Preliminary Document of Reference Committee E

Kenneth M. Certa, MD, Chair

*Pursuant to Policy D-600.956, adopted at the November 2021 Special Meeting, commentary submitted to the online member forums will be used to generate a preliminary document to inform the discussion at the in-person reference committee hearings.*

**BUSINESS ASSIGNED TO REFERENCE COMMITTEE E**

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COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT

3 – CORRECTING POLICY H-120.958

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 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 (56) 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.

Preliminary testimony on CSAPH Report 3 was limited (less than 2 commenters) and unanimously supportive. The policy changes contained within CSAPH Report 3 have previously been approved by the House of Delegates and the report seeks to rectify a drafting error.

RESOLUTION 501 – MARKETING GUARDRAILS FOR THE “OVER-MEDICALIZATION” OF CANNABIS USE

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 supportive. Several individuals and delegations, particularly from states which have more permissive marijuana laws, noted the difficulty of dealing with the perception of cannabis and 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 commenters noted that the AMA’s Cannabis Task Force is currently active in this space and may be a useful resource for clarifying some misperceptions of the legal landscape around cannabis.

RESOLUTION 502 – ENSURING CORRECT DRUG DISPENSING

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)

Preliminary testimony on Resolution 502 was supportive of the effort to reduce prescription errors, but 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. Another commenter noted that pharmacies currently distribute generic information sheets and believes that the cost to add a photograph would be minimal. 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.

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

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)

Preliminary testimony for Resolution 503 was positive. Several testified to the long-standing interest of the AMA in monitoring both drug shortages and the oversight of pharmacy benefit managers. All who testified were supportive of the AMA studying the issue.

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

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)

Online testimony for Resolution 504 was limited and unanimously supportive.

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

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)
Online testimony on Resolution 505 was supportive. Testimony noted the similarities between the practices observed in advertisements targeting children and other forms of medical misinformation. Another member, however, questioned if the FDA had the regulatory authority to place warning labels for Schedule I drugs.

7) RESOLUTION 506 – DRUG MANUFACTURING SAFETY

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)

Preliminary online testimony for Resolution 506 was limited and unanimously supportive.

8) RESOLUTION 507 – FEDERAL INITIATIVE TO TREAT CANNABIS DEPENDENCE

RESOLVED, That our American Medical Association urge the National Institutes of Health to award appropriate incentive grants to universities, pharmaceutical companies and other capable entities to develop treatment options for cannabis dependence; and that the cost of these grants be financed by taxes on those who profit from selling cannabis. (New HOD Policy)

Online testimony was unanimously supportive. One commenter noted that the language used within the resolution may need to be updated from “cannabis dependence” to “cannabis use disorder”, which is the nomenclature used in the DSM-5.

9) RESOLUTION 508 – SUPPLEMENTAL RESOURCES FOR INFLIGHT MEDICAL KIT

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)

Resolution 508 received universally supportive online testimony, with one commenter noting that inflight medical kits have historically been outdated and often inadequate to provide the requisite emergency care. One commenter 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.
(10) RESOLUTION 509 – REGULATION AND CONTROL OF
SELF-SERVICE LABS

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)

Preliminary testimony was limited and unanimously positive.

(11) RESOLUTION 510 – EVIDENCE-BASED DEFERRAL PERIODS FOR MSM CORNEAS AND TISSUE DONORS

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

Blood and Tissue Donor Deferral Criteria
Our AMA: (1) supports the use of rational, scientifically-based blood and tissue donation deferral periods for donation of blood, corneas, and other tissues 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 and tissue 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 and tissue 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)

Preliminary testimony for this resolution was unanimously supportive. Several commenters noted that the AMA supports evidence-based deferrals for other forms of donation and supported the idea of bringing policy more in line with modern science.

(12) RESOLUTION 511 – OVER THE COUNTER (OTC) HORMONAL BIRTH CONTROL

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)
Testimony for this resolution was supportive, noting that the current political landscape is becoming increasingly restrictive of reproductive health, and it is likely that access to abortions will be dramatically reduced in the coming years, particularly for rural and low-income populations. Concern was noted that there are potential health risks but low enough to support the resolution.

(13) RESOLUTION 512 – SCHEDULING AND BANNING THE SALE OF TIANEPTINE 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 Take Action)

Online testimony was limited and unanimously supportive.

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

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)

Preliminary testimony for Resolution 513 was mixed. While some commenters testified in support of the resolution as written, others commented in opposition stating that the proposed 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). Compared to an individual with an untreated opioid use disorder, this is untrue, and may instead discourage people from seeking MOUD treatment. In addition, opposition noted that the language in the proposed resolution should be updated to use the preferred terminology of MOUD rather than opioid replacement therapy.

(15) RESOLUTION 514 – OPPOSE PETITION TO THE DEA AND FDA ON 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.

Preliminary testimony was in support of Resolution 514, which opposes the scheduling of gabapentin and its salts. Commenters testified that some states have already classified gabapentin as a Schedule V substance, which limits prescriptions to 30 days or less. Others noted that gabapentin is one of the only non-opioid pain therapies available to clinicians, and that in their experience overdoses involving gabapentin are not from those using gabapentin recreationally, but rather those who are seeking pain relief. Finally, testimony highlighted the number of clinical settings in which gabapentin has been used safely and is a critical tool for physicians in their practice.

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

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)

Online testimony was universally in support of the effort to reduce the burden of polypharmacy. Several commenters 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, commenters noted the added complexity from over-the-counter herbs and supplements which are often not considered in the traditional polypharmacy burden. Much of the testimony was particularly supportive of the third resolve clause, calling for improved electronic health record tools to help manage this problem.

(17) RESOLUTION 516 – OPPOSE “MILD HYPERBARIC” FACILITIES FROM DELIVERING SUPPORTED CLINICAL TREATMENTS

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)

There was limited but supportive testimony on this item.

(18) RESOLUTION 517 – SAFEGUARD THE PUBLIC FROM WIDESPREAD UNSAFE USE OF “MILD HYPERBARIC OXYGEN THERAPY”

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)
There was limited but supportive testimony on this item.

(19) RESOLUTION 518 – OVER-THE-COUNTER ACCESS TO ORAL 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 a switch in status from prescription to over-the-counter for such products, 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)

Testimony for this resolution was mostly supportive, noting that the current political landscape is becoming increasingly restrictive of reproductive health, and it is likely that access to abortions will be dramatically reduced in the coming years, particularly for rural and low-income populations.

One commenter testified that the removal of an age restriction may have unintended consequences. In addition, one commenter noted that for young people, visits to renew birth control prescriptions are often their only interaction with a physician and serve as a useful opportunity for an annual exam. The issue of different forms of oral contraceptives (progestin only vs. combined) and their relative safety profiles was raised.

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

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)

Online testimony for Resolution 519 was supportive. The testimony noted that while ARPA-H funding is important, it will only be successful if it is not at the expense of funding for existing research agencies.
(21) RESOLUTION 520 – ADDRESSING INFORMAL 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)

There was robust, mixed online testimony on Resolution 520. Both supportive and opposing testimony noted that this resolution is backdropped by an ongoing infant formula shortage, and members disagreed as to whether the proposed resolution was the appropriate solution. Those testifying in support noted that during the formula shortage, desperate parents may be more susceptible to predatory actors or may be more inclined to minimize risks around questionably sourced milk. Opponents, however, argued that at a time in which parents are struggling to find formula and feed their infants, the AMA should not be limiting their options. Additional comments noted that milk procured from milk banks is often prohibitively expensive and risks deepening health inequity for those that cannot afford it. Disagreement between commenters largely centered around the first two resolve clauses, but there was a larger level of agreement for the third resolve clause, which calls upon the AMA to support research into how milk banking can be improved.

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

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)
Online testimony for this item was unanimously supportive with minimal additional commentary.

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

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)

There was limited but supportive testimony for Resolution 522.

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

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)

Online testimony for Resolution 523 was supportive. Some 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. Commenters in opposition were concerned with the first resolve clause’s use of the phrase “more stringent”, as it was unclear what specific regulations the authors were seeking. In addition, they noted that the conditional approval pathways outlined in the second resolve clause could cause payers to not cover medical devices that are safe and medically necessary simply due to the conditional approval classification.

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

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)

Online testimony was supportive of Resolution 524. Much testimony commented on how difficult managing TBI can be in a clinical setting due to lack of understanding and minimal supportive resources. Commenters testified for a desire to see additional resources for TBI care in rural settings, differentiating between athletic and non-athletic TBI, victims of domestic abuse, concerns of health inequities for minoritized populations, and the role of technological approaches for assessing and managing TBI.