Reference Committee E

CSAPH Report(s)

03 Correcting Policy H-120.958

Resolution(s)

501 Marketing Guardrails for the "Over-Medicalization" of Cannabis Use
502 Ensuring Correct Drug Dispensing
503 Pharmacy Benefit Managers and Drug Shortages
504 Scientific Studies Which Support Legislative Agendas
505 CBD Oil Use and the Marketing of CBD Oil
506 Drug Manufacturing Safety
507 Federal Initiative to Treat Cannabis Dependence
508 Supplemental Resources for Inflight Medical Kit
509 Regulation and Control of Self-Service Labs
510 Evidence-Based Deferral Periods for MSM Cornea and Tissue Donors
511 Over the Counter (OTC) Hormonal Birth Control
512 Scheduling and Banning the Sale of Tianeptine in the United States
513 Education for Patients on Opiate Replacement Therapy
514 Oppose Petition to the DEA and FDA on Gabapentin
515 Reducing Polypharmacy as a Significant Contributor to Senior Morbidity

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

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

> 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 ~~i~~on the ~~National Patient Safety Foundation's efforts to advance the science of safety in the medication use process and likewise work with 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 ~~machine-readable~~ coding system for prescription medicine packaging in an effort to improve patient safety; and
> (5) ~~participate in and report on the work of the Healthy People 2010 initiative in the area of safe medical products especially as it relates to existing AMA policy; and~~
> (6) seek opportunities to work collaboratively with other stakeholders ~~within the Medicine-Public Health initiative (H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention (CDC) the Agency for Health Care Policy and Research (AHCPR) and the Centers for Medicare & Medicaid Services (CMS)~~ 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.

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

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

> Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent "look alike-sound alike" errors in giving new drugs generic names;
> (2) continue participation in ~~the National Patient Safety Foundation's~~ efforts to advance the science of safety in the medication use process, including ~~and likewise~~ work with the National Coordinating Council for Medication Error Reporting and Prevention;

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

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

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent "look alike-sound alike" errors in giving new drugs generic names; (2) continue participation 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.

CONCLUSION

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

RECOMMENDATION

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

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

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

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

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

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

Whereas, In many states, "medical cannabis" and "medical marijuana" laws have put physicians in the uncomfortable position of being asked to prescribe cannabis for questionable medical indications; and

Whereas, In states where medical cannabis has been legalized, marketing for cannabis for "all your ills" has become excessive; and

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

- The percentage of women who use marijuana in pregnancy … is higher among younger women, women with less education, and women with unintended pregnancies. Marijuana exposure in pregnancy is associated with decreased cognitive function and attention problems in childhood;

- Unintentional marijuana consumption among children under age 9 continues a slow upward trend, as do emergency visits due to marijuana. Additionally, an estimated 23,000 homes with children in Colorado have marijuana stored potentially unsafely. Marijuana exposures in children can lead to significant clinical effects that require medical attention;" [1] and

Whereas, The American College of Obstetricians and Gynecologists (ACOG) warns that women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use, because of concerns regarding impaired neurodevelopment;" [2] and

Whereas, Infants exposed to marijuana during pregnancy had a decrease in birth weight, preterm delivery, and long-term adverse neurodevelopmental effects;[3] and

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

Whereas, There may be a correlation between heavy cannabis use during adolescence and neuropsychiatric diseases such as schizophrenia;[4] and

Whereas, The U.S. Surgeon General has issued a warning about “Marijuana Use and the Developing Brain;”[5,6] and

Whereas, ACOG has issued a statement discouraging obstetrician–gynecologists from prescribing or suggesting the use of marijuana for medicinal purposes during preconception, pregnancy, and lactation;[2] and

Whereas, Despite such warnings, cannabis is promoted as a treatment for hyperemesis with many pregnant women being marketed a neuroactive drug during critical developmental periods of the embryo and fetus;[7] and

Whereas, Two-thirds of Colorado’s cannabis dispensaries recommend marijuana for first trimester nausea although chronic cannabis use is actually associated with nausea and vomiting, which leads to emergency department visits;"[1] and

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

Whereas, As an example, the targeted marketing of menthol cigarettes to African-Americans has led to in 85% of Black smokers using menthol cigarettes compared to 29% of White smokers and contributing to health disparities;[8] and

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

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

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

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

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

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

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

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

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
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

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

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

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

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

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

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

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

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

Whereas, Pharmacy Benefit Managers (PBMs) are poorly regulated entities which act as middlemen between health plans, pharmacies and drug manufacturers; and

Whereas, They have been associated with adverse business practices including opaque operations ‘spread pricing’, and skyrocketing drug costs; and

Whereas, PBM’s play an important part in the pharmaceutical supply chain--sometimes bankrupting pharmacies and making (and breaking) markets for pharmaceutical agents; and

Whereas, Drug manufacturers are legally obligated to report existing or pending drug shortages to the Food and Drug Administration, that requirement extends only to drug supply disruptions, not detailed information on their supply chain, in which PBMs play a key role; and

Whereas, Common retail prescription medications are frequently and chronically ‘backordered’ at a retail pharmacy, but often readily available at the hospital; therefore be it

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

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

Whereas, An important tool in advancing an organization's agenda is the ability to produce scientific or economic studies as evidence for supporting such a position; and

Whereas, An important tool in advancing an organization's agenda is collaborating with diverse groups who together can present a unified perspective on a particular issue; and

Whereas, The AMA regularly works with numerous and varied organizations to build allies and obtain research data in support of its efforts to achieve its key public health and legislative goals; and

Whereas, The goals of organized medicine and allied organizations include advocacy on behalf of patients and public health in addition to physicians; and

Whereas, Advocacy supported by scientific and economic information carries more weight and benefits those advocacy efforts; and

Whereas, Opponents of the policy goals of organized medicine often have the capacity to produce such studies; and

Whereas, The recent debate before Congress to address surprise medical bills often found physician organizations at odds with the perspectives of not only the insurance industry, but also the business, labor, and patient advocacy organizations as well as numerous think thanks; and

Whereas, This debate reiterated the importance of developing allies and research data to help work to achieve these public health and legislative goals; therefore be it

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

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

Whereas, Cannabidiol (CBD) oil is advertised in health clubs and convenience stores and online; and

Whereas, CBD oil is often marketed in ways that falsely imply medical doctor approval, verification or endorsement; and

Whereas, There is only one Food and Drug Administration (FDA)-approved drug in which CBD is the active ingredient for the indication of two rare types of epilepsy syndromes; and

Whereas, It is known that the side effects of CBD include elevated liver enzymes, diarrhea, somnolence and decreased appetite; and

Whereas, CBD oil is promoted for the treatment of a vast range of mental and physical ailments including: seizures, schizophrenia, depression, anxiety, Tourette syndrome, ADHD, pain reduction and sleep disorders; and

Whereas, CBD is one of more than 100 identified compounds in the cannabis plant, commonly known as marijuana and CBD is put into products including ingestible oils, bath salts and drinks; and

Whereas, CBD oil is not an FDA-approved product and is considered a dietary supplement and the composition and purity of the product generally extracted from hemp is not overseen by any U.S. regulatory body and adulteration, contamination with pesticides, herbicides and heavy metals and variable percentage of CBD product can and does occur; therefore be it

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

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

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

Whereas, It has recently been revealed in the media as well as written notifications from pharmacies informing the American public that certain medications produced outside but consumed inside the United States have contained carcinogenic substances; and

Whereas, Such tainted medications are widely consumed within the US and include, but are not limited to, Valsartan and Losartan; and

Whereas, Multiple medications are produced overseas and marketed broadly within the US; and

Whereas, Significant budgetary hurdles exist in empowering the U.S. Food and Drug Administration to inspect all foreign drug manufacturers on a frequent and rigorous basis; therefore be it

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

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

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

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

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

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

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

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

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

Received: 04/07/22

Reference:

Lintzeris, N and associates, Nabiximois 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

Whereas, According to the Bureau of Transportation Statistics, 770 million passengers boarded domestic flights in the United States in the year 2018 and 802 million passengers boarded domestic flights in the US in the year 2019; and

Whereas, Inflight medical emergencies (IMEs) are estimated to occur in approximately 1 in 604 flights, or 24 to 130 IMEs per 1 million passengers; and

Whereas, IMEs are common and occur in constrained areas with limited medical resources; and

Whereas, Inflight medical events are increasingly frequent because a growing number of individuals with pre-existing medical conditions travel by air; and

Whereas, The most common inflight emergency involves syncope or near syncope, which requires measurement of blood pressure and pulse for optimal assessment; and

Whereas, Travelers with diabetes may have altered dietary habits and medication dosing, so are at risk for hyper- or hypoglycemia; and

Whereas, Health care personnel are asked to assist affected passengers and have variable level of training and expertise in evaluating vital signs; and

Whereas, Efforts by health care volunteers are protected by Good Samaritan laws, there is an obligation and opportunity to optimize treatment in these situations; and

Whereas, The minimum requirements for the emergency medical kit do not include automated blood pressure cuff, pulse oximeter or glucose monitors; and

Whereas, The noise level of the airplane makes it difficult to auscultate for blood pressure, with cruising noise levels at around 85 dB but up to 105 dB during takeoff and landing; and

Whereas, Resources include automated external defibrillators, advanced life support injectables including epinephrine, atropine, lidocaine, analgesics, and first aid materials, but do not include pulse oximeters, automated blood pressure cuffs or glucose monitors; and

Whereas, Treatment and support decisions can be optimized with accurate vital signs, oxygen levels and blood sugar levels; and

Whereas, Blood glucose testing equipment is not required in the U.S.; and

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

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

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

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

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

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

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

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

Received: 04/07/22

References:

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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

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

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

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

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

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

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

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

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

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

Whereas, The 5-year MSM deferral policy was instituted at a time when HIV tests were unreliable and has not been updated to reflect advances in HIV testing since 1994[3,4]; and

Whereas, All corneal donors are required to undergo HIV testing, which is now reliable within 4-8 days of viral exposure[5,6]; and

Whereas, No case of HIV transmission from a corneal transplant has ever been reported, even in cases when the corneal donors were HIV-positive[3,7,8,9,10,11]; and

Whereas, Corneas are an avascular tissue and are not a major reservoir of HIV[12]; and

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

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

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

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

Whereas, AMA Policy H-50.973, "Blood Donor Deferral Criteria," states that AMA supports blood donor deferral criteria that are "representative of current HIV testing technology" but does not address the FDA's even stricter deferral criteria for MSM donors of corneas and other tissues[28]; and

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

Whereas, An estimated 12.7 million visually impaired patients are in need of corneal transplant surgery worldwide, with only 1 cornea donated for every 70 corneal transplants needed[29]; therefore be it

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

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

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

Fiscal Note: Minimal - less than $1,000

Received: 04/08/22

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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

Whereas, Many individuals prefer to have control over the timing and occurrence of pregnancy; and

Whereas, Oral hormonal contraception birth control pills is available and very effective; and

Whereas, Safety considerations of birth control pills have been well reviewed and largely reduced for incidences of untoward complications; and

Whereas, The availability of birth control pills may reduce incidence of unexpected and unwanted pregnancy that may result in abortion and its risks; and

Whereas, Birth control pills are currently only available by prescription of a physician; and

Whereas, The American College of Obstetricians and Gynecologists recommends the elimination of the physician prescription requirement and allowing oral contraceptives (birth control pills) to be sold without a prescription; therefore be it

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related overdose fatalities; and (d) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug-related overdose; and (b) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.
3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.
4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Whereas, Excessive, unnecessary, or incompatible medication use increases the risk of adverse drug effects, including falls, cognitive impairment, adverse drug interactions and drug-disease interactions;[1, 4, 5] and

Whereas, Older patients often have multiple complex conditions making drug therapy an essential part of medical management; yet multiple medications in complex patients may shift the benefit of drug therapy from positive to negative;[2, 6] and

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

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

Whereas, Physicians are the natural source for patient education and engagement;[3] and

Whereas, It is advisable for the AMA to use its resources to educate patients about the dangers of polypharmacy, and to assist physicians to take steps to recognize and reduce it;[7-10] therefore be it

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

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

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

Fiscal Note: Not yet determined

Received: 05/03/22

REFERENCES:
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3. Science and storytelling: Making physicians' voices the loudest in the room, source: https://www.ama-assn.org/delivering-care/public-health/science-and-storytelling-making-physicians-voices-loudest-room (accessed April 3, 2022)
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8. Cooper, J. A., et al. (2015). "Interventions to improve the appropriate use of polypharmacy in older people: a Cochrane systematic review." BMJ Open 5(12): e009235.
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10. Steinman, M. A., Miao, Y., Boscardin, W. J., Komaiko, K. D., & Schwartz, J. B. (2014). Prescribing quality in older veterans: a multifocal approach. Journal of general internal medicine, 29(10), 1379-1386.

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