

## Reference Committee E

### CSAPH Report(s)

03 Correcting Policy H-120.958

### Resolution(s)

- 501 Marketing Guardrails for the "Over-Medicalization" of Cannabis Use
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\* *contained in the Handbook Addendum*

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-A-22

Subject: Correcting Policy H-120.958

Presented by: Alexander Ding, MD, MS, MBA, Chair

Referred to: Reference Committee E

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1 At the June 2020 Special Meeting of the House of Delegates, the Council on Science and Public  
2 Health's sunset report recommended that Policy H-120.958, "Supporting Safe Medical Products as  
3 a Priority Public Health Initiative" be retained in part and made the changes indicated here:

4  
5 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt  
6 methodology to help prevent "look alike-sound alike" errors in giving new drugs generic  
7 names;

8 (2) continue participation ~~in the National Patient Safety Foundation's efforts to advance the~~  
9 ~~science of safety in the medication use process and likewise work with the National~~  
10 ~~Coordinating Council for Medication Error Reporting and Prevention;~~

11 (3) support the FDA's Medwatch program by working to improve physicians' knowledge and  
12 awareness of the program and encouraging proper reporting of adverse events;

13 (4) vigorously work to support and encourage efforts to create and expeditiously implement a  
14 national ~~machine-readable~~ coding system for prescription medicine packaging in an effort to  
15 improve patient safety; and

16 (5) ~~participate in and report on the work of the Healthy People 2010 initiative in the area of~~  
17 ~~safe medical products especially as it relates to existing AMA policy; and~~

18 (6) seek opportunities to work collaboratively with other stakeholders within the Medicine-  
19 Public Health initiative

20 ~~(H 440.991) and with the Food and Drug Administration (FDA), National Institutes of Health~~  
21 ~~(NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention~~  
22 ~~(CDC) the Agency for Health Care Policy and Research (AHCPR) and the Centers for~~  
23 ~~Medicare & Medicaid Services (CMS) to provide information to individual physicians and~~  
24 ~~state medical societies on the need for public health infrastructure and local consortiums to~~  
25 ~~work on problems related to medical product safety.~~

26  
27 The recommended changes were adopted, and the revised policy was recorded in PolicyFinder.  
28

29 At the November 2021 Special Meeting, CSAPH Report 4 proposed changes to Policy H-120.958  
30 but erroneously proposed those changes to the version of the policy as it had existed before 2020's  
31 sunset report. The recommendation found in CSAPH Report 4-N-21 reads as follows:  
32

33 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt  
34 methodology to help prevent "look alike-sound alike" errors in giving new drugs generic  
35 names;

36 (2) continue participation ~~in the National Patient Safety Foundation's efforts to advance the~~  
37 ~~science of safety in the medication use process, including and likewise work with the National~~  
38 ~~Coordinating Council for Medication Error Reporting and Prevention;~~

- 1 (3) support the FDA’s Medwatch program by working to improve physicians’ knowledge and  
2 awareness of the program and encouraging proper reporting of adverse events;
- 3 (4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law  
4 113-54), including provisions on product identification and verification, data sharing, detection  
5 and response, and encourage efforts to create and expeditiously implement a national machine-  
6 readable coding system for prescription medicine packaging in an effort to improve patient  
7 safety;
- 8 (5) participate in and report on the work of the Healthy People ~~2010~~ 2030 initiative in the area  
9 of safe medical products especially as it relates to existing AMA policy; and
- 10 (6) seek opportunities to work collaboratively within the Medicine-Public Health initiative  
11 (H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health  
12 (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention  
13 (CDC) the Agency for ~~Health Care Policy and Research (AHCPR)~~ Healthcare Research and  
14 Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to provide  
15 information to individual physicians and state medical societies on the need for public health  
16 infrastructure and local consortiums to work on problems related to medical product safety.

17  
18 We recognize that the starting point for any changes to policy must be the current version of the  
19 policy as found in PolicyFinder, which is the June 2020 revision. That policy reads as follows:  
20

21 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt  
22 methodology to help prevent “look alike-sound alike” errors in giving new drugs generic  
23 names; (2) continue participation on the National Coordinating Council for Medication Error  
24 Reporting and Prevention; (3) support the FDA’s Medwatch program by working to improve  
25 physicians’ knowledge and awareness of the program and encouraging proper reporting of  
26 adverse events; (4) vigorously work to support and encourage efforts to create and  
27 expeditiously implement a national coding system for prescription medicine packaging in an  
28 effort to improve patient safety; and (5) seek opportunities to work collaboratively with other  
29 stakeholders to provide information to individual physicians and state medical societies on the  
30 need for public health infrastructure and local consortiums to work on problems related to  
31 medical product safety.

### 32 33 CONCLUSION

34  
35 The Council on Science and Public Health recommends reconciliation of the amendments to Policy  
36 H-120.958, “Supporting Safe Medical Products as a Priority Public Health Initiative,” as outlined  
37 below. This language ensures that AMA policy supports the Drug Supply Chain and Security Act  
38 as addressed in the Council’s pharmacovigilance report, acknowledges our willingness to engage  
39 with Healthy People 2030 on safe medical products, and streamlines the various federal agencies  
40 and stakeholders engaged in this important work.

### 41 42 RECOMMENDATION

43  
44 Your Council recommends that the following be adopted and the remainder of this report be filed.

- 45  
46 1. That Policy H-120.958, “Supporting Safe Medical Products as a Priority Public Health  
47 Initiative,” be amended by addition and deletion to read as follows:

48  
49 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to  
50 adopt methodology to help prevent “look alike-sound alike” errors in giving new drugs  
51 generic names; (2) continue participation in efforts to advance the science of safety in the

1 medication use process, including work with ~~on~~ the National Coordinating Council for  
2 Medication Error Reporting and Prevention; (3) support the FDA's Medwatch program by  
3 working to improve physicians' knowledge and awareness of the program and encouraging  
4 proper reporting of adverse events; (4) vigorously work to support the Drug Supply Chain  
5 and Security Act (DSCSA, Public Law 113-54), including provisions on product  
6 identification and verification, data sharing, detection and response, and encourage efforts  
7 ~~to create and expeditiously implement a national coding system for prescription medicine~~  
8 ~~packaging~~ in an effort to improve patient safety; (5) participate in the work of the Healthy  
9 People 2030 initiative in the area of safe medical products especially as it relates to  
10 existing AMA policy and (56) seek opportunities to work collaboratively with other  
11 stakeholders to provide information to individual physicians and state medical societies on  
12 the need for public health infrastructure and local consortiums to work on problems related  
13 to medical product safety.

Fiscal Note: \$1000

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501  
(A-22)

Introduced by: Young Physicians Section

Subject: Marketing Guardrails for the “Over-Medicalization” of Cannabis Use

Referred to: Reference Committee E

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1 Whereas, The cannabis-legalization movement has swept the country; and

2  
3 Whereas, In many states, “medical cannabis” and “medical marijuana” laws have put physicians  
4 in the uncomfortable position of being asked to prescribe cannabis for questionable medical  
5 indications; and

6  
7 Whereas, In states where medical cannabis has been legalized, marketing for cannabis for “all  
8 your ills” has become excessive; and

9  
10 Whereas, Emerging research in Colorado has shown that “marijuana use during pregnancy,  
11 concerns related to marijuana in homes with children, and adolescent use should continue to  
12 guide public health education and prevention efforts:

- 13  
14 - The percentage of women who use marijuana in pregnancy ... is higher among  
15 younger women, women with less education, and women with unintended  
16 pregnancies. Marijuana exposure in pregnancy is associated with decreased  
17 cognitive function and attention problems in childhood;  
18  
19 - Unintentional marijuana consumption among children under age 9 continues a  
20 slow upward trend, as do emergency visits due to marijuana. Additionally, an  
21 estimated 23,000 homes with children in Colorado have marijuana stored  
22 potentially unsafely. Marijuana exposures in children can lead to significant  
23 clinical effects that require medical attention;”<sup>1</sup> and  
24

25 Whereas, The American College of Obstetricians and Gynecologists (ACOG) warns that women  
26 who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana  
27 use, because of concerns regarding impaired neurodevelopment;”<sup>2</sup> and  
28

29 Whereas, Infants exposed to marijuana during pregnancy had a decrease in birth weight,  
30 preterm delivery, and long-term adverse neurodevelopmental effects;<sup>3</sup> and  
31

32 Whereas, In some states, women who are positive for cannabis are restricted from providing  
33 breastmilk to preterm babies in the neonatal intensive care unit; and  
34

35 Whereas, There may be a correlation between heavy cannabis use during adolescence and  
36 neuropsychiatric diseases such as schizophrenia;<sup>4</sup> and

1 Whereas, The U.S. Surgeon General has issued a warning about “Marijuana Use and the  
2 Developing Brain;”<sup>5,6</sup> and

3  
4 Whereas, ACOG has issued a statement discouraging obstetrician–gynecologists from  
5 prescribing or suggesting the use of marijuana for medicinal purposes during preconception,  
6 pregnancy, and lactation;<sup>2</sup> and

7  
8 Whereas, Despite such warnings, cannabis is promoted as a treatment for hyperemesis with  
9 many pregnant women being marketed a neuroactive drug during critical developmental periods  
10 of the embryo and fetus;<sup>7</sup> and

11  
12 Whereas, Two-thirds of Colorado’s cannabis dispensaries recommend marijuana for first  
13 trimester nausea although chronic cannabis use is actually associated with nausea and  
14 vomiting, which leads to emergency department visits;”<sup>1</sup> and

15  
16 Whereas, Marketing cannabis to vulnerable populations like pregnant women and adolescents  
17 can have long-term effects for population health; and

18  
19 Whereas, As an example, the targeted marketing of menthol cigarettes to African-Americans  
20 has led to in 85% of Black smokers using menthol cigarettes compared to 29% of White  
21 smokers and contributing to health disparities;<sup>8</sup> and

22  
23 Whereas, A report by a committee of the Food and Drug Administration concluded that if  
24 menthol cigarettes had been removed from the marketplace in 2010, then (a) by 2020, roughly  
25 17,000 premature deaths would have been avoided and about 2.3 million people would not  
26 have started smoking;<sup>8</sup> and

27  
28 Whereas, Inadequate information about the potential dangers/harms of cannabis (especially  
29 among vulnerable populations) is available, especially amid the storm of pro-cannabis  
30 marketing from that industry; and

31  
32 Whereas, This results in the lay public considering cannabis to be as safe as Tylenol, or carrots;  
33 and

34  
35 Whereas, Regulation of supplements continues to be highly flawed; and

36  
37 Whereas, There are a small number of cannabinoid products (such as marinol) which are  
38 indeed FDA-approved for specific indications; and

39  
40 Whereas, There appears to be a need for “guardrails” for the marketing of cannabis, especially  
41 to protect vulnerable populations; and

42  
43 Whereas, AMA has established policy to seek more data on cannabis, but in the meantime,  
44 cannabis and cannabinoid products are rapidly becoming the “snake oil” of our time; therefore  
45 be it

46  
47 **RESOLVED**, That our American Medical Association send a formal letter to the Food and Drug  
48 Administration and Federal Trade Commission requesting more direct oversight of the  
49 marketing of cannabis for medical use. (Directive to Take Action)

Fiscal note: Minimal - less than \$1,000

Date Received: 03/17/22

#### References

1. "Monitoring Health Concerns Related to Marijuana in Colorado: 2018" by the Colorado Department of Public Health & Environment at: <https://www.colorado.gov/pacific/cdphe/news/2018-marijuana-report>
2. "Marijuana Use During Pregnancy and Lactation" Committee Opinion 722. *American College of Obstetricians and Gynecologists. Obstet Gynecol* 2017; 130:e205-9.
3. "Marijuana Use During Pregnancy and Breastfeeding: Implications for Neonatal and Childhood Outcomes" *Pediatrics. Sept 2018; 142(3):e20181889*; at <https://pediatrics.aappublications.org/content/142/3/e20181889>.
4. Adolescent cannabis use and psychosis: epidemiology and neurodevelopmental models. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931552/>.
5. US Surgeon General's Advisory on Marijuana and the Developing Brain, at: [U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain | HHS.gov](https://www.hhs.gov/press/20190829-surgeongeneral-advisory-marijuana-use-and-the-developing-brain/)
6. US Surgeon General advises no marijuana for pregnant women, adolescents, *Modern Healthcare* (8/29/19) at: <https://www.modernhealthcare.com/government/us-surgeon-general-advises-no-marijuana-pregnant-women-adolescents>
7. Management of severe pregnancy sickness and hyperemesis gravidarum. *BMJ* 2018. At <https://www.bmj.com/content/363/bmj.k5000/rr>
8. FDA agrees to ban menthol to protect African Americans. Available at <https://www.ama-assn.org/press-center/press-releases/fda-agrees-ban-menthol-protect-african-americans>.

## RELEVANT AMA POLICY

### Cannabis Warnings for Pregnant and Breastfeeding Women H-95.936

Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed.

Citation: Res. 922, I-15; Reaffirmed: CSAPH Rep. 05, I-17;

### Taxes on Cannabis Products H-95.923

Our AMA encourages states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts.

Citation: CSAPH Rep. 05, I-17;

### Cannabis and Cannabinoid Research H-95.952

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be

supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.

4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.

5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to cannabis and cannabinoids.

7. Our AMA will create a Cannabis Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public.

Citation: CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19; Appended: Res. 913, I-19;

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

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for adult use should not be legalized (with adult defined for these purposes as age 21 and older); (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (8) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (10) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities; and (12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

Citation: CSAPH Rep. 05, I-17; Appended: Res. 913, I-19; Modified: CSAPH Rep. 4, I-20;

### **Cannabis Legalization for Medicinal Use D-95.969**



Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved cannabis or cannabis derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on cannabis use, effects and cannabis withdrawal syndrome.

Citation: CSAPH Rep. 05, I-17; Appended: Res. 211, A-18; Appended: CSAPH Rep. 3, I-19;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502  
(A-22)

Introduced by: New York

Subject: Ensuring Correct Drug Dispensing

Referred to: Reference Committee E

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1 Whereas, Medication errors affect millions of people every year with the clinical and economic  
2 consequences of those errors having been widely documented; and  
3

4 Whereas, Much is known about hospital medication errors because of their well-established  
5 reporting systems for continuous monitoring; and  
6

7 Whereas, In a hospital a dispensing error can be detected and prevented by nursing personnel  
8 at the administration stage; and  
9

10 Whereas, *The New York Times* published an article entitled "*How Chaos at Chain Pharmacies*  
11 *Is Putting Patients at Risk*" which stated that pharmacists at companies such as CVS, Rite Aid  
12 and Walgreens described understaffed and chaotic workplaces which made it difficult to perform  
13 their jobs safely and can lead to "dispensing errors"; and  
14

15 Whereas, Currently, in some states, any drug dispensed must bear a label on its container  
16 which identifies the name and address of the owner of the establishment in which it was  
17 dispensed, the date compounded, the number of the prescription under which it is recorded in  
18 the pharmacist's prescription files, the name of the prescriber, the name and address of the  
19 patient, and the directions for the use of the drug by the patient as given upon the prescription;  
20 and  
21

22 Whereas, When a prescription is filled in a retail pharmacy, the last checkpoint for safety is the  
23 patient or caregiver who may not have the training and knowledge to know that the dispensed  
24 drug is actually the medication prescribed; therefore be it  
25

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

Fiscal Note: Minimal - less than \$1,000

Received: 03/22/22

## **RELEVANT AMA POLICY**

### **Epidemiology of Drug Errors H-120.963**

The AMA will continue its collaborations with the Food and Drug Administration and the US Pharmacopoeial Convention, Inc., along with its own ongoing initiatives, to identify and eliminate causes of medication errors.

Citation: Sub. Res. 519, I-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: CSAPH Rep. 01, A-16

### **Supporting Safe Medical Products as a Priority Public Health Initiative H-120.958**

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 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 and encourage efforts to create and expeditiously implement a national coding system for prescription medicine packaging in an effort to improve patient safety; and (5) 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.

Citation: Res. 416, A-99; Appended: Res. 504, I-01; Reaffirmation A-10; Modified: CSAPH Rep. 01, A-20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503  
(A-22)

Introduced by: New York

Subject: Pharmacy Benefit Managers and Drug Shortages

Referred to: Reference Committee E

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- 1 Whereas, Pharmacy Benefit Managers (PBMs) are poorly regulated entities which act as  
2 middlemen between health plans, pharmacies and drug manufacturers; and  
3  
4 Whereas, They have been associated with adverse business practices including opaque  
5 operations 'spread pricing', and skyrocketing drug costs; and  
6  
7 Whereas, PBM's play an important part in the pharmaceutical supply chain--sometimes  
8 bankrupting pharmacies and making (and breaking) markets for pharmaceutical agents; and  
9  
10 Whereas, Drug manufacturers are legally obligated to report existing or pending drug shortages  
11 to the Food and Drug Administration, that requirement extends only to drug supply disruptions,  
12 not detailed information on their supply chain, in which PBMs play a key role; and  
13  
14 Whereas, Common retail prescription medications are frequently and chronically 'backordered'  
15 at a retail pharmacy, but often readily available at the hospital; therefore be it  
16  
17 RESOLVED, That our American Medical Association conduct a study which will investigate the  
18 role pharmacy benefit managers play in drug shortages. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 03/22/22

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504  
(A-22)

Introduced by: New York

Subject: Scientific Studies Which Support Legislative Agendas

Referred to: Reference Committee E

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- 1 Whereas, An important tool in advancing an organization's agenda is the ability to produce  
2 scientific or economic studies as evidence for supporting such a position; and  
3  
4 Whereas, An important tool in advancing an organization's agenda is collaborating with diverse  
5 groups who together can present a unified perspective on a particular issue; and  
6  
7 Whereas, The AMA regularly works with numerous and varied organizations to build allies and  
8 obtain research data in support of its efforts to achieve its key public health and legislative  
9 goals; and  
10  
11 Whereas, The goals of organized medicine and allied organizations include advocacy on behalf  
12 of patients and public health in addition to physicians; and  
13  
14 Whereas, Advocacy supported by scientific and economic information carries more weight and  
15 benefits those advocacy efforts; and  
16  
17 Whereas, Opponents of the policy goals of organized medicine often have the capacity to  
18 produce such studies; and  
19  
20 Whereas, The recent debate before Congress to address surprise medical bills often found  
21 physician organizations at odds with the perspectives of not only the insurance industry, but  
22 also the business, labor, and patient advocacy organizations as well as numerous think  
23 tanks; and  
24  
25 Whereas, This debate reiterated the importance of developing allies and research data to help  
26 work to achieve these public health and legislative goals; therefore be it  
27  
28 RESOLVED, That our American Medical Association continue and expand its efforts to work  
29 with allied groups, health care policy influencers such as think tanks, and entities that can  
30 produce high quality scientific evidence, to help generate support for the AMA's key advocacy  
31 goals. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000

Received: 03/22/22

## RELEVANT AMA POLICY

### Statement of Collaborative Intent G-620.030

(1) The AMA House of Delegates endorses the following preamble of a Statement of Collaborative Intent: The Federation of Medicine is a collaborative partnership in medicine. This partnership is comprised of the independent and autonomous medical associations in the AMA House of Delegates and their component and related societies. As the assemblage of the Federation of Medicine, the AMA House of Delegates is the framework for this partnership. The goals of the Federation of Medicine are to: (a) achieve a unified voice for organized medicine; (b) work for the common good of all patients and physicians; (c) promote trust and cooperation among members of the Federation; and (d) advance the image of the medical profession; and (e) increase overall efficiency of organized medicine for the benefit of our member physicians.

(2) The AMA House of Delegates endorses the following principles of a Statement of Collaborative Intent: (a) Organizations in the Federation will collaborate in the development of joint programs and services that benefit patients and member physicians.

(b) Organizations in the Federation will be supportive of membership at all levels of the Federation.

(c) Organizations in the Federation will seek ways to enhance communications among physicians, between physicians and medical associations, and among organizations in the Federation.

(d) Each organization in the Federation of Medicine will actively participate in the policy development process of the House of Delegates.

(e) Organizations in the Federation have a right to express their policy positions.

(f) Organizations in the Federation will support, whenever possible, the policies, advocacy positions, and strategies established by the Federation of Medicine.

(g) Organizations in the Federation will support an environment of mutual trust and respect.

(h) Organizations in the Federation will inform other organizations in the Federation in a timely manner whenever their major policies, positions, strategies, or public statements may be in conflict.

(i) Organizations in the Federation will support the development and use of a mechanism to resolve disputes among member organizations.

(j) Organizations in the Federation will actively work toward identification of ways in which participation in the Federation could benefit them.

(CLRPD/CEJA/C&B Report, A-97; Consolidated: CLRPD Rep. 3, I-01; Modified: BOT Rep. 23, A-02; Modified: CCB/CLRPD Rep. 3, A-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505  
(A-22)

Introduced by: Illinois

Subject: CBD Oil Use and the Marketing of CBD Oil

Referred to: Reference Committee E

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- 1 Whereas, Cannabidiol (CBD) oil is advertised in health clubs and convenience stores and  
2 online; and  
3
- 4 Whereas, CBD oil is often marketed in ways that falsely imply medical doctor approval,  
5 verification or endorsement; and  
6
- 7 Whereas, There is only one Food and Drug Administration (FDA)-approved drug in which CBD  
8 is the active ingredient for the indication of two rare types of epilepsy syndromes; and  
9
- 10 Whereas, It is known that the side effects of CBD include elevated liver enzymes, diarrhea,  
11 somnolence and decreased appetite; and  
12
- 13 Whereas, CBD oil is promoted for the treatment of a vast range of mental and physical ailments  
14 including: seizures, schizophrenia, depression, anxiety, Tourette syndrome, ADHD, pain  
15 reduction and sleep disorders; and  
16
- 17 Whereas, CBD is one of more than 100 identified compounds in the cannabis plant, commonly  
18 known as marijuana and CBD is put into products including ingestible oils, bath salts and drinks;  
19 and  
20
- 21 Whereas, CBD oil is not an FDA-approved product and is considered a dietary supplement and  
22 the composition and purity of the product generally extracted from hemp is not overseen by any  
23 U.S. regulatory body and adulteration, contamination with pesticides, herbicides and heavy  
24 metals and variable percentage of CBD product can and does occur; therefore be it  
25
- 26 RESOLVED, That our American Medical Association support banning the advertising of  
27 cannabidiol (CBD) as a component of marijuana in places that children frequent (New HOD  
28 Policy); and be it further  
29
- 30 RESOLVED, That our AMA support legislation to prohibit companies from selling CBD products  
31 if they make any unproven health and therapeutic claims, and to require companies to include a  
32 Food and Drug Administration-approved warning on CBD product labels. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 04/07/22

## **RELEVANT AMA POLICY**

### **Regulation of Cannabidiol Products H-120.926**

Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products; and (3) support comprehensive FDA regulation of cannabidiol products and practices necessary to ensure product quality, including identity, purity, and potency.

Citation: Res. 502, A-18; Appended: CSAPH Rep. 3, I-20



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506  
(A-22)

Introduced by: Illinois  
Subject: Drug Manufacturing Safety  
Referred to: Reference Committee E

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- 1 Whereas, It has recently been revealed in the media as well as written notifications from  
2 pharmacies informing the American public that certain medications produced outside but  
3 consumed inside the United States have contained carcinogenic substances; and  
4  
5 Whereas, Such tainted medications are widely consumed within the US and include, but are not  
6 limited to, Valsartan and Losartan; and  
7  
8 Whereas, Multiple medications are produced overseas and marketed broadly within the US; and  
9  
10 Whereas, Significant budgetary hurdles exist in empowering the U.S. Food and Drug  
11 Administration to inspect all foreign drug manufacturers on a frequent and rigorous basis;  
12 therefore be it  
13  
14 RESOLVED, That our American Medical Association support efforts to ensure that the U.S.  
15 Food and Drug Administration (FDA) resumes safety testing for all drug manufacturing facilities  
16 on a frequent and rigorous basis, as done in the past (Directive to Take Action); and be it further  
17  
18 RESOLVED, That our AMA call for the FDA to reaffirm the safety of the manufacture of drugs  
19 and the adequacy of volume in the pipeline. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/07/22

**RELEVANT AMA POLICY**

**D-100.983 - Prescription Drug Importation and Patient Safety**

Our AMA will: (1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported; (2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured; (3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; (4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts; (5) support the in-person purchase and importation of Health Canada-approved prescription

drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity; (6) advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured; and (7) support the personal importation of prescription drugs only if: (a) patient safety can be assured; (b) product quality, authenticity and integrity can be assured; (c) prescription drug products are subject to reliable, “electronic” track and trace technology; and (d) prescription drug products are obtained directly from a licensed foreign pharmacy, located in a country that has statutory and/or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States. BOT Rep. 3, I-04 Reaffirmation A-09 Reaffirmed in lieu of: Res. 817, I-16 Appended: CMS Rep. 01, I-18 Appended: Res. 115, A-19

**FDA Drug Safety Policies D-100.978**

Our AMA will monitor and respond, as appropriate, to the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA; P.L. 110-85) so that the Food and Drug Administration can more effectively ensure the safety of drug products for our patients.

Citation: Sub. Res. 505, A-08; Reaffirmed: CSAPH Rep. 1, A-21

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507  
(A-22)

Introduced by: Illinois  
Subject: Federal Initiative to Treat Cannabis Dependence  
Referred to: Reference Committee E

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1 Whereas, There is no effective medication for treating dependence on cannabis; and

2

3 Whereas, Many states are making cannabis available for recreational purposes; and

4

5 Whereas, It is well known the use of cannabis can lead to addiction; and

6

7 Whereas, Physicians have no Food and Drug Administration-approved, safe and effective  
8 medication to assist in treating cannabis addiction; therefore be it

9

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/07/22

Reference:

Lintzeris, N and associates, Nabiximolis for the treatment of cannabis dependence: A randomized clinical trial, JAMA Intern Med, 2019; 179(9):1242-1253

## RELEVANT AMA POLICY

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

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for adult use should not be legalized (with adult defined for these purposes as age 21 and older); (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency

department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (8) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (10) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities; and (12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

Citation: CSAPH Rep. 05, I-17; Appended: Res. 913, I-19; Modified: CSAPH Rep. 4, I-20

#### **D-95.969 - Cannabis Legalization for Medicinal Use**

Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved cannabis or cannabis derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on cannabis use, effects and cannabis withdrawal syndrome. CSAPH Rep. 05, I-17 Appended: Res. 211, A-18 Appended: CSAPH Rep. 3, I-19

#### **H-95.952 - Cannabis and Cannabinoid Research**

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.

3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.
6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to cannabis and cannabinoids.
7. Our AMA will create a Cannabis Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public. CSA Rep. 10, I-97 Modified: CSA Rep. 6, A-01 Modified: CSAPH Rep. 3, I-09 Modified in lieu of Res. 902, I-10 Reaffirmed in lieu of Res. 523, A-11 Reaffirmed in lieu of Res. 202, I-12 Reaffirmed: CSAPH Rep. 2, I-13 Modified: CSAPH Rep. 05, I-17 Reaffirmed in lieu of: Res. 434, A-19 Appended: Res. 913, I-19

#### **H-95.923 - Taxes on Cannabis Products**

Our AMA encourages states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts. CSAPH Rep. 05, I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 508  
(A-22)

Introduced by: Illinois

Subject: Supplemental Resources for Inflight Medical Kit

Referred to: Reference Committee E

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- 1 Whereas, According to the Bureau of Transportation Statistics, 770 million passengers boarded  
2 domestic flights in the United States in the year 2018 and 802 million passengers boarded  
3 domestic flights in the US in the year 2019; and  
4
- 5 Whereas, Inflight medical emergencies (IMEs) are estimated to occur in approximately 1 in 604  
6 flights, or 24 to 130 IMEs per 1 million passengers; and  
7
- 8 Whereas, IMEs are common and occur in constrained areas with limited medical resources; and  
9
- 10 Whereas, Inflight medical events are increasingly frequent because a growing number of  
11 individuals with pre-existing medical conditions travel by air; and  
12
- 13 Whereas, The most common inflight emergency involves syncope or near syncope, which  
14 requires measurement of blood pressure and pulse for optimal assessment; and  
15
- 16 Whereas, Travelers with diabetes may have altered dietary habits and medication dosing, so  
17 are at risk for hyper- or hypoglycemia; and  
18
- 19 Whereas, Health care personnel are asked to assist affected passengers and have variable  
20 level of training and expertise in evaluating vital signs; and  
21
- 22 Whereas, Efforts by health care volunteers are protected by Good Samaritan laws, there is an  
23 obligation and opportunity to optimize treatment in these situations; and  
24
- 25 Whereas, The minimum requirements for the emergency medical kit do not include automated  
26 blood pressure cuff, pulse oximeter or glucose monitors; and  
27
- 28 Whereas, The noise level of the airplane makes it difficult to auscultate for blood pressure, with  
29 cruising noise levels at around 85 dB but up to 105 dB during takeoff and landing; and  
30
- 31 Whereas, Resources include automated external defibrillators, advanced life support injectables  
32 including epinephrine, atropine, lidocaine, analgesics, and first aid materials, but do not include  
33 pulse oximeters, automated blood pressure cuffs or glucose monitors; and  
34
- 35 Whereas, Treatment and support decisions can be optimized with accurate vital signs, oxygen  
36 levels and blood sugar levels; and  
37
- 38 Whereas, Blood glucose testing equipment is not required in the U.S.; and

1 Whereas, A pulse oximeter is a lightweight and inexpensive device that can determine heart  
2 rate as well as oxygen saturation; and  
3

4 Whereas, An automated blood pressure cuff is a lightweight, inexpensive device that uses a  
5 pressure sensor and not sound to detect intraarterial systolic blood pressure; and  
6

7 Whereas, A glucose monitor is a lightweight and relatively inexpensive device that can provide  
8 an accurate point of care blood sugar level; and  
9

10 Whereas, A pulse oximeter, an automated blood pressure cuff and a glucose monitor are not  
11 among the standard supplies on a domestic U.S. flight; and  
12

13 Whereas, The costs of these devices is minimal in comparison to the cost of diverting a flight for  
14 emergency medical attention due to inadequate evaluation on board; and  
15

16 Whereas, In the absence of medical personnel during an inflight emergency, a pulse oximeter,  
17 automated blood pressure cuff and glucose monitor can be used to determine accurate data  
18 that can be shared with on ground medical support team; therefore be it  
19

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/07/22

References:

American Speech-Language-Hearing Association (ASHA). Feb 25, 2014 Durden, Rick Pulse Oximeters: Too Cheap to Ignore. The Aviation Consumer, October 29, 2019  
<https://www.bts.gov/>

Martin-Gill, C, Doyle, TJ Yealy, DM, In Flight Emergencies: A Review. JAMA 2018 Dec 25;320(24):2580-2590. doi: 10.1001/jama.2018.19842.

## RELEVANT AMA POLICY

### H-45.981- Improvement in US Airlines Aircraft Emergency Kits

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). Res. 507, A-97 Amended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of: Res. 502, A-16 Appended: Res. 524, A-18

**H-45.979 - Air Travel Safety**

Our AMA: (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies; (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar. CSA Rep. 5, I-98 Appended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Appended: Res. 718, A-14 Reaffirmation I-14 Reaffirmed in lieu of Res. 503, A-15 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17 Reaffirmed: BOT Rep. 22, A-18 Reaffirmed: BOT Rep. 30, A-18

**H-45.978 - In-flight Medical Emergencies**

Our AMA urges: (1) urges that decisions to expand the contents of in-flight emergency medical kits and place emergency lifesaving devices onboard commercial passenger aircraft be based on empirical data and medical consensus; in-flight medical supplies and equipment should be tailored to the size and mission of the aircraft, with careful consideration of flight crew training requirements; and (2) the Federal Aviation Administration to work with appropriate medical specialty societies and the airline industry to develop and implement comprehensive in-flight emergency medical systems that ensure:

- (a) rapid 24-hour access to qualified emergency medical personnel on the ground;
- (b) at a minimum, voice communication with qualified ground-based emergency personnel;
- (c) written protocols, guidelines, algorithms, and procedures for responding to in-flight medical emergencies;
- (d) efficient mechanisms for data collection, reporting, and surveillance, including development of a standardized incident report form;
- (e) adequate medical supplies and equipment aboard aircraft;
- (f) routine flight crew safety training;
- (g) periodic assessment of system quality and effectiveness; and
- (h) direct supervision by physicians with appropriate training in emergency and aerospace medicine. CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmation I-14 Reaffirmed in lieu of: Res. 502, A-16 Reaffirmed in lieu of: Res. 516, A-17



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 509  
(A-22)

Introduced by: Illinois

Subject: Regulation and Control of Self-Service Labs

Referred to: Reference Committee E

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1 Whereas, In recent years the number of laboratories selling self-ordered tests to patients has  
2 increased significantly; and  
3

4 Whereas, Laboratories advertise and promote their business on the Internet, and include  
5 companies like HealthOneLabs, Accessa Labs, Private MD Labs, Walk-In--Lab, HNL Lab Tests  
6 Direct, and several others; and  
7

8 Whereas, Most laboratories selling self-ordered tests to patients state that their tests are run  
9 with high-quality controls and procedures, and that correct and validated results are emailed to  
10 the consumer directly; and  
11

12 Whereas, Laboratories that sell self-ordered tests directly to patients clearly state that no  
13 medical referral is needed, and that their results are validated and reviewed by an "independent  
14 network of physicians," of unspecified qualifications or licensures; and  
15

16 Whereas, Many patients self-order tests out of fear or ignorance, and end up with results that  
17 they are unable to interpret or apply to their individual needs; and  
18

19 Whereas, Many patients go to their physician with pages of results which they may not have  
20 needed in the first place and try to obtain a diagnostic interpretation and/or a therapeutic  
21 intervention based on said results, which places the physician at medical and legal jeopardy;  
22 therefore be it  
23

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/07/22

**RELEVANT AMA POLICY**

**Direct-to-Consumer Laboratory Testing H-480.941**

Our AMA will: (1) advocate for vigilant oversight of direct-to-consumer (DTC) laboratory testing by relevant state and federal agencies; and (2) encourage physicians to educate their patients about the risks and benefits of DTC laboratory tests, as well as the risks associated with interpreting DTC test results without input from a physician or other qualified health care professional.

Citation: Res. 526, A-18; Reaffirmed: BOT Rep. 12, I-21

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 510  
(A-22)

Introduced by: Colorado, American Academy of Ophthalmology, GLMA: Health Professionals Advancing LGBTQ Equality, Society of Critical Care Medicine, American Society of Transplant Surgeons, American Society of Cataract and Refractive Surgery, California

Subject: Evidence-Based Deferral Periods for MSM Corneas and Tissue Donors

Referred to: Reference Committee E

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1 Whereas, On May 20, 1994, the US Public Health Service instituted a policy prohibiting  
2 donation of corneas and other tissues by “[men] who have had sex with another man [MSM] in  
3 the preceding 5 years” even if all required infectious disease testing is negative,<sup>1</sup> a policy which  
4 continues to be enforced today by the US Food and Drug Administration (FDA)<sup>2</sup>; and  
5

6 Whereas, The 5-year MSM deferral policy was instituted at a time when HIV tests were  
7 unreliable and has not been updated to reflect advances in HIV testing since 1994<sup>3,4</sup>; and  
8

9 Whereas, All corneal donors are required to undergo HIV testing, which is now reliable within  
10 4-8 days of viral exposure<sup>5,6</sup>; and  
11

12 Whereas, No case of HIV transmission from a corneal transplant has ever been reported, even  
13 in cases when the corneal donors were HIV-positive<sup>3,7,8,9,10,11</sup>; and  
14

15 Whereas, Corneas are an avascular tissue and are not a major reservoir of HIV<sup>12</sup>; and  
16

17 Whereas, Current FDA policy treats MSM corneal donors more strictly than other potentially  
18 high-risk donors (e.g. while MSM donors must be abstinent for 5 years, heterosexual donors in  
19 a sexual relationship with someone known to be HIV-positive are only ineligible for 1 year after  
20 last sexual contact with an HIV-positive individual)<sup>2</sup>; and  
21

22 Whereas, MSM blood donors are only ineligible for 3 months after last sexual contact, despite  
23 the known risk of HIV transmission through blood transfusions<sup>13</sup>; and there is no deferral period  
24 whatsoever for MSM donors of solid organs (such as hearts, lungs, kidneys, etc.)<sup>14,15</sup>; and  
25

26 Whereas, Many peer nations have no deferral period for MSM corneal donors whatsoever (e.g.  
27 Spain,<sup>16</sup> Italy,<sup>17</sup> Mexico,<sup>18</sup> Chile,<sup>19</sup> Argentina,<sup>20</sup> Germany,<sup>21</sup> Denmark,<sup>22</sup> South Africa<sup>23</sup>); and  
28

29 Whereas, Many other peer nations have deferral periods for MSM corneal donors far shorter  
30 than 5 years (e.g. 3 months in the United Kingdom,<sup>24</sup> 4 months in the Netherlands,<sup>25</sup> 4 months in  
31 France,<sup>26</sup> 12 months in Canada<sup>27</sup>); and  
32

33 Whereas, AMA Policy H-50.973, “Blood Donor Deferral Criteria,” states that AMA supports  
34 blood donor deferral criteria that are “representative of current HIV testing technology” but does  
35 not address the FDA’s even stricter deferral criteria for MSM donors of corneas and other  
36 tissues<sup>28</sup>; and

1 Whereas, A recent *JAMA Ophthalmology* study estimated that between 1558 and 3217 potential  
2 corneal donations were disqualified in 2018 alone in the United States and Canada due to the  
3 two countries' bans on MSM corneal donors<sup>3</sup>; and  
4

5 Whereas, An estimated 12.7 million visually impaired patients are in need of corneal transplant  
6 surgery worldwide, with only 1 cornea donated for every 70 corneal transplants needed<sup>29</sup>;  
7 therefore be it  
8

9 RESOLVED, That our American Medical Association amend current policy H-50.973, "Blood  
10 Donor Deferral Criteria," by addition and deletion as follows:  
11

12 Blood and Tissue Donor Deferral Criteria

13 Our AMA: (1) supports the use of rational, scientifically-based ~~blood and~~  
14 ~~tissue donation~~ deferral periods for donation of blood, corneas, and other tissues that  
15 are fairly and consistently applied to donors according to their individual risk; (2)  
16 opposes all policies on deferral of blood and tissue donations that are not based on  
17 evidence; (3) supports a blood and tissue donation deferral period for those determined  
18 to be at risk for transmission of HIV that is representative of current HIV testing  
19 technology; and (4) supports research into individual risk assessment criteria for blood  
20 and tissue donation (Modify Current HOD Policy); and be it further  
21

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

Fiscal Note: Minimal - less than \$1,000

Received: 04/08/22

**References:**

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## RELEVANT AMA POLICY

### Blood Donor Deferral Criteria H-50.973

Our AMA: (1) supports the use of rational, scientifically-based blood and tissue donation deferral periods 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 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 donation.

Citation: Res. 514, A-13; Modified: Res. 008, I-16; Modified: Res. 522, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 511  
(A-22)

Introduced by: Illinois

Subject: Over the Counter (OTC) Hormonal Birth Control

Referred to: Reference Committee E

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- 1 Whereas, Many individuals prefer to have control over the timing and occurrence of pregnancy;  
2 and  
3  
4 Whereas, Oral hormonal contraception birth control pills is available and very effective; and  
5  
6 Whereas, Safety considerations of birth control pills have been well reviewed and largely  
7 reduced for incidences of untoward complications; and  
8  
9 Whereas, The availability of birth control pills may reduce incidence of unexpected and  
10 unwanted pregnancy that may result in abortion and its risks; and  
11  
12 Whereas, Birth control pills are currently only available by prescription of a physician; and  
13  
14 Whereas, The American College of Obstetricians and Gynecologists recommends the  
15 elimination of the physician prescription requirement and allowing oral contraceptives (birth  
16 control pills) to be sold without a prescription; therefore be it  
17  
18 RESOLVED, That our American Medical Association recommend elimination of the requirement  
19 for a physician's prescription to purchase birth control pills (BCP) and over the counter (OTC)  
20 hormonal contraceptives and allow OTC purchase (New HOD Policy); and be it further  
21  
22 RESOLVED, That our AMA advocate for the revocation of Food and Drug Administration and/or  
23 Congressional regulations requiring a prescription for OTC hormonal BCP. (Directive to Take  
24 Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/08/22

**RELEVANT AMA POLICY**

**Over-the-Counter Access to Oral Contraceptives D-75.995**

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

Citation: Sub. Res. 507, A-13; Modified: BOT Rep. 10, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 512  
(A-22)

Introduced by: Mississippi

Subject: Scheduling and Banning the Sale of Tianeptine in the United States

Referred to: Reference Committee E

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1 Whereas, While Tianeptine is approved in some countries to treat depression and anxiety, it is  
2 an unapproved drug in the United States due to safety concerns; and  
3

4 Whereas, Tianeptine is legally sold over the counter in the United States commonly in gas  
5 stations and convenience stores; and  
6

7 Whereas, The U.S. Food and Drug Administration (FDA) is warning consumers they may  
8 inadvertently find themselves addicted to tianeptine and should avoid all products containing it,  
9 especially those that claim to treat opioid use disorder since reliance on these products may  
10 delay appropriate treatment and put consumers at greater risk of overdose and death; and  
11

12 Whereas, The FDA is aware of several serious adverse event reports including agitation,  
13 drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, confusion, nausea,  
14 vomiting, slowed or stopped breathing, coma, and death associated with tianeptine and these  
15 reports are increasing with poison control centers cases nationwide from 11 cases between  
16 2000 and 2013 to 151 in 2020 alone; and  
17

18 Whereas, Tianeptine is not approved in the United States for any medical use; and  
19

20 Whereas, Tianeptine is currently widely available for sale to the public, presenting safety risks  
21 and risk of abuse; and  
22

23 Whereas, Tianeptine is not currently controlled under the Controlled Substances Act, but is  
24 being scheduled on a state-by-state basis as a Schedule II controlled substance, as recently  
25 passed in Alabama and Michigan. Schedule II drugs by definition mean that a substance may  
26 lead to severe psychological or physical dependence and joins other substances such as  
27 morphine, methamphetamine, cocaine, methadone, hydrocodone, fentanyl, and phencyclidine  
28 (PCP) in that class; therefore be it  
29

30 RESOLVED, That our American Medical Association advocate to schedule Tianeptine as  
31 Schedule II whilst supporting research into the safety and efficacy of the substance (Directive to  
32 Take Action); and be it further  
33

34 RESOLVED, That our AMA advocate to ban the sale of Tianeptine directly to the public.  
35 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/07/22

<https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death>  
<https://en.wikipedia.org/wiki/Tianeptine>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 513  
(A-22)

Introduced by: Oklahoma

Subject: Education for Patients on Opiate Replacement Therapy

Referred to: Reference Committee E

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1 Whereas, We are in a time of potentially increased respiratory illness, given the threat of  
2 COVID-19 and flu season in the United States; and  
3

4 Whereas, We are simultaneously in a time of increased use of opiate replacement therapy for  
5 the treatment of opiate use disorder and chronic pain; and  
6

7 Whereas, Anecdotally, a death scenario occurs when patients in their 60s and 70s who are on  
8 relatively high dose maintenance opioid replacement therapy, take their usual dose after onset  
9 of a respiratory illness, and  
10

11 Whereas, AMA Policy D-95.987, "Prevention of Drug-Related Overdose," is to educate  
12 physicians and at-risk patients, but it fails to specifically address the needs of older patients who  
13 are at risk of death from opiate maintenance therapy when the onset of respiratory illness  
14 occurs; therefore be it  
15

16 RESOLVED, That our American Medical Association amend Policy D-95.987, "Prevention of  
17 Drug-Related Overdose," by addition to read as follows:  
18

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

28 2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their  
29 caregivers in the signs and symptoms of a drug-related overdose; and (b) encourage the  
30 continued study and implementation of appropriate treatments and risk mitigation  
31 methods for patients at risk for a drug-related overdose.

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

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

- 1 5. Our AMA implement an education program for patients on opiate replacement  
2 therapy and their family/caregivers to increase understanding of their increased  
3 risk of death with concurrent opiate maintenance therapy and the onset of a  
4 serious respiratory illness such as SARS-CoV-2. (Modify Current HOD Policy)

References:

<https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20030348>

Fiscal Note: Not yet determined

Received: 04/26/22

## RELEVANT AMA POLICY

### Prevention of Drug-Related Overdose D-95.987

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

2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug-related overdose; and (b) 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.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12;

Reaffirmed: BOT Rep. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18; Modified: Res. 506, I-21



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 514  
(A-22)

Introduced by: Oklahoma

Subject: Oppose Petition to the DEA and FDA on Gabapentin

Referred to: Reference Committee E

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1 Whereas, The mission of the American Medical Association is to promote the art and science of  
2 medicine and the betterment of public health; and  
3

4 Whereas, Gabapentin is approved by the U.S. Food and Drug Administration (FDA) to treat  
5 specific forms of epilepsy and neuropathic pain;(1),(2) and Gabapentin enacarbil, which is  
6 approved by the FDA for treatment of primary restless legs syndrome and postherpetic  
7 neuralgia, is a prodrug of gabapentin, and, accordingly, its therapeutic effects are attributable to  
8 gabapentin(3); and  
9

10 Whereas, From 2011 to 2017, total prescriptions for gabapentin doubled to 64.8 million  
11 prescriptions per year(4); and  
12

13 Whereas, A watchdog nonprofit group Public Citizen has filed a petition on 2/08/2022 with the  
14 FDA and the U.S. Drug Enforcement Administration (DEA), arguing that gabapentin's risks  
15 warrant additional safeguards by requesting regulators to make the drug a controlled  
16 substance(5); and  
17

18 Whereas, Public Citizen noted as of November 2020, seven states--Alabama, Kentucky,  
19 Michigan, North Dakota, Tennessee, Virginia, and West Virginia--had classified gabapentin as a  
20 schedule V drug, while another 12 states required prescription monitoring of the drug(5); and  
21

22 Whereas, Public Citizen requested that gabapentin come under the DEA's Schedule V  
23 category, which already includes the similar drug, pregabalin (Lyrica); and  
24

25 Whereas, Schedule V is the lowest rung on the DEA's drug schedule, meaning it has lower  
26 potential for abuse than Schedule I through IV drugs; and  
27

28 Whereas, Patients with pain should receive treatment that provides the greatest benefit and  
29 opioids are not the first-line therapy for chronic pain outside of active cancer treatment, palliative  
30 care, and end-of-life care(6); and  
31

32 Whereas, Evidence suggests that nonopioid treatments, including nonopioid medications and  
33 nonpharmacological therapies can provide relief to those suffering from chronic pain, and are  
34 safer(6); and  
35

36 Whereas, Gabapentin has been a lower risk alternative for pain management than opioids in the  
37 fight against opioid overdose(6); and  
38

39 Whereas, In 2019 the FDA issued a warning about serious breathing difficulties associated with  
40 gabapentin and pregabalin in patients with respiratory risk factors(7); and

1 Whereas, A systematic review on PubMed/Scopus that included 106 studies, did not find  
2 convincing evidence of a vigorous addictive power of gabapentinoids which is primarily  
3 suggested from their limited rewarding properties, marginal notes on relapses, and the very few  
4 cases with gabapentinoid-related behavioral dependence symptoms (ICD-10) in patients without  
5 a prior abuse history(8); and  
6

7 Whereas, There was no publication about people who sought treatment for the use of  
8 gabapentinoids(8); and  
9

10 Whereas, Pure overdoses of gabapentinoids appeared to be relatively safe but can become  
11 lethal (pregabalin > gabapentin) in mixture with other psychoactive drugs, especially opioids  
12 again and sedatives(8); and  
13

14 Whereas, Making gabapentinoids, medications with little addictive or habit-forming potential,  
15 schedule V will make it more complicated for patients to receive treatment and causes an  
16 unnecessary barrier for care; therefore be it  
17

18 RESOLVED, That our American Medical Association actively oppose the placement of (a)  
19 gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid), including its salts, and all products  
20 containing gabapentin (including the brand name products Gralise and Neurontin) and (b)  
21 gabapentin enacarbil (1-[[[{{(1RS)-1-[(2- methylpropanoyl)oxy]ethoxy} carbonyl)amino]methyl}  
22 cyclohexyl] acetic acid), including its salts, (including the brand name product Horizant) into  
23 schedule V of the Controlled Substances Act (Directive to Take Action); and be it further  
24

25 RESOLVED, That our AMA submit a timely letter to the Commissioner of the U.S. Food and  
26 Drug Administration for the proceedings assigned docket number FDA-2022-P-0149 in  
27 opposition to placement of gabapentin and gabapentin enacarbil into the schedule V of the  
28 Controlled Substance Act. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 04/26/22

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 515  
(A-22)

Introduced by: Senior Physicians Section

Subject: Reducing Polypharmacy as a Significant Contributor to Senior Morbidity

Referred to: Reference Committee E

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1 Whereas, Excessive, unnecessary, or incompatible medication use increases the risk of  
2 adverse drug effects, including falls, cognitive impairment, adverse drug interactions and drug-  
3 disease interactions;<sup>1, 4, 5</sup> and  
4

5 Whereas, Older patients often have multiple complex conditions making drug therapy an  
6 essential part of medical management; yet multiple medications in complex patients may shift  
7 the benefit of drug therapy from positive to negative;<sup>2, 6</sup> and  
8

9 Whereas, Although some EHRs are automatically screening patient med lists for  
10 incompatibilities, they may not include supplements and OTC meds; and fidelity with actual  
11 current regimens is compromised when self reporting is relied upon, especially in the setting of  
12 cognitive decline; and  
13

14 Whereas, Consumer patient education on polypharmacy has been raised by such groups as  
15 AARP, Consumer Reports, and governmental units such as CDC with questionable penetrance  
16 to the affected population; and  
17

18 Whereas, Physicians are the natural source for patient education and engagement;<sup>3</sup> and  
19

20 Whereas, It is advisable for the AMA to use its resources to educate patients about the dangers  
21 of polypharmacy, and to assist physicians to take steps to recognize and reduce it;<sup>7-10</sup> therefore  
22 be it  
23

24 RESOLVED, That our American Medical Association work with other organizations e.g., AARP,  
25 other medical specialty societies, PhRMA, and pharmacists to educate patients about the  
26 significant effects of all medications and most supplements, and to encourage physicians to  
27 teach patients to bring all medications and supplements or accurate, updated lists including  
28 current dosage to each encounter (Directive to Take Action); and be it further  
29

30 RESOLVED, That our AMA along with other appropriate organizations encourage physicians  
31 and ancillary staff if available to initiate discussions with patients on improving their medical care  
32 through the use of only the minimal number of medications (including prescribed or over-the-  
33 counter, including vitamins and supplements) needed to optimize their health (Directive to Take  
34 Action); and be it further  
35

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

Fiscal Note: Not yet determined

Received: 05/03/22

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**RELEVANT AMA POLICY**

**Improving the Quality of Geriatric Pharmacotherapy H-100.968**

Our AMA believes that the Food and Drug Administration should encourage manufacturers to develop low dose formulations of medications commonly used by older patients in order to meet the special needs of this group; require geriatric-relevant labeling for over-the-counter medications; provide incentives to pharmaceutical manufacturers to better study medication effects in the frail elderly and oldest-old in pre- and post-marketing clinical trials; and establish mechanisms for data collection, monitoring, and analysis of medication-related problems by age group.

Citation: CSA Rep. 5, A-02; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 01, A-20

**Supporting Safe Medical Products as a Priority Public Health Initiative H-120.958**

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 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 and encourage efforts to create and expeditiously implement a national coding system for prescription medicine packaging in an effort to improve patient safety; and (5) 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.

Citation: Res. 416, A-99; Appended: Res. 504, I-01; Reaffirmation A-10; Modified: CSAPH Rep. 01, A-20

**Geriatric Medicine H-295.981**

1. Our AMA reaffirms its support for: (a) the incorporation of geriatric medicine into the curricula of medical school departments and its encouragement for further education and research on the problems of aging and health care of the aged at the medical school, graduate and continuing medical education levels; and (b) increased training in geriatric pharmacotherapy at the medical student and residency level for all relevant specialties and encourages the Accreditation Council

for Graduate Medical Education and the appropriate Residency Review Committees to find ways to incorporate geriatric pharmacotherapy into their current programs.

2. Our AMA recognizes the critical need to ensure that all physicians who care for older adults, across all specialties, are competent in geriatric care, and encourages all appropriate specialty societies to identify and implement the most expedient and effective means to ensure adequate education in geriatrics at the medical school, graduate, and continuing medical education levels for all relevant specialties.

Citation: Res. 137, A-85; Reaffirmed by CLRPD Rep. 2, I-95; Appended: CSA Rep. 5, A-02; Appended: Res. 301, A-10; Reaffirmed: BOT Rep. 05, I-16

### **National Health Information Technology D-478.995**

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care.

2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care; and (D) advocates for continued research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems.

3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop, with physician input, minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs.

4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery.

5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process.

6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability.

7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability.

8. Our AMA will advocate for appropriate, effective, and less burdensome documentation requirements in the use of electronic health records.

9. Our AMA will urge EHR vendors to adopt social determinants of health templates, created with input from our AMA, medical specialty societies, and other stakeholders with expertise in social determinants of health metrics and development, without adding further cost or documentation burden for physicians.

Citation: Res. 730, I-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation A-10; Reaffirmed: BOT Rep. 16, A-11; Modified: BOT Rep. 16, A-11; Modified:

BOT Rep. 17, A-12; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed: BOT Rep. 24, A-13; Reaffirmed in lieu of Res. 724, A-13; Appended: Res. 720, A-13; Appended: Sub. Res. 721, A-13; Reaffirmed: CMS Rep. 4, I-13; Reaffirmation I-13; Appended: BOT Rep. 18, A-14; Appended: BOT Rep. 20, A-14; Reaffirmation A-14; Reaffirmed: BOT Rep. 17, A-15; Reaffirmed in lieu of Res. 208, A-15; Reaffirmed in lieu of Res. 223, A-15; Reaffirmation I-15; Reaffirmed: CMS Rep. 07, I-16; Reaffirmed: BOT Rep. 05, I-16; Appended: Res. 227, A-17; Reaffirmed in lieu of: Res. 243, A-17; Modified: BOT Rep. 39, A-18; Reaffirmed: BOT Rep. 45, A-18; Reaffirmed: BOT Rep. 19, A-18; Reaffirmation: A-19; Reaffirmed: CMS Rep. 3, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 516  
(A-22)

Introduced by: Undersea and Hyperbaric Medical Society

Subject: Oppose “Mild Hyperbaric” Facilities from Delivering Unsupported Clinical Treatments

Referred to: Reference Committee E

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1 Whereas, So called “mild hyperbaric facilities” have become numerous in the very recent past  
2 consisting of at least 288 locations in 31 states in the United States; and  
3

4 Whereas, These centers are treating and charging clients mostly for scientifically unsupported  
5 disease entities and conditions without any or with inadequate evidence and without intention to  
6 analyze results and add to the compendium of medical knowledge; and  
7

8 Whereas, These centers take advantage of vulnerable populations including those suffering  
9 from autism, multiple sclerosis, cerebral palsy, and post-stroke injuries; and  
10

11 Whereas, These centers offer clients improvement in general health and wellness without any  
12 substantiating science or even reasonably predicated mechanisms; and  
13

14 Whereas, When “mild hyperbaric” centers do treat conditions in which published experience and  
15 scientific evidence support the use of hyperbaric oxygen, they fail to use time-tested protocols.  
16 Typically, their treatments deliver pressures just over 1.0 ATA (atmospheres absolute) and less  
17 than 1.4 ATA. They also fail to deliver inhaled oxygen concentrations near 100% oxygen to the  
18 patient. Both of these fall very short of time-tested treatment parameters; and  
19

20 Whereas, Treatments are offered without physician oversight or prescription, and without  
21 appropriately trained staff; and  
22

23 Whereas, Treatments are delivered often in unsafe environments with inadequately trained staff  
24 and without required safety and fire suppression equipment in chambers that are not FDA-  
25 certified and for which no 510K application has been made; therefore be it  
26

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

Fiscal Note: Minimal - less than \$1,000

Received: 05/08/22

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 517  
(A-22)

Introduced by: Undersea and Hyperbaric Medical Society

Subject: Safeguard the Public from Widespread Unsafe Use of “Mild Hyperbaric Oxygen Therapy”

Referred to: Reference Committee E

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1 Whereas, There has been a recent proliferation of “mild hyperbaric” activities outside medical  
2 facilities in chiropractic centers, wellness centers and health spas. The magnitude of these  
3 practices is documented to be widespread, occurring in at least 288 centers in 31 states; and  
4

5 Whereas Pressure vessels (chambers) employed by these centers are not typically inspected,  
6 certified, or approved by the appropriate standards and regulatory agencies including the FDA  
7 and ASME (American Society of Mechanical Engineers). Many chambers are being imported  
8 from foreign countries. At least two U.S. companies are also involved in design, manufacture,  
9 and sales of inadequately designed chambers. In both cases, the manufacturers do not seek  
10 the required certification of pressure vessels for human occupancy inappropriately marketing  
11 these as medical hyperbaric chambers with no valid FDA 510K clearance; and  
12

13 Whereas, These treatments are being conducted without physician supervision or prescription.  
14 In the event of chamber integrity failure, patients are subject to serious injury and even death by  
15 barotrauma. Furthermore, additional complications including hypoglycemic reactions and  
16 unrecognized cardiac emergencies can occur and require immediate physician recognition and  
17 intervention; and  
18

19 Whereas, Without regard to the inherent risk of fire in this special environment, most of these  
20 facilities operate with chambers installed into business spaces not adherent to the safety  
21 regulations of the NFPA (National Fire Protection Association) and not protected by sprinkler  
22 systems, alarms or other safety equipment; and  
23

24 Whereas The staff delivering the actual hyperbaric exposures in “mild hyperbaric facilities” are  
25 not receiving comprehensive training in chamber operation, safety and emergency prevention;  
26 and  
27

28 Whereas, Heath Canada has already banned future sales of soft sided mild hyperbaric  
29 chambers often used in “mild hyperbaric” applications and called for the recall of those already  
30 sold; and  
31

32 Whereas, These centers often promote and advertise false and misleading applications in the  
33 treatment in non-compliance with FDA regulations; therefore be it  
34

35 RESOLVED, That our American Medical Association oppose the operation of unsafe “Mild  
36 Hyperbaric Facilities” (New HOD Policy); and be it further



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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/08/22

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2. Government of Canada. "Unauthorized soft-shelled hyperbaric chambers may pose serious health risks." Canada.ca, Government of Canada, Oct. 2019, [recalls-rappels.canada.ca/en/alert-recall/unauthorized-soft-shelled-hyperbaric-chambers-may-pose-serious-health-risks](https://recalls-rappels.canada.ca/en/alert-recall/unauthorized-soft-shelled-hyperbaric-chambers-may-pose-serious-health-risks).
3. National Fire Protection Association (NFPA) Part 99: Health Care Facilities Code 2021 Edition

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518  
(A-22)

Introduced by: American College of Obstetricians and Gynecologists

Subject: Over-the-Counter Access to Oral Contraceptives

Referred to: Reference Committee E

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1 Whereas, The benefits of contraception, named as one of the 10 great public health  
2 achievements of the 20th century by the Centers for Disease Control and Prevention, are widely  
3 recognized and include improved health and well-being, reduced global maternal mortality,  
4 health benefits of pregnancy spacing for maternal and child health, female engagement in the  
5 work force, and economic self-sufficiency;<sup>1</sup> and  
6

7 Whereas, Contraception can be lifesaving for people with serious medical conditions like heart  
8 disease, cancer or diabetes for whom an unplanned pregnancy can worsen preexisting health  
9 conditions; and  
10

11 Whereas, Oral contraceptives can have important non-contraceptive benefits, including  
12 decreasing risk of endometrial and ovarian cancer, treating heavy menstrual bleeding and  
13 dysmenorrhea, and reducing pelvic pain due to endometriosis;<sup>2</sup> and  
14

15 Whereas, Barriers to access are one reason for inconsistent or nonuse of contraception and  
16 the requirement for a prescription can be an obstacle for some contraceptive users; and  
17

18 Whereas, A national survey of 1,385 women reported that among the 68% of individuals who  
19 had ever tried to obtain a prescription for hormonal contraception, 29% had problems  
20 accessing the initial prescription or refills, reporting obstacles including challenges in obtaining  
21 an appointment or getting to a clinic, the health care provider requiring a clinic visit,  
22 examination, or Pap test, and not having a regular physician or clinic;<sup>3</sup> and  
23

24 Whereas, Surveys repeatedly have demonstrated interest among adolescents and adult  
25 women in over-the-counter access to oral contraceptives,<sup>4-6</sup> including a 2011 national survey  
26 about views on over-the-counter oral contraceptives,<sup>7</sup> a nationally representative, cross-  
27 sectional online survey of approximately 2,500 females (aged 15–44 years),<sup>8</sup> and focus group  
28 data from adolescent females and adult women;<sup>9-10</sup> and  
29

30 Whereas, Progestin-only emergency contraception (EC) is already available without a  
31 prescription for people of all ages in the United States; and  
32

33 Whereas, Pelvic and breast examinations, cervical cancer screening, and sexually transmitted  
34 infection screening are not required before initiating hormonal contraception;<sup>11-14</sup> and  
35

36 Whereas, Studies have shown that women can accurately use checklists to determine if they  
37 have contraindications to hormonal contraception; in one study, 96% of cases evaluated  
38 demonstrated agreement between a women's assessment of her contraindications using a  
39 checklist and a clinician's independent evaluation, and women often take a more conservative  
40 approach compared with clinicians;<sup>15-16</sup> and

1 Whereas, Data support that progestin-only hormonal methods are generally safe and carry no  
2 or minimal risk of venous thromboembolism (VTE);<sup>17</sup> and

3  
4 Whereas, The VTE risk with combined oral contraceptive use is small compared with the  
5 increased risk of VTE during pregnancy and the postpartum period;<sup>18</sup> and

6  
7 Whereas, Oral contraceptive pills are safe and effective for adolescent users, there is no  
8 scientific rationale for limiting access to a future over-the-counter oral contraceptive product by  
9 age, and over-the-counter access to hormonal contraception has the potential to reduce barriers  
10 and increase hormonal contraceptive use for adolescents;<sup>19</sup> and

11  
12 Whereas, An Oral Contraceptives Over-the-Counter Working Group was formed in 2004 with  
13 the aims “to improve access to contraception and reduce disparities in reproductive health  
14 outcomes by making a low-cost oral contraceptive product available OTC in the United States;”  
15 and

16  
17 Whereas, Over 100 organizations have signed onto the Oral Contraceptives Over-the-Counter  
18 Working Group’s statement of purpose, including the American Academy of Pediatrics, ACOG,  
19 the National Hispanic Medical Association, the North American Society for Pediatric and  
20 Adolescent Gynecology, and the Society for Adolescent Health and Medicine;<sup>20</sup> and

21  
22 Whereas, Policy statements from the American Academy of Family Physicians (AAFP), the  
23 American College of Obstetricians and Gynecologists (ACOG), and American Public Health  
24 Association (APHA) support OTC oral contraceptive access;<sup>21-23</sup> and

25  
26 Whereas, In December 2016, Ibis Reproductive Health announced a partnership with HRA  
27 Pharma to conduct the research needed and submit an application to the FDA to bring a  
28 progestin-only oral contraceptive pill to the United States OTC market;<sup>24</sup> and

29  
30 Whereas, Current AMA Policy directs our AMA to encourage manufacturers of oral  
31 contraceptives to submit the required application and supporting evidence to the US Food and  
32 Drug Administration for the Agency to consider approving a switch in status from prescription  
33 to over-the-counter for such products; and

34  
35 Whereas, HRA Pharma completed its final testing phase in 2021 on a progestin-only oral  
36 contraceptive and is expected to file a formal application for over-the-counter approval with the  
37 U.S. Food and Drug Administration before the end of 2022;<sup>25</sup> therefore be it

38  
39 RESOLVED, That our American Medical Association amend policy D-75.995, “Over-the-  
40 Counter Access to Oral Contraceptives,” by addition and deletion to read as follows:

41  
42 Our AMA:

- 43 1. Encourages ~~manufacturers of oral contraceptives to submit the required~~  
44 ~~application and supporting evidence to the US Food and Drug Administration for the~~  
45 ~~Agency to consider approving a~~ to swiftly review and approve a switch in status from  
46 prescription to over-the-counter for ~~such products~~ oral contraceptives, without age  
47 restriction.  
48 2. Encourages the continued study of issues relevant to over-the-counter access for  
49 oral contraceptives.  
50 3. Will work with expert stakeholders to advocate for the availability of hormonal  
51 contraception as an over-the-counter medication. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 05/11/22

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25. Draft abortion opinion renews urgency on over-the-counter birth control, Politico. <https://www.politico.com/news/2022/05/05/draft-abortion-opinion-sctotus-over-the-counter-birth-control-00030157>

## **RELEVANT AMA POLICY**

### **Over-the-Counter Access to Oral Contraceptives D-75.995**

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

Citation: Sub. Res. 507, A-13; Modified: BOT Rep. 10, A-18

### **Development and Approval of New Contraceptives H-75.990**

Our AMA: (1) supports efforts to increase public funding of contraception and fertility research; (2) urges the FDA to consider the special health care needs of Americans who are not adequately served by existing contraceptive products when considering the safety, effectiveness, risk and benefits of new contraception drugs and devices; and (3) encourages contraceptive manufacturers to conduct post-marketing surveillance studies of contraceptive products to document the latter's long-term safety, effectiveness and acceptance, and to share that information with the FDA.

Citation: BOT Rep. O, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11; Modified: CSAPH Rep. 1, A-21

### **Opposition to HHS Regulations on Contraceptive Services for Minors H-75.998**

(1) Our AMA continues to oppose regulations that require parental notification when prescription contraceptives are provided to minors through federally funded programs, since they create a breach of confidentiality in the physician-patient relationship. (2) The Association encourages physicians to provide comparable services on a confidential basis where legally permissible.

Citation: (Sub. Res. 65, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: Res. 825, I-04; Reaffirmed: CMS Rep. 1, A-14)

### **Coverage of Contraceptives by Insurance H-180.958**

1. Our AMA supports federal and state efforts to require that every prescription drug benefit plan include coverage of prescription contraceptives.
2. Our AMA supports full coverage, without patient cost-sharing, of all contraception without regard to prescription or over-the-counter utilization because all contraception is essential preventive health care.

Citation: Res. 221, A-98; Reaffirmation A-04; Reaffirmed: CMS Rep. 1, A-14; Reaffirmation: I-17; Modified: BOT Rep. 10, A-18

### **Reducing Unintended Pregnancy H-75.987**

Our AMA: (1) urges health care professionals to provide care for women of reproductive age, to assist them in planning for pregnancy and support age-appropriate education in esteem building, decision-making and family life in an effort to introduce the concept of planning for childbearing in the educational process; (2) supports reducing unintended pregnancies as a national goal; and (3) supports the training of all primary care physicians and relevant allied health professionals in the area of preconception counseling, including the recognition of long-acting reversible contraceptives as efficacious and economical forms of contraception.

Citation: Res. 512, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmation A-15; Appended: Res. 502, A-15; Reaffirmation I-16

**Access to Emergency Contraception H-75.985**

It is the policy of our AMA: (1) that physicians and other health care professionals should be encouraged to play a more active role in providing education about emergency contraception, including access and informed consent issues, by discussing it as part of routine family planning and contraceptive counseling; (2) to enhance efforts to expand access to emergency contraception, including making emergency contraception pills more readily available through pharmacies, hospitals, clinics, emergency rooms, acute care centers, and physicians' offices; (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims; (4) to support educational programs for physicians and patients regarding treatment options for the emergency treatment of sexual assault victims, including information about emergency contraception; and (5) to encourage writing advance prescriptions for these pills as requested by their patients until the pills are available over-the-counter.

Citation: (CMS Rep. 1, I-00; Appended: Res. 408, A-02; Modified: Res. 443, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

**Access to Emergency Contraception D-75.997**

1. Our AMA will: (a) intensify efforts to improve awareness and understanding about the availability of emergency contraception in the general public; and (b) support and monitor the application process of manufacturers filing for over-the-counter approval of emergency contraception pills with the Food and Drug Administration (FDA).
2. Our AMA: (a) will work in collaboration with other stakeholders (such as American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American College of Preventive Medicine) to communicate with the National Association of Chain Drug Stores and the National Community Pharmacists Association, and request that pharmacies utilize their web site or other means to signify whether they stock and dispense emergency contraception, and if not, where it can be obtained in their region, either with or without a prescription; and (b) urges that established emergency contraception regimens be approved for over-the-counter access to women of reproductive age, as recommended by the relevant medical specialty societies and the US Food and Drug Administration's own expert panel.

Citation: CMS Rep. 1, A-00; Appended: Res. 506, A-07; Reaffirmed: CMS Rep. 01, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 519  
(A-22)

Introduced by: Association for Clinical Oncology

Subject: Advanced Research Projects Agency for Health (ARPA-H)

Referred to: Reference Committee E

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1 Whereas, The current biomedical and cancer research enterprise has led to the discovery of  
2 innovative new treatments for all areas of healthcare through basic and translational research  
3 and clinical trials; and  
4  
5 Whereas, COVID-19 has disrupted biomedical and cancer research and continues to threaten  
6 research progress; and  
7  
8 Whereas, President Biden has called for a major investment in cutting edge/innovative federal  
9 research with the establishment of the Advanced Research Projects Agency for Health  
10 (ARPA-H); and  
11  
12 Whereas, Efforts to establish ARPA-H should ensure sustained and dedicated funding to  
13 achieve impactful translational research; and  
14  
15 Whereas, Any reform to the biomedical research enterprise and health innovation efforts should  
16 not impact the current or future resources of existing research enterprises; therefore be it  
17  
18 RESOLVED, That our American Medical Association urge Congress and the Administration to  
19 ensure that while providing adequate funding for the promising research conducted at Advanced  
20 Research Projects Agency for Health (ARPA-H), it also provides robust annual baseline  
21 increases in appropriations for other research agencies, centers, and institutes, including, but  
22 not limited to, the NIH and NCI. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/11/22

## **RELEVANT AMA POLICY**

### **Importance of Clinical Research H-460.930**

(1) Given the profound importance of clinical research as the transition between basic science discoveries and standard medical practice of the future, the AMA will a) be an advocate for clinical research; and b) promote the importance of this science and of well-trained researchers to conduct it.

(2) Our AMA continues to advocate vigorously for a stable, continuing base of funding and support for all aspects of clinical research within the research programs of all relevant federal agencies, including the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs and the Department of Defense.

(3) The AMA believes it is an inherent obligation of capitation programs and managed care organizations to invest in broad-based clinical research (as well as in health care delivery and outcomes research) to assure continued transition of new developments from the research bench to medical practice. The AMA strongly encourages these groups to make significant financial contributions to support such research.

(4) Our AMA continues to encourage medical schools a) to support clinical research; b) to train and develop clinical researchers; c) to recognize the contribution of clinical researchers to academic medicine; d) to assure the highest quality of clinical research; and e) to explore innovative ways in which clinical researchers in academic health centers can actively involve practicing physicians in clinical research.

(5) Our AMA encourages and supports development of community and practice-based clinical research networks.

Citation: CSA Rep. 2, I-96; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: CME Rep. 4, I-08; Modified: CSAPH Rep. 01, A-18



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 520  
(A-22)

Introduced by: Medical Student Section

Subject: Addressing Informal Milk Sharing

Referred to: Reference Committee E

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1 Whereas, A growing body of evidence supported by the American Academy of Pediatrics (AAP)  
2 indicates that breast milk protects growing infants--especially preterm infants--against a variety  
3 of dangerous diseases and conditions, including bacteremia, urinary tract infections, lower  
4 respiratory tract infections, necrotizing enterocolitis, and sudden infant death syndrome, among  
5 others<sup>1,2</sup>; and  
6

7 Whereas, Human milk sharing, also known as using donor human milk, provides access to  
8 breast milk for mothers who cannot provide enough for their infants, especially preterm infants  
9 in the Neonatal Intensive Care Unit (NICU)<sup>3</sup>; and  
10

11 Whereas, Donor human milk provides nutrients comparable to a mother's own milk, yielding  
12 positive effects on neurodevelopment and tolerance of feedings, as well as reduced risk of  
13 sepsis and necrotizing enterocolitis, reduced length of stay in the NICU, and direct cost savings  
14 <sup>4, 5</sup>; and  
15

16 Whereas, Informal or peer milk sharing, defined as the practice of donating or receiving donor  
17 human milk directly peer-to-peer, is growing in popularity, with tens of thousands of informal  
18 milk exchanges occurring via Facebook groups each year and national surveys of milk sharing  
19 participants finding that as many as 64% of respondents have obtained donor breast milk  
20 informally<sup>6-11</sup>; and  
21

22 Whereas, Informal milk sharing is associated with many quality concerns, such as dilution with  
23 non-human milk which infants are unable to properly digest for the first year of life<sup>3, 12, 13</sup>; and  
24

25 Whereas, Informal milk sharing also carries many safety risks including contamination via  
26 infectious or toxic environmental agents, with several studies finding that a significant number  
27 of informally shared human milk samples were colonized with disease-causing pathogens,  
28 including aerobic bacteria, gram-negative bacteria, and coliform bacteria<sup>14, 15, 16, 17</sup>; and  
29

30 Whereas, These safety risks are of special concern with the coronavirus disease 2019 (COVID-  
31 19) pandemic as it cannot be confirmed whether safety precautions known to protect against  
32 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission—including  
33 wearing a mask while expressing milk, washing hands and equipment thoroughly, and  
34 pasteurizing donor milk—have been taken with informally shared milk<sup>18, 19</sup>; and  
35

36 Whereas, Non-profit milk banks, which are regulated by the Human Milk Banking Association of  
37 North America (HMBANA), serve as a safe alternative to informal milk sharing by providing  
38 breast milk that is screened, pooled, tested, and pasteurized to be provided to infants in need<sup>20</sup>;  
39 and

1 Whereas, Non-profit milk banks are associated with many limitations in accessibility, including  
2 limited distribution as only 25 non-profit milk banks operate in the United States due to  
3 limitations in donor supply and access to funding<sup>3, 21, 22, 23</sup>; and  
4

5 Whereas, Already-limited milk supplies at non-profit milk banks are being further strained during  
6 the COVID-19 pandemic due to inadequate staffing, challenges with donor recruitment, and  
7 safety concerns about donor milk<sup>24</sup>; and  
8

9 Whereas, Access to non-profit milk bank breast milk is also limited by cost, as this milk  
10 generally costs \$3-\$5 per ounce, and although Medicaid, the Special Supplemental Nutrition  
11 Program for Women, Infants, and Children, and other aid-providing programs can help to cover  
12 costs, this coverage varies by state<sup>25, 26</sup>; and  
13

14 Whereas, The majority of the public is unable to access non-profit milk bank breast milk as a  
15 prescription is often required to receive this milk and the majority of non-profit milk bank breast  
16 milk is provided to NICUs due to limitations in supply<sup>3, 27</sup>; and  
17

18 Whereas, Concerns have risen about informal milk sharing outcompeting milk banks for receipt  
19 of human milk donations, and studies have found that women who participate in milk sharing  
20 are much more likely to have donated informally than to have donated to a milk bank<sup>5-10, 28, 29</sup>;  
21 and  
22

23 Whereas, The AAP, the U.S. Food and Drug Administration, the European Milk Bank  
24 Association, HMBANA, and the Academy of Breastfeeding Medicine have released statements  
25 within the last 5 years discouraging informal milk sharing in favor of milk banking<sup>3, 8, 9, 27, 30, 31</sup>;  
26 and  
27

28 Whereas, The AMA has existing policy supporting breastfeeding (H-245.982) and breast milk  
29 banking (H-245.972) but these policies and the policy statements they support make no mention  
30 of informal milk sharing or donation to milk banks; therefore be it  
31

32 RESOLVED, That our American Medical Association discourage the practice of informal milk  
33 sharing when said practice does not rise to health and safety standards comparable to those of  
34 milk banks, including but not limited to screening of donors and/or milk pasteurization (New  
35 HOD Policy); and be it further  
36

37 RESOLVED, That our AMA encourage breast milk donation to regulated human milk banks  
38 instead of via informal means (Directive to Take Action); and be it further  
39

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/11/22

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## RELEVANT AMA POLICY

### Breast Milk Banking H-245.972

Our AMA encourages breast milk banking.

Res. 443, A-07; Reaffirmed: CSAPH Rep. 01, A-17

### AMA Support for Breastfeeding H-245.982

1. Our AMA: (a) recognizes that breastfeeding is the optimal form of nutrition for most infants; (b) endorses the 2012 policy statement of American Academy of Pediatrics on Breastfeeding and the use of Human Milk, which delineates various ways in which physicians and hospitals can promote, protect, and support breastfeeding practices; (c) supports working with other interested organizations in actively seeking to promote increased breastfeeding by Supplemental Nutrition Program for Women, Infants, and Children (WIC Program) recipients, without reduction in other benefits; (d) supports the availability and appropriate use of breast pumps as a cost-effective tool to promote breast feeding; and (e) encourages public facilities to provide designated areas for breastfeeding and breast pumping; mothers nursing babies should not be singled out and discouraged from nursing their infants in public places.
2. Our AMA: (a) promotes education on breastfeeding in undergraduate, graduate, and continuing medical education curricula; (b) encourages all medical schools and graduate medical education programs to support all residents, medical students and faculty who provide breast milk for their infants, including appropriate time and facilities to express and store breast milk during the working day; (c) encourages the education of patients during prenatal care on the benefits of breastfeeding; (d) supports breastfeeding in the health care system by encouraging hospitals to provide written breastfeeding policy that is communicated to health care staff; (e) encourages hospitals to train staff in the skills needed to

implement written breastfeeding policy, to educate pregnant women about the benefits and management of breastfeeding, to attempt early initiation of breastfeeding, to practice "rooming-in," to educate mothers on how to breastfeed and maintain lactation, and to foster breastfeeding support groups and services; (f) supports curtailing formula promotional practices by encouraging perinatal care providers and hospitals to ensure that physicians or other appropriately trained medical personnel authorize distribution of infant formula as a medical sample only after appropriate infant feeding education, to specifically include education of parents about the medical benefits of breastfeeding and encouragement of its practice, and education of parents about formula and bottle-feeding options; and (g) supports the concept that the parent's decision to use infant formula, as well as the choice of which formula, should be preceded by consultation with a physician.

3. Our AMA: (a) supports the implementation of the WHO/UNICEF Ten Steps to Successful Breastfeeding at all birthing facilities; (b) endorses implementation of the Joint Commission Perinatal Care Core Measures Set for Exclusive Breast Milk Feeding for all maternity care facilities in the US as measures of breastfeeding initiation, exclusivity and continuation which should be continuously tracked by the nation, and social and demographic disparities should be addressed and eliminated; (c) recommends exclusive breastfeeding for about six months, followed by continued breastfeeding as complementary food are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant; (d) recommends the adoption of employer programs which support breastfeeding mothers so that they may safely and privately express breast milk at work or take time to feed their infants; and (e) encourages employers in all fields of healthcare to serve as role models to improve the public health by supporting mothers providing breast milk to their infants beyond the postpartum period.

4. Our AMA supports the evaluation and grading of primary care interventions to support breastfeeding, as developed by the United States Preventive Services Task Force (USPSTF).

5. Our AMA's Opioid Task Force promotes educational resources for mothers who are breastfeeding on the benefits and risks of using opioids or medication-assisted therapy for opioid use disorder, based on the most recent guidelines.

CSA Rep. 2, A-05; Res. 325, A-05; Reaffirmation A-07; Reaffirmation A-12; Modified in lieu of Res. 409; A-12 and Res. 410, A-12; Appended: Res. 410, A-16; Appended: Res. 906, I-17; Reaffirmation: I-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 521  
(A-22)

Introduced by: Medical Student Section

Subject: Encouraging Brain and Other Tissue Donation for Research and Educational Purposes

Referred to: Reference Committee E

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1 Whereas, Postmortem tissue contains invaluable information that can be used for medical  
2 research and educational purposes to improve our understanding of human physiology and  
3 pathophysiology and thus enhance patient care<sup>1</sup>; and  
4

5 Whereas, Recent research using postmortem brain tissue has been critical to our understanding  
6 of the pathogenesis of neurological and psychiatric illnesses such as Parkinson's disease,  
7 dementia, PTSD, autism, and major depression, and builds upon advances from neuroimaging,  
8 genetic, biomarker, and animal studies<sup>2-8</sup>; and  
9

10 Whereas, States have taken efforts to raise awareness of and increase donation for organ  
11 transplant, such as by asking individuals if they would like to join transplant donor registries  
12 when they apply for or renew their driver's licenses<sup>9,10</sup>; and  
13

14 Whereas, In Texas alone, nearly 7 million people have joined the Texas Donor Registry since a  
15 question regarding organ donation for transplantation was added to driver's license  
16 applications<sup>11</sup>; and  
17

18 Whereas, Ninety-eight percent of organ donation registration occurs at the Bureau of Motor  
19 Vehicles, and promotional materials and clerk educational training has been shown to increase  
20 organ donation registration by up to 7.8%<sup>10,12</sup>; and  
21

22 Whereas, Although some states offer an option for organ donation and/or tissue donation for  
23 research purposes via donor cards, brain tissue donation requires a separate consenting  
24 process that often occurs after death through the next of kin<sup>13,14</sup>; and  
25

26 Whereas, Willed body program recruitment is not standardized across institutions and can  
27 create a large financial and logistic burden on institutions<sup>1</sup>; and  
28

29 Whereas, Widespread efforts to inform individuals of the importance of tissue donation for  
30 research and health professions education and allow interested individuals the opportunity to  
31 easily provide informed consent to donate their bodies for research or education purposes could  
32 increase donation rates, decrease costs, and eliminate the need for families to make decisions  
33 for their loved ones postmortem<sup>15</sup>; and  
34

35 Whereas, These efforts could include strategies used to increase organ donation for  
36 transplantation, such as asking individuals if they would like to donate other tissue for research  
37 purposes when applying for or renewing a driver's license<sup>10</sup>; and

1 Whereas, A study of public perceptions surrounding whole-body donation found that 58.8% of  
2 participants reported insufficient understanding of the body and tissue donation process for  
3 research and educational purposes, 77.4% reported that they did not know how to register to  
4 become a whole-body donor, and 23.9% reported that they did not know they could be  
5 registered as both a transplant organ donor and whole-body donor or tissue donor<sup>16</sup>; and  
6

7 Whereas, Several studies have found that after receiving information about the tissue donation  
8 process, the majority of participants would be likely or somewhat likely to donate their brain  
9 tissue (>60%) for research<sup>17-19</sup>; and  
10

11 Whereas, While current AMA policies H-370.984, H-370.995, H-370.996, and H-370.998  
12 address increasing public education and donation rates for transplantation, they do not address  
13 postmortem tissue donation for primarily scientific or educational purposes; therefore be it  
14

15 RESOLVED, That our American Medical Association support the production and distribution of  
16 educational materials regarding the importance of postmortem tissue donation for the purposes  
17 of medical research and education (New HOD Policy); and be it further  
18

19 RESOLVED, That our AMA encourage the inclusion of additional information and consent  
20 options for brain and other tissue donation for research purposes on appropriate donor  
21 documents (New HOD Policy); and be it further  
22

23 RESOLVED, That our AMA encourage all persons to consider consenting to tissue donation  
24 including brain tissue for research purposes (Directive to Take Action); and be it further  
25

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/11/22

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## RELEVANT AMA POLICY

### Importance of Clinical Research H-460.930

- (1) Given the profound importance of clinical research as the transition between basic science discoveries and standard medical practice of the future, the AMA will a) be an advocate for clinical research; and b) promote the importance of this science and of well-trained researchers to conduct it.
- (2) Our AMA continues to advocate vigorously for a stable, continuing base of funding and support for all aspects of clinical research within the research programs of all relevant federal agencies, including the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs and the Department of Defense.
- (3) The AMA believes it is an inherent obligation of capitation programs and managed care organizations to invest in broad-based clinical research (as well as in health care delivery and outcomes research) to assure continued transition of new developments from the research bench to medical practice. The AMA strongly encourages these groups to make significant financial contributions to support such research.
- (4) Our AMA continues to encourage medical schools a) to support clinical research; b) to train and develop clinical researchers; c) to recognize the contribution of clinical researchers to academic medicine; d) to assure the highest quality of clinical research; and e) to explore innovative ways in which clinical researchers in academic health centers can actively involve practicing physicians in clinical research.
- (5) Our AMA encourages and supports the development of community and practice-based clinical research networks. CSA Rep. 2, I-96; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation: A-00; Reaffirmed: CME Rep. 4, I-08; Modified: CSAPH Rep. 1, A-18

### Physician Involvement in Research: Opinion E-7.1.1

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) and individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

- (a) Participate only in those studies for which they have relevant expertise.
- (b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:
  - (i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;
  - (ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;
  - (iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.
- (c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.
- (d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.
- (e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
- (f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating the results of the research.

AMA Principles of Medical Ethics: I, II, III, V Issued: 2016

### Organ Donation D-370.985

Our AMA will study potential models for increasing the United States organ donor pool.  
Res. 1, A-14; Reaffirmed in lieu of: Res. 5, I-14; Reaffirmed in lieu of: Res. 002, I-16

**Organ Donation and Honoring Organ Donor Wishes H-370.998**

Our AMA: (1) continues to urge the citizenry to sign donor cards and supports continued efforts to educate the public on the desirability of, and the need for organ donations, as well as the importance of discussing personal wishes regarding organ donation with appropriate family members; and (2) when a good faith effort has been made to contact the family, actively encourage Organ Procurement Organizations and physicians to adhere to provisions of the Uniform Anatomical Gift Act which allows for the procurement of organs when the family is absent and there is a signed organ donor card or advanced directive stating the decedent's desire to donate the organs.  
CSA Rep. D, I-80; CLRPD Rep. B, I-90; Amended: Res. 504, I-99, Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep.1, A-12

**Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients H-370.982**

Our AMA has adopted the following guidelines as policy: (1) Decisions regarding the allocation of scarce medical resources among patients should consider only ethically appropriate criteria relating to medical need. (a) These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients. (b) Research should be pursued to increase knowledge of outcomes and thereby improve the accuracy of these criteria. (c) Non-medical criteria, such as ability to pay, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered.

(2) Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible. (a) All candidates for treatment must be fully considered according to ethically appropriate criteria relating to medical need, as defined in Guideline 1. (b) When very substantial differences do not exist among potential recipients of treatment on the basis of these criteria, a "first-come-first-served" approach or some other equal opportunity mechanism should be employed to make final allocation decisions. (c) Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula.

(3) Decision making mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally. The nature of the physician-patient relationship entails that physicians of patients competing for a scarce resource must remain advocates for their patients, and therefore should not make the actual allocation decisions.

(4) Patients must be informed by their physicians of allocation criteria and procedures, as well as their chances of receiving access to scarce resources. This information should be in addition to all the customary information regarding the risks, benefits, and alternatives to any medical procedure. Patients denied access to resources have the right to be informed of the reasoning behind the decision.

(5) The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession.

(6) Physicians should continue to look for innovative ways to increase the availability of and access to scarce medical resources so that, as much as possible, beneficial treatments can be provided to all who need them.

(7) Physicians should accept their responsibility to promote awareness of the importance of an increase in the organ donor pool using all available means.  
CEJA Rep. K, A-93, Reaffirmed: CSA Rep. 12, I-99, Reaffirmed: CSA Rep. 6, A-00, Appended: Res. 512, A-02, Reaffirmed: CEJA Rep. 3, A-12

**Tissue and Organ Donation H-370.983**

Our AMA will assist the United Network for Organ Sharing in the implementation of their recommendations through broad-based physician and patient education. (Res. 533, A-92 Reaffirmed: CSA Rep. 12, I-99; Reaffirmed: CSA Rep. 6, A00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12

**Organ Donor Recruitment H-370.995**

Our AMA supports development of "state of the art" educational materials for the medical community and the public at large, demonstrating at least the following: (1) the need for organ donors;(2) the success rate for organ transplantation;(3) the medico-legal aspects of organ transplantation; (4) the integration of organ recruitment, preservation and transplantation; (5) cost/reimbursement mechanisms for organ transplantation; and(6) the ethical considerations of organ donor recruitment.  
Res. 32, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12)

**Organ Donor Recruitment H-370.996**

Our AMA (1) continues to urge Americans to sign donor cards; (2) supports continued efforts to teach physicians through continuing medical education courses, and the lay public through health education programs, about transplantation issues in general and the importance of organ donation in particular; (3) encourages state governments to attempt pilot studies on promotional efforts that stimulate each adult to respond "yes" or "no" to the option of signing a donor card; and (4) in collaboration with all other interested parties, support the exploration of methods to greatly increase organ donation, such as the "presumed consent" modality of organ donation. CSA Rep. D, A-81; Reaffirmed: CLRPD Rep. F, I-91; Appended: Res. 509, I-98; Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12; Reaffirmed: Res. 006, A-18



**Importance of Autopsies H-85.954**

1. Our AMA supports seeking the cooperation of the National Advisory Council on Aging of the National Institutes of Health in recommending to physicians, hospitals, institutes of scientific learning, universities, and most importantly the American people the necessity of autopsy for pathological correlation of the results of the immeasurable scientific advancements which have occurred in recent years. Our AMA believes that the information garnered from such stringent scientific advancements and correlation, as well as coalitions, should be used in the most advantageous fashion; and that the conclusions obtained from such investigations should be widely shared with the medical and research community and should be interpreted by these groups with the utmost scrutiny and objectivity.
2. Our AMA: (a) supports the efforts of the Institute of Medicine and other national organizations in formulating national policies to modernize and promote the use of autopsy to meet present and future needs of society; (b) promotes the use of updated autopsy protocols for medical research, particularly in the areas of cancer, cardiovascular, occupational, and infectious diseases; (c) promotes the revision of standards of accreditation for medical undergraduate and graduate education programs to more fully integrate autopsy into the curriculum and require postmortems as part of medical educational programs; (d) encourages the use of a national computerized autopsy data bank to validate technological methods of diagnosis for medical research and to validate death certificates for public health and the benefit of the nation; (e) requests The Joint Commission to consider amending the Accreditation Manual for Hospitals to require that the complete autopsy report be made part of the medical record within 30 days after the postmortem; (f) supports the formalization of methods of reimbursement for autopsy in order to identify postmortem examinations as medical prerogatives and necessary medical procedures; (g) promotes programs of education for physicians to inform them of the value of autopsy for medical legal purposes and claims processing, to learn the likelihood of effects of disease on other family members, to establish the cause of death when death is unexplained or poorly understood, to establish the protective action of necropsy in litigation, and to inform the bereaved families of the benefits of autopsy; and (h) promotes the incorporation of updated postmortem examinations into risk management and quality assurance programs in hospitals.
3. Our AMA reaffirms the fundamental importance of the autopsy in any effective hospital quality assurance program and urges physicians and hospitals to increase the utilization of the autopsy so as to further advance the cause of medical education, research and quality assurance.
4. Our AMA representatives to the Liaison Committee on Medical Education ask that autopsy rates and student participation in autopsies continue to be monitored periodically and that the reasons that schools do or do not require attendance be collected. Our AMA will continue to work with other interested groups to increase the rate of autopsy attendance.
5. Our AMA requests that the National Committee on Quality Assurance (NCQA) and other accrediting bodies encourage the performance of autopsies to yield benchmark information for all managed care entities seeking accreditation.
6. Our AMA calls upon all third-party payers, including CMS, to provide adequate payment directly for autopsies, and encourages adequate reimbursement by all third-party payers for autopsies.
7. It is the policy of our AMA: (a) that the performance of autopsies constitutes the practice of medicine; and (b) in conjunction with the pathology associations represented in the AMA House, to continue to implement all the recommendations regarding the effects of decreased utilization of autopsy on medical education and research, quality assurance programs, insurance claims processing, and cost containment.
8. Our AMA affirms the importance of autopsies and opposes the use of any financial incentives for physicians who acquire autopsy clearance.

CCB/CLRPD Rep. 3, A-14

**Endorsement of the Uniform Anatomical Gift Act (2006) H-370.968**

Our AMA endorses the Uniform Anatomical Gift Act of 2006 and urges all constituent state medical societies to work with donation stakeholders, including organ procurement organizations, eye banks, tissue banks, and other donation-related organizations, toward persuading their state legislatures to adopt UAGA (2006) in place of earlier versions of the UAGA. BOT Action in response to referred for decision, Res. 901, I-06; Reaffirmed: BOT Rep. 06, A-16

**Organ Donation Education H-370.984**

"Our AMA encourages all states and local organ procurement organizations to provide educational materials to driver education and safety classes."

Res. 504, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep.1, A-12; Modified: Res. 3, A-13

**Improving Body Donation Regulation H-460.890**

Our AMA recognizes the need for ethical, transparent, and consistent body and body part donation regulations.  
Res. 012, A-19

**Organ Donation After Cardiac Death Code of Medical E-6.1.2**

Increasing the supply of organs available for transplant serves the interests of patients and the public and is in keeping with physicians' ethical obligation to contribute to the health of the public and to support access to medical care. Physicians should support innovative approaches to increasing the supply of organs for transplantation while balancing this obligation with their duty to protect the interests of their individual patients.

Organ donation after cardiac death is one approach being undertaken to make greater numbers of transplantable organs available. In what is known as "controlled" donation after cardiac death, a patient who has decided to forgo life-sustaining treatment (or the patient's authorized surrogate when the patient lacks decision-making capacity) may be offered the opportunity to discontinue life support under conditions that would permit the patient to become an organ donor by allowing organs to be removed promptly after death is pronounced. Organ retrieval under this protocol thus differs from usual procedures for cadaveric donation when the patient has died as a result of catastrophic illness or injury.

Donation after cardiac death raises a number of special ethical concerns, including how and when death is declared, potential conflicts of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation, and the use of a surrogate decision maker.

In light of these concerns, physicians who participate in retrieving organs under a protocol of donation after cardiac death should observe the following safeguards:

- (a) Promote the development of and adhere to clinical criteria for identifying prospective donors whose organs are reasonably likely to be suitable for transplantation.
- (b) Promote the development of and adhere to clear and specific institutional policies governing donation after cardiac death.
- (c) Avoid actual or perceived conflicts of interest by:
  - (i) ensuring that the health care professionals who provide care at the end of life are distinct from those who will participate in retrieving organs for transplant;
  - (ii) ensuring that no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death
- (d) Ensure that the decision to withdraw life-sustaining treatment is made prior to and independent of any offer of opportunity to donate organs (unless organ donation is spontaneously broached by the patient or surrogate).
- (e) Obtain informed consent for organ donation from the patient (or surrogate), including consent specifically to the use of interventions intended not to benefit the patient but to preserve organs in order to improve the opportunity for successful transplantation.
- (f) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing the decision to withdraw a life-sustaining intervention.

[AMA Principles of Medical Ethics: I,III,V](#) Issued: 2016

#### **Studying Financial Incentives for Cadaveric Organ Donation E-6.1.3**

Physicians' ethical obligations to contribute to the health of the public and to support access to medical care extend to participating in efforts to increase the supply of organs for transplantation. However, offering financial incentives for donation raises ethical concerns about potential coercion, the voluntariness of decisions to donate, and possible adverse consequences, including reducing the rate of altruistic organ donation and unduly encouraging perception of the human body as a source of profit.

These concerns merit further study to determine whether, overall, the benefits of financial incentives for organ donation outweigh their potential harms. It would be appropriate to carry out pilot studies among limited populations to investigate the effects of such financial incentives for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Physicians who develop or participate in pilot studies of financial incentives to increase donation of cadaveric organs should ensure that the study:

- (a) Is strictly limited to circumstances of voluntary cadaveric donation with an explicit prohibition of the selling of organs.
- (b) Is scientifically well designed and clearly defines measurable outcomes and time frames in a written protocol.
- (c) Has been developed in consultation with the population among whom it is to be carried out.
- (d) Has been reviewed and approved by an appropriate oversight body, such as an institutional review board, and is carried out in keeping with guidelines for ethical research.
- (e) Offers incentives of only modest value and at the lowest level that can reasonably be expected to increase organ donation.

[AMA Principles of Medical Ethics: I, III, V, VII, VIII, IX](#), Issued: 2016

#### **Presumed Consent & Mandated Choice for Organs from Deceased Donors E-6.1.4**

Organ transplantation offers hope for patients suffering end-stage organ failure. However, the supply of organs for transplantation is inadequate to meet the clinical need. Proposals to increase donation have included studying possible financial incentives for donation and changing the approach to consent for cadaveric donation through "presumed consent" and "mandated choice."

Both presumed consent and mandated choice models contrast with the prevailing traditional model of voluntary consent to donation, in which prospective donors indicate their preferences, but the models raise distinct ethical concerns. Under presumed consent, deceased individuals are presumed to be organ donors unless they have indicated their refusal to donate. Donations under presumed consent would be ethically appropriate only if it could be determined that individuals were aware of the presumption that they were willing to donate organs and if effective and easily accessible mechanisms for documenting and honoring refusals to donate had been established. Physicians could proceed with organ procurement based on presumed consent only after verifying that there was no documented prior refusal and that the family was not aware of any objection to donation by the deceased.

Under mandated choice, individuals are required to express their preferences regarding donation at the time they execute a state-regulated task. Donations under mandated choice would be ethically appropriate only if an individual's choice was made on the basis of a meaningful exchange of information about organ donation in keeping with the principles of informed consent. Physicians could proceed with organ procurement based on mandated choice only after verifying that the individual's consent to donate was documented.

These models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh the ethical concerns.

Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:

- (a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.
- (b) Has been developed in consultation with the population among whom it is to be carried out.

(c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.

Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

[AMA Principles of Medical Ethics: I,III,V](#), Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 522  
(A-22)

Introduced by: Medical Student Section

Subject: Encouraging Research of Testosterone and Pharmacological Therapies for Post-Menopausal Individuals with Decreased Libido

Referred to: Reference Committee E

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1 Whereas, The most recent epidemiological research shows that approximately 40% of women  
2 in the United States have sexual concerns, with 12% reporting distressing sexual problems<sup>1</sup>;  
3 and

4  
5 Whereas, It is estimated that 1.2 billion women worldwide will be menopausal or  
6 postmenopausal by the year 2030<sup>2</sup>; and

7  
8 Whereas, Sexual dysfunction in women can manifest in a number of ways, such as impaired  
9 arousal, inability to achieve orgasm, pain with sexual activity, or Hypoactive Sexual Desire  
10 Disorder (HSDD), which is defined as a deficiency or absence of sexual fantasies and desire for  
11 sexual activity that may cause personal distress or interpersonal difficulty<sup>1,3</sup>; and

12  
13 Whereas, Decreased libido in women is currently evaluated and treated using the  
14 biopsychosocial model to account for biological, psychological, interpersonal, and sociocultural  
15 factors, yet some women may have decreased libido that is refractory to standard treatments<sup>1,4</sup>;  
16 and

17  
18 Whereas, Testosterone plays a key role in maintaining libido in women, as evidenced by  
19 numerous studies that show testosterone significantly improves various aspects of libido in  
20 androgen-deficient, premenopausal, naturally post-menopausal, and surgically post-  
21 menopausal women, and testosterone levels in postmenopausal women are 50% lower  
22 compared to premenopausal women<sup>5-10</sup>; and

23  
24 Whereas, A large meta-analysis, comprised of 43 articles, 36 randomized controlled trials, and  
25 8,480 naturally or surgically post-menopausal women monitored for at least 12 weeks, indicated  
26 that use of testosterone significantly increased various aspects of sexual function such as  
27 sexual frequency, sexual desire, pleasure, and orgasms, irrespective of concurrent use  
28 estrogens, with no statistically significant increase in adverse events<sup>11-13</sup>; and

29  
30 Whereas, A double-blinded, placebo-controlled clinical trial with 53 postmenopausal women  
31 with low libido who were given 10 milligrams of testosterone gel per day for three months, in  
32 addition to their ongoing hormone replacement therapy, did not show any significant adverse  
33 effects and showed a positive effect on psychological well-being<sup>6</sup>; and

34  
35 Whereas, Doses of testosterone therapy that approximate physiologically premenopausal  
36 concentrations in postmenopausal women have been associated with mild increase in acne,  
37 body and facial hair growth but not with hair loss, clitoromegaly or changes in voice, but safety  
38 data is not available beyond 24 months and further studies are needed to evaluate potential  
39 long-term adverse effects<sup>13,14</sup>; and

1 Whereas, The effective dosage of testosterone for postmenopausal women has not been  
2 elucidated, as a study of 71 surgically menopausal women suggested that positive change in  
3 sexual function is achieved only with supraphysiologic dosing, while in 2019, a group of experts  
4 from leading women’s health societies worldwide published a consensus statement supporting  
5 the benefit of testosterone therapy in doses that approximate physiologic concentrations in  
6 premenopausal women<sup>14,15</sup>; and  
7

8 Whereas, Clinical practice guidelines published by the Endocrine Society and the American  
9 College of Obstetricians and Gynecologists recommend a 3 to 6 month trial of testosterone  
10 therapy for postmenopausal women with a diagnosis of HSDD, with close monitoring for  
11 overuse and cessation of therapy if unresponsive after 6 months, but no current United States  
12 Food & Drug Administration (FDA) approved testosterone treatments exist for women with  
13 HSDD<sup>16</sup>; and  
14

15 Whereas, Compounded and off-label medications such as flibanserin and bremelanotide have  
16 been prescribed for many years for both men and women who want to boost levels of sexual  
17 desire, arousal, and orgasm; however, these two medications received FDA approval for use in  
18 pre-menopausal women only, in 2015 and 2019 respectively<sup>17</sup>; and  
19

20 Whereas, Although there are many FDA-approved testosterone preparations for men, and  
21 internationally accepted use of testosterone products in women, none are currently approved for  
22 women in the United States, further highlighting gender biases in healthcare and medical  
23 research that are evident from the incomplete understanding of pathophysiology of women’s  
24 sexual response and its treatment<sup>13,18</sup>; and  
25

26 Whereas, As evidenced by Code of Ethics 8.5 clause (i), the AMA supports “research that  
27 examines health care disparities, including research on the unique health needs of all genders,  
28 ethnic groups, and medically disadvantaged populations, and the development of quality  
29 measures and resources to help reduce disparities;” and  
30

31 Whereas, Due to the lack of FDA-approved medications for treating decreased libido in  
32 postmenopausal women, physicians are often reluctant to prescribe medications unless  
33 prompted by the patient and are forced to resort to modifying androgen formulations created for  
34 men, which can make dosing difficult when using these preparations for postmenopausal  
35 women<sup>17,18</sup>; and  
36

37 Whereas, Compounded or off-label medications like bremelanotide and flibanserin are  
38 expensive for patients as they are not covered by insurance or available at discounted rates,  
39 leaving many postmenopausal women to live with HSDD<sup>17</sup>; therefore be it  
40

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

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/11/22

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**RELEVANT AMA POLICY**

**Code of Medical Ethics 8.5 Disparities in Health Care**

Stereotypes, prejudice, or bias based on gender expectations and other arbitrary evaluations of any individual can manifest in a variety of subtle ways. Differences in treatment that are not directly related to differences in individual patients' clinical needs or preferences constitute inappropriate variations in health care. Such variations may contribute to health outcomes that are considerably worse in members of some populations than those of members of majority populations.

This represents a significant challenge for physicians, who ethically are called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics.

To fulfill this professional obligation in their individual practices physicians should:

- (a) Provide care that meets patient needs and respects patient preferences.
- (b) Avoid stereotyping patients.
- (c) Examine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.
- (d) Work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients.
- (e) Encourage shared decision making.
- (f) Cultivate effective communication and trust by seeking to better understand factors that can influence patients' health care decisions, such as cultural traditions, health beliefs and health literacy, language or other barriers to communication and fears or misperceptions about the health care system.

The medical profession has an ethical responsibility to:

(g) Help increase awareness of health care disparities.

(h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.

(i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

AMA Principles of Medical Ethics: I,IV,VII,VIII,IX

**Principles for the Implementation of clinical practice guidelines at the Local/State/Regional Level H-410.980**

Our AMA has adopted the following principles regarding the implementation of clinical practice guidelines at the local/state/regional level: (1) Relevant physician organizations and interested physicians shall have an opportunity for input/comment on all issues related to the local/state/regional implementation of clinical practice guidelines, including: issue identification; issue refinement, identification of relevant clinical practice guidelines, evaluation of clinical practice guidelines, selection and modification of clinical practice guidelines, implementation of clinical practice guidelines, evaluation of impact of implementation of clinical practice guidelines, periodic review of clinical practice guideline recommendations, and justifications for departure from clinical practice guidelines..

(2) Effective mechanisms shall be established to ensure opportunity for appropriate input by relevant physician organizations and interested physicians on all issues related to the local/state/regional implementation of clinical practice guidelines, including: effective physician notice prior to implementation, with adequate opportunity for comment; and an adequate phase-in period prior to implementation for educational purposes.

(3) clinical practice guidelines that are selected for implementation at the local/state/regional level shall be limited to practice parameters that conform to established principles, including relevant AMA policy on practice parameters.

(4) Prioritization of issues for local/state/regional implementation of clinical practice guidelines shall be based on various factors, including: availability of relevant and high quality practice parameter(s), significant variation in practice and/or outcomes, prevalence of disease/illness, quality considerations, resource consumption/cost issues, and professional liability considerations.

(5) clinical practice guidelines shall be used in a manner that is consistent with AMA policy and with their sponsors' explanations of the appropriate uses of their clinical practice guidelines, including their disclaimers to prevent inappropriate use.

(6) clinical practice guidelines shall be adapted at the local/state/regional level, as appropriate, to account for local/state/regional factors, including demographic variations, patient case mix, availability of resources, and relevant scientific and clinical information.

(7) clinical practice guidelines implemented at the local/state/regional level shall acknowledge the ability of physicians to depart from the recommendations in clinical practice guidelines, when appropriate, in the care of individual patients.

(8) The AMA and other relevant physician organizations should develop principles to assist physicians in appropriate documentation of their adherence to, or appropriate departure from, clinical practice guidelines implemented at the local/state/regional level.

(9) clinical practice guidelines, with adequate explanation of their intended purpose(s) and uses other than patient care, shall be widely disseminated to physicians who will be impacted by the clinical practice guidelines.

(10) Information on the impact of clinical practice guidelines at the local/state/regional level shall be collected and reported by appropriate medical organizations.

CMS Rep. D, A-93; Reaffirmed: CMS Rep. 10, A-03; Reaffirmed: CMS Rep. 4, A-13

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 523  
(A-22)

Introduced by: Medical Student Section

Subject: Improving Research Standards, Approval Processes, and Post-Market  
Surveillance Standards for Medical Devices

Referred to: Reference Committee E

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1 Whereas, Thirty-two million Americans, or 1 in 10, have at least one medical device<sup>1</sup>; and  
2  
3 Whereas, A medical device is defined within the Food Drug & Cosmetic Act as “... an  
4 instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other  
5 similar or related article, including a component part, or accessory...intended for use in the  
6 diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of  
7 disease..., or intended to affect the structure or any function of the body...and which does not  
8 achieve any of its primary intended purposes through chemical action...[and] is not dependent  
9 upon being metabolized for the achievement of any of its primary intended purposes”<sup>2</sup>; and  
10  
11 Whereas, The Food and Drug Administration (FDA) has three regulatory classifications for  
12 medical devices: Class I (minimal potential harm), Class II (moderate risk of harm), and Class III  
13 (potential high risk of illness or injury)<sup>2-3</sup>; and  
14  
15 Whereas, The FDA approves the safety and efficacy of medical devices through three major  
16 processes, one of which is Premarket Notification (PMN), also known as the 510(k) approval  
17 pathway or 510(k) exception<sup>4</sup>; and  
18  
19 Whereas, The 510(k) approval pathway “is intended to support the FDA’s public health mission  
20 by meeting two important goals: making available to consumers devices that are safe and  
21 effective, and fostering innovation in the medical device industry”<sup>5</sup>; and  
22  
23 Whereas, A Class II device can be cleared to market by submission and FDA review through  
24 the 510(k) exception if that device is substantially equivalent to a “predicate device”, even if the  
25 “predicate device” had not been recently tested<sup>4,6,7</sup>; and  
26  
27 Whereas, Using predicate devices for safety and efficacy standards may not accurately reflect  
28 modern performance and safety standards<sup>8</sup>; and  
29  
30 Whereas, A number of devices approved via the 510(k) exception were later found to be less  
31 efficacious than anticipated or even unsafe in their indicated usage, including transvaginal and  
32 surgical meshes, metal-on-metal hip implants, and bioresorbable vascular scaffolds<sup>9-13</sup>; and  
33  
34 Whereas, Medical devices cleared through the 510(k) exception comprise more than two-thirds  
35 of the products recalled by the FDA for safety concerns<sup>14</sup>; and  
36  
37 Whereas, There were attempts to improve the 510(k) pathway via the Safety of Untested and  
38 New Devices Act of 2012 (SOUND Device Act) and again in 2019, but predicate devices have  
39 remained the standard to evaluate device safety and efficacy<sup>15,16</sup>; and



1 Whereas, One way to improve medical device standards is to mandate that 510(k) devices  
2 demonstrate improved safety and effectiveness compared to marketed devices for the same  
3 clinical purpose<sup>16</sup>; and  
4

5 Whereas, Post-market surveillance is a critical component of medical device safety and  
6 effectiveness because: 1) adverse events may not become apparent until the device has been  
7 widely disseminated, and 2) increased emphasis on priority reviews and shortening premarket  
8 approval times has decreased the standard of medical device approvals<sup>16,17</sup>; and  
9

10 Whereas, Current post-market surveillance only identifies a small fraction of adverse events  
11 because it is based on mandated reports and passive surveillance<sup>16</sup>; and  
12

13 Whereas, Post-market surveillance can be improved by giving conditional approval and  
14 collecting data, including confirmatory trials<sup>16</sup>;  
15

16 Whereas, Current policy (H-100.992) only outlines the AMA's position on approval processes for  
17 biological drugs, but does not cover medical devices; therefore be it  
18

19 RESOLVED, That our American Medical Association support improvements to the Food and  
20 Drug Administration 510(k) exception to ensure the safety and efficacy of medical devices to: (a)  
21 make more stringent guidelines for which devices can qualify for the 510(k) exceptions; (b)  
22 mandate all 510(k) devices demonstrate equivalent or improved safety and effectiveness  
23 compared to market devices for the same clinical purpose (New HOD Policy); and be it further  
24

25 RESOLVED, That our AMA support stronger post-market surveillance requirements of medical  
26 devices, including but not limited to (a): conditional approval of devices until sufficient post-  
27 market surveillance data determining device safety can be collected, followed by confirmatory  
28 trials, and (b) a publicly available summary of medical devices approved under expedited  
29 programs along with associated clinical trial data and list of reported adverse events (New HOD  
30 Policy); and be it further  
31

32 RESOLVED, That our AMA amend policy H-100.992 to include medical devices by addition to  
33 read as follows:  
34

35 FDA, H-100.992

36 1. Our AMA reaffirms its support for the principles that:

37 (a) an FDA decision to approve a new drug or medical device, to withdraw a drug or  
38 medical device's approval, or to change the indications for use of a drug or medical  
39 device must be based on sound scientific and medical evidence derived from  
40 controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket  
41 incident reports as provided by statute;

42 (b) this evidence should be evaluated by the FDA, in consultation with its Advisory  
43 Committees and expert extramural advisory bodies; and

44 (c) any risk/benefit analysis or relative safety or efficacy judgments should not be  
45 grounds for limiting access to or indications for use of a drug or medical device unless  
46 the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and post  
47 market reports shows that the drug or medical device is unsafe and/or ineffective for  
48 its labeled indications. (Modify Current HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000

Received: 05/11/22

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**RELEVANT AMA POLICY**

**Use of Remote Sensing & Monitoring Devices 1.2.9**

Sensing and monitoring devices can benefit patients by allowing physicians and other health care professionals to obtain timely information about the patient's vital signs or health status without requiring an in-person, face-to-face encounter. Implantable devices can also enable physicians to identify patients rapidly and expedite access to patients' medical records. Devices that transmit patient information wirelessly to remote receiving stations can offer convenience for both patients and physicians, enhance the efficiency and quality of care, and promote increased access to care, but also raise concerns about safety and the confidentiality of patient information. Individually, physicians who employ remote sensing and monitoring devices in providing patient care should:

- (a) Determine whether using one or more such devices is appropriate in light of individual patients' medical needs and circumstances, including patients' ability to use the chosen device appropriately.
  - (b) Explain how the device(s) will be used in the patient's care and what will be expected of the patient in using the technology, and disclose any limitations, risks, or medical uncertainties associated with the device(s) and data transmission.
  - (c) Obtain the patient's or surrogate's informed consent before implementing the device in treatment. Collectively, physicians should:
    - (d) Support research into the safety, efficacy, and possible non-medical uses of remote sensing and monitoring devices, including devices intended to transmit biometric data and implantable radio frequency ID devices.
    - (e) Advocate for appropriate oversight of remote sensing and monitoring devices.
- AMA Principles of Medical Ethics: I, III, V Issued: 2016

#### **Reprocessing of Single-Use Medical Devices H-480.959**

1. Our AMA: (a) supports the Food and Drug Administration (FDA) guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" that was issued on August 2, 2000; (b) supports the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry; (c) encourages increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices; and (d) supports the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved.
  2. Our AMA strongly opposes any rules or regulations regarding the repair or refurbishment of medical tools, equipment, and instruments that are not based on objective scientific data.
- CSA Rep. 3, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Appended: Res. 217, I-17

#### **Required Reporting of Adverse Events 8.8**

Physicians' professional commitment to advance scientific knowledge and make relevant information available to patients, colleagues, and the public carries with it the responsibility to report suspected adverse events resulting from the use of a drug or medical device.

Mandated pre- and post-marketing studies provide basic safeguards for public health but are inherently limited in their ability to detect rare or unexpected consequences of use of a drug or medical device. Thus spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations are irreplaceable as a source of information about the safety of drugs and devices. As the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events.

Cases in which there is clearly a causal relationship between use of a drug/device and an adverse event, especially a serious event, will be rare. Physicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship, to suspect that an adverse event has occurred. A physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to:

- (a) Communicate that information to the professional community through established reporting mechanisms.
- (b) Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention to the appropriate regulatory agency.

AMA Principles of Medical Ethics: I, V, VII Issued: 2016

#### **Use of Wireless Radio-Frequency Devices in Hospitals H-215.972**

Our AMA encourages: (1) collaborative efforts of the Food and Drug Administration, American Hospital Association, American Society for Healthcare Engineering, Association for the Advancement of Medical Instrumentation, Emergency Care Research Institute, and other appropriate organizations to develop consistent guidelines for the use of wireless radio-frequency transmitters (e.g., cellular telephones, two-way radios) in hospitals and standards for medical equipment and device manufacturers to ensure electromagnetic compatibility between radio-frequency transmitters and medical devices; and that our AMA work with these organizations to increase awareness among physicians and patients about electromagnetic compatibility and electromagnetic interference in hospital environments;

- (2) hospital administrators to work with their clinical/biomedical engineering staff, safety committees, and other appropriate personnel to adopt and implement informed policies and procedures for (a) managing the use of wireless radio-frequency sources in the hospital, particularly in critical patient care areas; (b) educating staff, patients, and visitors about risks of electromagnetic interference (EMI); (c) reporting actual or suspected EMI problems; and (d) testing medical devices for susceptibility to EMI when electromagnetic compatibility information is lacking;
- (3) medical device and electronic product manufacturers to design and test their products in conformance with current electromagnetic immunity standards and inform users about possible symptoms of electromagnetic interference (EMI). If a possibility of EMI problems affecting medical devices exists, steps should be taken to ensure that all sources of electromagnetic energy are kept at sufficient distance; and
- (4) physicians to become knowledgeable about electromagnetic compatibility and electromagnetic interference (EMI), recognize EMI as a potential problem in hospital environments, and report suspected EMI problems to the Food and Drug Administration MedWatch program or appropriate hospital personnel.

CSA Rep 4, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

#### **Medical Device Safety and Physician Responsibility H-480.972**

The AMA supports: (1) the premise that medical device manufacturers are ultimately responsible for conducting the necessary testing, research and clinical investigation and scientifically proving the safety and efficacy of medical devices approved by the Food and Drug Administration; and (2) conclusive study and development of Center for Devices and Radiological Health/Office of Science and Technology recommendations regarding safety of article surveillance and other potentially harmful electronic devices with respect to pacemaker use.

Res. 507, I-95; Res. 509, A-96; Appended: Res. 504, A-99; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: CSAPH Rep. 01, A-19

#### **Guidelines for Mobile Medical Applications and Devices D-480.972**

1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence based.
4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.

CSAPH Rep. 5, A-14; Appended: Res. 201, A-15; Appended: Res. 305, I-16; Modified: Res. 903, I-19

#### **Interoperability of Medical Devices H-480.953**

Our AMA believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation.

Res. 519, A-09; Reaffirmation: I-15; Reaffirmed: BOT Rep. 05, I-16

#### **Medical Device "Use Before Dates" D-480.977**

Our AMA will encourage the US Food and Drug Administration to clearly define and interpret the definition and meaning of the "use before date" for medical devices.

Res. 508, A-12

#### **Access to Medical Care D-480.991**

Our AMA shall work with the Centers for Medicare and Medicaid Services to maximize access to the devices and procedures available to Medicare patients by ensuring reimbursement at least covers the cost of said device or procedure.

Res. 130, A-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 1, A-14

#### **Encouraging Alternatives to PVC/DEHP Products in Health H-135.945**

Our AMA: (1) encourages hospitals and physicians to reduce and phase out polyvinyl chloride (PVC) medical device products, especially those containing Di(2-ethylhexyl)phthalate (DEHP), and urge adoption of safe, cost-effective, alternative products where available; and (2) urges expanded manufacturer development of safe, cost-effective alternative products to PVC medical device products, especially those containing DEHP.

BOT Action in response to referred for decision Res. 502, A-06; Reaffirmed: CSAPH Rep. 01, A-16

#### **Protecting Social Media Users by Updating FDA Guidelines D-105.995**

Our AMA will lobby the Food and Drug Administration to: (1) update regulations to ensure closer regulation of paid endorsements of drugs or medical devices by individuals on social media; and (2) develop guidelines to ensure that compensated parties on social media websites provide information that includes the risks and benefits of specific drugs or medical devices and off-use prescribing in every related social media communication in a manner consistent with advertisement guidelines on traditional media forms.

Res. 209, I-15

### **Patient Access to Treatments Prescribed by Their Physicians H-120.988**

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.  
Res. 30, A-88, Reaffirmed: BOT Rep. 53, A-94, Reaffirmed and Modified: CSA Rep. 3, A-97, Reaffirmed and Modified: Res. 528, A-99, Reaffirmed: CMS Rep. 8, A-02, Reaffirmed: CMS Rep. 6, A-03, Modified: Res. 517, A-04, Reaffirmation, I-07, Reaffirmed: Res. 819, I-07, Reaffirmation, A-09, Reaffirmation, I-10, Modified: BOT Rep. 5, I-14, Reaffirmed: Res. 505, A-15, [Reaffirmed: CMS Rep. 6, I-20](#); Reaffirmed: Res. 509, I-20

### **Registry of Implantable Devices H-480.986**

It is the policy of the AMA: (1) to support the concept of a computerized national tracking system for long-term implanted devices that pose a significant risk of serious harm or death to patients if they malfunction or fail completely; (2) that such a system include the communication of the potential for malfunction or failures to the attending surgeon or physician and from the physician to the patient; and (3) to work with all involved parties to satisfactorily address this issue.

BOT Rep. JJ, A-90, Reaffirmed: Sunset Report I-00, Reaffirmed: CSAPH Rep. 1, A-10, Reaffirmed: CSAPH Rep. 01, A-20

### **Latex Allergy Warning H-480.970**

The AMA supports the appropriate labeling of latex-containing medical devices with warnings about possible allergic reactions. The AMA strongly encourages health care facilities to provide non-latex alternatives of at least comparable efficacy alongside their latex counterparts in all areas of patient care.

Sub Res. 502, A-96, Appended Res. 504, I-97, Reaffirmed: CSAPH Rep. 3, A-07, Reaffirmed: CSAPH Rep. 01, A-17

### **Physicians and Clinical Trials D-460.979**

Our AMA supports elimination of the use of restrictive covenants or clauses that interfere with scientific communication in agreements between pharmaceutical companies or manufacturers of medical instruments, equipment and devices, and physician researchers.

Res. 610, I-04, Modified: CSAPH Rep. 1, A-14

### **Availability of Professionals for Research H-460.982**

(1) In its determination of personnel and training needs, major public and private research foundations, including the Institute of Medicine of the National Academy of Sciences, should consider the future research opportunities in the biomedical sciences as well as the marketplace demand for new researchers. (2) The number of physicians in research training programs should be increased by expanding research opportunities during medical school, through the use of short-term training grants and through the establishment of a cooperative network of research clerkships for students attending less research-intensive schools. Participation in research training programs should be increased by providing financial incentives for research centers, academic physicians, and medical students. (3) The current annual production of PhDs trained in the biomedical sciences should be maintained. (4) The numbers of nurses, dentists, and other health professionals in research training programs should be increased. (5) Members of the industrial community should increase their philanthropic financial support to the nation's biomedical research enterprise. Concentration of support on the training of young investigators should be a major thrust of increased

funding. The pharmaceutical and medical device industries should increase substantially their intramural and extramural commitments to meeting postdoctoral training needs. A system of matching grants should be encouraged in which private industry would supplement the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration sponsored Career Development Awards, the National Research Service Awards and other sources of support. (6) Philanthropic foundations and voluntary health agencies should continue their work in the area of training and funding new investigators. Private foundations and other private organizations should increase their funding for clinical research faculty positions. (7) The National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration should modify the renewal grant application system by lengthening the funding period for grants that have received high priority scores through peer review. (8) The support of clinical research faculty from the National Institutes of Health Biomedical Research Support Grants (institutional grants) should be increased from its current one percent. (9) The academic medical center, which provides the multidisciplinary research environment for the basic and clinical research faculty, should be regarded as a vital medical resource and be assured adequate funding in recognition of the research costs incurred.

BOT Rep. NN, A-87, Reaffirmed: Sunset Report, I-97, Reaffirmed: CSA Rep. 13, I-99, Reaffirmed: CME Rep. 4, I-08, Modified: Res. 305, A-12, Modified: CME Rep. 2, A-12

#### **Comparative Effectiveness Research H-460.909**

A. Value. Value can be thought of as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information. Quality comparative clinical effectiveness research (CER) will improve health care value by enhancing physician clinical judgment and fostering the delivery of patient-centered care.

B. Independence. A federally sponsored CER entity should be an objective, independent authority that produces valid, scientifically rigorous research.

C. Stable Funding. The entity should have secure and sufficient funding in order to maintain the necessary infrastructure and resources to produce quality CER. Funding source(s) must safeguard the independence of a federally sponsored CER entity.

D. Rigorous Scientifically Sound Methodology. CER should be conducted using rigorous scientific methods to ensure that conclusions from such research are evidence-based and valid for the population studied. The primary responsibility for the conduct of CER and selection of CER methodologies must rest with physicians and researchers.

E. Transparent Process. The processes for setting research priorities, establishing accepted methodologies, selecting researchers or research organizations, and disseminating findings must be transparent and provide physicians and researchers a central and significant role.

F. Significant Patient and Physician Oversight Role. The oversight body of the CER entity must provide patients, physicians (MD, DO), including clinical practice physicians, and independent scientific researchers with substantial representation and a central decision-making role(s). Both physicians and patients are uniquely motivated to provide/receive quality care while maximizing value.

G. Conflicts of Interest Disclosed and Minimized. All conflicts of interest must be disclosed, and safeguards developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders with such conflicts of interest do not undermine the integrity and legitimacy of the research findings and conclusions.

H. Scope of Research. CER should include long term and short-term assessments of diagnostic and treatment modalities for a given disease or condition in a defined population of patients. Diagnostic and treatment modalities should include drugs, biologics, imaging and laboratory tests, medical devices, health services, or combinations. It should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data. The priority areas of CER should be on high volume, high cost diagnosis, treatment, and health services for which there is significant variation in practice. Research priorities and methodology should factor in any systematic variations in disease prevalence or response across groups by race, ethnicity, gender, age, geography, and economic status.

I. Dissemination of Research. The CER entity must work with health care professionals and health care professional organizations to effectively disseminate the results in a timely manner by significantly expanding dissemination capacity and intensifying efforts to communicate to physicians utilizing a variety of strategies and methods. All research findings must be readily and easily accessible to physicians as well as the public without limits imposed by the federally supported CER entity. The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

J. Coverage and Payment. The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

K. Patient Variation and Physician Discretion. Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition, patient autonomy and choice may play a significant role in both CER findings and diagnostic/treatment planning in the clinical setting. As a result, sufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative.

CMS Rep. 5, I-08, Reaffirmed: Res. 203, I-09, Reaffirmation: I-10, Reaffirmed: CMS Rep. 05, I-16, Reaffirmed: CMS Rep. 4, I-19

**FDA H-100.992**

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

Citation: Res. 119, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmation A-06; Appended: Sub. Res. 509, A-06; Reaffirmation I-07; Reaffirmation I-09; Reaffirmation I-10; Modified: CSAPH Rep. 02, I-18; Modified: CSAPH Rep. 02, I-19; Reaffirmed: BOT Rep. 5, I-20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 524  
(A-22)

Introduced by: Medical Student Section

Subject: Increasing Access to Traumatic Brain Injury Resources in Primary Care Settings

Referred to: Reference Committee E

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- 1 Whereas, There has been a recent 43% increase in incidence of mild traumatic brain injuries  
2 (TBIs) in the United States in both non-athletic and athletic populations<sup>1</sup>; and  
3  
4 Whereas, The Centers for Disease Control and Prevention (CDC) acknowledges that non-  
5 athletic TBIs affect diverse patient populations<sup>2,3</sup>; and  
6  
7 Whereas, 64.4% of TBIs are non-sports related, caused by activities of daily living, traffic or  
8 work-related accidents, falls, motor vehicle crashes, recreation, acts of interpersonal violence,  
9 and blast injuries<sup>4,5,6</sup>; and  
10  
11 Whereas, Studies show that adult patients with non-athletic TBIs experience increased mortality  
12 rates and long-term consequences such as increased incidence of post-concussion symptoms<sup>7</sup>;  
13 and  
14  
15 Whereas, A study by the Center for Disease Control suggests that rates of pediatric  
16 hospitalization and death are higher in non-athletes compared to that of athletic brain injuries  
17 due to a lack of early intervention<sup>7,8,9,10</sup>; and  
18  
19 Whereas, Approximately 48% of patients are lost to follow-up three months after hospitalization  
20 for TBIs<sup>11</sup>; and  
21  
22 Whereas, Almost 88% victims of domestic violence survivors suffer TBIs, which can lead to  
23 devastating and permanent physical, behavioral, and cognitive consequences<sup>12</sup>; and  
24  
25 Whereas, Due to a lack of universally accepted diagnostic criteria, clinicians rely on likely  
26 mechanism of injury for diagnosis of TBI, which may delay care for victims of domestic violence  
27 who often do not report their injuries<sup>12,13</sup>; and  
28  
29 Whereas, Victims of domestic violence often face unstable social situations, homelessness, and  
30 impaired cognitive states as a result of years of repeated brain injury, thus when they do seek  
31 medical care for their injuries, they experience added barriers to follow-up care, such as  
32 transportation, communication, and education<sup>12</sup>; and  
33  
34 Whereas, 89% of women experiencing an intimate partner violence-related TBI reported post-  
35 concussion syndrome, and early intervention for victims of domestic violence with mild TBIs are  
36 correlated with a reduction in post-concussive and other residual symptoms<sup>14,15</sup>; and  
37 Whereas, Due to longer time to admission for acute-injury admissions, ethnic minorities,  
38 including those with history of homelessness and incarceration, experience inequity in post-



1 injury rehabilitation, and are less likely to obtain post-injury hospital admission compared to  
2 Non-Hispanic White patients<sup>16,17</sup>; and

3  
4 Whereas, When the severity of injury may not differ significantly between patients of color and  
5 white patients, there are non-medical factors including systemic and environmental barriers  
6 contributing to the delay in access to acute TBI-rehabilitation in patients of color<sup>16</sup>; and

7  
8 Whereas, Patients with non-athletic TBI are more likely to seek treatment via primary care  
9 providers<sup>13</sup>; and

10  
11 Whereas, Over the past year, only 12–23% of adult female victims report to seeking treatment  
12 from their primary care physician for their injuries and subsequent morbidity after experiencing  
13 intimate partner violence<sup>18</sup>; and

14  
15 Whereas, Patients who access primary care physicians for post-TBI care may be less likely to  
16 receive equitable treatment compared to athletes who have access to athletic trainers, coaches,  
17 and specialty physicians with return-to-play models of treatment <sup>19,20</sup>; and

18  
19 Whereas, Primary care providers who were trained by the CDC's Heads Up program on TBIs  
20 were able to improve their patients' rate of treatment success and symptom recovery<sup>13,21</sup>; and

21  
22 Whereas, Providing patients with information emphasizing the importance of post-injury care,  
23 encouraging interdisciplinary collaboration, and equipping primary physicians with the tools  
24 needed for appropriate treatment and referral services improves patients' functional recovery  
25 and treatment success<sup>22</sup>; and

26  
27 Whereas, The treatment tools provided to primary care physicians include screening for  
28 neurosurgical emergencies or cervical spine injury and targeted treatment for specific symptoms  
29 of post-injury headaches, sleep disturbance, and psychological distress through medication and  
30 environmental and behavioral changes<sup>13,23</sup>; and

31  
32 Whereas, The AMA recognizes the need for TBI prevention and remediation of post-injury  
33 morbidities (H-470.954); and

34  
35 Whereas, Current AMA policy does not emphasize ethnic minorities or victims of domestic  
36 violence in existing policy for TBIs, nor does it address post-injury rehabilitation in non-athletic  
37 injuries; therefore be it

38  
39 RESOLVED, That our American Medical Association recognize disparities in the care for  
40 traumatic brain injuries, and acknowledge non-athletic traumatic brain injuries as a significant  
41 cause of morbidity and mortality, particularly for ethnic minorities and victims of domestic  
42 violence; (New HOD Policy) and be it further

43  
44 RESOLVED, That our AMA support increased access to traumatic brain injury resources in  
45 primary care settings which advocate for early intervention, encourage follow-up retention of  
46 patients for post-injury rehabilitation, and improved patient quality of life. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000

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**RELEVANT AMA POLICY**

**H-470.954 Reduction of Sports Related Injury and Concussion**

1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences.
2. Our AMA supports the adoption of evidence-based, age-specific guidelines on the evaluation and management of concussion in all athletes for use by physicians, other health professionals, and athletic organizations.

3. Our AMA will work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the ability of physicians to prevent, diagnose, and manage concussions and other sports-related injuries.
4. Our AMA urges appropriate agencies and organizations to support research to: (a) assess the short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span; (b) identify determinants of concussion and other sports-related injuries in pediatric and adult athletes, including how injury thresholds are modified by the number of and time interval between head impacts and concussions; (c) develop and evaluate effective risk reduction measures to prevent or reduce sports-related injuries and concussions and their sequelae across the lifespan; and (d) develop objective biomarkers to improve the identification, management, and prognosis of athletes suffering from concussion to reduce the dependence on self-reporting and inform evidence-based, age-specific guidelines for these patients.
5. Our AMA supports research into the detection, causes, and prevention of injuries along the continuum from subconcussive head impacts to conditions such as chronic traumatic encephalopathy (CTE).  
CSAPH Rep. 3, A-15; Appended: Res. 905, I-16

#### **H-470.984 Brain Injury in Boxing**

The AMA supports the following series of steps designed to protect amateur and professional boxers from injuries:

- (1) Encourage the establishment of a "National Registry of Boxers" for all amateur and professional boxers, including "sparring mates," in the country. The proposed functions of a computer-based central registry would be to record the results of all licensed bouts, including technical knockouts, knockouts, and other boxing injuries, and to compile injury and win/loss records for individual boxers.
- (2) Recommend to all boxing jurisdictions that the ring physician should be authorized to stop any bout in progress, at any time, to examine a contestant and, when indicated, to terminate a bout that might, in his opinion, result in serious injury for either contestant.
- (3) Urge state and local commissions to conduct frequent medical training seminars for all ring personnel.
- (4) Recommend to all boxing jurisdictions that no amateur or professional boxing bout should be permitted unless: (a) the contest is held in an area where adequate neurosurgical facilities are immediately available for skilled emergency treatment of an injured boxer; (b) a portable resuscitator with oxygen equipment and appropriate endotracheal tubes are available at ringside; and (c) a comprehensive evacuation plan for the removal of any seriously injured boxer to hospital facilities is ready.
- (5) Inform state legislatures that unsupervised boxing competition between unlicensed boxers in "tough man" contests is a most dangerous practice that may result in serious injury or death to contestants, and should be condemned.
- (6) Urge state and local boxing commissions to mandate the use of safety equipment, such as plastic safety mats and padded cornerposts, and to encourage continued development of safety equipment.
- (7) Urge state and local boxing commissions to extend all safety measures to sparring partners.
- (8) Urge state and local boxing commissions to upgrade, standardize and strictly enforce medical evaluations for boxers.

CSA Rep. F, A-82; Reaffirmed: A-83; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: Sub. Res. 408, I-93; Reaffirmed: CSA Rep. 3, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: CSAPH Rep. 3, A-15

#### **H-515.965 Family and Intimate Partner Violence**

- (1) Our AMA believes that all forms of family and intimate partner violence (IPV) are major public health issues and urges the profession, both individually and collectively, to work with other interested parties to prevent such violence and to address the needs of survivors. Physicians have a major role in lessening the prevalence, scope and severity of child maltreatment, intimate partner violence, and elder abuse, all of which fall under the rubric of family violence. To support physicians in practice, our AMA will continue to campaign against family violence and remains open to working with all interested parties to address violence in US society.
- (2) Our AMA believes that all physicians should be trained in issues of family and intimate partner violence through undergraduate and graduate medical education as well as continuing professional development. The AMA, working with state, county and specialty medical societies as well as academic medical centers and other appropriate groups such as the Association of American Medical Colleges, should develop and disseminate model curricula on violence for incorporation into undergraduate and graduate medical education, and all parties should work for the rapid distribution and adoption of such curricula. These curricula should include coverage of the diagnosis, treatment, and reporting of child maltreatment, intimate partner violence, and elder abuse and provide training on interviewing techniques, risk assessment, safety planning, and procedures for linking with resources to assist survivors. Our AMA supports the inclusion of questions on family violence issues on licensure and certification tests.
- (3) The prevalence of family violence is sufficiently high and its ongoing character is such that physicians, particularly physicians providing primary care, will encounter survivors on a regular basis. Persons in clinical settings are more likely to have experienced intimate partner and family violence than non-clinical populations. Thus, to improve clinical services as well as the public health, our AMA encourages physicians to: (a) Routinely inquire about the family violence histories of their patients as this knowledge is essential for effective diagnosis and care; (b) Upon identifying patients currently experiencing abuse or threats from intimates, assess and discuss safety issues with the patient before he or she leaves the office, working with the patient to develop a safety or exit plan for use in an emergency

situation and making appropriate referrals to address intervention and safety needs as a matter of course; (c) After diagnosing a violence-related problem, refer patients to appropriate medical or health care professionals and/or community-based trauma-specific resources as soon as possible; (d) Have written lists of resources available for survivors of violence, providing information on such matters as emergency shelter, medical assistance, mental health services, protective services and legal aid; (e) Screen patients for psychiatric sequelae of violence and make appropriate referrals for these conditions upon identifying a history of family or other interpersonal violence; (f) Become aware of local resources and referral sources that have expertise in dealing with trauma from IPV; (g) Be alert to men presenting with injuries suffered as a result of intimate violence because these men may require intervention as either survivors or abusers themselves; (h) Give due validation to the experience of IPV and of observed symptomatology as possible sequelae; (i) Record a patient's IPV history, observed traumata potentially linked to IPV, and referrals made; (j) Become involved in appropriate local programs designed to prevent violence and its effects at the community level.

(4) Within the larger community, our AMA:

(a) Urges hospitals, community mental health agencies, and other helping professions to develop appropriate interventions for all survivors of intimate violence. Such interventions might include individual and group counseling efforts, support groups, and shelters.

(b) Believes it is critically important that programs be available for survivors and perpetrators of intimate violence.

(c) Believes that state and county medical societies should convene or join state and local health departments, criminal justice and social service agencies, and local school boards to collaborate in the development and support of violence control and prevention activities.

(5) With respect to issues of reporting, our AMA strongly supports mandatory reporting of suspected or actual child maltreatment and urges state societies to support legislation mandating physician reporting of elderly abuse in states where such legislation does not currently exist. At the same time, our AMA oppose the adoption of mandatory reporting laws for physicians treating competent, non-elderly adult survivors of intimate partner violence if the required reports identify survivors. Such laws violate basic tenets of medical ethics. If and where mandatory reporting statutes dealing with competent adults are adopted, the AMA believes the laws must incorporate provisions that: (a) do not require the inclusion of survivors' identities; (b) allow competent adult survivors to opt out of the reporting system if identifiers are required; (c) provide that reports be made to public health agencies for surveillance purposes only; (d) contain a sunset mechanism; and (e) evaluate the efficacy of those laws. State societies are encouraged to ensure that all mandatory reporting laws contain adequate protections for the reporting physician and to educate physicians on the particulars of the laws in their states.

(6) Substance abuse and family violence are clearly connected. For this reason, our AMA believes that:

(a) Given the association between alcohol and family violence, physicians should be alert for the presence of one behavior given a diagnosis of the other. Thus, a physician with patients with alcohol problems should screen for family violence, while physicians with patients presenting with problems of physical or sexual abuse should screen for alcohol use.

(b) Physicians should avoid the assumption that if they treat the problem of alcohol or substance use and abuse they also will be treating and possibly preventing family violence.

(c) Physicians should be alert to the association, especially among female patients, between current alcohol or drug problems and a history of physical, emotional, or sexual abuse. The association is strong enough to warrant complete screening for past or present physical, emotional, or sexual abuse among patients who present with alcohol or drug problems.

(d) Physicians should be informed about the possible pharmacological link between amphetamine use and human violent behavior. The suggestive evidence about barbiturates and amphetamines and violence should be followed up with more research on the possible causal connection between these drugs and violent behavior.

(e) The notion that alcohol and controlled drugs cause violent behavior is pervasive among physicians and other health care providers. Training programs for physicians should be developed that are based on empirical data and sound theoretical formulations about the relationships among alcohol, drug use, and violence. CSA Rep. 7, I-00; Reaffirmed: CSAPH Rep. 2, I-09; Modified: CSAPH Rep. 01, A-19