resources specifically for physician practices, the AMA should support existing resources rather than offering our own programs. Therefore, your Reference Committee recommends that this resolution be adopted as amended.

(22) RESOLUTION 925 – GRAPHIC WARNING LABEL ON ALL CIGARETTE PACKAGES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that policy H-495.989 be amended by addition and deletion, to read as follows:

H-495.989 Tobacco Product Labeling
Our AMA:
(1) supports ~~working toward~~ requiring more explicit and effective health warnings, such as graphic warning labels, regarding the use of tobacco (and alcohol) products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco, and ingredients of tobacco products sold in the United States)~~,~~ ~~including the extension of labeling requirements of ingredients to tobacco products sold in the United States~~; (2) encourages the Food and Drug Administration, as required under Federal law, to revise its rules to require color graphic warning labels on all cigarette packages depicting the negative health consequences of smoking; ~~(2)~~(3) supports legislation or regulations that require (a) tobacco companies to accurately label their products indicating nicotine content in easily understandable and meaningful terms that have plausible biological significance; (b) picture-based warning labels on tobacco products produced in, sold in, or exported from the United States; (c) an increase in the size of warning labels to include the statement that smoking is ADDICTIVE and may result in DEATH; and (d) all advertisements for cigarettes and each pack of cigarettes to carry a legible, boxed warning such as: "Warning: Cigarette Smoking causes CANCER OF THE MOUTH, LARYNX, AND LUNG, is a major cause of HEART DISEASE AND EMPHYSEMA, is ADDICTIVE, and may result in DEATH. Infants and children living with smokers have an increased risk of respiratory infections and cancer;" and ~~(3)~~(4) urges the Congress to require that: (a) warning labels on cigarette packs should appear on the front and the back and occupy twenty-five percent of the total surface area on each side

and be set out in black-and-white block; (b) in the case of cigarette advertisements, warning labels of cigarette packs should be moved to the top of the ad and should be enlarged to twenty-five percent of total ad space; and (c) warning labels following these specifications should be included on cigarette packs of U.S. companies being distributed for sale in foreign markets. CSA Rep. 3, A-04 Modified: Res. 402, A-13

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that amended Policy H-495.989 be adopted in lieu of Resolution 925.

Resolution 925 asks that our 1. AMA evaluate all opportunities for effective advocacy by organized medicine to require graphic warning labels depicting the dangers of smoking on all cigarette packages; and 2. endorse efforts of the Campaign for Tobacco Free Kids and the Food and Drug Administration to require tobacco companies to include graphic warning labels depicting the dangers of smoking on all cigarette packages.

Your Reference Committee heard testimony unanimously supporting the intent of Resolution 925. The FDA issued graphic warning labels in 2011, but the FDA rule was found to be in violation of the First Amendment. Since that time, the FDA has been sued by public health and medical groups to compel the agency to introduce a new graphic-warning rule. The AMA has existing policy supporting explicit and effective health warnings on tobacco products. Rather than adopting a separate policy on this issue, your Reference Committee recommends amending existing policy to incorporate the intent of this resolution.

(23) RESOLUTION 927 – THE DEA ORDER TO REDUCE OPIOID PRODUCTION

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the second Resolve of Resolution 927 be referred for decision.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 927 be amended by addition of a fourth Resolve, to read as follows:

RESOLVED, That our AMA and the physician community reaffirm their commitment to delivering compassionate and ethical pain management, promoting safe opioid prescribing, reducing opioid-related harm and the diversion of controlled substances, improving access to treatment for substance use disorders, and fostering a public health based-approach to addressing opioid-related morbidity and mortality.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the first and third Resolves of Resolution 927 be adopted, and that the fourth Resolve of Resolution 927 be adopted as amended.

Resolution 927 asks that our American Medical Association 1. encourage relevant stakeholders to research the overall effects of opioid production cuts; 2. encourage the DEA to postpone any opioid production cuts until the potential effects of production quotas are better elucidated; and 3. encourage the DEA to be more transparent when developing medication production guidelines.

Considerable testimony was offered in support of Resolution 927 based on the belief that a reduction in the manufacturing quotas for schedule II opioids would lead to drug shortages, problems with access to opioid medications, and pain management disparities. There was agreement about a lack of transparency on the part of the Drug Enforcement Administration in making this type of decision and in the need to be vigilant about unintended consequences and the effects of quota reductions. While the agency has announced a 25% reduction in production quotas for most Schedule II opioids (33% for hydrocodone containing products), more than 10.5 billion dosage forms would still be available, and production quotas are subject to revision based on manufacturing issues and demand. Some concern was expressed about the optics of our AMA opposing the quota reduction (Resolve 2) given the nation's ongoing struggle with prescription opioid-related morbidity and mortality and its association with resurgence in heroin overdoses and deaths. Several speakers highlighted the need for physicians and other prescribers to play important roles in mitigating harm while preserving access to appropriate pain management, including opioid based treatment strategies. Therefore, your Reference Committee recommends several actions to address this issue in a measured fashion.

(24) RESOLUTION 901 – DISCLOSURE OF SCREENING TEST RISKS AND BENEFITS, PERFORMED WITHOUT A DOCTOR'S ORDER

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 901 be referred.

Resolution 901 asks that our AMA 1. advocate that if a screening test is being marketed as having a medical benefit and is offered and performed by a wellness program vendor without a specific order by the individual's physician or other licensed provider, they must provide the patient with the test specific evidence based guidance that supports the utility of the test; 2. advocate that if the procedure is not supported by specific evidence based guidance as a screening test for that patient and the patient still would like the screening test, the Wellness Program Vendor must offer the patient the opportunity to discuss the risks, benefits, and alternatives with a physician licensed to practice medicine in the state in which the test is being performed; 3. engage with federal regulators on whether vendors of health and wellness programs are in compliance with regulations applicable to marketing to patients in view of the impact of such programs on patients; and 4. continue to work with state medical societies, interested medical specialty societies and state agencies to provide public education regarding appropriate use of vendor wellness programs.

Multiple viewpoints were expressed on this resolution. Commercial vendors not connected with the patient's treating physician have invaded this space, based on profit-seeking motives. Patients do not understand the evidence base for many of the screening tests. Potential problems with broad use of the term "wellness program" were noted. Concerns were expressed about the operation of such vendors or organizations that promote such screening programs in an era of shared decision-making. Examples were presented where screening test visits have been used for the basis for billing the Medicare Annual Wellness visit and patients were unaware. Some speakers noted that these screen tests may be the only option available for underserved populations. Because of the complexity and important of this issue, considerable support was offered for referral. Your Reference Committee agrees but would like to emphasize the urgency of addressing this issue in a comprehensive manner.

Policy recommended for reaffirmation:
H-425.997 Preventive Services
1. Our AMA encourages the development of policies and mechanisms to assure the continuity, coordination and continuous availability of patient care, including professional preventive care and early-detection screening services, provided the services are cost effective. 2. It is the policy of the AMA that any preventive service that is being considered for inclusion in public or private sector insurance products have evidence-based data to demonstrate improved outcomes or quality of life and the cost effectiveness of the service. 3. Our AMA believes that preventive care should ideally be coordinated by a patient's physician. BOT Rep. A, NCCMC Rec. 31, A-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report and Reaffirmed and Appended: CMS Rep. 7, A-00 Reaffirmed in lieu of Res. 104, A-06 Reaffirmation A-07 Modified and Reaffirmed: Sub. Res. 101, A-08

(25) RESOLUTION 906 – UNIVERSAL COLOR SCHEME FOR RESPIRATORY INHALERS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 906 be referred.

Resolution 906 asks that our AMA 1. work with leading respiratory inhaler manufacturing companies and health agencies such as the Federal Drug Administration and the American Pharmacists Association to develop consensus of a universal color scheme for short-acting beta-2 agonist respiratory inhalers that are used as "rescue inhalers" in the United States; 2. work with leading respiratory inhaler manufacturing companies to ensure the universal color scheme for respiratory inhalers would allow for the least disruption possible to current inhaler colors, taking into account distribution of each brand and impact on current users if color were to change; and 3. work with leading respiratory inhaler manufacturing companies to ensure that universal color scheme for respiratory inhalers be designed for adherence and sustainability, including governance for future companies entering the respiratory inhaler market, and reserving colors for possible new drug classes in the future.

Your Reference Committee heard mixed testimony on the issue of color coding for respiratory inhalers. Testimony in support noted that this is a potentially practical approach that would potentially guarantee safety and help address patients with low health literacy. Testimony in opposition noted that this would be costly to implement and may not improve patient care. Your Reference Committee is aware that a previous CSA Report detailed the potential problems associated with color coding pharmaceutical products. The FDA's current draft guidance on "Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors" recommends avoiding color coding in most instances. Problems have also been identified with the universal color coding system used in the United Kingdom, including what to do with combination drug inhalers. Therefore, your Reference Committee recommends referral for further study.

(26) RESOLUTION 907 – CLINICAL IMPLICATIONS AND POLICY CONSIDERATIONS OF CANNABIS USE

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 907 be referred.

Resolution 907 asks that our AMA:

1) Amend Policy H-95.998, "AMA Policy Statement on Cannabis," by deletion to read as follows: Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) ~~sale of cannabis should not be legalized; (3)~~ public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and ~~(4)~~ (3) additional research should be encouraged; and
2) Amend Policy D-95.976 "Cannabis - Expanded AMA Advocacy," by deletion to read as follows: 1. Our AMA will educate the media and legislators as to the

health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available. 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research. 3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis. 4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. ~~It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States.~~"

Your Reference Committee heard testimony both in support of and in opposition to this Resolution. The Council on Science and Public Health spoke in support of referral, a recommendation that was supported by many others who testified. As growing numbers of states are legalizing both “medical” and the recreational use of cannabis, there is the need to support an effective regulatory framework in those jurisdictions. It was noted that the National Academy of Engineering, Science, and Medicine will be issuing a comprehensive report in January of 2017 on the health effects and therapeutic benefits of cannabis. Our AMA should review that report and update our policy accordingly. Therefore, your Reference Committee recommends referral.

(27) RESOLUTION 909 – PROMOTING RETROSPECTIVE AND COHORT STUDIES ON PREGNANT WOMEN AND THEIR CHILDREN

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 909 be <u>referred for decision</u>.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy H-525.991 be <u>reaffirmed</u>.

Resolution 909 asks that our AMA 1. recommend to the US Department of Health and Human Services that the Federal Policy for the Protection of Human Subjects, or “Common Rule”, be updated to define pregnant women as “scientifically complex” rather than a “vulnerable population” for research purposes; and 2. urge the federal government to prioritize clinical research and generation and dissemination of data, emphasizing retrospective and cohort studies, on common medications’ effects on underlying medical conditions across the entire continuum from pregnancy through lactation and development to better inform prescribing. Additionally, Resolution 909 asks the AMA to support federal legislation to 1) establish an interagency taskforce within the Department of Health and Human Services to improve federal interagency and key stakeholder communication, coordination and collaboration to advance research on medications in pregnancy and breastfeeding, and 2) to require the United States Food

and Drug Administration to provide regular reports to Congress tracking the inclusion of pregnant and breastfeeding women in clinical trials.

Your Reference Committee heard mixed testimony on this item. While there was support for mechanisms that would facilitate the inclusion of pregnant women in clinical research, others were confused about what it would mean for the conduct of clinical trials to reclassify pregnant women from "vulnerable" to "scientifically complex." Others emphasized that the pregnant woman is not necessarily "vulnerable," but that the protections of the "vulnerable" class are in place for the unborn fetus. Support for retrospective and cohort studies on common medications throughout the continuum of pregnancy throughout lactation was offered. Your Reference Committee is aware that AMA comments submitted on recent proposed changes to the Common Rule did not address the issue of pregnant women in research. Your Reference Committee believes that there is a need to determine the reasoning for not addressing pregnant women in the Common Rule comments, as well as to clarify what the term "scientifically complex" means, and suggests that the resolution be referred for decision so that these points can be clarified. However, because your Reference Committee supports the concept of research elucidating medication effects in pregnant women, it also recommends reaffirmation of Policy H-525.991, which encourages the inclusion of pregnant women in research when appropriate.

Policy recommended for reaffirmation:
H-525.991 Inclusion of Women in Clinical Trials
Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice. Res. 183, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 05, A-16

(28) RESOLUTION 920 – HAPTENATION AND HYPERSENSITIVITY DISORDERS COMMUNICATION

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 920 <u>not be adopted</u>.

Resolution 920 asks that our AMA re-engage its communication efforts to make physicians aware of the process of haptenation and sensitization and their multiple ramifications, as well as to help physicians teach patients methods to avoid exposure to haptens, and to help physicians include chemical sensitivity in the differential diagnosis, take a history focused on exposures to toxins and symptoms related to known toxins and testing.

Your Reference Committee received mostly negative testimony on this resolution. The sponsor spoke to the existence of chemical sensitivity (a broader term for a "haptenation" disorder) as a pathophysiologic condition. Others testified that the resolution was complicated, and confused multiple issues. Your Reference Committee

agrees that the evidence on this issue is limited and the resolution is confusing. Therefore, Your Reference Committee recommends that Resolution 920 not be adopted.

(29) RESOLUTION 928 – CLOSING THE LOOP ON PHARMCEUTICALS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies H-135.925, H-135.936, and D-135.993 be reaffirmed in lieu of Resolution 928.

Resolution 928 asks that our American Medical Association 1. take a leadership role in working with large, national chains and corporate conglomerates that dispense pharmaceutical drugs to address the growing and negative environmental impact caused by the improper disposal of these pharmaceutical drugs and their metabolites; 2. urge federal agencies to mandate pharmaceutical companies and retailers to take on the responsibility of taking back and properly disposing of outdated, expired, or unused drugs in an environmentally responsible and proper way; and 3. educate the public on the growing hazards and necessary methods to deal with the threat to our water systems posed by the improper disposal of pharmaceutical drugs and their metabolites.

Your Reference Committee heard limited testimony in support of the intent of this resolution. The AMA already has policy that addresses this resolution, broadly supporting efforts to safely dispose of unused medications (H-135.936). Policy also encourages the pharmaceutical industry to fund the programs (H-135.925) and supports changing laws or regulations to allow medication recycling and disposal to occur. Existing policy also addresses the potential environmental impacts of improper disposal, such as the contamination of drinking water (D-135.993). Therefore, your Reference Committee recommends reaffirmation of existing policy in lieu of Resolution 928.

Policies recommended for reaffirmation:
H-135.925 Medications Return Program
1. Our AMA supports access to safe, convenient, and environmentally sound medication return for unwanted prescription medications. 2. Our AMA supports such a medication disposal program be fully funded by the pharmaceutical industry, including costs for collection, transport and disposal of these materials as hazardous waste. 3. Our AMA supports changes in federal law or regulation that would allow a program for medication recycling and disposal to occur. Res. 214, A-16

H-135.936 Proper Disposal of Unused Prescription and Over-the-Counter (OTC) Drugs
1. Our AMA supports initiatives designed to promote and facilitate the safe and appropriate disposal of unused medications. 2. Our AMA will work with other national organizations and associations to inform, encourage, support and guide hospitals, clinics, retail pharmacies, and narcotic treatment programs in modifying their US Drug Enforcement Administration registrations to become authorized medication collectors and operate collection receptacles at their registered locations. 3. Our AMA will work with other appropriate organizations to develop a voluntary mechanism to accept non-controlled medication for appropriate disposal or recycling. Sub. Res. 515, A-10 Reaffirmation A-11 Appended: Res. 209, I-14

D-135.993 Contamination of Drinking Water by Pharmaceuticals and Personal Care Products

Our AMA supports the EPA and other federal agencies in engaging relevant stakeholders, which may include, but is not limited to the AMA, pharmaceutical companies, pharmaceutical retailers, state and specialty societies, and public health organizations in the development of guidelines for physicians and the public for the proper disposal of pharmaceuticals and personal care products to prevent contamination of drinking water systems. Res. 403, A-06 Modified: CSAPH 01, A-16

Madam Speaker, this concludes the report of Reference Committee K. I would like to thank Lawrence Cheung, MD; Theodore Christopher, MD; Shane Hopkins, MD; Stephen Richards, DO; Lee Stevens, MD; Linda Villarreal, MD; and all those who testified before the Committee, as well as our AMA staff.

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