

DISCLAIMER

The following is a preliminary report of actions taken by the House of Delegates at its 2018 Meeting and should not be considered final. Only the Official Proceedings of the House of Delegates reflect official policy of the Association.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-18)

Report of Reference Committee E

Douglas Martin, MD, Chair

1 Your Reference Committee recommends the following consent calendar for acceptance:

2
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

- 1 15. Resolution 511 – Education for Recovering Patients on Opiate Use After Sobriety
- 2 16. Resolution 516 – Waste Incinerator Ban
- 3 17. Resolution 518 – Portable Listening Devices and Noise Induced Hearing Loss
- 4 18. Resolution 521 – EPA Glider Truck Standard
- 5 19. Resolution 523 – Biosimilar Interchangeability Pathway

6
7 **RECOMMENDED FOR REFERRAL**

- 8
- 9 20. Resolution 507 – Opioid Treatment Programs Reporting to Prescription
 - 10 Monitoring Programs
 - 11 21. Resolution 515 – Information Regarding Animal-Derived Medications

12
13 **RECOMMENDED FOR NOT ADOPTION**

- 14
- 15 22. Resolution 505 – Researching Drug Facilitated Sexual Assault Testing
 - 16 23. Resolution 513 – Hand Sanitizer Effectiveness
 - 17 24. Resolution 522 – Silence Science: EPA Proposed Data Policy
 - 18 25. Resolution 525 – Tramadol Change from DEA Schedule IV to Schedule III

19
20 **RECOMMENDED FOR REAFFIRMATION IN LIEU OF**

- 21
- 22 26. Resolution 503 – Advocating for Anonymous Reporting of Overdoses by First
 - 23 Responders and Emergency Physicians
 - 24 27. Resolution 512 – Physician and Patient Education About the Risk of Synthetic
 - 25 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 (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 **HOD ACTION: The recommendations in Board of Trustees**
 12 **Report 10 adopted and the remainder of the report filed.**
 13

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

- 22 1. That our AMA amend Policy D-75.995, “Over-the-Counter Access to Oral
 23 Contraceptives;”
 24 D-75.995, “Over-the-Counter Access to Oral Contraceptives”
 25 Our AMA:
 26 1. ~~Our AMA Encourages will recommend to the US Food and Drug~~
 27 ~~Administration that manufacturers of oral contraceptives be encouraged~~
 28 ~~to submit the required application and supporting evidence to the US~~
 29 ~~Food and Drug Administration for the Agency to consider approving a~~
 30 ~~switch in status from prescription to over-the-counter for such products.~~
 31 2. ~~Our AMA Encourages the continued study of issues relevant to over-the-~~
 32 ~~counter access for oral contraceptives. (Modify HOD Policy)~~
 33 2. That our AMA amend Policy H-180.958, “Coverage of Prescription
 34 Contraceptives by Insurance;”
 35 H-180.958, “Coverage of ~~Prescription~~ Contraceptives by Insurance”
 36 1. Our AMA supports federal and state efforts to require that every
 37 prescription drug benefit plan include coverage of prescription
 38 contraceptives.
 39 2. Our AMA supports full coverage, without patient cost-sharing, of all
 40 contraception without regard to prescription or over-the-counter utilization
 41 because all contraception is essential preventive health care. (Modify
 42 HOD Policy)
 43

44 Testimony was supportive of the Board’s report and its inclusion of several issues
 45 related to a potential over-the-counter oral contraceptive product. Therefore, your
 46 Reference Committee recommends that the recommendations in Board of Trustees
 47 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 **HOD ACTION: The recommendation in Board of Trustees**
11 **Report 22 adopted and the remainder of the report filed.**
12
13

14 Board of Trustees Report 22, in response to Resolution 516-A-17, Resolve 3, outlines
15 the current requirements concerning the verification of a medical professional's
16 credentials in the event of an in-flight medical emergency (IFME) and existing AMA
17 policies on physician identification of credentials and delivery of health care by Good
18 Samaritans. The Board of Trustees recommends existing AMA Policy H-45.979, "Air
19 Travel Safety," be reaffirmed in lieu of Resolve 3, Resolution 516-A-17, and the
20 remainder of the report be filed. (Reaffirm Current HOD Policy)
21

22 The Board of Trustees was thanked for developing this report. Your Reference
23 Committee heard testimony in support of the report's recommendations, and in line with
24 reaffirmation of existing AMA Policy H-45.979. Therefore, your Reference Committee
25 urges adoption of the report's recommendation.
26

27 Policy recommended for reaffirmation:
28

29 H-45.979, "Air Travel Safety"

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

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

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

23 Our American Medical Association:

- 24 1. Encourages research into the use of animal-assisted therapy as a part of a
25 therapeutic treatment plan.
- 26 2. Supports public education efforts on legitimately trained service animals, as
27 defined by the Americans with Disabilities Act (ADA).
- 28 3. Supports a national certification program and registry for legitimately trained
29 service animals, as defined by the ADA.
- 30 4. Encourages health care facilities to set evidence-based policy guidelines for
31 animal visitation. (New HOD Policy)
32

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

1 (4) BOARD OF TRUSTEES REPORT 30 – IN-FLIGHT
2 EMERGENCIES (RESOLUTION 516-A-17, RESOLVE 5)
3

4 RECOMMENDATION:
5

6 Madam Speaker, your Reference Committee recommends
7 that the recommendation in Board of Trustees Report 30
8 be adopted and the remainder of the report be filed.
9

10 **HOD ACTION: The recommendation in Board of Trustees**
11 **Report 30 adopted and the remainder of the report filed.**
12

13 Board of Trustees Report 30, in response to Resolution 516-A-17, Resolve 5, outlines
14 the current options for physician continuing medical education (CME), guidance, and
15 policy on the topic of in-flight medical emergencies (IFMEs). The Board of Trustees
16 recommends the existing AMA Policy H-45.979, “Air Travel Safety,” be reaffirmed in lieu
17 of Resolve 5, Resolution 516-A-17, and the remainder of the report be filed. (Reaffirm
18 Current HOD Policy)
19

20 Your Reference Committee heard testimony regarding anecdotal experiences related to
21 IFMEs and the need to ensure that onboard medical supplies are appropriate for treating
22 the most common emergencies. Several individuals and organizations, such as AsMA,
23 commented that the report concisely listed resources for physician education related to
24 IFMEs. Overall, the majority of testimony supported the report and its recommendations.
25 Therefore, your Reference Committee recommends that Board of Trustees Report 30
26 recommendations be adopted and the remainder of the report filed.
27

28 Policy recommended for reaffirmation:
29

30 H-45.979, “Air Travel Safety”

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

1 (5) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 3 – PROVIDING FOR PRESCRIPTION DRUG
3 DONATION
4

5 RECOMMENDATION:
6

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

11
12 **HOD ACTION: The recommendation in Council on Science
13 and Public Health Report 3 adopted and the remainder of
14 the report filed.**
15

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

25 Our AMA encourages:

- 26 1. States with laws establishing prescription drug repository and/or “return and
27 reuse” programs to implement such laws and to consider integrating them with
28 existing recycling or disposal programs. (New AMA Policy)
- 29 2. States that lack drug repository and/or “return and reuse” programs to enact such
30 laws in consultation with their state board of pharmacy. (New AMA Policy).
- 31 3. State medical associations in states where there is a prescription drug repository
32 or a “return and reuse” program for unused medication supplies to educate
33 physicians in their state regarding the existence of such programs. (New HOD
34 Policy).
35

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

1 (6) RESOLUTION 504 – ENDING THE RISK EVALUATION
2 AND MITIGATION STRATEGY (REMS) POLICY ON
3 MIFEPRISTONE (MIFEPREX)
4

5 RECOMMENDATION:
6

7 Madam Speaker, your Reference Committee recommends
8 that Resolution 504 be adopted.
9

10 **HOD ACTION: Resolution 504 adopted.**
11

12 Resolution 504 asks that the American Medical Association support efforts urging the
13 Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy (REMS)
14 on mifepristone. (New HOD Policy)
15

16 Limited but supportive testimony was heard to eliminate the current REMS program for
17 mifepristone, including from the American Congress of Obstetricians and Gynecologists.
18 In 2016, the label for mifepristone was updated to reflect contemporary, and more
19 effective dosing practices. Testimony further supported a long history of safe
20 mifepristone use, low rates of serious adverse events, and a mortality rate that is 14
21 times less than pregnancy-related death. Eliminating the mifepristone REMS also was
22 noted as a way to increase access to this treatment. Your Reference Committee
23 recommends that Resolution 504 be adopted.
24

25 (7) RESOLUTION 514 – EFFECTS OF VIRTUAL REALITY
26 ON HUMAN HEALTH
27

28 RECOMMENDATION:
29

30 Madam Speaker, your Reference Committee recommends
31 that Resolution 514 be adopted.
32

33 **HOD ACTION: Resolution 514 adopted.**
34

35 Resolution 514 asks that our American Medical Association supports further study on
36 the impact of virtual reality on human health. (New HOD Policy)
37

38 Your Reference Committee heard testimony supportive of this resolution, including the
39 scope of anticipated risks and need for additional research to examine potential for
40 harmful effects of this emerging technology. Therefore, your Reference Committee
41 recommends that Resolution 514 be adopted.

1 (8) RESOLUTION 524 – NALOXONE ON COMMERCIAL
2 AIRLINES
3

4 RECOMMENDATION:
5

6 Madam Speaker, your Reference Committee recommends
7 that Resolution 524 be adopted.
8

9 **HOD ACTION: Resolution 524 adopted.**

10
11 Resolution 524 asks that the American Medical Association supports the addition of
12 naloxone to the airline medical kit, that the AMA encourage airlines to voluntarily include
13 naloxone in their airline medical kits, and that the AMA encourage the addition of
14 naloxone to the emergency medical kits of all US airlines (14CFR Appendix A to Part
15 121 - First Aid Kits and Emergency Medical Kits). (New HOD Policy)
16

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

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

24 RECOMMENDATION:
25

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

29 **HOD ACTION: Resolution 526 adopted.**

30
31 Resolution 526 asks that our American Medical Association: (1) advocate for vigilant
32 oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal
33 agencies; and (2) encourage physicians to educate their patients about the risks and
34 benefits of DTC laboratory tests, as well as the risks associated with interpreting DTC
35 test results without input from a physician or other qualified health care professional.
36 (Directive to Take Action)
37

38 Your Reference Committee heard testimony supportive of the proposed resolution,
39 which mentioned a need for increasing oversight of DTC testing by federal agencies,
40 and encouraging communication of risks of DTC tests by physicians. Therefore, your
41 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 502 be changed to read as
17 follows:

18
19 EXPEDITED PRESCRIPTION CANNABIDIOL (CBD)
20 DRUG RESCHEDULING

21
22 **HOD ACTION: Resolution 502 adopted in lieu of Resolution**
23 **509 with a change in title.**

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

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

39
40 Your Reference Committee heard significant testimony in support of Resolution 502.
41 Many testified in support of steps to assure that prescription medications that have been
42 studied in randomized controlled trials and evaluated by the FDA should not be
43 classified as schedule 1 drugs. An FDA approved medication should be accessible by
44 patients and dispensable by pharmacies. Strong opposition to Resolution 509 was
45 noted; reclassifying all cannabidiol products to be non-scheduled is too broad, and it is
46 only appropriate to reclassify FDA approved products. Your Reference Committee
47 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 **HOD ACTION: Resolution 508 adopted with a change in**
17 **title.**
18

19 Resolution 508 asks that our American Medical Association support regulated research
20 to determine the efficacy and safety of mitochondrial donation as a means of preventing
21 the transmission of mitochondrial diseases. (New HOD Policy)
22

23 Testimony was provided in support of this resolution encouraging regulated research for
24 mitochondrial donation. Therefore, your Reference Committee recommends that
25 Resolution 508 be adopted, with a change in title to more accurately reflect describe the
26 policy.
27

28 (12) BOARD OF TRUSTEES REPORT 38 – TIMELY
29 REFERRAL TO PAIN MANAGEMENT SPECIALIST
30 (RESOLUTION 714-A-17)
31

32 RECOMMENDATION A:
33

34 Madam Speaker, your Reference Committee recommends
35 that the recommendation in Board of Trustees Report 38
36 be amended by addition and deletion to read as follows:
37

38 The Board of Trustees recommends that Policy H-185.931 be amended by
39 addition and deletion in lieu of Resolution 714-A-17 and the remainder of the
40 report be filed:
41

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

43 1. Our American Medical Association (AMA) supports efforts to improve the
44 quality of care for patients with pain, ensuring access to multiple analgesic
45 strategies, including non-opioid options and interventional approaches when
46 appropriate, with a focus on achieving improvement in function and activities of
47 daily living.
48

49 2. Our AMA supports guidance on pain management for different clinical
50 indications developed by the specialties who manage those conditions and

1 disseminated the same way other clinical guidelines are promoted, such as
 2 through medical journals, medical societies, and other appropriate outlets.

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

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

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

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

29
 30 Board of Trustees Report 38 is in response to Resolution 714-A-17. This report
 31 discusses whether the AMA should urge CMS to adopt clinical practice guidelines on the
 32 management and treatment of pain. The Board of Trustees recommends that Policy H-
 33 185.931 be amended by addition and deletion in lieu of Resolution 714-A-17 and the
 34 remainder of the report be filed:

35 H-185.931, "Coverage for Pain Management"

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

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

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

49 2.4. Our AMA supports health insurance coverage that gives patients access to
 50 the full range of evidence-based chronic pain management modalities, and that

1 coverage for these services be equivalent to coverage provided for medical or
2 surgical benefits.

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

8
9 **RECOMMENDATION B:**

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

15
16 **HOD ACTION: The recommendation in Board of Trustees**
17 **Report 38 adopted as amended and the remainder of the**
18 **report filed.**

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

28
29 (13) **COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT**
30 **2 – DRUG SHORTAGES: UPDATE**

31
32 **RESOLUTION 517 – IMPACT OF NATURAL DISASTERS ON**
33 **PHARMACEUTICAL SUPPLY AND PUBLIC HEALTH**

34
35 **RECOMMENDATION A:**

36
37 Madam Speaker, your Reference Committee recommends
38 that the recommendation in Council on Science and Public
39 Health Report 2 be amended by addition to read as
40 follows:.

41
42 The CSAPH recommends that Policy H-100.956 be
43 amended by addition and deletion to read as follows:

44 H-100.956, "National Drug Shortages"

- 45 1. Our AMA supports recommendations that have been
46 developed by multiple stakeholders to improve
47 manufacturing quality systems, identify efficiencies in
48 regulatory review that can mitigate drug shortages, and
49 explore measures designed to drive greater investment
50 in production capacity for products that are in short

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

- 1 8. Our AMA will collaborate with medical specialty society
2 partners and other stakeholders in identifying and
3 supporting legislative remedies to allow for more
4 reasonable and sustainable payment rates for
5 prescription drugs.
- 6 9. Our AMA urges that during the evaluation of potential
7 mergers and acquisitions involving pharmaceutical
8 manufacturers, the Federal Trade Commission consult
9 with the FDA to determine whether such an activity has
10 the potential to worsen drug shortages.
- 11 10. Our AMA urges the FDA to require manufacturers to
12 provide greater transparency regarding production
13 locations of drugs and provide more detailed
14 information regarding the causes and anticipated
15 duration of drug shortages.
- 16 11. Our AMA encourages electronic health records (EHR)
17 vendors to make changes to their systems to ease the
18 burden of making drug product changes.
- 19 12. Our AMA urges the FDA to evaluate and provide
20 current information regarding the quality of outsourcer
21 compounding facilities.
- 22 13. Our AMA urges DHHS and the U.S. Department of
23 Homeland Security (DHS) to examine and consider
24 drug shortages as a national security initiative and
25 include vital drug production sites in the critical
26 infrastructure plan.
- 27 14. Our AMA considers drug shortages to be an urgent
28 public health crisis, and recent shortages have had a
29 dramatic and negative impact on the delivery and
30 safety of appropriate health care to patients. (Modify
31 Current HOD Policy)

32
33 RECOMMENDATION B:

34
35 Madam Speaker, your Reference Committee recommends
36 that the recommendation in Council on Science and Public
37 Health Report 2 be adopted as amended in lieu of
38 Resolution 517 and the remainder of the report be filed.

39
40 **HOD ACTION: The recommendation in Council on Science**
41 **and Public Health Report 2 adopted as amended in lieu of**
42 **Resolution 517 and the remainder of the report filed.**

43
44 Council on Science and Public Health Report 2 is in response to policy H-100.956, which
45 directs the Council to continue to evaluate the drug shortage issue and report back at
46 least annually to the House of Delegates on progress made in addressing drug
47 shortages in the U.S. This ninth report in the series updates information on drug
48 shortages since the 2017 report was developed, specifically commenting on the increase
49 in drug shortages due to hurricanes that have impacted the pharmaceutical industry in
50 Puerto Rico as well as other relevant policy considerations regarding manufacturer

1 processes recently brought to light which have implications for the United States health
2 care system. The Council on Science and Public Health recommends that Policy H-
3 100.956 be amended by addition and deletion to read as follows:

4 H-100.956, "National Drug Shortages"

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

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

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

23 National Drug Shortages H-100.956

- 24 1. Our AMA supports recommendations that have been developed by multiple
25 stakeholders to improve manufacturing quality systems, identify efficiencies in
26 regulatory review that can mitigate drug shortages, and explore measures
27 designed to drive greater investment in production capacity for products that
28 experience drug shortages, and will work in a collaborative fashion with these
29 and other stakeholders to implement these recommendations in an urgent
30 fashion.
- 31 2. Our AMA supports authorizing the Secretary of Health and Human Services
32 to expedite facility inspections and the review of manufacturing changes, drug
33 applications and supplements that would help mitigate or prevent a drug
34 shortage.
- 35 3. Our AMA will advocate that the US Food and Drug Administration (FDA)
36 and/or Congress require drug manufacturers to establish a plan for continuity
37 of supply of vital and life-sustaining medications and vaccines to avoid
38 production shortages whenever possible. This plan should include
39 establishing the necessary resiliency and redundancy in manufacturing
40 capability to minimize disruptions of supplies in foreseeable circumstances
41 including the possibility of a disaster affecting a plant.
- 42 4. The Council on Science and Public Health shall continue to evaluate the drug
43 shortage issue, including the impact of group purchasing organizations on
44 drug shortages, and report back at least annually to the House of Delegates
45 on progress made in addressing drug shortages.
- 46 5. Our AMA urges the development of a comprehensive independent report on
47 the root causes of drug shortages. Such an analysis should consider federal
48 actions, the number of manufacturers, economic factors including federal
49 reimbursement practices, as well as contracting practices by market
50 participants on competition, access to drugs, and pricing. In particular, further

1 transparent analysis of economic drivers is warranted. The Centers for
2 Medicare & Medicaid Services should review and evaluate its 2003 Medicare
3 reimbursement formula of average sales price plus 6% for unintended
4 consequences including serving as a root cause of drug shortages.

- 5 6. Our AMA urges regulatory relief designed to improve the availability of
6 prescription drugs by ensuring that such products are not removed from the
7 market due to compliance issues unless such removal is clearly required for
8 significant and obvious safety reasons.
- 9 7. Our AMA supports the view that wholesalers should routinely institute an
10 allocation system that attempts to fairly distribute drugs in short supply based
11 on remaining inventory and considering the customer's purchase history.
- 12 8. Our AMA will collaborate with medical specialty partners in identifying and
13 supporting legislative remedies to allow for more reasonable and sustainable
14 payment rates for prescription drugs.
- 15 9. Our AMA urges that during the evaluation of potential mergers and
16 acquisitions involving pharmaceutical manufacturers, the Federal Trade
17 Commission consult with the FDA to determine whether such an activity has
18 the potential to worsen drug shortages. (Modify Current HOD Policy)

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

1 (14) RESOLUTION 506 – NON-THERAPEUTIC GENE
2 THERAPIES

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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

HOD ACTION: Resolution 506 referred for decision.

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.

1 (15) RESOLUTION 511 – EDUCATION FOR RECOVERING
2 PATIENTS ON OPIATE USE AFTER SOBRIETY
3

4 RECOMMENDATION A:
5

6 Madam Speaker, your Reference Committee recommends
7 that Resolution 511 be amended by addition to read as
8 follows:
9

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

13 1. Our AMA: (A) recognizes the great burden that opioid
14 addiction and prescription drug abuse places on patients
15 and society alike and reaffirms its support for the
16 compassionate treatment of such patients; (B) urges that
17 community-based programs offering naloxone and other
18 opioid overdose prevention services continue to be
19 implemented in order to further develop best practices in
20 this area; and (C) encourages the education of health care
21 workers and opioid users about the use of naloxone in
22 preventing opioid overdose fatalities; and (D) will continue
23 to monitor the progress of such initiatives and respond as
24 appropriate.

25 2. Our AMA will: (A) advocate for the appropriate education
26 of at-risk patients and their caregivers in the signs and
27 symptoms of opioid overdose; and (B) encourage the
28 continued study and implementation of appropriate
29 treatments and risk mitigation methods for patients at risk
30 for opioid overdose.

31 3. Our AMA support the development and implementation
32 of appropriate education programs for persons in recovery
33 from opioid addiction and their friends/families that address
34 how a return to opioid use after a period of abstinence can,
35 due to reduced opioid tolerance, result in overdose and
36 death. (Modify Current HOD Policy)
37

38 RECOMMENDATION B:
39

40 Madam Speaker, your Reference Committee recommends
41 that Resolution 511 be adopted as amended.
42

43 **HOD ACTION: Resolution 511 adopted as amended.**
44

45 Resolution 511 asks that our American Medical Association (AMA) amend Policy D-95-
46 987 by addition to read as follows:

47 Prevention of Opioid Overdose D-95.987

48 1. Our AMA: (A) recognizes the great burden that opioid addiction and
49 prescription drug abuse places on patients and society alike and reaffirms its
50 support for the compassionate treatment of such patients; (B) urges that

1 community-based programs offering naloxone and other opioid overdose
 2 prevention services continue to be implemented in order to further develop
 3 best practices in this area; and (C) encourages the education of health care
 4 workers and opioid users about the use of naloxone in preventing opioid
 5 overdose fatalities; and (D) will continue to monitor the progress of such
 6 initiatives and respond as appropriate.

7 2. Our AMA will: (A) advocate for the appropriate education of at-risk patients
 8 and their caregivers in the signs and symptoms of opioid overdose; and (B)
 9 encourage the continued study and implementation of appropriate treatments
 10 and risk mitigation methods for patients at risk for opioid overdose.

11 3. That our AMA implement an appropriate education program for recovering
 12 opioid abuse patients and their friends/families that opioid use after significant
 13 sobriety time can result in overdose and death. (Modify Current HOD Policy)
 14

15 Testimony affirmed that individuals who previously misused prescription or illicit opioids,
 16 and who developed physical dependence and/or opioid use disorder, are at increased
 17 risk of overdose after a period of sobriety. This includes those who have been
 18 incarcerated. While there was affirmation of the need to address this specific risk, an
 19 amendment was offered for the AMA to support the development of education from
 20 those who are experts in this area because skepticism was expressed about the ability
 21 of the AMA to reach the intended audience. Therefore, your Reference Committee
 22 recommends that Resolution 511 be adopted as amended.
 23

24 (16) RESOLUTION 516 – WASTE INCINERATOR BAN

25 RECOMMENDATION A:

26 Madam Speaker, your Reference Committee recommends
 27 that the first Resolve of Resolution 516 be amended by
 28 addition and deletion to read as follows:
 29
 30

31
 32 RESOLVED, That our American Medical Association
 33 (AMA) amend Policy H-135.939 as follows:
 34

35 Green Initiatives and the Health Care Community H-
 36 135.939
 37

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

1 RECOMMENDATION B:

2
3 Madam Speaker, your Reference Committee recommends
4 that the second resolve of Resolution 516 be amended by
5 deletion as follows:

6
7 ~~RESOLVED, That our AMA request and actively advocate~~
8 ~~for national legislation that bans waste incinerators in our~~
9 ~~nation due to their adverse health effects, negative~~
10 ~~environmental impact, and lack of cost effectiveness.~~
11 ~~(Directive to Take Action)~~

12
13 RECOMMENDATION C:

14
15 Madam Speaker, your Reference Committee recommends
16 that Resolution 516 be adopted as amended.

17
18 **HOD ACTION: Resolution 516 adopted as amended.**

19
20 Resolution 516 asks that our American Medical Association (AMA) amend policy H-
21 135.939 as follows:

22 Green Initiatives and the Health Care Community H-135.939

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

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

35
36 Reference Committee heard testimony supportive of Resolution 516. Testimony focused
37 on possible health hazards from waste incinerators, and supported alternatives to waste
38 incinerators that might be anticipated to represent safer and more economical waste
39 management, as well as more sustainable practices. It was also noted that our AMA has
40 existing policy that supports clean energy production. The second Resolve of Resolution
41 516 asked that our AMA ban waste incinerators by amending existing policy. However,
42 the evidence presented is insufficient to support a substantial change in the AMA's
43 policy on waste incinerators. Therefore, your Reference Committee recommends that
44 the Resolution 516 be adopted as amended.

1 (17) RESOLUTION 518 – PORTABLE LISTENING DEVICES
2 AND NOISE INDUCED HEARING LOSS
3

4 RECOMMENDATION A:
5

6 Madam Speaker, your Reference Committee recommends
7 that Policy H-440.957 be amended by addition and
8 deletion to read as follows:
9

10 H-440.957, "Reporting Potential for Hearing Loss Due to
11 Personal Listening Devices"

12 It is the policy of the AMA that (1) physicians counsel
13 patients about the potential loss of hearing associated with
14 the misuse of personal listening devices; (2) research be
15 directed at more specific definition of the relationship
16 between acute and chronic use of personal listening
17 devices and the occurrence of short-term and long-term
18 noise-induced hearing loss; and (3) the AMA work with the
19 National Institute on Deafness and Other Communication
20 Disorders to enhance awareness, knowledge and
21 remediation of causes of noise induced hearing loss; and
22 (4) portable listening devices limit the maximum sound
23 amplitude to safe levels.
24

25 RECOMMENDATION B:
26

27 Madam Speaker, your Reference Committee recommends
28 that Policy H-440.957 be adopted as amended in lieu of
29 Resolution 518.
30

31 **HOD ACTION: Policy H-440.957 adopted as amended in**
32 **lieu of Resolution 518.**
33

34 Resolution 518 asks that our American Medical Association (AMA) update its policy on
35 portable listening devices to support the use of Portable listening devices that limit the
36 maximum sound amplitude to safe levels and that our AMA advocate on a federal level
37 for labeling on earbuds that do not have amplitude limiters to warn of the risk of hearing
38 loss with extended use at high volume levels for extended periods as described in the
39 CSAPH Report 6-A-08. (New HOD Policy)
40

41 Your Reference Committee heard largely supportive testimony on this issue. Although
42 the Council on Science and Public Health (CSAPH) commented that current policy
43 based on CSAPH report A-08 is still relevant, other testimony commented that a subset
44 of new devices may be an issue. However, because of uncertainty regarding the
45 evidence, your Reference Committee believes that amending current policy to reflect the
46 first Resolve is appropriate. However, because of the lack of evidence noted by CSAPH,
47 your Reference Committee feels that actively advocating for labeling is not warranted or
48 appropriate for the AMA to pursue at this time. Therefore, your Reference Committee
49 recommends that Policy H-440.957 be amended in lieu of Resolution 518.
50

1 (18) RESOLUTION 521 –EPA GLIDER TRUCK STANDARD

2
3 RECOMMENDATION A:

4
5 Madam Speaker, your Reference Committee recommends
6 that Policy D-135.996 be amended by addition and
7 deletion to read as follows:

8
9 D-135.996, “Reducing Sources of Diesel Exhaust”

10 Our AMA will: (1) encourage the US Environmental
11 Protection Agency to set and enforce ~~finalize~~ the most
12 stringent feasible standards to control pollutant emissions
13 from both large and small non-road engines including
14 construction equipment, farm equipment, boats, ~~and~~ and
15 ~~trains, and glider trucks~~; (2) encourage all states to
16 continue to pursue opportunities to reduce diesel exhaust
17 pollution, including reducing harmful emissions from glider
18 trucks and existing diesel engines; ~~and~~ (3) call for all trucks
19 traveling within the United States, regardless of country of
20 origin, to be in compliance with the most stringent and
21 current new diesel emissions standards promulgated by
22 US EPA; and (4) send a letter to U.S. Environmental
23 Protection Agency (EPA) Administrator opposing the
24 EPA’s proposal to roll back the “glider Kit Rule” which
25 would effectively allow the unlimited sale of re-conditioned
26 diesel truck engines that do not meet current EPA new
27 diesel engine emission standards.

28
29 RECOMMENDATION B:

30
31 Madam Speaker, your Reference Committee recommends
32 that Policy D-135.996 be adopted as amended in lieu of
33 Resolution 521.

34
35 **HOD ACTION: Policy D-135.996 adopted as amended in**
36 **lieu of Resolution 521.**

37
38 Resolution 521 asks that our American Medical Association send a letter to U.S.
39 Environmental Protection Agency (EPA) Administrator opposing the EPA’s proposal to
40 roll back the “Glider Kit Rule” which would effectively allow the unlimited sale of re-
41 conditioned diesel truck engines that do not meet current EPA new diesel engine
42 emission standards. (Directive to Take Action)

43
44 Your Reference Committee heard limited but supportive testimony of Resolution 521,
45 especially as it relates to the public health impacts of diesel truck engines. After
46 reviewing Policy D-135.996, your Reference Committee concluded that the addition of
47 “glider trucks” to part one of the Policy would maintain the intent of Resolution 521.
48 Therefore, your Reference Committee recommends that Policy D-135.996 be reaffirmed
49 as amended in lieu of Resolution 521.

1 (19) RESOLUTION 523 – BIOSIMILAR
2 INTERCHANGEABILITY PATHWAY
3

4 RECOMMENDATION A:
5

6 Madam Speaker, your Reference Committee recommends
7 that Resolution 523 be amended by deletion to read as
8 follows:
9

10 RESOLVED, That our American Medical Association
11 strongly support the ~~rigorous~~ pathway for demonstrating
12 biosimilar interchangeability that was proposed in draft
13 guidance by the FDA in 2017, including requiring
14 manufacturers to use studies to determine whether
15 alternating between a reference product and the proposed
16 interchangeable biosimilar multiple times impacts the
17 safety or efficacy of the drug (New HOD Policy); and be it
18 further
19

20 RESOLVED, That our AMA issue a request to the FDA
21 that the agency finalize the biosimilars interchangeability
22 pathway outlined in its draft guidance “Considerations in
23 Demonstrating Interchangeability With a Reference
24 Product” with all due haste, so as to allow development
25 and designation of interchangeable biosimilars to proceed,
26 allowing transition to an era of less expensive biologics
27 that provide safe, effective, and accessible treatment
28 options for patients. (Directive to Take Action)
29

30 RECOMMENDATION B:
31

32 Madam Speaker, your Reference Committee recommends
33 that Resolution 523 be adopted as amended.
34

35 **HOD ACTION: Resolution 523 adopted as amended.**
36

37 Resolution 523 asks that our American Medical Association strongly support the rigorous
38 pathway for demonstrating biosimilar interchangeability that was proposed in draft
39 guidance by the FDA in 2017, including requiring manufacturers to use studies to
40 determine whether alternating between a reference product and the proposed
41 interchangeable biosimilar multiple times impacts the safety or efficacy of the drug (New
42 HOD Policy) and that our AMA issue a request to the FDA that the agency finalize the
43 biosimilars interchangeability pathway outlined in its draft guidance “Considerations in
44 Demonstrating Interchangeability With a Reference Product” with all due haste, so as to
45 allow development and designation of interchangeable biosimilars to proceed, allowing
46 transition to an era of less expensive biologics that provide safe, effective, and
47 accessible treatment options for patients. (Directive to Take Action)
48

49 Your Reference Committee heard strongly supportive testimony around the need to
50 develop a vibrant biosimilar pathway, including development of standards for

1 manufacturers to seek approval of a biosimilar as interchangeable. While biosimilars are
2 widely viewed as having significant cost-savings potential, the extent of realized savings
3 will be variable. The FDA strongly agreed with the need for further maturation of the
4 biosimilar approval pathway and indicated their intention to finalize guidance on
5 considerations in demonstrating interchangeability with a reference product by May
6 2019. Adoption of Resolution 523 as amended is recommended.

7
8 (20) RESOLUTION 507 – OPIOID TREATMENT PROGRAMS
9 REPORTING TO PRESCRIPTION MONITORING
10 PROGRAMS

11
12 RECOMMENDATION:

13
14 Madam Speaker, your Reference Committee recommends
15 that Resolution 507 be referred.

16
17 **HOD ACTION: Resolution 507 referred.**

18
19 Resolution 507 asks that our American Medical Association (AMA) amend the policy
20 Opioid Treatment and Prescription Drug Monitoring Programs D-95.980 by deletion as
21 follows:

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

25
26 Divided and polarizing testimony was offered on this resolution. Those opposing Opioid
27 Treatment Programs (OTPs) reporting to Prescription Drug Monitoring Programs
28 (PDMPs) cited concerns about privacy and confidentiality, the stigma that already exists
29 around individuals being treated for opioid use disorder and the likelihood that opening
30 PDMPs up to OTP reporting would have a substantial chilling effect on the willingness of
31 patients to enter into treatment. Evidence supporting this view includes the fact that
32 more than 20 state PDMPs are either under the control of, or easily accessible by law
33 enforcement. Additionally, testimony noted that Resolution 507 conflicts with current
34 federal law (42 CFR Part 2) as it pertains to the structure, function, and reporting
35 requirements of OTPs. Given the nature and extent of the current opioid epidemic,
36 supporters of mandatory reporting by OTPs noted the importance of understanding a
37 patient's controlled substance prescription history in order to inform appropriate clinical
38 decision-making. This opinion views PDMPs as clinical decision support tools.

39
40 Current AMA Policy H-95.946 supports the view that PDMPs should be clinical decision
41 support tools, and in addition, encourages all state agencies responsible for maintaining
42 and managing a PDMP to do so in a manner that treats PDMP data as health
43 information that is protected from release outside of the health care system. Our AMA
44 also holds that strong confidentiality safeguards and protections of state databases must
45 be in place to limit access by non-health care individuals to only those instances in which
46 probable cause exists that an unlawful act or breach of the standard of care may have
47 occurred. Policy H-95.947 supports the refinement of state-based prescription drug
48 monitoring programs and development and implementation of appropriate technology to
49 allow for Health Insurance Portability and Accountability Act (HIPAA)-compliant sharing
50 of information. Policy H-315.965 supports: (1) regulatory and legislative changes that

1 better balance patients' privacy protections against the need for health professionals to
2 be able to offer appropriate medical services to patients with substance use disorders;
3 (2) regulatory and legislative changes that enable physicians to fully collaborate with all
4 clinicians involved in providing health care services to patients with substance use
5 disorders; and (3) continued protections against the unauthorized disclosure of
6 substance use disorder treatment records outside the healthcare system.

7
8 This is a complicated subject with far reaching ramifications and overlapping AMA
9 policies. Your Reference Committee believes referral is required to adequately address
10 this important issue.

11
12 (21) RESOLUTION 515 – INFORMATION REGARDING
13 ANIMAL-DERIVED MEDICATIONS

14
15 RECOMMENDATION:

16
17 Madam Speaker, your Reference Committee recommends
18 that Resolution 515 be referred.

19
20 **HOD ACTION: Resolution 515 referred.**

21
22 Resolution 515 asks that our American Medical Association (AMA) supports efforts to
23 improve cultural awareness pertaining to the use of animal-derived medications when
24 considering different prescription options and (New HOD Policy) and that our AMA
25 encourage the U.S. Food and Drug Administration to make available to the public an
26 easily accessible database that identifies medications containing ingredients derived
27 from animals. (Directive to Take Action)

28
29 Limited testimony was offered on this resolution. It is known that certain chemical
30 products used as additives or stabilizers for prescription drugs are derived from animal
31 sources. The consumption of such products may be objectionable to certain religions or
32 based on consumer choice. Testimony from the U.S. Food and Drug Administration
33 agreed with the validity of this view, but noted the potential complexity of establishing
34 registries for individual drug formulations that might be "culturally competent." Therefore,
35 your Reference Committee recommends that Resolution 515 be referred.

36
37 (22) RESOLUTION 505 – RESEARCHING DRUG
38 FACILITATED SEXUAL ASSAULT TESTING

39
40 RECOMMENDATION:

41
42 Madam Speaker, your Reference Committee recommends
43 that Resolution 505 not be adopted.

44
45 **HOD ACTION: Resolution 505 not adopted.**

46
47 Resolution 505 asks that our American Medical Association study the feasibility and
48 implications of offering drug testing at point of care for date rape drugs, including
49 rohypnol, ketamine, and gamma-hydroxybutyrate, in cases of suspected non-
50 consensual, drug-facilitated sexual assault. (Directive to Take Action)

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

18
19 (23) RESOLUTION 513 – HAND SANITIZER
20 EFFECTIVENESS

21
22 RECOMMENDATION:

23
24 Madam Speaker, your Reference Committee recommends
25 that Resolution 513 not be adopted.

26
27 **HOD ACTION: Resolution 513 not adopted.**

28
29 Resolution 513 asks that our American Medical Association urge the U.S. Food and
30 Drug Administration and the Centers for Disease Control and Prevention to continue to
31 study the use of hand sanitizers in clinical settings, including the risks and benefits to
32 patients and health care professionals. (Directive to Take Action)

33
34 Your Reference Committee heard divided testimony regarding this issue. Although the
35 intent was supported by some testimony, the FDA provided comment in opposition
36 because they are already taking significant action on the use of hand sanitizers and the
37 ingredients used in hand sanitizer products. FDA also commented that the task of
38 evaluating hand sanitizers is their task, not the purview of the CDC. Because this work is
39 underway at the FDA, your Reference Committee recommends that Resolution 513 not
40 be adopted.

1 (24) RESOLUTION 522 – SILENCE SCIENCE: EPA
2 PROPOSED DATA POLICY
3

4 RECOMMENDATION:
5

6 Madam Speaker, your Reference Committee recommends
7 that Resolution 522 not be adopted.
8

9 **HOD ACTION: Resolution 522 not adopted.**
10

11 Resolution 522 asks that Our American Medical Association (AMA) submit comments
12 during the public comment period, or join comments written by other medical
13 organizations, to express concern with the U.S. Environmental Protection Agency's
14 (EPA) proposal to limit the use of research studies published in peer reviewed scientific
15 journals that describe the adverse health effects of exposure to air pollution and other
16 environmental exposures and that our AMA reaffirm the value and integrity of the journal
17 peer review process by sending a letter to the EPA stating that studies that have been
18 published in scientific peer reviewed journals should be used by the agency in informing
19 EPA regulatory policy making. (Directive to Take Action)
20

21 Your Reference Committee heard testimony generally in support of this Resolution.
22 Testimony did state that several organizations, including medical groups, academicians,
23 and industry, have already individually or jointly submitted comments to the EPA
24 requesting an extension to the 30-day comment period regarding the proposal
25 mentioned in the Resolution. Testimony noted the AMA signed on to a letter written by
26 the American Thoracic Society (ATS) requesting a 60-day extension to the comment
27 period. On May 24th, EPA extended the deadline and scheduled a public hearing on the
28 proposed rule for July 17th. The AMA does intend to submit comments regarding the
29 proposed rule, either by joining a Federation Member's letter or developing comments.
30 Because response to this resolution is underway, your Reference Committee
31 recommends that Resolution 522 not be adopted.
32

33 (25) RESOLUTION 525 – TRAMADOL CHANGE FROM DEA
34 SCHEDULE IV TO SCHEDULE III
35

36 RECOMMENDATION:
37

38 Madam Speaker, your Reference Committee recommends
39 that Resolution 525 be not be adopted.
40

41 **HOD ACTION: Resolution 525 not adopted.**
42

43 Resolution 525 asks that the American Medical Association petition the United States
44 Drug Enforcement Administration to change tramadol from a Schedule IV to a Schedule
45 III controlled substance. (Directive to Take Action)
46

47 Your Reference Committee heard testimony generally opposing review of the current
48 schedule of tramadol. It was pointed out that changing from a schedule IV to a schedule
49 III controlled substance would not significantly change the control measures of the drug
50 since prescribing standards are the same for schedule III and IV substance. Additionally,

1 it was noted that to change the schedule of a drug, the DEA would be required to review
2 currently available evidence to determine the appropriate schedule for the drug. Your
3 Reference Committee agrees with testimony that supports retaining the schedule of
4 tramadol by the DEA and therefore recommends that Resolution 525 not be adopted.

5
6 (26) RESOLUTION 503 – ADVOCATING FOR ANONYMOUS
7 REPORTING OF OVERDOSES BY FIRST
8 RESPONDERS AND EMERGENCY PHYSICIANS

9
10 RECOMMENDATION:

11
12 Madam Speaker, your Reference Committee recommends
13 that Policy H-95.940 be reaffirmed in lieu of Resolution
14 503.

15
16 **HOD ACTION: Policy H-95.940 reaffirmed in lieu of**
17 **Resolution 503.**

18
19 Resolution 503 asks that our American Medical Association support non-fatal and fatal
20 opioid overdose reporting to the appropriate agencies. (New HOD Policy)

21
22 Your Reference Committee heard testimony generally in support of Resolution 503.
23 However, ambiguity around maintaining patient and physician anonymity was noted, as
24 well as specifications on which agencies are considered appropriate for notification.

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

33
34 Policy recommended for reaffirmation:

35
36 H-95.940, “Addressing Emerging Trends in Illicit Drug Use”

37 Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive
38 substances (NPS), are a public health threat; (2) supports ongoing efforts of the National
39 Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease
40 Control and Prevention, the Department of Justice, the Department of Homeland
41 Security, state departments of health, and poison control centers to assess and monitor
42 emerging trends in illicit drug use, and to develop and disseminate fact sheets, other
43 educational materials, and public awareness campaigns; (3) supports a collaborative,
44 multiagency approach to addressing emerging drugs of abuse, including information and
45 data sharing, increased epidemiological surveillance, early warning systems informed by
46 laboratories and epidemiologic surveillance tools, and population driven real-time social
47 media resulting in actionable information to reach stakeholders; (4) encourages
48 adequate federal and state funding of agencies tasked with addressing the emerging
49 drugs of abuse health threat; (5) encourages the development of continuing medical
50 education on emerging trends in illicit drug use; and (6) supports efforts by federal, state,

1 and local government agencies to identify new drugs of abuse and to institute the
2 necessary administrative or legislative actions to deem such drugs illegal in an expedited
3 manner. Sub. Res. 901, I-14 Modified: CSAPH Rep. 02, A-17

4
5 (27) RESOLUTION 512 – PHYSICIAN AND PATIENT
6 EDUCATION ABOUT THE RISK OF SYNTHETIC
7 CANNABINOID USE

8
9 RECOMMENDATION:

10
11 Madam Speaker, your Reference Committee recommends
12 that Policies H-95.940 and D-95.970 be reaffirmed in lieu
13 of Resolution 512.

14
15 **HOD ACTION: Policies H-95.940 and D-95.970 reaffirmed in**
16 **lieu of Resolution 512.**

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

25
26 Your Reference Committee heard testimony in strong support of this Resolution. The
27 Council on Science and Public Health offered comments regarding their Report 2 from
28 A-17 that addressed this issue and the resulting policy that addresses this topic.
29 Therefore, your Reference Committee recommends that Policies H-95.940 and D-
30 95.970 be reaffirmed in lieu of Resolution 512.

31
32 Policies recommended for reaffirmation:

33
34 H-95.940, “Addressing Emerging Trends in Illicit Drug Use”

35 Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive
36 substances (NPS), are a public health threat; (2) supports ongoing efforts of the National
37 Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease
38 Control and Prevention, the Department of Justice, the Department of Homeland
39 Security, state departments of health, and poison control centers to assess and monitor
40 emerging trends in illicit drug use, and to develop and disseminate fact sheets, other
41 educational materials, and public awareness campaigns; (3) supports a collaborative,
42 multiagency approach to addressing emerging drugs of abuse, including information and
43 data sharing, increased epidemiological surveillance, early warning systems informed by
44 laboratories and epidemiologic surveillance tools, and population driven real-time social
45 media resulting in actionable information to reach stakeholders; (4) encourages
46 adequate federal and state funding of agencies tasked with addressing the emerging
47 drugs of abuse health threat; (5) encourages the development of continuing medical
48 education on emerging trends in illicit drug use; and (6) supports efforts by federal, state,
49 and local government agencies to identify new drugs of abuse and to institute the

1 necessary administrative or legislative actions to deem such drugs illegal in an expedited
2 manner. Sub. Res. 901, I-14 Modified: CSAPH Rep. 02, A-17
3
4 D-95.970, "Emerging Drugs of Abuse are a Public Health Threat"
5 Our AMA will participate as a stakeholder in a Centers for Disease Control and
6 Prevention/U.S. Drug Enforcement Administration (CDC/DEA) taskforce for the
7 development of a national forum for discussion of new psychoactive substances (NPS)-
8 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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