

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-18)

### Report of Reference Committee E

Douglas Martin, MD, Chair

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1 Your Reference Committee recommends the following consent calendar for acceptance:  
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#### 3 **RECOMMENDED FOR ADOPTION**

- 4
- 5 1. Board of Trustees Report 10 – Over-the-Counter Contraceptive Drug Access  
6 (Resolution 110-A-17)
  - 7 2. Board of Trustees Report 22 – In-Flight Emergencies (Resolution 516-A-17,  
8 Resolve 3)
  - 9 3. Board of Trustees Report 29 – Support for Service Animals, Emotional Support  
10 Animals, Animals in Healthcare, and Medical Benefits of Pet Ownership  
11 (Resolution 508-A-17)
  - 12 4. Board of Trustees Report 30 – In-Flight Emergencies (Resolution 516-A-17,  
13 Resolve 5)
  - 14 5. Council on Science and Public Health Report 3 – Providing for Prescription Drug  
15 Donation
  - 16 6. Resolution 504 – Ending the Risk Evaluation and Mitigation Strategy (REMS)  
17 Policy on Mifepristone (Mifeprex)
  - 18 7. Resolution 514 – Effects of Virtual Reality on Human Health
  - 19 8. Resolution 524 – Naloxone on Commercial Airlines
  - 20 9. Resolution 526 – Direct-to-Consumer (DTC) Laboratory Testing  
21

#### 22 **RECOMMENDED FOR ADOPTION WITH CHANGE IN TITLE**

- 23
- 24 10. Resolution 502 – Expedited Prescription CBD Drug Rescheduling  
25 Resolution 509 – Opposing the Classification of Cannabidiol as a Schedule 1  
26 Drug
  - 27 11. Resolution 508 – Reintroduction of Mitochondrial Donation in the United States  
28

#### 29 **RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED**

- 30
- 31 12. Board of Trustees Report 38 – Timely Referral to Pain Management Specialist  
32 (Resolution 714-A-17)
  - 33 13. Council on Science and Public Health Report 2 – Drug Shortages: Update  
34 Resolution 517 – Impact of Natural Disasters on Pharmaceutical Supply and  
35 Public Health
  - 36 14. Resolution 506 – Non-Therapeutic Gene Therapies
  - 37 15. Resolution 511 – Education for Recovering Patients on Opiate Use After Sobriety
  - 38 16. Resolution 516 – Waste Incinerator Ban
  - 39 17. Resolution 518 – Portable Listening Devices and Noise Induced Hearing Loss
  - 40 18. Resolution 521 – EPA Glider Truck Standard
  - 41 19. Resolution 523 – Biosimilar Interchangeability Pathway

1 **RECOMMENDED FOR REFERRAL**

- 2  
3 20. Resolution 507 – Opioid Treatment Programs Reporting to Prescription  
4 Monitoring Programs  
5 21. Resolution 515 – Information Regarding Animal-Derived Medications  
6

7 **RECOMMENDED FOR NOT ADOPTION**

- 8  
9 22. Resolution 505 – Researching Drug Facilitated Sexual Assault Testing  
10 23. Resolution 513 – Hand Sanitizer Effectiveness  
11 24. Resolution 522 – Silence Science: EPA Proposed Data Policy  
12 25. Resolution 525 – Tramadol Change from DEA Schedule IV to Schedule III  
13

14 **RECOMMENDED FOR REAFFIRMATION IN LIEU OF**

- 15  
16 26. Resolution 503 – Advocating for Anonymous Reporting of Overdoses by First  
17 Responders and Emergency Physicians  
18 27. Resolution 512 – Physician and Patient Education About the Risk of Synthetic  
19 Cannabinoid Use  
20

21 Resolutions handled via the Reaffirmation Consent Calendar:

- 22  
23 Resolution 501 – Synthetic Cannabinoids  
24 Resolution 510 – Alcohol Use and Cancer  
25 Resolution 519 – Warning Labels for Children’s Digital and Video Games  
26 Resolution 520 – Handling of Hazardous Drugs

1 (1) BOARD OF TRUSTEES REPORT 10 – OVER-THE-  
2 COUNTER CONTRACEPTIVE DRUG ACCESS  
3 (RESOLUTION 110-A-17)  
4

5 RECOMMENDATION:  
6

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

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

- 19 1. That our AMA amend Policy D-75.995, “Over-the-Counter Access to Oral  
20 Contraceptives;”  
21 D-75.995, “Over-the-Counter Access to Oral Contraceptives”

22 Our AMA:

- 23 1. ~~Our AMA Encourages~~ will recommend to the US Food and Drug  
24 Administration that manufacturers of oral contraceptives be encouraged  
25 to submit the required application and supporting evidence to the US  
26 Food and Drug Administration for the Agency to consider approving a  
27 switch in status from prescription to over-the-counter for such products.  
28 2. ~~Our AMA Encourages~~ the continued study of issues relevant to over-the-  
29 counter access for oral contraceptives. (Modify HOD Policy)
- 30 2. That our AMA amend Policy H-180.958, “Coverage of Prescription  
31 Contraceptives by Insurance;”  
32 H-180.958, “Coverage of ~~Prescription~~ Contraceptives by Insurance”
- 33 1. Our AMA supports federal and state efforts to require that every  
34 prescription drug benefit plan include coverage of prescription  
35 contraceptives.  
36 2. Our AMA supports full coverage, without patient cost-sharing, of all  
37 contraception without regard to prescription or over-the-counter utilization  
38 because all contraception is essential preventive health care. (Modify  
39 HOD Policy)  
40

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

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

4 RECOMMENDATION:  
5

6 Madam Speaker, your Reference Committee recommends  
7 that the recommendation in Board of Trustees Report 22  
8 be adopted and the remainder of the report be filed.  
9

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

18 The Board of Trustees was thanked for developing this report. Your Reference  
19 Committee heard testimony in support of the report's recommendations, and in line with  
20 reaffirmation of existing AMA Policy H-45.979. Therefore, your Reference Committee  
21 urges adoption of the report's recommendation.  
22

23 Policy recommended for reaffirmation:  
24

25 H-45.979, "Air Travel Safety"

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

1 (3) BOARD OF TRUSTEES REPORT 29 – SUPPORT FOR  
2 SERVICE ANIMALS, EMOTIONAL SUPPORT ANIMALS,  
3 ANIMALS IN HEALTHCARE, AND MEDICAL BENEFITS  
4 OF PET OWNERSHIP (RESOLUTION 508-A-17)  
5

6 RECOMMENDATION:  
7

8 Madam Speaker, your Reference Committee recommends  
9 that the recommendation in Board of Trustees Report 29  
10 be adopted and the remainder of the report be filed.  
11

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

19 Service Animals, Animal-Assisted Therapy, and Animals in Healthcare

20 Our American Medical Association:

- 21 1. Encourages research into the use of animal-assisted therapy as a part of a  
22 therapeutic treatment plan.
- 23 2. Supports public education efforts on legitimately trained service animals, as  
24 defined by the Americans with Disabilities Act (ADA).
- 25 3. Supports a national certification program and registry for legitimately trained  
26 service animals, as defined by the ADA.
- 27 4. Encourages health care facilities to set evidence-based policy guidelines for  
28 animal visitation. (New HOD Policy)  
29

30 Testimony commended the clarity this report provided regarding the various  
31 classifications of animals used in healthcare and for the treatment of various conditions.  
32 Commenters were unanimously supportive of the recommendations in the report.  
33 Additionally, an amendment was offered, but due to insufficient evidence regarding the  
34 amendment, your reference Committee does not believe it is appropriate. Therefore,  
35 your Reference Committee recommends that Board of Trustees Report 29 be adopted.  
36

37 (4) BOARD OF TRUSTEES REPORT 30 – IN-FLIGHT  
38 EMERGENCIES (RESOLUTION 516-A-17, RESOLVE 5)  
39

40 RECOMMENDATION:  
41

42 Madam Speaker, your Reference Committee recommends  
43 that the recommendation in Board of Trustees Report 30  
44 be adopted and the remainder of the report be filed.  
45

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

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

3  
4 Your Reference Committee heard testimony regarding anecdotal experiences related to  
5 IFMEs and the need to ensure that onboard medical supplies are appropriate for treating  
6 the most common emergencies. Several individuals and organizations, such as AsMA,  
7 commented that the report concisely listed resources for physician education related to  
8 IFMEs. Overall, the majority of testimony supported the report and its recommendations.  
9 Therefore, your Reference Committee recommends that Board of Trustees Report 30  
10 recommendations be adopted and the remainder of the report filed.

11  
12 Policy recommended for reaffirmation:

13  
14 H-45.979, "Air Travel Safety"

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

30  
31 (5) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT  
32 3 – PROVIDING FOR PRESCRIPTION DRUG  
33 DONATION

34  
35 RECOMMENDATION:

36  
37 Madam Speaker, your Reference Committee recommends  
38 that the recommendation in Council on Science and Public  
39 Health Report 3 be adopted and the remainder of the  
40 report be filed.

41  
42 Council on Science and Public Health Report 3 is in response to Resolution 207-I-17  
43 and Resolution 525-A-17. Both of the resolutions reflect concerns about the intersection  
44 of rising drug costs, wastage and expiration of unused pharmaceutical products  
45 prompting their disposal, and existing problems with patient access and their ability to  
46 pay for needed therapies. The focus of this report is the recycling and re-dispensing of  
47 unused medications and authorized drug repository and/or return and reuse programs  
48 for prescription medications in states. The Council on Science and Public Health  
49 recommends that the following statements be adopted in lieu of Resolution 207-I-17 and  
50 Resolution 525-A-17 and the remainder of the report be filed:

1 Our AMA encourages:

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

11  
12 Limited but broadly supportive testimony was offered on this report. Therefore, your  
13 Reference Committee recommends that Council on Science and Public Health Report 3  
14 be adopted.

15  
16 (6) RESOLUTION 504 – ENDING THE RISK EVALUATION  
17 AND MITIGATION STRATEGY (REMS) POLICY ON  
18 MIFEPRISTONE (MIFEPREX)

19  
20 RECOMMENDATION:

21  
22 Madam Speaker, your Reference Committee recommends  
23 that Resolution 504 be adopted.

24  
25 Resolution 504 asks that the American Medical Association support efforts urging the  
26 Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy (REMS)  
27 on mifepristone. (New HOD Policy)

28  
29 Limited but supportive testimony was heard to eliminate the current REMS program for  
30 mifepristone, including from the American Congress of Obstetricians and Gynecologists.  
31 In 2016, the label for mifepristone was updated to reflect contemporary, and more  
32 effective dosing practices. Testimony further supported a long history of safe  
33 mifepristone use, low rates of serious adverse events, and a mortality rate that is 14  
34 times less than pregnancy-related death. Eliminating the mifepristone REMS also was  
35 noted as a way to increase access to this treatment. Your Reference Committee  
36 recommends that Resolution 504 be adopted.

37  
38 (7) RESOLUTION 514 – EFFECTS OF VIRTUAL REALITY  
39 ON HUMAN HEALTH

40  
41 RECOMMENDATION:

42  
43 Madam Speaker, your Reference Committee recommends  
44 that Resolution 514 be adopted.

45  
46 Resolution 514 asks that our American Medical Association supports further study on  
47 the impact of virtual reality on human health. (New HOD Policy)

48  
49 Your Reference Committee heard testimony supportive of this resolution, including the  
50 scope of anticipated risks and need for additional research to examine potential for

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

3  
4 (8) RESOLUTION 524 – NALOXONE ON COMMERCIAL  
5 AIRLINES

6  
7 RECOMMENDATION:

8  
9 Madam Speaker, your Reference Committee recommends  
10 that Resolution 524 be adopted.

11  
12 Resolution 524 asks that the American Medical Association supports the addition of  
13 naloxone to the airline medical kit, that the AMA encourage airlines to voluntarily include  
14 naloxone in their airline medical kits, and that the AMA encourage the addition of  
15 naloxone to the emergency medical kits of all US airlines (14CFR Appendix A to Part  
16 121 - First Aid Kits and Emergency Medical Kits). (New HOD Policy)

17  
18 Your Reference Committee heard testimony strongly in support of this resolution.  
19 Access to naloxone should be broad. Therefore, your Reference Committee  
20 recommends that Resolution 524 be adopted.

21  
22 (9) RESOLUTION 526 – DIRECT-TO-CONSUMER (DTC)  
23 LABORATORY TESTING

24  
25 RECOMMENDATION:

26  
27 Madam Speaker, your Reference Committee recommends  
28 that Resolution 526 be adopted.

29  
30 Resolution 526 asks that our American Medical Association: (1) advocate for vigilant  
31 oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal  
32 agencies; and (2) encourage physicians to educate their patients about the risks and  
33 benefits of DTC laboratory tests, as well as the risks associated with interpreting DTC  
34 test results without input from a physician or other qualified health care professional.  
35 (Directive to Take Action)

36  
37 Your Reference Committee heard testimony supportive of the proposed resolution,  
38 which mentioned a need for increasing oversight of DTC testing by federal agencies,  
39 and encouraging communication of risks of DTC tests by physicians. Therefore, your  
40 Reference Committee recommends that Resolution 526 be adopted.



1 (10) RESOLUTION 502 – EXPEDITED PRESCRIPTION CBD  
2 DRUG RESCHEDULING  
3

4 RESOLUTION 509 – OPPOSING THE CLASSIFICATION  
5 OF CANNABIDIOL AS A SCHEDULE 1 DRUG  
6

7 RECOMMENDATION A:  
8

9 Madam Speaker, your Reference Committee recommends  
10 that the Resolution 502 be adopted in lieu of Resolution  
11 509.  
12

13 RECOMMENDATION B:  
14

15 Madam Speaker, your Reference Committee recommends  
16 that the title of Resolution 506 be changed to read as  
17 follows:  
18

19 EXPEDITED PRESCRIPTION CANNABIDIOL (CBD)  
20 DRUG RESCHEDULING  
21

22 Resolution 502 asks that our American Medical Association (AMA) encourage state  
23 controlled substance authorities, boards of pharmacy, and legislative bodies to take the  
24 necessary steps including regulation and legislation to reschedule U.S. Food and Drug  
25 Administration (FDA)-approved cannabidiol products, or make any other necessary  
26 regulatory or legislative change, as expeditiously as possible so that they will be  
27 available to patients immediately after approval by the FDA and rescheduling by the U.S.  
28 Drug Enforcement Administration and that our AMA advocate that an FDA-approved  
29 cannabidiol medication should be governed only by the federal and state regulatory  
30 provisions that apply to other prescription-only products, such as dispensing through  
31 pharmacies, rather than by these various state laws applicable to unapproved cannabis  
32 products. (New HOD Policy)  
33

34 Resolution 509 asks that our American Medical Association support the reclassification  
35 of Cannabidiol (CBD) as a non-scheduled drug. (New HOD Policy)  
36

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

1 (11) RESOLUTION 508 – REINTRODUCTION OF  
2 MITOCHONDRIAL DONATION IN THE UNITED STATES  
3

4 RECOMMENDATION A:  
5

6 Madam Speaker, your Reference Committee recommends  
7 that Resolution 508 be adopted.  
8

9 RECOMMENDATION B:  
10

11 Madam Speaker, your Reference Committee recommends that the title of  
12 Resolution 508 be changed to read as follows:  
13

14 MITOCHONDRIAL DONATION  
15

16 Resolution 508 asks that our American Medical Association support regulated research  
17 to determine the efficacy and safety of mitochondrial donation as a means of preventing  
18 the transmission of mitochondrial diseases. (New HOD Policy)  
19

20 Testimony was provided in support of this resolution encouraging regulated research for  
21 mitochondrial donation. Therefore, your Reference Committee recommends that  
22 Resolution 508 be adopted, with a change in title to more accurately reflect describe the  
23 policy.  
24

25 (12) BOARD OF TRUSTEES REPORT 38 – TIMELY  
26 REFERRAL TO PAIN MANAGEMENT SPECIALIST  
27 (RESOLUTION 714-A-17)  
28

29 RECOMMENDATION A:  
30

31 Madam Speaker, your Reference Committee recommends  
32 that the recommendation in Board of Trustees Report 38  
33 be amended by addition and deletion to read as follows:  
34

35 The Board of Trustees recommends that Policy H-185.931 be amended by  
36 addition and deletion in lieu of Resolution 714-A-17 and the remainder of the  
37 report be filed:  
38

39 Policy H-185.931, "Workforce and Coverage for Chronic Pain Management"

40 1. Our American Medical Association (AMA) supports efforts to improve the  
41 quality of care for patients with pain, ensuring access to multiple analgesic  
42 strategies, including non-opioid options and interventional approaches when  
43 appropriate, with a focus on achieving improvement in function and activities of  
44 daily living.  
45

46 2. Our AMA supports guidance on pain management for different clinical  
47 indications developed by the specialties who manage those conditions and  
48 disseminated the same way other clinical guidelines are promoted, such as  
49 through medical journals, medical societies, and other appropriate outlets.  
50

1 4.3. Our American Medical Association (AMA) will advocate for an increased  
 2 focus on comprehensive, multidisciplinary pain management approaches that  
 3 include the ability to assess co-occurring mental health or substance use  
 4 conditions, are physician led, and recognize the interdependency of treatment  
 5 methods in addressing chronic pain.

6  
 7 2.4. Our AMA supports health insurance coverage that gives patients access to  
 8 the full range of evidence-based chronic pain management modalities, and that  
 9 coverage for these services be equivalent to coverage provided for medical or  
 10 surgical benefits.

11  
 12 3.5. Our AMA supports efforts to expand the capacity of practitioners and  
 13 programs capable of providing physician-led interdisciplinary pain management  
 14 services, as well as an expanded behavioral health workforce to improve the  
 15 availability of services to address the psychological, behavioral, and social  
 16 aspects of pain and pain management within mutildisciplinary pain clinics, which  
 17 have the ability to address the physical, psychological, and medical aspects of  
 18 the patient's condition and presentation and involve Ppatients and their  
 19 caregivers should be involved in the decision-making process.

20 (Modify Current HOD Policy)

21  
 22 6. Our AMA supports an expanded availability of comprehensive multidisciplinary  
 23 pain medicine clinics for patients in both urban and rural areas, and an  
 24 improvement in payment models for comprehensive multidisciplinary pain clinics  
 25 services such that such services can become more financially viable.

26  
 27 Board of Trustees Report 38 is in response to Resolution 714-A-17. This report  
 28 discusses whether the AMA should urge CMS to adopt clinical practice guidelines on the  
 29 management and treatment of pain. The Board of Trustees recommends that Policy H-  
 30 185.931 be amended by addition and deletion in lieu of Resolution 714-A-17 and the  
 31 remainder of the report be filed:

32 H-185.931, "Coverage for Pain Management"

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

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

41 ~~4.3.~~ Our ~~American Medical Association (AMA)~~ will advocate for an increased  
 42 focus on comprehensive, multidisciplinary pain management approaches that  
 43 include the ability to assess co-occurring mental health or substance use  
 44 conditions, are physician led, and recognize the interdependency of treatment  
 45 methods in addressing chronic pain.

46 ~~2.4.~~ Our AMA supports health insurance coverage that gives patients access to  
 47 the full range of evidence-based ~~chronic~~ pain management modalities, and that  
 48 coverage for these services be equivalent to coverage provided for medical or  
 49 surgical benefits.

1 3-5. Our AMA supports efforts to expand the capacity of practitioners and  
2 programs capable of providing physician-led interdisciplinary pain management  
3 services, which have the ability to address the physical, psychological, and  
4 medical aspects of the patient's condition and presentation and involve patients  
5 and their caregivers in the decision-making process. (Modify Current HOD Policy)  
6

7 RECOMMENDATION B:

8  
9 Madam Speaker, your Reference Committee recommends  
10 that the recommendation in Board of Trustees Report 38  
11 be adopted as amended and the remainder of the report  
12 be filed.  
13

14 Your Reference Committee heard Testimony highly supportive of the Board of Trustees  
15 recommendations to amend current policy. This testimony reflected both the need for  
16 physician autonomy with respect to pain management and also referral for specialty care  
17 when appropriate. Amendments were offered that were positive additions to expand the  
18 policy to include interventional approaches and expanded availability of comprehensive  
19 multidisciplinary centers; further testimony was in agreement. Your Reference  
20 Committee concurs that the amended policy is an appropriate response and therefore  
21 recommends adoption as amended.  
22

23 (13) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT  
24 2 – DRUG SHORTAGES: UPDATE  
25

26 RESOLUTION 517 – IMPACT OF NATURAL DISASTERS ON  
27 PHARMACEUTICAL SUPPLY AND PUBLIC HEALTH  
28

29 RECOMMENDATION A:

30  
31 Madam Speaker, your Reference Committee recommends  
32 that the recommendation in Council on Science and Public  
33 Health Report 2 be amended by addition to read as  
34 follows:.  
35

36 The CSAPH recommends that Policy H-100.956 be  
37 amended by addition and deletion to read as follows:  
38 H-100.956, "National Drug Shortages"

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

- 1           (DHHS) to expedite facility inspections and the review  
2 of manufacturing changes, drug applications and  
3 supplements that would help mitigate or prevent a drug  
4 shortage.
- 5           3. Our AMA will advocate that the US Food and Drug  
6 Administration (FDA) and/or Congress require drug  
7 manufacturers to establish a plan for continuity of  
8 supply of vital and life-sustaining medications and  
9 vaccines to avoid production shortages whenever  
10 possible. This plan should include establishing the  
11 necessary resiliency and redundancy in manufacturing  
12 capability to minimize disruptions of supplies in  
13 foreseeable circumstances including the possibility of a  
14 disaster affecting a plant.
- 15           4. The Council on Science and Public Health shall  
16 continue to evaluate the drug shortage issue, including  
17 the impact of group purchasing organizations on drug  
18 shortages, and report back at least annually to the  
19 House of Delegates on progress made in addressing  
20 drug shortages.
- 21           5. Our AMA urges the development of a comprehensive  
22 independent report on the root causes of drug  
23 shortages. Such an analysis should consider federal  
24 actions, the number of manufacturers, economic  
25 factors including federal reimbursement practices, as  
26 well as contracting practices by market participants on  
27 competition, access to drugs, and pricing. In particular,  
28 further transparent analysis of economic drivers is  
29 warranted. The federal Centers for Medicare &  
30 Medicaid Services (CMS) should review and evaluate  
31 its 2003 Medicare reimbursement formula of average  
32 sales price plus 6% for unintended consequences  
33 including serving as a root cause of drug shortages.
- 34           6. Our AMA urges regulatory relief designed to improve  
35 the availability of prescription drugs by ensuring that  
36 such products are not removed from the market due to  
37 compliance issues unless such removal is clearly  
38 required for significant and obvious safety reasons.
- 39           7. Our AMA supports the view that wholesalers should  
40 routinely institute an allocation system that attempts to  
41 fairly distribute drugs in short supply based on  
42 remaining inventory and considering the customer's  
43 purchase history.
- 44           8. Our AMA will collaborate with medical specialty society  
45 partners and other stakeholders in identifying and  
46 supporting legislative remedies to allow for more  
47 reasonable and sustainable payment rates for  
48 prescription drugs.
- 49           9. Our AMA urges that during the evaluation of potential  
50 mergers and acquisitions involving pharmaceutical

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

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

25  
26 RECOMMENDATION B:

27  
28 Madam Speaker, your Reference Committee recommends  
29 that the recommendation in Council on Science and Public  
30 Health Report 2 be adopted as amended in lieu of  
31 Resolution 517 and the remainder of the report be filed.

32  
33 Council on Science and Public Health Report 2 is in response to policy H-100.956, which  
34 directs the Council to continue to evaluate the drug shortage issue and report back at  
35 least annually to the House of Delegates on progress made in addressing drug  
36 shortages in the U.S. This ninth report in the series updates information on drug  
37 shortages since the 2017 report was developed, specifically commenting on the increase  
38 in drug shortages due to hurricanes that have impacted the pharmaceutical industry in  
39 Puerto Rico as well as other relevant policy considerations regarding manufacturer  
40 processes recently brought to light which have implications for the United States health  
41 care system. The Council on Science and Public Health recommends that Policy H-  
42 100.956 be amended by addition and deletion to read as follows:

43 H-100.956, "National Drug Shortages"

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

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

- 1           14. Our AMA considers drug shortages to be an urgent public health crisis, and  
2           recent shortages have had a dramatic and negative impact on the delivery  
3           and safety of appropriate health care to patients. (Modify Current HOD  
4           Policy)  
5

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

11           National Drug Shortages H-100.956

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



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

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

21  
22 (14) RESOLUTION 506 – NON-THERAPEUTIC GENE  
23 THERAPIES

24  
25 RECOMMENDATION A:

26  
27 Madam Speaker, your Reference Committee recommends  
28 that Resolution 506 be amended by addition and deletion  
29 to read as follows:  
30

31 RESOLVED, that our American Medical Association  
32 ~~partners with relevant institutions to~~ encourages the  
33 development of safety guidelines, and regulations, ~~and~~  
34 ~~permissible uses of~~ regarding performance enhancing,  
35 non-therapeutic gene therapies.  
36

37 RECOMMENDATION B:

38  
39 Madam Speaker, your Reference Committee recommends  
40 that Resolution 506 be adopted as amended.  
41

42 RECOMMENDATION C:

43  
44 Madam Speaker, your Reference Committee recommends  
45 that the title of Resolution 506 be changed to read as  
46 follows:  
47

48 GENE DOPING

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

5  
6 Your Reference Committee heard testimony generally in support of this Resolution.  
7 However, it was noted by many, including the Council on Science and Public Health, that  
8 other organizations are in a better position to lead this effort. Testimony also noted the  
9 ethical opinion that gene-therapy should only be a therapeutic treatment and questioned  
10 the inclusion of “permissible uses.” Therefore, your Reference Committee recommends  
11 that Resolution 506 be adopted as amended with a change in title to more accurately  
12 reflect the policy.

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

15  
16 RECOMMENDATION A:

17  
18 Madam Speaker, your Reference Committee recommends  
19 that Resolution 511 be amended by addition to read as  
20 follows:

21  
22 RESOLVED, that our American Medical Association (AMA)  
23 amend Policy D-95-987 by addition to read as follows  
24 D-95.987, “Prevention of Opioid Overdose”

25 1. Our AMA: (A) recognizes the great burden that opioid  
26 addiction and prescription drug abuse places on patients  
27 and society alike and reaffirms its support for the  
28 compassionate treatment of such patients; (B) urges that  
29 community-based programs offering naloxone and other  
30 opioid overdose prevention services continue to be  
31 implemented in order to further develop best practices in  
32 this area; and (C) encourages the education of health care  
33 workers and opioid users about the use of naloxone in  
34 preventing opioid overdose fatalities; and (D) will continue  
35 to monitor the progress of such initiatives and respond as  
36 appropriate.

37 2. Our AMA will: (A) advocate for the appropriate education  
38 of at-risk patients and their caregivers in the signs and  
39 symptoms of opioid overdose; and (B) encourage the  
40 continued study and implementation of appropriate  
41 treatments and risk mitigation methods for patients at risk  
42 for opioid overdose.

43 3. Our AMA support the development and implementation  
44 of appropriate education programs for persons in recovery  
45 from opioid addiction and their friends/families that address  
46 how a return to opioid use after a period of abstinence can,  
47 due to reduced opioid tolerance, result in overdose and  
48 death. (Modify Current HOD Policy)

1 RECOMMENDATION B:  
2

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

5  
6 Resolution 511 asks that our American Medical Association (AMA) amend Policy D-95-  
7 987 by addition to read as follows:

## 8 Prevention of Opioid Overdose D-95.987

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

25  
26 Testimony affirmed that individuals who previously misused prescription or illicit opioids,  
27 and who developed physical dependence and/or opioid use disorder, are at increased  
28 risk of overdose after a period of sobriety. This includes those who have been  
29 incarcerated. While there was affirmation of the need to address this specific risk, an  
30 amendment was offered for the AMA to support the development of education from  
31 those who are experts in this area because skepticism was expressed about the ability  
32 of the AMA to reach the intended audience. Therefore, your Reference Committee  
33 recommends that Resolution 511 be adopted as amended.

1 (16) RESOLUTION 516 – WASTE INCINERATOR BAN

2  
3 RECOMMENDATION A:

4  
5 Madam Speaker, your Reference Committee recommends  
6 that the first Resolve of Resolution 516 be amended by  
7 addition and deletion to read as follows:

8  
9 RESOLVED, That our American Medical Association  
10 (AMA) amend Policy H-135.939 as follows:

11  
12 Green Initiatives and the Health Care Community H-  
13 135.939

14  
15 Our AMA supports ~~and shall prioritize~~: (1) responsible  
16 waste management and clean energy production policies  
17 that do not pose minimize health risks, including the  
18 promotion of appropriate recycling and waste reduction; (2)  
19 the use of ecologically sustainable products, foods, and  
20 materials when possible; (3) the development of products  
21 that are non-toxic, sustainable, and ecologically sound; (4)  
22 building practices that help reduce resource utilization and  
23 contribute to a healthy environment; and (5) community-  
24 wide adoption of 'green' initiatives and activities by  
25 organizations, businesses, homes, schools, and  
26 government and health care entities; (Modify Current HOD  
27 Policy)

28  
29 RECOMMENDATION B:

30  
31 Madam Speaker, your Reference Committee recommends  
32 that the second resolve of Resolution 516 be amended by  
33 deletion as follows:

34  
35 ~~RESOLVED, That our AMA request and actively advocate~~  
36 ~~for national legislation that bans waste incinerators in our~~  
37 ~~nation due to their adverse health effects, negative~~  
38 ~~environmental impact, and lack of cost effectiveness.~~  
39 ~~(Directive to Take Action)~~

40  
41 RECOMMENDATION C:

42  
43 Madam Speaker, your Reference Committee recommends  
44 that Resolution 516 be adopted as amended.

45  
46 Resolution 516 asks that our American Medical Association (AMA) amend policy H-  
47 135.939 as follows:

48 Green Initiatives and the Health Care Community H-135.939

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

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

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

11  
12 Reference Committee heard testimony supportive of Resolution 516. Testimony focused  
13 on possible health hazards from waste incinerators, and supported alternatives to waste  
14 incinerators that might be anticipated to represent safer and more economical waste  
15 management, as well as more sustainable practices. It was also noted that our AMA has  
16 existing policy that supports clean energy production. The second Resolve of Resolution  
17 516 asked that our AMA ban waste incinerators by amending existing policy. However,  
18 the evidence presented is insufficient to support a substantial change in the AMA's  
19 policy on waste incinerators. Therefore, your Reference Committee recommends that  
20 the Resolution 516 be adopted as amended.

21  
22 (17) RESOLUTION 518 – PORTABLE LISTENING DEVICES  
23 AND NOISE INDUCED HEARING LOSS

24  
25 RECOMMENDATION A:

26  
27 Madam Speaker, your Reference Committee recommends  
28 that Policy H-440.957 be amended by addition and  
29 deletion to read as follows:

30  
31 H-440.957, "Reporting Potential for Hearing Loss Due to  
32 Personal Listening Devices"

33 It is the policy of the AMA that (1) physicians counsel  
34 patients about the potential loss of hearing associated with  
35 the misuse of personal listening devices; (2) research be  
36 directed at more specific definition of the relationship  
37 between acute and chronic use of personal listening  
38 devices and the occurrence of short-term and long-term  
39 noise-induced hearing loss; ~~and~~ (3) the AMA work with the  
40 National Institute on Deafness and Other Communication  
41 Disorders to enhance awareness, knowledge and  
42 remediation of causes of noise induced hearing loss; and  
43 (4) portable listening devices limit the maximum sound  
44 amplitude to safe levels.

45  
46 RECOMMENDATION B:

47  
48 Madam Speaker, your Reference Committee recommends  
49 that Policy H-440.957 be adopted as amended in lieu of  
50 Resolution 518.

1 Resolution 518 asks that our American Medical Association (AMA) update its policy on  
2 portable listening devices to support the use of Portable listening devices that limit the  
3 maximum sound amplitude to safe levels and that our AMA advocate on a federal level  
4 for labeling on earbuds that do not have amplitude limiters to warn of the risk of hearing  
5 loss with extended use at high volume levels for extended periods as described in the  
6 CSAPH Report 6-A-08. (New HOD Policy)  
7

8 Your Reference Committee heard largely supportive testimony on this issue. Although  
9 the Council on Science and Public Health (CSAPH) commented that current policy  
10 based on CSAPH report A-08 is still relevant, other testimony commented that a subset  
11 of new devices may be an issue. However, because of uncertainty regarding the  
12 evidence, your Reference Committee believes that amending current policy to reflect the  
13 first Resolve is appropriate. However, because of the lack of evidence noted by CSAPH,  
14 your Reference Committee feels that actively advocating for labeling is not warranted or  
15 appropriate for the AMA to pursue at this time. Therefore, your Reference Committee  
16 recommends that Policy H-440.957 be amended in lieu of Resolution 518.  
17

18 (18) RESOLUTION 521 –EPA GLIDER TRUCK STANDARD  
19

20 RECOMMENDATION A:  
21

22 Madam Speaker, your Reference Committee recommends  
23 that Policy D-135.996 be amended by addition and  
24 deletion to read as follows:  
25

26 D-135.996, “Reducing Sources of Diesel Exhaust”

27 Our AMA will: (1) encourage the US Environmental  
28 Protection Agency to finalize the most stringent feasible  
29 standards to control pollutant emissions from both large  
30 and small non-road engines including construction  
31 equipment, farm equipment, boats, ~~and~~ trains, and glider  
32 trucks; (2) encourage all states to continue to pursue  
33 opportunities to reduce diesel exhaust pollution, including  
34 reducing harmful emissions from existing diesel; and (3)  
35 call for all trucks traveling within the United States,  
36 regardless of country of origin, to be in compliance with  
37 new diesel emissions standards promulgated by US EPA.  
38 Res. 428, A-04 Reaffirmed in lieu of Res. 507, A-09  
39 Reaffirmation A-11 Reaffirmation A-14  
40

41 RECOMMENDATION B:  
42

43 Madam Speaker, your Reference Committee recommends  
44 that Policy D-135.996 be adopted as amended in lieu of  
45 Resolution 521.  
46

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

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

3  
4 Your Reference Committee heard limited but supportive testimony of Resolution 521,  
5 especially as it relates to the public health impacts of diesel truck engines. After  
6 reviewing Policy D-135.996, your Reference Committee concluded that the addition of  
7 “glider trucks” to part one of the Policy would maintain the intent of Resolution 521.  
8 Therefore, your Reference Committee recommends that Policy D-135.996 be reaffirmed  
9 as amended in lieu of Resolution 521.

10  
11 (19) RESOLUTION 523 – BIOSIMILAR  
12 INTERCHANGEABILITY PATHWAY

13  
14 RECOMMENDATION A:

15  
16 Madam Speaker, your Reference Committee recommends  
17 that Resolution 523 be amended by deletion to read as  
18 follows:

19  
20 RESOLVED, That our American Medical Association  
21 strongly support the ~~rigorous~~ pathway for demonstrating  
22 biosimilar interchangeability that was proposed in draft  
23 guidance by the FDA in 2017, including requiring  
24 manufacturers to use studies to determine whether  
25 alternating between a reference product and the proposed  
26 interchangeable biosimilar multiple times impacts the  
27 safety or efficacy of the drug (New HOD Policy); and be it  
28 further

29  
30 RESOLVED, That our AMA issue a request to the FDA  
31 that the agency finalize the biosimilars interchangeability  
32 pathway outlined in its draft guidance “Considerations in  
33 Demonstrating Interchangeability With a Reference  
34 Product” with all due haste, so as to allow development  
35 and designation of interchangeable biosimilars to proceed,  
36 allowing transition to an era of less expensive biologics  
37 that provide safe, effective, and accessible treatment  
38 options for patients. (Directive to Take Action)

39  
40 RECOMMENDATION B:

41  
42 Madam Speaker, your Reference Committee recommends  
43 that Resolution 523 be adopted as amended.

44  
45 Resolution 523 asks that our American Medical Association strongly support the rigorous  
46 pathway for demonstrating biosimilar interchangeability that was proposed in draft  
47 guidance by the FDA in 2017, including requiring manufacturers to use studies to  
48 determine whether alternating between a reference product and the proposed  
49 interchangeable biosimilar multiple times impacts the safety or efficacy of the drug (New  
50 HOD Policy) and that our AMA issue a request to the FDA that the agency finalize the

1 biosimilars interchangeability pathway outlined in its draft guidance “Considerations in  
2 Demonstrating Interchangeability With a Reference Product” with all due haste, so as to  
3 allow development and designation of interchangeable biosimilars to proceed, allowing  
4 transition to an era of less expensive biologics that provide safe, effective, and  
5 accessible treatment options for patients. (Directive to Take Action)  
6

7 Your Reference Committee heard strongly supportive testimony around the need to  
8 develop a vibrant biosimilar pathway, including development of standards for  
9 manufacturers to seek approval of a biosimilar as interchangeable. While biosimilars are  
10 widely viewed as having significant cost-savings potential, the extent of realized savings  
11 will be variable. The FDA strongly agreed with the need for further maturation of the  
12 biosimilar approval pathway and indicated their intention to finalize guidance on  
13 considerations in demonstrating interchangeability with a reference product by May  
14 2019. Adoption of Resolution 523 as amended is recommended.  
15

16 (20) RESOLUTION 507 – OPIOID TREATMENT PROGRAMS  
17 REPORTING TO PRESCRIPTION MONITORING  
18 PROGRAMS  
19

20 RECOMMENDATION:  
21

22 Madam Speaker, your Reference Committee recommends  
23 that Resolution 507 be referred.  
24

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

28 That our AMA will seek changes to ~~allow states the flexibility to~~ require opioid  
29 treatment programs to report to prescription monitoring programs. (Modify  
30 Current HOD Policy)  
31

32 Divided and polarizing testimony was offered on this resolution. Those opposing Opioid  
33 Treatment Programs (OTPs) reporting to Prescription Drug Monitoring Programs  
34 (PDMPs) cited concerns about privacy and confidentiality, the stigma that already exists  
35 around individuals being treated for opioid use disorder and the likelihood that opening  
36 PDMPs up to OTP reporting would have a substantial chilling effect on the willingness of  
37 patients to enter into treatment. Evidence supporting this view includes the fact that  
38 more than 20 state PDMPs are either under the control of, or easily accessible by law  
39 enforcement. Additionally, testimony noted that Resolution 507 conflicts with current  
40 federal law (42 CFR Part 2) as it pertains to the structure, function, and reporting  
41 requirements of OTPs. Given the nature and extent of the current opioid epidemic,  
42 supporters of mandatory reporting by OTPs noted the importance of understanding a  
43 patient’s controlled substance prescription history in order to inform appropriate clinical  
44 decision-making. This opinion views PDMPs as clinical decision support tools.  
45

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



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

13  
14 This is a complicated subject with far reaching ramifications and overlapping AMA  
15 policies. Your Reference Committee believes referral is required to adequately address  
16 this important issue.

17  
18 (21) RESOLUTION 515 – INFORMATION REGARDING  
19 ANIMAL-DERIVED MEDICATIONS

20  
21 RECOMMENDATION:

22  
23 Madam Speaker, your Reference Committee recommends  
24 that Resolution 515 be referred.

25  
26 Resolution 515 asks that our American Medical Association (AMA) supports efforts to  
27 improve cultural awareness pertaining to the use of animal-derived medications when  
28 considering different prescription options and (New HOD Policy) and that our AMA  
29 encourage the U.S. Food and Drug Administration to make available to the public an  
30 easily accessible database that identifies medications containing ingredients derived  
31 from animals. (Directive to Take Action)

32  
33 Limited testimony was offered on this resolution. It is known that certain chemical  
34 products used as additives or stabilizers for prescription drugs are derived from animal  
35 sources. The consumption of such products may be objectionable to certain religions or  
36 based on consumer choice. Testimony from the U.S. Food and Drug Administration  
37 agreed with the validity of this view, but noted the potential complexity of establishing  
38 registries for individual drug formulations that might be "culturally competent." Therefore,  
39 your Reference Committee recommends that Resolution 515 be referred.

40  
41 (22) RESOLUTION 505 – RESEARCHING DRUG  
42 FACILITATED SEXUAL ASSAULT TESTING

43  
44 RECOMMENDATION:

45  
46 Madam Speaker, your Reference Committee recommends  
47 that Resolution 505 not be adopted.

48  
49 Resolution 505 asks that our American Medical Association study the feasibility and  
50 implications of offering drug testing at point of care for date rape drugs, including

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

3  
4 Supportive testimony was offered on the intent of this Resolution. However, several  
5 dissenting points were raised including concerns about chain of custody of evidence  
6 required for legal proceedings, specific responsibilities of the treating physician, relevant  
7 jurisdictions for obtaining and preserving evidence, and the fact that the point-of-care  
8 (POC) tests referred to in the resolution will not provide useful results in this setting.  
9 Many urine drug tests (UDTs) utilized in clinical care are grounded in immunoassay (IA)  
10 technology. IA UDTs are designed to detect a specific drug or a class of drugs as either  
11 present or absent based on a designated threshold cut-off concentration. Results based  
12 on IAs are considered presumptive and are often used as an initial screening test (i.e.,  
13 qualitatively positive or negative) in clinical UDT. POC tests are typically non-  
14 instrumented IA devices (strips, dipcards) that can be used in clinics and are  
15 presumptive, qualitative, variable, and have a number of other limitations. Several of the  
16 drugs mentioned in the Resolution, and other related substances that have been  
17 implicated in drug facilitated sexual assault cannot be tested for using a POC device.  
18 Your Reference Committee does not believe that POC testing in drug facilitated sexual  
19 assault is worthy of further study at this point and recommends that Resolution 505 not  
20 be adopted.

21  
22 (23) RESOLUTION 513 – HAND SANITIZER  
23 EFFECTIVENESS

24  
25 RECOMMENDATION:

26  
27 Madam Speaker, your Reference Committee recommends  
28 that Resolution 513 not be adopted.

29  
30 Resolution 513 asks that our American Medical Association urge the U.S. Food and  
31 Drug Administration and the Centers for Disease Control and Prevention to continue to  
32 study the use of hand sanitizers in clinical settings, including the risks and benefits to  
33 patients and health care professionals. (Directive to Take Action)

34  
35 Your Reference Committee heard divided testimony regarding this issue. Although the  
36 intent was supported by some testimony, the FDA provided comment in opposition  
37 because they are already taking significant action on the use of hand sanitizers and the  
38 ingredients used in hand sanitizer products. FDA also commented that the task of  
39 evaluating hand sanitizers is their task, not the purview of the CDC. Because this work is  
40 underway at the FDA, your Reference Committee recommends that Resolution 513 not  
41 be adopted.

42  
43 (24) RESOLUTION 522 – SILENCE SCIENCE: EPA  
44 PROPOSED DATA POLICY

45  
46 RECOMMENDATION:

47  
48 Madam Speaker, your Reference Committee recommends  
49 that Resolution 522 not be adopted.

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

10  
11 Your Reference Committee heard testimony generally in support of this Resolution.  
12 Testimony did state that several organizations, including medical groups, academicians,  
13 and industry, have already individually or jointly submitted comments to the EPA  
14 requesting an extension to the 30-day comment period regarding the proposal  
15 mentioned in the Resolution. Testimony noted the AMA signed on to a letter written by  
16 the American Thoracic Society (ATS) requesting a 60-day extension to the comment  
17 period. On May 24th, EPA extended the deadline and scheduled a public hearing on the  
18 proposed rule for July 17th. The AMA does intend to submit comments regarding the  
19 proposed rule, either by joining a Federation Member's letter or developing comments.  
20 Because response to this resolution is underway, your Reference Committee  
21 recommends that Resolution 522 not be adopted.

22  
23 (25) RESOLUTION 525 – TRAMADOL CHANGE FROM DEA  
24 SCHEDULE IV TO SCHEDULE III

25  
26 RECOMMENDATION:

27  
28 Madam Speaker, your Reference Committee recommends  
29 that Resolution 525 be not be adopted.

30  
31 Resolution 525 asks that the American Medical Association petition the United States  
32 Drug Enforcement Administration to change tramadol from a Schedule IV to a Schedule  
33 III controlled substance. (Directive to Take Action)

34  
35 Your Reference Committee heard testimony generally opposing review of the current  
36 schedule of tramadol. It was pointed out that changing from a schedule IV to a schedule  
37 III controlled substance would not significantly change the control measures of the drug  
38 since prescribing standards are the same for schedule III and IV substance. Additionally,  
39 it was noted that to change the schedule of a drug, the DEA would be required to review  
40 currently available evidence to determine the appropriate schedule for the drug. Your  
41 Reference Committee agrees with testimony that supports retaining the schedule of  
42 tramadol by the DEA and therefore recommends that Resolution 525 not be adopted.

1 (26) RESOLUTION 503 – ADVOCATING FOR ANONYMOUS  
2 REPORTING OF OVERDOSES BY FIRST  
3 RESPONDERS AND EMERGENCY PHYSICIANS  
4

5 RECOMMENDATION:  
6

7 Madam Speaker, your Reference Committee recommends  
8 that Policy H-95.940 be reaffirmed in lieu of Resolution  
9 503.

10  
11 Resolution 503 asks that our American Medical Association support non-fatal and fatal  
12 opioid overdose reporting to the appropriate agencies. (New HOD Policy)  
13

14 Your Reference Committee heard testimony generally in support of Resolution 503.  
15 However, ambiguity around maintaining patient and physician anonymity was noted, as  
16 well as specifications on which agencies are considered appropriate for notification.  
17

18 Your Reference Committee supported the intent of the resolution, but, after reviewing  
19 policy H-95.940 parts three and four, concluded that existing policy limited ambiguity  
20 noted during testimony by supporting ongoing efforts to continuously monitor trends in  
21 illicit drug use, taking a multi-stakeholder approach to addressing the issue while  
22 ensuring that all information gained through these collaborative measures be actionable  
23 and timely. Therefore, your Reference Committee recommends that Policy H-95.940 be  
24 reaffirmed in lieu of Resolution 503.  
25

26 Policy recommended for reaffirmation:  
27

28 H-95.940, “Addressing Emerging Trends in Illicit Drug Use”

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

1 (27) RESOLUTION 512 – PHYSICIAN AND PATIENT  
2 EDUCATION ABOUT THE RISK OF SYNTHETIC  
3 CANNABINOID USE  
4

5 RECOMMENDATION:  
6

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

10  
11 Resolution 512 asks that our American Medical Association (AMA) encourage all  
12 physicians to become aware of the adverse psychiatric and medical effects, including  
13 coagulopathy with severe bleeding, related to the use of synthetic cannabinoids, which  
14 may or may not be contaminated and that our AMA encourage physicians to educate  
15 their patients about synthetic cannabinoids and strongly advise them that the use of  
16 these drugs carries significant health risks that can produce psychiatric morbidity and  
17 hematological mortality. (New HOD Policy)  
18

19 Your Reference Committee heard testimony in strong support of this Resolution. The  
20 Council on Science and Public Health offered comments regarding their Report 2 from  
21 A-17 that addressed this issue and the resulting policy that addresses this topic.  
22 Therefore, your Reference Committee recommends that Policies H-95.940 and D-  
23 95.970 be reaffirmed in lieu of Resolution 512.  
24

25 Policies recommended for reaffirmation:  
26

27 H-95.940, “Addressing Emerging Trends in Illicit Drug Use”

28 Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive  
29 substances (NPS), are a public health threat; (2) supports ongoing efforts of the National  
30 Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease  
31 Control and Prevention, the Department of Justice, the Department of Homeland  
32 Security, state departments of health, and poison control centers to assess and monitor  
33 emerging trends in illicit drug use, and to develop and disseminate fact sheets, other  
34 educational materials, and public awareness campaigns; (3) supports a collaborative,  
35 multiagency approach to addressing emerging drugs of abuse, including information and  
36 data sharing, increased epidemiological surveillance, early warning systems informed by  
37 laboratories and epidemiologic surveillance tools, and population driven real-time social  
38 media resulting in actionable information to reach stakeholders; (4) encourages  
39 adequate federal and state funding of agencies tasked with addressing the emerging  
40 drugs of abuse health threat; (5) encourages the development of continuing medical  
41 education on emerging trends in illicit drug use; and (6) supports efforts by federal, state,  
42 and local government agencies to identify new drugs of abuse and to institute the  
43 necessary administrative or legislative actions to deem such drugs illegal in an expedited  
44 manner. Sub. Res. 901, I-14 Modified: CSAPH Rep. 02, A-17  
45

46 D-95.970, “Emerging Drugs of Abuse are a Public Health Threat”

47 Our AMA will participate as a stakeholder in a Centers for Disease Control and  
48 Prevention/U.S. Drug Enforcement Administration (CDC/DEA) taskforce for the  
49 development of a national forum for discussion of new psychoactive substances (NPS)-  
50 related issues. CSAPH Rep. 02, A-17

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

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