DISCLAIMER

The following is a preliminary report of actions taken by the House of Delegates at its 2022 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-22)

Report of Reference Committee E

Kenneth M. Certa, MD, Chair

Your reference committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Council on Science and Public Health Report 3 - Correcting Policy H-120.958
2. Resolution 509 - Regulation and Control of Self-Service Labs
3. Resolution 510 - Evidence-Based Deferral Periods for MSM Corneas and Tissue Donors
4. Resolution 519 - Advanced Research Projects Agency for Health (ARPA-H)
5. Resolution 522 - Encouraging Research of Testosterone and Pharmacological Therapies for Post-Menopausal Individuals with Decreased Libido

RECOMMENDED FOR ADOPTION AS AMENDED

6. Resolution 501 - Marketing Guardrails for the “Over-Medicalization” of Cannabis Use
7. Resolution 502 - Ensuring Correct Drug Dispensing
8. Resolution 504 - Scientific Studies Which Support Legislative Agendas
9. Resolution 505 - CBD Oil Use and the Marketing of CBD Oil
10. Resolution 506 - Drug Manufacturing Safety
11. Resolution 512 - Scheduling and Banning the Sale of Tianeptine in the United States
12. Resolution 513 - Education for Patients on Opiate Replacement Therapy
13. Resolution 514 - Oppose Petition to the DEA and FDA on Gabapentin
14. Resolution 515 - Reducing Polypharmacy as a Significant Contributor to Senior Morbidity
15. Resolution 520 - Addressing Informal Milk Sharing
16. Resolution 521 - Encouraging Brain and Other Tissue Donation for Research and Educational Purposes
17. Resolution 524 - Increasing Access to Traumatic Brain Injury Resources in Primary Care Settings
18. Resolution 525 – Reforming the FDA Accelerated Approval Process
19. Resolution 526 – Adoption of Accessible Medical Diagnostic Equipment Standards

RECOMMENDED FOR ADOPTION IN LIEU OF

20. Resolution 503 - Pharmacy Benefit Managers and Drug Shortages
21. Resolution 508 - Supplemental Resources for Inflight Medical Kit
22. Resolution 511 - Over the Counter (OTC) Hormonal Birth Control
    Resolution 518 - Over-the-Counter Access to Oral Contraceptives
23. Resolution 516 - Oppose “Mild Hyperbaric” Facilities from Delivering Unsupported Clinical Treatments
    Resolution 517 - Safeguard the Public from Widespread Unsafe Use of “Mild Hyperbaric Oxygen Therapy”

RECOMMENDED FOR REFERRAL

24. Resolution 523 - Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices

Resolutions handled via the reaffirmation consent calendar:

- Resolution 507 - Federal Initiative to Treat Cannabis Dependence

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 – CORRECTING POLICY H-120.958

RECOMMENDATION:

Recommendation in Council on Science and Public Health Report 2 be adopted, and the rest of the report filed.

HOD ACTION: Recommendation in Council on Science and Public Health Report 2 adopted, and the rest of the report filed.

1. That Policy H 120.958, "Supporting Safe Medical Products as a Priority Public Health Initiative," be amended by addition and deletion to read as follows:

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent "look alike-sound alike" errors in giving new drugs generic names; (2) continue participation in efforts to advance the science of safety in the medication use process, including work with on the National Coordinating Council for Medication Error Reporting and Prevention; (3) support the FDA's Medwatch program by working to improve physicians' knowledge and awareness of the program and encouraging proper reporting of adverse events; (4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law 113-54), including provisions on product identification and verification, data sharing, detection and response, ~~and encourage efforts to create and expeditiously implement a national coding system for prescription medicine packaging~~ in an effort to improve patient safety; (5) participate in the work of the Healthy People 2030 initiative in the area of safe medical products especially as it relates to existing AMA policy and (~~5~~6) seek opportunities to work collaboratively with other stakeholders to provide information to individual physicians and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety.

Your Reference Committee heard limited testimony in support of CSAPH Report 3. Testimony noted that the policy changes contained within CSAPH Report 3 have previously been approved by HOD and the report seeks to rectify a drafting error. Therefore, your Reference Committee recommends CSAPH Report 3 be adopted.

(2) RESOLUTION 509 – REGULATION AND CONTROL OF SELF-SERVICE LABS

RECOMMENDATION:

Resolution 509 be adopted.

HOD ACTION: Resolution 509 adopted.

RESOLVED, That our American Medical Association study issues with patient-directed self-service testing, including the accreditation and licensing of laboratories that sell self-ordered tests and physician liability related to non-physician-ordered tests. (Directive to Take Action)

Your Reference Committee heard unanimously supportive testimony. Testimony described concerns regarding physician liability and burden associated with handling results from self-ordered tests, as well as potential for patient harm. Therefore, your Reference Committee recommends adoption as written.
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(3) RESOLUTION 510 – EVIDENCE-BASED DEFERRAL PERIODS FOR MSM CORNEAS AND TISSUE DONORS

RECOMMENDATION:

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

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

RESOLVED, That our American Medical Association amend current policy H-50.973, "Blood Donor Deferral Criteria," by addition and deletion as follows:

Blood <u>and Tissue</u> Donor Deferral Criteria
Our AMA: (1) supports the use of rational, scientifically-based ~~blood and tissue donation~~ deferral periods <u>for donation of blood, corneas, and other tissues</u> that are fairly and consistently applied to donors according to their individual risk; (2) opposes all policies on deferral of blood and tissue donations that are not based on evidence; (3) supports a blood <u>and tissue</u> donation deferral period for those determined to be at risk for transmission of HIV that is representative of current HIV testing technology; and (4) supports research into individual risk assessment criteria for blood <u>and tissue</u> donation (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA continue to lobby the United States Food and Drug Administration to use modern medical knowledge to revise its decades-old deferral criteria for MSM donors of corneas and other tissues. (Directive to Take Action)

Testimony for this resolution was supportive. Several speakers noted that our AMA supports evidence-based deferrals for other forms of donation and supported the idea of bringing outdated policy more in line with modern science. Speakers also noted the importance of corneal donations on reversing blindness and emphasized the low risk of HIV transmission within corneal donations. Therefore, your Reference Committee recommends that Resolution 510 be adopted.

(4) RESOLUTION 519 – ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)

RECOMMENDATION:

Resolution 519 be <u>adopted</u>.

HOD ACTION: Resolution 519 adopted.

RESOLVED, That our American Medical Association urge Congress and the Administration to ensure that while providing adequate funding for the promising research conducted at Advanced Research Projects Agency for Health (ARPA-H), it also provides robust annual baseline increases in appropriations for other research agencies, centers, and institutes, including, but not limited to, the NIH and NCI. (Directive to Take Action)

Testimony for Resolution 519 was supportive. The testimony noted that while ARPA-H funding is important, it will only be successful when combined with robust funding for the existing research agencies. They also described the need for an entity (similar to the Defense Advanced Research Projects Agency) that could identify innovation and build solutions to further support the health care field. Therefore, your Reference Committee recommends that Resolution 519 be adopted.

(5) RESOLUTION 522 – ENCOURAGING RESEARCH OF TESTOSTERONE AND PHARMACOLOGICAL THERAPIES FOR POST-MENOPAUSAL INDIVIDUALS WITH DECREASED LIBIDO

RECOMMENDATION:

Resolution 522 be adopted.

HOD ACTION: Resolution 522 adopted.

RESOLVED, That our AMA encourage expansion of research on the use of testosterone therapy and other pharmacological interventions in treatment of decreased libido in postmenopausal individuals. (Directive to Take Action)

Your Reference Committee heard testimony in support of Resolution 522. It was noted that research is still needed to understand the use of testosterone treatment in women. Testimony also noted that most of the testosterone treatments used have been approved in men and current literature is insufficient in addressing the possible benefits and harms in women. An amendment offered asked for our AMA to work with the FDA on approval of existing medications that treat decreased libido, but there was a lack of clarity as to which medications were considered and are dependent upon the research proposed. Your Reference Committee also stated that our AMA should focus on promoting research that will inform physicians about these treatments. Therefore, your Reference Committee recommends that Resolution 522 be adopted.

RECOMMENDED FOR ADOPTION AS AMENDED

(6) RESOLUTION 501 – MARKETING GUARDRAILS FOR THE "OVER-MEDICALIZATION" OF CANNABIS USE

RECOMMENDATION A:

That Resolution 501 be <u>amended by addition</u> of a second resolve to read as follows:

RESOLVED, That our AMA generate a formal letter for use by state medical societies requesting more direct oversight by state government of the marketing of cannabis. (Directive to Take Action)

RECOMMENDATION B:

That Resolution 501 be <u>amended by addition</u> of a third resolve to read as follows:

RESOLVED, That our AMA study marketing practices of cannabis, cannabis products and cannabis paraphernalia that influence vulnerable populations, such as children or pregnant people. (Directive to Take Action)

RECOMMENDATION C:

That existing Policy H-95.936, "Cannabis Warnings for Pregnant and Breastfeeding Women" be <u>reaffirmed</u>.

RECOMMENDATION D:

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

HOD ACTION: Resolution 501 <u>adopted as amended</u>.

RESOLVED, That our American Medical Association send a formal letter to the Food and Drug Administration and Federal Trade Commission requesting more direct oversight of the marketing of cannabis for medical use. (Directive to Take Action)

Testimony for Resolution 501 was unanimously supportive. Several individuals and delegations, particularly from states which have more permissive cannabis laws, noted the difficulty of dealing with the perception of cannabis for medical use. A significant portion of testimony focused on the complicated status of cannabis regulation, including whether the FDA or FTC had the regulatory authority to achieve the goals of the proposed resolution. Other speakers noted that our AMA's Cannabis Task Force is currently active in this space and may be a useful resource for clarifying some uncertainties within the legal landscape around cannabis. Testimony was focused on the need for further research on this topic, especially around marketing to children, pregnant women, and other vulnerable populations.

One speaker noted that the responsibility for these falls to each state and called for coordination among state medical societies. Your Reference Committee agrees that the marketing of cannabis for medical use is of concern, especially regarding vulnerable populations, and suggests further research be conducted to better understand the current practices. Therefore, your Reference Committee additionally suggests reaffirmation of H-95.936 (Cannabis Warnings for Pregnant and Breastfeeding Women) and to adopt Resolution 501 as amended.

(7) RESOLUTION 502 – ENSURING CORRECT DRUG DISPENSING

RECOMMENDATION A:

Resolution 502 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association ~~request that~~ work with the United States Food and Drug Administration, ~~work with~~ the pharmaceutical and pharmacy industries, state boards of pharmacy, patient advocacy groups, and standards-setting organizations to ~~facilitate the ability~~ evaluate the feasibility of pharmacies ~~to ensure that~~ including a color photo of a prescribed medication and information about its dosage with ~~is attached to~~ the sales receipt to ensure that the drug dispensed is that which has been prescribed. (Directive to Take Action)

RECOMMENDATION B:

Resolution 502 be adopted as amended.

HOD ACTION: Resolution 502 adopted as amended.

RESOLVED, That our American Medical Association request that the United States Food and Drug Administration work with the pharmaceutical and pharmacy industries to facilitate the ability of pharmacies to ensure that a color photo of a prescribed medication and its dosage is attached to the sales receipt to ensure that the drug dispensed is that which has been prescribed. (Directive to Take Action)

Testimony on Resolution 502 was largely supportive of the effort to reduce prescription errors. Some questioned the economics of the approach proposed, including concerns that prescription drug prices could be impacted, and if color photos would be a cost-effective measure. They also added that many insurance companies may require filling of substitutes rather than what the patient discussed with their physician, which would reduce the patient's ability to catch dispensing errors without visual aids. Some speakers did not want to put the burden on patients to confirm the correct medication was dispensed and were not clear on how this would work for medications other than pills/tablets (ie, creams). Additionally, it was noted that it is not solely the FDA's decision to facilitate the addition of photos on sales receipts. Your Reference Committee agrees that a photo could reduce errors but recognizes

there are additional decision makers that would need to be included in discussions. Therefore, your Reference Committee supports Resolution 502 with amendments specifically facilitating a discussion with the FDA, state boards, pharmacists, and other stakeholder groups.

(8) RESOLUTION 504 – SCIENTIFIC STUDIES WHICH SUPPORT LEGISLATIVE AGENDAS

RECOMMENDATION A:

Resolution 504 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association continue and expand its efforts to work with allied groups, health care policy influencers such as think tanks, and entities that can produce high quality scientific evidence, to help generate ~~support for~~ data to inform our ~~the~~ AMA's key advocacy goals. (Directive to Take Action)

RECOMMENDATION B:

Resolution 504 be adopted as amended.

HOD ACTION: Resolution 504 adopted as amended.

RESOLVED, That our American Medical Association continue and expand its efforts to work with allied groups, health care policy influencers such as think tanks, and entities that can produce high quality scientific evidence, to help generate support for the AMA's key advocacy goals. (Directive to Take Action)

Your Reference Committee heard limited testimony on Resolution 504. One amendment was proffered to strengthen the language by ensuring the generation of data to inform our AMA's advocacy goals. Your Reference Committee agreed with this amendment, noting that it is in alignment with our AMA's previous policy on evidence-based goals. Therefore, your Reference Committee recommends that Resolution 504 be adopted as amended.

(9) RESOLUTION 505 – CBD OIL USE AND THE MARKETING OF CBD OIL

RECOMMENDATION A:

That the second resolve of Resolution 505 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA support legislation and regulatory actions at the federal and state level to prohibit companies from selling CBD products if they make any unproven health and therapeutic claims~~, and to require companies to include a Food and Drug Administration-approved warning on CBD product labels~~. (New HOD Policy)

RECOMMENDATION B:

That Resolution 505 be adopted as amended.

HOD ACTION: Resolution 505 adopted as amended.

RESOLVED, That our American Medical Association support banning the advertising of cannabidiol (CBD) as a component of marijuana in places that children frequent (New HOD Policy); and be it further

RESOLVED, That our AMA support legislation to prohibit companies from selling CBD products if they make any unproven health and therapeutic claims, and to require companies to include a Food and Drug Administration-approved warning on CBD product labels. (New HOD Policy)

Testimony was roundly supportive, with minimal opposition. Testimony noted the similarities between the practices observed in advertisements targeting children and other forms of medical misinformation. Testimony noted a lack of evidence supporting CBD products with the exception of one FDA-approved CBD medication for narrow indications. Supportive speakers noted that CBD myth-debunking is a time-consuming activity for physicians, and that marketing that could influence children is particularly concerning. Testimony relayed from the FDA noted that CBD oil is not regulated as a dietary supplement because it is excluded from the dietary supplement definition. Following consideration of testimony and discussion of the complex regulatory environment related to CBD products, your Reference Committee recommends amended language to the second resolved clause to support legislative or regulatory actions at the federal and state level to prohibit companies from selling CBD products that make unproven medical claims. Your Reference Committee recommends that Resolution 505 be adopted as amended.

(10) RESOLUTION 506 – DRUG MANUFACTURING SAFETY

RECOMMENDATION A:

That the first resolve of Resolution 506 be amended by addition and deletion to read as follows:

RESOLVED, That our American Medical Association support efforts to ensure that the U.S. Food and Drug Administration (FDA) resumes inspections of ~~safety testing for~~ all drug manufacturing facilities on a frequent and rigorous basis, as done in the past (Directive to Take Action); and be it further

RECOMMENDATION B:

That the second resolve of Resolution 506 be amended by addition to read as follows:

RESOLVED, That our AMA call for the FDA to: (a) assure ~~reaffirm~~ the safety of the manufacture of drugs ~~and~~, drug ingredients and precursors; (b) work proactively with industry to prevent or minimize drug shortages; (c) work with industry to oversee the adequacy of product ~~volume~~ in the pipeline. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 506 be adopted as amended.

HOD ACTION: Resolution 506 adopted as amended.

RESOLVED, That our American Medical Association support efforts to ensure that the U.S. Food and Drug Administration (FDA) resumes safety testing for all drug manufacturing facilities on a frequent and rigorous basis, as done in the past (Directive to Take Action); and be it further

RESOLVED, That our AMA call for the FDA to reaffirm the safety of the manufacture of drugs and the adequacy of volume in the pipeline. (Directive to Take Action)

In-person testimony was unanimously supportive. The FDA offered amendments modifying the language about "safety testing" and adding language to the second resolve regarding working proactively to prevent and minimize drug shortages. An additional amendment was offered to broaden the scope of the resolution beyond pharmaceuticals to include chemical substrates. Therefore, your Reference Committee recommends the adoption of this resolution as amended.

(11) RESOLUTION 512 – SCHEDULING AND BANNING THE SALE OF TIANEPTINE IN THE UNITED STATES

RECOMMENDATION A:

That the first resolve of Resolution 512 be deleted.

RECOMMENDATION B:

That the second resolve of Resolution 512 be amended by addition to read as follows:

RESOLVED, That our AMA advocate to ban the sale of Tianeptine directly to the public in the absence of research into the safety and efficacy of the substance. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 512 be adopted as amended.

RECOMMENDATION D:

That the title of Resolution 512 be changed to read as follows:

BANNING THE SALE OF TIANEPTINE TO THE PUBLIC IN THE UNITED STATES

HOD ACTION: Resolution 512 be adopted as amended with a change in title.

BANNING THE SALE OF TIANEPTINE TO THE PUBLIC IN THE UNITED STATES

RESOLVED, That our American Medical Association advocate to schedule Tianeptine as Schedule II whilst supporting research into the safety and efficacy of the substance (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate to ban the sale of Tianeptine directly to the public. (Directive to

Testimony was supportive of Resolution 512. Speakers clarified that tianeptine could not be scheduled unless it is approved by the FDA for medical use. The authors of the resolution stated that there are various technical aspects to scheduling a drug but supported efforts by the Reference Committee to take action to remove this drug from public sales as it is easily made available and regularly abused, especially by children. Your Reference Committee agrees with the concern regarding tianeptine. Therefore, your Reference Committee recommends adoption of Resolution 512 as amended with a change in title.

(12) RESOLUTION 513 – EDUCATION FOR PATIENTS ON OPIATE REPLACEMENT THERAPY

RECOMMENDATION A:

That Resolution 513 be amended by addition and deletion to read as follows:

5. Our AMA implement an education program for patients with substance use disorder ~~on opiate replacement therapy~~ and their family/caregivers to increase understanding of the increased risk of adverse outcomes associated with having a substance use disorder and ~~their increased risk of death with concurrent opiate maintenance therapy and the onset of~~ a serious respiratory illness such as COVID-19 ~~SARS-CoV-2~~. (Modify Current HOD Policy)

RECOMMENDATION B:

That Resolution 513 be adopted as amended.

HOD ACTION: Resolution 513 adopted as amended.

RESOLVED, That our American Medical Association amend Policy 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 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) 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 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 implement an education program for patients on opiate replacement therapy and their family/caregivers to increase understanding of their increased risk of death with concurrent opiate maintenance therapy and the onset of a serious respiratory illness such as SARS-CoV-2. (Modify Current HOD Policy)

Your Reference Committee heard mixed testimony on Resolution 513. There was testimony noting that this resolution could give the impression that medication for an opioid use disorder (MOUD) increases the risk of death with a concurrent respiratory illness (such as COVID-19), when in fact, an individual with an untreated substance use disorder is at higher risk, and such statements may discourage individuals from seeking beneficial MOUD. Opposition noted that the language in this resolution should be updated to use less stigmatizing terminology of MOUD rather than opioid replacement therapy. Amendments were proffered to support education on the increased risk of adverse outcomes associated with having SUD and respiratory illness. Your Reference Committee agreed with these amendments, noting that the amended language is in alignment with the less stigmatizing language in current AMA policy. Your Reference Committee acknowledges that the original resolution title contains outdated language but that this resolution modifies already titled policy, and as such it will not be contained in the policy database. Therefore, your Reference Committee recommends that Resolution 513 be adopted as amended.

(13) RESOLUTION 514 – OPPOSE PETITION TO THE DEA AND FDA ON GABAPENTIN

RECOMMENDATION A:

That Resolution 514 be amended by addition of a third resolve to read as follows:

RESOLVED, That our American Medical Association 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.

RECOMMENDATION B:

That Resolution 514 be adopted as amended.

RECOMMENDATION C:

That the title of Resolution 514 be changed:

OPPOSING SCHEDULING OF GABAPENTIN

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

OPPOSING SCHEDULING OF GABAPENTIN

RESOLVED, our American Medical Association 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 of the Controlled Substances Act; and be it further

RESOLVED, our American Medical Association 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.

Your Reference Committee heard a great deal of testimony in support of Resolution 514, which opposes the scheduling of gabapentin and its salts. Speakers testified that some states have already classified gabapentin as a Schedule V substance, which limits prescriptions to 30 days or less, but some testified that this did not notably reduce access in a state with Schedule V status. Others noted that gabapentin is one of the only non-opioid pain therapies available to clinicians. Testimony highlighted the number of clinical settings in which gabapentin has been used safely and is a critical tool for physicians in their practice. Many testifying in support noted the clinical value of gabapentin for treating both chronic and acute pain and reducing the dose of opioids. Supporters expressed that scheduling gabapentin would create unnecessary barriers for patients. Some testimony also noted the benefits of having gabapentin appear in Prescription Drug Monitoring Programs, however substances

can appear in a PDMP without being scheduled. An amendment was proffered for an additional resolve calling for a study of off-label use and the risks and benefits in the general population and among those with substance use disorders. Therefore, your Reference Committee agrees with the proposed amendment and recommends adoption of Resolution 514 as amended.

(14) RESOLUTION 515 – REDUCING POLYPHARMACY AS A SIGNIFICANT CONTRIBUTOR TO SENIOR MORBIDITY

RECOMMENDATION A:

That the third resolve of Resolution 515 be amended by deletion to read as follows:

RESOLVED, That our AMA work with other stakeholders and EHR vendors to address the continuing problem of inaccuracies in medication reconciliation and propagation of such inaccuracies in electronic health records~~, and to include non-prescription medicines in medication compatibility screens~~. (Directive to Take Action)

RECOMMENDATION B:

That Resolution 515 be amended by addition of a fourth resolve to read as follows:

RESOLVED, That our AMA work with other stakeholders and EHR vendors to include non-prescription medicines and supplements in medication lists and compatibility screens. (Directive to Take Action)

RECOMMENDATION C:

That Resolution 515 be adopted as amended.

HOD ACTION: Resolution 515 adopted as amended.

RESOLVED, That our American Medical Association work with other organizations e.g., AARP, other medical specialty societies, PhRMA, and pharmacists to educate patients about the significant effects of all medications and most supplements, and to encourage physicians to teach patients to bring all medications and supplements or accurate, updated lists including current dosage to each encounter (Directive to Take Action); and be it further

RESOLVED, That our AMA along with other appropriate organizations encourage physicians and ancillary staff if available to initiate discussions with patients on improving their medical care through the use of only the minimal number of medications (including prescribed or over-the-counter, including vitamins and supplements) needed to optimize their health (Directive to Take Action); and be it further

RESOLVED, That our AMA work with other stakeholders and EHR vendors to address the continuing problem of inaccuracies in medication reconciliation and propagation of such inaccuracies in electronic health records, and to include non-prescription medicines in medication compatibility screens. (Directive to Take Action)

Your Reference Committee heard testimony largely in support of the effort to reduce the problem of polypharmacy. Several speakers spoke to the problems faced by the senior population when dealing with multiple prescriptions all with unique dosing regimens, often prescribed by more than one physician. In addition, several speakers noted the added complexity from over-the-counter herbs and supplements which are often not considered in the traditional polypharmacy discussion. Much of the testimony was particularly supportive of the third resolve, calling for improved electronic health record tools to help manage this problem. Amendments were offered to split a resolve for increased clarity. Your Reference Committee therefore recommends Resolution 515 for adoption with amendments.

(15) RESOLUTION 520 – ADDRESSING INFORMAL MILK SHARING

RECOMMENDATION A:

That the first resolve of Resolution 520 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA encourage ~~discourage~~ the practice of breast ~~informal~~ milk sharing, and work with the appropriate stakeholders to develop standards that promote safe and equitable access ~~when said practice does not rise to health and safety standards comparable to those of milk banks, including but not limited to screening of donors and/or milk pasteurization~~; (New HOD Policy)

RECOMMENDATION B:

That the second resolve of Resolution 520 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA encourage ~~breast milk donation to regulated human milk banks instead of via informal means; (Directive to Take Action)~~ the education of patients about the potential risks of breast milk sharing when acceptable health and safety standards are not met (New HOD Policy) and be it further

RECOMMENDATION C:

That the third resolve of Resolution 520 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA supports further research into the status of breast milk donation in the U.S. and how rates of donation ~~for regulated human milk banks~~ may be improved. (New HOD Policy)

RECOMMENDATION D:

Resolution 520 be adopted as amended.

RECOMMENDATION E:

That the title of Resolution 520 be changed to read as follows:

BREAST MILK SHARING

HOD ACTION: Resolution 520 adopted as amended with a change in title.

BREAST MILK SHARING

RESOLVED, That our AMA discourage the practice of informal milk sharing when said practice does not rise to health and safety standards comparable to those of milk banks, including but not limited to screening of donors and/or milk pasteurization; (New HOD Policy) and be it further

RESOLVED, That our AMA encourage breast milk donation to regulated human milk banks instead of via informal means; (Directive to Take Action) and be it further

RESOLVED, That our AMA supports further research into the status of milk donation in the U.S. and how rates of donation for regulated human milk banks may be improved. (New HOD Policy)

Your Reference Committee heard mixed testimony on Resolution 520. Testimony noted that this resolution is backdropped by an ongoing infant formula shortage. Testimony in support noted that during the formula shortage, parents may be more susceptible to predatory actors or turn to questionably sourced milk. Some argued that at a time in which parents are struggling to find formula and feed their infants, our AMA should be offering solutions. Additional testimony noted that milk procured from milk banks is often prohibitively expensive and risks deepening health inequity for those that cannot afford it. Your Reference Committee considered several amendments to address the concerns and preserves the intent of the resolution. Therefore, your Reference Committee recommends that Resolution 520 be adopted as amended.

(16) RESOLUTION 521 – ENCOURAGING BRAIN AND OTHER TISSUE DONATION FOR RESEARCH AND EDUCATIONAL PURPOSES

RECOMMENDATION A:

That the first resolve of Resolution 521 be amended by deletion to read as follows:

RESOLVED, That our AMA support the production and distribution of educational materials regarding the importance of ~~postmortem~~ tissue donation for the purposes of medical research and education; (Directive to Take Action) and be it further

RECOMMENDATION B:

That the second resolve of Resolution 521 be amended by addition to read as follows:

RESOLVED, That our AMA encourage the inclusion of additional information and informed consent options for brain and other tissue donation for research purposes on appropriate donor documents; (Directive to Take Action) and be it further

RECOMMENDATION C:

That the fourth resolve of Resolution 521 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA encourage efforts to facilitate recovery, transportation and storage of ~~postmortem~~ tissue, including brain tissue, for research and education purposes. (Directive to Take Action)

RECOMMENDATION D:

That Resolution 521 be adopted as amended.

HOD ACTION: Resolution 521 adopted as amended.

RESOLVED, That our AMA support the production and distribution of educational materials regarding the importance of postmortem tissue donation for the purposes of medical research and education; (Directive to Take Action) and be it further

RESOLVED, That our AMA encourage the inclusion of additional information and consent options for brain and other tissue donation for research purposes on appropriate donor documents; (Directive to Take Action) and be it further

RESOLVED, That our AMA encourage all persons to consider consenting to tissue donation including brain tissue for research purposes; (Directive to Take Action) and be it further

RESOLVED, That our AMA encourage efforts to facilitate recovery of postmortem tissue including brain tissue for research and education purposes. (Directive to Take Action)

Your Reference Committee heard mixed testimony mostly in support of Resolution 521. It was noted that the use of brain and other tissues helps advance scientific studies. Some testimony stated that there is a lack of infrastructure to ensure appropriate distribution and storage of donated tissue and noted that the costs for this infrastructure should be considered. Testimony also noted that the resolution should be inclusive of all tissues, including tissue used for transplantation. Your Reference Committee agreed with this inclusion and amended the language to remove the mention of postmortem tissue. Therefore, your Reference Committee recommends that Resolution 521 be adopted as amended.

(17) RESOLUTION 524 – INCREASING ACCESS TO TRAUMATIC BRAIN INJURY RESOURCES IN PRIMARY CARE SETTINGS

RECOMMENDATION A:

That the second resolve of Resolution 524 be amended by addition to read as follows:

RESOLVED, That our AMA supports increased access to currently available traumatic brain injury resources in primary care settings which advocate for early intervention, encourage follow-up retention of patients for post-injury rehabilitation, and improved patient quality of life. (New HOD Policy)

RECOMMENDATION B:

That Resolution 524 be amended by addition of a third resolve to read as follows:

RESOLVED, That our AMA work with relevant stakeholders to develop and distribute evidence-based guidelines for traumatic brain injury care in primary care settings.

RECOMMENDATION C:

That Resolution 524 be adopted as amended.

HOD ACTION: Resolution 524 adopted as amended.

RESOLVED, That our AMA recognize disparities in the care for traumatic brain injuries, and acknowledge non-athletic traumatic brain injuries as a significant cause of morbidity and mortality, particularly for ethnic minorities and victims of domestic violence; (New HOD Policy) and be it further

RESOLVED, That our AMA supports increased access to traumatic brain injury resources in primary care settings which advocate for early intervention, encourage follow-up retention of patients for post-injury rehabilitation, and improved patient quality of life. (New HOD Policy)

Your Reference Committee heard mixed testimony. All speakers agreed that resources should be disseminated to primary care providers (PCP), especially given the increasing number of non-athletic patients being seen within PCP offices. This includes those in rural settings, survivors of domestic abuse, patients with long-term TBI, and those in minoritized populations. Some testimony expressed concern that they were unaware of any available evidence-based resources, which led to your Reference Committee recommending an additional resolve to address this gap. Speakers in support of this resolution were able to identify several current resources that are available for dissemination, which were confirmed by your Reference Committee. Your Reference Committee also recognizes the limited data in this area and supports working with stakeholders to develop additional evidence-based guidelines. Therefore, your Reference Committee recommends Resolution 524 be adopted with amendments.

(18) RESOLUTION 525 – REFORMING THE FDA ACCELERATED APPROVAL PROCESS

RECOMMENDATION A:

That the first resolve of Resolution 525 be amended by addition and deletion to read as follows:

RESOLVED, That our AMA supports mechanisms to address issues in the Food & Drug Administration (FDA)'s Accelerated Approval process, including but not limited to: efforts to ameliorate delays in post-marketing confirmatory study timelines and~~, the creation of expiration dates for accelerated approvals,~~ protocols for the withdrawal of approvals when post-marketing studies fail~~, justifications for the use of surrogate endpoints used to demonstrate clinical benefit, and special considerations for certain diseases~~; and be it further

RECOMMENDATION B:

That Resolution 525 be adopted as amended.

HOD ACTION: That Resolution 525 adopted as amended.

RESOLVED, Our AMA supports mechanisms to address issues in the Food & Drug Administration (FDA)'s Accelerated Approval process, including but not limited to: efforts to ameliorate delays in post-marketing confirmatory study timelines, the creation of expiration dates for accelerated approvals, protocols for the withdrawal of approvals when post-marketing studies fail, justifications for the use of surrogate endpoints used to demonstrate clinical benefit, and special considerations for certain diseases; and be it further

RESOLVED, Our AMA will support specific solutions to issues in the FDA's Accelerated Approval process if backed by evidence that such solutions would not adversely impact the likelihood of investment in novel drug development.

Your Reference Committee heard mixed testimony regarding this resolution. An amendment to the first resolved clause was suggested striking certain phrases that could be overly prescriptive, which was generally supported. Speakers also noted that federal rulemaking will be underway prior to the next AMA Interim meeting, so there is an urgent timeline to adopt a resolution if our AMA wishes to engage in advocacy on this issue. Therefore, your Reference Committee recommends adopting Resolution 525 as amended.

(19) RESOLUTION 526 – ADOPTION OF ACCESIBLE MEDICAL DIAGNOSTIC EQUIPMENT STANDARDS

RECOMMENDATION A:

Resolution 526 be amended by addition and deletion to read as follows:

That our American Medical Association support ~~the enforcement of~~ evidence-based federal accessibility standards for medical diagnostic equipment, as well as grants, tax incentives and deductions that help physicians implement these standards.

RECOMMENDATION B:

Resolution 526 be adopted as amended.

HOD ACTION: 529 adopted as amended.

RESOLVED, That our AMA support the enforcement of proposed federal accessibility standards for medical diagnostic equipment, as well as tax incentives and deductions that help physicians implement these standards.

Your Reference Committee heard mixed testimony on Resolution 526. Speakers expressed the need for diagnostic medical care to be accessible. Speakers expressed concerns regarding resultant costs to physician practices, and that language supporting enforcement of standards could be detrimental. An amendment was proffered striking the "enforcement" terminology in favor of evidence-based federal accessibility standards and suggesting the addition of grants as an additional means to help physicians implement accessibility standards. Your Reference Committee recommends this resolution be adopted as amended.

RECOMMENDED FOR ADOPTION IN LIEU OF

(20) RESOLUTION 503 – PHARMACY BENEFIT MANAGERS AND DRUG SHORTAGES

RECOMMENDATION:

That Alternate Resolution 503 be <u>adopted in lieu</u> of Resolution 503.

RESOLVED, That our American Medical Association amend current policy H-100.956, "National Drug Shortages" by addition to read as follows:

5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations <u>and pharmacy benefit managers</u> on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.

6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing Organization (GPO), <u>pharmacy benefit managers,</u> and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers.

HOD ACTION: Alternate Resolution 503 <u>adopted in lieu</u> of Resolution 503.

RESOLVED, That our American Medical Association conduct a study which will investigate the role pharmacy benefit managers play in drug shortages. (Directive to Take Action)

Your Reference Committee heard testimony mostly in support of Resolution 503. It was noted that it has been a long-standing interest of our AMA to monitor both drug shortages and the oversight of pharmacy benefit managers, because drug shortages are a public health crisis that negatively impacts patient care. The Council on Science and Public Health testified they report on drug shortages yearly and can include the role of PBMs in their I-22 report. Your Reference Committee noted that studying the role of PBMs is necessary and should be included in CSAPH annual reports and supported amending existing AMA policy D-110.987 in lieu of Resolution 503 to reflect this. Therefore, your Reference Committee recommends that Alternate Resolution 503 be adopted.

National Drug Shortages H-100.956

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing Organization (GPO), and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers.
7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.

13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of global reporting requirements for indicators of drug shortages.
14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing.
15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.
16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

(21) RESOLUTION 508 – SUPPLEMENTAL RESOURCES FOR INFLIGHT MEDICAL KIT

RECOMMENDATION:

That Alternate Resolution 508 be adopted in lieu of Resolution 508.

RESOLVED, That our American Medical Association amend current policy H-45.981, "Improvement in US Airlines Aircraft Emergency Kits," by addition to read as follows:

1. Our AMA urges federal action to require all US air carriers to report data on in-flight medical emergencies, specific uses of in-flight medical kits and emergency lifesaving devices, and unscheduled diversions due to in-flight medical emergencies; this action should further require the Federal Aviation Administration to work with the airline industry and appropriate medical specialty societies to periodically review data on the incidence and outcomes of in-flight medical emergencies and issue recommendations regarding the contents of in-flight medical kits and the use of emergency lifesaving devices aboard commercial aircraft.

2. Our AMA will: (a) support the addition of naloxone to the airline medical kit; (b) encourage airlines to voluntarily include naloxone in their airline medical kits; and (c) encourage the addition of naloxone to the emergency medical kits of all US airlines (14CFR Appendix A to Part 121 - First Aid Kits and Emergency Medical Kits).

3. That our American Medical Association advocate for U.S. passenger airlines to carry standard pulse oximeters, automated blood pressure cuffs and blood glucose monitoring devices in their emergency medical kits.

HOD ACTION: That Alternate Resolution 508 adopted in lieu of Resolution 508.

RESOLVED, That our American Medical Association amend current policy H-45.981, "Improvement in US Airlines Aircraft Emergency Kits," by addition to read as follows:

1. Our AMA urges federal action to require all US air carriers to report data on in-flight medical emergencies, specific uses of in-flight medical kits and emergency lifesaving devices, and unscheduled diversions due to in-flight medical

emergencies; this action should further require the Federal Aviation Administration to work with the airline industry and appropriate medical specialty societies to periodically review data on the incidence and outcomes of in-flight medical emergencies and issue recommendations regarding the contents of in-flight medical kits and the use of emergency lifesaving devices aboard commercial aircraft.

2. Our AMA will: (a) support the addition of naloxone, epinephrine auto injector and glucagon to the airline medical kit; (b) encourage airlines to voluntarily include naloxone, epinephrine auto injector and glucagon in their airline medical kits; and (c) encourage the addition of naloxone, epinephrine auto injector and glucagon to the emergency medical kits of all US airlines (14CFR Appendix A to Part 121 - First Aid Kits and Emergency Medical Kits).

3. That our American Medical Association advocate for U.S. passenger airlines to carry standard pulse oximeters, automated blood pressure cuffs and blood glucose monitoring devices in their emergency medical kits.

RESOLVED, That our American Medical Association advocate for U.S. passenger airlines to carry standard pulse oximeters, automated blood pressure cuffs and blood glucose monitoring devices in their emergency medical kits. (Directive to Take Action)

Speakers emphasized the need to provide proper medical care for all patients which requires additional diagnostic equipment within inflight medical kits. Several speakers commented on the difficulty of taking blood pressure with a manual blood pressure device and a stethoscope given the noise level within an airplane, but additional equipment should be functioning and regularly maintained. The Reference Committee was reminded that there are many other factors the FAA considers when adding supplies to an airplane (ie, weight, size, training for crew). One speaker added, however, that the proposed resolution may be streamlined by amending existing policy (Improvement in US Airlines Aircraft Emergency Kits H-45.981) rather than creating a new standalone policy. Your Reference Committee recommends amendments to H-45.981 to include an automated blood pressure device, pulse oximeter, and glucometer in addition to current AMA policy within inflight medical kits in lieu of Resolution 508.

(22) RESOLUTION 511 – OVER THE COUNTER (OTC) HORMONAL BIRTH CONTROL
RESOLUTION 518 – OVER-THE-COUNTER ACCESS TO ORAL CONTRACEPTIVES

RECOMMENDATION:

Alternate Resolution 518 be adopted in lieu of Resolutions 511 and 518.

OVER-THE-COUNTER HORMONAL CONTRACEPTIVES

RESOLVED, That our American Medical Association amends policy D-75.995, "Over-the-Counter Access to Oral Contraceptives," by addition and deletion to read as follows:

Our AMA:

1. Encourages ~~manufacturers of oral contraceptives to submit the required application and supporting evidence to~~ the US Food and Drug Administration ~~for the Agency to consider approving~~ to approve a switch in status from prescription to over-the-counter for ~~such products~~ oral contraceptives, without age restriction.

2. Encourages the continued study of issues relevant to over-the-counter access for oral contraceptives.

3. Will work with expert stakeholders to advocate for the availability of hormonal contraception as an over-the-counter medication. (Modify Current HOD Policy)

HOD ACTION: Alternate Resolution 518 adopted in lieu of Resolutions 511 and 518.

Resolution 511
RESOLVED, That our American Medical Association recommend elimination of the requirement for a physician's prescription to purchase birth control pills (BCP) and over the counter (OTC) hormonal contraceptives and allow OTC purchase (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for the revocation of Food and Drug Administration and/or Congressional regulations requiring a prescription for OTC hormonal BCP. (Directive to Take Action)

Resolution 518
RESOLVED, That our American Medical Association amends policy D-75.995, "Over-the-Counter Access to Oral Contraceptives," by addition and deletion to read as follows:

Our AMA:

1. Encourages ~~manufacturers of oral contraceptives to submit the required application and supporting evidence to~~ the US Food and Drug Administration for the Agency to consider approving a to swiftly review and approve a switch in status from prescription to over-the-counter for ~~such products~~ oral contraceptives, without age restriction.

2. Encourages the continued study of issues relevant to over-the-counter access for oral contraceptives.

3. Will work with expert stakeholders to advocate for the availability of hormonal contraception as an over-the-counter medication. (Modify Current HOD Policy)

Your Reference Committee heard mostly supportive testimony on Resolutions 511 and 518. Testimony noted that the current political landscape is becoming increasingly restrictive of reproductive health, making access to OTC contraception imperative. Concern was noted that there are potential health risks for providing access to OTC contraception but stated that the benefits outweigh the potential harms. Testimony was supportive of adopting the language outlined in Resolution 518 and your Reference Committee agreed with this. Testimony also highlighted overwhelming support for the inclusion of access to OTC contraception without an age restriction; having an age requirement might limit access for people who do not have identification. Therefore, your Reference Committee recommends that Alternate Resolution 518 be adopted in lieu of Resolutions 511 and 518.

(23) RESOLUTION 516 – OPPOSE "MILD HYPERBARIC" FACILITIES FROM DELIVERING SUPPORTED CLINICAL TREATMENTS
RESOLUTION 517 – SAFEGUARD THE PUBLIC FROM WIDESPREAD UNSAFE USE OF "MILD HYPERBARIC OXYGEN THERAPY"

RECOMMENDATION:

That Alternate Resolution 516 be adopted in lieu of Resolutions 516 and 517.

OPPOSE UNSAFE USE OF "MILD HYPERBARIC THERAPY"

RESOLVED, That our American Medical Association oppose the operation of "mild hyperbaric facilities" unless and until effective treatments can be delivered in safely in facilities with appropriately trained staff including physician supervision and prescription and only when the intervention has scientific support or rationale. (New HOD Policy); and be it further

RESOLVED, That our AMA work with the U.S. Food and Drug Administration and other regulatory bodies to close facilities offering "mild hyperbaric therapy" until and unless they adopt and adhere to all established safety regulations, adhere to the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and adherent to applicable safety regulations. (Directive to Take Action)

HOD ACTION: That Alternate Resolution 516 adopted in lieu of Resolutions 516 and 517.

Resolution 516
RESOLVED, That our American Medical Association oppose the operation of "mild hyperbaric facilities" unless and until effective treatments can be delivered in safe facilities with appropriately trained staff including physician supervision and prescription and only when the intervention has scientific support or rationale. (New HOD Policy)

Resolution 517
RESOLVED, That our American Medical Association oppose the operation of unsafe "Mild Hyperbaric Facilities" (New HOD Policy); and be it further

RESOLVED, That our AMA work with the U.S. Food and Drug Administration and other regulatory bodies to close these facilities until and unless they adopt and adhere to all established safety regulations, adhere to the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and adherent to applicable safety regulations. (Directive to Take Action)

Testimony was unanimously supportive of these resolutions. Testimony noted several safety concerns of these facilities, such as inappropriate targeting of vulnerable populations, inappropriate dosing and delaying patients seeking proper treatment. As such, your Reference Committee recommends the alternate resolution be adopted in lieu of Resolutions 516 and 517.

RECOMMENDED FOR REFERRAL

RESOLUTION 523 – IMPROVING RESEARCH STANDARDS, APPROVAL PROCESSES, AND POST-MARKET SURVEILLANCE STANDARDS FOR MEDICAL DEVICES

RECOMMENDATION:

Resolution 523 be referred.

HOD ACTION: Resolution 523 referred.

RESOLVED, That our AMA support improvements to the Food and Drug Administration 510(k) exception to ensure the safety and efficacy of medical devices to: (a) make more stringent guidelines for which devices can qualify for the 510(k) exceptions; (b) mandate all 510(k) devices demonstrate equivalent or improved safety and effectiveness compared to market devices for the same clinical purpose; (Directive to Take Action) and be it further

RESOLVED, That our AMA support stronger post-market surveillance requirements of medical devices, including but not limited to (a): conditional approval of devices until sufficient post-market surveillance data determining device safety can be collected, followed by confirmatory trials, and (b) a publicly available summary of medical devices approved under expedited programs along with associated clinical trial data and list of reported adverse events; (Directive to Take Action) and be it further

RESOLVED, That our AMA amend policy H-100.992 to include medical devices by addition as follows:

FDA, H-100.992
+
1. Our AMA reaffirms its support for the principles that:

(a) an FDA decision to approve a new drug or medical device, to withdraw a drug or medical device's approval, or to change the indications for use of a drug or medical device 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 or medical device unless the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and post market reports shows that the drug or medical device is unsafe and/or ineffective for its labeled indications. (Modify Current HOD Policy)

Members testified that while supporting the underlying principles of reforming 510(k) medical device approval pathways to support patient safety, they felt that the language in the proffered resolution could be improved. Speakers voiced concern regarding the complexity of this issue.

Some speakers noted the potential for significant resultant costs that could be passed on to patients or physicians and noted that conditionally approved devices might be subject to less insurance coverage. An additional speaker questioned what is meant by "more stringent." Testimony was given that non-autonomous artificial intelligence software should be considered a medical device. Testimony also noted that all types of medical devices (examples provided included sunglasses, vision charts and splints) are not equivalent, and it may not be appropriate to apply the same requirements for safety and efficacy across the board. A speaker expressed concern regarding the potential negative impact that this resolution could have on smaller physician-owned medical device companies. Multiple speakers suggested referral of this resolution. Your Reference Committee agrees that this is an important issue but has a high level of complexity and recommends this resolution for referral.

Mister Speaker, this concludes the preliminary report of Reference Committee E. I would like to thank Druv Bhagavan, Mark A. Dobbertien, DO, Nancy Ann Ellerbroek, MD, Karl Napekoski, MD, Elizabeth Torres, MD, Raymond Tsai, MD, and all those who testified before the Committee as well as our AMA staff.

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