Reference Committee E

CSAPH Report(s)

01 Oppose Scheduling of Gabapentin

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

03 Regulation and Control of Self-Service Labs

Resolution(s)

501 AMA Study of Chemical Castration in Incarceration

502 Pain Management for Long-Acting Reversible Contraception and other Gynecological Procedures

503 Increasing Diversity in Stem Cell Biobanks and Disease Models

504 Moved to Reference Committee B - Now Resolution 256

505 Improving Access to Opioid Antagonists for Vulnerable and Underserved Populations

506 Moved to Reference Committee F - Now Resolution 609

507 Recognizing the Burden of Rare Disease

508 Development and Implementation of Recommendations for Responsible Media Coverage of Opioid Overdoses

509 Addressing Medical Misinformation Online

510 Comparative Effectiveness Research

511 Regulation of Phthalates in Adult Personal Sexual Products

512 Wheelchairs on Airplanes

513 Substance Use History is Medical History

514 Adolescent Hallucinogen-Assisted Therapy Policy

515 Regulate Kratom and Ban Over-The-Counter Sales

516 Fasting is Not Required for Lipid Analysis

517* Genetic Predisposition and Healthcare Disparities, Including Cardiovascular Disease in South Asians Residing in the United States

518* Defending NIH funding of Animal Model Research From Legal Challenges

519* Rescheduling or Descheduling Testosterone

520* Supporting Access to At-Home Injectable Contraceptives

521* Preventing the Elimination of Cannabis from Occupational and Municipal Drug Testing Programs

522* Approval Authority of the FDA

523* Reducing Youth Abuse of Dextromethorphan

524* Ensuring Access to Reproductive Health Services Medications

Contained in the Handbook Addendum

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 01-A-23

Subject: Oppose Scheduling of Gabapentin

Presented by: Noel Deep, MD, Chair

Referred to: Reference Committee E

American Medical Association (AMA) Policy D-120.927, "Oppose Scheduling of Gabapentin," calls for the study of off-label use and potential risks and benefits of gabapentin to the general population as well as to those individuals with substance use disorders. This report investigates the evidence base for off-label prescribing of gabapentin, the regulatory landscape of gabapentin for maximizing patient access and minimizing stigma, and adverse events during the ongoing overdose crisis.

BACKGROUND

In February 2022, the U.S. Food and Drug Administration (FDA) received a petition from a consumer advocacy group requesting that gabapentin and gabapentin enacarbil be designated as schedule V under the Controlled Substances Act of 1970. In June 2022, Resolution 514-A-22 (now policy D-120.927) was adopted by the House of Delegates which called upon the AMA to oppose this petition and any other efforts to schedule gabapentin and its salts pending review of the risk and benefits of gabapentin use in the general public and those with substance use disorders.

METHODS

English language articles were selected from searches of PubMed, Cochrane Library and Google Scholar using the search terms "gabapentin OR neurontin", "gabapentin AND off-label", "gabapentin AND controlled substance", "gabapentin AND substance use disorder" and "gabapentin AND opioids". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

History of Gabapentin

Gabapentin, a gabapentinoid originally marketed under the trade name Neurontin by Parke-Davis, is an analog of the neurotransmitter gamma-aminobutryic acid. While the exact mechanism of action for gabapentin is not known, it is generally accepted that it binds to the α2δ subunit of calcium-activated ion channels.[1] It is hypothesized that this then further modulates neurotransmitter release, which may affect the dopaminergic pathways associated with reward-seeking behavior and substance use disorders.

Neurontin (gabapentin) was initially approved by the FDA in 1993 for adjunctive therapy of partial onset seizures in patients aged 12 or older.[2] In 2000, that indication was expanded by the FDA for

pediatric patients over the age of three. In 2002, a second indication for post-herpetic neuralgia was approved by the FDA. It is currently available as a generic medication. Despite the relatively narrow scope of approved indications, Neurontin (gabapentin) was marketed by its manufacturer, Parke-Davis, for a variety of off-label indications such as neuropathic pain, epilepsy monotherapy, bipolar disorder, migraine, and attention-deficit disorder, due to data which showed improved outcomes in these disease states.[3] It was estimated that prior to generic competition becoming available in 2004, Neurontin (gabapentin) products were grossing over $3 billion a year in sales.

To maximize market penetration, Parke-Davis was accused of pursuing illegal strategies like the ethically dubious *quid pro quo* solicitation of ghost-written, pro-Neurontin editorials.[4] As a result, Parke-Davis's parent organization Warner-Lambert (and ultimately Pfizer, after it acquired the company in 2000) pleaded guilty to two counts of violating the Food, Drug & Cosmetics Act and was required to pay $430 million in both civil and criminal damages.[5] A separate lawsuit for these marketing practices from Blue Cross Blue Shield of Louisiana, was settled for $325 million, and a third lawsuit regarding anti-trust activity to prevent generic gabapentin off the market, was settled in 2014 for $190 million.[6] Pfizer did not admit wrongdoing in the latter two settlements.

It is critical to understand the history of Neurontin advertising when assessing the perception of off-label prescribing of gabapentin. A portion of off-label gabapentin prescriptions could be due to misleading marketing information. However, it should be noted that these were unethical and illegal *business* practices, and should be viewed separately from issues of safety, efficacy, or overall utility in patient care.

Gabapentin and its salts are FDA-approved to treat postherpetic neuralgia and adjunctive treatment of epilepsy with partial onset seizures, yet one study found that up to 95 percent of gabapentin prescriptions were for off-label uses such as fibromyalgia, bipolar affective disorder, and alcohol use disorder.[7] Another study found that amongst 160 commonly prescribed drugs, gabapentin had the highest off-label prescription rate, and that 80 percent of the time, its off-label usage had little-to-no scientific support.[8] As of a 2020 survey, seven states have made gabapentin a schedule V controlled substance, and 13 states have added it to their prescription drug monitoring programs (PDMP). At least three other states have considered scheduling or otherwise monitoring prescriptions of gabapentin.

Evidence for Off-Label Uses of Gabapentin

A title search for the term "gabapentin" of Cochrane Library reveals seven systematic reviews or meta-analyses of gabapentin uses, and over 1,700 individual trials. Gabapentin is currently only FDA approved for postherpetic neuralgia and adjunctive therapy in epilepsy, but trials have been conducted to evaluate gabapentin for a plethora of other indications. To give a sense of the sheer breadth of applications for which gabapentin has been investigated, a sample of the 1700 trials include, but are not limited to: diabetic neuropathy, restless leg syndrome (RLS), sleep, smoking cessation, alcohol use disorder, cocaine use disorder, cannabis use disorder, fibromyalgia, tinnitus, social phobia, carpal tunnel syndrome, post-surgery pain, uremic pruritis, radicular pain, migraine, bipolar disorder, delirium, surgery pretreatment, topical anti-itching, post-operative nausea, phantom limb pain, acute mania, hot flashes and postural tachycardia syndrome.

Due to the volume of studied off-label uses of gabapentin and the varying range of study quality, it is impossible to synthesize the evidence base for each indication. Table One, presented below, attempts to capture some of the most common off-label uses of gabapentin and the current understanding of the evidence for its use.

The current evidence shows that gabapentin may have some useful off-label applications primarily in the fields of pain management and mental health, such as diabetic neuropathy[9], post-operative pain[10], and conditional anxiety.[11] For some applications, such as fibromyalgia[12] or migraine prophylaxis[13], the current evidence base is less compelling. This report should not be construed as clinical instructions or an endorsement of the off-label usage of gabapentin. Prescribers should utilize evidence-based decision-making when prescribing any medication for off-label uses.

Gabapentin and the Ongoing Overdose Epidemic

Proponents of scheduling gabapentin raise concerns over potential misuse, morbidity, and mortality associated with gabapentin.[14] Overdoses solely attributed to gabapentin are described in the literature as "rare".[15] However, approximately 9.7 percent of overdose deaths examined in the United States between 2019-2020 detected gabapentin.[16] Of those overdose deaths, almost 90 percent had at least one opioid (prescription or illicit) present in conjunction with gabapentin. Similar results were observed in a study of fatalities associated with gabapentin in England – of 913 deaths in which gabapentin was detected, opioids were co-detected in 91 percent.[17] In 25 percent of cases in which gabapentin and an opioid (including methadone and buprenorphine) were present, the two medications were co-prescribed. Finally, they found that only one of 913 deaths could be attributed solely to gabapentin toxicity. Gabapentin is recognized as a 'cutting' agent for heroin.[18] As such, gabapentin's role appears to potentiate additional respiratory depression when used concomitantly with other drugs known to cause respiratory depression, such as opioids. In a 2019 warning from the FDA, they indicated that "[t]here is less evidence supporting the risk of serious breathing difficulties in healthy individuals taking gabapentinoids alone."[19]

Gabapentin monotherapy misuse is less documented. Individuals may use high doses of gabapentin to induce euphoria but many, if not all, of these cases are observed in individuals with a history of substance use disorders.[20] In Germany (a country with a significantly lower overdose mortality rate than the United States), a survey of addiction medicine specialists placed gabapentin in a similar risk category as medications without misuse risk, such as non-steroidal anti-inflammatory drugs.[21]

It is difficult to assess the extent of gabapentin misuse. Online marketing surveys from the United Kingdom estimate that gabapentin misuse across the general population is as high as 1 percent.[22] However, this number does not appear to be corroborated by clinical data, which found that there were only 576 reported cases of gabapentin misuse to the FDA's Adverse Events Reporting System across a 5-year period during which there were approximately 200 million prescriptions of gabapentin filled in the United States.[23]

Rather, gabapentin misuse is often reported in the context of potentiating other substances, such as individuals under routine drug screens who potentiate buprenorphrine and/or naloxone with gabapentin to induce euphoria while testing negative for opioids. Approximately 9 percent of individuals seeking treatment for opioid use disorders self-reported misuse of gabapentin upon entry into opioid use treatment clinics in the United States from 2019-2020.[24] Systematic reviews have found that the largest risk factor for gabapentin misuse is an opioid use disorder.[25]

The growing rates of use of gabapentin and subsequent perception of its misuse are tied to the ongoing drug-related overdose epidemic. Based on the Centers for Disease Control and Prevention Clinical Practice Guidelines for Prescribing Opioids for Pain, utilization of multimodal pain management approaches is critical to supporting effective care[26]. As such, gabapentin has seen increases in prescribing as a key component of this multimodal approach, particularly in patients who have comorbidities that limit the use of other pain management medications.[27] In parallel to

concerns with increased opioid use, despite clear evidence for improved outcomes, stigmatizing language of diversion and criminal activity is emerging surrounding gabapentinoid products. The AMA has significant policy, advocacy, and ongoing work supporting evidence-based decision making regarding the proper care of patients with pain and/or opioid use disorders. Research has shown repeatedly that the best outcomes are those which are patient-centric, recognizing that opioid use disorder is a medical diagnosis requiring treatment, not a criminal issue requiring incarceration.[28,29]

REGULATING GABAPENTIN

Only a small number of states have chosen to pursue statutory or regulatory strategies specific to gabapentin. This includes classifying the medication as a schedule V controlled substance and requiring use of the PDMP; or requiring use of the PDMP without scheduling gabapentin. The Drug Enforcement Administration (DEA), with authority from the Controlled Substances Act, maintains a list of substances which are placed under increased regulatory scrutiny, including registration, production quotas, restrictions on research, and criminal or civil penalties for possession.[30] Substances are placed in different categories, or schedules, based on three factors: potential for misuse, whether there are accepted medical uses, and the potential for addiction. Schedule V is the lowest risk category, and are generally used for antidiarrheal, antitussive, and analgesic medications. Examples of schedule V drugs include Lomotil, Motofen, Parepectolin, and Lyrica (a gabapentinoid).

When the original resolution regarding gabapentin scheduling was presented at the House of Delegates at the 2022 Annual Meeting, testimony provided anecdotal evidence towards concerning patterns of misuse in non-prescribed gabapentin usage, particularly in incarcerated populations. Since potential for misuse is a key criterion for DEA scheduling, it is important to appreciate the magnitude of misuse. However, published literature on misuse of gabapentin is limited, and primarily in populations co-using with opioids. For example, in one study of individuals seeking inpatient opioid detoxification, 71 percent of respondents indicated that they were using gabapentin without a prescription for the purpose of reducing opioid withdrawal symptoms, and 58 percent reported they used gabapentin without a prescription to reduce their cravings for opioids.[31] At the population-level, one study of law enforcement found 407 cases of diverted gabapentin between the years of 2002 to 2015, with a peak rate of 0.027 cases per 100,000 population.[32] Another study found that 3 percent of commercially insured patients requested 3 or more prescription claims above the established dosage thresholds if they were seeking gabapentin on its own.[33] This number rose to 24 percent if they were seeking gabapentin co-prescribed with opioids. Due to the interconnectivity of gabapentin misuse with opioid use disorders – including instances which are intended to reduce opioid use – it is difficult to assess the true misuse risk of gabapentin.

Currently, gabapentin is not scheduled as a controlled substance by the DEA, but seven states (Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia) have classified gabapentin as a schedule V controlled substance.[3] While schedule V is the lowest risk categorization of the Controlled Substances Act of 1970 (although states may have different definitions under their own controlled substance regulations), it still requires physicians and other health care professionals who prescribe or dispense controlled substances to register with the DEA. Schedule V controlled substances are subject to restrictions on storage, security, and the amount, timing and frequency of refills.[34] A sub-population of patients particularly sensitive to changes in regulations are those within the carceral system, where prescribing of gabapentin is already heavily scrutinized, and the stigma and criminalization of pain treatment is highest.[35]

There are 13 states, including Connecticut, Indiana, Louisiana, Ohio, Oregon, and Utah, that have required reporting of gabapentin prescriptions into their PDMPs. These requirements are meant, in part, to allow physicians, pharmacists and other health care professionals to view recent prescriptions and prescription patterns of gabapentin and other controlled substances, such as opioids and benzodiazepines, to support evidence-based prescribing decisions. The AMA and many others have long supported using PDMPs as part of the clinical decision-making process, but emphasized that information in a PDMP is only one of many factors a physician should consider when determining whether to prescribe controlled substances[36].

With respect to the question whether to add gabapentin as a Schedule V Controlled Substance, the role of the PDMP needs additional consideration. When PDMP requirements first came into vogue, the general argument for mandating their use was the potential to reduce opioid-related misuse and opioid-related mortality. There is some evidence showing use of PDMPs increased the ability of physicians and pharmacists to identify multiple prescriber events, that is, when an individual received three or more opioid prescriptions from three or more different prescribers or dispensers within a short time frame, typically 30 days.[37] Many states have reported reductions in these multiple prescription events, but as detailed in AMA Board of Trustees Report 3-I-16, merely identifying a multiple prescriber event is not sufficient to know whether a patient is engaging in aberrant behavior, someone who has uncoordinated care, or is pursuing illegal prescriptions. Thus, while reductions in multiple prescriber events are likely positive, it is not clear whether the reductions have led to improved patient outcomes. In addition, there has been no reduction in opioid-related mortality as PDMP use has increased. In 2022, physicians and other health care professionals used PDMPs more than 1.1 billion times while the overdose epidemic grew to more than 107,000 fatalities.[38] Furthermore, there is no compelling evidence suggesting that PDMPs helped improve outcomes for patients with pain. There also continues to be confusion about how to optimize PDMPs in clinical practice.[39]

It is important to note that PDMPs have limitations. While different PDMP platforms claim to allow for interstate access of patient information, such retrieval is not always reliable if the user has not set the PDMP up to view all states—or even all neighboring states. There also continue to be challenges in reporting intervals from when a prescription is dispensed to when data is uploaded to the PDMP. Physicians and other health care professionals also continue to report frustration with PDMP-induced disruptions or poor interoperability with electronic health records.[40,41] Given the absence of data suggesting that a PDMP reduces drug-related misuse or other harms, along with a clear-eyed view of PDMP limitations, it is unlikely that having gabapentin in the PDMP—by virtue of it being a Schedule V Controlled Substance—will improve outcomes, increase meaningfully available information, or improve patient outcomes.

In comparing states which designated gabapentin as a schedule V controlled substance and states which required gabapentin reporting to the PDMP alone, states that designated gabapentin a controlled substance (which includes automatic registration in the state PDMP), saw a significant decrease in the number of gabapentin prescriptions.[42] By contrast, states which implemented a PDMP reporting-only approach saw little change in the number of gabapentin prescriptions.[43] This is not surprising as the requirements for prescribing a Schedule V controlled substance are greater than for a non-controlled substance.

Proponents of scheduling gabapentin as a controlled substance use this evidence, that designating gabapentin as a schedule V controlled substance reduces prescriptions, as a surrogate for decreasing patient harm.[44] The literature regarding scheduling gabapentin as a controlled substance lacks information regarding indication for use or patient oriented outcomes, such as pain control, increased functioning, prevalence of adverse events or evidence of decreases in misuse. Stigma and

prescribing barriers have the potential to impede access to care, particularly pain management. When strategies simply aim to decrease the overall number of prescriptions, marginalized and/or underserved patients will often be turned away first. Black patients are at highest risk for receiving inadequate pain treatment and are up to 36 percent less likely to receive *any* analgesic pharmacotherapy compared to white patients.[45,46] In the event that they do present with a substance use disorder, Black patients covered by Medicaid have a 50 percent lower rate of prescribing buprenorphine compared to white patients when controlled against other clinical and demographic factors.[47] There are many reasons for this inequity, but at its core, the implicit bias and associations made between Black patients, pain medication, and criminal behavior is difficult to ignore.[48] It is likely that further stigmatization of gabapentin prescribing and emphasis on misuse and diversion could result in similar inequities.

In addition, the nation's overdose epidemic and its intense focus on reducing opioid prescriptions provide a useful point of comparison. In 2012-2013, physicians began to reduce opioid prescriptions in response to growing concerns about misuse. Between 2012-2021, opioid prescriptions have declined in every state—46.4 percent nationwide.[49] As noted above, this reduction has not led to reduced drug-related overdose or death. The inverse actually has occurred. This is not to say that reduction in opioid prescribing were not warranted in certain circumstances, but as noted by the AMA in comments to the CDC and others, the focus should always have been on ensuring patients with pain received the right care at the right time, which may include opioid therapy[50]. The AMA supports continued efforts to enhance medical education and training, including those focused on medications that may be misused or used without a prescription. The AMA further supports efforts, including research and medical society collaboration to support effective pain care. These efforts could be interpreted to include gabapentin, but are certainly not limited to one medication and its potential uses, as noted above. These efforts already occur without having to increase the barriers to gabapentin by making it a Schedule V controlled substance. An end goal of simply reducing prescriptions is shortsighted and inappropriate.

Beyond regulatory solutions, best practices for prescribing gabapentin continue to evolve. The FDA is the appropriate agency to continue to evaluate drug safety. The AMA and organized medicine are the appropriate entities to support and encourage enhanced education about prescribing practices, including gabapentin.[51]

CONCLUSION

With the longevity of gabapentin on the market, combined with the incredibly wide range of trials, and the low incidence of adverse events, there is not a compelling reason to designate gabapentin as a controlled substance. The available evidence does not demonstrate that the benefits of scheduling gabapentin outweigh the risk of patient harm. Instead, strategies to increase prescriber awareness of gabapentin's potentiator effect and more thoughtful prescribing, particularly in groups at high-risk for overdose, will target increases in medication safety. The recognition of stigma and bias is critical for continued evidence-based decision-making and increased access to those in need.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed.

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

Our AMA will:

1. actively oppose the placement of (a) gabapentin ~~(2-[1-(aminomethyl) cyclohexyl] acetic acid)~~, including its salts, and all products containing gabapentin ~~(including the brand name products Gralise and Neurontin)~~ and (b) gabapentin enacarbil ~~(1-{[({(1RS)-1-[(2-methylpropanoyl)oxy]ethoxy}carbonyl)amino]methyl}cyclohexyl) acetic acid)~~, including its salts, ~~(including the brand name product Horizant)~~ into schedule V or other restricted class of the Controlled Substances Act;

~~2. submit a timely letter to the Commissioner of Food and Drug for the proceedings assigned docket number FDA-2022-P-0149 in opposition to placement of gabapentin and gabapentin enacarbil into the schedule V of the Controlled Substance Act; and~~

~~3. study the off-label use and potential risks and benefits of gabapentin to the general population as well as to those individuals with substance use disorders.~~

2. affirm that given currently available data, the FDA and DEA have used the appropriate process for evaluating the safety, efficacy, and risk of misuse and dependency for gabapentin and its salts;

3. support the promotion of gabapentin-related research and education, particularly the risk of gabapentinoids when taken concomitantly with opioids, including in current clinical practice and undergraduate, graduate and post-graduate education. (Modify Current AMA Policy)

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

Fiscal Note: less than $1,000

TABLE 1: SELECT STUDIES EVALUATING OFF-LABEL GABAPENTIN USES

Indication	# of Participants	Total Daily Dose Range (mg)	Clinical Measures Evaluated[a]	Favors Gabapentin Usage Over Risk of Use?	Reference
Diabetic neuropathy	5914	>1200	Substantial (>50%) or moderate (>30%) reduction in pain	Yes	9
Postoperative pain	370	250-500	Summed pain intensity difference	Yes	10
Conditional anxiety	934	300-1200	State-Trait Anxiety Inventory	Yes	11
Bipolar disorder	282	600-4800	Young Mania Rating Scale	No	11
Panic disorder	103	600-3600	Panic and Agoraphobia Scale	No	11
Depression	28	300-1800	Clinical Global Impressions-Severity Scale	Yes	11
Fibromyalgia	150	2400	50% reduction in pain	No	12
Migraine prophylaxis	1009	900-2400	Headache frequency	No	13
Sleep	4684	600-3600	Pittsburgh sleep quality index score	Yes	52
Cocaine use disorder	235	1600-2400	Report or evidence of use	No	53
Alcohol use disorder	269	600-1500	Report of heavy alcohol use	Yes	54
Hot flashes	600	1800	Frequency and severity of hot flashes	Yes	55
Restless leg syndrome	87	200	RLS rating scale and sleep quality	Yes	56
Chronic pelvic pain (women)	60	300-2700	Difference in pain score (vs. placebo)	Yes	57
Carpal tunnel syndrome	140	900	Global symptom score	No	58

[a] – Some clinical measures used in studies were excluded from summary for brevity.

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 02-A-23

Subject:	Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices
Presented by:	Noel Deep, MD, Chair
Referred to:	Reference Committee E

Resolution 523-A-22, "Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices" was referred by the House of Delegates (HOD). This report serves as the Council on Science and Public Health's (CSAPH) findings and recommendations regarding medical device regulation.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "medical device AND 510(k)" and "medical device AND post-market surveillance". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

In the context of regulatory oversight by the Food and Drug Administration (FDA), a medical device has a broad definition. According to the Food, Drug and Cosmetic Act:

> a device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
> […]
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

As such, the breadth of items captured within this regulatory framework is expansive, ranging from tongue depressors and eyeglasses to x-ray machines and hip replacements. In addition to physical objects used as medical devices, software and algorithms are also captured within this definition. As such, the FDA classifies software into two broad categories: software *in* a medical device and software *as* a medical device (SaMD). CSAPH recognizes that software, particularly SaMD, is rapidly becoming a large part of medical care and may warrant further examination beyond the

findings and recommendations of this report, which are intended to be generalizable to all medical devices.

DISCUSSION

The 510(k) Regulatory Pathway

When applying for a new medical device, the device is first evaluated for risk category: I (lowest risk), II (medium risk) or III (highest risk). Risk category is determined by a variety of factors, such as by comparing the device to a similar, known, device. If a device is found to be like a device already approved by the FDA, it may be classified as low (class I) or medium (class II) risk. Examples of devices commonly found to be class I include electric toothbrushes, tongue depressors, bandages, hospital beds, and non-electric wheelchairs. Examples of devices commonly found to be class II include catheters, pregnancy test kits, syringes, contact lenses, and surgical gloves. Examples of devices commonly found to be class III include breast implants, pacemakers, defibrillators, and cochlear implants. Approximately 1% of all new medical device applications from 2003 to 2017 were evaluated as high risk (class III).[i,ii]

If a medical device is found to be class I they are typically exempt from normal testing. If deemed a class II risk, manufacturers may submit a 510(k) application as pre-market notification (PMN) to the FDA. Class II risk devices are subjected to an equivalence evaluation comparing this product to one currently on the market through these 510(k) processes. 510(k) applications are processed within 90 days and once approved, the device is eligible for market. By contrast, class III devices must undergo pre-market approval (PMA) which requires two large clinical trials. According to a 2010 industry survey, pursuing pre-market approval in the United States takes on average 54 months to complete compared to 11 months in European countries.[iii]

Medical device market approval differs from drug approval in a few critical ways, which may help illustrate why the 510(k) pathway is so desirable for medical device manufacturers. Table 1 in the appendix of this report highlights some of these differences. Clinical trial design for medical devices can be extremely difficult, and in some cases unethical. For example, a placebo control for a medical device could require a high-risk sham surgery. As such, subjecting all new medical devices to undergo clinical trials may substantially hinder innovation, particularly from physicians seeking small tweaks or customizations to products they use routinely.

But on the other hand, if a medical device does cause harm to a patient, one cannot simply discontinue having an implanted device without significant intervention unlike if they were experiencing adverse events to a new medication that could be quickly stopped. As such, the 510(k) pathway has been subject to intense public scrutiny, both in the media and by elected officials.[iv] Many recalls of medical devices are voluntarily initiated by the manufacturer due to liability concerns or public perception decreasing sales rather than by official FDA action.

The FDA has recently begun piloting a new program within the 510(k) framework, called the Safety and Performance Based Pathway. This pathway provides an alternative to the current equivalence evaluation for a small subset of devices that are highly studied and well-known. In the Safety and Performance Based Pathway, the FDA sets forth explicit benchmarks that medical devices must satisfy to demonstrate safety and efficacy to gain 510(k) approval.[v] For example, if a resorbable surgical sutures manufacturer wished to market a new design, the FDA has guidance for the appropriate diameter, needle attachment, tensile strength, sterilization, shelf life and resorption profile for new suture designs to meet to receive 510(k) classification.[vi] This pathway provides

added safety and efficacy requirements to this moderate risk class. However, participation in the Safety and Performance Based Pathway is currently optional.

Device Equivalence

To be eligible for the 510(k) approval, a manufacturer must first establish that their device is "substantially equivalent" to a previously known, FDA-approved predicate device.[vii] For the purposes of regulatory approval, the FDA considers both safety and functionality when determining equivalence. First, they investigate whether the device is to be used for the same primary purpose, and they then evaluate whether the device is expected to have a similar safety profile. For example, if a device were to change its power source (such as hardwired vs. rechargeable) with no other modifications, it would likely be deemed substantially equivalent. Similarly, if the material of the device were to change to another material known to be safe to the FDA, it is likely to be found substantially equivalent. A flowchart of the FDA decision making process has been included in the Appendix of this report.

However, there is a flaw with the approach of substantial equivalence. If a device is found to be unsafe after receiving market approval and then subjected to a recall, any *subsequent* devices which used the original, now-unsafe device as their predicate, are not subjected to any increased scrutiny or recalls. Recent analysis found that between the period of 2017 and 2021, the FDA initiated recalls of 156 devices using their highest risk categorization – devices with a reasonable probability to cause severe morbidity and mortality. Of those 156 devices recalled, 44.1 percent of them had received 510(k) approval using substantial equivalence to a device that had also been the subject of a recall.[viii] Further, 48.1 percent of devices recalled within the studied period have themselves been used as the predicate for another device's 510(k) approval. This post marketing safety information and related devices draw significant attention to potential problems with the current 510(k) approval process with a lack of criterion for granting approval for devices outside the most well-studied and well-understood.

Post-Market Surveillance

It should be noted that the study described above only studied a cohort of devices which were the subject of FDA-initiated recalls. There are likely a non-trivial number of devices that are still being used as comparators for substantial equivalence that have been found to be unsafe and then production halted or voluntarily recalled by the manufacturer. However, there is limited publicly available information to monitor this risk. This scenario highlights the importance of rigorous post-market surveillance for devices that have been approved using the 510(k) pathway.

Among the post-market surveillance activities required by the FDA is the reporting of adverse events. Under Medical Device Reporting regulations (Title 21 Code of Federal Regulations part 803), manufacturers, importers, and device user facilities (such as a hospital, nursing home or outpatient treatment facilities) are mandatory reporters to the FDA regarding serious device malfunction, including death. Reports are made to the device manufacturer (if known) and the FDA. Health care professionals, patients, and caregivers are able to report suspected adverse events for medical devices using the FDA's MedWatch portal.

Adverse events are viewable to health care professionals and the public using the FDA's Manufacturer and User Facility Device Experience (MAUDE) portal.[ix] However, a 2019 exposé found that over 5 million incidents of reported adverse events were being kept from public view using an internal "alternative summary reporting" repository rather than the publicly available MAUDE database.[x] Not only did this practice prevent physicians and patients from knowing the

real risks of currently approved medical devices, it also prevented manufacturers of new devices from knowing the risk profile of substantially similar predicate devices they were using for 510(k) approval. The FDA has stated that it has since abandoned this practice of internal incident report storage.[xi]

Health Equity Considerations

It should also be noted that implicit in the 510(k) substantial equivalence method of approval is that it tends to maintain the status quo. For example, most, if not all, pulse oximeters currently used in the United States are approved via the 510(k) pathway.[xii] Pulse oximeters estimate blood oxygen saturation by shining light through the skin, typically on a fingertip or an ear lobe. Oxygenated blood absorbs red light more efficiently than de-oxygenated blood, thus allowing for estimates of oxygenation by simply measuring the amount of red light that passes through a tissue. However, oxygenated blood is not the only thing that absorbs red light – melanin, melanosomes, and melanocytes (ie, skin pigmentation), also absorb or scatter red light. A retrospective study found that practitioners missed hypoxemia diagnoses in 11.7 percent of Black patients compared to 3.6 percent of white patients due to pulse oximetry overestimating blood oxygenation.[xiii]

In the context of the COVID-19 pandemic, that suggests that excluding other factors, Black patients would be nearly 4-times less likely to receive oxygenation therapy such as a ventilator, which could prevent progression to acute respiratory distress syndrome.[xiv] As a result of these findings, the FDA released a safety communication indicating oximeters may be less accurate in darker skin tones.[xv] The failure of pulse oximeters to accurately measure oxygen saturation in all skin tones is a clear example of how inequity enters the health care system from many sources and can cascade. For example, even if a provider wished to start a patient on oxygenation therapy, Medicare reimbursement for supplemental oxygen therapy is only approved if a patient has a blood oxygenation reading less than or equal to 89 percent, which is less likely in Black patients if a pulse oximeter is used.[xvi] In November 2022, the FDA hosted an advisory committee meeting to discuss concerns of pulse oximeters and skin pigmentation. Dr. Jesse Ehrenfeld, president-elect of the AMA, was a participant of this meeting and delivered comments and recommendations on behalf of the AMA.

It is important to assess whether approving a new pulse oximeter design that reaches the same level of performance as a predicate device is appropriate as our appreciation of inequity grows and some categories of devices no longer match the values we wish to uphold.

Off-Label Use of Medical Devices

While the FDA has attempted to pilot programs, such as the Safety and Performance Based Pathway, that would improve the balance of fostering innovation and patient safety, they may not have the legislative authority or resources available to make these new programs mandatory. Without authority to pursue reforms to medical device regulation, there are concerns that the FDA may become more and more likely to begin regulating the practice of medicine to achieve similar goals.

The FDA has the authority to ban medical devices if they present a substantial deception to patients about the benefits or an unreasonable and substantial risk of injury. However, there are recent concerns of misuse of the banning process. In 2020, the FDA published a rule banning the use of electrical stimulation devices (ESD) for the treatment of self-injurious and/or aggressive behavior.[xvii] The FDA reported that the use of ESDs for this indication was unsafe and could lead to significant physical and psychological harm. ESDs were still approved for other indications such

as smoking cessation.[xviii] The approval of devices for specific indications while banning the same device for others is, per AMA policy, the FDA regulating the practice of medicine. The AMA has extensive policy and significant history defending the rights of physicians to practice medicine and protect off-label prescribing of pharmaceutics and devices.

Within the text of the FDA's rule on banning ESDs for aggressive behavior, they cite the 510(k) pathway as part of their justification for the banning of a specific indication, as they evaluate risk of a device based on its intended function, not on all potential functionalities. For example, daily wear vs. extended wear for gas permeable contact lenses are two separate risk categories. Evaluation of "substantially similar" for the purposes of 510(k) approval includes analysis of similar function. In 2021, the D.C. Circuit Court of Appeals overturned the ban, finding that the FDA was in fact regulating the practice of medicine, per the holdings of *Judge Rotenberg Educational Center v. United States Food and Drug Administration*.[xix]

CONCLUSION

While the FDA has made strides in improving the 510(k) process for medical device approval, such as through the Safety and Performance Based Pathway, recent data have shown serious safety concerns. These safety concerns denote the need for the process to be re-examined to support the purpose and benefits of accelerated pathways along with providing the FDA with the statutory authority to address the larger, systemic issues without impeding on the practice of medicine.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following be adopted, and the remainder of the report be filed:

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

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

Fiscal Note: less than $1,000Appendix

TABLE 1

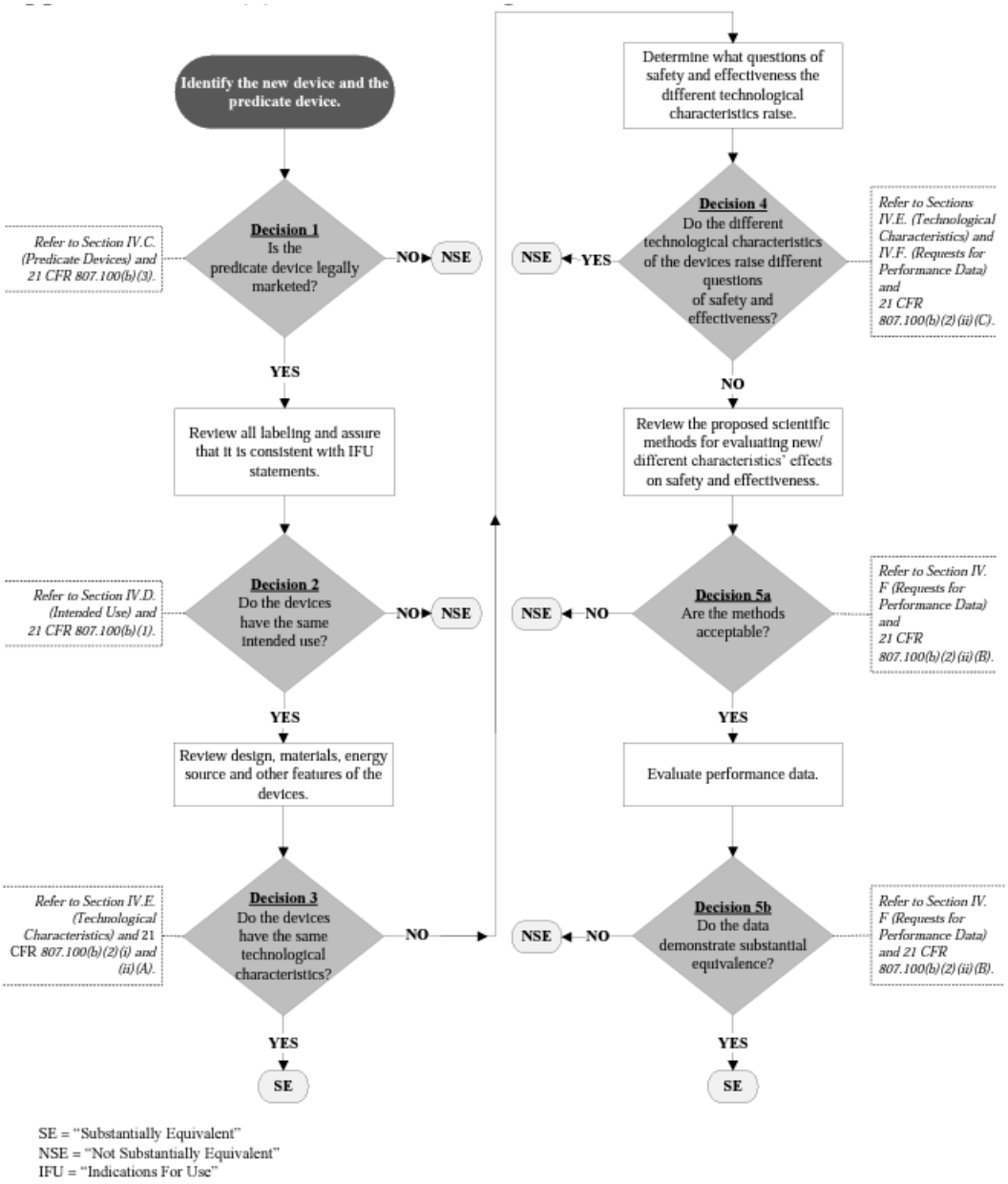
Comparison of regulatory requirements for drugs, biologics, and devices

Modified from Congressional Research Service, "Medical Product Regulation: Drugs, Biologics, and Devices", published September 29th, 2021. https://sgp.fas.org/crs/misc/IF11083.pdf.

	Drug	**Biologic**	**Class II (Medium Risk) Device**	**Class III (High Risk) Device**
Authorization Type	Approval	Licensure	Clearance	Approval
Submission to FDA	New Drug Application	Biologics License Application	510(k) notification	Pre-market approval
Clinical Trials?	Yes	Yes	No	Yes (few exceptions)
Evidence Required by FDA	Substantial evidence of effectiveness, adequate evidence of safety	Substantial evidence of effectiveness, adequate evidence of safety	Substantial equivalence to a known, approved device	Reasonable assurance that the device is safe and effective for its intended use(s)

FDA 510(k) Decision-Making Flowchart

Modified from Food and Drug Administration, *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"*, July 28, 2014. Accessed January 23rd, 2023.



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"
IFU = "Indications For Use"

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 03-A-23

Subject: Regulation and Control of Self-Service Labs

Presented by: Noel Deep, MD, Chair

Referred to: Reference Committee E

At the 2022 Annual Meeting of the American Medical Association (AMA), the House of Delegates adopted Policy D-260.992, "Regulation and Control of Self-Service Labs." That directive called for a study into "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". This report serves as the Council on Science and Public Health's (CSAPH) findings and recommendations regarding self-service testing, also known as direct access testing (DAT) or direct-to-consumer (DTC) testing. The Council has previously studied DTC genetic testing which shares many issues with DAT. For the purposes of this report, DAT refers solely to non-genetic, non-imaging based diagnostic testing.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "direct access testing", "self-service laboratory", "direct to consumer laboratory", and "self-service laboratory AND liability". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

Patient-directed testing has existed in the United States for decades, such as over-the-counter glucose testing kits available since the early 1980s. Currently, pharmacies sell a variety of at-home tests for pregnancy, illicit drug use, or other biomarkers. However, starting in the late 2010s, diagnostic companies began to offer a compilation of blood-based DATs such as hormone panels, electrolytes, heavy metal screening, metabolic panels, and prostate specific antigen (PSA). According to one estimate, the market for DAT in the United States currently exceeds $350 million per year, up from just $15 million per year in 2010.[1] Another source estimates that the DTC genetic and DAT lab services markets combined will exceed $2.4 billion per year by 2025.[2] For the purposes of this report, DAT will refer to medical tests that are not available as over-the-counter kits and are performed by a laboratory after being purchased by an individual without a prescription.

The DAT business model removes the health care professional, often the primary care physician, from the care decision-making and allows an individual to directly purchase their test from the laboratory. Overall, there is limited literature on DAT, the model, and outcomes for patients and their care. According to the Frequently Asked Questions webpage of one DAT company, orders for these tests are provided by a licensed clinician upon demand, but these tests are not reimbursed by insurance as they are not the treating health care professional and they do not provide CPT codes.[3]

While the process may vary from company to company, they generally follow similar steps. First, a patient is presented with a menu of available testing options. They then select the test(s) they would like performed, and then pay up-front for the test. A licensed clinician then orders the test, which the companies claim does not constitute a patient-physician relationship. The patient then visits a nearby facility for their sample(s) to be taken, and they receive their results within a few days. Results are often reported in the same manner as they would from a prescribed test in the usual course of care– a single value with solely the reference range as context. Unlike tests that come from a prescribing physician within a health-system, DAT companies do not provide any diagnostic assessment, counseling, or guidance on laboratory results. Patients are encouraged to share their results with their physicians, but it is unclear if or how any DAT facilities enter results into the electronic medical record or otherwise to alert a health care professional that a test has been performed.

DISCUSSION

Patient Safety

The most obvious concern around DAT is patient safety. Assuming the patient identifies an appropriate test to measure the biomarker of interest, patients often receive a single numerical value and a reference range for their test results with no additional description or suggested next steps. However, interpreting medical tests is more than simply seeing if a number is within the reference range. Physicians have years of training and experience to incorporate the quantitative information of medical tests with the qualitative information collected from the patient, including past medical history or signs and symptoms. Take for example the measurement of thyroid stimulating hormone (TSH), which typically has a reference range listed of 1 to 4.5 mlU/L, depending on the assay. A non-trained individual may receive a result of 4.3 mlU/L, see that it is within the provided reference range, and assume they have healthy thyroid function. However, a trained physician may recognize that in combination with presenting symptoms or other risk factors, that this individual may have early hypothyroidism and can begin intervention.[4]

Risk assessment is a critical factor for interpreting and acting upon medical test results, but it is also a key consideration for prescribing the test in the first place. For example, for PSA screening the USPSTF recommends a shared decision-making model, in which men aged 55 to 69 should be informed of the potential risks and benefits of PSA screening before making the decision with their physician.[5] PSA levels could be elevated from several non-cancer sources, such as benign prostatic hyperplasia or prostatitis, and that the risk of dying from prostate cancer was approximately 2.5 percent. Studies have found that approximately 80 percent of men who pursued aggressive clinical action such as brachytherapy due to elevated PSA levels experienced erectile dysfunction or incontinence as a result of treatment.[6] In recommending a screening one needs to consider the risks of false positives and over-diagnosis of benign, non-fatal prostate cancers outweighed that may outweigh benefits of early detection. USPSTF has found that PSA testing outside of a very specific risk category offers poor or even negative value to the patient.[7] This crucial risk-benefit analysis and discussion is missing when an individual can simply order a PSA test from a DAT website and may lead to unwanted outcomes. DAT companies do not follow any clinical guidelines for any test provided. They do not limit test offerings to those in the appropriate risk categories.

Legal Landscape

While the definition varies from state to state, the practice of medicine is typically defined as diagnosing, treating, or advising a patient on their symptoms or disease. It appears that DAT

companies are pursuing a loophole – if they explicitly do not advise a patient on what their test results mean, or use a biomarker to diagnose, they contend it is not practicing medicine. Currently 37 states allow DAT with varying levels of restriction. It should be noted that depending on the state, DAT companies might utilize a dentist, nurse practitioner, physician assistant, naturopathic doctor, licensed acupuncturist, or chiropractor to order tests.

There are also concerns about the duty of the physician when a patient presents with DAT results and requests their physician take clinical action. While the Council does not intend to offer clinical guidance, it cannot identify any scenario in which the action by the physician, if they choose to act at all, can be anything but re-ordering the test through appropriate channels. This is especially true in instances where the patient may have ordered a test the physician is inexperienced with – how can they be expected to act upon, and be liable for, a test they would not have ordered themselves? Current AMA policy and the Code of Medical Ethics regarding direct-to-consumer diagnostic imaging services states that any physician ordering a test is the responsible party for diagnosis and subsequent patient counseling.[8]

Finally, there are also concerns about the regulations of the laboratories performing the tests. There are two main ways in which clinical testing is regulated in the United States. First, if a test is fully self-contained (ie, a test kit), then it is reviewed for medical claims by the Food and Drug Administration (FDA) as an in vitro medical device. For all other medical testing, such as laboratory developed tests, laboratories are regulated, inspected, and certified by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvements Amendment (CLIA). The FDA categorizes laboratory tests based on complexity, which CMS then uses to develop regulations. Depending on the categorization of test complexity, CLIA may require quality standards for facility administration, laboratory systems, personnel qualifications, quality assessment, and quality control. CLIA certification is provided by CMS-approved accrediting bodies, such as the Joint Commission or the College of American Pathologists. Studies have found that the introduction of CLIA resulted in an increase in laboratory quality and customer satisfaction.[9]

There have been reports that some companies offering DAT skirt the CLIA certification process by claiming that since they only provide a context-free biomarker value, they are providing "health information" rather than a medical test.[10] Ensuring that these tests are performed in CLIA-certified laboratories is critical for maintaining the accuracy of the results while also making sure patients' samples and data are secure and stored appropriately.

Examining the Appeal

When assessing issues of DAT regulations, it is also important to understand the use-cases and surrounding ecosystem that has caused the market for DATs to flourish. DAT marketing often emphasizes a few key points: it is faster, the cost is upfront and known (ie, there is no unknown co-pay that will be administered later), and that an individual will be able to take control over their health. The first two claims are interconnected and point to the role health insurance companies play in reimbursement for testing. For example, studies have shown that when individuals enroll in a high deductible insurance plan, they are approximately 10 percent less likely to receive laboratory tests due to the financial disincentive.[11] It is also important to recognize that an insurance provider may require prior authorization, and then ultimately decline coverage, for outpatient laboratory testing which adds significant delays and cost uncertainty for a patient.

Additionally, there are several tests offered by DAT companies for conditions which unfortunately carry high levels of social stigma – particularly infectious diseases such as sexually transmitted

infections or hepatitis. In these instances, availability of a test which can be ordered online and without an uncomfortable conversation with their physician may be attractive to many patients. Tests for influenza or other respiratory viruses that can be ordered for home sample collection may also reduce the risk of transmission in a hospital or clinic setting. However, those instances in which DATs may be an appealing option further underscore the need for ensuring DAT facilities are CLIA-certified and responsible for the appropriate patient counseling on result interpretation and any necessary lifestyle changes.

Finally, DATs are often marketed to the individual who is seeking to better understand and control their health. For example, DAT companies may offer cholesterol panel testing, which would be appealing to someone who has changed their diet or exercise routine and is eager to see results. While those goals should be applauded, there are multiple risks associated with this approach. First, if the test is inaccurate, the individual will be given a false understanding of changes in their health. Second, the individual may not properly understand the time it may take for their changes to have an impact on a clinical biomarker, nor may they appreciate the healthy fluctuation the biomarker levels may have from day-to-day, or the size of impact their lifestyle changes may have on the biomarker. In some instances, an individual could discontinue medication or other treatments if they are given inaccurate test results devoid of context. Again, this highlights the critical importance of physician counseling in health management, as none of this information is currently communicated to patients utilizing DAT companies.

CONCLUSION

In a system of complex insurance reimbursement and high out-of-pocket plans, DATs may appear appealing for patients. However, current DAT practices appear to skirt regulatory requirements, could easily be misinterpreted by patients, and lack appropriate diagnostic and counseling practices by a physician. Potential utilization of DAT may be warranted in the realm of infectious disease when immediate testing would be beneficial for public health; however, test results should still be carefully communicated to the patient and monitored by a physician who is responsible for the patient's care.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following recommendations be adopted, and the remainder of the report be filed:

1. Direct access testing, in which patients may order a diagnostic laboratory test on demand, should only be provided by teams which are physician-led, and performed in facilities that are CLIA-certified.

2. Health care professionals who offer direct access testing services, for which a patient does not have a referral, recognize that agreeing to perform direct-to-consumer testing on request:
    a. establishes a patient relationship, with all the ethical and professional obligations such relationship entails; and
    b. assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Health care professionals may choose to refer the patient for post-test counseling to an appropriate provider who accepts the patient, but they maintain ethical and professional responsibility until the patient has been seen by that provider; and

shall report all required findings to relevant oversight entities, such as state public health agencies, even if the patient and the laboratory are not co-localized in the same jurisdiction. (New HOD Policy)

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

Fiscal Note: less than $1,000

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501
(A-23)

Introduced by: Medical Student Section

Subject: AMA Study of Chemical Castration in Incarceration

Referred to: Reference Committee E

Whereas, Chemical castration is defined as the use of pharmacologic agents, including anti-antagonists and gonadotropin-releasing hormone agonists, to reduce serum testosterone levels and quell libido in individuals diagnosed with a paraphilic disorder and other individuals who commit sexual offenses, in an effort to reduce the occurrence of sexual offenses[1,2]; and

Whereas, 4,984 people are currently incarcerated for sexual offenses in federal prisons[3,4]; and

Whereas, Several states have passed or debated statutes requiring chemical castration for individuals who commit sexual offenses as a sentence and/or as a requirement for parole, most recently Alabama in 2019, where offenders are required to pay for their own treatment, and in Tennessee in 2020[1,5-8]; and

Whereas, Diagnostic and Statistical Manual of Mental Disorders (DSM)-V defines “paraphilic disorder” as “recurrent and intense sexual arousal over a period of at least 6 months with nonconsenting victims through voyeurism, exhibitionism, frotteurism, sexual sadism, and pedophilia” and estimated lifetime prevalences are 12% for males and 4% for females[9]; and

Whereas, Chemical castration can be traced to the 1900s eugenics movement where people with developmental delays and psychiatric diagnoses were forcibly sterilized, including up to 60,000 incarcerated women diagnosed with and intellectual disability[1]; and

Whereas, Chemical castration via injection with Depo-Provera (medroxyprogesterone acetate) and surgical sterilization have historically disproportionately targeted Black individuals in the United States, including the deceptive, experimental testing of Depo-Provera as a method of birth control on young Black females in the 1960s[10,11]; and

Whereas, The current method of chemical castration for incarcerated males who committed sex offenses in several states, including California and Florida, is via injection with Depo-Provera, although no medication, including Depo-Provera, is currently FDA-approved for chemical castration[12]; and

Whereas, Limited evidence exists for the effectiveness of chemical castration, with several studies noting that chemical castration does not address the core psychological impulses relating to sexually aberrant behavior[12,13]; and

Whereas, When chemical castration is a requirement for parole, judges, not medical doctors, are charged with deciding whether or not a prisoner receives chemical castration therapy, suggesting that chemical castration constitutes punishment instead of rehabilitative therapy[12]; and

Whereas, The Association for the Treatment of Sexual Abusers (ATSA) published a 2012 statement on the use of chemical castration for individuals with paraphilic disorders and individuals who commit sexual offenses, concluding that chemical castration may be effective for certain patients when combined with other non-pharmacologic interventions such as psychotherapy[14]; and

Whereas, The issue of chemical castration is rife with ethical quandaries and valid arguments may exist both in support of and in opposition to this practice[15]; and

Whereas, In situations where chemical castration is a requirement for parole, some may argue that this requirement unjustly coerces an individual to agree to a medical procedure, while others may argue that if chemical castration was not required, an individual may never be allowed the possibility of parole at all and may remain incarcerated[15]; and

Whereas, Scientific research, medical information, and expert opinions from physicians on the issue of chemical castration for individuals who commit sexual offenses, especially in the last 5 years, are difficult to find most likely since the population affected by chemical castration have not been the subject of much retrospective research; and

Whereas, The American Psychiatric Association raised concerns in July 2021 about the use of chemical castration as a condition for parole, citing ethical concerns over the minimal to absent involvement of physicians and calling the "court-driven, one-size-fits-all approach to anti-androgen treatment inconsistent with contemporary medical practice"[16]; and

Whereas, Our American Medical Association previously adopted Policy 140.955, "Court-Ordered Castration," which stated that "The AMA opposes physician participation in castration and other surgical or medical treatments initiated solely for criminal punishment," but this policy was later rescinded due to being considered duplicative of Code of Medical Ethics Opinion 9.7.2, "Court-Initiated Medical Treatment in Criminal Cases"[17-18]; and

Whereas, While the AMA Code of Medical Ethics Opinion 9.7.2 states that "physicians who provide care under court order should: (a) Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control," the morality of chemical castration under this Code is unclear, including its use as efficacious treatment, as a mechanism for social control, as a tool for public safety, and as an alternative to incarceration[1,5-8,15,18]; therefore be it

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

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

Received: 3/31/23

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RELEVANT AMA POLICY

Court-Initiated Medical Treatment in Criminal Cases, E-9.7.2

Court-initiated medical treatments raise important questions as to the rights of prisoners, the powers of judges, and the ethical obligations of physicians. Although convicted criminals have fewer rights and protections than other citizens, being convicted of a crime does not deprive an offender of all protections under the law. Court-ordered medical treatments raise the question whether professional ethics permits physicians to cooperate in administering and overseeing such treatment. Physicians have civic duties, but medical ethics do not require a physician to carry out civic duties that contradict fundamental principles of medical ethics, such as the duty to avoid doing harm.

In limited circumstances physicians can ethically participate in court-initiated medical treatments. Individual physicians who provide care under court order should:

(a) Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control.

(b) Treat patients based on sound medical diagnoses, not court-defined behaviors. While a court has the authority to identify criminal behavior, a court does not have the ability to make a medical diagnosis or to determine the type of treatment that will be administered. When the treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, the physician's diagnosis must be confirmed by an

independent physician or a panel of physicians not responsible to the state. A second opinion is not necessary in cases of court-ordered counseling or referrals for psychiatric evaluations.
(c) Decline to provide treatment that is not scientifically validated and consistent with nationally accepted guidelines for clinical practice.
(d) Be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given.
Issued: 2016

Informed Consent, E-2.1.1
Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.
The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:
(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
(i) the diagnosis (when known);
(ii) the nature and purpose of recommended interventions;
(iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.
(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.
In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.
Issued: 2016

Patient-Physician Relationships, E-1.1.1
The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.
A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).
However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:
(a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.
(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.
(c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.
Issued: 2016

Standards of Care for Inmates of Correctional Facilities H-430.997
Our AMA believes that correctional and detention facilities should provide medical, psychiatric, and substance use disorder care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism.
Citation: Res. 60, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Amended: Res. 416, I-99; Reaffirmed: CEJA Rep. 8, A-09; Reaffirmation I-09; Modified in lieu of Res. 502, A-12; Reaffirmation: I-12; Modified: CSAPH Rep. 1, A-22;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502
(A-23)

Introduced by: Medial Student Section

Subject: Pain Management for Long-Acting Reversible Contraception and other Gynecological Procedures

Referred to: Reference Committee E

Whereas, A U.S.-based prospective study of over 9,256 women known as the Contraceptive CHOICE Project showed that increasing access to long-acting reversible contraceptives (LARC) will lead to a decrease in both unintended pregnancies and annual healthcare costs[1]; and

Whereas, AMA policy H-75.987 supports a national goal of reducing unintended pregnancies via counseling women of children bearing age on family planning and LARC use; and

Whereas, Intrauterine devices (IUDs) are between 99.6% and 99.9% effective as long-acting reversible contraceptives and 99.9% effective as emergency contraceptives[2,3]; and

Whereas, The 2017-2019 National Survey of Family Growth states that 10.4% of women age 15-49 in the United States use long-acting reversible contraceptives and use of LARCs has risen five-fold in the last decade among women aged 15-44[4,5]; and

Whereas, Without the use of analgesics or anesthesia, nearly 89% of women report moderate to severe pain during placement of a tenaculum, which precedes insertion of an intrauterine device (IUD), removal of lost IUDs, as well as endometrial biopsy, uterine aspiration, colposcopy, and hysteroscopy[6]; and

Whereas, A 2014 study found that, on a scale of 100, the mean patient maximum pain upon IUD insertion was 64.8 compared to 35.3 rated by the physician, highlighting a discrepancy between patients' experienced pain and providers' assumption of pain[7]; and

Whereas, Studies report that physicians often underestimate female pain and treat female pain less extensively than male pain; consequently, physicians are less likely to recommend analgesics and are more likely to recommend psychological treatment for female pain than for male pain[8-13]; and

Whereas, In addition to LARC insertion procedures, a substantial portion of other gynecologic procedures are routinely performed in offices and in clinics, including colposcopy with biopsy, loop electrosurgical excision procedure (LEEP), endometrial biopsy, uterine aspiration, dilation and evacuation (D&E), saline infusion sonogram, and hysterosalpingogram, among others under circumstances with limited validated options for analgesia[14]; and

Whereas, Local anesthesia, general anesthesia, and oral or intravenous sedation is commonly used in vasectomy procedures for pain control and clear guidelines regarding use of sedation or anesthesia for vasectomies are explicitly outlined in American Urological Association clinical guidelines[15]; and

Whereas, Studies have shown that medical professionals hold false beliefs about Black people feeling less pain, so that Black women stand to face compounded effects of racism and sexism when seeking appropriate treatment for pain[16]; and

Whereas, Current research suggests that anticipated pain is correlated with increased perceived pain throughout the duration of IUD insertion, especially in marginalized populations[17]; and

Whereas, While studies have shown LARCs to be associated with high rates of satisfaction following insertion, this level of satisfaction is negatively impacted by pain experienced during the procedure[18]; and

Whereas, Negative experiences related to gynecologic procedures may lead to patients delaying otherwise routine gynecologic care, which can lead to preventable healthcare inequities surrounding undiagnosed gynecological cancers, endometriosis, infections, thereby impacting a patient's quality of life and potentially resulting in preventable death[19]; and

Whereas, Multiple analgesic treatment regimens, including prophylactic NSAIDs, cervical ripening, and topical cervical lidocaine, have been shown to prove inadequate analgesia prior to IUD insertion, while intracervical lidocaine block and ketorolac injection have demonstrated potential analgesic efficacy around the time of IUD insertion[20-23]; and

Whereas, Adequate management of postoperative pain after gynecologic procedures has been associated with fewer postoperative hospital admissions[24]; and

Whereas, The American College of Obstetricians and Gynecologists (ACOG) acknowledges that, of the patients that undergo IUD insertion, “many report moderate to severe pain” and that more research is needed to identify effective options to reduce pain for IUD insertion[25]; and

Whereas, ACOG specifically recommends that physicians consider analgesia or sedation for women who are at higher risk for increased pain during IUD insertion, such as nulliparous women, patients requiring cervical dilation, or patients who have had a past painful insertion experience[25]; and

Whereas, Our American Medical Association endorses training physicians on adequate pain control and urges for informed consent for other in-office procedures such as policy H-69.945 “Neonatal Male Circumcision”, but does not have a policy that explicitly discusses pain management for gynecological procedures; therefore be it

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

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

Fiscal Note: Minimal - less than $1,000

Received: 3/31/23

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RELEVANT AMA POLICY

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;

Pain Management H-410.950
Our AMA adopts the following guidelines on Invasive Pain Management Procedures for the Treatment of Chronic Pain, Including Procedures Using Fluoroscopy:

Interventional chronic pain management means the diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing sub-acute, chronic, persistent, and intractable pain. The practice of pain management includes comprehensive assessment of the patient, diagnosis of the cause of the patient's pain, evaluation of alternative treatment options, selection of appropriate treatment options, termination of prescribed treatment options when appropriate, follow-up care, the diagnosis and management of complications, and collaboration with other health care providers.

Invasive pain management procedures include interventions throughout the course of diagnosing or treating pain which is chronic, persistent and intractable, or occurs outside of a surgical, obstetrical, or post- operative course of care. Invasive pain management techniques include:

1. ablation of targeted nerves;
2. procedures involving any portion of the spine, spinal cord, sympathetic nerves or block of major peripheral nerves, including percutaneous precision needle placement within the spinal column with placement of drugs such as local anesthetics, steroids, and analgesics, in the spinal column under fluoroscopic guidance or any other radiographic or imaging modality; and
3. surgical techniques, such as laser or endoscopic diskectomy, or placement of intrathecal infusion pumps, and/or spinal cord stimulators.

At present, invasive pain management procedures do not include major joint injections (except sacroiliac injections), soft tissue injections or epidurals for surgical anesthesia or labor analgesia.

When used for interventional pain management purposes such invasive pain management procedures do not consist solely of administration of anesthesia; rather, they are interactive procedures in which the physician is called upon to make continuing adjustments based on medical inference and judgments. In such instances, it is not the procedure itself, but the purpose and manner in which such procedures are utilized, that demand the ongoing application of direct and immediate medical judgment. These procedures are therefore within the practice of medicine, and should be performed only by physicians with appropriate training and credentialing.

Invasive pain management procedures require physician-level training. However, certain technical aspects of invasive pain management procedures may be delegated to appropriately trained, licensed or certified, credentialed non-physicians under direct and/or personal supervision of a physician who possesses appropriate training and privileges in the performance of the procedure being supervised, and

in compliance with local, state, and federal regulations. Invasive pain management procedures employing radiologic imaging are within the practice of medicine and should be performed only by physicians with appropriate training and credentialing.
Citation: (BOT Rep. 16, A-13)

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;

Preconception Care H-425.976
1. Our AMA supports the 10 recommendations developed by the Centers for Disease Control and Prevention for improving preconception health care that state:

(1) Individual responsibility across the lifespan--each woman, man, and couple should be encouraged to have a reproductive life plan;
(2) Consumer awareness--increase public awareness of the importance of preconception health behaviors and preconception care services by using information and tools appropriate across various ages; literacy, including health literacy; and cultural/linguistic contexts;
(3) Preventive visits--as a part of primary care visits, provide risk assessment and educational and health promotion counseling to all women of childbearing age to reduce reproductive risks and improve pregnancy outcomes;
(4) Interventions for identified risks--increase the proportion of women who receive interventions as follow-up to preconception risk screening, focusing on high priority interventions (i.e., those with evidence of effectiveness and greatest potential impact);
(5) Inter-conception care--use the inter-conception period to provide additional intensive interventions to women who have had a previous pregnancy that ended in an adverse outcome (i.e., infant death, fetal loss, birth defects, low birth weight, or preterm birth);
(6) Pre-pregnancy checkup--offer, as a component of maternity care, one pre-pregnancy visit for couples and persons planning pregnancy;
(7) Health insurance coverage for women with low incomes--increase public and private health insurance coverage for women with low incomes to improve access to preventive women's health and pre-conception and inter-conception care;
(8) Public health programs and strategies--integrate components of pre-conception health into existing local public health and related programs, including emphasis on inter-conception interventions for women with previous adverse outcomes;
(9) Research--increase the evidence base and promote the use of the evidence to improve preconception health; and
(10) Monitoring improvements--maximize public health surveillance and related research mechanisms to monitor preconception health.

2. Our AMA supports the education of physicians and the public about the importance of preconception care as a vital component of a woman's reproductive health.
3. Our AMA supports the use of pregnancy intention screening and contraceptive screening in appropriate women and men as part of routine well-care and recommend it be appropriately documented in the medical record.
Citation: Res. 414, A-06; Reaffirmation I-07; Reaffirmed: CSAPH Rep. 01, A-17; Appended: Res. 401, A-19;

Neonatal Male Circumcision H-60.945
1. Our AMA: (a) encourages training programs for pediatricians, obstetricians, and family physicians to incorporate information on the use of local pain control techniques for neonatal circumcision; (b) supports the general principles of the 2012 Circumcision Policy Statement of the American Academy of Pediatrics, which reads as follows: "Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for

families who choose it. Specific benefits identified included prevention of urinary tract infections, penile cancer, and transmission of some sexually transmitted infections, including HIV." and (c) urges that as part of the informed consent discussion, the risks and benefits of pain control techniques for circumcision be thoroughly discussed to aid parents in making their decisions.
2. Our AMA encourages state Medicaid reimbursement of neonatal male circumcision.
Citation: (CSA Rep. 10, I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified: Res. 503, A-13)

E2.1.1 Informed Consent
Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.
The process of **informed consent** occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's **informed consent** (or the **consent** of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:
(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
(i) the diagnosis (when known);
(ii) the nature and purpose of recommended interventions;
(iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.
(c) Document the **informed consent** conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written **consent**, the **consent** form should be included in the record.
In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior **informed consent**. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain **consent** for ongoing treatment in keeping with these guidelines.
Issued: 2016

Pain as the Fifth Vital Sign D-450.956
Our AMA will: (1) work with The Joint Commission to promote evidence-based, functional and effective pain assessment and treatment measures for accreditation standards; (2) strongly support timely and appropriate access to non-opioid and non-pharmacologic treatments for pain, including removing barriers to such treatments when they inhibit a patient's access to care; (3) advocate that pain as the fifth vital sign be eliminated from professional standards and usage; and (4) advocate for the removal of the pain management component of patient satisfaction surveys as it pertains to payment and quality metrics.
Citation: BOT Rep. 19, A-16; Reaffirmation: A-19;

H-515.952 Adverse Childhood Experiences and Trauma-Informed Care
Adverse Childhood Experiences and Trauma-Informed Care H-515.952
1. Our AMA recognizes trauma-informed care as a practice that recognizes the widespread impact of trauma on patients, identifies the signs and symptoms of trauma, and treats patients by fully integrating knowledge about trauma into policies, procedures, and practices and seeking to avoid re-traumatization.
2. Our AMA supports:
a. evidence-based primary prevention strategies for Adverse Childhood Experiences (ACEs);
b. evidence-based trauma-informed care in all medical settings that focuses on the prevention of poor health and life outcomes after ACEs or other trauma at any time in life occurs;
c. efforts for data collection, research, and evaluation of cost-effective ACEs screening tools without additional burden for physicians.
d. efforts to educate physicians about the facilitators, barriers and best practices for providers implementing ACEs screening and trauma-informed care approaches into a clinical setting; and
e. funding for schools, behavioral and mental health services, professional groups, community, and government agencies to support patients with ACEs or trauma at any time in life; and
f. increased screening for ACEs in medical settings, in recognition of the intersectionality of ACEs with

significant increased risk for suicide, negative substance use-related outcomes including overdose, and a multitude of downstream negative health outcomes.
3. Our AMA supports the inclusion of ACEs and trauma-informed care into undergraduate and graduate medical education curricula.
Citation: Res. 504, A-19; Appended: CSAPH Rep. 3, A-21;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503
(A-23)

Introduced by: Medical Student Section

Subject: Increasing Diversity in Stem Cell Biobanks and Disease Models

Referred to: Reference Committee E

Whereas, Despite racial and ethnic minorities composing almost 40% of the U.S. population, most biomedical and clinical research uses a largely homogenous population that is usually 79.7% White, with 98% of over 10,000 NIH-funded cancer clinical trials not meeting NIH's own criteria and goals for minority participation[1-3]; and

Whereas, A principal component analysis of embryonic stem cell lines from the 1000 Genomes Project discovered 93 percent of 143 sequenced human embryonic stem cell lines clustered with reference samples of European ancestry[4]; and

Whereas, An analysis of 555 completed stem cell clinical trials showed only 45% documented information regarding patients' race and ethnicity, of which, Native American or Alaskan, Black, and Multiracial groups were underrepresented when compared to U.S. population data[5]; and

Whereas, Given that 72.6% of induced pluripotent stem cell lines (iPSCs) are Caucasian in origin, there is limited availability of racially and ethnically diverse iPSC biobanks and patient-derived disease models[5-7]; and

Whereas, The availability of diverse iPSC lines has not kept pace with advances in iPSC disease models and technologies, leading to biased insights on disease mechanisms, disease susceptibility, and drug responses in population-specific genetic variants[7-11]; and

Whereas, The history of research involving minorities has included questionable and harmful actions, such as the 1932 Tuskegee Syphilis Study, resulting in a greater unwillingness among minorities to participate in research studies[12,13]; and

Whereas, Recruitment materials used in U.S. biobanks are predominantly in English and above a fifth-grade reading level, limiting participation by underrepresented populations[14]; and

Whereas, Biobank recruitment strategies are often convenience-based, with hospital-based researchers recruiting patients not representative of those most afflicted by disease[12]; and

Whereas, Exclusion criteria in clinical trials often leads to participants with characteristics that are skewed, and the unnecessary exclusion of participants (e.g. non-English speakers, people with mental and physical disabilities), that better represent the actual demographic after treatment approval[15,16]; and

Whereas, Lack of diverse iPSC models for drug toxicity assessments fails to account for variations in metabolic activity, which leads to higher rates of adverse events in minority populations, resulting in patient harm and waste of resources[9,17]; and

Whereas, Existing studies investigating the diversity of stem cell research encompass only major racial and ethnic groups (e.g. Asian or Latino), despite health disparities existing among specific subgroups (e.g. Cambodian or Colombian)[6,18]; and

Whereas, An initiative by California's Stem Cell Agency addresses gaps in the diversity of stem cell lines through its publicly accessible iPSC Repository, with 2,600 iPSCs lines inclusive of minority populations including African, Hispanic, Native American, and East and South Asian populations[19]; and

Whereas, The NIH-sponsored All of Us Research Program endorses diversity as a core value and aims to build one of the largest diverse biobanks[20]; and

Whereas, Our American Medical Association supports the Diversity Trials Act that strives to ensure clinical trials focus on diseases disproportionately impacting underrepresented populations to discover scientific advances benefiting all communities[21]; and

Whereas, A recent study from the Stanford University Center for Biomedical Ethics (SCBE) recommends that reviewers and editors give priority to manuscripts that have significant minority group representation and to those that replicate prior studies that were primarily focused on White populations[22,23]; and

Whereas, A recent study SCBE recommends that race and/or ethnicity be included as variables in experiments requiring the use of stem cell lines such that potentially variable outcomes of intervention between racial or ethnic groups can be assessed[23,24]; and

Whereas, Our AMA is committed to supporting stem cell research and its diversification through a number of methodologies, as described in H-460.911, H-460.915, H-460.889, H-460.924, and 7.3.8 Research with Stem Cells[24-26]; therefore be it

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

RESOLVED, That our AMA amend Policy H-460.915, “Cloning and Stem Cell Research,” by addition to read as follows:

Cloning and Stem Cell Research, H-460.915

Our AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) urges the use of stem cell lines from different ethnicities in disease models; ~~(2)~~(3) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); ~~(3)~~(4) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); ~~(4)~~(5) encourages strong public support of federal

funding for research involving human pluripotent stem cells and ~~(5)~~(6) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology (Modify Current HOD Policy); and be it further

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

Fiscal Note: Minimal - less than $1,000

Received: 3/31/23

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RELEVANT AMA POLICY

Increasing Minority, Female, and other Underrepresented Group Participation in Clinical Research H-460.911

1. Our AMA advocates that:
a. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations. b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and c. Resources be provided to community level agencies that work with those minorities, females, and other underrepresented groups who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Black Individuals/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.
2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities, females, and other underrepresented groups in clinical trials: a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs; b. Increased outreach to all physicians to encourage recruitment of patients from underrepresented groups in clinical trials; c. Continued education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety, and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate recruitment of underrepresented groups and methods for increasing trial accessibility for patients; d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and e. Fiscal support for minority, female, and other underrepresented groups recruitment efforts and increasing trial accessibility.
3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.
Citation: BOT Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18; Modified: Res. 016, I-22;

Cloning and Stem Cell Research H-460.915

Our AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); (3) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); (4) encourages strong public support of federal funding for research involving human pluripotent stem cells; and (5) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology.
Citation: (CSA Rep. 5, A-03; Reaffirmed: CSAPH Rep. 1, A-13)

Support of Embryonic/Pluripotent Stem Cell Research H-460.889
Our AMA will encourage strong public support of federal funding for research involving human pluripotent stem cells.
Citation: CSAPH Rep. 01, A-19;

E-7.3.8 Research with Stem Cells
Human **stem cells** are widely seen as offering a source of potential treatment for a range of diseases and are thus the subject of much **research**. Clinical studies have validated the use of adult **stem cells** in a limited number of therapies, but have yet to confirm the utility of embryonic **stem cells**.

Physicians who conduct **research** using **stem cells** obtained from any source (established tissue, umbilical cord blood, or embryos) must, at a minimum:
(a) Adhere to institutional review board (IRB) requirements.
(b) Ensure that the **research** is carried out **with** appropriate oversight and monitoring.
(c) Ensure that the **research** is carried out **with** appropriate informed consent. In addition to disclosure of **research** risks and potential benefits, at minimum, the consent disclosure should address:
(i) for a donor of **cells** to be used in **stem** cell **research**:
a. the process by which **stem cells** will be obtained;
b. what specifically will be done **with** the **stem cells**;
c. whether an immortal cell line will result; and
d. the primary and anticipated secondary uses of donated embryos and/or derived **stem cells**, including potential commercial uses.
(ii) for a recipient of **stem cells** in clinical **research**:
a. the types of tissue from which the **stem cells** derive (e.g., established tissue, umbilical cord blood, or embryos); and
b. unique risks posed by investigational **stem** cell products (when applicable), such as tumorigenesis, immunological reactions, unpredictable behavior of **cells**, and unknown long-term health effects.

The professional community as well as the public remains divided about the use of embryonic **stem cells** for either **research** or therapeutic purposes. The conflict regarding **research with** embryonic **stem cells** centers on the moral status of embryos, a question that divides ethical opinion and that cannot be resolved by medical science. Regardless whether they are obtained from embryos donated by individuals or couples undergoing in vitro fertilization, or from cloned embryos created by somatic cell nuclear transfer (SCNT), use of embryonic **stem cells** currently requires the destruction of the human embryo from which the **stem cells** derive.

The pluralism of moral visions that underlies this debate must be respected. Participation in **research** involving embryonic **stem cells** requires respect for embryos, **research** participants, donors, and recipients. Embryonic **stem** cell **research** does not violate the ethical standards of the profession. Every physician remains free to decide whether to participate in **stem** cell **research** or to use its products.

Physicians should continue to be guided by their commitment to the welfare of patients and the advancement of medical science.
Physicians who conduct **research** using embryonic **stem cells** should be able to justify greater risks for subjects, and the greater respect due embryos than **stem cells** from other sources, based on expectations that the **research** offers substantial promise of contributing significantly to scientific or therapeutic knowledge.
Issued: 2016

Race and Ethnicity as Variables in Medical Research H-460.924
Our AMA policy is that: (1) race and ethnicity are valuable research variables when used and interpreted appropriately; (2) health data be collected on patients, by race and ethnicity, in hospitals, managed care organizations, independent practice associations, and other large insurance organizations; (3) physicians recognize that race and ethnicity are conceptually distinct; (4) our AMA supports research into the use of methodologies that allow for multiple racial and ethnic self-designations by research participants; (5) our

AMA encourages investigators to recognize the limitations of all current methods for classifying race and ethnic groups in all medical studies by stating explicitly how race and/or ethnic taxonomies were developed or selected; (6) our AMA encourages appropriate organizations to apply the results from studies of race-ethnicity and health to the planning and evaluation of health services; and (7) our AMA continues to monitor developments in the field of racial and ethnic classification so that it can assist physicians in interpreting these findings and their implications for health care for patients.
Citation: CSA Rep. 11, A-98; Appended: Res. 509, A-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmed: CEJA Rep. 01, A-21;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505
(A-23)

Introduced by:	Medical Student Section
Subject:	Improving Access to Opioid Antagonists for Vulnerable and Underserved Populations
Referred to:	Reference Committee E

Whereas, In the United States, the opioid epidemic is a growing health crisis and has been declared a public health emergency[1]; and

Whereas, Natural opioids are derived from the poppy plant, such as morphine and codeine, while synthetic opioids are artificially synthesized such as fentanyl, carfentanil, and methadone[2]; and

Whereas, Natural and synthetic opioid overdose-related deaths are a significant cause of death in the U.S., contributing to more than 100,000 deaths from April 2020 to April 2021, a 28.5% increase from the year prior[3,4]; and

Whereas, Naloxone is a competitive antagonist with a high affinity for the mu-opioid receptor that can reverse opioid-induced respiratory depression and rescue opioid overdose, with a half-life of 30 to 120 minutes[5]; and

Whereas, The widespread distribution and use of naloxone has been shown to decrease opioid overdose-related deaths without significantly increasing the incidence of opioid use[6-8]; and

Whereas, Naloxone may precipitate withdrawal, which can lead to physical and psychological side effects for the patient, including mood changes, which may adversely affect bystanders or medical staff[9,10]; and

Whereas, The need for large or repeated doses of naloxone to reverse synthetic opioid overdose further complicates medical management, adding to healthcare worker stress, especially in times of shortage[11]; and

Whereas, Patients who overdosed on fentanyl-adulterated opioid tablets who received naloxone had recurrence of respiratory depression beyond the standard observation period for opioid overdose[12]; and

Whereas, Synthetic opioids have an increased potency compared to natural opioids, which frequently necessitates higher initial dosing or additional administrations to rescue respiratory depression in the setting of overdose[13-15]; and

Whereas, It has been estimated that nearly 80% of fatal opioid-related overdose deaths involved synthetic opioids[16]; and

Whereas, Between 2013 and 2019, synthetic opioid overdose-related deaths increased 1,040%, with more than 55,000 deaths related to synthetic opioid overdose in 2020 alone[17-19]; and

Whereas, A multi-agency meeting was held in 2019 to discuss the threat of synthetic opioids and urge the development of drugs aimed at rescuing respiratory depression and overdose caused by synthetic opioids specifically; among those present were representatives from the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases, the National Institute of Drug Abuse, the Food and Drug Administration (FDA), the Chemical Countermeasures Research Program, the Biomedical Advanced Research and Development Authority, and the Defense Threat Reduction Agency[20]; and

Whereas, Respiratory stimulant drugs such as hypothalamic hormones, nicotinic receptor agonists, ampakines, serotonin agonists, antioxidants, and potassium channel blockers have been used in animal studies to reverse opioid-induced respiratory depression as alternatives to naloxone, but require further study before safe clinical use[11,21,22]; and

Whereas, Preliminary studies of nalmefene, a mu-opioid receptor antagonist more potent than narcan, have shown potential reversal of opioid-induced respiratory depression[22]; and

Whereas, Experimental drugs such as methocinnamox, an opioid receptor antagonist, have been shown to prevent respiratory depression following heroin exposure in Rhesus monkeys, but have not yet reached clinical trials[23]; and

Whereas, Approximately 1 in 4 women on Medicaid were prescribed opioids during pregnancy[24]; and

Whereas, This high level of opioid use during pregnancy correlates with increased incidence of neonatal abstinence syndrome (NAS) among babies, which is a group of psychological and neurobehavioral signs of withdrawal that may occur in a newborn exposed to opioids or psychotropic substances in utero that between 50% to 80% of infants exposed to opioids in utero will develop[24,25]; and

Whereas, Barriers to treatment for pregnant women with opioid use disorder (OUD) include legal consequences, shame associated with opioids, and misinformation among healthcare professionals resulting in reluctance to provide care[25]; and

Whereas, The American College of Obstetricians and Gynecologists (ACOG) recommends screening for substance use as a part of comprehensive obstetric care, and further recommends that screening should be done at the first prenatal visit universally for all patients[26]; and

Whereas, The American Academy of Addiction Psychiatry (AAAP) supports voluntary screening of pregnant women for substance use disorders for the purpose of providing prenatal care and treatment to mother and fetus[27]; and

Whereas, Universal screening rather than targeted or risk-based screening, as targeted screening can be influenced by negative stereotyping, and may disproportionately target marginalized communities[29]; and

Whereas, A large systematic review of non-randomized trials found that take-home naloxone programs have led to improved survival rates among program participants and reduced opioid overdose mortality rates in the community, and are accompanied by only a low rate of adverse events[28]; and

Whereas, The rate of opioid overdose-related inpatient stays in rural areas increased 76.3% between 2010 and 2017[30]; and

Whereas, The rate of overdose deaths involving opioids among American Indian and Alaskan Natives increased from 2.2 deaths per 100,000 individuals in 2000 to 13.7 deaths per 100,000 individuals in 2016[31]; and

Whereas, A recent systematic review illustrated the need to manage opioid use disorder (OUD) in rural American Indian / Alaskan Native communities with harm reduction education and medication assisted treatment[32]; and

Whereas, The United States Department of Health and Human Services identifies naloxone distribution as a top harm-reduction strategy for addressing the opioid epidemic[33]; and

Whereas, Recent studies of naloxone access in rural areas have identified common barriers, including cost, distance to clinics and providers, stigma felt by customers asking for naloxone, and unawareness of current state-specific standing-order laws[34–37]; and

Whereas, Medicare Part D, the largest single payer of naloxone prescriptions in the United States, dispensed naloxone at a rate of 4.9 per 1000 enrollees compared to 2.9 per 1000 enrollees in non-metropolitan areas, suggesting a growing disparity in naloxone availability in rural areas[38]; and

Whereas, A CDC's August 2019 *Vital Signs* report noted that the amount of naloxone dispensed is 25 times greater in the highest-dispensing counties compared to the lowest-dispensing counties, and that rural counties in the United States are 3 times more likely to be a low-dispensing county than in metropolitan areas[39]; and

Whereas, A study found Arizona was the only state that had enough naloxone availability to prevent 80% of witnessed overdoses in 2017[40]; and

Whereas, Stigma towards drug use in public pharmacy spaces – including fear of naloxone customers being stereotyped as an "addict" and discomfort of pharmacy staff introducing the subject of naloxone – is a recurrent finding in studies examining challenges of naloxone distribution[37,41–43]; and

Whereas, The stigmatization of purchasing medications may be reduced with telehealth and mail-order options for naloxone prescription and delivery[,44]; and

Whereas, Numerous studies, models, and systematic reviews of the literature have demonstrated take-home naloxone programs reduce opioid overdose mortality[45–51]; and

Whereas, Our American Medical Association supports legal use of naloxone regardless of prescription status (H-95.932); and

Whereas, Our AMA already has clear policy (H-420.950 and H-420.962) addressing the key legal, ethic and social concerns around substance use disorder in pregnancy and perinatal addiction, but lacks policy specifically supporting universal screening for opioid use as a tool to combat substance use disorder in pregnancy; and

Whereas, AMA policy advocates for the prevention of drug-related overdose (D-95.987) and general opioid mitigation (D-95.964), but does not explicitly address the growing concern of synthetic opioids nor the limitations of naloxone; therefore be it

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

Increasing Availability of Naloxone H-95.932

1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other healthcare professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.
6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.
7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
8. Our AMA supports the widespread implementation of easily accessible Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions) throughout the country following distribution and legislative edicts similar to those for Automated External Defibrillators.
9. Our AMA supports the legal access to and use of naloxone in all public spaces regardless of whether the individual holds a prescription.
10. Our AMA supports efforts to increase the availability, delivery, possession and use of mail-order naloxone to help

prevent opioid-related overdose, especially in underserved communities and American Indian reservations. (Modify Current HOD Policy)

and be it further

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

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

and be it further

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

Prevention of Drug-Related Overdose D-95.987
1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of patients with a SUD and people who use drugs; (b) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to be implemented in order to further develop best practices in this area; (c) encourages the education of health care workers and people who use drugs about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related overdose fatalities; and (d) will continue to monitor the progress of such initiatives and respond as appropriate.
2.Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug- related overdose; ~~and~~ (b) support the development of adjuncts and alternatives to naloxone to combat synthetic opioid-induced respiratory depression and overdose; and (c)

encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.

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

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

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

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

Fiscal Note: Minimal - less than $1,000

Received: 3/31/23

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RELEVANT AMA POLICY

Opioid Mitigation D-95.964
Our AMA: (1) encourages relevant federal agencies to evaluate and report on outcomes and best practices related to federal grants awarded for the creation of Quick Response Teams and other innovative local strategies to address the opioid epidemic, and will share that information with the Federation; and (2) will update model state legislation regarding needle and syringe exchange to state and specialty medical societies.
Citation: BOT Rep. 09, I-19;

Treating Opioid Use Disorder in Hospitals D-95.967
1. Our AMAs Opioid Task Force will work together with the American Hospital Association and other relevant organizations to identify best practices that are being used by hospitals and others to treat opioid use disorder as a chronic disease, including identifying patients with this condition; initiating or providing opioid agonist or partial agonist therapy in inpatient, obstetric and emergency department settings; providing cognitive and behavioral therapy as well as other counseling as appropriate; establishing appropriate discharge plans, including education about opioid use disorder; and participating in community-wide systems of care for patients and families affected by this chronic medical disease.
2. Our AMA will advocate for states to evaluate programs that currently exist or have received federal or state funding to assist physicians, hospitals and their communities to coordinate care for patients with the chronic disease of opioid use disorder.
3. Our AMA will take all necessary steps to seek clarification of interpretations of 21 CFR 1306.07 by the DEA and otherwise seek administrative, statutory and regulatory solutions that will allow for (a) prescribers with the waiver permitting the prescribing of buprenorphine for opioid use disorder to be able to do so, when indicated, for hospitalized inpatients, using a physician order rather than an outpatient prescription, and (b) hospital inpatient pharmacies to be able to fill such authorizations by prescribers without this constituting a violation of federal regulations.
Citation: Res. 223, A-18;

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 possession, distribution, and use of “drug paraphernalia” designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies.
5. Our AMA will implement an education program for patients with substance use disorder and their family/caregivers to increase understanding of the increased risk of adverse outcomes associated with having a substance use disorder and a serious respiratory illness such as COVID-19.
6. Our AMA supports efforts to increase access to fentanyl test strips and other drug checking supplies for purposes of harm reduction.
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; Appended: Res. 513, A-22; Modified: Res. 211, I-22;

Increasing Availability of Naloxone H-95.932
1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other health care professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.
6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.
7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
8. Our AMA supports the widespread implementation of easily accessible Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions) throughout the country following distribution and legislative edicts similar to those for Automated External Defibrillators.
9. Our AMA supports the legal access to and use of naloxone in all public spaces regardless of whether the individual holds a prescription.
Citation: BOT Rep. 22, A-16; Modified: Res. 231, A-17; Modified: Speakers Rep. 01, A-17; Appended: Res. 909, I-17; Reaffirmed: BOT Rep. 17, A-18; Modified: Res. 524, A-19; Reaffirmed: BOT 09, I-19; Reaffirmed: Res. 219, A-21;

Medications for Opioid Use Disorder in Correctional Facilities H-430.987
1. Our AMA endorses: (a) the medical treatment model of employing medications for opioid use disorder (OUD) as the standard of care for persons with OUD who are incarcerated; and (b) medications for persons with OUD who are incarcerated, an endorsement in collaboration with relevant organizations including but not limited to the American Society of Addiction Medicine and the American Academy of Addiction Psychiatry.
2. Our AMA advocates for legislation, standards, policies and funding that require correctional facilities to increase access to evidence-based treatment of OUD, including initiation and continuation of medications for OUD, in conjunction with psychosocial treatment when desired by the person with OUD, in correctional facilities within the United States and that this apply to all individuals who are incarcerated, including individuals who are pregnant, postpartum, or parenting.
3. Our AMA advocates for legislation, standards, policies, and funding that require correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including individuals who are pregnant, postpartum, or parenting, are released to offer post-incarceration treatment plans for

OUD, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths, including naloxone (or any other medication that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose), and help ensure post-incarceration medical coverage and accessibility to mental health and substance use disorder treatments, that include medication and behavioral health and social supports for addiction treatment.
4. Our AMA advocates for all correctional facilities to use a validated screening tool to identify opioid withdrawal and take steps to determine potential need for treatment for OUD and opioid withdrawal syndrome for all persons upon entry.
Citation: Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17; Modified: Res. 503, A-21;

Substance Use Disorders During Pregnancy H-420.950
Our AMA will: (1) oppose any efforts to imply that the diagnosis of substance use disorder during pregnancy represents child abuse; (2) support legislative and other appropriate efforts for the expansion and improved access to evidence-based treatment for substance use disorders during pregnancy; (3) oppose the removal of infants from their mothers solely based on a single positive prenatal drug screen without appropriate evaluation; and (4) advocate for appropriate medical evaluation prior to the removal of a child, which takes into account (a) the desire to preserve the individual's family structure, (b) the patient's treatment status, and (c) current impairment status when substance use is suspected.
Citation: Res. 209, A-18; Modified: Res. 520, A-19;

Perinatal Addiction - Issues in Care and Prevention H-420.962
Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant and breastfeeding women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant and breastfeeding women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care.
Citation: CSA Rep. G, A-92; Reaffirmation A-99; Reaffirmation A-09; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Modified: Alt. Res. 507, A-16; Modified: Res. 906, I-17; Reaffirmed: Res. 514, A-19;

Increasing Availability of Naloxone H-95.932
1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community-based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other health care professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.
6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.
7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
8. Our AMA supports the widespread implementation of easily accessible Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions)

throughout the country following distribution and legislative edicts similar to those for Automated External Defibrillators.
9. Our AMA supports the legal access to and use of naloxone in all public spaces regardless of whether the individual holds a prescription.
Citation: BOT Rep. 22, A-16; Modified: Res. 231, A-17; Modified: Speakers Rep. 01, A-17; Appended: Res. 909, I-17; Reaffirmed: BOT Rep. 17, A-18; Modified: Res. 524, A-19; Reaffirmed: BOT 09, I-19; Reaffirmed: Res. 219, A-21;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507
(A-23)

Introduced by: Medical Student Section

Subject: Recognizing the Burden of Rare Disease

Referred to: Reference Committee E

Whereas, Rare diseases, also known as orphan diseases, are defined as conditions that affect less than 200,000 individuals in the United States (US), categorized into various overlapping disease classes including but not limited to chromosomal disorders, connective tissue diseases, blood diseases, metabolic disorders, skin diseases, and autoimmune conditions[1-3]; and

Whereas, Rare diseases cumulatively affect a significant number of people in the US, estimated to be between 25-30 million individuals[4]; and

Whereas, Congress passed The Orphan Drug Act (ODA) to incentivize drug companies to develop treatments for rare diseases and rapidly deploy novel agents to target conditions affecting fewer than 200,000 persons in the United States, or conditions for which a drug will not be profitable within 7 years following approval by the FDA[5-7]; and

Whereas, Current orphan drug legislation to support biopharmaceutical R&D portfolio diversity, enhance patent exclusivity, and provide distinct FDA designations is not sufficient to promote novel drug development for different rare disease classes as 90% of these patients are without an FDA approved treatment[8-10]; and

Whereas, The Affordable Care Act does not specifically address orphan drugs coverage, and even when new treatment options such as drug prescriptions or medical devices are available for people with rare diseases, 61% of patients are denied or delayed in accessing treatment due to insurance company pre-approval[8,11]; and

Whereas, There are many disparities in rare disease health care including 39% of respondents traveling 60 or more miles for medical care, 17% considering or completing relocation, and 29% being granted access to treatment not approved by FDA[1,8]; and

Whereas, The mean health related quality of life scores of those with orphan diseases were the poorest compared to individuals with common chronic diseases, which may be attributed to diagnostic challenges, decreased access to medical information and treatment, and negative psychological impact such as coping with uncertainty[12]; and

Whereas, In 2019, health care costs associated with orphan diseases may be comparable to heart disease or cancer at $966 billion, accounting for direct, indirect, and non-medical costs associated with diagnosis and amounting to nearly 50% of the total national bill, despite a vastly lower percentage of rare disease within the population[10,13,14]; and

Whereas, The number of documented cases of many rare diseases are only expected to increase given recent advances in genomics and personalized medicine[15]; and

Whereas, There is a lack of reliable epidemiological data for patients with orphan diseases and insufficient knowledge on the pathophysiology of these conditions among health care providers, leading to inadequate access to information on disease prevalence and treatment outcomes[16]; and

Whereas, A lack of knowledge has made treatment options difficult for patients with orphan diseases to access, contributing to difficulty and delay in diagnosis, as shown by a National Organization for Rare Diseases (NORD) 2019 report that found 28% of individuals diagnosed with a rare disease did not receive a diagnosis for seven years or more and 38% of individuals received a misdiagnosis[8,17,18]; and

Whereas, Due to barriers in accessing treatment options, patients with rare diseases have difficulty finding treatment information and patient registries, such as Rare Disease Registries have become a tool for both patients and physicians to be educated on their condition[19]; and

Whereas, Natural history studies and patient registries collecting longitudinal, patient-driven data aided by machine learning help advance our understanding of rare diseases and how they progress over time, facilitating clinical research and the development of novel therapeutics[8,20]; and

Whereas, Recent automated tracking systems, such as RENEW, are being used to gather new global genomic discoveries onto an accessible database for genome sequencing of patients for improved therapeutic outcomes[21]; and

Whereas, Incorporation of genomic research as clinical diagnostic tests can increase large scale sequencing projects of structural variants and sharing of data that shortens the time to diagnosis by producing increased cohort sizes for development of personalized therapeutic options[22]; and

Whereas, With future advances in techniques such as genome-wide pooled CRISPR screening and plasmid-based reporter assays, which can shorten time to diagnosis, precision therapeutics could be used as a targeted and efficient approach in orphan disease treatment[23,24]; and

Whereas, With only 30% of the genome accounted for in the diagnosis of rare disease there is still 75% of phenotypic variations within the genome unaccounted for, in which future novel gene discovery through sequencing efforts can overcome this diagnostic challenge[24]; and

Whereas, AMA policy H-185.963 emphasizes insurance coverage for childhood and congenital diseases, but does not sufficiently include the orphan disease population or specialized genomic research considerations needed for timely diagnosis and treatment; therefore be it

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

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

Fiscal Note: Minimal - less than $1,000

Received: 4/3/23

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RELEVANT AMA POLICY

Genetic Information and Insurance Coverage H-185.972
AMA believes: (1) Health insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any health benefit coverage or establish eligibility, continuation, enrollment or contribution requirements.
(2) Health insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.
(3) Health insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
(4) Health insurance providers and other holders of genetic information should be prohibited from releasing genetic information without express prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.
Citation: BOT Rep. 15, I-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed in lieu of Res. 102, A-10; Reaffirmation: A-17; Reaffirmed: BOT Rep. 12, I-21;

Insurance Coverage for Adults with Childhood Diseases H-185.963
Our AMA: (1) urges public and private third party payers to increase access to health insurance products for adults with congenital and/or childhood diseases that are designed for the unique needs of this population; and
(2) emphasizes that any health insurance product designed for adults with congenital and/or childhood diseases include the availability of specialized treatment options, medical services, medical equipment and pharmaceuticals, as well as the accessibility of an adequate number of physicians specializing in the care of this unique population.
Citation: CMS Rep. 2, I-99; Modified and Reaffirmed: CMS Rep. 5, A-09; Reaffirmed: CMS Rep. 01, A-19;

Coverage of Children's Deformities, Disfigurement and Congenital Defects H-185.967
1. The AMA declares: (a) that treatment of a minor child's congenital or developmental deformity or disorder due to trauma or malignant disease should be covered by all insurers; (b) that such coverage shall include treatment which, in the opinion of the treating physician, is medically necessary to return the patient to a more normal appearance (even if the procedure does not materially affect the function of the body part being treated); and (c) that such insurability should be portable, i.e., not denied as a pre-existing condition if the patient's insurance coverage changes before treatment has been either initiated or completed.
2. Our AMA will advocate for appropriate funding for comprehensive dental coverage (including dental implants) for children with orofacial clefting.
Citation: (Sub. Res. 119, I-97; Reaffirmed, A-03; Reaffirmation A-05; Reaffirmation A-08; Appended: Res. 109, A-13)

Addressing Financial Incentives to Shop for Lower-Cost Health Care H-185.920
1. Our AMA supports the following continuity of care principles for any financial incentive program (FIP):
a. Collaborate with the physician community in the development and implementation of patient incentives.
b. Collaborate with the physician community to identify high-value referral options based on both quality and cost of care.
c. Provide treating physicians with access to patients' FIP benefits information in real-time during patient consultations, allowing patients and physicians to work together to select appropriate referral options.
d. Inform referring and/or primary care physicians when their patients have selected an FIP service prior to the provision of that service.
e. Provide referring and/or primary care physicians with the full record of the service encounter.
f. Never interfere with a patient-physician relationship (eg, by proactively suggesting health care items or services that may or may not become part of a future care plan).
g. Inform patients that only treating physicians can determine whether a lower-cost care option is medically appropriate in their case and encourage patients to consult with their physicians prior to making changes to established care plans.
2. Our AMA supports the following quality and cost principles for any FIP:
a. Remind patients that they can receive care from the physician or facility of their choice consistent with their health plan benefits.
b. Provide publicly available information regarding the metrics used to identify, and quality scores

associated with, lower and higher-cost health care items, services, physicians and facilities.
c. Provide patients and physicians with the quality scores associated with both lower and higher-cost physicians and facilities, as well as information regarding the methods used to determine quality scores. Differences in cost due to specialty or sub-specialty focus should be explicitly stated and clearly explained if data is made public.
d. Respond within a reasonable timeframe to inquiries of whether the physician is among the preferred lower-cost physicians; the physician's quality scores and those of lower-cost physicians; and directions for how to appeal exclusion from lists of preferred lower-cost physicians.
e. Provide a process through which patients and physicians can report unsatisfactory care experiences when referred to lower-cost physicians or facilities. The reporting process should be easily accessible by patients and physicians participating in the program.
f. Provide meaningful transparency of prices and vendors.
g. Inform patients of the health plan cost-sharing and any financial incentives associated with receiving care from FIP-preferred, other in-network, and out-of-network physicians and facilities.
h. Inform patients that pursuing lower-cost and/or incentivized care, including FIP incentives, may require them to undertake some burden, such as traveling to a lower-cost site of service or complying with a more complex dosing regimen for lower-cost prescription drugs.
i. Methods of cost attribution to a physician or facility must be transparent, and the assumptions underlying cost attributions must be publicly available if cost is a factor used to stratify physicians or facilities.
3. Our AMA supports requiring health insurers to indemnify patients for any additional medical expenses resulting from needed services following inadequate FIP-recommended services.
4. Our AMA opposes FIPs that effectively limit patient choice by making alternatives other than the FIP-preferred choice so expensive, onerous and inconvenient that patients effectively must choose the FIP choice.
5. Our AMA encourages state medical associations and national medical specialty societies to apply these principles in seeking opportunities to collaborate in the design and implementation of FIPs, with the goal of empowering physicians and patients to make high-value referral choices.
6. Our AMA encourages objective studies of the impact of FIPs that include data collection on dimensions such as:
a. Patient outcomes/the quality of care provided with shopped services;
b. Patient utilization of shopped services;
c. Patient satisfaction with care for shopped services;
d. Patient choice of health care provider;
e. Impact on physician administrative burden; and
f. Overall/systemic impact on health care costs and care fragmentation.
Citation: CMS Rep. 2, I-19;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 508
(A-23)

Introduced by: Medical Student Section

Subject: Development and Implementation of Recommendations for Responsible Media Coverage of Opioid Overdoses

Referred to: Reference Committee E

Whereas, The number of opioid-related overdose deaths in the United States has been steadily increasing since 1999, reaching 80,816 deaths in 2021[1-3]; and

Whereas, The media has the capacity to condition people's perceptions of and attitudes towards disease severity[4]; and

Whereas, By selectively including or excluding content, perspectives, and material, media platforms have a powerful capacity to frame issues, shape community attitudes, and impact political decision making[5]; and

Whereas, Media coverage of the opioid overdose crisis has impacted public attitudes regarding the crisis and the subsequent response[5-7]; and

Whereas, The *Herald Sun* newspaper in Australia effectively put heroin at the forefront of the public agenda by consistently highlighting heroin-related overdose deaths in the 1990s[5]; and

Whereas, In the United States from 2008-2013, the news media used an increasing amount of stigmatizing language, such as referring to victims of addiction as "substance abusers" or "addicts" (appeared in 49% of stories) in lieu of less stigmatizing substitutes such as "person with a substance use disorder" (appeared in 2% of stories), potentially leading to increased stigma regarding opioid addiction among the American public[6]; and

Whereas, In the United States from 1998-2012, coverage of the opioid epidemic focused on criminal justice solutions for the opioid epidemic; this coverage shifted to increasingly emphasize treatment, harm reduction, and prevention from 2013-2017, largely mirroring increased public acceptance that the War on Drugs had failed[7]; and

Whereas, Despite increased coverage of the opioid epidemic in the United States occurring through the framework of prevention and treatment from 2013-2017, many evidence-based solutions were rarely mentioned, including the use of medication for treatment (9% of stories), syringe service programs (5% of stories), and safe injection sites (2% of stories)[7]; and

Whereas, The lack of mention of these evidence-based interventions in the news media is correlated with reduced public acceptance of these approaches for treatment of the opioid epidemic[7-9]; and

Whereas, The stigma surrounding opioid addiction and strategies for harm reduction have significantly hindered the public health response to the opioid epidemic in the United States[10]; and

Whereas, Increased stigma associated with media coverage of the opioid epidemic adversely impacts the ability of patients to seek and receive treatment for opioid addiction, as 25% of individuals report negative impacts on their job or fear of a negative opinion of community members as reasons for not seeking treatment[11]; and

Whereas, News media framing of the opioid epidemic in the context of race has contributed to the differentiation of “white from black (and brown) suffering, white from black culpability, and white from black deservingness” in the public discourse[12]; and

Whereas, Coded language used by the media can also contribute to the framing of issues, for example by establishing “urban” as code for Black or Latino and “suburban”/“rural” as code for White, effectively creating perceived separate spaces for white and Black drug users[12]; and

Whereas, This difference in framing leads to a system where Black and Brown people who use drugs are more likely to be incarcerated and less likely to be offered access to healthcare providers, addiction treatment, and tools to prevent overdose and infection[12]; and

Whereas, News media framing of White victims of the opioid epidemic as innocent and their deaths as shocking or out of the ordinary contrasts with persistent framing of the opioid epidemic in Black or Brown communities as normal, contributing to increased stigma[13]; and

Whereas, Stigmatization and marginalization of victims of opioid addiction are associated with greater support for punitive policies instead of investment in prevention and treatment programs[14]; and

Whereas, Ecological studies have shown a significant tendency for increases in fatal overdoses to follow increased media coverage of opioid-related deaths[15]; and

Whereas, Our American Medical Association supports the development of standards for media coverage of mass shootings to help address the gun violence public health crisis in Policy H-145.971, showing that the precedent exists for the AMA to encourage more thoughtful public engagement with health-related issues; therefore be it

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

Fiscal Note: Minimal - less than $1,000

Received: 4/3/23

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RELEVANT AMA POLICY

Development and Implementation of Recommendations for Responsible Media Coverage of Mass Shootings H-145.971

Our AMA encourages the Centers for Disease Control and Prevention, in collaboration with other public and private organizations, to develop recommendations and/or best practices for media coverage of mass shootings, including informed discussion of the limited data on the relationship between mental illness and gun violence, recognizing the potential for exacerbating stigma against individuals with mental illness.

Citation: Res. 212, I-18; Modified: Res. 934, I-19;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 509
(A-23)

Introduced by: Medical Student Section

Subject: Addressing Medical Misinformation Online

Referred to: Reference Committee E

Whereas, Medical misinformation is information contrary to the consensus of the scientific community that may or may not be intended to mislead, while medical disinformation is misinformation that is deliberately spread with intent to mislead[1-3]; and

Whereas, Medical misinformation is spread by many different sources online, such as online forums, advertisements, user comments on news and retail sites, social media, search engines, digital magazines, and products sold by online retailers[1,3,4,5]; and

Whereas, Medical misinformation has a large impact on a wide variety of healthcare topics including smoking, statin use, use of unproven treatments, harassment of health workers, and vaccine hesitancy[5,6]; and

Whereas, It was found that misinformation propagated significantly farther and faster online than did accurate information[5,7,8]; and

Whereas, Misinformation about the Zika virus was three times more likely to be shared than were verified stories as seen on multiple social media sites, with half of the top-10 news stories regarding Zika thought to be misinformation[7,8]; and

Whereas, More than half of the United States population used the internet as their primary source for health information in 2018, indicating a reliance on websites for health information[9]; and

Whereas, Research has shown that exposure to just five online misinformation posts about the COVID-19 vaccine were sufficient to make respondents less likely to want a COVID-19 vaccine[5,10]; and

Whereas, Search engine algorithms provide results based on the user's search history and usage of suggested sites or videos, meaning that if one clicks on a site or video promoting medical misinformation, they will have more misinformation sites or videos promoted to them over accurate information[5,11]; and

Whereas, The likelihood that a person will view a particular website and then trust in that website are influenced by its order of appearance on major search engines[12,13]; and

Whereas, Search engines often fail to ensure that the search results provided are credible or trustworthy[13]; and

Whereas, Search engine algorithms can lead a single (potentially unintentional) click on a medical misinformation link to result in an echo chamber effect where personalized results are heavily in favor of medical misinformation[13]; and

Whereas, Sites or product owners can pay to be promoted on the front page of a search engine and therefore increase their influence, creating a potential source of misinformation if not moderated properly[12]; and

Whereas, Search engines for online retailer sites such as Amazon are biased in favor of misinformative products such as anti-vaccination books, ranking them higher in search results[13]; and

Whereas, Inadequate moderation and verification of user testimonials on both WebMD and online retailers like Amazon have promoted the idea of using apricot seeds as a cancer treatment, leading to a 4.60 out of 5 rating for effectiveness on WebMD despite the site's own description of apricot seeds as "likely unsafe"[1]; and

Whereas, Three measures for quality of information showed that the websites from the first 10 pages of Google searches on COVID-19 were lacking in quality, with only 52.7% of prevention-focused websites mentioning physical distancing, and the number of sites suggesting treatment via oxygen, ventilation and fluids was equal to the number of sites suggesting hydroxychloroquine[14]; and

Whereas, Our AMA endorses efforts to combat medical misinformation in Policy D-440.915, but this policy is currently limited to online medical misinformation from social media, without any regard for any other potential online vectors such as search engines, online retailers, or any other type of website online; therefore be it

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

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

Our AMA:

(1) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to further strengthen their content moderation policies related to medical and public health misinformation, including, but not limited to enhanced content monitoring, augmentation of recommendation engines focused on false information, and stronger integration of verified health information;

(2) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to recognize the spread of medical and public health misinformation over dissemination networks and collaborate with relevant stakeholders to address this problem as appropriate, including but not limited to altering underlying network dynamics or redesigning platform algorithms;

(3) will continue to support the dissemination of accurate medical and public health information by public health organizations and health policy experts; and
(4) will work with public health agencies in an effort to establish relationships with journalists and news agencies to enhance the public reach in disseminating accurate medical and public health information.

Fiscal Note: Minimal - less than $1,000

Received: 4/3/23

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RELEVANT AMA POLICY

Medical and Public Health Misinformation in the Age of Social Media D-440.915
Our AMA: (1) encourages social media companies and organizations to further strengthen their content moderation policies related to medical and public health misinformation, including, but not limited to enhanced content monitoring, augmentation of recommendation engines focused on false information, and stronger integration of verified health information; (2) encourages social media companies and organizations to recognize the spread of medical and public health misinformation over dissemination networks and collaborate with relevant stakeholders to address this problem as appropriate, including but not limited to altering underlying network dynamics or redesigning platform algorithms; (3) will continue to support the dissemination of accurate medical and public health information by public health organizations and health policy experts; and (4) will work with public health agencies in an effort to establish relationships with journalists and news agencies to enhance the public reach in disseminating accurate medical and public health information.
Citation: Res. 421, A-21; Reaffirmed: BOT Rep. 15, A-22;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 510
(A-23)

Introduced by: Medical Student Section

Subject: Comparative Effectiveness Research

Referred to: Reference Committee E

Whereas, Pharmaceutical companies submit investigational new drug (IND) applications to seek Food and Drug Administration (FDA) approval for new medications and supplemental new drug (NDA) applications to seek FDA approval for additional clinical indications for a previously approved medication[1,2]; and

Whereas, Widespread off-label use of many medications by physicians indicates that pharmaceutical companies do not submit NDAs at a rate that keeps pace with emerging clinical practice[2]; and

Whereas, A study of 197 new drugs that were approved by the FDA and became available as generics between 1997 and 2020 demonstrated that new FDA indications for additional clinical conditions were added for 64 drugs (32%), which occurred almost exclusively while they were still patented even when off-label uses for those drugs emerged afterward, suggesting that generic availability disincentivizes pharmaceutical company trials to seek new indications[3]; and

Whereas, While off-label use of drugs by physicians is common and often beneficial for patient access to treatment, the lack of adequate clinical trials, such as those conducted by pharmaceutical companies, to seek new FDA indications when off-label uses emerge limits the evidence basis for their use and importantly, reimbursement by insurance plans[4]; and

Whereas, Pharmaceutical companies patent, run clinical trials for, and profit from INDs that are structurally, functionally, and therapeutically similar to existing generic medications or natural products that are widely available in other formulations[5,6]; and

Whereas, As a natural product, melatonin is not patentable and can be purchased over the counter as a dietary supplement for 10 cents a tablet[7]; and

Whereas, Ramelteon (brand name Rozerem) is a melatonin derivative which aims to improve sleep by stimulating the melatonin receptor, thus employing the same mechanism of action as the naturally occurring substance melatonin[8,9]; and

Whereas, As a non-natural product, Ramelteon was able to be patented, leading to a cost of approximately 10 dollars per pill, which is 100x the cost of a melatonin dietary supplement pill, despite lack of testing to show a difference in efficacy between Ramelteon and melatonin[9]; and

Whereas, As another example, ketamine, an NMDA receptor antagonist approved by the FDA in 1970 as an anesthetic, demonstrated efficacy as an off-label antidepressant in the early 2000s[10,11]; and

Whereas, Despite ketamine's efficacy as an off-label antidepressant and its wide availability and low cost in generic oral and IV formulations, no pharmaceutical company has attempted to add depression as an FDA indication for oral or IV ketamine, even though FDA indications are often tied to insurance reimbursement[12]; and

Whereas, Experts attribute the lack of a ketamine FDA approval for depression to its 2002 patent expiration, which then allowed the production of generic ketamine, reducing potential profit, and removing the incentive for pharmaceutical companies to conduct expensive clinical trials to add depression as an indication for oral or IV ketamine[12]; and

Whereas, While adding depression as an indication for oral or IV ketamine is not necessary, as these available generic formulations can still be prescribed for depression off-label, Johnson & Johnson proceeded to conduct clinical trials for an IND application for a similar compound that could be patented and sold for higher profits, which resulted in the 2019 FDA approval of esketamine (brand name Spravato) nasal spray[13]; and

Whereas, A cost-effectiveness study of esketamine concluded that its price would need to decrease by nearly half in order to be cost-effective for treatment-resistant depression in the US[14]; and

Whereas, Many of the esketamine clinical trials analyzed for its FDA approval only compared it to placebo and not to existing formulations of the structurally similar oral or IV ketamine, and several studies suggest that differences in antidepressant efficacy between esketamine and ketamine may be negligible or that ketamine may even be superior to esketamine[15]; and

Whereas, Ketamine remains inadequately studied and does not have an FDA indication as an antidepressant, despite its wide availability as a generic, relatively low cost (especially compared to the patented esketamine), and potential clinical benefit to millions of Americans suffering from treatment-resistant depression[12,16,17]; and

Whereas, The AMA "supports programs whose purpose is to contain the rising costs of prescription drugs" (H-110.997); and

Whereas, The AMA supports "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" (H-120.988); and

Whereas, Proper comparisons in clinical trials can give physicians the scientific evidence needed to provide the best care for their patients, while simultaneously containing the cost of prescription drugs by avoiding prescribing drugs that have significantly greater cost but show no additional clinical benefit; therefore be it

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

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

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

Received: 4/3/23

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RELEVANT AMA POLICY

E7.2.3 Patents & Dissemination of Research Products

A patent grants the holder the right, for a limited time, to prevent others from commercializing his or her inventions. By requiring full disclosure of the invention, and thus enabling another trained in the art to replicate it, the patent system protects the holder's discovery, yet also fosters information sharing. Patenting is also thought to encourage private investment into research.

With respect to genetic research, patenting raises unique questions. Arguments have been made that the patenting of human genetic material sets a troubling precedent for the ownership or commodification of human life. However, DNA sequences are not tantamount to human life and it is unclear where and whether qualities uniquely human are found in genetic material. Moreover, while genetic research holds great potential for developing new medical therapies it remains unclear what role patenting will play in ensuring such development.

Physicians who develop medical innovations may ethically patent their discoveries or products but should uphold the following guidelines:
(a) Not use patents (or other means, such as trade secrets or confidentiality agreements) to limit the availability of medical innovations. Patent protection should not hinder the goal of achieving better medical treatments and technologies.

(b) Not allow patents to languish. Physicians who hold patents should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.
(c) For patents on genetic materials recognize that:
(i) patents on processes, e.g. to isolate and purify gene sequences, are ethically preferable to patents on the substances themselves;
(ii) patents on purified proteins (substance patents) are ethically preferable to patents on genes or DNA sequences.

Descriptions for (substance) patents on proteins, genes, or genetic sequences should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question.
Issued: 2016

Pharmaceutical Costs H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation.
Citation: CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22;

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;

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.
Citation: Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by 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; Reaffirmation: I-22;

Generic Drugs H-125.984
Our AMA believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice.
(2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name products.
(3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.
(4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program.
(5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products.
(6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength).
(7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.
Citation: CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmation A-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 525, A-10; Reaffirmed in lieu of Res. 224, I-14; Reaffirmed in lieu of: Res. 922, I-18;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 511
(A-23)

Introduced by: Medical Student Section

Subject: Regulation of Phthalates in Adult Personal Sexual Products

Referred to: Reference Committee E

Whereas, The American Academy of Pediatrics characterizes phthalates as ubiquitous contaminants in food, indoor air, soils, and sediments[1]; and

Whereas, Typical routes of exposure include transfer from hands to mouth, breathing in phthalates in the air, undergoing medical procedures that use devices or equipment containing di(2-ethylhexyl) phthalate (DEHP), and consuming food containing phthalates as a result of packaging or processing[2]; and

Whereas, In animal studies, phthalates have been shown to cause fetal death, malformations, and reproductive toxicity, and in one systematic review, prenatal phthalate exposure was associated with neurodevelopmental outcomes, including lower IQ and problems with attention and hyperactivity[3]; and

Whereas, It is important to understand the impact of phthalates on health as number of animal studies have primarily shown phthalate exposure can cause harmful reproductive and developmental effects[4]; and

Whereas, Human studies have been observational to link phthalate metabolites in urine to a variety of health outcomes such as an increased risk of type 2 diabetes in some populations of women, delayed puberty in women, and relationships of decreased sperm with increased urinary phthalate concentration[5-7]; and

Whereas, Currently, eight phthalates are banned from children's toys and childcare items by the United States Consumer Product Safety Commission (CPSC) due to harmful health effects, including on reproductive development[10,11]; and

Whereas, Although the data is unclear on the adverse effects of exposure of skin and mucous membranes to DEHP, there are associations between di(2-ethylhexyl) phthalate (DEHP) and adverse health outcomes[13]; and

Whereas, The FDA has recognized the adverse health effects of phthalates in medical devices in indwelling devices and transfusion devices, and has also advised against the use of phthalates in pharmaceuticals regulated by the Center for Drug Evaluation and Research (CDER)[15]; and

Whereas, The United States Consumer Product Safety Commission (US CPSC) published a risk assessment for exposure to phthalates and phthalate alternatives in 2014[16]; and

Whereas, There is little data pertaining to how widespread the negative outcomes for phthalate exposure are in humans and there is also a lack of human studies about phthalate exposure from sex toys specifically; and

Whereas, Given the evidence that phthalates have a possibility of having a negative impact on human health, specifically in the case of DEHP, it would be appropriate for our AMA to take a stance on the use of these compounds in all consumer products, sexual or otherwise; and

Whereas, Our American Medical Association has current policy (H-135.945) that addresses the health risks of DEHP in medical devices; therefore be it

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

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

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

Fiscal Note: Minimal - less than $1,000

Received: 4/3/23

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RELEVANT AMA POLICY

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.

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

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 512
(A-23)

Introduced by: American Academy of Physical Medicine & Rehabilitation; American Association of Neuromuscular & Electrodiagnostic Medicine

Subject: Wheelchairs on Airplanes

Referred to: Reference Committee E

Whereas, More than five million Americans use a wheelchair for mobility[1]; and

Whereas, The Americans with Disability Act requires all modes of public transportation, except for airlines, to have the capability for wheelchair users to stay in their wheelchairs during transport and be able to enter and exit boats, buses, or trains; and

Whereas, Currently, patients who are unable to walk due to a medical illness or condition and who use a wheelchair for mobility must transfer or be transferred by airline staff to a special airline chair to enter an aircraft and then must transfer or be transferred by airline personnel to a seat in the aircraft, risking injury due to incorrect transfer technique by inexperienced personnel, such as hitting the armrests; and

Whereas, Patients with significant musculoskeletal weakness or spinal or other deformity have wheelchairs with specialized seating to support their bodies in comfortable and safe positions, but airplane seats have no special support, leaving the patients unstable in their seats and at risk of injury during turbulence or unusual landings; and

Whereas, A feasibility study was commissioned by Congress through the Federal Aviation Administration (FAA) Reauthorization Act of 2018 and the results "did not show any issues in this preliminary assessment that seem likely to present design and engineering challenges so formidable that they call into question the technical feasibility of an in-cabin wheelchair securement system and the value of exploring the concept further,"[2]; and

Whereas, New wheelchair securement systems have been tested that exceed the FAA safety requirement of 16 G deceleration forces for airplane seats[2,3]; and

Whereas, Patients who use wheelchairs as their only means of mobility who have traveled on airplanes have experienced lost and broken wheelchairs, leaving them at the airport with no means of mobility and subsequent avoidance of air travel altogether[4]; therefore be it

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

Fiscal Note: Minimal - less than $1,000

Received: 5/2/23

REFERENCES

1. Taylor, D. M. (2018). Americans with Disabilities: 2014. *US Census Bureau*, 1-32.
2. Technical Feasibility of a Wheelchair Securement Concept for Airline Travel: A Preliminary Assessment, National Academies of Sciences, Engineering, and Medicine 2021, Washington DC: The National Academies Press
3. *A Benefit Analysis for Aircraft 16-G Dynamic Seats* (Rep. No. DOT/FAA/AR-00/13). (2000, April).
4. Duerstock, B.S., et al. (2019). Report on the Challenges of Air Transportation Experienced by People with Disabilities.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 513
(A-23)

Introduced by:	American Academy of Child and Adolescent Psychiatry, American Academy of Psychiatry and the Law, American Association for Geriatric Psychiatry, American Psychiatric Association, American Academy of Addiction Psychiatry, American Society of Addiction Psychiatry
Subject:	Substance Use History is Medical History
Referred to:	Reference Committee E

Whereas, Addiction is a chronic brain disease[1] and is the most severe form of substance use disorder, a chronic medical illness with potential for both recurrence and remission[2]; and

Whereas, Substance use disorder has been recognized by our American Medical Association as a treatable disease in policy H-95.922, "*Substance Use and Substance Use Disorders"*; and

Whereas, 20.1 million Americans have a substance use disorder and only 6.9% receive treatment[3] and 1 in 7 people in the United States will develop a substance use disorder over the course of their lifetime[2]; and

Whereas, Substance use disorder has historically been viewed as a moral failing and social problem rather than a chronic medical illness, and treatment of substance use disorders has been siloed from mainstream healthcare and patients with substance use disorders have been subjected to discrimination and stigma by the healthcare system and healthcare providers; and

Whereas, Medical schools teach substance use history as part of a patient's social history and not the past medical history; and

Whereas, Electronic health record software is designed to capture substance use history in the social history section and not in the past medical history section of clinical documentation; and

Whereas, Negative attitudes among healthcare professionals regarding patients with substance use disorders are linked with reduced empathy and engagement with patients, reduced delivery of evidence-based treatment services and poorer patient outcomes[4]; and

Whereas, Existing AMA policies D-95.981, *"Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction"* and H-95.922 call for our AMA to take a positive stance as the leader in matters concerning substance use disorders, including addiction and to assist in reducing the stigma associated with substance use; and

Whereas, Drugs and alcohol are biologically active substances that upon ingestion alter one's physiological functioning and have a direct impact on health; and

Whereas, History-gathering about substance use and the chronic treatable medical illness of substance use disorder as part of a patient's past medical history would destigmatize substance use and would promote the provision of evidence-based care; therefore be it

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

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

RESOLVED, That our AMA work with relevant stakeholders to advocate for electronic health record vendors to modify their software to allow for substance use history to be documented in the past medical history and to move the substance use history from the social history section of electronic health record technology. (Directive to Take Action)

Fiscal Note: Minimal - less than $1,000

Received: 5/2/23

REFERENCES

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2. U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016.
3. Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/
4. van Boekel LC, Brouwers EPM, van Weeghel J, Garretsen HFL. Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review. Drug and Alcohol Dependence 2013;131:23– 35

RELEVANT AMA POLICY

Substance Use Disorders as a Public Health Hazard H-95.975
Our AMA: (1) recognizes that substance use disorders are a major public health problem in the United States today and that its solution requires a multifaceted approach;
(2) declares substance use disorders are a public health priority;
(3) supports taking a positive stance as the leader in matters concerning substance use disorders, including addiction;
(4) supports studying innovative approaches to the elimination of substance use disorders and their resultant street crime, including approaches which have been used in other nations; and
(5) opposes the manufacture, distribution, and sale of substances created by chemical alteration of illicit substances, herbal remedies, and over-the-counter drugs with the intent of circumventing laws prohibiting possession or use of such substances.
Citation: Res. 7, I-89; Appended: Sub. Res. 401, Reaffirmed: Sunset Rep., I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: CSAPH Rep. 01, A-19;

Substance Use and Substance Use Disorders H-95.922
Our AMA:
(1) will continue to seek and participate in partnerships designed to foster awareness and to promote screening, diagnosis, and appropriate treatment of substance misuse and substance use disorders;
(2) will renew efforts to: (a) have substance use disorders addressed across the continuum of medical education; (b) provide tools to assist physicians in screening, diagnosing, intervening, and/or referring patients with substance use disorders so that they have access to treatment; (c) develop partnerships

with other organizations to promote national policies to prevent and treat these illnesses, particularly in adolescents and young adults; and (d) assist physicians in becoming valuable resources for the general public, in order to reduce the stigma and enhance knowledge about substance use disorders and to communicate the fact that substance use disorder is a treatable disease; and
(3) will support appropriate federal and state legislation that would enhance the prevention, diagnosis, and treatment of substance use disorders.
Citation: CSAPH Rep. 01, A-18; Reaffirmed: BOT Rep. 14, I-20;

Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction D-95.981
1. Our AMA:
a. will collaborate with relevant medical specialty societies to develop continuing medical education curricula aimed at reducing the epidemic of misuse of and addiction to prescription controlled substances, especially by youth;
b. encourages medical specialty societies to develop practice guidelines and performance measures that would increase the likelihood of safe and effective clinical use of prescription controlled substances, especially psychostimulants, benzodiazepines and benzodiazepines receptor agonists, and opioid analgesics;
c. encourages physicians to become aware of resources on the nonmedical use of prescription controlled substances that can assist in actively engaging patients, and especially parents, on the benefits and risks of such treatment, and the need to safeguard and monitor prescriptions for controlled substances, with the intent of reducing access and diversion by family members and friends;
d. will consult with relevant agencies on potential strategies to actively involve physicians in being "a part of the solution" to the epidemic of unauthorized/nonmedical use of prescription controlled substances; and
e. supports research on: (i) firmly identifying sources of diverted prescription controlled substances so that solutions can be advanced; and (ii) issues relevant to the long-term use of prescription controlled substances.
2. Our AMA, in conjunction with other Federation members, key public and private stakeholders, and pharmaceutical manufacturers, will pursue and intensify collaborative efforts involving a public health approach in order to:
a. reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications;
b. increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and
c. reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction.
Citation: CSAPH Rep. 2, I-08; Appended: Res. 517, A-15; Reaffirmed: BOT Rep. 5, I-15; Reaffirmed: BOT Rep. 09, I-19; Reaffirmed: BOT Rep. 14, I-20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 514
(A-23)

Introduced by: American Academy of Child and Adolescent Psychiatry, American Academy of Psychiatry and the Law, American Association for Geriatric Psychiatry, American Psychiatric Association, American Society of Addiction Medicine

Subject: Adolescent Hallucinogen-Assisted Therapy Policy

Referred to: Reference Committee E

Whereas, Hallucinogens including but not limited to psilocybin and MDMA (3,4-methylenedioxy-methamphetamine) are designated as drugs with no currently accepted medical use[1]; and

Whereas, There are emerging research findings demonstrating clinically significant reduction of refractory depression and post-traumatic stress disorder (PTSD), respectively, in adult patients[2]; and

Whereas, Additional research is needed to better understand the benefits and harms of psychedelic therapy in pediatric patients; and

Whereas, The majority of the states have pending legislation or ballot initiatives to decriminalize psychedelics and licensure would be provided to prescribe psychedelics or to allow for psychedelic-assisted psychotherapy[3]; and

Whereas, The prevalence of adolescent depression continues to increase and adolescent suicide is the second leading cause of death among people aged 15 to 24, there is a need for more investment in adolescent mental health research, interventions, and treatments[4]; and

Whereas, Clinical treatments should be determined by scientific evidence in accordance with applicable regulatory standards and not by ballot initiatives or popular opinion; therefore be it

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

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

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

Received: 5/2/23

REFERENCES

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2. Siegel, J.S., Daily, J.E., Perry, D.A., Nicol, G.E. (2023). Psychedelic Drug Legislative Reform and Legalization in the US. JAMA Psychiatry, 80(1):77-83.
3. Zagorski, N. (2020). Psychedelics for Psychiatric Disorders: More Research Needed. Psychiatric News, published Online 13 Apr.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 515
(A-23)

Introduced by: Mississippi

Subject: Regulate Kratom and Ban Over-The-Counter Sales

Referred to: Reference Committee E

Whereas, Kratom is a herbal supplement derived from a tropical tree, Mitragyna speciosa, that has been used for centuries in Southeast Asia to alleviate pain, fatigue, and enhance mood; and

Whereas, Kratom has been marketed in the US as an over-the-counter supplement for similar uses, but there is limited scientific evidence to support its safety and efficacy, and concerns have been raised about its potential for addiction, abuse, and adverse effects, including seizures, liver damage, and death; and

Whereas, Kratom is not currently regulated by the Food and Drug Administration (FDA) and has not undergone clinical trials to determine its safety and effectiveness; and

Whereas, The American Medical Association recognizes the potential for kratom to be used as an alternative treatment for opioid addiction, but also acknowledges the need for further research to determine its safety and effectiveness; and

Whereas, The AMA believes that the regulation of kratom is necessary to ensure the safety and well-being of patients and the general public; therefore be it

RESOLVED, That our American Medical Association recommend the following:

1. Kratom should be regulated by the FDA, and its safety and efficacy should be determined through clinical trials before it can be marketed or prescribed as a treatment for any condition.
2. Over-the-counter sales of kratom should be banned, and kratom should be available only by prescription from a licensed healthcare provider if it is deemed to have a medicinal use after proper research.
3. Individuals who are currently using kratom for pain management or other conditions should have access to appropriate medical care to manage their conditions and withdrawal symptoms, if needed.
4. Criminalization of kratom use should not be the intent of this resolution, and individuals who are using kratom for legitimate medical reasons should not be subject to criminal penalties although if it is banned, this does not exclude criminalization of drug trafficking.
5. The Drug Enforcement Administration should conduct a comprehensive review of the potential for kratom abuse and dependence and consider appropriate scheduling under the Controlled Substances Act. A schedule 3 would make it unavailable over the counter but avoid criminal penalties.
6. Research funding should be made available to study the potential therapeutic uses and risks of kratom, and to develop evidence-based guidelines for its safe use.

7. Education and public awareness campaigns should be launched to inform healthcare providers, patients, and the general public about the potential risks and benefits of kratom and the need for caution in its use. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 5/2/23

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 516
(A-23)

Introduced by: Senior Physicians Section

Subject: Fasting is Not Required for Lipid Analysis

Referred to: Reference Committee E

Whereas, Our American Medical Association has recognized that cardiovascular morbidity and mortality is an urgent public health concern; and

Whereas, Lipids analysis is one of the most ordered lab tests; and

Whereas, All adult patients should have a lipid analysis for assessment of their cardiovascular risk; and

Whereas, Patients are usually asked to fast for eight hours for lipid analysis; and

Whereas, Studies show that lipids and lipoproteins change only minimally in response to normal food intake[1]; and

Whereas, There is no scientific evidence that fasting is superior to non-fasting in evaluating cardiovascular risk from lipid analysis; and

Whereas, All adult patients with diabetes should have a lipid analysis and fasting may increase risk of hypoglycemia, a risk minimized by non-fasting in patients with diabetes; and

Whereas, Guidelines from relevant medical societies in the United States, United Kingdom, Europe, and elsewhere endorse non-fasting lipid profiles; and

Whereas, Pediatrics does not require fasting blood for lipid analysis in children and adolescents since the sample could be drawn at the same time as their physician visit; and

Whereas, Not fasting would simplify timing of blood draws while avoiding the inconvenience of early morning sampling, additional trips to the lab and a second copay; therefore be it

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

Fiscal Note: Approximately $50k for the development of CME-accredited interactive e-learning including staff costs and external vendor contracting.

Received: 4/26/23

REFERENCES

1. Nordestgaard, B. G., Langsted, A., Mora, S., Kolovou, G., Baum, H., Bruckert, E., ... & Langlois, M. (2016). Fasting is not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cut-points—a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine. *European heart journal*, *37*(25), 1944-1958.

RELEVANT AMA POLICY

Prevention of Coronary Artery Disease H-425.990
The AMA believes that (1) total serum cholesterol should be measured under supervision of a physician, with proper safeguards for quality assurance and (2) when serum cholesterol levels are excessive, appropriate measures should be taken to educate the patient concerning methods to improve serum lipids and thereby reduce the risk of coronary heart disease.
Citation: Res. 165, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: CSAPH Rep. 01, A-18;

Point of Care Availability for Blood Glucose Testing D-260.994
Our AMA will work with the Food and Drug Administration and the Centers for Medicare & Medicaid Services to maintain the Clinical Laboratory Improvement Act exempt status of point-of-care glucose testing.
Citation: (Res. 727, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 517
(A-23)

Introduced by: New Jersey

Subject: Genetic Predisposition and Healthcare Disparities, Including Cardiovascular Disease in South Asians Residing in the United States

Referred to: Reference Committee E

Whereas**,** South Asians, individuals with origins in Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan, and Sri Lanka, comprise nearly 5.4 million people and are a rapidly growing ethnic minority group in the United States; and

Whereas**,** South Asians have a higher risk of cardiovascular disease compared to other ethnic groups, including higher rates of coronary artery disease, stroke, and type 2 diabetes; and

Whereas, The risk factors for cardiovascular disease in South Asians are different from those in other ethnic groups, including higher rates of insulin resistance, low levels of high-density lipoprotein (HDL) cholesterol, and a genetic predisposition to heart disease; and

Whereas, South Asians face unique cultural and linguistic barriers to accessing healthcare services, including lack of knowledge about preventive care, language barriers, and cultural beliefs that may affect health-seeking behaviors; and

Whereas, There is a paucity of data on the populations' unique cardiovascular disease risk profiles, etiologic mechanisms, and effective interventions to address the health disparities affecting South Asians in the United States; therefore be it

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

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

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

Received: 5/4/23

REFERENCES

1. Volgman AS, Palaniappan LS, Aggarwal NT, Gupta M, Khandelwal A, Krishnan AV, et.al. Atherosclerotic Cardiovascular Disease in South Asians in the United States: Epidemiology, Risk Factors, and Treatments: A Scientific Statement from the American Heart Association. Circulation. 2018;138:e1–e34. DOI: 10.1161/CIR.0000000000000580
2. Jayapal Celebrates House Passage of Landmark South Asian Heart Health Legislation https://jayapal.house.gov/2022/07/27/jayapal-celebrates-house-passage-of-landmark-south-asian-heart-health-legislation/
3. Volgman AS, Palaniappan LS, Aggarwal NT, Gupta M, Khandelwal A, Krishnan AV, et.al. Atherosclerotic Cardiovascular Disease in South Asians in the United States: Epidemiology, Risk Factors, and Treatments: A Scientific Statement from the American Heart Association. Circulation. 2018;138:e1–e34. DOI: 10.1161/CIR.0000000000000580
4. Jayapal Celebrates House Passage of Landmark South Asian Heart Health Legislation https://jayapal.house.gov/2022/07/27/jayapal-celebrates-house-passage-of-landmark-south-asian-heart-health-legislation/

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518
(A-23)

Introduced by: American Thoracic Society

Subject: Defending NIH funding of Animal Model Research From Legal Challenges

Referred to: Reference Committee E

Whereas, Our American Medical Association has long supported the ethical use of animals in research to study human diseases; and

Whereas, Our AMA has clearly established policy in support of ethical animal model research; and

Whereas, Animal rights organizations oppose animal model research in all its forms; and

Whereas, People for the Ethical Treatment of Animals (PETA) has filed a suit (PETA v Tabak) in federal court challenging National Institutes of Health's (NIH's) decision to fund 5 grants studying sepsis in rodents; and

Whereas, Sepsis is a serious health condition that results in an estimated 1.7 million cases in the US and approximately 350,000 US deaths annually; and

Whereas, Further research is needed to understand how to prevent sepsis infections and to develop more effective interventions to treat sepsis infections; and

Whereas, If the court rules in favor of the plaintiffs it may establish a precedent that will invite further legal challenges to federal support for animal model research; therefore be it

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

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

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

Received: 5/10/23

RELEVANT AMA POLICY

Medical Research Involving Animals H-460.957
The AMA urges state and county medical societies to support the appropriate and humane use of animals in research and to help ensure the continued availability of animals for essential medical education and medical research; and reaffirms its support for the appropriate and compassionate use of animals in biomedical research programs.
Citation: Sub. Res. 94, I-90; Sub. Res. 511, A-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: CSAPH Rep. 01, A-16;

Use of Animals in Research H-460.979
(1) Researchers should include in their protocols a commitment to ethical principles that promote high standards of care and humane treatment of all animals used in research. Further, they should provide animal review committees with sufficient information so that effective review can occur. For their part, institutions should strengthen their animal review committees to provide effective review of all research protocols involving animals. (2) The appropriate and humane use of animals in biomedical research should not be unduly restricted. Local and national efforts to inform the public about the importance of the use of animals in research should be supported. (3) The development of suitable alternatives to the use of animals in research should be encouraged among investigators and supported by government and private organizations. The selection of alternatives ultimately must reside with the research investigator.
Citation: BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CEJA Rep. 7, A-07; Reaffirmed: CSAPH Rep. 01, A-17;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 519
(A-23)

Introduced by: GLMA: Health Professionals Advancing LGBTQ+ Equality

Subject: Rescheduling or Descheduling Testosterone

Referred to: Reference Committee E

Whereas, An estimated 2.3 million Americans received testosterone therapy in 2013, with one-half of all prescriptions written by primary care clinicians[1]; and

Whereas, Testosterone therapy treats conditions for cisgender men, cisgender women, and can help bring a transgender or gender diverse (TGD) person's physical characteristics in line with their gender identity, significantly reducing negative psychological outcomes such as depression, anxiety and suicidality[2]; and

Whereas, A significant proportion of all testosterone prescriptions are written for TGD people with an estimated 78% of the estimated 480,000 transgender men and non-binary adults in the US seeking hormone therapy[3]; and

Whereas, The United States is the only developed country that treats testosterone as a controlled substance[4]; and

Whereas, In 1990 the US Drug Enforcement Administration (DEA) classified testosterone and other anabolic androgenic steroids (AAS) as Schedule III substances, which have a potential for low or moderate physical dependence or high psychological dependence when misused[5]; and

Whereas, The DEA classification creates barriers to testosterone therapy and subjects patients to criminalization, discrimination, and harassment[6]; and

Whereas, The DEA classification potentially limits the utilization of telemedicine for provision of testosterone therapy[7]; and

Whereas, Rescheduling or descheduling testosterone has the potential to eliminate numerous barriers to access for patients, especially TGD persons[6]; therefore be it

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

Fiscal Note: Minimal - less than $1,000

Received: 5/10/23

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RELEVANT AMA POLICY

Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations H-160.991
1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of
continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating
factors.
3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.
CSA Rep. C, I-81 Reaffirmed: CLRPD Rep. F, I-91 CSA Rep. 8 - I-94 Appended: Res. 506, A-00 Modified and Reaffirmed: Res. 501, A-07 Modified: CSAPH Rep. 9, A-08 Reaffirmation A-12 Modified: Res. 08, A-16 Modified: Res. 903, I-17 Modified: Res. 904, I-17 Res. 16, A-18 Reaffirmed: CSAPH Rep. 01, I-18

Removing Financial Barriers to Care for Transgender Patients H-185.950
Our AMA supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician.
Res. 122 A-08 Modified: Res. 05, A-16 Reaffirmed: Res. 012, A-22

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 520
(A-23)

Introduced by: Illinois

Subject: Supporting Access to At-Home Injectable Contraceptives

Referred to: Reference Committee E

Whereas, Nearly half of all pregnancies in the United States are unplanned; and

Whereas, Costs of unplanned pregnancy within the healthcare system reach over 4.5 billion dollars annually; and

Whereas, Improper contraceptive adherence is cited as the cause of over half of these unplanned pregnancies; and

Whereas, Increased access to reliable methods of contraception would target this failure and therefore decrease the number of unplanned pregnancies; and

Whereas, Injectable contraceptives are more than 99% effective when given on time; and

Whereas, The necessity of clinic visits every three months is a barrier for many women to access this form of contraception; and

Whereas, Other forms of injectable medications have been trusted to patients, such as insulin, migraine medications, and fertility treatments, among others; and

Whereas, Multiple studies have found women prefer to do contraceptive injections themselves as opposed to visiting an office and have maintained similar efficacy as compared to in-office treatment; and

Whereas, There is now a sub-cutaneous form of injectable contraceptive treatment available with the same efficacy as intramuscular injections, allowing easier and less painful use by patients at home; therefore be it

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

Fiscal Note: Minimal - less than $1,000

Received: 5/5/23

RELEVANT AMA POLICY

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;

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;

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

Our AMA: (1) encourages the US Food and Drug Administration to approve a switch in status from prescription to over-the-counter for oral contraceptives, without age restriction; (2) encourages the continued study of issues relevant to over-the-counter access for oral contraceptives; and (3) will work with expert stakeholders to advocate for the availability of hormonal contraception as an over-the-counter medication.

Citation: Sub. Res. 507, A-13; Modified: BOT Rep. 10, A-18; Modified: Res. 518, A-22;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 521
(A-23)

Introduced by: Illinois

Subject: Preventing the Elimination of Cannabis from Occupational and Municipal Drug Testing Programs

Referred to: Reference Committee E

Whereas, The Drug-Free Workplace Act of 1988 (41 U.S.C. 81) is an act of the United States which requires some federal contractors and all federal grantees to agree that they will provide drug-free workplaces as a precondition of receiving a contract or grant from a Federal agency; and

Whereas, Virtually all employers and municipalities follow these guidelines for their drug testing protocols even though they may not have any federal ties; and

Whereas, Cannabis metabolite (THC-COOH) analysis has been part of all urine drug testing programs since the inception of 41 U.S.C.81 in November 1988; and

Whereas, The American College of Occupational and Environmental Medicine (ACOEM) recommends that the implications for workplace safety be a primary consideration and that those in safety-sensitive identified positions should be held to a higher standard until a scientifically valid method to identify impairment has been developed; and

Whereas, Cannabis can significantly impair judgment, motor coordination, and reaction time; and

Whereas, It is well documented that persons experiencing impairment from any drug or medication tend to underestimate the severity of their impairment; and

Whereas, In the first year (2020) of legalization of recreational cannabis in Illinois, more than 1100 people were killed in traffic accidents in the state – an astounding 16% increase from 2019 reversing a downward trend of fatalities over the past decade; and

Whereas, Chicago witnessed a far more dramatic spike in traffic fatalities (139 killed) – a 45% increase from 2019; and

Whereas, Traffic accidents and deaths have been documented to increase when cannabis is legalized; and

Whereas, Initiating THC use at a potency of 12% is associated with almost a fivefold higher risk for progression to cannabis use disorder symptom onset within a year; and

Whereas, THC exhibits adverse cardiac, neurological and psychiatric effects that are dose-related and therefore the use of cannabis is deemed inadvisable for persons performing safety-sensitive work; and

Whereas, Cannabis use also can cause violent behavior through increased aggressiveness, paranoia, and personality changes (more suspicious, aggressive, and anger); therefore be it

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

Fiscal Note: Minimal - less than $1,000

Received: 5/5/23

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RELEVANT AMA POLICY

Issues in Employee Drug Testing H-95.984

The AMA (1) reaffirms its commitment to educate physicians and the public about the scientific issues of drug testing; (2) supports monitoring the evolving legal issues in drug testing of employee groups, especially the issues of positive drug tests as a measure of health status and potential employment discrimination resulting therefrom; (3) takes the position that urine alcohol and other drug testing of employees should be limited to (a) preemployment examinations of those persons whose jobs affect the health and safety of others, (b) situations in which there is reasonable suspicion that an employee's (or physician's) job performance is impaired by alcohol and/or other drug use, (c) monitoring as part of a comprehensive program of treatment and rehabilitation of substance use disorders, and (d) urine, alcohol and other drug testing of all physicians and appropriate employees of health care institutions may be appropriate under these same conditions; and (4) urges employers who choose to establish alcohol and other drug testing programs to use confirmed, positive test results in employees primarily to motivate those employees to seek appropriate assistance with their alcohol or other drug problems, preferably through employee assistance programs.

Citation: (CSA Rep. A, A-87; Reaffirmed: Sub. Res. 39, A-90, CSA Rep. D, I-90; BOT Rep. I, A-90; CSA Rep. 2, I-95; Reaffirmed: BOT Rep. 17, I-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: Res. 817, I-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 522
(A-23)

Introduced by: Association for Clinical Oncology

Subject: Approval Authority of the FDA

Referred to: Reference Committee E

Whereas, The Food and Drug Administration (FDA) is the agency in the executive branch charged with reviewing the science provided by the manufacturers of drugs, convening panels of medical experts in the field, reviewing the relevant medical literature, determining the safety and efficacy of drugs and devices, and approving said drugs and devices for use[1]; and

Whereas, The FDA follows a rigorous, evidence-based review process that has administrative safeguards and opportunities for dissenting views to be heard; and

Whereas, A federal district judge without any medical training or expertise has overturned an FDA decision about a drug, mifepristone, which was both deemed to be safe and effective, and the Supreme Court has maintained access to this drug by staying the district court's decision for the time being[2]; and

Whereas, The drug has been on the market for over 20 years and has been proven safe and effective[3]; and

Whereas, This precedent would allow the judicial branch to negate the procedures of the executive branch and put access to future drugs at risk without consideration of science and medical needs; and

Whereas, This precedent could also have a chilling effect on innovation, research and development if every FDA approval is considered subject to review and reversal; and

Whereas, Physicians must be able to depend on the FDA for accurate and unbiased assessments of drugs; therefore be it

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

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

Received: 5/10/23

REFERENCES
1. Food and Drug Administration. What We Do. (2018). https://www.fda.gov/about-fda/what-we-do
2. Ollstein AM & Gerstein J. Supreme Court maintains abortion pill access for now as legal fight continues. *Politico*. April 21, 2023. https://www.politico.com/news/2023/04/21/supreme-court-maintains-abortion-pill-access-for-now-as-legal-fight-continues-00093349
3. Food and Drug Administration. Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation. (2023). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation

RELEVANT AMA POLICY

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: 523
(A-23)

Introduced by: Indiana

Subject: Reducing Youth Abuse of Dextromethorphan

Referred to: Reference Committee E

Whereas, Prescription opioids caused nearly 16,500 deaths in 2020; and

Whereas, The U.S. Food and Drug Administration (FDA), overriding the advice of an expert panel, reported in July 2012 that it would not require doctors to have special training before they could prescribe long-acting prescription opioids; and

Whereas, The FDA has said companies that make the drugs would be required to underwrite the cost of voluntary programs aimed at teaching doctors how to best use long-acting prescription opioids; and

Whereas, Dextromethorphan (DXM) is a type of cough suppressant drug, known as an antitussive, that is either prescribed or available over the counter (OTC) to treat pain, coughs, colds, and several other conditions; and

Whereas, DXM is classified as an opioid, though it does not have the same effect on the brain's opioid receptors as other opioids, although when taken in large doses, it does cause depressant or even hallucinogenic effects; and

Whereas, Because DXM is commonly found in OTC medicines, it is rather easy to obtain, especially by minors; therefore be it

RESOLVED, That our American Medical Association seek and support methods to reduce the sale of products containing dextromethorphan to minors. (Directive to Take Action)

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

Received: 5/10/23

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 524
(A-23)

Introduced by: New York

Subject: Ensuring Access to Reproductive Health Services Medications

Referred to: Reference Committee E

Whereas, Mifepristone is one of two drugs used for medication abortion, a protocol that has been approved by the U.S. Food and Drug Administration for two decades; and

Whereas, Mifepristone is used in combination with misoprostol to end an early pregnancy; and

Whereas, Mifepristone has been safely used in the United States more than 5 million times; and

Whereas, Mifepristone is a drug approved by the FDA in 2000 for terminating pregnancies through 49 days gestation; and

Whereas, Medication abortion offers many women a less invasive procedure, and medication abortion regimen is supported by major medical organizations as a safe and effective method; and

Whereas, The Alliance for Hippocratic Medicine v. FDA seeks to constrain the options physicians are able to provide to their patients even in protected states; and

Whereas, A Texas judge on April 7, 2023 revoked the Food and Drug Administration's approval of mifepristone; and

Whereas, Approval of practically every drug in the US could be undermined by a Texas court's recent ruling on mifepristone, threatens the country's entire regulatory structure; and

Whereas, Both these cases represent an egregious interference in the practice of medicine and impacts the patient-physician relationship; and

Whereas, The implications of this case could impact reproductive healthcare services for generations to come; and

Whereas, It is highly likely that state medical associations will be asked to join litigation surrounding these cases; therefore be it

RESOLVED, That our American Medical Association advocate and support the continuation of the Food and Drug Administration’s authority to determine whether drugs are safe and effective (Directive to Take Action); and be it further

RESOLVED, That our AMA support legal efforts to ensure that mifepristone and misoprostol are available to anyone for whom they are prescribed (New HOD Policy); and be it further

RESOLVED, That our AMA support efforts, including joining in an Amicus Brief, to ensure that both these medications continue to be available, and that the FDA retain its regulatory authority. (Directive to Take Action)

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

Received: 5/10/23

RELEVANT AMA POLICY

Supporting Access to Mifepristone (Mifeprex) H-100.948

Our AMA will support mifepristone availability for reproductive health indications, including via telemedicine, telehealth, and at retail pharmacies and continue efforts urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone.
Citation: Res. 504, A-18; Modified: Res. 027, A-22; Reaffirmed: Res. 317, I-22;