AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-18)

Report of Reference Committee E

Douglas Martin, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Board of Trustees Report 10 – Over-the-Counter Contraceptive Drug Access (Resolution 110-A-17)
2. Board of Trustees Report 22 – In-Flight Emergencies (Resolution 516-A-17, Resolve 3)
3. Board of Trustees Report 29 – Support for Service Animals, Emotional Support Animals, Animals in Healthcare, and Medical Benefits of Pet Ownership (Resolution 508-A-17)
4. Board of Trustees Report 30 – In-Flight Emergencies (Resolution 516-A-17, Resolve 5)
5. Council on Science and Public Health Report 3 – Providing for Prescription Drug Donation
6. Resolution 504 – Ending the Risk Evaluation and Mitigation Strategy (REMS) Policy on Mifepristone (Mifeprex)
7. Resolution 514 – Effects of Virtual Reality on Human Health
8. Resolution 524 – Naloxone on Commercial Airlines
9. Resolution 526 – Direct-to-Consumer (DTC) Laboratory Testing

RECOMMENDED FOR ADOPTION WITH CHANGE IN TITLE

10. Resolution 502 – Expedited Prescription CBD Drug Rescheduling
    Resolution 509 – Opposing the Classification of Cannabidiol as a Schedule 1 Drug
11. Resolution 508 – Reintroduction of Mitochondrial Donation in the United States

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

12. Board of Trustees Report 38 – Timely Referral to Pain Management Specialist (Resolution 714-A-17)
13. Council on Science and Public Health Report 2 – Drug Shortages: Update
    Resolution 517 – Impact of Natural Disasters on Pharmaceutical Supply and Public Health
14. Resolution 506 – Non-Therapeutic Gene Therapies
15. Resolution 511 – Education for Recovering Patients on Opiate Use After Sobriety
16. Resolution 516 – Waste Incinerator Ban
17. Resolution 518 – Portable Listening Devices and Noise Induced Hearing Loss
18. Resolution 521 – EPA Glider Truck Standard
19. Resolution 523 – Biosimilar Interchangeability Pathway

RECOMMENDED FOR REFERRAL

20. Resolution 507 – Opioid Treatment Programs Reporting to Prescription Monitoring Programs
21. Resolution 515 – Information Regarding Animal-Derived Medications

RECOMMENDED FOR NOT ADOPTION

22. Resolution 505 – Researching Drug Facilitated Sexual Assault Testing
23. Resolution 513 – Hand Sanitizer Effectiveness
24. Resolution 522 – Silence Science: EPA Proposed Data Policy
25. Resolution 525 – Tramadol Change from DEA Schedule IV to Schedule III

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

26. Resolution 503 – Advocating for Anonymous Reporting of Overdoses by First Responders and Emergency Physicians
27. Resolution 512 – Physician and Patient Education About the Risk of Synthetic Cannabinoid Use

Resolutions handled via the Reaffirmation Consent Calendar:

Resolution 501 – Synthetic Cannabinoids
Resolution 510 – Alcohol Use and Cancer
Resolution 519 – Warning Labels for Children's Digital and Video Games
Resolution 520 – Handling of Hazardous Drugs

(1) BOARD OF TRUSTEES REPORT 10 – OVER-THE-COUNTER CONTRACEPTIVE DRUG ACCESS (RESOLUTION 110-A-17)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendations in Board of Trustees Report 10 be adopted and the remainder of the report be filed.

Board of Trustees Report 10 is in response to Resolution 110-A-17 and discusses a variety of concerns that have been raised regarding over-the-counter (OTC) oral contraceptives, including barriers to access, cost of a potential OTC oral contraceptive, and safety. It also includes discussion of the existing FDA pathway for the conversion of prescription products, such as oral contraceptives, to OTC products if manufacturers submit the required application and data. The Board of Trustees recommends the following be adopted in lieu of Resolution 110-A-17, and the remainder of the report be filed:

1. That our AMA amend Policy D-75.995, "Over-the-Counter Access to Oral Contraceptives;"
   D-75.995, "Over-the-Counter Access to Oral Contraceptives"
   Our AMA:
   1. ~~Our AMA~~ Encourages ~~will recommend to the US Food and Drug Administration that~~ manufacturers of oral contraceptives ~~be encouraged~~ to submit the required application and supporting evidence to the US Food and Drug Administration for the Agency to consider approving a switch in status from prescription to over-the-counter for such products.
   2. ~~Our AMA~~ Encourages the continued study of issues relevant to over-the-counter access for oral contraceptives. (Modify HOD Policy)
2. That our AMA amend Policy H-180.958, "Coverage of Prescription Contraceptives by Insurance;"
   H-180.958, "Coverage of ~~Prescription~~ Contraceptives by Insurance"
   1. Our AMA supports federal and state efforts to require that every prescription drug benefit plan include coverage of prescription contraceptives.
   2. Our AMA supports full coverage, without patient cost-sharing, of all contraception without regard to prescription or over-the-counter utilization because all contraception is essential preventive health care. (Modify HOD Policy)

Testimony was supportive of the Board's report and its inclusion of several issues related to a potential over-the-counter oral contraceptive product. Therefore, your Reference Committee recommends that the recommendations in Board of Trustees Report 10 be adopted.

(2) BOARD OF TRUSTEES REPORT 22 – IN-FLIGHT EMERGENCIES (RESOLUTION 516-A-17, RESOLVE 3)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendation in Board of Trustees Report 22 be adopted and the remainder of the report be filed.

Board of Trustees Report 22, in response to Resolution 516-A-17, Resolve 3, outlines the current requirements concerning the verification of a medical professional's credentials in the event of an in-flight medical emergency (IFME) and existing AMA policies on physician identification of credentials and delivery of health care by Good Samaritans. The Board of Trustees recommends existing AMA Policy H-45.979, "Air Travel Safety," be reaffirmed in lieu of Resolve 3, Resolution 516-A-17, and the remainder of the report be filed. (Reaffirm Current HOD Policy)

The Board of Trustees was thanked for developing this report. Your Reference Committee heard testimony in support of the report's recommendations, and in line with reaffirmation of existing AMA Policy H-45.979. Therefore, your Reference Committee urges adoption of the report's recommendation.

Policy recommended for reaffirmation:

H-45.979, "Air Travel Safety"
Our AMA: (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies; (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar. CSA Rep. 5, I-98 Appended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Appended: Res. 718, A-14 Reaffirmation I-14 Reaffirmed in lieu of Res. 503, A-15 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17

(3) BOARD OF TRUSTEES REPORT 29 – SUPPORT FOR SERVICE ANIMALS, EMOTIONAL SUPPORT ANIMALS, ANIMALS IN HEALTHCARE, AND MEDICAL BENEFITS OF PET OWNERSHIP (RESOLUTION 508-A-17)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendation in Board of Trustees Report 29 be adopted and the remainder of the report be filed.

Board of Trustees Report 29 is in response to Resolution 508-A-17. Considerable confusion exists in differentiating service animals, emotional support animals (ESAs), and companion animals as well as the role of animals in animal-assisted therapy (AAT). This report defines the different categories of assistance animals and outlines the current landscape of evidence related to the use of animals in medical treatments. The Board of Trustees recommends the following policy be adopted in lieu of Resolution 508-A-17, and the remainder of the report be filed:

Service Animals, Animal-Assisted Therapy, and Animals in Healthcare
Our American Medical Association:

1. Encourages research into the use of animal-assisted therapy as a part of a therapeutic treatment plan.
2. Supports public education efforts on legitimately trained service animals, as defined by the Americans with Disabilities Act (ADA).
3. Supports a national certification program and registry for legitimately trained service animals, as defined by the ADA.
4. Encourages health care facilities to set evidence-based policy guidelines for animal visitation. (New HOD Policy)

Testimony commended the clarity this report provided regarding the various classifications of animals used in healthcare and for the treatment of various conditions. Commenters were unanimously supportive of the recommendations in the report. Additionally, an amendment was offered, but due to insufficient evidence regarding the amendment, your reference Committee does not believe it is appropriate. Therefore, your Reference Committee recommends that Board of Trustees Report 29 be adopted.

(4) BOARD OF TRUSTEES REPORT 30 – IN-FLIGHT EMERGENCIES (RESOLUTION 516-A-17, RESOLVE 5)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendation in Board of Trustees Report 30 be adopted and the remainder of the report be filed.

Board of Trustees Report 30, in response to Resolution 516-A-17, Resolve 5, outlines the current options for physician continuing medical education (CME), guidance, and policy on the topic of in-flight medical emergencies (IFMEs). The Board of Trustees recommends the existing AMA Policy H-45.979, “Air Travel Safety,” be reaffirmed in lieu

of Resolve 5, Resolution 516-A-17, and the remainder of the report be filed. (Reaffirm Current HOD Policy)

Your Reference Committee heard testimony regarding anecdotal experiences related to IFMEs and the need to ensure that onboard medical supplies are appropriate for treating the most common emergencies. Several individuals and organizations, such as AsMA, commented that the report concisely listed resources for physician education related to IFMEs. Overall, the majority of testimony supported the report and its recommendations. Therefore, your Reference Committee recommends that Board of Trustees Report 30 recommendations be adopted and the remainder of the report filed.

Policy recommended for reaffirmation:

H-45.979, "Air Travel Safety"
Our AMA: (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies; (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar. CSA Rep. 5, I-98 Appended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Appended: Res. 718, A-14 Reaffirmation I-14 Reaffirmed in lieu of Res. 503, A-15 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17

(5) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 3 – PROVIDING FOR PRESCRIPTION DRUG DONATION

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that the recommendation 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 is in response to Resolution 207-I-17 and Resolution 525-A-17. Both of the resolutions reflect concerns about the intersection of rising drug costs, wastage and expiration of unused pharmaceutical products prompting their disposal, and existing problems with patient access and their ability to pay for needed therapies. The focus of this report is the recycling and re-dispensing of unused medications and authorized drug repository and/or return and reuse programs for prescription medications in states. The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 207-I-17 and Resolution 525-A-17 and the remainder of the report be filed:

Our AMA encourages:

1. States with laws establishing prescription drug repository and/or "return and reuse" programs to implement such laws and to consider integrating them with existing recycling or disposal programs. (New AMA Policy)
2. States that lack drug repository and/or "return and reuse" programs to enact such laws in consultation with their state board of pharmacy. (New AMA Policy).
3. State medical associations in states where there is a prescription drug repository or a "return and reuse" program for unused medication supplies to educate physicians in their state regarding the existence of such programs. (New HOD Policy).

Limited but broadly supportive testimony was offered on this report. Therefore, your Reference Committee recommends that Council on Science and Public Health Report 3 be adopted.

(6) RESOLUTION 504 – ENDING THE RISK EVALUATION AND MITIGATION STRATEGY (REMS) POLICY ON MIFEPRISTONE (MIFEPREX)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 504 be adopted.

Resolution 504 asks that the American Medical Association support efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy (REMS) on mifepristone. (New HOD Policy)

Limited but supportive testimony was heard to eliminate the current REMS program for mifepristone, including from the American Congress of Obstetricians and Gynecologists. In 2016, the label for mifepristone was updated to reflect contemporary, and more effective dosing practices. Testimony further supported a long history of safe mifepristone use, low rates of serious adverse events, and a mortality rate that is 14 times less than pregnancy-related death. Eliminating the mifepristone REMS also was noted as a way to increase access to this treatment. Your Reference Committee recommends that Resolution 504 be adopted.

(7) RESOLUTION 514 – EFFECTS OF VIRTUAL REALITY ON HUMAN HEALTH

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 514 be adopted.

Resolution 514 asks that our American Medical Association supports further study on the impact of virtual reality on human health. (New HOD Policy)

Your Reference Committee heard testimony supportive of this resolution, including the scope of anticipated risks and need for additional research to examine potential for

harmful effects of this emerging technology. Therefore, your Reference Committee recommends that Resolution 514 be adopted.

(8) RESOLUTION 524 – NALOXONE ON COMMERCIAL AIRLINES

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 524 be adopted.

Resolution 524 asks that the American Medical Association supports the addition of naloxone to the airline medical kit, that the AMA encourage airlines to voluntarily include naloxone in their airline medical kits, and that the AMA encourage the addition of naloxone to the emergency medical kits of all US airlines (14CFR Appendix A to Part 121 - First Aid Kits and Emergency Medical Kits). (New HOD Policy)

Your Reference Committee heard testimony strongly in support of this resolution. Access to naloxone should be broad. Therefore, your Reference Committee recommends that Resolution 524 be adopted.

(9) RESOLUTION 526 – DIRECT-TO-CONSUMER (DTC) LABORATORY TESTING

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 526 be adopted.

Resolution 526 asks that our American Medical Association: (1) advocate for vigilant oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal agencies; and (2) encourage physicians to educate their patients about the risks and benefits of DTC laboratory tests, as well as the risks associated with interpreting DTC test results without input from a physician or other qualified health care professional. (Directive to Take Action)

Your Reference Committee heard testimony supportive of the proposed resolution, which mentioned a need for increasing oversight of DTC testing by federal agencies, and encouraging communication of risks of DTC tests by physicians. Therefore, your Reference Committee recommends that Resolution 526 be adopted.

(10) RESOLUTION 502 – EXPEDITED PRESCRIPTION CBD DRUG RESCHEDULING

RESOLUTION 509 – OPPOSING THE CLASSIFICATION OF CANNABIDIOL AS A SCHEDULE 1 DRUG

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the Resolution 502 be adopted in lieu of Resolution 509.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the title of Resolution 506 be changed to read as follows:

EXPEDITED PRESCRIPTION CANNABIDIOL (CBD) DRUG RESCHEDULING

Resolution 502 asks that our American Medical Association (AMA) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration and that our AMA advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products. (New HOD Policy)

Resolution 509 asks that our American Medical Association support the reclassification of Cannabidiol (CBD) as a non-scheduled drug. (New HOD Policy)

Your Reference Committee heard significant testimony in support of Resolution 502. Many testified in support of steps to assure that prescription medications that have been studied in randomized controlled trials and evaluated by the FDA should not be classified as schedule 1 drugs. An FDA approved medication should be accessible by patients and dispensable by pharmacies. Strong opposition to Resolution 509 was noted; reclassifying all cannabidiol products to be non-scheduled is too broad, and it is only appropriate to reclassify FDA approved products. Your Reference Committee agrees and recommends that Resolution 502 be adopted in lieu of resolution 509.

(11) RESOLUTION 508 – REINTRODUCTION OF MITOCHONDRIAL DONATION IN THE UNITED STATES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 508 be adopted.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the title of Resolution 508 be changed to read as follows:

MITOCHONDRIAL DONATION

Resolution 508 asks that our American Medical Association support regulated research to determine the efficacy and safety of mitochondrial donation as a means of preventing the transmission of mitochondrial diseases. (New HOD Policy)

Testimony was provided in support of this resolution encouraging regulated research for mitochondrial donation. Therefore, your Reference Committee recommends that Resolution 508 be adopted, with a change in title to more accurately reflect describe the policy.

(12) BOARD OF TRUSTEES REPORT 38 – TIMELY REFERRAL TO PAIN MANAGEMENT SPECIALIST (RESOLUTION 714-A-17)

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the recommendation in Board of Trustees Report 38 be amended by addition and deletion to read as follows:

The Board of Trustees recommends that Policy H-185.931 be amended by addition and deletion in lieu of Resolution 714-A-17 and the remainder of the report be filed:

Policy H-185.931, "Workforce and Coverage for ~~Chronic~~ Pain Management"
1. Our American Medical Association (AMA) supports efforts to improve the quality of care for patients with pain, ensuring access to multiple analgesic strategies, including non-opioid options and interventional approaches when appropriate, with a focus on achieving improvement in function and activities of daily living.

2. Our AMA supports guidance on pain management for different clinical indications developed by the specialties who manage those conditions and disseminated the same way other clinical guidelines are promoted, such as through medical journals, medical societies, and other appropriate outlets.

~~1.~~3. Our American Medical Association (AMA) will advocate for an increased focus on comprehensive, multidisciplinary pain management approaches that include the ability to assess co-occurring mental health or substance use conditions, are physician led, and recognize the interdependency of treatment methods in addressing chronic pain.

~~2.~~4. Our AMA supports health insurance coverage that gives patients access to the full range of evidence-based chronic pain management modalities, and that coverage for these services be equivalent to coverage provided for medical or surgical benefits.

~~3.~~5. Our AMA supports efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services, as well as an expanded behavioral health workforce to improve the availability of services to address the psychological, behavioral, and social aspects of pain and pain management within mutildisciplinary pain clinics.~~which have the ability to address the physical, psychological, and medical aspects of the patient's condition and presentation and involve~~ P~~p~~atients and their caregivers should be involved in the decision-making process.
(Modify Current HOD Policy)

6. Our AMA supports an expanded availability of comprehensive multidisciplinary pain medicine clinics for patients in both urban and rural areas, and an improvement in payment models for comprehensive multidisciplinary pain clinics services such that such services can become more financially viable.

Board of Trustees Report 38 is in response to Resolution 714-A-17. This report discusses whether the AMA should urge CMS to adopt clinical practice guidelines on the management and treatment of pain. The Board of Trustees recommends that Policy H-185.931 be amended by addition and deletion in lieu of Resolution 714-A-17 and the remainder of the report be filed:

H-185.931, "Coverage for Pain Management"

1. Our American Medical Association (AMA) supports efforts to improve the quality of care for patients with pain, ensuring access to multiple analgesic strategies, including non-opioid options when appropriate, with a focus on achieving improvement in function and activities of daily living.

2. Guidance on pain management for different clinical indications should be developed by the specialties who manage those conditions and disseminated the same way other clinical guidelines are promoted, such as through medical journals, medical societies, and other appropriate outlets.

~~1.~~3. Our ~~American Medical Association (~~AMA~~)~~ will advocate for an increased focus on comprehensive, multidisciplinary pain management approaches that include the ability to assess co-occurring mental health or substance use conditions, are physician led, and recognize the interdependency of treatment methods in addressing chronic pain.

~~2.~~4. Our AMA supports health insurance coverage that gives patients access to the full range of evidence-based ~~chronic~~ pain management modalities, and that coverage for these services be equivalent to coverage provided for medical or surgical benefits.

~~3.~~5. Our AMA supports efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services, which have the ability to address the physical, psychological, and medical aspects of the patient's condition and presentation and involve patients and their caregivers in the decision-making process. (Modify Current HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the recommendation in Board of Trustees Report 38 be adopted as amended and the remainder of the report be filed.

Your Reference Committee heard Testimony highly supportive of the Board of Trustees recommendations to amend current policy. This testimony reflected both the need for physician autonomy with respect to pain management and also referral for specialty care when appropriate. Amendments were offered that were positive additions to expand the policy to include interventional approaches and expanded availability of comprehensive multidisciplinary centers; further testimony was in agreement. Your Reference Committee concurs that the amended policy is an appropriate response and therefore recommends adoption as amended.

(13) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 2 – DRUG SHORTAGES: UPDATE

RESOLUTION 517 – IMPACT OF NATURAL DISASTERS ON PHARMACEUTICAL SUPPLY AND PUBLIC HEALTH

RECOMMENDATION A:

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

The CSAPH recommends that Policy H-100.956 be amended by addition and deletion to read as follows:
H-100.956, “National Drug Shortages”

1. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply ~~experience drug shortages~~, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
2. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services

(DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.

3. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
4. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
5. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.
6. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
7. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
8. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
9. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical

manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.

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

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 2 be adopted as amended in lieu of Resolution 517 and the remainder of the report be filed.

Council on Science and Public Health Report 2 is in response to policy H-100.956, which directs the Council to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates on progress made in addressing drug shortages in the U.S. This ninth report in the series updates information on drug shortages since the 2017 report was developed, specifically commenting on the increase in drug shortages due to hurricanes that have impacted the pharmaceutical industry in Puerto Rico as well as other relevant policy considerations regarding manufacturer processes recently brought to light which have implications for the United States health care system. The Council on Science and Public Health recommends that Policy H-100.956 be amended by addition and deletion to read as follows:

H-100.956, "National Drug Shortages"

1. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply ~~experience drug shortages~~, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

2. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
3. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
4. The Council on Science and Public Health shall continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
5. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.
6. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
7. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
8. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
9. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
10. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug shortages.
11. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
12. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
13. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

14. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients. (Modify Current HOD Policy)

Resolution 517 asks that our American Medical Association (AMA) study the impact of natural disasters on the pharmaceutical supply chain and downstream effects on patient care, as well as the adequacy of our governmental response to mitigating these recent natural disasters; (Direction to Take Action) and that our American Medical Association amend policy H-100.956 by addition as follows:

National Drug Shortages H-100.956

1. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that experience drug shortages, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
2. Our AMA supports authorizing the Secretary of Health and Human Services to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
3. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
4. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
5. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The Centers for Medicare & Medicaid Services should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.
6. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
7. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.

8. Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
9. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages. (Modify Current HOD Policy)

Testimony was overwhelmingly supportive of the Council's report and recommendations, as well as the recommendation contained in the second Resolve of Resolution 517 to amend the drug shortages Policy. Significant discussion revolved around the major impact shortages are having on patient care and delivery. This current report from the Council covers the topic of natural disasters and the ability of the government to respond in such situations, as was recommended in Resolve 1 of Resolution 517. The report made recommendations regarding critical infrastructure to give the government, as well as drug manufacturers, better ability to recover after natural disasters. Your Reference Committee believes that the amendment offered to number 4 of the CSAPH recommendation adequately addresses Resolution 517, Resolve 2. Therefore, your Reference Committee recommends adoption of CSAPH Report 2 as amended in lieu of Resolution 517.

(14) RESOLUTION 506 – NON-THERAPEUTIC GENE THERAPIES

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 506 be amended by addition and deletion to read as follows:

RESOLVED, that our American Medical Association ~~partners with relevant institutions to~~ encourages the development of safety guidelines~~,~~ and regulations~~, and permissible uses of~~ regarding performance enhancing, non-therapeutic gene therapies.

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 506 be adopted as amended.

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that the title of Resolution 506 be changed to read as follows:

GENE DOPING

Resolution 506 asks that our American Medical Association partners with relevant institutions to encourage the development of safety guidelines, regulations, and permissible uses of performance enhancing, non-therapeutic gene therapies. (Directive to Take Action)

Your Reference Committee heard testimony generally in support of this Resolution. However, it was noted by many, including the Council on Science and Public Health, that other organizations are in a better position to lead this effort. Testimony also noted the ethical opinion that gene-therapy should only be a therapeutic treatment and questioned the inclusion of "permissible uses." Therefore, your Reference Committee recommends that Resolution 506 be adopted as amended with a change in title to more accurately reflect the policy.

(15) RESOLUTION 511 – EDUCATION FOR RECOVERING PATIENTS ON OPIATE USE AFTER SOBRIETY

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 511 be <u>amended by addition</u> to read as follows:

RESOLVED, that our American Medical Association (AMA) amend Policy D-95-987 by addition to read as follows
D-95.987, "Prevention of Opioid Overdose"
1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.
3. <u>Our AMA support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death. (Modify Current HOD Policy)</u>

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 511 be adopted as amended.

Resolution 511 asks that our American Medical Association (AMA) amend Policy D-95-987 by addition to read as follows:

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.
3. That our AMA implement an appropriate education program for recovering opioid abuse patients and their friends/families that opioid use after significant sobriety time can result in overdose and death. (Modify Current HOD Policy)

Testimony affirmed that individuals who previously misused prescription or illicit opioids, and who developed physical dependence and/or opioid use disorder, are at increased risk of overdose after a period of sobriety. This includes those who have been incarcerated. While there was affirmation of the need to address this specific risk, an amendment was offered for the AMA to support the development of education from those who are experts in this area because skepticism was expressed about the ability of the AMA to reach the intended audience. Therefore, your Reference Committee recommends that Resolution 511 be adopted as amended.

(16) RESOLUTION 516 – WASTE INCINERATOR BAN

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that the first Resolve of Resolution 516 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association (AMA) amend Policy H-135.939 as follows:

Green Initiatives and the Health Care Community H-135.939

Our AMA supports ~~and shall prioritize~~: (1) responsible waste management and clean energy production policies that ~~do not pose~~ minimize health risks, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities; (Modify Current HOD Policy)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that the second resolve of Resolution 516 be amended by deletion as follows:

~~RESOLVED, That our AMA request and actively advocate for national legislation that bans waste incinerators in our nation due to their adverse health effects, negative environmental impact, and lack of cost effectiveness. (Directive to Take Action)~~

RECOMMENDATION C:

Madam Speaker, your Reference Committee recommends that Resolution 516 be adopted as amended.

Resolution 516 asks that our American Medical Association (AMA) amend policy H-135.939 as follows:

Green Initiatives and the Health Care Community H-135.939

Our AMA supports and shall prioritize: (1) responsible waste management and clean energy production policies that do not pose health risks, including the

promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities; (Modify Current HOD Policy)

And that our AMA request and actively advocate for national legislation that bans waste incinerators in our nation due to their adverse health effects, negative environmental impact, and lack of cost effectiveness. (Directive to Take Action)

Reference Committee heard testimony supportive of Resolution 516. Testimony focused on possible health hazards from waste incinerators, and supported alternatives to waste incinerators that might be anticipated to represent safer and more economical waste management, as well as more sustainable practices. It was also noted that our AMA has existing policy that supports clean energy production. The second Resolve of Resolution 516 asked that our AMA ban waste incinerators by amending existing policy. However, the evidence presented is insufficient to support a substantial change in the AMA's policy on waste incinerators. Therefore, your Reference Committee recommends that the Resolution 516 be adopted as amended.

(17) RESOLUTION 518 – PORTABLE LISTENING DEVICES AND NOISE INDUCED HEARING LOSS

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy H-440.957 be <u>amended by addition and deletion</u> to read as follows:

H-440.957, "Reporting Potential for Hearing Loss Due to Personal Listening Devices"
It is the policy of the AMA that (1) physicians counsel patients about the potential loss of hearing associated with the misuse of personal listening devices; (2) research be directed at more specific definition of the relationship between acute and chronic use of personal listening devices and the occurrence of short-term and long-term noise-induced hearing loss; ~~and~~ (3) the AMA work with the National Institute on Deafness and Other Communication Disorders to enhance awareness, knowledge and remediation of causes of noise induced hearing loss~~.~~<u>; and (4) portable listening devices limit the maximum sound amplitude to safe levels.</u>

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy H-440.957 be <u>adopted as amended in lieu of Resolution 518</u>.

Resolution 518 asks that our American Medical Association (AMA) update its policy on portable listening devices to support the use of Portable listening devices that limit the maximum sound amplitude to safe levels and that our AMA advocate on a federal level for labeling on earbuds that do not have amplitude limiters to warn of the risk of hearing loss with extended use at high volume levels for extended periods as described in the CSAPH Report 6-A-08. (New HOD Policy)

Your Reference Committee heard largely supportive testimony on this issue. Although the Council on Science and Public Health (CSAPH) commented that current policy based on CSAPH report A-08 is still relevant, other testimony commented that a subset of new devices may be an issue. However, because of uncertainty regarding the evidence, your Reference Committee believes that amending current policy to reflect the first Resolve is appropriate. However, because of the lack of evidence noted by CSAPH, your Reference Committee feels that actively advocating for labeling is not warranted or appropriate for the AMA to pursue at this time. Therefore, your Reference Committee recommends that Policy H-440.957 be amended in lieu of Resolution 518.

(18) RESOLUTION 521 –EPA GLIDER TRUCK STANDARD

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Policy D-135.996 be amended by addition and deletion to read as follows:

D-135.996, “Reducing Sources of Diesel Exhaust”
Our AMA will: (1) encourage the US Environmental Protection Agency to finalize the most stringent feasible standards to control pollutant emissions from both large and small non-road engines including construction equipment, farm equipment, boats, ~~and~~ trains, and glider trucks; (2) encourage all states to continue to pursue opportunities to reduce diesel exhaust pollution, including reducing harmful emissions from existing diesel; and (3) call for all trucks traveling within the United States, regardless of country of origin, to be in compliance with new diesel emissions standards promulgated by US EPA. Res. 428, A-04 Reaffirmed in lieu of Res. 507, A-09 Reaffirmation A-11 Reaffirmation A-14

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Policy D-135.996 be adopted as amended in lieu of Resolution 521.

Resolution 521 asks that our American Medical Association send a letter to U.S. Environmental Protection Agency (EPA) Administrator opposing the EPA’s proposal to roll back the “Glider Kit Rule” which would effectively allow the unlimited sale of re-

conditioned diesel truck engines that do not meet current EPA new diesel engine emission standards. (Directive to Take Action)

Your Reference Committee heard limited but supportive testimony of Resolution 521, especially as it relates to the public health impacts of diesel truck engines. After reviewing Policy D-135.996, your Reference Committee concluded that the addition of "glider trucks" to part one of the Policy would maintain the intent of Resolution 521. Therefore, your Reference Committee recommends that Policy D-135.996 be reaffirmed as amended in lieu of Resolution 521.

(19) RESOLUTION 523 – BIOSIMILAR INTERCHANGEABILITY PATHWAY

RECOMMENDATION A:

Madam Speaker, your Reference Committee recommends that Resolution 523 be amended by deletion to read as follows:

RESOLVED, That our American Medical Association strongly support the ~~rigorous~~ pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug (New HOD Policy); and be it further

RESOLVED, That our AMA issue a request to the FDA that the agency finalize the biosimilars interchangeability pathway outlined in its draft guidance "Considerations in Demonstrating Interchangeability With a Reference Product" with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients. (Directive to Take Action)

RECOMMENDATION B:

Madam Speaker, your Reference Committee recommends that Resolution 523 be adopted as amended.

Resolution 523 asks that our American Medical Association strongly support the rigorous pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug (New HOD Policy) and that our AMA issue a request to the FDA that the agency finalize the

biosimilars interchangeability pathway outlined in its draft guidance "Considerations in Demonstrating Interchangeability With a Reference Product" with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients. (Directive to Take Action)

Your Reference Committee heard strongly supportive testimony around the need to develop a vibrant biosimilar pathway, including development of standards for manufacturers to seek approval of a biosimilar as interchangeable. While biosimilars are widely viewed as having significant cost-savings potential, the extent of realized savings will be variable. The FDA strongly agreed with the need for further maturation of the biosimilar approval pathway and indicated their intention to finalize guidance on considerations in demonstrating interchangeability with a reference product by May 2019. Adoption of Resolution 523 as amended is recommended.

(20) RESOLUTION 507 – OPIOID TREATMENT PROGRAMS REPORTING TO PRESCRIPTION MONITORING PROGRAMS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 507 be <u>referred</u>.

Resolution 507 asks that our American Medical Association (AMA) amend the policy Opioid Treatment and Prescription Drug Monitoring Programs D-95.980 by deletion as follows:

> That our AMA will seek changes to ~~allow states the flexibility to~~ require opioid treatment programs to report to prescription monitoring programs. (Modify Current HOD Policy)

Divided and polarizing testimony was offered on this resolution. Those opposing Opioid Treatment Programs (OTPs) reporting to Prescription Drug Monitoring Programs (PDMPs) cited concerns about privacy and confidentiality, the stigma that already exists around individuals being treated for opioid use disorder and the likelihood that opening PDMPs up to OTP reporting would have a substantial chilling effect on the willingness of patients to enter into treatment. Evidence supporting this view includes the fact that more than 20 state PDMPs are either under the control of, or easily accessible by law enforcement. Additionally, testimony noted that Resolution 507 conflicts with current federal law (42 CFR Part 2) as it pertains to the structure, function, and reporting requirements of OTPs. Given the nature and extent of the current opioid epidemic, supporters of mandatory reporting by OTPs noted the importance of understanding a patient's controlled substance prescription history in order to inform appropriate clinical decision-making. This opinion views PDMPs as clinical decision support tools.

Current AMA Policy H-95.946 supports the view that PDMPs should be clinical decision support tools, and in addition, encourages all state agencies responsible for maintaining and managing a PDMP to do so in a manner that treats PDMP data as health information that is protected from release outside of the health care system. Our AMA also holds that strong confidentiality safeguards and protections of state databases must

be in place to limit access by non-health care individuals to only those instances in which probable cause exists that an unlawful act or breach of the standard of care may have occurred. Policy H-95.947 supports the refinement of state-based prescription drug monitoring programs and development and implementation of appropriate technology to allow for Health Insurance Portability and Accountability Act (HIPAA)-compliant sharing of information. Policy H-315.965 supports: (1) regulatory and legislative changes that better balance patients' privacy protections against the need for health professionals to be able to offer appropriate medical services to patients with substance use disorders; (2) regulatory and legislative changes that enable physicians to fully collaborate with all clinicians involved in providing health care services to patients with substance use disorders; and (3) continued protections against the unauthorized disclosure of substance use disorder treatment records outside the healthcare system.

This is a complicated subject with far reaching ramifications and overlapping AMA policies. Your Reference Committee believes referral is required to adequately address this important issue.

(21) RESOLUTION 515 – INFORMATION REGARDING ANIMAL-DERIVED MEDICATIONS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 515 be referred.

Resolution 515 asks that our American Medical Association (AMA) supports efforts to improve cultural awareness pertaining to the use of animal-derived medications when considering different prescription options and (New HOD Policy) and that our AMA encourage the U.S. Food and Drug Administration to make available to the public an easily accessible database that identifies medications containing ingredients derived from animals. (Directive to Take Action)

Limited testimony was offered on this resolution. It is known that certain chemical products used as additives or stabilizers for prescription drugs are derived from animal sources. The consumption of such products may be objectionable to certain religions or based on consumer choice. Testimony from the U.S. Food and Drug Administration agreed with the validity of this view, but noted the potential complexity of establishing registries for individual drug formulations that might be "culturally competent." Therefore, your Reference Committee recommends that Resolution 515 be referred.

(22) RESOLUTION 505 – RESEARCHING DRUG FACILITATED SEXUAL ASSAULT TESTING

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 505 not be adopted.

Resolution 505 asks that our American Medical Association study the feasibility and implications of offering drug testing at point of care for date rape drugs, including

rohypnol, ketamine, and gamma-hydroxybutyrate, in cases of suspected non-consensual, drug-facilitated sexual assault. (Directive to Take Action)

Supportive testimony was offered on the intent of this Resolution. However, several dissenting points were raised including concerns about chain of custody of evidence required for legal proceedings, specific responsibilities of the treating physician, relevant jurisdictions for obtaining and preserving evidence, and the fact that the point-of-care (POC) tests referred to in the resolution will not provide useful results in this setting. Many urine drug tests (UDTs) utilized in clinical care are grounded in immunoassay (IA) technology. IA UDTs are designed to detect a specific drug or a class of drugs as either present or absent based on a designated threshold cut-off concentration. Results based on IAs are considered presumptive and are often used as an initial screening test (i.e., qualitatively positive or negative) in clinical UDT. POC tests are typically non-instrumented IA devices (strips, dipcards) that can be used in clinics and are presumptive, qualitative, variable, and have a number of other limitations. Several of the drugs mentioned in the Resolution, and other related substances that have been implicated in drug facilitated sexual assault cannot be tested for using a POC device. Your Reference Committee does not believe that POC testing in drug facilitated sexual assault is worthy of further study at this point and recommends that Resolution 505 not be adopted.

(23) RESOLUTION 513 – HAND SANITIZER EFFECTIVENESS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 513 not be adopted.

Resolution 513 asks that our American Medical Association urge the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention to continue to study the use of hand sanitizers in clinical settings, including the risks and benefits to patients and health care professionals. (Directive to Take Action)

Your Reference Committee heard divided testimony regarding this issue. Although the intent was supported by some testimony, the FDA provided comment in opposition because they are already taking significant action on the use of hand sanitizers and the ingredients used in hand sanitizer products. FDA also commented that the task of evaluating hand sanitizers is their task, not the purview of the CDC. Because this work is underway at the FDA, your Reference Committee recommends that Resolution 513 not be adopted.

(24) RESOLUTION 522 – SILENCE SCIENCE: EPA PROPOSED DATA POLICY

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 522 not be adopted.

Resolution 522 asks that Our American Medical Association (AMA) submit comments during the public comment period, or join comments written by other medical organizations, to express concern with the U.S. Environmental Protection Agency's (EPA) proposal to limit the use of research studies published in peer reviewed scientific journals that describe the adverse health effects of exposure to air pollution and other environmental exposures and that our AMA reaffirm the value and integrity of the journal peer review process by sending a letter to the EPA stating that studies that have been published in scientific peer reviewed journals should be used by the agency in informing EPA regulatory policy making. (Directive to Take Action)

Your Reference Committee heard testimony generally in support of this Resolution. Testimony did state that several organizations, including medical groups, academicians, and industry, have already individually or jointly submitted comments to the EPA requesting an extension to the 30-day comment period regarding the proposal mentioned in the Resolution. Testimony noted the AMA signed on to a letter written by the American Thoracic Society (ATS) requesting a 60-day extension to the comment period. On May 24th, EPA extended the deadline and scheduled a public hearing on the proposed rule for July 17th. The AMA does intend to submit comments regarding the proposed rule, either by joining a Federation Member's letter or developing comments. Because response to this resolution is underway, your Reference Committee recommends that Resolution 522 not be adopted.

(25) RESOLUTION 525 – TRAMADOL CHANGE FROM DEA SCHEDULE IV TO SCHEDULE III

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 525 be <u>not be adopted.</u>

Resolution 525 asks that the American Medical Association petition the United States Drug Enforcement Administration to change tramadol from a Schedule IV to a Schedule III controlled substance. (Directive to Take Action)

Your Reference Committee heard testimony generally opposing review of the current schedule of tramadol. It was pointed out that changing from a schedule IV to a schedule III controlled substance would not significantly change the control measures of the drug since prescribing standards are the same for schedule III and IV substance. Additionally, it was noted that to change the schedule of a drug, the DEA would be required to review currently available evidence to determine the appropriate schedule for the drug. Your Reference Committee agrees with testimony that supports retaining the schedule of tramadol by the DEA and therefore recommends that Resolution 525 not be adopted.

(26) RESOLUTION 503 – ADVOCATING FOR ANONYMOUS REPORTING OF OVERDOSES BY FIRST RESPONDERS AND EMERGENCY PHYSICIANS

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policy H-95.940 be reaffirmed in lieu of Resolution 503.

Resolution 503 asks that our American Medical Association support non-fatal and fatal opioid overdose reporting to the appropriate agencies. (New HOD Policy)

Your Reference Committee heard testimony generally in support of Resolution 503. However, ambiguity around maintaining patient and physician anonymity was noted, as well as specifications on which agencies are considered appropriate for notification.

Your Reference Committee supported the intent of the resolution, but, after reviewing policy H-95.940 parts three and four, concluded that existing policy limited ambiguity noted during testimony by supporting ongoing efforts to continuously monitor trends in illicit drug use, taking a multi-stakeholder approach to addressing the issue while ensuring that all information gained through these collaborative measures be actionable and timely. Therefore, your Reference Committee recommends that Policy H-95.940 be reaffirmed in lieu of Resolution 503.

Policy recommended for reaffirmation:

H-95.940, “Addressing Emerging Trends in Illicit Drug Use”
Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive substances (NPS), are a public health threat; (2) supports ongoing efforts of the National Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease Control and Prevention, the Department of Justice, the Department of Homeland Security, state departments of health, and poison control centers to assess and monitor emerging trends in illicit drug use, and to develop and disseminate fact sheets, other educational materials, and public awareness campaigns; (3) supports a collaborative, multiagency approach to addressing emerging drugs of abuse, including information and data sharing, increased epidemiological surveillance, early warning systems informed by laboratories and epidemiologic surveillance tools, and population driven real-time social media resulting in actionable information to reach stakeholders; (4) encourages adequate federal and state funding of agencies tasked with addressing the emerging drugs of abuse health threat; (5) encourages the development of continuing medical education on emerging trends in illicit drug use; and (6) supports efforts by federal, state, and local government agencies to identify new drugs of abuse and to institute the necessary administrative or legislative actions to deem such drugs illegal in an expedited manner. Sub. Res. 901, I-14 Modified: CSAPH Rep. 02, A-17

(27) RESOLUTION 512 – PHYSICIAN AND PATIENT EDUCATION ABOUT THE RISK OF SYNTHETIC CANNABINOID USE

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Policies H-95.940 and D-95.970 be reaffirmed in lieu of Resolution 512.

Resolution 512 asks that our American Medical Association (AMA) encourage all physicians to become aware of the adverse psychiatric and medical effects, including coagulopathy with severe bleeding, related to the use of synthetic cannabinoids, which may or may not be contaminated and that our AMA encourage physicians to educate their patients about synthetic cannabinoids and strongly advise them that the use of these drugs carries significant health risks that can produce psychiatric morbidity and hematological mortality. (New HOD Policy)

Your Reference Committee heard testimony in strong support of this Resolution. The Council on Science and Public Health offered comments regarding their Report 2 from A-17 that addressed this issue and the resulting policy that addresses this topic. Therefore, your Reference Committee recommends that Policies H-95.940 and D-95.970 be reaffirmed in lieu of Resolution 512.

Policies recommended for reaffirmation:

H-95.940, “Addressing Emerging Trends in Illicit Drug Use”
Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive substances (NPS), are a public health threat; (2) supports ongoing efforts of the National Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease Control and Prevention, the Department of Justice, the Department of Homeland Security, state departments of health, and poison control centers to assess and monitor emerging trends in illicit drug use, and to develop and disseminate fact sheets, other educational materials, and public awareness campaigns; (3) supports a collaborative, multiagency approach to addressing emerging drugs of abuse, including information and data sharing, increased epidemiological surveillance, early warning systems informed by laboratories and epidemiologic surveillance tools, and population driven real-time social media resulting in actionable information to reach stakeholders; (4) encourages adequate federal and state funding of agencies tasked with addressing the emerging drugs of abuse health threat; (5) encourages the development of continuing medical education on emerging trends in illicit drug use; and (6) supports efforts by federal, state, and local government agencies to identify new drugs of abuse and to institute the necessary administrative or legislative actions to deem such drugs illegal in an expedited manner. Sub. Res. 901, I-14 Modified: CSAPH Rep. 02, A-17

D-95.970, “Emerging Drugs of Abuse are a Public Health Threat”
Our AMA will participate as a stakeholder in a Centers for Disease Control and Prevention/U.S. Drug Enforcement Administration (CDC/DEA) taskforce for the development of a national forum for discussion of new psychoactive substances (NPS)-related issues. CSAPH Rep. 02, A-17

Madam Speaker, this concludes the report of Reference Committee E. I would like to thank Allan Anderson, MD, Jessica Cho, MD, Robert H. Emmick, MD, Jean Elizabeth Forsberg, MD, J. Leonard Lichtenfeld, MD, and all those who testified before the Committee as well as our AMA staff.

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