

DISCLAIMER

The following is a preliminary report of actions taken by the House of Delegates at its 2024 Annual 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-24)

Report of Reference Committee E

Robert Panton, MD, Chair

1 Your Reference Committee recommends the following consent calendar for acceptance:
2

3 **RECOMMENDED FOR ADOPTION**
4

- 5 1. Council on Science and Public Health Report 2 – Comparative
6 Effectiveness Research
- 7 2. Council on Science and Public Health Report 7 – Androgen Deprivation
8 in Incarceration
- 9 3. Council on Science and Public Health Report 8 – Decreasing
10 Regulatory Barriers to Appropriate Testosterone Prescribing
- 11 4. Council on Science and Public Health Report 12 – Universal Screening
12 for Substance Use and Substance Use Disorders during Pregnancy
- 13 5. Resolution 511 - National Penicillin Allergy Day and Penicillin Allergy
14 Evaluation & Appropriate Delabeling
- 15 6. Resolution 513 - Biotin Supplement Packaging Disclaimer
- 16 7. Resolution 514 - Safety With Devices Producing Carbon Monoxide
17

18 **RECOMMENDED FOR ADOPTION AS AMENDED**
19

- 20 8. Council on Science and Public Health Report 1 – Council on Science
21 and Public Health Sunset Review of 2014 House Policies
- 22 9. Council on Science and Public Health Report 4 - Sex and Gender
23 Differences in Medical Research
- 24 10. Council on Science and Public Health Report 5 –
25 Biosimilar/Interchangeable Terminology
26 Resolution 504 - FDA Regulation of Biosimilars
- 27 11. Resolution 502 – Tribally-Directed Precision Medicine Research
- 28 12. Resolution 505 - Mitigating the Harms of Colorism and Skin Bleaching
29 Agents
- 30 13. Resolution 507 - Ban on Dual Ownership, Investment, Marketing or
31 Distribution of Recreational Cannabis by Medical Cannabis Companies
- 32 14. Resolution 509 - Addressing Sarcopenia and its Impact on Quality of
33 Life
34 Resolution 517 – Regulation of Nicotine Analogue Products

1 **RECOMMENDED FOR ADOPTION WITH CHANGE IN TITLE**

- 2
3 15. Resolution 515 - Advocacy for More Stringent Regulations/Restrictions
4 on the Distribution of Marijuana
5

6 **RECOMMENDED FOR REFERRAL**

- 7
8 16. Resolution 501 - Fragrance Regulation

9 **RECOMMENDED FOR NOT ADOPTION**

- 10
11 17. Resolution 506 - Screening for Image Manipulation in Research
12 Publications
13

14 **RECOMMENDED FOR REAFFIRMATION IN LIEU OF**

- 15
16 18. Resolution 503 - Unregulated Hemp-Derived Intoxicating Cannabinoids,
17 and Derived Psychoactive Cannabis Products (DPCPs)
18 19. Resolution 508 - AMA to support regulations to decrease overdoses in
19 children due to ingestion of edible cannabis
20 20. Resolution 510 - Study to investigate the validity of claims made by the
21 manufacturers of OTC Vitamins, Supplements and "Natural Cures"
22 21. Resolution 512 - Opioid Overdose Reversal Agents Where AED's Are
23 Located
24

25 For the purposes of clarity, items marked with double underline or ~~double strikethrough~~
26 are highlighted in yellow.

27
28 **Amendments**

29 **If you wish to propose an amendment to an item of business, click here:**

30 [SUBMIT NEW AMENDMENT](#)

RECOMMENDED FOR ADOPTION

- 1
2
3
4 (1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
5 2 – COMPARATIVE EFFECTIVENESS RESEARCH
6

7 **RECOMMENDATION:**
8

9 **Madam Speaker, your Reference Committee recommends that Council on**
10 **Science and Public Health Report 2 be adopted and the remainder of the**
11 **report be filed.**
12

13 **HOD ACTION: Council on Science and Public Health Report 2**
14 **adopted as amended and the remainder of the report filed.**
15

16 **The Council on Science and Public Health recommends that the**
17 **following be adopted and the remainder of the report be filed:**

18 **(1) That policy H-450.922, “Comparative Effectiveness Research”**
19 **be amended by deletion to read as follows:**

20 **~~Our AMA will:~~**

21 **~~(1) study the feasibility of including comparative effectiveness~~**
22 **~~studies in various FDA drug regulatory processes, including~~**
23 **~~comparisons with existing standard of care, available generics and~~**
24 **~~biosimilars, and drugs commonly used off-label and over-the-~~**
25 **~~counter; and~~**

26 **~~(2) ask the National Institutes of Health to support and fund~~**
27 **~~comparative effectiveness research for approved drugs, including~~**
28 **~~comparisons with existing standard of care, available generics and~~**
29 **~~biosimilars, and drugs commonly used off-label and over-the-~~**
30 **~~counter. (Amend HOD Policy)~~**

31 **(2) That policies H-120.988, “Patient Access to Treatments**
32 **Prescribed by Their Physicians”, and H-460.909, “Comparative**
33 **Effectiveness Research” be reaffirmed. (Reaffirm HOD Policy)**

34 **(3) That our AMA support efforts to encourage and incentivize**
35 **premarket comparative effectiveness research comparing emerging**
36 **medications to existing treatment options to increase transparency**
37 **about a treatment’s efficacy once approved.**
38

39 The Council on Science and Public Health recommends that the following be adopted and
40 the remainder of the report be filed:

41 (1) That policy H-450.922, “Comparative Effectiveness Research” be amended by
42 deletion to read as follows:

43 ~~Our AMA will:~~

44 ~~(1) study the feasibility of including comparative effectiveness studies in various FDA drug~~
45 ~~regulatory processes, including comparisons with existing standard of care, available~~
46 ~~generics and biosimilars, and drugs commonly used off-label and over the counter; and~~

47 ~~(2) ask the National Institutes of Health to support and fund comparative effectiveness~~
48 ~~research for approved drugs, including comparisons with existing standard of care,~~

1 available generics and biosimilars, and drugs commonly used off-label and over-the-
2 counter. (Amend HOD Policy)

3 (2) That policies H-120.988, "Patient Access to Treatments Prescribed by Their
4 Physicians", and H-460.909, "Comparative Effectiveness Research" be reaffirmed.
5 (Reaffirm HOD Policy)

6
7 Your Reference Committee heard supportive testimony for comparative effectiveness
8 research as a general concept, but with a mixed discussion as to the most appropriate
9 way for it to be utilized as a federal regulatory tool. On one hand, testimony cited the need
10 for comparative effectiveness research to be a tool primarily left for clinical decision-
11 making, while others felt that federal regulatory bodies could benefit from including it into
12 their regulatory activities, either implicitly or explicitly. However, testimony described how
13 inviting the FDA or CMS to even investigate these matters, even if not used for regulatory
14 decisions, would require undue resources and potentially bias decision-making.
15 Amendments were proffered to increase funding for comparative effectiveness research
16 generally, but your Reference Committee finds that these requests are current policy of
17 our AMA and reaffirmed via the original recommendations of this report. As such, your
18 Reference Committee recommends that Council on Science and Public Health Report 2
19 be adopted.

1 (2) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 7 – ANDROGEN DEPRIVATION IN INCARCERATION
3

4 **RECOMMENDATION:**
5

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

10 **HOD ACTION: Council on Science and Public Health Report 7**
11 **adopted and the remainder of the report filed.**
12

13 The Council on Science and Public Health recommends that the following be adopted and
14 the remainder of the report be filed:

- 15 1. That Policy H-430.977, “AMA Study of Chemical Castration in Incarceration” be
16 rescinded. (Rescind HOD Policy)
17 2. That our AMA:
18 a. Opposes laws, regulations, and actions of the court which remove physician autonomy
19 and clinical judgement from treatment decisions regarding androgen deprivation (also
20 known as chemical castration) for those convicted of sexual crimes.
21 b. Opposes linkages of criminal sentencing, parole, or probation to court-mandated
22 androgen deprivation.
23 c. Encourages data collection on the utilization, court mandates, duration of therapy, and
24 clinical outcomes of androgen deprivation in the carceral setting.
25 d. Supports continued research for effective treatments for paraphilic disorders, including
26 efforts to reduce stigma and recruit patients with paraphilic disorders into clinical trials.
27 (New HOD Policy)
28 3. That Policies D-430.997, “Support for Health Care Services to Incarcerated Persons,”
29 H-430.978 “Improving Care to Lower the Rate of Recidivism,” and H-345.981 “Access to
30 Mental Health Services” be reaffirmed. (Reaffirm HOD Policy)
31

32 Your Reference Committee heard overall agreement for the sentiment that medication,
33 including those used for androgen deprivation, should never be used as punishment.
34 However, some testimony described an ongoing tension around its use and the
35 approach to incarceration. Testimony cited the desire to have more options for patients
36 to avoid or reduce their time incarcerated and the significant negative health impacts it
37 can have, while also recognizing that it would be impossible to provide truly informed,
38 uncoerced consent for androgen deprivation treatment when the alternative is
39 imprisonment. Your Reference Committee heard testimony describing how the use of
40 the term “court-mandated” in the original report recommendations should allow for our
41 AMA to advocate for treatment of paraphilic disorders. Such treatment should be guided
42 by the patient-physician relationship and could be used as the basis for a modified
43 criminal sentence, but would not mandate the use of a specific medication. As such,
44 your Reference Committee recommends that Council on Science and Public Health
45 Report 7 be adopted.

1 (3) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 8 – DECREASING REGULATORY BARRIERS TO
3 APPROPRIATE TESTOSTERONE PRESCRIBING
4

5 **RECOMMENDATION:**
6

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

10 **HOD ACTION: Council on Science and Public Health Report 8**
11 **adopted and the remainder of the report filed.**
12
13

14 The Council on Science and Public Health recommends that the following be adopted,
15 and the remainder of the report be filed:

16 1. That policy D-270.983, “Decreasing Regulatory Barriers to Appropriate Testosterone
17 Prescribing,” be amended by addition to read as follows:

18 A. Our AMA will ask the FDA to review the available evidence and other data on
19 testosterone and submit updated recommendations, if warranted, to the DEA, for its
20 consideration of the scheduling of testosterone-containing drug products.

21 B. Our AMA supports policies to remove barriers that delay or impede patient access to
22 prescribed testosterone. (New HOD Policy)

23 C. Our AMA will continue to work alongside our partner organizations to promote
24 advocacy and physician education on testosterone prescribing. (New HOD Policy)

25 2. That Policies H-65.976, “Nondiscriminatory Policy for the Health Care Needs of LGBTQ
26 Populations,” H-140.824, “Healthcare Equity Through Informed Consent and a
27 Collaborative Healthcare Model for the Gender Diverse Population,” H-160.991, “Health
28 Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations,” H-185.927
29 “Clarification of Evidence-Based Gender-Affirming Care,” H-95.946, “Prescription Drug
30 Monitoring Program Confidentiality,” H-315.983, “Patient Privacy and Confidentiality,” D-
31 185.981, “Addressing Discriminatory Health Plan Exclusions or Problematic Benefit
32 Substitutions for Essential Health Benefits Under the Affordable Care Act,” and D-480.964,
33 “Established Patient Relationships and Telemedicine” be reaffirmed. (Reaffirm HOD
34 Policy)

35
36 Your Reference Committee received widespread support for this report. Testimony
37 highlighted the necessity of ensuring access to prescribed testosterone when clinically
38 indicated, particularly as a part of gender-affirming care. Testimony noted this
39 medication is crucial for transgender, non-binary, and gender-diverse individuals, whose
40 access to such care has been threatened or criminalized. Further, testimony recognized
41 the importance of testosterone for patient well-being and health. As such, your
42 Reference Committee recommends that this report be adopted.

1 (4) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 12 – UNIVERSAL SCREENING FOR SUBSTANCE USE
3 AND SUBSTANCE USE DISORDERS DURING
4 PREGNANCY
5

6 **RECOMMENDATION:**
7

8 **Madam Speaker, your Reference Committee recommends that Council on**
9 **Science and Public Health Report 12 be adopted and the remainder of the**
10 **report filed.**
11

12 **HOD ACTION: Council on Science and Public Health Report 12**
13 **adopted and the remainder of the report filed.**
14

15 The Council on Science and Public Health recommends that the following be adopted,
16 and the remainder of the report be filed:

17 1. That our AMA:

18 A. Encourage ongoing research on the benefits and risks of universal screening for
19 substance use during pregnancy including the impact of mandatory reporting laws,
20 evaluation of patient outcomes, effectiveness across different age groups, optimal
21 screening intervals, equity considerations, and efficacy of different screening tools.

22 B. Support the development and dissemination of physician education and training on
23 federal and state laws governing mandatory notification and reporting of substance use
24 during pregnancy, and the benefits and consequences of screening implementation in
25 health care settings on a state-by-state basis. (New HOD Policy)

26 2. That AMA policy H-420.950, "Substance Use Disorders During Pregnancy," be
27 amended by addition and deletion to read as follows:

28 Our AMA will:

29 (1) support brief interventions (such as engaging a patient in a short conversation,
30 providing feedback and advice) and referral for early comprehensive treatment of
31 pregnant individuals with opioid use and opioid use disorder (including naloxone or other
32 overdose reversal medication education and distribution) using a coordinated
33 multidisciplinary approach without criminal sanctions;
34

35 (2) acknowledges the health benefits of identifying substance use during pregnancy
36 and opposes any efforts, including mandatory reporting laws, that to imply that a positive
37 verbal substance use screen, a positive toxicology test, or the diagnosis of substance use
38 disorder during pregnancy automatically represents child abuse or neglect;
39

40 (3) support legislative and other appropriate efforts for the expansion and improved access
41 to evidence-based treatment for substance use disorders during pregnancy;
42

43 (4) oppose the filing of a child protective services report or the removal of infants from
44 their ~~mothers~~ parent(s) solely based on a ~~single positive~~ prenatal drug screen and/or
45 biological test(s) for substance use without appropriate evaluation;
46

47 (5) advocate for appropriate medical evaluation prior to the removal of a child, which takes
48 into account (a) the desire to preserve the individual's family structure, (b) the patient's
49 treatment status, and (c) current impairment status when substance use is suspected or
50 confirmed; and

1
2 (6) advocate that state and federal child protection laws be amended so that pregnant
3 people with substance use and substance use disorders are only reported to child welfare
4 agencies when protective concerns are identified by the clinical team, rather than through
5 automatic or mandated reporting of all pregnant people with a positive toxicology test,
6 positive verbal substance use screen, or diagnosis of a substance use disorder, or use of
7 evidence-based treatments for substance use disorder. (Modify Current HOD Policy)
8 That current AMA policies H-420.969, "Legal Interventions During Pregnancy," and D-
9 95.983, "Mandatory Drug Screening Reporting" be reaffirmed. (Reaffirm HOD Policy)

10
11 Testimony heard for this report was overwhelmingly supportive noting the conflict between
12 the importance of universal screening during pregnancy to improve health outcomes and
13 the need for caution due to punitive policies such as mandatory reporting laws. Testimony
14 emphasized the need for ongoing research and education of physicians on state and
15 federal laws that impact their practice to assist in navigating the changing landscape. A
16 single testimony in opposition stated that everyone should be screened to minimize the
17 impact of substance use disorder in the United States. As such, your Reference
18 Committee recommends the report be adopted.

19
20 (5) RESOLUTION 511 - NATIONAL PENICILLIN ALLERGY
21 DAY AND PENICILLIN ALLERGY EVALUATION &
22 APPROPRIATE DELABELING

23
24 **RECOMMENDATION:**

25
26 **Madam Speaker, your Reference Committee recommends that Resolution**
27 **511 be adopted.**

28
29 **HOD ACTION: Resolution 511 adopted.**

30
31 RESOLVED, that National Penicillin Allergy Day, September 28, be recognized by the
32 American Medical Association (New HOD Policy); and be it further

33
34 RESOLVED, that our AMA promote penicillin allergy evaluation and appropriate
35 delabeling. (New HOD Policy)

36
37 Your Reference Committee heard mostly supportive testimony on this item. Several
38 testified to their own personal experiences treating patients labeled as having a penicillin
39 allergy. Specifically, patients were erroneously deemed to have a penicillin allergy as a
40 child due to concomitant viral rash while on penicillin. This has a longstanding impact on
41 treatment options throughout their lifetime as well as antibiotic stewardship. Several noted
42 the availability of a reliable skin test that can be performed in the clinic. While a few
43 questioned the necessity of a specific day, this was rendered as a simple mechanism to
44 raise awareness. As such, your Reference Committee recommends Resolution 511 be
45 adopted.

1 (6) RESOLUTION 513 - BIOTIN SUPPLEMENT PACKAGING
2 DISCLAIMER

3
4 **RECOMMENDATION:**

5
6 **Madam Speaker, your Reference Committee recommends that Resolution**
7 **513 be adopted.**

8
9 **HOD ACTION: Resolution 513 adopted.**

10
11 RESOLVED, that our American Medical Association support efforts to have over-the-
12 counter biotin supplements provide a clear disclaimer on the bottle that states the
13 possibility of lab test interference (New HOD Policy); and be it further

14
15 RESOLVED, that our AMA advocates for greater awareness among both patients and
16 physicians in regards to biotin megadose interference. (Directive to Take Action)

17
18 Your Reference Committee heard unanimously supportive testimony on this item.
19 Testimony described how utilizing over-the-counter biotin supplements can confound
20 blood test results, and the importance of counseling and awareness to prevent these
21 easily avoidable issues. As such, your Reference Committee recommends Resolution 513
22 be adopted.

23
24 (7) RESOLUTION 514 - SAFETY WITH DEVICES
25 PRODUCING CARBON MONOXIDE

26
27 **RECOMMENDATION:**

28
29 **Madam Speaker, your Reference Committee recommends that Resolution**
30 **514 be adopted.**

31
32 **HOD ACTION: Resolution 514 adopted.**

33
34 RESOLVED, that our American Medical Association support the United States Consumer
35 Product Safety Commission in implementing higher safety standards for consumer
36 products that produce carbon monoxide; and be it further

37
38 RESOLVED, that our AMA support public education efforts to minimize harm caused by
39 carbon monoxide poisoning produced in enclosed spaces or too close to exterior
40 openings.

41
42 Your Reference Committee heard limited but supportive testimony for this item. The
43 testimony described the tragedy of carbon monoxide poisoning because of unsafe
44 generator usage during the 2021 ice storms in Texas, and how regulators and the industry
45 have been sluggish to respond. As such, your Reference Committee recommends that
46 Resolution 514 be adopted.

RECOMMENDED FOR ADOPTION AS AMENDED

- 1
2
3 (8) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
4 1 - COUNCIL ON SCIENCE AND PUBLIC HEALTH
5 SUNSET REVIEW OF 2014 HOUSE POLICIES
6

7 **RECOMMENDATION A:**
8

9 **Madam Speaker, your Reference Committee**
10 **recommends that Council on Science and Public**
11 **Health Report 1 be amended by addition and**
12 **deletion to read as follows:**
13

14 **That our American Medical Association policies**
15 **listed in the appendix to this report be acted upon in**
16 **the manner indicated, with the exception of Policies**
17 **H-120.975 and H-440.922, which should be amended**
18 **by addition and deletion to read as follows:**
19

20 **Certifying ~~Indigent~~ Patients Unable to Pay for**
21 **Pharmaceutical Manufacturers' Free Drug Programs**
22 **Our AMA: (1) supports Pharmaceutical Research**
23 **and Manufacturers of America (PhRMA) programs**
24 **for ~~indigent~~ patients unable to pay and the**
25 **development of a universal application process,**
26 **eligibility criteria and form for all prescription drug**
27 **patient assistance programs to facilitate enrollment**
28 **of patients and physicians; (2) encourages PhRMA**
29 **to provide information to physicians and hospital**
30 **medical staffs about member programs that provide**
31 **pharmaceuticals to ~~indigent~~ patients unable to pay;**
32 **(3) urges drug companies to develop user-friendly**
33 **and culturally sensitive uniform centralized policies**
34 **and procedures for certifying ~~indigent patients for~~**
35 **free or discounted medications for patients unable**
36 **to pay; and (4) opposes the practice of charging**
37 **patients to apply for or gain access to**
38 **pharmaceutical assistance programs. (Sub. Res.**
39 **105, I-92; Sub. Res. 507, A-96; Appended: Sub. Res.**
40 **513, I-97; Reaffirmation I-98; Reaffirmation I-00;**
41 **Reaffirmation A-01; Amended: Res. 513, A-02;**
42 **Reaffirmed and Appended: Sub. Res. 705, I-03;**
43 **Reaffirmed and Modified: BOT Rep. 13, A-04;**
44 **Reaffirmation I-04; Modified: CSAPH Rep. 1, A-14)**
45

46 **Gambling Disorder Can Become Compulsive**
47 **Behavior H-440.922**

48 **The AMA: (1) encourages physicians to advise their**
49 **patients of the addictive potential of gambling; (2)**

1 encourages states which operate gambling
2 programs to provide a fixed percentage of their
3 revenue for education, prevention and treatment of
4 gambling ~~compulsive behavior~~ disorder; and (3)
5 requests that states which operate gambling
6 programs affix to all lottery tickets and display at all
7 lottery counters a sign which states that gambling
8 ~~disorder~~ may become a gambling disorder
9 ~~compulsive behavior~~ and help is available through
10 your local gambling hotline. (Res. 430, A-94;
11 Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH
12 Rep. 1, A-14)

13
14 **RECOMMENDATION B:**

15
16 **Madam Speaker, your Reference Committee**
17 **recommends that Council on Science and Public**
18 **Health Report 1 be adopted as amended and the**
19 **remainder of the report be filed.**

20
21 **HOD ACTION: Council on Science and Public**
22 **Health Report 1 adopted as amended and the**
23 **remainder of the report filed.**

24
25 The Council on Science and Public Health recommends that the House of Delegates
26 policies listed in the appendix to this report be acted upon in the manner indicated and the
27 remainder of this report be filed. (Directive to Take Action)

28
29 Your Reference Committee heard limited but supportive testimony for the annual sunset
30 review of 2014 policies, with editorial amendments to align grammar and/or person-first
31 language where appropriate. As such, your Reference Committee recommends adoption
32 as amended.

1 (9) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 4 – SEX AND GENDER DIFFERENCES IN MEDICAL
3 RESEARCH
4

5 **RECOMMENDATION A:**
6

7 **Madam Speaker, your Reference Committee recommends that Council on**
8 **Science and Public Health Report 4 be amended by addition and deletion to**
9 **read as follows:**

10
11 **That policy H-525.988, “Sex and Gender Differences in Medical Research”**
12 **be amended by addition and deletion to read as follows:**

13 **Our AMA:**

14 (1) reaffirms that gender **and sex** exclusion in broad medical studies
15 questions the validity of the studies' impact on the health care of society at
16 large;

17 (2) affirms the need to include **people of all genders sexes and gender**
18 **identities and expressions** in studies that involve the health of society at
19 large and publicize its policies;

20 (3) supports increased funding into areas of women's health and sexual
21 and gender minority health research;

22 (4) supports increased research on women's health and sexual and gender
23 minority health and the participation of women and sexual and
24 gender **minorities minority communities** in clinical trials, the results of
25 which will permit development of evidence-based prevention and treatment
26 strategies for all women and sexual and gender **minorities minority**
27 **individuals** from diverse cultural and ethnic groups, geographic locations,
28 and socioeconomic status;

29 (5) recommends that all medical/scientific journal editors require, where
30 appropriate, a sex based and gender-based analysis of data, even if such
31 comparisons are negative; and

32 (6) recommends that medical and scientific journals diversify their review
33 processes to better represent women and sexual and
34 gender **minorities minority individuals; and**

35 (7) supports the FDA's requirement of actionable clinical trial diversity
36 action plans from drug and device sponsors that include **women, and**
37 **sexual and gender minorities minority populations; and**

38 (8) supports the FDA's efforts in conditioning drug and device approvals on
39 **post-marketing studies which evaluate the efficacy and safety of those**
40 **products in women and sexual and gender minorities minority**
41 **populations when those groups were not adequately represented in clinical**
42 **trials; and**

43 (9) supports and encourages the National Institutes of Health and other
44 grant-making entities to fund post-market research investigating
45 pharmacodynamics and pharmacokinetics for generic drugs that did not
46 adequately enroll women, and **sexual and gender minorities minority**
47 **populations** in their clinical trials, prioritizing instances when those
48 **populations represent a significant portion of patients or reported adverse**
49 **drug events. (Amend HOD Policy)**

1 **RECOMMENDATION B:**

2
3 **Madam Speaker, your Reference Committee recommends that Council on**
4 **Science and Public Health Report 4 be adopted as amended and the**
5 **remainder be filed.**

6
7 **HOD ACTION: Council on Science and Public Health Report 4**
8 **adopted as amended and the remainder filed.**

9
10 The Council on Science and Public Health recommends that the following be adopted and
11 the remainder of the report be filed:

12 That policy H-525.988, "Sex and Gender Differences in Medical Research" be amended
13 by addition and deletion to read as follows:

14 Our AMA:

15 (1) reaffirms that gender exclusion in broad medical studies questions the validity of the
16 studies' impact on the health care of society at large;

17 (2) affirms the need to include all genders in studies that involve the health of society at
18 large and publicize its policies;

19 (3) supports increased funding into areas of women's health and sexual and gender
20 minority health research;

21 (4) supports increased research on women's health and sexual and gender minority health
22 and the participation of women and sexual and gender minorities in clinical trials, the
23 results of which will permit development of evidence-based prevention and treatment
24 strategies for all women and sexual and gender minorities from diverse cultural and ethnic
25 groups, geographic locations, and socioeconomic status;

26 (5) recommends that all medical/scientific journal editors require, where appropriate, a
27 sex-based and gender-based analysis of data, even if such comparisons are negative;
28 and

29 (6) recommends that medical and scientific journals diversify their review processes to
30 better represent women and sexual and gender minorities.; and

31 (7) supports the FDA's requirement of actionable clinical trial diversity action plans from
32 drug and device sponsors that include women, and sex and gender minorities; and

33 (8) supports the FDA's efforts in conditioning drug and device approvals on post-marketing
34 studies which evaluate the efficacy and safety of those products in women and sex and
35 gender minorities when those groups were not adequately represented in clinical trials;

36 and

37 (9) supports and encourages the National Institute of Health and other grant-making
38 entities to fund post-market research investigating pharmacodynamics and
39 pharmacokinetics for generic drugs that did not adequately enroll women, and sex and
40 gender minorities in their clinical trials, prioritizing instances when those populations
41 represent a significant portion of patients or reported adverse drug events. (Amend HOD
42 Policy)

43
44 Your Reference Committee heard unanimously supportive testimony on this item, citing
45 the urgent need to increase women and sexual and gender minority community
46 participation in clinical research, both as participants and as researchers themselves.
47 Several testified to their own experiences managing patient care for individuals who have
48 not been represented in clinical trials, further highlighting the timeliness of this policy. One
49 editorial amendment was offered to streamline the language which your Reference

- 1 Committee found friendly. As such, your Reference Committee recommends that Council
- 2 on Science and Public Health Report 4 be adopted as amended.

1 (10) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 5 – BIOSIMILAR/INTERCHANGEABLE TERMINOLOGY
3 RESOLUTION 504 - FDA REGULATION OF BIOSIMILARS
4

5 **RECOMMENDATION A:**
6

7 **Madam Speaker, your Reference Committee**
8 **recommends that the third recommendation of Council**
9 **on Science and Public Health Report 5 be amended by**
10 **addition and deletion to read as follows:**
11

12 **3. That Policy D-125.989 “Substitution of Biosimilar**
13 **Medicines and Related Medical Products” be amended**
14 **by addition and deletion to read as follows:**

15 **Our AMA urges that State Pharmacy Practice Acts and**
16 **substitution practices for biosimilars in the outpatient**
17 **arena: (1) preserve physician autonomy to designate**
18 **which biologic or biosimilar product is dispensed to**
19 **their patients; (2) allow substitution when physicians**
20 **expressly authorize substitution of an**
21 **interchangeable a biologic or biosimilar product;**
22 **(3) ~~limit the authority of pharmacists to automatically~~**
23 **~~substitute only those biosimilar products that are~~**
24 **~~deemed interchangeable by the FDA. in the absence of~~**
25 **express physician authorization to the contrary, allow**
26 **substitution of the biologic or biosimilar product when**
27 **(a) the biologic product is highly similar to the reference**
28 **product, notwithstanding minor differences in clinically**
29 **inactive components; and (b) there are no data**
30 **indicating clinically meaningful differences between the**
31 **biological product and the reference product in terms**
32 **of the safety, purity, and potency of the product; and (c)**
33 **the prescribing physician has been adequately notified**
34 **by the pharmacist. (Modify Current HOD Policy)**
35

36 **RECOMMENDATION B:**
37

38 **Madam Speaker, your Reference Committee**
39 **recommends that Council on Science and Public Health**
40 **Report 5 be amended by addition of a fifth**
41 **recommendation to read as follows:**
42

43 **5. That our AMA support evidence-based physician**
44 **education on the clinical equivalence of biosimilars, the**
45 **FDA approval process, and post-market surveillance**
46 **requirements. (New HOD Policy)**

1 **RECOMMENDATION C:**

2
3 **Madam Speaker, your Reference Committee**
4 **recommends that recommendations in Council on**
5 **Science and Public Health Report 5 be adopted in lieu**
6 **of Resolution 504.**

7
8 **RECOMMENDATION D:**

9
10 **Madam Speaker, your Reference Committee**
11 **recommends that Council on Science and Public Health**
12 **Report 5 be filed.**

13
14 **HOD ACTION: Council on Science and Public**
15 **Health 5 adopted in lieu of Resolution 504 as**
16 **amended.**

17
18 The Council on Science and Public Health recommends that the following be adopted and
19 the remainder of the report be filed:

20 1. That Policy H-125.976, "Biosimilar Interchangeability Pathway" be rescinded. (Rescind
21 HOD Policy)

22 2. That our AMA encourage the FDA to continually collect data and critically evaluate
23 biosimilar utilization including the appropriateness of the term "interchangeable" in
24 regulatory activities. (Directive to Take Action)

25 3. That Policy D-125.989 "Substitution of Biosimilar Medicines and Related Medical
26 Products" be amended by addition and deletion to read as follows:

27 Our AMA urges that State Pharmacy Practice Acts and substitution practices for
28 biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which
29 biologic or biosimilar product is dispensed to their patients; (2) allow substitution when
30 physicians expressly authorize substitution of an interchangeable a biologic or
31 biosimilar product; (3) limit the authority of pharmacists to automatically substitute only
32 those biosimilar products that are deemed interchangeable by the FDA. in the absence of
33 express physician authorization to the contrary, allow substitution of the biologic or
34 biosimilar product when (a) the biologic product is highly similar to the reference product,
35 notwithstanding minor differences in clinically inactive components; and (b) there are no
36 data indicating clinically meaningful differences between the biological product and the
37 reference product in terms of the safety, purity, and potency of the product. (Modify
38 Current HOD Policy)

39 4. That Policy D-125.987, "Biosimilar Product Naming and Labeling" be reaffirmed.
40 (Reaffirm HOD Policy)

41
42 RESOLVED, that our American Medical Association recognize that, by definition,
43 Biosimilar medications are clinically equivalent to their reference Biologic and therefore do
44 not need a designation of "interchangeability;" (New HOD Policy); and be it further

45
46 RESOLVED, that our AMA support a rigorous approval process for Biosimilar medications
47 and oppose the application of the redundant designation of "interchangeability" with the
48 reference biologic drug (New HOD Policy); and it be further
49

1 RESOLVED, that AMA support the development of a model and a process for biologic
2 and biosimilar medication prescribing that protects physician decision-making when a
3 pharmacy-level substitution is not clinically appropriate (New HOD Policy); and be it further
4

5 RESOLVED, that our AMA support physician education on the clinical equivalence of
6 Biosimilars, the FDA approval process and the post-market surveillance that is required.
7 (New HOD Policy)
8

9 Your Reference Committee heard testimony unanimously in support of biosimilars as a
10 class of medication that are critically important for stabilizing and lowering the price of
11 expensive biologic medicines. However, there was an important but nuanced discussion
12 as to the best tactic for our AMA to adopt regarding the term “interchangeable”. On the
13 one hand, testimony cited recent research from American regulatory scientists and the
14 experiences of the European regulatory agencies, having concluded that the term
15 interchangeable is an unnecessary regulatory category, which needlessly prevents
16 patients from accessing safe and effective medicine. They felt our AMA should strongly
17 oppose such a designation. On the other hand, others stated that the FDA has already
18 indicated their desire to remove the interchangeable designation, and our AMA would
19 achieve the same result by taking a more supportive and less prescriptive stance with the
20 FDA. Additionally, proponents of the latter approach noted the difficulties with unwinding
21 state pharmacy laws and the relative infancy of biosimilars research would make a
22 declarative statement premature. There was discussion as to the development of a
23 process for performing and reporting biosimilar substitutions as noted in Resolution 504,
24 which your Reference Committee feels is adequately addressed by the Council
25 recommendations as amended. As such, your Reference Committee recommends that
26 amended Council on Science and Public Health Report 5 be adopted in lieu of Resolution
27 504.

1 (11) RESOLUTION 502 - TRIBALLY-DIRECTED PRECISION
2 MEDICINE RESEARCH

3
4 **RECOMMENDATION A:**

5
6 **Madam Speaker, your Reference Committee recommends that Resolution**
7 **502 be amended by deletion to read as follows:**

8
9 RESOLVED, that our American Medical Association support clinical funding
10 supplements to the National Institutes of Health, the U.S. Food and Drug
11 Administration, and the Indian Health Service to promote greater participation of
12 the Indian Health Service, Tribal, and Urban Indian Health Programs in ~~clinical~~
13 research.

14
15 **RECOMMENDATION B:**

16
17 **Madam Speaker, your Reference Committee recommends that Resolution**
18 **502 be adopted as amended.**

19
20 **HOD ACTION: Resolution 502 adopted as amended.**

21
22 RESOLVED, that our American Medical Association support clinical funding supplements
23 to the National Institutes of Health, the U.S. Food and Drug Administration, and the Indian
24 Health Service to promote greater participation of the Indian Health Service, Tribal, and
25 Urban Indian Health Programs in clinical research.

26
27 Your Reference Committee heard testimony in overwhelming support of funding tribally-
28 directed precision medicine research. Testimony underscored the critical need for
29 Indigenous populations to be actively included in research. Speakers highlighted the
30 unique genetic, environmental, and cultural factors affecting these communities, which
31 can significantly influence health outcomes. By funding tribally-directed research, we can
32 also ensure that precision medicine approaches are tailored to address the specific health
33 needs and disparities faced by Indigenous peoples. This inclusion is not only a matter of
34 equity but also essential for the advancement of medical knowledge and the development
35 of more effective, culturally appropriate healthcare interventions. Thus, your Reference
36 Committee strongly recommends that this proposal be adopted as amended.

1 (12) RESOLUTION 505 - MITIGATING THE HARMS OF
2 COLORISM AND SKIN BLEACHING AGENTS
3

4 **RECOMMENDATION A:**

5
6 **Madam Speaker, your Reference Committee recommends that the first**
7 **resolve of Resolution 505 be amended by deletion to read as follows:**
8

9 ~~**RESOLVED, that our American Medical Association support efforts to**~~
10 ~~**reduce the unsupervised use of skin lightening agents, especially due to**~~
11 ~~**colorism or social stigma, that do not limit evidence-based use by qualified**~~
12 ~~**clinicians (New HOD Policy); and be it further**~~
13

14 **RECOMMENDATION B:**

15
16 **Madam Speaker, your Reference Committee recommends that Resolution**
17 **505 be amended by addition of a new first resolve to read as follows:**
18

19 ~~**RESOLVED, That our AMA work with all relevant stakeholders to affirm the**~~
20 ~~**longstanding and evolving evidence-based use of skin lightening agents;**~~
21 ~~**and be it further**~~
22

23 **RECOMMENDATION C:**

24
25 **Madam Speaker, your Reference Committee recommends that Resolution**
26 **505 be amended by addition of a new second resolve to read as follows:**
27

28 ~~**RESOLVED, That our AMA work with the World Medical Association and**~~
29 ~~**other interested parties to advocate for public education regarding**~~
30 ~~**appropriate medical utilization of skin lightening agents and the harms of**~~
31 ~~**skin lightening motivated by cultural stigma and colorism; and be it further**~~
32

33 **RECOMMENDATION D:**

34
35 **Madam Speaker, your Reference Committee recommends that the third**
36 **resolve of Resolution 505 be amended by deletion to read as follows:**
37

38 ~~**RESOLVED, That our AMA work with the World Medical Association and**~~
39 ~~**other interested parties to mitigate the harms of colorism and**~~
40 ~~**unsupervised use of skin lightening agents. (Directive to Take Action)**~~
41

42 **RECOMMENDATION E:**

43
44 **Madam Speaker, your Reference Committee recommends that Resolution**
45 **505 be adopted as amended.**
46

47 **HOD ACTION: Resolution 505 adopted as amended.**

1 RESOLVED, that our American Medical Association support efforts to reduce the
2 unsupervised use of skin lightening agents, especially due to colorism or social stigma,
3 that do not limit evidence-based use by qualified clinicians (New HOD Policy); and be it
4 further

5
6 RESOLVED, that our AMA work with the World Medical Association and other interested
7 parties to mitigate the harms of colorism and unsupervised use of skin lightening agents.
8 (Directive to Take Action)

9
10 Your Reference Committee heard mixed testimony on Resolution 505. There was
11 testimony in support of the intent to protect individuals from skin-lightening or bleaching
12 products when used inappropriately. Testimony described how the social pressures of
13 structural racism often place an unhealthy and oversized emphasis on lighter skin tones.
14 When faced with these social pressures and stigma, individuals can turn to unsafe
15 products that can cause severe damage to their skin and increase their risk for cancer
16 just to achieve a lighter skin tone. However, testimony noted that as written, this
17 resolution may inadvertently capture instances where skin-lightening is medically
18 indicated, such as in pigment disorders. An amendment was proffered to delineate these
19 situations. As such, your Reference Committee recommends that Resolution 505 be
20 adopted as amended.

1 (13) RESOLUTION 507 - BAN ON DUAL OWNERSHIP,
2 INVESTMENT, MARKETING OR DISTRIBUTION OF
3 RECREATIONAL CANNABIS BY MEDICAL CANNABIS
4 COMPANIES

5
6 **RECOMMENDATION A:**

7
8 **Madam Speaker, your Reference Committee recommends that Resolution**
9 **507 be amended by addition and deletion to read as follows:**

10
11 **RESOLVED, that our American Medical Association support a permanent**
12 **ban on medical cannabis, psychedelic agent, and/or empathogenic**
13 **agent companies (and ~~its~~their related holding conglomerates) from**
14 **owning, investing in, distributing, or promoting recreational (or “adult**
15 **use”) cannabis, psychedelic agents, and/or empathogenic agents or any**
16 **other activity relating to recreational use of cannabis, psychedelic agents,**
17 **and/or empathogenic agents. (New HOD Policy)**

18
19 **RECOMMENDATION B:**

20
21 **Madam Speaker, your Reference Committee recommends that Resolution**
22 **507 be adopted as amended.**

23
24 **RECOMMENDATION C:**

25
26 **Madam Speaker, your Reference Committee recommends that the title of**
27 **Resolution 507 be changed to read as follows:**

28
29 **BAN ON DUAL OWNERSHIP, INVESTMENT, MARKETING OR**
30 **DISTRIBUTION OF ADULT-USE CANNABIS, PSYCHEDELIC AGENTS, OR**
31 **EMPATHOGENS BY MEDICAL COMPANIES**

32 **HOD ACTION: Resolution 507 adopted as amended with a change in title.**

33
34 **RESOLVED, that our American Medical Association support a permanent ban on medical**
35 **cannabis companies (and its related holding conglomerates) from owning, investing in,**
36 **distributing, or promoting recreational (or “adult use”) cannabis or any other activity**
37 **relating to recreational use of cannabis. (New HOD Policy)**

38
39 Your Reference Committee heard limited but supportive testimony on this item. Those
40 that testified in support described how cannabis companies may face a conflict of
41 interest while producing products intended for medical usage, while simultaneously
42 lobbying for their products to be sold to any consumer. One specialty group testified that
43 they are supportive of this approach generally and offered an amendment to expand the
44 approach to include other classes of drugs, such as psychedelic agents or
45 empathogens. As such, your Reference Committee recommends adoption as amended.

1 (14) RESOLUTION 509 - ADDRESSING SARCOPENIA AND
2 ITS IMPACT ON QUALITY OF LIFE
3

4 **RECOMMENDATION A:**
5

6 **Madam Speaker, your Reference Committee recommends that the first**
7 **resolve of Resolution 509 be amended by addition and deletion to read as**
8 **follows:**
9

10 **RESOLVED, that our American Medical Association supports collaborate**
11 **~~with appropriate entities to develop and implement~~ educational awareness**
12 **targeting healthcare professionals, caregivers, and the elderly at-risk**
13 **populations to increase knowledge about sarcopenia, its risk factors and**
14 **consequences, in order to facilitate prevention, early recognition and**
15 **evidence-based management as a routine part of clinical practice with**
16 **elderly patients (Directive to Take Action); and be it further**
17

18 **RECOMMENDATION B:**
19

20 **Madam Speaker, your Reference Committee recommends that Resolution**
21 **509 be adopted as amended.**
22

23 **HOD ACTION: Resolution 509 adopted as amended.**
24

25 RESOLVED, that our American Medical Association collaborate with appropriate entities
26 to develop and implement educational awareness targeting healthcare professionals,
27 caregivers, and the elderly population to increase knowledge about sarcopenia, its risk
28 factors and consequences, in order to facilitate prevention, early recognition and
29 evidence-based management as a routine part of clinical practice with elderly patients
30 (Directive to Take Action); and be it further
31

32 RESOLVED, that our AMA (1) support nutritional interventions aimed at optimizing protein
33 intake, essential amino acids, and micronutrients; (2) promote regular physical activity,
34 including resistance training, aerobic exercise, and balance exercises, tailored to
35 individual capabilities and preferences (New HOD Policy); and be it further
36

37 RESOLVED, that our AMA support allocation of resources for research initiatives aimed
38 at advancing our understanding of sarcopenia, its pathophysiology, risk factors, and
39 treatment modalities (New HOD Policy); and be it further
40

41 RESOLVED, that our AMA advocate for policy changes to support reimbursement for
42 sarcopenia screening, diagnosis, and interventions (Directive to Take Action); and be it
43 further

44 RESOLVED, that our AMA collaborate with all stakeholders to integrate sarcopenia
45 prevention and management into public health agendas and aging-related initiatives.
46 (Directive to Take Action)
47

48 Your Reference Committee heard testimony unanimously in support of the underlying
49 intent behind this resolution. Testimony described how the American population is aging,
50 and there is generally low awareness for diagnosing, subsequent treatment, and the

1 reimbursement landscape for sarcopenia. However, several testifying noted the large
2 fiscal note attached to this resolution, and an amendment was proffered to retain the
3 intent of the resolution while communicating that our AMA would not be the sole entity
4 responsible for creating this content. It is expected that this amendment would lower the
5 estimated fiscal note without precluding our AMA from acting. Additional amendments
6 were recommended to modify the scope to include that sarcopenia may impact any
7 patient, particularly those using weight loss medications. As such, your Reference
8 Committee recommends Resolution 509 be adopted as amended.

1 (15) RESOLUTION 517 – REGULATION OF NICOTINE
2 ANALOGUE PRODUCTS
3

4 **RECOMMENDATION A:**
5

6 **Madam Speaker, your Reference Committee recommends that the second**
7 **resolve of Resolution 517 be amended by deletion to read as follows:**
8

9 **RESOLVED, that our AMA urge the Food and Drug Administration (FDA)**
10 **~~Center for Drug Effectiveness and Research~~ swiftly exert its authority to**
11 **regulate all nicotine analogue products as drugs (Directive to Take Action).**
12

13 **RECOMMENDATION B:**
14

15 **Madam Speaker, your Reference Committee recommends that Resolution**
16 **517 be adopted as amended.**
17

18 **HOD ACTION: Resolution 517 adopted as amended.**
19

20 RESOLVED, that our American Medical Association oppose the development, production
21 market and sales of nicotine analogue consumer products (New HOD Policy); and be it
22 further

23
24 RESOLVED, that our AMA urge the Food and Drug Administration (FDA) Center for Drug
25 Effectiveness and Research swiftly exert its authority to regulate all nicotine analogue
26 products as drugs (Directive to Take Action).
27

28 Your Reference Committee heard unanimously supportive testimony of the intent of this
29 resolution. Testimony described the frustrations of trying to keep up with the rapidly
30 evolving landscape of tobacco and nicotine products, many of which are currently being
31 designed to circumvent the regulations specifically in place to protect the public's well-
32 being. Your Reference Committee does proffer one amendment to strike reference to a
33 specific entity within the FDA, as there are other groups such as the Center for Tobacco
34 Products, which may also be appropriate targets for advocacy by our AMA. As such,
35 your Reference Committee recommends adoption as amended.

1 **RECOMMENDED FOR ADOPTION WITH CHANGE IN TITLE**

2
3 **(16)** RESOLUTION 515 - ADVOCACY FOR MORE
4 STRINGENT REGULATIONS/RESTRICTIONS ON THE
5 DISTRIBUTION OF MARIJUANA

6
7 **RECOMMENDATION:**

8
9 **Madam Speaker, your Reference Committee recommends that Resolution**
10 **515 be adopted with change in title to read as follows:**

11
12 **ADVOCACY FOR MORE STRINGENT REGULATIONS/RESTRICTIONS ON**
13 **THE DISTRIBUTION OF CANNABIS**

14
15 **HOD ACTION: Resolution 515 adopted with a change in title.**

16
17 RESOLVED, that our American Medical Association study possible legislative, legal or
18 regulatory means to make the cannabis industry responsible for increasing costs of
19 medical and social care for people affected by the problems caused by cannabinoids
20 similar to regulations for smoking cessation in the United States (Directive to Take Action).

21
22 Your Reference Committee heard limited but supportive testimony for this item.
23 Testimony noted that there is a need for a change in the name of the resolution from
24 marijuana to cannabis to be consistent with other policies. Additionally, testimony spoke
25 to the need to cover the costs of treatment, since the industry is creating more potent
26 products and patients often have adverse effects. As such, your Reference Committee
27 recommends that Resolution 515 be adopted.

RECOMMENDED FOR REFERRAL

(17) RESOLUTION 501 – FRAGRANCE REGULATION

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that Resolution 501 be referred.

HOD ACTION: Resolution 501 referred.

RESOLVED, that our American Medical Association recognize fragrance sensitivity as a disability where the presence of fragranced products can limit accessibility of healthcare settings (New HOD Policy); and be it further

RESOLVED, that our AMA encourage all hospitals, outpatient clinics, urgent cares, and other patient care areas inclusive of medical schools to adopt a fragrance-free policy that pertains to employees, patients, and visitors of any kind (New HOD Policy); and be it further

RESOLVED, that our AMA work with relevant parties to advocate for governmental regulatory bodies, including but not limited to the Occupational Safety and Health Administration (OSHA), the Centers for Disease Control and Prevention (CDC), and the National Institute for Occupational Safety and Health (NIOSH) to recommend fragrance-free policies in all medical offices, buildings, and places of patient care (Directive to Take Action); and be it further

RESOLVED, that our AMA work with relevant parties to support the appropriate labeling of fragrance-containing personal care products, cosmetics, and drugs with warnings about possible allergic reactions or adverse events due to the fragrance, and advocates for increased categorization in the use of a “fragrance free” designation (Directive to Take Action); and be it further

RESOLVED, that our AMA support increased identification of hazardous chemicals in fragrance compounds, as well as research focused on fragrance sensitivity in order to remove these allergens from products applied to one’s body. (New HOD Policy)

Your Reference Committee heard significant mixed testimony on this item. Proponents cited poor regulations for the labeling of fragrances and potential allergens in many consumer products, and the impact these products can have on a patient’s ability to access care. Conversely, opponents described how blanket fragrance-free policies may also exclude patients from receiving care and place physicians in legal jeopardy, such as in instances where a patient with a scented product may be seeking emergency care. While there were disagreements as to the feasibility of larger fragrance-free policies, there was a consensus around the desire for our AMA to investigate the “fragrance-free” designation for consumer products, and the correct labeling of allergens. Additionally, there was significant disagreement as to whether it was appropriate to designate fragrance sensitivity as a disability. While several amendments were offered to alleviate some concerns, there did not appear to be a consensus formed as to the direction our

- 1 AMA should take. As such, your Reference Committee recommends that Resolution 501
- 2 be referred.

RECOMMENDED FOR NOT ADOPTION

1
2
3 **(18)** RESOLUTION 506 - SCREENING FOR IMAGE
4 MANIPULATION IN RESEARCH PUBLICATIONS

5
6 **RECOMMENDATION:**

7
8 **Madam Speaker, your Reference Committee recommends that Resolution**
9 **506 be not adopted.**

10
11 **HOD ACTION: Resolution 506 referred.**

12
13 RESOLVED, that our American Medical Association support the creation of a nationally
14 collaborative database of manipulated images from retracted publications to provide a test
15 bank for researchers developing augmented intelligence-integrated image screening
16 tools. (New HOD Policy)

17
18 Your Reference Committee heard testimony in opposition to this resolution. Testimony
19 noted the lack of a standardized tool to identify manipulated images for this use and the
20 necessity of a database for this purpose. Testimony questioned whether our AMA was the
21 appropriate entity to be pursuing these measures, and that several publishers are already
22 pursuing or utilize their own image detection software. Therefore, your Reference
23 Committee recommends Resolution 506 not be adopted.

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

(19) RESOLUTION 503 - UNREGULATED HEMP-DERIVED
INTOXICATING CANNABINOIDS, AND DERIVED
PSYCHOACTIVE CANNABIS PRODUCTS (DPCPS)

RECOMMENDATION:

Madam Speaker, your Reference Committee recommends that policies H-95.952 and H-95.940 be reaffirmed in lieu of Resolution 503.

HOD ACTION: Resolution 503 referred for decision.

RESOLVED, that our American Medical Association work with other interested organizations to increase public awareness and promote education on the dangers of Derived Psychoactive Cannabis Products (DPCPs) and Hemp-Derived Intoxicating Cannabinoids (Directive to Take Action); and be it further

RESOLVED, that our AMA work with other interested organizations to advocate to close the loophole in the 2018 Farm bill that allows Derived Psychoactive Cannabis Products (DPCPs) and Hemp-Derived Intoxicating Cannabinoids to be regulated as hemp (Directive to Take Action); and be it further

RESOLVED, that our AMA work with other interested organizations to advocate for prohibition of Derived Psychoactive Cannabis Products (DPCPs) and Hemp-Derived Intoxicating Cannabinoids (unless and until properly tested in humans) (Directive to Take Action); and be it further

RESOLVED, that our AMA work with other interested organizations to advocate for further research on the health impacts of Derived Psychoactive Cannabis Products (DPCPs) and Hemp-Derived Intoxicating Cannabinoids, including the potential dangers of these products to children, pregnant women and other vulnerable populations (Directive to Take Action); and be it further

RESOLVED, that our AMA report back on this issue at A-25. (Directive to Take Action)

Your Reference Committee heard mixed testimony on Resolution 503. Speakers who testified in opposition noted the significant body of work completed by your Council on Science and Public Health on emerging trends in new psychoactive substances and cannabinoids more broadly. This resolution is covered by existing policy, H-95.952 and H-95.940 (below), and your Reference Committee questions whether new policies are needed for every new chemical compound. Further, opposing testimony noted that advocating for legislation related to the 2018 Farm Bill may cause unwanted conflicts with farming groups. As such, your Reference Committee recommends that these policies are reaffirmed in lieu of Resolution 503.

Cannabis and Cannabinoid Research H-95.952

1. Our American Medical Association calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled

- 1 evidence suggests possible efficacy and the application of such results to the
2 understanding and treatment of disease.
- 3 2. Our AMA urges that marijuana's status as a federal schedule I controlled
4 substance be reviewed with the goal of facilitating the conduct of clinical
5 research and development of cannabinoid-based medicines, and alternate
6 delivery methods. This should not be viewed as an endorsement of state-
7 based medical cannabis programs, the legalization of marijuana, or that
8 scientific evidence on the therapeutic use of cannabis meets the current
9 standards for a prescription drug product.
- 10 3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement
11 Administration (DEA), and the Food and Drug Administration (FDA) to
12 develop a special schedule and implement administrative procedures to
13 facilitate grant applications and the conduct of well-designed clinical research
14 involving cannabis and its potential medical utility. This effort should include:
15 a. disseminating specific information for researchers on the development of
16 safeguards for cannabis clinical research protocols and the development
17 of a model informed consent form for institutional review board evaluation;
18 b. sufficient funding to support such clinical research and access for
19 qualified investigators to adequate supplies of cannabis for clinical
20 research purposes;
21 c. confirming that cannabis of various and consistent strengths and/or
22 placebo will be supplied by the National Institute on Drug Abuse to
23 investigators registered with the DEA who are conducting bona fide
24 clinical research studies that receive FDA approval, regardless of whether
25 or not the NIH is the primary source of grant support.
- 26 4. Our AMA supports research to determine the consequences of long-term
27 cannabis use, especially among youth, adolescents, pregnant women, and
28 women who are breastfeeding.
- 29 5. Our AMA urges legislatures to delay initiating the legalization of cannabis for
30 recreational use until further research is completed on the public health,
31 medical, economic, and social consequences of its use.
- 32 6. Our AMA will advocate for urgent regulatory and legislative changes necessary
33 to fund and perform research related to cannabis and cannabinoids.
- 34 7. Our AMA will create a Cannabis Task Force to evaluate and disseminate
35 relevant scientific evidence to health care providers and the public.

36 **Addressing Emerging Trends in Illicit Drug Use H-95.940**

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

1 new drugs of abuse and to institute the necessary administrative or legislative
2 actions to deem such drugs illegal in an expedited manner.

3
4 **(20) RESOLUTION 508 - AMA TO SUPPORT REGULATIONS**
5 **TO DECREASE OVERDOSES IN CHILDREN DUE TO**
6 **INGESTION OF EDIBLE CANNABIS**

7
8 **RECOMMENDATION:**

9
10 **Madam Speaker, your Reference Committee recommends that policy H-**
11 **95.924 be reaffirmed in lieu of Resolution 508.**

12
13 **HOD ACTION: Resolution 508 referred for decision.**

14
15 RESOLVED, that our American Medical Association work with the Food and Drug
16 Administration to strengthen how marijuana manufacturers can advertise their products,
17 including regulations that ensure the packaging does not appeal to children (Directive to
18 Take Action); and be it further

19
20 RESOLVED, that our AMA propose public awareness campaigns aimed at informing the
21 general population, especially parents and guardians, about the risks associated with
22 edible cannabis and the importance of safe storage and handling (Directive to Take
23 Action); and be it further

24
25 RESOLVED, that our AMA emphasize the importance of childproof packaging for all
26 cannabis products, along with advocating for stricter regulations to enforce this
27 requirement. (New HOD Policy)

28
29 Your Reference Committee heard supportive testimony that highlighted the urgent need
30 for stricter regulations on how cannabis products are packaged and advertised. Strong
31 support exists for this initiative, particularly due to concerns that parents may
32 underestimate the safety risks, necessitating education for both parents and youth.
33 Testimonies revealed alarming incidents where children suffered adverse events as
34 current packaging often resembles candy or vitamins. Your Reference Committee
35 reviewed current cannabis policy, H-95.924 (below), and determined that current policy
36 encompasses the intent of this resolution, to strengthen regulations to educate the public,
37 and support childproof packaging. As such, your Reference Committee recommends
38 reaffirming policy H-95.924, "Cannabis Legalization for Adult Use."

39
40 **Cannabis Legalization for Adult Use (commonly referred to as**
41 **recreational use) H-95.924**

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51
1. Our American Medical Association believes that cannabis is a dangerous drug and as such is a serious public health concern.
 2. Our AMA believes that the sale of cannabis for adult use should not be legalized (with adult defined for these purposes as age 21 and older).
 3. Our AMA discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding.
 4. Our AMA believes states that have already legalized cannabis (for medical or adult use or both) should be required to take steps to

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regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth.

5. Our AMA believes laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness.
6. Our AMA encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder.
7. Our AMA supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use.
8. Our AMA encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety.
9. Our AMA encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis.
10. Our AMA will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving.
11. Our AMA supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities.
12. Our AMA will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

1 (21) RESOLUTION 510 - STUDY TO INVESTIGATE THE
2 VALIDITY OF CLAIMS MADE BY THE MANUFACTURERS
3 OF OTC VITAMINS, SUPPLEMENTS AND "NATURAL
4 CURES"
5

6 **RECOMMENDATION:**
7

8 **Madam Speaker, your Reference Committee recommends that policy H-**
9 **150.954 be reaffirmed in lieu of Resolution 510.**

10
11 **HOD ACTION: Policy H-150.954 reaffirmed in lieu of Resolution 510.**
12

13 RESOLVED, that our American Medical Association study the growing problem of
14 advertisements on OTC Vitamins, Supplements, and "Natural Cures" that claim health
15 benefits and cures. With report back at A-25 (Directive to Take Action); and be it further
16

17 RESOLVED, that our AMA collaborate with all the specialties which are affected by these
18 claims and gather scientific evidence showing benefits and false claims (Directive to Take
19 Action); and be it further
20

21 RESOLVED, that our AMA request that the FDA exercise its full scope of authority to
22 protect our patients by removing all the advertisements containing false claims of medical
23 cures. (Directive to Take Action)
24

25 Your Reference Committee heard testimony that was supportive of increased
26 regulations on dietary supplement manufacturers, but mixed as to whether the proposed
27 resolution was the appropriate method to achieve those goals. Testimony noted that our
28 AMA has extensive policy on dietary supplements and the role of the FDA in regulating
29 them, and has a demonstrated history of advocacy on this issue. Your Reference
30 Committee would note that our AMA has collaborated with other stakeholders in the
31 [Dietary Supplement Quality Collaborative](#), [written to Congress on mandatory product](#)
32 [listing](#) for dietary supplements, and [developed award-winning continuing medical](#)
33 [education](#) in collaboration with the FDA on this topic. As such, your Reference
34 Committee recommends reaffirmation of existing policy.
35

36 **Dietary Supplements and Herbal Remedies H-150.954**

37 (1) Our AMA supports efforts to enhance U.S. Food and Drug
38 Administration (FDA) resources, particularly to the Office of Dietary
39 Supplement Programs, to appropriately oversee the growing dietary
40 supplement sector and adequately increase inspections of dietary
41 supplement manufacturing facilities.

42 (2) Our AMA supports the FDA having appropriate enforcement tools and
43 policies related to dietary supplements, which may include mandatory
44 recall and related authorities over products that are marketed as dietary
45 supplements but contain drugs or drug analogues, the utilization of risk-
46 based inspections for dietary supplement manufacturing facilities, and the
47 strengthening of adverse event reporting systems.

48 (3) Our AMA supports continued research related to the efficacy, safety,
49 and long-term effects of dietary supplement products.

50 (4) Our AMA will work with the FDA to educate physicians and the public
51 about FDA's Safety Reporting Portal (SRP) and to strongly encourage

1 physicians and the public to report potential adverse events associated
2 with dietary supplements and herbal remedies to help support FDA's
3 efforts to create a database of adverse event information on these forms
4 of alternative/complementary therapies.

5 (5) Our AMA strongly urges physicians to inquire about patients' use of
6 dietary supplements and engage in risk-based conversations with them
7 about dietary supplement product use.

8 (6) Our AMA continues to strongly urge Congress to modify and modernize
9 the Dietary Supplement Health and Education Act to require that:

10 (a) dietary supplements and herbal remedies including the products
11 already in the marketplace undergo FDA approval for evidence of safety
12 and efficacy;

13 (b) dietary supplements meet standards established by the United States
14 Pharmacopeia for identity, strength, quality, purity, packaging, and
15 labeling;

16 (c) FDA establish a mandatory product listing regime that includes a
17 unique identifier for each product (such as a QR code), the ability to
18 identify and track all products produced by manufacturers who have
19 received warning letters from the FDA, and FDA authorities to decline to
20 add labels to the database if the label lists a prohibited ingredient or new
21 dietary ingredient for which no evidence of safety exists or for products
22 which have reports of undisclosed ingredients; and

23 (d) regulations related to new dietary ingredients (NDI) are clarified to
24 foster the timely submission of NDI notifications and compliance regarding
25 NDIs by manufacturers.

26 (7) Our AMA supports FDA postmarketing requirements for manufacturers
27 to report adverse events, including drug interactions; and legislation that
28 declares metabolites and precursors of anabolic steroids to be drug
29 substances that may not be used in a dietary supplement.

30 (8) Our AMA will work with the Federal Trade Commission (FTC) to
31 support enforcement efforts based on the FTC Act and current FTC policy
32 on expert endorsements and supports adequate funding and resources for
33 FTC enforcement of violations of the FTC Act.

34 (9) Our AMA strongly urges that criteria for the rigor of scientific evidence
35 needed to support a structure/function claim on a dietary supplement be
36 established by the FDA and minimally include requirements for robust
37 human studies supporting the claim.

38 10) Our AMA strongly urges dietary supplement manufacturers and
39 distributors to clearly label all products with truthful and not misleading
40 information and for the product labeling to:

41 (a) not include structure/function claims that are not supported by evidence
42 from robust human studies;

43 (b) not contain prohibited disease claims;

44 (c) eliminate "proprietary blends" and list and accurately quantify all
45 ingredients contained in the product;

46 (d) require advisory statements regarding potential supplement-drug and
47 supplement-laboratory interactions and risks associated with overuse and
48 special populations; and

49 (e) include accurate and useful disclosure of ingredient measurement.

50 (11) Our AMA supports and encourages the FDA's regulation and
51 enforcement of labeling violations and FTC's regulation and enforcement
52 of advertisement violations of prohibited disease claims made on dietary
53 supplements and herbal remedies.

54 (12) Our AMA urges that in order to protect the public, manufacturers be
55 required to investigate and obtain data under conditions of normal use on

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adverse effects, contraindications, and possible drug interactions, and that such information be included on the label.
(13) Our AMA will continue its efforts to educate patients and physicians about the risks associated with the use of dietary supplements and herbal remedies and supports efforts to increase patient, healthcare practitioner, and retailer awareness of resources to help patients select quality supplements, including educational efforts to build label literacy.

1 (22) RESOLUTION 512 - OPIOID OVERDOSE REVERSAL
2 AGENTS WHERE AED'S ARE LOCATED
3

4 **RECOMMENDATION:**
5

6 **Madam Speaker, your Reference Committee recommends that policy H-**
7 **95.932 be reaffirmed in lieu of Resolution 512.**
8

9 **HOD ACTION: Resolution 512 adopted.**
10

11 RESOLVED, that our American Medical Association support the expansion of naloxone
12 availability through colocation of intranasal naloxone with AEDs in public locations. (New
13 HOD Policy)
14

15 Your Reference Committee heard overwhelming positive testimony for expanded access
16 to naloxone, and supportive of the intent of the proposed resolution. Other testimony
17 noted implementation challenges of naloxone expiration and management of refilling
18 used naloxone. However, your Reference Committee did not hear testimony describing
19 how the proposed resolution differs from current policy of our AMA (subsection 8 of the
20 policy below) and as such, your Reference Committee recommends reaffirmation.
21

22 **Increasing Availability of Naloxone and Other Safe and Effective**
23 **Overdose Reversal Medications H-95.932**

- 24 1. Our American Medical Association supports legislative, regulatory, and
25 national advocacy efforts to increase access to affordable naloxone and
26 other safe and effective overdose reversal medications, including but not
27 limited to collaborative practice agreements with pharmacists and
28 standing orders for pharmacies and, where permitted by law, community-
29 based organizations, law enforcement agencies, correctional settings,
30 schools, and other locations that do not restrict the route of administration
31 for naloxone and other safe and effective overdose reversal medications
32 delivery.
- 33 2. Our AMA supports efforts that enable law enforcement agencies to carry
34 and administer naloxone and other safe and effective overdose reversal
35 medications.
- 36 3. Our AMA encourages physicians to co-prescribe naloxone and other safe
37 and effective overdose reversal medications to patients at risk of overdose
38 and, where permitted by law, to the friends and family members of such
39 patients.
- 40 4. Our AMA encourages private and public payers to include all forms of
41 naloxone and other safe and effective overdose reversal medications on
42 their preferred drug lists and formularies with minimal or no cost sharing.
- 43 5. Our AMA supports liability protections for physicians and other healthcare
44 professionals and others who are authorized to prescribe, dispense and/or
45 administer naloxone and other safe and effective overdose reversal
46 medications pursuant to state law.
- 47 6. Our AMA supports efforts to encourage individuals who are authorized to
48 administer naloxone and other safe and effective overdose reversal
49 medications to receive appropriate education to enable them to do so
50 effectively.

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7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone and other safe and effective overdose reversal medications with the Food and Drug Administration.
8. Our AMA supports the widespread implementation of easily accessible naloxone and other safe and effective overdose reversal medications rescue stations (public availability of naloxone and other safe and effective overdose reversal medications through wall-mounted display/storage units that also include instructions) throughout the country following distribution and legislative edicts similar to those for Automated External Defibrillators.
9. Our AMA supports the legal access to and use of naloxone and other safe and effective overdose reversal medications in all public spaces regardless of whether the individual holds a prescription.
10. Our AMA supports efforts to increase the availability, delivery, possession and use of mail-order overdose reversal medications, including naloxone, to help prevent opioid-related overdose, especially in vulnerable populations, including but not limited to underserved communities and American Indian reservation populations.

Madam Speaker, this concludes the report of Reference Committee E. I would like to thank Carl Streed, Jr, MD, Catriona Hong, Vivek Rao, MD, Kenath Shamir, MD, Charles Van Way, MD, Erin Schwab, MD, and all those who testified before the Committee.

Carl Streed, Jr, MD (Alternate)
GLMA Health Professionals Advancing
LGBTQ Equality

Kenath Shamir, MD (Alternate)
Massachusetts

Catriona Hong (Alternate)
Connecticut

Charles Van Way, MD
Missouri

Vivek Rao, MD (Alternate)
Texas

Erin Schwab, MD
Colorado

Robert Panton
Illinois
Chai