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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (I-18)

Report of Reference Committee K

Darlyne Menscer, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Resolution 901 – Support for Preregistration in Biomedical Research
2. Resolution 906 – Increased Access to Identification Cards for the Homeless Population
3. Resolution 908 – Increasing Accessibility to Incontinence Products
4. Resolution 927 – Oppose FDA's Decision to Approve Primatene Mist HFA for Over the Counter Use

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

5. Board of Trustees Report 12 – Information Regarding Animal-Derived Medications
6. Council on Science and Public Health Report 1 – Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals
7. Council on Science and Public Health Report 2 – Improving FDA Expedited Approval Pathways
8. Resolution 902 – Increasing Patient Access to Sexual Assault Nurse Examiners
9. Resolution 903 – Regulating Front-of-Package Labels on Food Products
10. Resolution 904 – Support for Continued 9-1-1 Modernization and the National Implementation of Text-to-911 Service
11. Resolution 905 – Support Offering HIV Post Exposure Prophylaxis to all Survivors of Sexual Assault
12. Resolution 911 – Regulating Tattoo and Permanent Makeup Inks
13. Resolution 912 – Comprehensive Breast Cancer Treatment
14. Resolution 913 – Addressing the Public Health Implications of Pornography
15. Resolution 916 – Ban on Tobacco Flavoring Agents with Respiratory Toxicity
16. Resolution 917 – Protect and Maintain the Clean Air Act
17. Resolution 918 – Allergen Labeling on Food Packaging
18. Resolution 920 – Continued Support for Federal Vaccination Funding
19. Resolution 921 – Food Environments and Challenges Accessing Healthy Food
20. Resolution 924 – Utilizing Blood from "Therapeutic" Donations
21. Resolution 926 – E-Cigarettes, Revisited

RECOMMENDED FOR REFERRAL

22. Resolution 915 – Mandatory Reporting
23. Resolution 919 – Opioid Mitigation

RECOMMENDED FOR NOT ADOPTION

24. Resolution 914 – Common Sense Strategy for Tobacco Control and Harm Reduction

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

25. Resolution 922 – Full Information on Generic Drugs
26. Resolution 923 – Scoring of Medication Pills

Resolutions not considered:

- Resolution 907 – Developing Diagnostic Criteria and Evidence-Based Treatment
- Options for Problematic Pornography Viewing
- Resolution 909 – Use of Person-Centered Language
- Resolution 910 – Shade Structures in Public and Private Planning and Zoning Matters
- Resolution 925 – Eliminating the Death Toll from Combustible Cigarettes

(1) RESOLUTION 901 – SUPPORT FOR PREREGISTRATION IN BIOMEDICAL RESEARCH

RECOMMENDATION:

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

HOD ACTION: Resolution 901 adopted.

Resolution 901 asks that our American Medical Association support preregistration in order to mitigate publication bias and improve the reproducibility of biomedical research. (New HOD Policy)

Your Reference Committee heard testimony largely in support of this resolution, including on behalf of the National Institutes of Health. Many who testified noted the need for negative data and results to be published in journals for a complete picture of an evidence-base. These results are not commonly published or made available because of the bias to publish positive results. Many peer-reviewed journals have already adopted pre-registration. Additionally, several noted that the pre-registration of research study protocols would ensure that researchers maintain research integrity, and do not alter study design for more favorable results. Some sentiment was expressed for broadening the concept beyond randomized controlled trials. Your Reference Committee believes the current language is sufficient and recommends that Resolution 901 be adopted.

(2) RESOLUTION 906 – INCREASED ACCESS TO IDENTIFICATION CARDS FOR THE HOMELESS POPULATION

RECOMMENDATION:

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

HOD ACTION: Resolution 906 adopted.

Resolution 906 asks that our American Medical Association (AMA) recognize that among the homeless population, a lack of identification card serves as a barrier to accessing medical care as well as and fundamental services that support health and that our AMA support legislative and policy changes that streamline, simplify, and reduce or eliminate the cost of obtaining identification cards for the homeless population. (New HOD Policy)

Your Reference Committee heard testimony in strong support of this resolution. It was noted that many persons who are homeless lack photo identification due to the difficulty of maintaining important documents while homeless. People without photo identification have difficulty accessing critical services and benefits, including health care. A proposed amendment called for the development of model state legislation on this issue, but your Reference Committee believes that because the policy changes relate to simplifying existing processes and reducing or eliminating costs, this is not necessary. Therefore, your Reference Committee recommends that Resolution 906 be adopted.

(3) RESOLUTION 908 – INCREASING ACCESSIBILITY TO INCONTINENCE PRODUCTS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 908 be adopted.

HOD ACTION: Resolution 908 adopted.

Resolution 908 asks that our American Medical Association support increased access to affordable incontinence products. (New HOD Policy)

Your Reference Committee heard mostly supportive testimony for this item, emphasizing lack of access to incontinence products as an important issue for patient health and safety. Some support was offered for referral and for broadening the therapeutic target to include "bowel and bladder management." In order to focus on the most common condition and terminology, your Reference Committee recommends that Resolution 908 be adopted as written.

(4) RESOLUTION 927 – OPPOSE FDA'S DECISION TO APPROVE PRIMATENE MIST HFA FOR OVER THE COUNTER USE

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 927 be adopted in lieu of Policy H-115.972.

HOD ACTION: Resolution 927 adopted in lieu of Policy H-115.972.

Resolution 927 asks that our American Medical Association send a letter to the US Food and Drug Administration (FDA) expressing: 1) our strong opposition to FDA making the decision to allow inhaled epinephrine to be sold as an over-the counter medication without first soliciting public input, and 2) our opposition to the approval of over-the-counter sale of inhaled epinephrine as it is currently not a recommended treatment for asthma. (Directive to Take Action).

Testimony voiced strong support for this resolution, opposing the return of an over-the-counter formulation of an epinephrine inhaler for the treatment of mild, intermittent asthma. Comments were directed to the belief that epinephrine is a potentially dangerous substance and its use is not endorsed in any treatment guidelines for asthma. Many noted that inexpensive, over-the-counter medications for asthma are a risk to patient safety. Your Reference Committee agrees and recommends that Resolution 927 be adopted. Policy H-115.972 is in conflict with this resolution. Therefore, we recommend that it be rescinded.

H-115.972, "Over-the-Counter Inhalers in Asthma"
Our AMA: (1) supports strengthening the product labeling for over-the-counter (OTC) epinephrine inhalers to better educate users about patterns of inappropriate use; to include clear statements that the use of OTC inhalers can be dangerous; to urge users to seek medical care if symptoms do not improve or if they meet criteria for the presence of persistent

disease; and to encourage explicit discussions with physicians about dosage when these products are used; (2) encourages the FDA to reexamine whether OTC epinephrine inhalers should be removed from the market; and (3) In the event that these products continue to be marketed OTC, further information should be obtained to determine whether OTC availability is a risk factor for asthma morbidity and mortality.

(5) BOARD OF TRUSTEES REPORT 12 – INFORMATION REGARDING ANIMAL-DERIVED MEDICATIONS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the recommendations in Board of Trustees Report 12 be amended by deletion to read as follows:

Animal-Derived Ingredients
Our AMA:

1. Urges ~~the U.S. Food and Drug Administration to require~~ manufacturers to include all ingredients and components present in medical products on the product label, including both active and inactive ingredients, and denote any derived from an animal source. (New HOD Policy)
2. Encourages cultural awareness regarding patient preferences associated with medical products containing active or inactive ingredients or components derived from animal sources. (New HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the recommendations in Board of Trustees Report 12 be adopted as amended and the remainder of the report be filed.

HOD ACTION: Board of Trustees Report 12 adopted as amended and the remainder of the report filed.

Board of Trustees Report 12, in response to Resolution 515-A-18, summarizes the issue of animal-derived ingredients and current evidence related to animal-derived components of medical products. Some chemical products used as inactive excipients for prescription drugs, as well as some active prescription medications and also some surgical implants, dressings, and mesh, are derived from animal sources. The consumption or use of such products may be objectionable to certain religions or based on consumer choice. The Board of Trustees recommends the following be adopted in lieu of Resolution 515-A-18, and the remainder of the report be filed:

Animal-Derived Ingredients
Our AMA:

1. Urges the U.S. Food and Drug Administration to require manufacturers to include all ingredients and components present in medical products on the

product label, including both active and inactive ingredients, and denote any derived from an animal source. (New HOD Policy)

2. Encourages cultural awareness regarding patient preferences associated with medical products containing active or inactive ingredients or components derived from animal sources. (New HOD Policy)

Your Reference Committee heard limited and mixed testimony regarding this report developed by the Board of Trustees. The FDA noted that it would require an enormous undertaking for them to require manufacturers to include this information on product labels and suggested urging manufacturers to include more informative labeling. Additional testimony noted that determining the make-up of sourced inactive ingredients is a difficult task, as was noted in the report. Your Reference Committee agrees that asking the FDA to take on this issue is overly-burdensome. Therefore, your Reference Committee recommends that the recommendations in Board of Trustees Report 12 be adopted as amended.

(6) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 1 – IMPROVING SCREENING AND TREATMENT GUIDELINES FOR DOMESTIC VIOLENCE AGAINST LESBIAN, GAY, BISEXUAL, TRANSGENDER, QUEER/QUESTIONING, AND OTHER INDIVIDUALS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that recommendation 1 in Council on Science and Public Health Report 1 be amended by addition and deletion to read as follows:

Policy D-515.980, "Improving Screening and Treatment Guidelines for ~~Domestic~~ Intimate Partner Violence (IPV) Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals (LGBTQ)"

Our AMA will: (1) ~~study recent domestic violence data and the unique issues faced by the LGBTQ population; and (2)~~ promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ ~~victims~~ survivors of ~~domestic violence~~ IPV, (2) encourage physicians to familiarize themselves with resources available in their communities for LGBTQ survivors of IPV, ~~and~~ (3) advocate for federal funding to support programs and services for survivors of IPV ~~intimate partner violence~~ that do not discriminate against underserved communities, including on the basis of sexual orientation and gender identity, and (4) encourage the dissemination of research to educate physicians and the community regarding the prevalence of IPV in the LGBTQ population, the accuracy of screening tools, effectiveness of early detection and interventions, as well as the benefits and harms of screening. (Modify Current HOD policy)

RECOMMENDATION B:

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.

HOD ACTION: Council on Science and Public Health Report 1 adopted as amended and the remainder of the report filed.

Council on Science and Public Health Report 1 is in response to Policy D-515.980 and notes that the lifetime prevalence of IPV in the LGBTQ community is estimated to be comparable to or higher than that among heterosexual couples. There is limited information available on the aspects of IPV that are unique to same-sex relationships and the effects on LGBTQ survivors' mental and physical health. Despite the limited research available on this topic, physicians should be alert to the possibility of IPV among their LGBTQ patients and should familiarize themselves with resources available in their communities for LGBTQ survivors of IPV. The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report be filed:

1. That Policy D-515.980, "Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals" be amended by addition and deletion to read as follows:

   Our AMA will: (1) ~~study recent domestic violence data and the unique issues faced by the LGBTQ population; and (2)~~ promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ ~~victims~~ survivors of domestic violence, (2) encourage physicians to familiarize themselves with resources available in their communities for LGBTQ survivors of intimate partner violence, and (3) advocate for federal funding to support programs and services for survivors of intimate partner violence that do not discriminate against underserved communities, including on the basis of sexual orientation and gender identity. (Modify Current HOD policy)

2. Our AMA encourages research on intimate partner violence in the LGBTQ community to include studies on the prevalence, the accuracy of screening tools, effectiveness of early detection and interventions, as well as the benefits and harms of screening. (New HOD Policy)

3. That Policy H-160.991, "Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations," be reaffirmed.

   Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors. (Reaffirm HOD Policy)

Your Reference Committee heard testimony in strong support of this Council on Science and Public Health report and its recommendations. While the Council found limited research on this topic, the available data suggests that IPV in the LGBTQ community is comparable to or

higher than that among heterosexual couples. Physicians should be aware of the possibility of IPV in their LGBTQ patients. Testimony called for an amendment to support education in addition to research on this topic. CSAPH supported the amendment. Your Reference Committee felt this amendment was more appropriate in the existing directive rather than in the research policy. Therefore, your Reference Committee recommends adoption of the report's recommendations as amended.

(7) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 2 – FDA EXPEDITED REVIEW PROGRAMS AND PROCESSES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 2 be amended by addition and deletion to read as follows:

1(b) the~~is~~ evidence for drug approval should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies, as appropriate;

1(d) confirmatory trials for drugs approved under ~~expedited programs~~ accelerated approval should be planned ~~and underway~~ at the time of expedited approval;

(e) the FDA should pursue having in place a systematic process to ensure that sponsors adhere to their obligations for conducting confirmatory trials, ~~and Congress should establish a firmer threshold to trigger expedited withdrawal when sponsors fail to fulfill their postmarketing study obligations~~;

1(g) FDA should make the annual summary of drugs approved under expedited programs more readily available and consider adding information on confirmatory clinical trials for such drugs to the drugs trials snapshot ~~a simple system to assign a grade for each approval of prescription drugs occurring via expedited programs in order to signal, and provide in a transparent manner, the quality of clinical trial evidence used to establish safety and effectiveness, and whether confirmatory trials are required for labeled indications~~.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 2 be adopted as amended and the remainder of the report be filed.

HOD ACTION: Council on Science and Public Health Report 2 adopted as amended and the remainder of the report filed.

Council on Science and Public Health Report 2 is in response to Resolution 201-I-17 and examines expedited FDA drug approval programs or processes in place in the United States, including so-called fast track, accelerated approval, designated breakthrough therapies, and "priority review" for drugs and biologics, and whether the operation of such programs needs to be re-examined or modified. The Council on Science and Public Health recommends that Policy H-100.992 be amended by addition and deletion to read as follows in lieu of Res-201-I-17, and the remainder of the report be filed:

(1) Our AMA ~~reaffirms its~~ support<u>s</u> ~~for~~ the principles that:

(a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute;

(b) the<u>ir</u>~~is~~ evidence <u>for drug approval</u> should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies;

<u>(c) expedited programs for drug approval serve the public interest as long as sponsors for drugs that are approved based on surrogate endpoints or limited evidence conduct confirmatory trials in a timely fashion to establish the expected clinical benefit and predicted risk-benefit profile;</u>

<u>(d) confirmatory trials for drugs approved under expedited programs should be planned and underway at the time of expedited approval;</u>

(<u>e</u>) <u>the FDA should pursue having in place a systematic process to ensure that sponsors adhere to their obligations for confirmatory trials, and Congress should establish a firmer threshold to trigger expedited withdrawal when sponsors fail to fulfill their postmarketing study obligations;</u>

(~~d~~ <u>f</u>) any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications; and,

<u>(g) FDA should consider a simple system to assign a grade for each approval of prescription drugs occurring via expedited programs in order to signal, and provide in a transparent manner, the quality of clinical trial evidence used to establish safety and effectiveness, and whether confirmatory trials are required for labeled indications.</u>

(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history. (Modify Current HOD Policy)

Generally supportive testimony was offered on Council on Science and Public Health Report 2 and the Council was thanked for developing an informative report. Testimony noted that FDA labeling guidance is not supportive of using letters, or other grades to signify levels of evidence, and that drugs approved under expedited programs or processes are ultimately held to the same evidentiary standard for determining safety and effectiveness. The Council

offered amendments to reflect concerns expressed by the FDA and others. Your Reference Committee agrees with amending the recommendation to reflect those viewpoints.

(8) RESOLUTION 902 – INCREASING PATIENT ACCESS TO SEXUAL ASSAULT NURSE EXAMINERS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 902 be amended by addition to read as follows:

RESOLVED, That our American Medical Association advocate for increased post-pubertal patient access to Sexual Assault Nurse Examiners, and other trained and qualified clinicians, in the emergency department for medical forensic examinations. (New HOD Policy)

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:

INCREASING PATIENT ACCESS TO SEXUAL ASSAULT MEDICAL FORENSIC EXAMINATIONS

HOD ACTION: Resolution 902 adopted as amended with a change in title.

Resolution 902 asks that our American Medical Association advocate for increased patient access to Sexual Assault Nurse Examiners in the emergency department. (New HOD Policy)

Your Reference Committee heard testimony largely in support of this resolution. Many noted that the registered nurses who have completed specialized education and clinical preparation in the medical forensic care of an individual who has experienced sexual assault or abuse are an important resource for these survivors. Additionally, several comments noted that other clinicians, in addition to nurses, are trained and qualified to perform medical forensic examinations. It was also stated that a medical forensic examination in a pre-pubertal patient could unintentionally induce additional trauma and an amendment was offered to specify this examination is optimal for post-pubertal patients. Your Reference Committee agrees that both nurses and other clinicians who are trained and qualified to perform medical forensic examinations are important for patient care and that the examination could be problematic for pre-pubertal patients, who should receive specialized care, and therefore recommends that Resolution 902 be adopted as amended.

(9) RESOLUTION 903 – REGULATING FRONT-OF-PACKAGE LABELS ON FOOD PRODUCTS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the following alternate Resolution be adopted in lieu of Resolution 903.

HOD ACTION: The alternate Resolution adopted in lieu of Resolution 903.

FRONT-OF-PACKAGE LABELS FOR FOOD PRODUCTS WITH ADDED SUGARS

RESOLVED, That our AMA encourage the FDA to: (1) develop front-of-package warning labels for foods that are high in added sugars based on the established recommended daily value and (2) limit the amount of added sugars permitted in a food product containing front-of-package health or nutrient content claims. (New HOD Policy)

Resolution 903 asks that our American Medical Association support additional U.S. Food and Drug Administration criteria that limit the amount of added sugar a food product can contain if it carries any front-of-package label advertising nutritional or health benefits and that our AMA support the use of front-of-package warning labels on foods that contain excess added sugar. (New HOD Policy)

Your Reference Committee heard testimony supporting the intent of this resolution. Concerns were raised regarding the lack of a standard for excess added sugar. The sponsor addressed this issue by referencing the recommended daily value for added sugars. Testimony also noted there are several initiatives underway at FDA related to this issue including: the revised nutrition facts label requirements for added sugars that take effect in 2020 or 2021 depending on the company's annual food sales, and the final proposed rule to update the regulatory definition of the nutrient content claim "healthy" and how to depict "healthy" on the package. Your Reference Committee believes that expressing support for increased transparency for consumers related to high added sugars in food products is needed, but suggests alternate language to streamline the policy.

(10) RESOLUTION 904 – SUPPORT FOR CONTINUED 9-1-1 MODERNIZATION AND THE NATIONAL IMPLEMENTATION OF TEXT-TO-911 SERVICE

RECOMMENDATION A:

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

RESOLVED, That our American Medical Association support the funding ~~of federal grant programs for the modernization of the~~ for and modernization of 9-1-1 infrastructure, including incorporation of text-to-911 technology. (New HOD Policy)

RECOMMENDATION B:

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

HOD ACTION: Resolution 904 adopted as amended.

Resolution 904 asks that our American Medical Association support the funding of federal grant programs for modernization of the 9-1-1 infrastructure, including incorporation of text to 911 technology. (New HOD Policy)

Your Reference Committee heard testimony largely in support of Resolution 904. Your Reference Committee discussed that other funding, beyond federal grant programs, is likely also needed. Therefore, your Reference Committee suggests a minor amendment to also include support for additional avenues of funding and recommends adoption as amended.

(11) RESOLUTION 905 – SUPPORT OFFERING HIV POST EXPOSURE PROPHYLAXIS TO ALL SURVIVORS OF SEXUAL ASSAULT

RECOMMENDATION A:

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

RESOLVED, That our American Medical Association (AMA) ~~advocate for~~ support education of physicians about the effective use of HIV Post-Exposure Prophylaxis (PEP) and the U.S. PEP Clinical Practice Guidelines; (New HOD Policy), and be it further

RECOMMENDATION B:

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

RESOLVED, That our AMA support increased access to, and coverage for, PEP for HIV ~~and~~, as well as enhanced public education on its ~~about the~~ effective use ~~of Post-Exposure Prophylaxis for HIV~~; (New HOD Policy) and be it further

RECOMMENDATION C:

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

RESOLVED, That our AMA amend policy H-20.900 by insertion as follows:

H-20.900, "HIV, Sexual Assault, and Violence"
Our AMA believes that HIV testing and Post-Exposure Prophylaxis (PEP) should be offered to all ~~victims~~ survivors of sexual assault~~,~~ who present within 72 hours of a substantial exposure risk, that these ~~victims~~ survivors should be encouraged to be retested in six months if the initial test is negative, and that strict confidentiality of test results be maintained. (Modify Current HOD Policy)

RECOMMENDATION D:

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

HOD ACTION: Resolution 905 adopted as amended.

Resolution 905 asks that our American Medical Association (AMA) advocate for education of physicians about the effective use of HIV Post-Exposure Prophylaxis (PEP) and the U.S. PEP Clinical Practice Guidelines; that our AMA support increased public education about the effective use of Post-Exposure Prophylaxis for HIV; and that our AMA amend policy H-20.900 by insertion as follows:

H-20.900, "HIV, Sexual Assault, and Violence"
Our AMA believes that HIV testing and Post-Exposure Prophylaxis (PEP) should be offered to all ~~victims~~ survivors of sexual assault, that these ~~victims~~ survivors should be encouraged to be retested in six months if the initial test is negative, and that strict confidentiality of test results be maintained. (Modify Current HOD Policy)

Testimony strongly supported the intent of the resolution and the need to enhance education and provide HIV prophylaxis in a timely fashion to survivors of sexual assault. Postexposure prophylaxis (PEP) should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. "Updated Guidelines for Antiretroviral

Postexposure" are available from the CDC along with an informational leaflet for patients (Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States). The importance of improving treatment in this area is based on available data indicating a significant proportion of such victims are not offered treatment. Amendments were suggested on enhancing public education, improving access and coverage, and clarifying that treatment must be started within 72 hours to be effective. Your Reference Committee agrees and recommends adoption with those amendments.

(12) RESOLUTION 911 – REGULATING TATTOO AND PERMANENT MAKEUP INKS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-440.909 be amended by addition to read as follows:

1. The AMA encourages the state regulation of tattoo artists and tattoo facilities to ensure adequate procedures to protect the public health; and encourages tattoo artists, tattoo facilities, and physicians to report all adverse reactions associated with tattooing to the Food and Drug Administration MedWatch program.

2. The AMA encourages manufacturers of tattoo inks to provide a list of their ingredients to protect public health;

3. The AMA encourages tattoo artists and tattoo facilities to obtain informed consent from their clients, that includes potential risks, prior to performing a tattooing procedure;

4. The AMA, in consultation with relevant stakeholders, develop model state legislation for regulation of tattoo artists and tattoo facilities to ensure adequate procedures to protect the public health and safety. (Modify HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy H-440.909, as amended, be adopted in lieu of Resolution 911.

HOD ACTION: Policy H-440.909, as amended, adopted in lieu of Resolution 911.

Resolution 911 asks that our American Medical Association encourage the Food and Drug Administration to adopt regulatory standards for tattoo and permanent makeup inks that include at minimum the disclosures expected for injectable drugs and cosmetics and mandate that this information be available to both the body licensed to perform the tattoo and to the

person receiving the tattoo and that our AMA study the safety of any chemical in tattoo and permanent makeup inks. (Directive to Take Action)

Your Reference Committee heard limited and mixed testimony regarding this Resolution. Some stated that this is a critical need and others noted that the oversite of tattoo facilities is regulated by states and this is not necessary. Still others noted that the agencies that regulate the practice of tattooing need assistance. The authors of the resolution stated that informed consent was an important component that was misunderstood in their originally submitted resolution and submitted an alternate resolution that amends current policy; additional testimony was supportive of this alternate resolution. Your Reference Committee agrees that the alternate resolution amending current policy is appropriate and recommends that Policy H-440.909 be adopted as amended.

(13) RESOLUTION 912 – COMPREHENSIVE BREAST CANCER TREATMENT

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 amend Policy H-55.973, "Breast Reconstruction," by addition and deletion as follows:
Our AMA: (1) believes that reconstruction of the breast for post-treatment rehabilitation of patients ~~the postmastectomy cancer post-treatment patient~~ with in situ or invasive breast neoplasm should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or salpingo-oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided. (Modify Current HOD Policy)

RECOMMENDATION B:

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

HOD ACTION: Resolution 912 adopted as amended.

Resolution 912 asks that our American Medical Association amend Policy H-55.973, "Breast Reconstruction," by addition and deletion as follows:

Our AMA: (1) believes that reconstruction of the breast for rehabilitation of the ~~postmastectomy cancer~~ post-treatment patient with in situ or invasive breast neoplasm should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided. (Modify Current HOD Policy)

Your Reference Committee heard extensive supportive testimony for this resolution and a minor amendment that was proposed. Your Reference Committee supports the amendments and has also chosen to alter the policy slightly to use person-first language. Therefore, your Reference Committee recommends that Resolution 912 be adopted as amended.

(14) RESOLUTION 913 – ADDRESSING THE PUBLIC HEALTH IMPLICATIONS OF PORNOGRAPHY

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 913 be amended by deletion to read as follows:

RESOLVED, That our American Medical Association support efforts to mitigate the negative public health impacts of pornography as it relates to vulnerable populations~~, including but not limited to women and children~~. (New HOD Policy)

RECOMMENDATION B:

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

HOD ACTION: Resolution 913 adopted as amended.

Resolution 913 asks that our American Medical Association support efforts to mitigate the negative public health impacts of pornography as it relates to vulnerable populations, including but not limited to women and children. (New HOD Policy)

A concern was expressed about use of the term “vulnerable” and whether it could be considered limiting and some sentiment was offered for referral. Otherwise, testimony was broadly supportive and noted the need to address the links between pornography, behavior, and sex trafficking. Your Reference Committee concurs with the general support offered for this resolution, but believes that truncating the language after populations allows for a more inclusive approach.

(15) RESOLUTION 916 – BAN ON TOBACCO FLAVORING AGENTS WITH RESPIRATORY TOXICITY

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-495.971 be amended to read as follows:

H-495.971 Opposition to Addition of Flavors to ~~Cigarettes~~ Tobacco Products
Our AMA: (1) supports state and local legislation to prohibit the sale or distribution of flavored tobacco products; ~~and~~ (2) urges local and state medical societies and federation members to support state and local legislation to prohibit the sale or distribution of flavored tobacco products; and (3) encourages the FDA to prohibit the use of flavoring agents in tobacco products, which includes electronic nicotine delivery systems.

RECOMMENDATION B:

Madam Speaker, you Reference Committee recommends that Policy H-495.971 be adopted as amended in lieu of Resolution 916.

HOD ACTION: Policy H-495.971 adopted as amended in lieu of Resolution 916.

Resolution 916 asks that our American Medical Association call for the immediate ban on flavoring agents in electronic nicotine delivery systems (ENDS) and other tobacco products that have known respiratory toxicity including but not limited to diacetyl, 2,3 pentanedione, acetoin, cinnamaldehyde, benzaldehyde, eugenol, vanillin/ethyl vanillin, and menthol and that the AMA urge the U.S. Food and Drug Administration (FDA) to require comprehensive testing of flavoring agents used in ENDS and other tobacco products to assess the potential negative health effects of chronic exposure to these flavoring agents. (Directive to Take Action)

Your Reference Committee heard testimony both in support of and in opposition to Resolution 916. While the intent of the resolution was supported, it was noted that existing policy broadly supports banning flavors in electronic cigarettes, particularly those that appeal to youth. It was felt by some that focusing on eliminating flavors with known respiratory toxicity would be taking a step backwards, as not all toxicity is known or can be easily assessed. Your Reference Committee agreed that a strong statement calling for a ban on the use of flavoring agents in tobacco products was warranted. Therefore, your Reference Committee recommends amending existing policy as outlined.

(16) RESOLUTION 917 – PROTECT AND MAINTAIN THE CLEAN AIR ACT

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 917 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association (AMA) oppose legislative or regulatory changes ~~provisions of the Affordable Clean Energy proposed rule~~ that would allow power plants to avoid complying with new source review requirements to install air pollution control equipment when annual pollution emissions increase (New HOD Policy); and be it further

RESOLVED, That our AMA ~~send a letter to the Environmental Protection Agency (EPA)~~ work with other organizations to promote a public relations campaign, strongly expressing our opposition to EPA's Affordable Clean Energy rule and its proposed amendments of the New Source Review requirements under the Clean Air Act. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 917 be adopted as amended.

HOD ACTION: Resolution 917 adopted as amended.

Resolution 917 asks that our American Medical Association (AMA) oppose provisions of the Affordable Clean Energy proposed rule that would allow power plants to avoid complying with new source review requirements to install air pollution control equipment when annual pollution emissions increase and that our AMA send a letter to the Environmental Protection Agency (EPA) expressing our opposition to EPA's Affordable Clean Energy rule and its proposed amendments of the New Source Review requirements under the Clean Air Act. (Directive to Take Action)

Testimony strongly supported the intent of this resolution. The value of a letter was questioned given the deadline has passed for submission of comments on the Affordable Clean Energy rule, and the AMA has already signed on to such a letter as part of its participation in the Federation-based Climate Change Consortium. Instead, it was suggested that some sort of public campaign was necessary, a concept that received considerable support. A suggestion also was made to broaden the policy to express more general opposition to potential legislative or regulatory efforts intended to weaken provisions in the Clean Energy Act. Your Reference Committee agrees with the suggested amendments.

(17) RESOLUTION 918 – ALLERGEN LABELING ON FOOD PACKAGING

RECOMMENDATION A:

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

RESOLVED, That our American Medical Association ~~petition the Food and Drug Administration~~ encourage food manufacturers to pursue more obvious ~~labeling on food~~ packaging distinctions between products that contain~~sing~~ the ~~eight~~ most common food allergens identified in the Food Allergen Labeling and Consumer Protection Act and products that do not contain these allergens ~~: milk, eggs, peanuts, tree nuts, wheat, soy, fish and crustacean shellfish~~. (Directive to Take Action)

RECOMMENDATION B:

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

HOD ACTION: Resolution 918 adopted as amended.

Resolution 918 asks that our American Medical Association petition the Food and Drug Administration to pursue more obvious labeling on food packaging containing the eight most common food allergens: milk, eggs, peanuts, tree nuts, wheat, soy, fish and crustacean shellfish. (Directive to Take Action)

Your Reference Committee heard limited testimony in support of this resolution. The FDA already enforces the Food Allergen Labeling and Consumer Protection Act, which requires food labels to clearly identify the food source names of any ingredients that are one of the major food allergens. However, product packaging developed by food manufacturers could be improved to ensure that similar products that contain and do not contain common food allergens are not confused by consumers. Your Reference Committee removed the specific list of allergens should the FDA update that list in the future to include additional allergens (i.e. sesame). Therefore, your Reference Committee recommends that Resolution 918 be adopted as amended.

(18) RESOLUTION 920 – CONTINUED SUPPORT FOR FEDERAL VACCINATION FUNDING

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-440.928 (3) be amended in lieu of Resolution 920 to read as follows:

H-440.928 Update on Immunizations and Vaccine Purchases

Our AMA: (3) ~~supports~~ will release a public statement and actively advocate for increased federal funding for vaccines, including activities funded through Section 317 of the Public Health Service Act, which supports purchasing vaccines and implementing the national vaccine strategy, and includes~~ing~~ monies for education of the American public about the importance of immunization, education and training for health professionals, and for support to state and local governments to remove barriers to effective immunization.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy H-440.928, as amended, be adopted in lieu of Resolution 920.

HOD ACTION: Policy H-440.928, as amended, adopted in lieu of Resolution 920.

Resolution 920 asks that our American Medical Association release a public statement of support for federal vaccination funding efforts such as Section 317, and actively advocate for sustained funding. (Directive to Take Action)

Your Reference Committee heard testimony in strong support of federal funding for vaccines through Section 317 of the Public Health Service Act. It was asked that the resolution be amended to define the Section 317 Immunization Program. Since existing policy addresses funding for vaccines and the activities funded through the Section 317 immunization program, your Reference Committee believes that amending this policy was the best course of action. Therefore, your Reference Committee recommends adopting existing policy as amended.

(19) RESOLUTION 921 – FOOD ENVIRONMENTS AND CHALLENGES ACCESSING HEALTHY FOOD

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 921 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association ~~work with~~ encourage the U.S. Department of Agriculture and appropriate stakeholders to ~~advocate for the~~ study ~~of~~ the national prevalence, ~~and~~ impact, and solutions to the problems of food mirages, food swamps, and food oases as food environments distinct from food deserts. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 921 be adopted as amended.

HOD ACTION: Resolution 921 adopted as amended.

Resolution 921 asks that our American Medical Association work with appropriate stakeholders to advocate for the study of the national prevalence and impact of food mirages, food swamps, and food oases as food environments distinct from food deserts. (Directive to Take Action)

Your Reference Committee heard testimony in strong support of this resolution. Food environments include the food available in our day-to-day environments and are a determinant of what we eat. Differences in income, education, and nutritional knowledge are major factors that shape our eating habits and impact our health. While many resources are available addressing access and affordability of healthy food, the U.S. Department of Agriculture's most recent report on "Access to Affordable and Nutritious Food: Measuring and Understanding Food Deserts and their Consequences" was from 2009. Your Reference Committee believes that an update of this report is warranted and that the United States Department of Agriculture is in the best position to conduct this study with input from stakeholders. The sponsor offered an amendment to include the identification of solutions to this problem. Your Reference Committee supports this amendment.

(20) RESOLUTION 924 – UTILIZING BLOOD FROM "THERAPEUTIC" DONATIONS

RECOMMENDATION A:

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

RESOLVED, that our American Medical Association encourage ~~advocate for CMS~~ the U.S. Food and Drug Administration to engage in dialogue with the American Association of Blood Banks and relevant stakeholders~~Red Cross~~ to reanalyze their therapeutic phlebotomy policies on variances, ~~donor eligibility criteria, to accept blood from a broader category of individuals,~~including but not limited to hereditary hemochromatosis. (New HOD Policy)

RECOMMENDATION B:

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

HOD ACTION: Resolution 924 adopted as amended.

Resolution 924 asks that our American Medical Association advocate for CMS to engage in dialogue with Red Cross to reanalyze their donor eligibility criteria, to accept blood from a broader category of individuals, including but not limited to hereditary hemochromatosis. (Directive to Take Action)

Your Reference Committee heard testimony largely in support of the intent of this resolution. Testimony noted that CMS is not the appropriate organization to undertake this ask; the FDA is the agency responsible for regulations regarding blood donation. Testimony also noted that there are several other organizations besides the American Red Cross who perform therapeutic blood donations, and this should be reflected in the statement. Those who testified overwhelmingly noted that the ability to utilize blood donations from a larger cohort of individuals would aid in the alleviation of blood shortages. Your Reference Committee agrees and recommends that Resolution 924 be adopted as amended.

(21) RESOLUTION 926 – E-CIGARETTES, REVISITED

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 926 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association recognize the use of e-cigarettes and vaping as an urgent public health ~~crisis~~ epidemic and actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21. (Directive to Take Action)

RECOMMENDATION B:

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

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the title of Resolution 924 be changed to read as follows:

ADDRESSING THE PUBLIC HEALTH EPIDEMIC OF E-CIGARETTES

HOD ACTION: Resolution 926 adopted as amended with a change in title.

Resolution 926 asks that our American Medical Association recognize the use of e-cigarettes and vaping as an urgent public health crisis and actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21. (Directive to Take Action)

Your Reference Committee heard testimony unanimously supportive of this resolution. A minor amendment was offered changing the terminology from “public health crisis” to “public health epidemic.” Your Reference Committee agrees with this change as the FDA has recently recognized the use of e-cigarettes among teens as an epidemic. Therefore, your Reference Committee recommends that Resolution 926 be adopted as amended.

(22) RESOLUTION 915 – MANDATORY REPORTING

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 915 be referred.

HOD ACTION: Resolution 915 referred.

Resolution 915 asks that our American Medical Association oppose mandated reporting of entire classes of patients and specific diagnoses unless compelling evidence exists to demonstrate that a serious public health and/or safety risk will be mitigated as a result of such reporting. (New HOD Policy)

Testimony on Resolution 915 was strongly in support of referral. It was noted that public health surveillance is an essential public health function that has traditionally relied on health care providers, hospitals, and laboratories to report to public health agencies specific conditions or outbreaks that may impact the broader population. It was also noted that efforts are underway to implement electronic case reporting, by which cases of reportable conditions are automatically generated from EHRs and transmitted to public health agencies for review and action. It was clear that the benefits of public health reporting need to be balanced against the burden that mandatory reporting places on physicians. Due to the complex nature of this issue, your Reference Committee agrees with referral.

(23) RESOLUTION 919 – OPIOID MITIGATION

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 919 be referred.

HOD ACTION: Resolution 919 referred.

Resolution 919 asks that our American Medical Association review the following opioid mitigation strategies based on their effectiveness in Huntington, WV, and Clark County, IN, and provide feedback concerning their utility in dealing with opioids:

(1) The creation of an opioid overdose team that decreases the risk of future overdose and overdose death, increases access to opioid-related services and increases the likelihood that an individual will pursue drug rehabilitation.
(2) A needle exchange program that is open multiple days a week and is mobile offers not only a source for needles but also Narcan, other supplies, health care and information.
(3) The creation of a drug court that allows a judge to have greater flexibility in determining the legal consequences of an arrest for an opioid-related crime. It also allows for the judicial patience necessary to deal with the recidivism of this population.
(4) Offering more acute-care inpatient drug rehab beds, although those ready for treatment need to be willing to travel significant distances to get to a treatment bed.
(5) Make available Narcan intranasal spray OTC through pharmacies and the syringe exchange, overdose team, etc.

(6) Encourage prevention education in K-12 programs that uses multiple media with anti-drug messaging delivered in the school system but also in the home. (Directive to Take Action)

Extensive testimony reflected the continuing concerns about opioid-related morbidity and mortality and the fact that numerous community, state, federal, hospital and healthcare system, and other private and public initiatives have been undertaken or are underway to combat the epidemic, including many that are aligned with the focus areas noted in this resolution. The AMA has already evaluated many of these approaches in reports to the House of Delegates and has extensive policy related to opioids, overdose, pain management, naloxone, drug courts, needle exchange, safe injection facilities, and education on risk mitigation and pain care. The AMA also has formed a federation-based Opioid Task Force and more recently a Pain Care Task Force. The AMA also hosts an end-the-opioid-epidemic website that maintains a repository of state and medical specialty society resources at the intersection of pain, opioids, and addiction. These activities will continue for the foreseeable future. Because of the multitude of parallel efforts, strong sentiment was expressed for a need to evaluate effective mitigation approaches and to provide practical guidance on best practices around the nation. Ultimately, because of the complexity of this issue your Reference Committee recommends referral, which would allow for a coordinated AMA effort to be implemented.

(24) RESOLUTION 914 – COMMON SENSE STRATEGY FOR TOBACCO CONTROL AND HARM REDUCTION

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 914 not be adopted.

HOD ACTION: Resolution 914 not adopted.

Resolution 914 asks that our American Medical Association advocate for a "protect adult choice and youth's health" "common sense" tobacco strategy (with a report back to the House of Delegates annually) under which:

- Current educational, promotional and policy initiatives (e.g. taxation) to reduce the use of tobacco products by inhalation and orally would continue, including advocating for the prohibition of the sale of ALL nicotine containing products to individuals under 21 years unless via prescription for medical purposes.
- E-cigarettes (non-tobacco products containing nicotine) would be accessible at an affordable price to adults who wish to use them, and would be available to individuals below 21 years of age only as part of state sanctioned tobacco cessation activities. States and local jurisdictions would be free to require vendors to post warnings regarding the possible health risks of the use of nicotine inhalation products.
- Non-nicotine, non-drug containing vaping and other inhalation products would not be considered tobacco products, but would be monitored by state and local jurisdictions as any other personal use product regarding safety and public accommodation. (New HOD Policy)

Your Reference Committee heard testimony mostly in opposition to Resolution 914. The Council on Science and Public Health testified that based on a recent review of the evidence, their report adopted by the House of Delegates at A-18 concluded that the use of electronic cigarettes is not harmless and significant concerns exist that novel, non-combustible products

may pose a significant threat to tobacco cessation and prevention efforts. Furthermore, electronic cigarettes use among youth and young adults is a public health concern. Available data suggest that youth who use electronic cigarettes are more likely to smoke combustible cigarettes. While there was support for prohibiting the sale of nicotine products to individuals under the age of 21, that is existing policy. Therefore, your Reference Committee recommends that Resolution 914 not be adopted.

(25) RESOLUTION 922 – FULL INFORMATION ON GENERIC DRUGS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies H-125.981 and H-125.984 be reaffirmed in lieu of Resolution 922.

HOD ACTION: Policies H-125.981 and H-125.984 reaffirmed in lieu of Resolution 922.

Resolution 922 asks that American Medical Association advocate that generic drugs have an FDA-approved package insert available when dispensed that discloses active and inactive ingredients and clear language with bio-equivalent data as compared to parent branded drug. (Directive to Take Action)

Limited testimony was offered on this resolution. Testimony from the Council on Science and Public health emphasized the two previous reports authored by the Council on this topic, and the fact that a common misconception exists that the average serum values between the brand and generic equivalents can vary by a factor of -20 to +25%, which could lead to large differences between multisource products. When evaluating the bioequivalence of a generic product for approval, results are analyzed according to whether the generic or “test” product, when substituted for the brand-name or “reference product,” is significantly less bioavailable, and alternatively, whether the brand-name product, when substituted for a generic product, is significantly less bioavailable (that is, compared by using the two 1-sided tests). By convention, all data are expressed as a ratio of the average response (area under the curve and serum concentration maximum) for test versus the reference product, so the limit expressed in the second analysis is 125% (the reciprocal of 80%). Tests are carried out using an analysis of variance and calculating a 90% confidence interval (CI) for the average of each pharmacokinetic parameter, which must be entirely within the 80% to 125% boundaries. The width of the Confidence Interval reflects, in part, the within-subject variability of the test and reference products. When applying the required statistical criteria to bioequivalence studies, generic products whose mean arithmetic bioavailability parameters differ by more than ~5% from the reference product begin failing the Confidence Interval requirement. Accordingly, your Reference Committee does not believe the asks of this resolution would provide meaningful information and recommends reaffirmation of existing policy.

Policies recommended for reaffirmation:

H-125.981, “Generic Medications”

Our AMA encourages the Food and Drug Administration to maintain standards and criteria used for approving generic medications to ensure bioequivalence under various conditions and in relevant patient populations.

H-125.984, “Generic Drugs”
Our AMA believes that:
(1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice.
(2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name products.
(3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.
(4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program.
(5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products.
(6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength).
(7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

(26) RESOLUTION 923 – SCORING OF MEDICATION PILLS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policy H-115.973 <u>be reaffirmed in lieu of Resolution 923</u>.

HOD ACTION: Policy H-115.973 <u>reaffirmed in lieu of Resolution 923</u>.

Resolution 923 asks that our American Medical Association advocate that the FDA require scoring of all tablets and pills depending on their composition, so that the patient may be able to dose adjust their medication number requirement as prescribed by their physician at a lower cost to the patient. (Directive to Take Action)

Your Reference Committee heard mixed testimony on this resolution. Several spoke in support and noted that cost issues necessitate the scoring of medications. Others spoke in opposition noting that some medications cannot be split because of safety reasons or because of composition, for example oral contraceptives. The Council on Science and Public Health noted that the FDA currently considers medication splitting during the drug approval process

for the evaluation of safety issues and has also provided guidance for manufacturers regarding what criteria should be met when evaluating and labeling tablets that have been scored. Because the FDA already has a framework for manufacturers in place on this issue and because AMA has policy urging manufacturers to score medications when appropriate, your Reference Committee feels that reaffirmation of current AMA policy H-115.973 in lieu of this resolution is appropriate.

Policy recommended for reaffirmation:

H-115.973, “Medication Scoring”
Our AMA:
(1) recommends to pharmaceutical manufacturers that, when appropriate, tablets be scored on both sides and so constructed that they will more readily divide in half and not fragment upon attempts at division; and
(2) opposes third party policies that mandate the use of pill-splitting or pill-breaking to reduce pharmaceutical or healthcare costs without proper input from the pharmaceutical manufacturers and practicing physicians.

Madam Speaker, this concludes the report of Reference Committee K. I would like to thank Robert L. Allison, MD, Daniel B. Kimball, Jr, MD, Sarah Marsicek, MD, Daniel M. Meyer, MD, Reid Orth, MD, William S. Pease, MD, and all those who testified before the Committee. Additionally, I would like to thank our AMA staff, especially Barry Dickinson, who is serving on his 44th and final Reference Committee.

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