DISCLAIMER

The following is a preliminary report of actions taken by the House of Delegates at its 2023 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-23)

Report of Reference Committee E

Jean Hausheer, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Council on Science and Public Health Report 3 - Regulation and Control of Self-Service Labs
2. Resolution 501 – AMA Study of Chemical Castration in Incarceration
3. Resolution 510 - Comparative Effectiveness Research
4. Resolution 511 - Regulation of Phthalates in Adult Personal Sexual Products
5. Resolution 520 - Supporting Access to At-Home Injectable Contraceptives

RECOMMENDED FOR ADOPTION WITH A CHANGE IN TITLE

6. Resolution 509 - Addressing Medical Misinformation Online

RECOMMENDED FOR ADOPTION AS AMENDED

7. Council on Science and Public Health Report 1 - Oppose Scheduling of Gabapentin
8. Council on Science and Public Health Report 2 - Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices
9. Resolution 502 - Pain Management for Long-Acting Reversible Contraception and other Gynecological Procedures
10. Resolution 503 - Increasing Diversity in Stem Cell Biobanks and Disease Models
11. Resolution 507 - Recognizing the Burden of Rare Disease
12. Resolution 508 - Development and Implementation of Recommendations for Responsible Media Coverage of Opioid Overdoses
13. Resolution 513 - Substance Use History is Medical History
14. Resolution 514 - Adolescent Hallucinogen-Assisted Therapy Policy
15. Resolution 516 - Fasting is Not Required for Lipid Analysis
16. Resolution 517 - Genetic Predisposition and Healthcare Disparities, Including Cardiovascular Disease in South Asians Residing in the United States
17. Resolution 521 - Preventing the Elimination of Cannabis from Occupational and Municipal Drug Testing Programs

RECOMMENDED FOR ADOPTION IN LIEU OF

18. Resolution 505 - Improving Access to Opioid Antagonists for Vulnerable and Underserved Populations
    Resolution 525 - Decriminalizing and Destigmatizing Perinatal Substance Use Treatment
19. Resolution 512 - Wheelchairs on Airplanes
20. Resolution 515 - Resolution to Regulate Kratom and Ban Over-The-Counter Sales
21. Resolution 519 - Rescheduling or Descheduling Testosterone

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

22. Resolution 518 - Defending NIH funding of Animal Model Research From Legal Challenges
23. Resolution 522 - Approval Authority of the FDA

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

Amendments
If you wish to propose an amendment to an item of business, click here: SUBMIT NEW AMENDMENT

RECOMMENDED FOR ADOPTION

(1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 3 – REGULATION AND CONTROL OF SELF-SERVICE LABS

RECOMMENDATION:

That Council on Science and Public Health 3 be adopted and the remainder of the report filed.

HOD ACTION: That Council on Science and Public Health 3 adopted and the remainder of the report filed.

1. Direct access testing, in which patients may order a diagnostic laboratory test on demand, should only be provided by teams which are physician-led, and performed in facilities that are CLIA-certified.
Health care professionals who offer direct access testing services, for which a patient does not have a referral, recognize that agreeing to perform direct-to-consumer testing on request:
a. establishes a patient relationship, with all the ethical and professional obligations such relationship entails; and
b. assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Health care professionals may choose to refer the patient for post-test counseling to an appropriate provider who accepts the patient, but they maintain ethical and professional responsibility until the patient has been seen by that provider; and
c. shall report all required findings to relevant oversight entities, such as state public health agencies, even if the patient and the laboratory are not co-localized in the same jurisdiction. (New HOD Policy)

2. That Policy H-480.941, "Direct-to-Consumer Laboratory Testing," calling for regulation of direct-to-consumer testing and education of patients of risks and benefits, be reaffirmed. (Reaffirmation of Current AMA Policy)

Your Reference Committee heard limited testimony on CSAPH Report 3. Testimony noted that many companies engage in the practice of direct access testing, sometimes without physician-led teams. Speakers noted that there is a need for changes in the current business model to promote patient safety and access. Additionally, speakers testified that our AMA needs to ensure that direct access tests have oversight and follow relevant rules and regulations. Therefore, your Reference Committee recommends CSAPH Report 3 be adopted.

(2) RESOLUTION 501 - AMA STUDY OF CHEMICAL CASTRATION IN INCARCERATION

RECOMMENDATION:

That Resolution 501 be <u>adopted</u>.

HOD ACTION: That Resolution 501 <u>adopted.</u>

RESOLVED, That our AMA study the use of chemical castration in the treatment of incarcerated individuals with paraphilic disorders and for other individuals who commit sexual offenses, including ethical concerns over coercion in its use as an alternative to incarceration and in probation and parole proceedings. (Directive to Take Action)

Your Reference Committee heard testimony in support of Resolution 501 to study chemical castration in incarcerated individuals. Testimony noted the multiple complexities that surround this issue. These complexities include: (1) the disproportionate impact of current practices on Black individuals, LGBTQAI+, and other minoritized groups, (2) requests for the use of chemical castration for sentence reduction, and (3) the potential impact of chemical castration on recidivism. Testimony provided described a need for ethical guidelines and for our AMA to study this issue for incarcerated people. Therefore, your Reference Committee recommends Resolution 501 be adopted.

(3) RESOLUTION 510 - COMPARATIVE EFFECTIVENESS RESEARCH

RECOMMENDATION:

That Resolution 510 be <u>adopted</u>.

HOD ACTION: That Resolution 510 <u>adopted.</u>

RESOLVED, That our American Medical Association study the feasibility of including comparative effectiveness studies in various FDA drug regulatory processes, including comparisons with existing standard of care, available generics and biosimilars, and drugs commonly used off-label and over-the-counter (Directive to Take Action); and be it further

RESOLVED, That our AMA ask the National Institutes of Health to support and fund comparative effectiveness research for approved drugs, including comparisons with existing standard of care, available generics and biosimilars, and drugs commonly used off-label and over-the-counter. (Directive to Take Action)

Overall, testimony heard by your Reference Committee was supportive of Resolution 510. Testimony noted that there are financial incentives to study on-patent drugs, but not generics. For example, testimony described how esketamine was approved without comparative effectiveness research over generic ketamine, leading to the more expensive drug being the only FDA-approved drug for certain indications. Speakers noted that by better incorporating comparative effectiveness research into regulatory

decisions, these studies could lead to fiscally responsible healthcare. As such, your Reference Committee recommends this Resolution be adopted.

(4) RESOLUTION 511 - REGULATION OF PHTHALATES IN ADULT PERSONAL SEXUAL PRODUCTS

RECOMMENDATION:

That Resolution 511 be adopted.

HOD ACTION: That Resolution 511 adopted.

RESOLVED, That our American Medical Association amend policy H-135.945 by addition and deletion to read as follows:

Encouraging Alternatives to PVC/Phthalate ~~DEHP~~ Products in Health H-135.945

Our AMA:
(1) encourages hospitals and physicians to reduce and phase out polyvinyl chloride (PVC) ~~medical device~~ products, especially those containing phthalates such as Di(2-ethylhexyl)phthalate (DEHP), and urge adoption of safe, cost-effective, alternative products where available; ~~and~~
(2) urges expanded manufacturer development of safe, cost-effective alternative products to PVC ~~medical device~~ products, especially those containing phthalates such as DEHP;
(3) encourages the U.S. Consumer Product Safety Commission to conduct a risk assessment of adult personal sexual products as a source of phthalates; and
(4) supports consumer education about the potential for exposure to toxic substances in adult personal sexual products. (Modify Current HOD Policy)

Your Reference Committee heard limited, but unanimously supportive testimony on this Resolution. Testimony noted that phthalates have commonly been removed from water bottles and children's toys, and adult personal sexual products should be held to a similar standard. Therefore, your Reference Committee recommends that Resolution 511 be adopted.

(5) RESOLUTION 520 - SUPPORTING ACCESS TO AT-HOME INJECTABLE CONTRACEPTIVES

RECOMMENDATION:

That Resolution 520 be <u>adopted</u>.

HOD ACTION: That Resolution 520 <u>adopted.</u>

RESOLVED, That our American Medical Association support access to at-home contraceptive injections as a method of birth control for women across the nation. (New HOD Policy)

Testimony for Resolution 520 was unanimously supportive. Speakers noted that the ability of patients to choose their method of contraception and retain bodily autonomy is critical. Testimony also described various barriers patients face, including the inability to take time off work, travel, or arrange childcare to receive injectable contraception. Speakers mentioned several studies demonstrate self-administration of at-home injectable contraceptives is feasible, and the CDC has recommended that these administrations be made available. Therefore, your Reference Committee recommends that Resolution 520 be adopted.

RECOMMENDED FOR ADOPTION WITH A CHANGE IN TITLE

(6) RESOLUTION 509 - ADDRESSING MEDICAL MISINFORMATION ONLINE

RECOMMENDATION:

That Resolution 509 be adopted with a change in title to read as follows:

MEDICAL AND PUBLIC HEALTH MISINFORMATION ONLINE

HOD ACTION: That Resolution 509 adopted with a change in title to read as follows:

MEDICAL AND PUBLIC HEALTH MISINFORMATION ONLINE

RESOLVED, That our American Medical Association policy D-440.915 be amended by addition and deletion to read as follows:

Medical and Public Health Misinformation in the ~~Age of Social Media~~Online D-440.915

Our AMA:
(1) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to further strengthen their content moderation policies related to medical and public health misinformation, including, but not limited to enhanced content monitoring, augmentation of recommendation engines focused on false information, and stronger integration of verified health information;
(2) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to recognize the spread of medical and public health misinformation over dissemination networks and collaborate with relevant stakeholders to address this problem as appropriate, including but not limited to altering underlying network dynamics or redesigning platform algorithms;
(3) will continue to support the dissemination of accurate medical and public health information by public health organizations and health policy experts; and
(4) will work with public health agencies in an effort to establish relationships with journalists and news agencies to enhance the public reach in disseminating accurate medical and public health information. (Modify Current HOD Policy)

Your Reference Committee heard unanimous testimony in support of this resolution. Testimony noted the extent of this issue beyond social media. Further, that this new policy could continue to work to curb misinformation and potentially build such collaborations in the future. As such, your Reference Committee recommends that this resolution be adopted.

RECOMMENDED FOR ADOPTION AS AMENDED

(7) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 1 – OPPOSE SCHEDULING OF GABAPENTIN

RECOMMENDATION A:

That the third point of the first recommendation in Council on Science and Public Health Report 1 be amended by addition and deletion to read as follows:

3. support the promotion of gabapentinoid-related research and education, particularly the risk of gabapentinoids when taken concomitantly with opioids~~,~~ and the potential for gabapentinoid withdrawal, ~~including~~ in current clinical practice and undergraduate, graduate and post-graduate education.

RECOMMENDATION B:

That Council on Science and Public Health Report 1 be adopted as amended and the remainder of the report be filed.

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

1. That Policy D-120.927, "Oppose Scheduling of Gabapentin" be amended by addition and deletion to read as follows with recognition that several aspects of this directive have been accomplished:
Our AMA will:

1. actively oppose the placement of (a) gabapentin ~~(2-[1-(aminomethyl) cyclohexyl] acetic acid)~~, including its salts, and all products containing gabapentin ~~(including the brand name products Gralise and Neurontin)~~ and (b) gabapentin enacarbil ~~(1-{[({(1RS)-1-[(2-methylpropanoyl)oxy]ethoxy}carbonyl)amino]methyl}cyclohexyl) acetic acid)~~, including its salts, ~~(including the brand name product Horizant)~~ into schedule V or other restricted class of the Controlled Substances Act;
~~2. submit a timely letter to the Commissioner of Food and Drug for the proceedings assigned docket number FDA-2022-P-0149 in opposition to placement of gabapentin and gabapentin enacarbil into the schedule V of the Controlled Substance Act; and~~
~~3. study the off-label use and potential risks and benefits of gabapentin to the general population as well as to those individuals with substance use disorders.~~
2. affirm that given currently available data, the FDA and DEA have used the appropriate process for evaluating the safety, efficacy, and risk of misuse and dependency for gabapentin and its salts;
3. support the promotion of gabapentin-related research and education, particularly the risk of gabapentinoids when taken concomitantly with opioids, including in current clinical

practice and undergraduate, graduate and post-graduate education. (Modify Current AMA Policy)

2. That our AMA reaffirm Policies H-120.988, “Patient Access to Treatments Prescribed by Their Physicians”, H-120.922, “Improved Access and Coverage to Non-Opioid Modalities to Address Pain”, and H-95.922, “Substance Use and Substance Use Disorders.” (Reaffirm Current AMA Policy)

Your Reference Committee heard testimony that was largely supportive of the Council on Science and Public Health recommendations for opposing the scheduling of gabapentin. Testimony in support recognized the undue barriers in pain management that would arise by scheduling gabapentin along with added administrative burden. An amendment was offered to include the risks associated with gabapentin withdrawal as an important educational effort that your Reference Committee finds appropriate. Opposition to the recommendations of this report centered around the utility of inclusion of gabapentin in prescription drug monitoring databases in states where scheduling of gabapentin is already implemented. However, your Reference Committee was compelled by the supportive testimony over barriers to pain management access and thus, recommends that CSAPH Report 1 be adopted as amended.

(8) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 2 – IMPROVING RESEARCH STANDARDS, APPROVAL PROCESSES, AND POST-MARKET SURVEILLANCE STANDARDS FOR MEDICAL DEVICES

RECOMMENDATION A:

That the first recommendation of Council on Science and Public Health 2 be amended by deletion to read as follows:

1. Our AMA believes that to support innovation while protecting patient safety, approval pathways for medical devices should incorporate the following principles:
a. Evidence-based, measurable performance benchmarks, such as those used in the Safety and Performance Based Pathway, should be used wherever possible for classes of known, well-studied medical devices; and
b. For a subset of higher risk devices receiving approval but have not completed clinical trials, time-limited approvals may be appropriate, after which the manufacturer may be required to provide post-market data to support full device approval; and
c. Medical devices with known safety concerns should not be usable as predicate devices for the purposes of proving substantial equivalence. In the event safety concerns of predicate devices arise after approval has been granted, additional due diligence should be initiated as appropriate; and
d. Approval for medical devices should include criteria for adequate performance in racialized, minoritized, or otherwise historically excluded groups when feasible; and
~~e. Reports of adverse events for medical devices should always be available in a publicly accessible, searchable database such as the Manufacturer and User Facility Device Experience.~~

RECOMMENDATION B:

That Council on Science and Public Health Report 2 be adopted as amended and the remainder of the report be filed.

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

1. Our AMA believes that to support innovation while protecting patient safety, approval pathways for medical devices should incorporate the following principles:
a. Evidence-based, measurable performance benchmarks, such as those used in the Safety and Performance Based Pathway, should be used wherever possible for classes of known, well-studied medical devices; and
b. For a subset of higher risk devices receiving approval but have not completed clinical trials, time-limited approvals may be appropriate, after which the manufacturer may be required to provide post-market data to support full device approval; and
c. Medical devices with known safety concerns should not be usable as predicate devices for the purposes of proving substantial equivalence. In the event safety concerns of predicate devices arise after approval has been granted, additional due diligence should be initiated as appropriate; and
d. Approval for medical devices should include criteria for adequate performance in racialized, minoritized, or otherwise historically excluded groups; and
e. Reports of adverse events for medical devices should always be available in a publicly accessible, searchable database such as the Manufacturer and User Facility Device Experience. (New HOD Policy)

2. That Policy H-120.988, “Patient Access to Treatments Prescribed by Their Physicians”, supporting a physician’s right to prescribe medical devices off-label, be reaffirmed. (Reaffirm Current HOD Policy)

Testimony was mostly supportive, with an amendment to strike reference to adverse event databases which may receive unverified or unsubstantiated reports. As such, your Reference Committee recommends adoption as amended.

(9) RESOLUTION 502 - PAIN MANAGEMENT FOR LONG-ACTING REVERSIBLE CONTRACEPTION AND OTHER GYNECOLOGICAL PROCEDURES

RECOMMENDATION A:

That the first resolve of Resolution 502 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA recognizes that disproportionate care ~~the disparity~~ in pain management has been historically present in gynecological procedures and has multifactorial causes, including insurance coverage for pain management which contributes to disparate care in gynecologic procedures compared to procedures of similarly reported pain ~~and encourages discussion of pain control options, risks, and benefits with patients as a part of the shared decision making process~~ (New HOD Policy); and be it further

RECOMMENDATION B:

That Resolution 502 be amended by addition of a third resolve to read as follows:

Our AMA shall advocate for equitable insurance coverage for the placement of long-acting reversible contraceptives and other gynecological procedures, including associated pain management. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 502 be adopted as amended.

HOD ACTION: That Resolution 502 adopted as amended.

RESOLVED, That our AMA recognizes the disparity in pain management in gynecological procedures compared to procedures of similarly reported pain and encourages discussion of pain control options, risks, and benefits with patients as a part of the shared decision making process (New HOD Policy); and be it further

RESOLVED, That our AMA supports further research into evidence-based anesthetic and anxiolytic medication options for long-acting reversible contraception procedures and other gynecological procedures, including but not limited to colposcopy, endometrial biopsy, and LEEP procedures. (New HOD Policy)

Your Reference Committee heard overwhelming support for this resolution, particularly related to the multifactorial causes in disparities of pain management in gynecological procedures. An amendment was put forth and supported by several others highlighting the intersection of insurance coverage in this disparity. Your Reference Committee recommends Resolution 502 be adopted as amended.

(10) RESOLUTION 503 - INCREASING DIVERSITY IN STEM CELL BIOBANKS AND DISEASE MODELS

RECOMMENDATION A:

That the second resolve of Resolution 503 be amended by addition to read as follows:

RESOLVED, Our AMA amends Policy H-460.915, "Cloning and Stem Cell Research,"

Cloning and Stem Cell Research, H-460.915
Our AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) urges the use of stem cell lines from different race, ethnicities, and genetic ancestries in disease models; ~~(2)~~(3) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); ~~(3)~~(4) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); ~~(4)~~(5) encourages strong public support of federal funding for research involving human pluripotent stem cells and ~~(5)~~(6) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology; and be it further

RECOMMENDATION B:

That the third resolve of Resolution 503 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA strongly encourages institutional biobanks to collect ~~racially and ethnically diverse~~ samples diverse with respect to race, ethnicity, and genetic ancestry, such that future induced pluripotent stem cell disease models better represent the population.

RECOMMANDATION C:

That Resolution 503 be adopted as amended.

HOD ACTION: That Resolution 503 adopted as amended.

RESOLVED, That our AMA encourages research institutions and stakeholders to re-evaluate recruitment strategies and materials to encourage participation by underrepresented populations (New HOD Policy); and it be further

RESOLVED, Our AMA amends Policy H-460.915, "Cloning and Stem Cell Research,"
Cloning and Stem Cell Research, H-460.915
Our AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) urges the use of stem cell lines from different ethnicities in disease models; ~~(2)~~(3) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); ~~(3)~~(4) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); ~~(4)~~(5) encourages strong public support of federal funding for research involving human pluripotent stem cells and ~~(5)~~(6) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA strongly encourages institutional biobanks to collect racially and ethnically diverse samples such that future induced pluripotent stem cell disease models better represent the population. (New HOD Policy)

Your Reference Committee heard unanimous testimony in support of Resolution 503. An amendment that included an exception for mitochondrial diseases was offered that would have altered the intent of this Resolution and was thus not included. In addition, your Reference Committee proposes an amendment to better align with our AMA policy on language describing race, ethnicity, and genetic ancestry, while maintaining the thrust of the underlying resolution. Your Reference Committee recommends adoption as amended.

(11) RESOLUTION 507 - RECOGNIZING THE BURDEN OF RARE DISEASE

RECOMMENDATION A:

That the second resolve of Resolution 507 be amended by addition to read as follows:

RESOLVED, That our AMA support efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies and medical device companies to develop novel therapeutics and devices to better understand and treat orphan diseases. (New HOD Policy)

RECOMMENDATION B:

That Resolution 507 be amended by addition of a third resolve to read as follows:

RESOLVED, That our AMA support the study, approval, and coverage of implantable medical devices and therapeutics via FDA Humanitarian Device Exemption for treatment of orphan diseases. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 507 be adopted as amended.

HOD ACTION: Resolution 507 adopted as amended.

RESOLVED, That our American Medical Association recognize the under-treatment and under-diagnosis of orphan diseases, the burden of costs to health care systems and affected individuals, and the health disparities among patients with orphan diseases (New HOD Policy); and be it further

RESOLVED, That our AMA support efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies to develop novel therapeutics to better understand and treat orphan diseases. (New HOD Policy)

Your Reference Committee heard unanimous supportive testimony on this item. Testimony described how our AMA must stand up for patients, especially ones with orphan diseases that are underdiagnosed, undertreated, and underinsured. Speakers noted that patient registries need more support to promote long term monitoring. Amendments were proffered to recognize the treatment of rare diseases goes beyond drugs and encompasses medical devices, which your Reference Committee agreed was appropriate. Therefore, your Reference Committee recommends Resolution 507 be adopted as amended.

(12) RESOLUTION 508 - DEVELOPMENT AND IMPLEMENTATION OF RECOMMENDATIONS FOR RESPONSIBLE MEDIA COVERAGE OF OPIOID OVERDOSES

RECOMMENDATION A:

That Resolution 508 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association encourage the Centers for Disease Control and Prevention, in collaboration with other public and private ~~organizations~~ interested parties, to develop recommendations or best practices for media coverage and portrayal of opioid drug overdoses, including practices to prevent the spread of misinformation. (New HOD Policy)

RECOMMENDATION B:

That Resolution 508 be adopted as amended.

HOD ACTION: Resolution 508 adopted as amended.

RESOLVED, That our American Medical Association encourage the Centers for Disease Control and Prevention, in collaboration with other public and private organizations, to develop recommendations or best practices for media coverage and portrayal of opioid drug overdoses. (New HOD Policy)

Testimony for Resolution 508 was unanimous in support. The testimony noted that media coverage can stigmatize people who use substances. Testimony provided context that media reports often contain outdated and racialized language that is ill-informed, biased, and medically inaccurate. Speakers also noted that our AMA can help drive the public conversation towards evidence-based solutions and reporting on overdoses. Amendments were proffered to include collaboration with interested parties and to add language that includes encouraging practices to prevent the spread of misinformation. An additional, conflicting amendment was received which would move our AMA to a more active role, which was not included, since the current language aligns with similar AMA media policy. Therefore, your Reference Committee recommends that Resolution 508 be adopted as amended.

(13) RESOLUTION 513 - SUBSTANCE USE HISTORY IS MEDICAL HISTORY

RECOMMENDATION A:

That the first resolve of Resolution 513 be amended by addition to read as follows:

RESOLVED, That our American Medical Association support that substance use history, when indicated, is part of the medical history and should be documented in the medical history section of a patient's health record (New HOD Policy); and be it further

RECOMMENDATION B:

That the third resolve of Resolution 513 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA work with relevant parties ~~stakeholders~~, including experts in privacy and confidentiality, to advocate for electronic health record vendors to modify their software to allow for substance use history to be documented in the past medical history and to move the substance use history from the social history section of electronic health record technology with protections in place to meet privacy standards and regulations for substance use disorders records and without interfering with existing EHR screening and referral capabilities and functionality. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 513 be adopted as amended.

HOD ACTION: That Resolution 513 adopted as amended.

RESOLVED, That our American Medical Association support that substance use history is part of the medical history and should be documented in the medical history section of a patient's health record (New HOD Policy); and be it further

RESOLVED, That our AMA support that all medical schools train medical students to take a thorough and nonjudgmental substance use history as part of a patient's medical history (New HOD Policy); and be it further

RESOLVED, That our AMA work with relevant stakeholders to advocate for electronic health record vendors to modify their software to allow for substance use history to be

documented in the past medical history and to move the substance use history from the social history section of electronic health record technology. (Directive to Take Action)

Your Reference Committee heard mixed testimony for this item. Proponents noted that by increasing the visibility of both individual instances of substance use and substance use disorders, it would encourage providers to be more active and engaged with screening patients for future care. Additionally, they noted that improved charting of substance use and substance use disorders would improve data collection and potential billing. Others voiced concern regarding the privacy of patients, particularly in states with more restrictive laws regarding substance use. Finally, there were additional concerns around the potential stigmatizing effect of conflating individual instances of substance use with a diagnosis of substance use disorder. As such, your Reference Committee recommends adoption of the amended Resolution.

(14) RESOLUTION 514 - ADOLESCENT HALLUCINOGEN-ASSISTED THERAPY POLICY

RECOMMENDATION A:

That Resolution 514 be amended by addition and deletion to read as follows:

RESOLVED, that our AMA advocate against the use of any psychedelics or entactogenic compound (such as psilocybin or MDMA) to treat any psychiatric disorder except those which have received FDA approval or those prescribed inwithin the context of approved investigational studies (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate for continued research and therapeutic discovery into psychedelic and entactogenic agents with the same scientific integrity and regulatory standards applied to other promising therapies in medicine. (Directive to Take Action)

RECOMMENDATION B:

That Resolution 514 be adopted as amended.

RECOMMENDATION C:

That the title of Resolution 514 be changed to read as follows:

HALLUCINOGEN-ASSISTED THERAPY POLICY

HOD ACTION: That Resolution 514 be adopted as amended with a change in title.

HALLUCINOGEN-ASSISTED THERAPY POLICY

RESOLVED, that our AMA advocate against the use of psychedelics to treat any psychiatric disorder except within the context of approved investigational studies (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate for continued research and therapeutic discovery into psychedelic agents with the same scientific integrity and regulatory standards applied to other promising therapies in medicine. (Directive to Take Action)

Your Reference Committee heard mixed testimony regarding Resolution 514. While there was concern for improper and illicit use of these compounds, many noted that they may hold significant opportunity for medical treatments. As such, amendments were proffered to maintain access to medications when they are proven to be safe and effective while pushing back against improper use. The title was modified to remove reference to adolescent populations and reflect the testimony heard seeking protections for all patients. Your Reference Committee recommends adoption of the amended Resolution.

(15) RESOLUTION 516 - FASTING IS NOT REQUIRED FOR LIPID ANALYSIS

RECOMMENDATION A:

That Resolution 516 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association support the development of ~~develop~~ educational programs affirming that fasting is not required for routine screening via lipid analysis. (Directive to Take Action)

Recommendation B:

That Resolution 516 be adopted as amended.

Recommendation C:

That the title of Resolution 516 be changed to read as follows:

FASTING IS NOT REQUIRED FOR ALL LIPID ANALYSIS

HOD ACTION: That Resolution 516 adopted as amended with a change in title:

FASTING IS NOT REQUIRED FOR ALL LIPID ANALYSIS

RESOLVED, That our American Medical Association develop educational programs affirming that fasting is not required for lipid analysis. (Directive to Take Action)

Your Reference Committee heard testimony that was broadly supportive of Resolution 516. Testimony highlighted how fasting lipid testing restricts equitable access to lipid testing, for example, for individuals who struggle to make multiple trips to a laboratory for screening or struggle with fasting requirements. Testimony also noted that our AMA can support other educational efforts on the appropriateness of fasting for lipid testing for different indications. Your Reference Committee recommends adoption as amended.

(16) RESOLUTION 517 - GENETIC PREDISPOSITION AND HEALTHCARE DISPARITIES, INCLUDING CARDIOVASCULAR DISEASE IN SOUTH ASIANS RESIDING IN THE UNITED STATES

RECOMMENDATION A:

That Resolution 517 be amended by addition and deletion to read as follows:

RESOLVED, that our AMA support and advocate for additional NIH funding to study disparities in population health ~~due to genetic predispositions,~~ which lead to diseases with high morbidity such as cardiovascular disease in South Asian patients (Directive to Take Action); and be it further

RESOLVED, that our AMA encourage the development of collaborative partnerships with other organizations, institutions, policymakers, and interested parties ~~stakeholders~~ to reduce health disparities ~~arising from genetic predispositions~~ and any accompanying cultural and linguistic barriers, through the creation of educational campaigns and outreach programs. (New HOD Policy)

RECOMMENDATION B:

That Resolution 517 be adopted as amended.

RECOMMENDATION C:

That the title of Resolution 517 be changed to read as follows:

HEALTHCARE DISPARITIES, INCLUDING CARDIOVASCULAR DISEASE, IN SOUTH ASIANS RESIDING IN THE UNITED STATES

HOD ACTION: Resolution 517 adopted as amended with a change in title:

HEALTHCARE DISPARITIES, INCLUDING CARDIOVASCULAR DISEASE, IN SOUTH ASIANS RESIDING IN THE UNITED STATES

RESOLVED, that our AMA support and advocate for additional NIH funding to study disparities in population health due to genetic predispositions, which lead to diseases with high morbidity such as cardiovascular disease in South Asian patients (Directive to Take Action); and be it further

RESOLVED, that our AMA encourage the development of collaborative partnerships with other organizations, institutions, policymakers, and stakeholders to reduce health disparities arising from genetic predispositions and any accompanying cultural and linguistic barriers, through the creation of educational campaigns and outreach programs. (New HOD Policy)

Your Reference Committee heard unanimous support for this resolution as the health disparities in South Asians are under-recognized and under-researched. The Council on Science and Public Health proffered an amendment to reduce the risk of moving back towards racial essentialism by eliminating the language surrounding genetic predisposition, and instead opening research to all potential causes of this inequity. Therefore, your Reference Committee recommends that this Resolution be adopted as amended.

(17) RESOLUTION 521 - PREVENTING THE ELIMINATION OF CANNABIS FROM OCCUPATIONAL AND MUNICIPAL DRUG TESTING PROGRAMS

RECOMMENDATION A:

That Resolution 521 be <u>amended by addition and deletion</u> to read as follows:

RESOLVED, That our American Medical Association support the continued inclusion of cannabis metabolite analysis in <u>relevant</u> ~~all urine/hair/oral fluid~~ drug testing analysis performed for occupational and municipal purposes (pre-employment, post-accident, random and for-cause). (New HOD Policy)

RECOMMENDATION B:

That Resolution 521 be <u>adopted as amended</u>.

HOD ACTION: Resolution 521 <u>adopted as amended.</u>

RESOLVED, That our American Medical Association support the continued inclusion of cannabis metabolite analysis in all urine/hair/oral fluid drug testing analysis performed for occupational and municipal purposes (pre-employment, post-accident, random and for-cause). (New HOD Policy)

Your Reference Committee heard limited testimony regarding Resolution 521. It was noted in testimony that while occupational and municipal drug testing is meant to protect others, the use of the word “all” may be burdensome. Particularly due to cannabis metabolite testing limitations and conflicting state and federal regulations, employers may wish to exercise discretion over when and what to test for. Thus, your Reference Committee recommends adoption as amended.

RECOMMENDED FOR ADOPTION IN LIEU OF

(18) RESOLUTION 505 - IMPROVING ACCESS TO OPIOID ANTAGONISTS FOR VULNERABLE AND UNDERSERVED POPULATIONS
RESOLUTION 525 - DECRIMINALIZING AND DESTIGMATIZING PERINATAL SUBSTANCE USE TREATMENT

RECOMMENDATION:

That Alternate Resolution 505 be adopted in lieu of Resolutions 505 and 525.

DE-STIGMATIZATION AND MANAGEMENT OF SUBSTANCE USE DISORDERS

RESOLVED, That our AMA amend Policy H-420.950, "Substance Use Disorders During Pregnancy" by addition to read as follows:

Our AMA will:
(1) support brief interventions (such as engaging a patient in a short conversation, providing feedback and advice) and referral for early comprehensive treatment of pregnant individuals with opioid use and opioid use disorder (including naloxone or other overdose reversal medication education and distribution) using a coordinated multidisciplinary approach without criminal sanctions;
~~(1)~~ (2) oppose any efforts to imply that a positive verbal substance use screen, a positive toxicology test, or the diagnosis of substance use disorder during pregnancy automatically represents child abuse;
~~(2)~~ (3) support legislative and other appropriate efforts for the expansion and improved access to evidence-based treatment for substance use disorders during pregnancy;
~~(3)~~ (4) oppose the filing of a child protective services report or the removal of infants from their mothers solely based on a single positive prenatal drug screen without appropriate evaluation;
~~(4)~~ (5) advocate for appropriate medical evaluation prior to the removal of a child, which takes into account (a) the desire to preserve the individual's family structure, (b) the patient's treatment status, and (c) current impairment status when substance use is suspected;
(6) advocate that state and federal child protection

laws be amended so that pregnant people with substance use and substance use disorders are only reported to child welfare agencies when protective concerns are identified by the clinical team, rather than through automatic or mandated reporting of all pregnant people with a positive toxicology test, positive verbal substance use screen, or diagnosis of a substance use disorder. (Modify Current HOD Policy); and be it further

RESOLVED, That our American Medical Association amend Policy H-95.932, "Increasing Availability of Naloxone", by addition to read as follows:

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

1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone and other safe and effective overdose reversal medications, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone and other safe and effective overdose reversal medications delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone and other safe and effective overdose reversal medications .
3. Our AMA encourages physicians to co-prescribe naloxone and other safe and effective overdose reversal medications to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone and other safe and effective overdose reversal medications on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other healthcare professionals and others who are authorized to prescribe, dispense and/or administer naloxone and other safe and effective overdose reversal medications pursuant to state law.

6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone and other safe and effective overdose reversal medications to receive appropriate education to enable them to do so effectively.

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. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA amend D-95.987, "Prevention of Drug-Related Overdose" by addition to read as follows:

1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other safe and effective overdose reversal medications and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other safe and effective overdose reversal medications and other

harm reduction measures in preventing opioid and other drug-related overdose fatalities; and (d) will continue to monitor the progress of such initiatives and respond as appropriate.

2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug- related overdose; and (b) support the development of adjuncts and alternatives to naloxone to combat synthetic opioid-induced respiratory depression and overdose; and (c) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.

3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.

4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the possession, distribution, and use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.

5. Our AMA will implement an education program for patients with substance use disorder and their family/caregivers to increase understanding of the increased risk of adverse outcomes associated with having a substance use disorder and a serious respiratory illness such as COVID-19.

6. Our AMA supports efforts to increase access to fentanyl test strips and other drug checking supplies for purposes of harm reduction. (Modify Current HOD Policy); and be it further

RESOLVED, that our AMA study the feasibility, potential methodologies, and implications of early universal screening for substance use and substance use disorders during pregnancy.

HOD ACTION: Alternate Resolution 505 adopted in lieu of Resolutions 505 and 525

RESOLVED, That our American Medical Association amend Policy H-95.932, "Increasing Availability of Naloxone", by addition to read as follows:

Increasing Availability of Naloxone H-95.932

1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other healthcare professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.
6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.
7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
8. Our AMA supports the widespread implementation of easily accessible Naloxone rescue stations (public availability of Naloxone 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 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 naloxone to help prevent opioid-related overdose, especially in underserved communities and American Indian reservations. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA amend Policy H-420.950, “Substance Use Disorders During Pregnancy” by addition to read as follows:

Substance Use Disorders During Pregnancy H-420.950
Our AMA will: (1) oppose any efforts to imply that the diagnosis of substance use disorder during pregnancy represents child abuse; (2) support legislative and other appropriate efforts for the expansion and improved access to evidence-based treatment for substance use disorders during pregnancy; (3) oppose the removal of infants from their mothers solely based on a single positive prenatal drug screen without appropriate evaluation; ~~and~~ (4) advocate for appropriate medical evaluation prior to the removal of a child, which takes into account (a) the desire to preserve the individual’s family structure, (b) the patient’s treatment status, and (c) current impairment status when substance use is suspected, and (5) support universal opioid use screenings at prenatal care visits with early intervention, comprehensive naloxone use education and distribution for those who screen positive and following overdose-related emergency department visits. (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA amend D-95.987, "Prevention of Drug-Related Overdose" by addition to read as follows:

Prevention of Drug-Related Overdose D-95.987

1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug- related overdose fatalities; and (d) will continue to monitor the progress of such initiatives and respond as appropriate.

2.Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug- related overdose; ~~and~~ (b) support the development of adjuncts and alternatives to naloxone to combat synthetic opioid-induced respiratory depression and overdose; and (c) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.

3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.

4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the possession, distribution, and use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.

5. Our AMA will implement an education program for patients with substance use disorder and their family/caregivers to increase understanding of the increased risk of adverse outcomes associated with having a substance use disorder and a serious respiratory illness such as COVID-19.

6. Our AMA supports efforts to increase access to fentanyl test strips and other drug checking supplies for purposes of harm reduction. (Modify Current HOD Policy)

RESOLVED, That our AMA will advocate that prenatal and peripartum toxicology tests should not be obtained without the informed consent of the birthing parent, if they have capacity to provide consent.

Your Reference Committee heard robust testimony and received multiple amendments on these resolutions. The first and third resolves, related to access to naloxone and the development of adjuncts and alternatives, were unanimously supported. These resolves were clarified with broadening the language to acknowledge the growing market of synthetic agents as well as including other vulnerable populations. Most testimony was heard surrounding the complex issue of screening for substance use in the perinatal period particularly when paired with mandatory reporting requirements to child protective services. Your Reference Committee heard from the abundance of testimony that screening without criminal sanctions would be appropriate to support immediacy of treatment in this critical time as well as maintain the importance of the family bond. An amendment was proffered to study the feasibility and implications for universal screening

in perinatal patients. Therefore, your Reference Committee recommends alternate Resolution 505 be adopted in lieu of Resolutions 505 and 525.

(19) RESOLUTION 512 - WHEELCHAIRS ON AIRPLANES

RECOMMENDATION:

That Alternate Resolution 512 be adopted in lieu of Resolution 512.

RESOLVED, That our AMA advocate that Congress, the Federal Aviation Administration, and any other relevant parties make air travel accessibility accomodations for wheelchair users, including but not limited to aircraft modifications to allow wheelchair users to safely travel while remaining in their personal wheelchair. (Directive to Take Action)

HOD ACTION: Alternate Resolution 512 adopted in lieu of Resolution 512.

RESOLVED, That our AMA encourage Congress and the FAA to change the rules for commercial flights so that modifications must be made to planes to allow passengers whose only means of mobility is the wheelchair to stay in their personal wheelchairs during flight and while entering and exiting the plane. (New HOD Policy)

Your Reference Committee heard passionate testimony on Resolution 512. There were many who testified of their experiences and challenges traveling with personal wheelchairs, noting damage to their durable medical equipment, potential for personal harm from transfers required without their wheelchair, or emotional distress caused by missing wheelchairs. While there was additional testimony opposing this resolution with recommendation for referral, others noted pending legislation and a recent consensus study report from the National Academies of Science, Engineering, and Medicine on the feasibility of wheelchair securement on airplanes. As such, your Reference Committee recommends adoption of the Alternate Resolution.

(20) RESOLUTION 515 - RESOLUTION TO REGULATE KRATOM AND BAN OVER-THE-COUNTER SALES

RECOMMENDATION:

That Alternate Resolution 515 be adopted in lieu of Resolution 515.

REGULATION AND STUDY OF KRATOM

RESOLVED, That our American Medical association recommend the following:

1. **The safety and efficacy of kratom should be determined through research and clinical trials, and subsequently evaluated by the relevant regulatory entities for its appropriateness for ~~over-the-counter~~ sale and potential oversight via the Controlled Substances Act, before it can be marketed, purchased, or prescribed.**
2. **Individuals who are currently using kratom for pain management or other conditions should have access to appropriate medical care to manage their conditions and withdrawal symptoms, if needed.**
3. **Individuals who are using kratom only for personal use should not face criminal consequences.**
4. **Kratom should be regulated by the FDA, and its safety and efficacy should be determined through clinical trials before it can be marketed or prescribed as a treatment for any condition (New HOD Policy); and be it further**

RESOLVED, That Policy H-95.934, Kratom and Its Growing Use Within the United States, be rescinded.

HOD ACTION: Alternate Resolution 515 adopted in lieu of Resolution 515.

RESOLVED, that our American Medical Association recommends the following:
1. Kratom should be regulated by the FDA, and its safety and efficacy should be determined through clinical trials before it can be marketed or prescribed as a treatment for any condition.
2. Over-the-counter sales of kratom should be banned, and kratom should be available only by prescription from a licensed healthcare provider if it is deemed to have a medicinal use after proper research.
3. Individuals who are currently using kratom for pain management or other conditions should have access to appropriate medical care to manage their conditions and withdrawal symptoms, if needed.
4. Criminalization of kratom use should not be the intent of this resolution, and individuals who are using kratom for legitimate medical reasons should not be subject to

criminal penalties although if it is banned, this does not exclude criminalization of drug trafficking.
5. The Drug Enforcement Administration should conduct a comprehensive review of the potential for kratom abuse and dependence and consider appropriate scheduling under the Controlled Substances Act. A schedule 3 would make it unavailable over the counter but avoid criminal penalties.
6. Research funding should be made available to study the potential therapeutic uses and risks of kratom, and to develop evidence-based guidelines for its safe use.
7. Education and public awareness campaigns should be launched to inform healthcare providers, patients, and the general public about the potential risks and benefits of kratom and the need for caution in its use. (New HOD Policy)

Your Reference Committee heard extensive mixed testimony regarding kratom, and whether current AMA policy was appropriate. Testimony was heard supporting the need for further investigation of kratom's medicinal utility and misuse potential before it should be regulated, marketed, sold, or prescribed. Further, for those patients who may already be using kratom for personal use or self-treatment, testimony noted support for coordination of treatment and alignment with current policy related to the decriminalization of substance use. Therefore, your Reference Committee recommends rescinding current conflicting kratom policy and adopting the Alternate Resolution.

Kratom and its Growing Use Within the United States H-95.934
Our AMA supports legislative or regulatory efforts to prohibit the sale or distribution of Kratom in the United States which do not inhibit proper scientific research.

(21) RESOLUTION 519 - RESCHEDULING OR DESCHEDULING TESTOSTERONE

RECOMMENDATION:

That Alternate Resolution 519 be adopted in lieu of Resolution 519.

DECREASING REGULATORY BARRIERS TO APPROPRIATE TESTOSTERONE PRESCRIBING

RESOLVED, That the AMA ask the FDA to review the available evidence and other data on ~~the abuse potential of~~ testosterone and submit updated recommendations, if warranted, to the DEA, for its consideration of the scheduling of testosterone-containing drug products. (Directive to Take Action); and be it further

RESOLVED, That the AMA, pending FDA review and updated recommendation of scheduling, advocate to expand access to testosterone by decreasing state and health insurer regulatory requirements for testosterone prescribing, including but not limited to PDMP state database reporting, 30-day prescription supply limitations, mail delivery limitations, and telehealth access limitations. (Directive to Take Action)

HOD ACTION: That the first resolve of Alternate Resolution 519 adopted in lieu of Resolution 519 and that the second resolve of Alternate Resolution 519 be referred.

RESOLVED, That our American Medical Association urge the United States Drug Enforcement Administration to reschedule or deschedule testosterone as a Schedule III substance. (New HOD Policy)

Your Reference Committee heard broadly positive testimony regarding the increase in access to testosterone as related to Resolution 519. The Council on Legislation proffered an amendment to denote the procedure of working with the FDA and other regulatory bodies to evaluate the scheduling of testosterone products for action, which was supported in testimony by others. Additional amendments were also offered which noted the many other ways in which testosterone access is limited unnecessarily. Your Reference Committee clarified the additional amendments to keep consistent with respect for FDA's regulatory authority, while maintaining ability to advocate for improved access of testosterone. Thus, your Reference Committee recommends adoption of the Alternate Resolution 519.

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

(22) RESOLUTION 518 - DEFENDING NIH FUNDING OF ANIMAL MODEL RESEARCH FROM LEGAL CHALLENGES

RECOMMENDATION:

That policies H-460.979, H-460.957, H-460.932, H-460.953, and H-460.964 be reaffirmed in lieu of Resolution 518.

HOD ACTION: Policies H-460.979, H-460.957, H-460.932, H-460.953, and H-460.964 reaffirmed in lieu of Resolution 518.

RESOLVED, That our American Medical Association join other medical professional societies in an amicus brief supporting that National Institutes of Health's decision to fund grants to study sepsis in rodent animal models (Directive to Take Action); and be it further

RESOLVED, That our AMA reaffirm its support of the use of animal model research that abides by National Institutes of Health's ethical guides on the use of animals in research. (New HOD Policy)

Your Reference Committee heard mixed testimony on Resolution 518. Speakers noted that researchers do seek alternatives to animals when reasonable, and that our AMA should not seek to limit animal research since it is often the foundation of medical advances. Additional testimony noted that while there has been little success in finding new drug candidates for treating sepsis, animal models have revealed critical biochemical phenomena which advance our understanding of sepsis. Speakers who testified in opposition sought to reaffirm existing AMA policy, noting that more sophisticated models for human disease are needed, and that the majority of sepsis studies in rodents have failed. Our AMA has existing policy on the ethical standards of using animals in research and would not be barred from briefing a court if deemed appropriate. As such, your Reference Committee recommends that these several policies are reaffirmed in lieu of Resolution 518.

Use of Animals in Research H-460.979
(1) Researchers should include in their protocols a commitment to ethical principles that promote high standards of care and humane treatment of all animals used in research. Further, they should provide animal review committees with sufficient information so that effective review can occur. For their part, institutions should strengthen their animal review committees to provide effective review of all research protocols involving animals. (2) The appropriate and humane use of animals in biomedical research should not be unduly restricted. Local and national efforts to inform the public about the importance of the use of animals in research should be supported. (3) The development of suitable alternatives to the use of animals in research should be encouraged among investigators

and supported by government and private organizations. The selection of alternatives ultimately must reside with the research investigator.

Medical Research Involving Animals H-460.957
The AMA urges state and county medical societies to support the appropriate and humane use of animals in research and to help ensure the continued availability of animals for essential medical education and medical research; and reaffirms its support for the appropriate and compassionate use of animals in biomedical research programs.

Increased Public Education Regarding Animal Research H-460.932
Our AMA: (1) supports providing educational materials on the appropriate and compassionate use of animals in biomedical research to students of all grades from kindergarten through grade 12; (2) encourages physicians to work actively in their communities to introduce educational materials on the appropriate and compassionate use of animals in biomedical research into the curricula of all grades from kindergarten through grade 12; and (3) continues to oppose the use of violence, intimidation, and distortion by the opponents of the appropriate and compassionate use of animals in biomedical research.

Biomedical Research and Animal Activism H-460.953
Our AMA:
(1) supports working through Congress to oppose legislation which inappropriately restricts the choice of scientific animal models used in research and will work with Congress and the USDA to ensure that needs and views of patients and the scientific community are heard during any further consideration of USDA's role in laboratory animal oversight; and
(2) supports laws which make it a federal crime, and similar legislation at state levels to make it a felony, to trespass and/or destroy laboratory areas where biomedical research is conducted.

Use of Animals in Research H-460.964
Our AMA: (1) strongly reemphasizes its support for the humane use of animals in biomedical research in all educational institutions and research facilities; and (2) supports and promotes legislation that is favorable to biomedical research at local, state and national levels and continues to oppose restrictive legislation.

(23) RESOLUTION 522 - APPROVAL AUTHORITY OF THE FDA

RECOMMENDATION:

That policies H-100.948 and H-100.992 be <u>reaffirmed in lieu</u> of Resolution 522.

HOD ACTION: Policies H-100.948 and H-100.992 <u>reaffirmed in lieu</u> of Resolution 522.

RESOLVED, That our American Medical Association consider filing an amicus brief if a mifepristone-access case is formally heard at the Supreme Court to allow the Food and Drug Administration (FDA) to continue its mission of providing safe and effective drugs without political or ideological interference. (Directive to Take Action)

Testimony for Resolution 522 was universally supportive of the intent of the resolution but noted existing policies to the same effect. Several speakers noted that in the current political climate, some policies promoted by those without medical training threaten the physician-patient relationship. Speakers noted that our AMA should support the FDA in its continued mission as it has done in the past. However, testimony from the Council on Science and Public Health noted that our AMA has already fulfilled the directive of this resolution and has submitted an amicus brief in support of the FDA and mifepristone access in multiple courts, including the Supreme Court. Amicus briefs have been submitted in (1) Northern District of Texas (Amarillo Division) [Document 91-1, case 2:22-cv-00223-Z], (2) Court of Appeals for the Fifth Circuit [Document 111 of case 23-10362], and (3) the Supreme Court of the United States. Testimony suggested reaffirmation of current policy would prevent disrupting ongoing strong advocacy efforts. Therefore, your Reference Committee recommends reaffirming current AMA policy to continue supporting our AMA's ability to engage in these cases in the courts.

Supporting Access to Mifepristone (Mifeprex) H-100.948
Our AMA will support mifepristone availability for reproductive health indications, including via telemedicine, telehealth, and at retail pharmacies and continue efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone.

FDA H-100.992
1. Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
2. The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
3. It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history
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Madam Speaker, this concludes the report of Reference Committee E. I would like to thank Daniel Kerekes, MD, Alan Klitzke, MD, Reilly Bealer, MD, Raymond Lorenzoni, MD, Jennifer R. Rushton, MD, Raymond Tsai, MD, and all those who testified before the Committee.

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