Reference Committee E

CSAPH Report(s)

02* Use of Drugs to Chemically Restrain Agitated Individuals Outside of Hospital Settings

Resolution(s)

- 501 Ensuring Correct Drug Dispensing
- 502 Scientific Studies Which Support Legislative Agendas
- 503 Access to Evidence-Based Addiction Treatment in Correctional Facilities
- 504* Healthy Air Quality
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^{*} Contained in the Handbook Addendum

REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (June 2021) Use of Drugs to Chemically Restrain Agitated Individuals Outside of Hospital Settings (Reference Committee E)

EXECUTIVE SUMMARY

Objective. The term "excited delirium" (ExD) is controversial and lacks a defined set of behavioral signs and symptoms used to identify a person in distress and in need of urgent medical or psychiatric help. Additionally, several media reports have recently highlighted the use of ketamine and other sedative/hypnotic agents by non-medical professionals to chemically incapacitate a person for a law enforcement purpose, and in many cases, ExD is listed as the reason for the use of a sedative/hypnotic agent. The Board of Trustees has requested that the Council on Science and Public Health study the use of ketamine and chemical restraints in the context of "excited delirium" and report back to the House of Delegates.

Methods. English-language reports were selected from a PubMed and Google Scholar search using the text terms "excited delirium," "delirium," "fatalities excited delirium," "excited delirium restraint," "excited delirium sedatives," "excited delirium ketamine," "police ketamine," "EMS ketamine," and "crisis response team." Articles were filtered based on relevance. Additional articles were identified by manual review of the references cited in these publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

Results. The assessment, diagnosis, and treatment of ExD remains controversial. Despite a lack of scientific evidence, a universally recognized definition, a clear understanding of pathophysiologic mechanisms, or a specific diagnostic test, law enforcement and EMS personnel are taught that ExD is a potentially deadly medical condition. Even deaths attributed to ExD have no consistent anatomical findings, resulting in ExD diagnosis being one of exclusion, defined by epidemiology and the subjective description of a clinical presentation. The individuals most likely to be disproportionately identified as experiencing ExD, and to die from resulting first responder actions, or as a consequence of administration of chemical sedation for a presumed case of ExD, are otherwise healthy Black males in their mid-30s who are viewed as aggressive, impervious to pain, displaying bizarre behavior, and using substances – characterizations that may be based less on evidence and more on generalizations, misconceptions, bias, and racism. Additionally, the identification of ExD has frequently been used in defense cases of law enforcement violence, despite reported autopsy results listing asphyxiation as the cause of death.

Conclusion. Reviews of law enforcement agencies and EMS have been called for to evaluate the prevalence of ketamine use in the field in unmonitored individuals and also to assess that training and guidelines for law enforcement and EMS have been established by supervising medical and behavioral health specialists. Such reviews are appropriate. It is important to assure that deescalation training be widely implemented, and that personnel are conducting themselves according to guidelines and training to ensure patient safety. New crisis intervention team models in which medical and behavioral health specialists, not police, are those first deployed to respond to behavioral emergencies in the community should be encouraged. These models can help assure that decision makers in medical and mental health emergencies who are most appropriate to the circumstances are present with first responders, and that administration of any pharmacological treatments in a non-hospital setting is done equitably, in an evidence-based, anti-racist, and stigma-free way.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-JUN-21

Subject: Use of Drugs to Chemically Restrain Agitated Individuals Outside of Hospital

Settings

Presented by: Kira A. Geraci-Ciardullo, MD, MPH, Chair

Referred to: Reference Committee E

BACKGROUND

Recent media reports refer to "excited delirium" in discussions about police brutality and the use of conducted electrical devices (CED). 1-4 The term "excited delirium" is controversial and lacks a defined set of behavioral signs and symptoms used to identify a person perceived as in distress and in need of urgent medical or psychiatric help. Additionally, several media reports have recently highlighted the use of ketamine and other sedative/hypnotic agents by non-medical professionals to chemically incapacitate a person for a law enforcement purpose and not for a legitimate medical reason. 4-6 In many cases, "excited delirium" is listed as the reason for the use of a sedative/hypnotic agent. The AMA Board of Trustees has requested that the AMA Council on Science and Public Health study the use of ketamine and chemical restraints in the context of "excited delirium" and report back to the AMA House of Delegates.

METHODS

 English-language reports were selected from a PubMed and Google Scholar search using the text terms "excited delirium," "fatalities excited delirium," "excited delirium restraint," "excited delirium sedatives," "excited delirium ketamine," "police ketamine," "EMS ketamine," and "crisis response team." Articles were filtered based on relevance. Additional articles were identified by manual review of the references cited in these publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

AMA POLICY

No current AMA policy exists related specifically to excited delirium or the use of chemical restraints by law enforcement. AMA Policy H-515.968, "Informing the Public & Physicians about Health Risks of Sedative Hypnotics, Especially Rohypnol," emphasizes that Rohypnol (a benzodiazepine), other benzodiazepines, and other sedatives and hypnotics carry the risk of misuse, morbidity and mortality. Policy H-345.979, "Evaluation of Delirium," supports efforts to educate physicians regarding the importance of evaluation of delirium for high-risk patients and patients who are symptomatic.

- AMA has several polices related to law enforcement that are applicable to the topic of this report.
- Policy H-65.954, "Policing Reform," recognizes police brutality as a manifestation of structural racism which disproportionately impacts Black, Indigenous, and other people of color, notes
- 37 AMA's willingness to work with interested national, state, and local medical societies in a public

health effort to support the elimination of excessive use of force by law enforcement officers, states 1 2 that AMA will advocate against the utilization of racial and discriminatory profiling by law 3 enforcement through appropriate anti-bias training, individual monitoring, and other measures, and 4 will advocate for legislation and regulations which promote trauma-informed, community-based 5 safety practices. Policy H-345.972, "Mental Health Crisis Interventions," supports jail diversion and community based treatment options for mental illness, implementation of law enforcement-6 7 based crisis intervention training programs for assisting those individuals with a mental illness, 8 such as the Crisis Intervention Team model programs, federal funding to encourage increased 9 community and law enforcement participation in crisis intervention training programs, and 10 legislation and federal funding for evidence-based training programs by qualified mental health 11 professionals aimed at educating corrections officers in effectively interacting with people with 12 mental health and other behavioral issues in all detention and correction facilities. Policy 13 H-145.977, "Use of Conducted Electrical Devices by Law Enforcement Agencies," recommends that law enforcement departments and agencies should have in place specific guidelines, rigorous 14 15 training, and an accountability system for the use of CEDs that is modeled after available national guidelines, encourages additional independent research involving actual field deployment of CEDs 16 17 to better understand the risks and benefits under conditions of actual use, and urges law enforcement departments and agencies have a standardized protocol developed with the input of 18 19 the medical community for the evaluation, management and post-exposure monitoring of subjects 20 exposed to CEDs.

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32 33 AMA has policy related to Emergency Medical Services (EMS) and prehospital patient care. Policy H-130.976, "On-Site Emergency Care" reaffirms endorsement of the concept of appropriate medical direction of all prehospital emergency medical services and notes that trauma management differs markedly between locales, settings, and types of patients receiving care and for these reasons, physician supervision of prehospital services is essential to ensure that the critical decision to resuscitate in the field or to transfer the patient rapidly is made swiftly and correctly. Policy H-160.949, "Practicing Medicine by Non-Physicians" opposes allowing non-physician groups to engage in the practice of medicine without physician (MD, DO) training or appropriate physician (MD, DO) supervision and supports the requirement of appropriate physician supervision of nonphysician clinical staff in all areas of medicine. Policy H-130.937, "Delivery of Health Care by Good Samaritans" notes that bystander physicians should recognize that prehospital EMS systems operate under the authority and direction of a licensed EMS physician, who has both ultimate medical and legal responsibility for the system.

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48 49 Ethical Opinion 1.2.7, "Use of Restraints," states that all individuals have a fundamental right to be free from unreasonable bodily restraint. At times, however, health conditions may result in behavior that puts patients at risk of harming themselves. In such situations, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient. Except in emergencies, patients should be restrained only on a physician's explicit order. Patients should never be restrained punitively, for convenience, or as an alternate to reasonable staffing. Physicians who order chemical or physical restraints should: (a) Use best professional judgment to determine whether restraint is clinically indicated for the individual patient. (b) Obtain the patient's informed consent to the use of restraint, or the consent of the patient's surrogate when the patient lacks decision-making capacity. Physicians should explain to the patient or surrogate: (i) why restraint is recommended; (ii) what type of restraint will be used; (iii) length of time for which restraint is intended to be used. (c) Regularly review the need for restraint and document the review and resulting decision in the patient's medical record. In certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily. In such situations, the least restrictive restraint reasonable should be implemented and the restraint should be removed promptly when no longer needed.

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EXCITED DELIRIUM

Delirium is a well-defined clinical entity with both hypoactive and hyperactive manifestations, commonly caused by an underlying medical condition and not associated with sudden death. The term "excited delirium" (ExD) has been used since the 1980s to refer to a subcategory of delirium that has primarily been described in forensic literature and the term "excited delirium syndrome" (ExDS) was originally used in the forensic literature to describe findings in a subgroup of patients with ExD who suffered lethal consequences from untreated severe agitation. Currently, ExD and ExDS are used interchangeably in literature and media.

History

In 1849, the lead psychiatrist at McLane Asylum for the Insane introduced a condition synonymous to ExD into medical literature as "Bell Mania." The term "excited delirium" first emerged in 1985 from two University of Miami professors who set out to explain a new phenomenon of sudden deaths, mostly in police custody, of otherwise healthy men under the influence of a non-lethal amount of cocaine. So Soon after, the term gained academic traction, as the United States saw a dramatic rise in use of cocaine and other sympathomimetic substances along with increased efforts to deinstitutionalize patients with chronic mental illness. Currently, ExD and ExDS are referred to as conditions of illness marked by a combination of autonomic hyperadrenergic dysfunction, agitation, and delirium. The purported root of ExD, involving psychiatric, neurologic, and metabolic imbalance, is highly variable and linked to a complicated array of co-morbid and severe health issues. 11

Historically, the concept of ExD was synonymous with death, but over time the term has made its way into the emergency medicine, psychiatric, law enforcement, prehospital, and medicolegal literature to generally describe patients displaying altered mental status with severe agitation and perceived combative or assaultive behavior that has eluded a unifying, prospective clinical definition. Studies have failed to define ExD as one specific clinical entity, and it remains without a plausible biological pathway to sudden death. Multiple published series highlight that when CEDs and/or police restraints are used, ExD most often becomes fatal. 12-17 CSAPH Report 6-A-09, *Use of Tasers® by Law Enforcement Agencies*, included a very brief paragraph on ExD and notes that ExD is not a validated diagnostic entity in either the World Health Organization's International Classification of Diseases or the *Diagnostic and Statistical Manual of Mental Disorders*, but is widely accepted in forensic pathology and is cited by medical examiners to explain the sudden incustody deaths of individuals who are combative and highly agitated. 18

Pathophysiology

 Although it is extensively used in academic and medical literature, considerable debate exists in medicine about how to characterize ExD and ExDS, if they even exist, and how ExD contributes to sudden death. The pathophysiologic mechanisms of ExD have not been elucidated and ExD does not currently have a known etiology. ^{10,19-21} However, ExD has been characterized in the literature by delirium, agitation, acidosis, and hyperadrenergic autonomic dysfunction, typically in the setting of drug use or serious mental illness or a combination of both. ¹¹ Currently, a general function of the sympathetic nervous system is associated with the listed clinical manifestations of ExD, with possible nervous system dysfunction in some way inciting symptoms. While some authors correlate elevated synaptic dopamine levels to ExD, its causes are yet to be discovered and the absence of a unique pathophysiologic cause or specific diagnostic test remains. ²²⁻²⁴

No consistent anatomical features define ExD. Due to the biological ambiguity in diagnosing ExD, postmortem findings from autopsy and forensic evidence collection to identify or support ExD are unlikely, and a postmortem diagnosis of ExD is one of exclusion.^{8,17,25,26} Because ExD does not currently have a known specific etiology or a consistent anatomic feature, it can only be explained by its epidemiology and described clinical presentation.²⁰

Epidemiology

Studies have shown that delirium occurs in between 11 and 42 percent of general medical inpatients and 50 percent of elderly hospitalized patients. This figure is even greater for those with pre-existing cognitive impairments, terminal illness, or in need of intensive care.²⁷ Patients diagnosed with delirium are found to have extended stays in the hospital by five to ten additional days, and are more likely to be transferred to a long-term care facility post-release.²⁸

Those who are most likely to be identified as having ExD are men, with 83 to 95 percent of ExD cases occurring in this population.²⁴ Otherwise healthy males in their mid-30s who are seen as "aggressive, impervious to pain, and display bizarre behavior" have the highest rate of mortality from ExD/ExDS.¹⁰ Despite similar rates of drug use across race and ethnicity in the United States,²⁹ epidemiological studies show that it is specifically and disproportionately younger Black men who use cocaine and other psychostimulants and are in police custody that are at highest risk for death from ExD/ExDS.^{24,30,31} Mortality rates associated with ExD/ExDS have been reported to be between 8 to 16.5 percent.^{11,24,32}

LAW ENFORCEMENT, EMS, AND EXCITED DELIRIUM

Because of its reference in forensic literature, law enforcement groups and EMS have started training staff to identify ExD as a potentially deadly medical condition, despite the absence of a unique pathophysiologic cause or specific diagnostic test. ExD often presents itself as a behavioral issue initially evaluated by law enforcement with subsequent EMS involvement. Additionally, the identification of ExD/ExDS has been frequently used in defense cases of police violence. Some of the cases in which ExD has been invoked in defending the deaths of people, all Black, in police custody include Natasha McKenna, Manuel Ellis, Elijah McCain, George Floyd, and Daniel Prude.

 The prevalence of ExD appears to vary widely, both because of varying definitions and context. Reports estimate that ExD is in question in more than 3 percent of police interventions that use force and more than 10 percent of the deaths that occur within law enforcement custody are associated with ExD.²⁴ Reports also note that between 38 and 86 percent of all fatal ExD cases occur in police custody²⁴ and that law enforcement officers encounter one person with ExD in every 58 use of force incidents.²⁵ In cases of suspected ExD, law enforcement officers are encouraged to contact EMS personnel; the combined effort of EMS and law enforcement to provide effective care to those with ExDS has been termed the "dual response."^{33,34} Training for EMS personnel states that treatment of ExDS must be focused on rapidly, safely, and effectively sedating the patient and providing intensive, supportive care.³⁷

Since ExD lacks a consensus clinical definition and few pathophysiological findings exist about the condition, wrongly characterizing symptoms as ExD, especially by law enforcement with little medical knowledge, frequently leads to additional and potentially fatal medical complications including hypoxia. ^{17,38-40} The profile of a death attributed to ExD is usually a sudden, unexpected one that occurs most frequently in the summer. ⁴¹ It usually occurs immediately following chemical or physical restraint to control ExD and occurs most frequently when the patient is in the prone

position; both chemical restraints and CEDs have been cited to result in sudden death due to ExD. 15,17,42 An FBI Law Enforcement Bulletin article discussing ExD describes it as "a serious and potentially deadly medical condition involving psychotic behavior, elevated temperature and an extreme flight-or fight response," and notes that "these patients often die within 1 hour of police involvement."³³

Studies have evaluated the factors associated with death attributed to ExD in police custody and the confounding effect that restraint has on the risk of death. Results have indicated that a diagnosis of ExD and potentially fatal restraint are "inextricably interwoven." Some form of restraint was described in 90 percent of all ExD deaths, making it the most common factor that is a plausible cause or contributing cause of the death. Authors note that there is no evidence to support ExD as a cause of death in the absence of restraint. The reported autopsy results for the individuals referenced above, in which law enforcement officers cited ExD as the cause of death provide examples of this: in the death of Natasha McKenna, "excited delirium," was noted although a stun gun was utilized 4 times resulting in loss of consciousness; the death of Elijah McClain was "undetermined," although carotid hold and excessive restraint were utilized; the death of Manuel Ellis was reported as "hypoxia due to physical restraint;" George Floyd died from "asphyxia due to neck and back compression;" and Daniel Prude's death was due to "complications of asphyxia in the setting of physical restraint."

While the mortality rate associated with ExD is estimated to be between 8 and 16.5 percent, ^{11,24,32} in the past three decades, a significant decrease in restraint-related deaths of those with ExD has been noted. The period from 2004 to 2011 shows a 33 percent reduction in fatalities from ExD compared to the period 1988 to 1995; authors comment that the decrease is likely due to an increase in warnings and repeated recommendations concerning the association between restraint, especially in a prone position and fatal ExD.²⁴ However, little information related to the specific details of law enforcement or EMS training related to ExD could be located.

CHEMICAL RESTRAINT

A chemical restraint is when a drug is used to restrict the movement of a patient or in some cases to sedate a patient. Chemical restraint is used in emergency, acute, and psychiatric medical settings to reduce agitation, aggression, or violent behaviors. Drugs that are often used as chemical restraints include benzodiazepines, antipsychotics, and dissociative anesthetics. However, no drugs are U.S. Food and Drug Administration (FDA) approved for use as chemical restraints. The long history of restraint and associated controversies of the use of restraints (physical, mechanical, and chemical) in patients is outside of the scope of this report.

Drugs Used as Chemical Restraints

Medications that are typically used for chemical restraint include the dissociative ketamine, benzodiazepine sedatives such as midazolam, and antipsychotic medications including olanzapine or haloperidol, both alone or in combination.

Studies over the last several years have evaluated and compared the efficacy of sedation for several medications used for chemical restraint, as well as adverse effects associated with them. ⁴⁵⁻⁴⁹ A recent systematic review summarizes available evidence on the effectiveness and safety of chemical restraint from 21 randomized controlled trials conducted in pre-hospital, hospital emergency department, or ward settings and notes limited comparability between studies in drug choice, combination, dose, method of, or timing of repeat administrations. Drugs used in chemical restraint and included in the review include olanzapine, haloperidol, droperidol, risperidol,

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flunitrazepam, midazolam, promethazine, ziprasidone, sodium valproate, or lorazepam. The review notes little clarity about the superiority of any of the drugs and recommends additional research on the topic.⁵⁰

Because sedation with slower-onset chemical restraints, such as haloperidol and some benzodiazepines present a risk of delay to adequate sedation, ketamine has emerged as a potentially preferred drug for the control of patient agitation in a pre-hospital context and for a law enforcement purpose. 35,37,39,40,51-54 Although little literature exists directly reporting the frequency of EMS use, authors note that this medication could easily be implemented into out-of-hospital protocols and that ketamine offers a "safe and effective method of controlling the severely agitated patient."35,37

Ketamine

Ketamine is FDA approved for use as an anesthetic agent for diagnostic and surgical procedures and esketamine (a pure ketamine stereoisomer) is FDA approved for treatment-resistant depression. Ketamine and esketamine are classified as Schedule III controlled substances.

 Ketamine is commonly used off-label in medical settings as an analgesic, antidepressant, and antiinflammatory medication. No FDA-approved indication for use to treat ExD exists, which is understandable given that there is no medical consensus on definitions of or diagnostic criteria for ExD. Therefore, no standard dosing regimen has been established and there has been no consideration of co-morbid medical conditions for ketamine use for ExD. A rapidly growing movement calls for expanded use of ketamine for several applications, both in and out of the hospital, including for sedation of agitated patients in non-clinical situations and for restraint in custody.^{35,55}

Ketamine Use as a Chemical Restraint by Law Enforcement and EMS

Police officers and EMS professionals are the most likely first responders to encounter agitated patients exhibiting what they might consider to be symptoms of ExD. While law enforcement usually evaluates this syndrome, it is usually EMS personnel who provide the sedation, in the "dual response" model. While several chemical restraints are used to sedate those purportedly experiencing ExD within law enforcement custody and in EMS contexts, most commonly the sedative is ketamine. Authors report that the use of ketamine for restraint of an agitated patient induces rapid, predictable sedation within three to four minutes when given by intramuscular injection. ^{37,54,56}

A recent national survey assessed ketamine training, use, and perceptions among paramedics in civilian prehospital settings. The survey noted that training related to ketamine use was commonly reported among paramedics, however, few are authorized to administer the drug according to their agency protocol. Of those paramedics authorized to use ketamine, most had limited experience administering the drug, but have the perception that the use of ketamine for sedation is safe and effective. Dosing guidelines, safety profile, and efficacy have been described in only a limited fashion for the use of ketamine to chemically restrain a patient in a pre-hospital scenario. 151

Many police departments have seen a dramatic rise in ketamine administration over the past several years. As an example, a 2018 City of Minneapolis report "MPD Involvement in Pre-Hospital Sedation" documented an average of 4 cases of ketamine use per year prior to 2015, 14 uses in 2015, and 62 instances in 2017.⁵⁷ From January 2018 through April 2018, 11 instances of ketamine use were documented in police reports, exceeding the annual use in each year from 2010-2014.⁵⁷

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Additionally, the report from Minneapolis presented 8 cases that occurred between 2016 and 2018 in which EMS professionals and Minneapolis Police Department (MPD) officers cooperated in order to administer ketamine. These cases involved instances in which the police officers, with limited medical training, directed EMS professionals to use ketamine.⁵⁷ A recent investigation of the death of Elijah McCain in Colorado determined that the use of ketamine contributed to his death.⁵⁸

Little information related to the specific details of law enforcement or EMS training related to the use of ketamine or other chemical restraints could be located. Reviews of law enforcement agencies and EMS have been called for to evaluate the prevalence of ketamine use in the field in unmonitored individuals and to assess that training and guidelines have been established by supervising medical and behavioral health specialists, are appropriate, include de-escalation training, and personnel are conducting themselves according to guidelines and training to ensure patient safety. 35,57,58 Additionally, agencies currently using ketamine for sedation of agitation are encouraged to report their outcomes and protocols to increase the body of evidence and determine best safe practices for this indication. 35

Ketamine Pharmacology in Pre-hospital Contexts

Ketamine dose dependently exerts broad influences on consciousness and perception, with some patients reporting dissociative and extracorporeal sensations. The most common psychoactive effects reported after a single subanesthetic intravenous administration of ketamine include dissociation, positive psychotomimetic effects (conceptual disorganization, hallucinations, suspiciousness, unusual thought content, and frank paranoia), and negative psychotomimetic effects (blunted affect, emotional withdrawal, and psychomotor retardation). In addition, studies have identified unfavorable effects of administration of ketamine on cognition (including amnesia), vestibular perturbations, nausea/vomiting, tachycardia, hypertension, palpitations, hypersalivation, and respiratory depression. Ketamine has also been found to have negative interactions with alcohol in intoxicated individuals and those taking MAO inhibitors, which is of concern because when ketamine is used by EMS in out-of-hospital settings, individuals may be under the influence of alcohol, cannabis, sedative-hypnotics, or other psychoactive drugs or under medical treatment with a pharmaceutical with potential adverse drug-drug interactions with ketamine.^{48,59-62}

Because of the ketamine dose-response and side effects, careful administration and medical expertise is necessary, especially in non-medical and non-hospital contexts. ^{17,38-40} In general, the duration of sedation should only be long enough to allow for patient assessment, initial treatment, and transfer to a medical facility; restraint beyond this timeframe may induce additional medical complications. Ketamine dosing is dependent on a person's body weight, with a reported standard dosing of 5mg per kilogram of bodyweight starting at 250 mg for pre-hospital treatment. ^{44,51,63,64} Because of this weight dosing requirement, incorrect dosing of ketamine by law enforcement or EMS can and has led to serious adverse events or death. ⁵⁸ A recent investigation of the death of Elijah McClain in Aurora, Colorado found that an incorrect estimation of weight for a weight-based dose calculation contributed to his death. ⁵⁸ Additionally, several studies have reported that while ketamine provides rapid sedation for agitated patients, its use in a pre-hospital setting is associated with higher intubation and hospital admission rates when used by EMS. ^{35,38,48,51,54,60,62,65,66} Studies have also linked the use of ketamine to death from metabolic

46 EMS.^{35,38,48,5} acidosis.⁶⁷⁻⁶⁹

CRISIS INTERVENTION TEAM PROGRAMS

Crisis Intervention Team programs (CITs) are community partnerships of law enforcement, behavioral health providers, people with mental and substance use disorders, along with their families and others. CITs have become a globally recognized model for safely and effectively assisting people who experience crises in the community. The Substance Abuse and Mental Health Services Administration (SAMHSA) notes that the need for CIT programs is urgent, as communities are challenged with insufficient mental health funding and services. Advocates of CITs, including the National Alliance on Mental Illness (NAMI), note that the programs can reduce police encounters and arrests of people with mental illness while simultaneously increasing the likelihood that individuals will receive mental health services. Additional goals of CITs include improving police responses to people in crisis; diverting individuals from the criminal justice system when appropriate; and developing more robust community-based crisis-response systems that minimize both the role of law enforcement and the need to utilize emergency departments. A foundational aspect of successful CITs is a strong and ongoing community partnership.

CITs promote both law enforcement officer safety and the safety of the individual in crisis. NAMI notes that CITs give law enforcement officers more tools to do their job safely and effectively and promotes the expansion of CITs nationwide, providing resources and working with stakeholders to establish standards and promote innovation for CITs. While law enforcement agencies have a central role in program development and ongoing operations, a continuum of crisis services available to citizens prior to police involvement is core to the model. SAMHSA notes that for safety and optimal engagement, two person CIT teams should be put in place to support communities and EMS should be aware of the teams and partner as warranted. SAMHSA guides also note minimum expectations for CITs, including the involvement of a licensed and/or credentialed behavioral health clinician, response to where the person in need is located, and connecting the individual to appropriate care, with a warm hand-off and coordinated transportation. SAMHSA guides and CIT International, the leading national organization promoting successful CIT models, detail best practices for CIT services 15,76 and experts have documented and noted challenges for rural communities.

The Denver Support Team Assisted Response program (STAR), which has been operational for six months, is an example of a CIT. STAR pairs a mental health clinician and a paramedic to address low-level incidents, such as trespassing and mental health episodes, that would have otherwise fallen to uniformed law enforcement officers carrying firearms. In its first six months, STAR has responded to 748 incidents, none of which required police or led to arrests or jail time.^{78,79}

Officials note that "STAR represents a more empathetic approach to policing that keeps people out of an often-cyclical criminal justice system by connecting people with services like shelter, food aid, counseling, and medication. The program also deliberately cuts down on encounters between uniformed officers and civilians." The STAR policing alternative empowers behavioral health experts to dictate patient interactions, even when police officers are around, and has been hailed as a success in local Denver communities. ^{78,79} Many communities around the United States are exploring alternatives to incarceration and law enforcement response to minor incidents.

NATIONAL ASSOCIATION POSITIONS

The American Psychiatric Association (APA) released a position statement in 2020 related to ExD and the use of ketamine. APA does not recognize ExD as a mental disorder and states that the term should not be used until a clear set of diagnostic criteria are validated. APA notes that persons being detained by the police and described as having ExD have frequently received medication

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from EMS personnel intended to chemically sedate them, without a medical condition warranting the use of the drug. The APA statement further cautions that chemical sedation medications, including ketamine, used outside of hospital contexts have significant risks, including respiratory suppression. APA also states that an investigation should be undertaken of cases labeled as ExD, that all relevant data be analyzed for disproportionate application of the term, and that all jurisdictions should develop, implement, and routinely update evidence-based protocols for the administration of chemical restraint medications.⁸⁰

The American College of Emergency Physicians (ACEP) recognizes ExD as a medical condition and notes that the exact pathophysiology of ExD remains unidentified. 11,32,81 In articles on the topic, ACEP representatives note that a large component of treating patients is helping law enforcement and EMS recognize possible ExDS patients, and that prehospital ExDS should be presumed if a patient is disoriented or not making sense, constantly physically active, impervious to pain, has superhuman strength, is sweating and breathing rapidly, has tactile hyperthermia, and fails to respond to a police presence. ACEP experts have also advocated that chemical sedation, with ketamine or benzodiazepines, is a first-line treatment. 32,81

In a 2020 statement, ACEP and the American Society of Anesthesiologists (ASA) discussed the safe use of ketamine in the emergency department and in prehospital care for effective pain management, sedation, the control of delirium in acute psychotic emergencies and drug intoxications. ACEP and ASA noted the dependence on an appropriate medical assessment by a paramedic with medical direction. The statement notes firm opposition to the use of ketamine or any other sedative/hypnotic agent to chemically incapacitate someone solely for a law enforcement purpose and not for a legitimate medical reason.⁸²

The American College of Medical Toxicologists (ACMT) hosts educational information related to ExD and ExDS, including definitions, signs and symptoms, and treatment with chemical support/sedation. ⁸³ In a statement released in 2020, ACMT recognized ExD as a condition that warrants consideration of the decision to administer sedating medications. Based on current evidence, ACMT supports the use of sedative and dissociative medications by appropriately trained prehospital paramedical professionals for treatment of severe agitation when other measures have failed, but ACMT does not support the use of these medications solely for the purpose of behavior control on behalf of law enforcement. ⁸⁴

In 2020, ACMT, the American Society of Addiction Medicine (ASAM), and the Opioid Response Network (ORN) co-hosted an Addiction Toxicology Case Conference on the topic of intoxication and ExD. The webinar, for continuing medical education credit, featured "discussion of druginduced agitated delirium with experts dissecting the mechanism and common course of events that occur in the most severe type of agitated delirium, often referred to as Excited Delirium Syndrome. Myths and misperceptions in care of patients with agitation and delirium [were] addressed, as [was] discussion of the appropriate use of sedation..."83

The National Association of EMS Physicians (NAEMSP) recognizes that EMS personnel often encounter agitated and combative patients, and these patients frequently require clinical treatment and transportation. A 2016 statement details the NAEMSP position on a several issues related to patient restraint. Notably, NAEMSP believes that EMS agencies should develop scientific protocols for dealing with violent or combative patients, that EMS agencies must assure that all personnel are knowledgeable about the clinical conditions that are associated with agitated or combative behavior and are trained to apply the principles of the system's restraint protocol during patient care. The NAEMSP position statement provides significant details about restraint protocols, notes the use of chemical restraint for Exp. and that chemical restraint usually with a

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butyrophenone, a benzodiazepine, ketamine or other dissociative agents, or a combination of these agents, is an effective and safe method of protecting the violent or combative patient from self-injury. Importantly, the NAEMSP notes that local law enforcement restraint policies/practices may differ from EMS-based restraint protocols, but both agencies should recognize their roles and work cooperatively and proactively to ensure the safe care of patients when application of restraint(s) is necessary.⁸⁶

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CONCLUSION

The assessment, diagnosis, and treatment of ExD remains controversial. Despite a lack of scientific evidence, a universally recognized definition, a clear understanding of pathophysiologic mechanisms, or a specific diagnostic test, law enforcement and EMS personnel are taught that ExD is a potentially deadly medical condition – including at time, by physicians. Even deaths attributed to ExD have no consistent anatomical findings, resulting in ExD diagnosis being one of exclusion, defined by epidemiology and the subjective description of a clinical presentation. The individuals most likely to be disproportionately identified as experiencing ExD, and to die from resulting first responder actions, or as a consequence of administration of chemical sedation for a presumed case of ExD, are otherwise healthy Black males in their mid-30s who are viewed as aggressive, impervious to pain, displaying bizarre behavior, and using substances – characterizations that may be based less on evidence and more on generalizations, misconceptions, bias, and racism. Additionally, the identification of ExD has frequently been used in defense cases of law enforcement violence, despite reported autopsy results listing asphyxiation as the cause of death.

While chemical restraint is used in emergency, acute, and psychiatric medical settings to reduce agitation, aggression, or violent behaviors, a rapidly growing movement calls for expanded use of chemical restraint, specifically using ketamine, for several applications, both in and out of the hospital, including for sedation of agitated patients in non-clinical situations and for chemical restraint of persons in law enforcement custody. Police officers and EMS professionals are the most likely first responders to encounter patients perceived to be exhibiting purported ExD. While law enforcement usually evaluates this syndrome, it is usually EMS personnel who provide the sedation, in the "dual response" model.

 Reviews of law enforcement agencies and EMS have been called for to evaluate the prevalence of ketamine use in the field in unmonitored individuals and to assess that training and guidelines have been established by supervising medical and behavioral health specialists. Such reviews are appropriate. It is important to assure that de-escalation training be widely implemented, and that personnel are conducting themselves according to guidelines and training to ensure patient safety. New CIT models in which medical and behavioral health specialists, not police, are those first deployed to respond to behavioral emergencies in the community should be encouraged. These models can help assure that decision makers in medical and mental health emergencies who are most appropriate to the circumstances are present with first responders, and that administration of any pharmacological treatments in a non-hospital setting is done equitably, in an evidence-based, stigma-free way.

1 RECOMMENDATION 2 3 The Council on Science and Public Health recommends that the following be adopted and the 4 remainder of the report be filed: 5 6 1. That the following new AMA policy be adopted: 7 8 Use of Drugs to Chemically Restrain Agitated Individuals Outside of Hospital Settings 9 Our American Medical Association: 10 1. Believes that current evidence does not support "excited delirium" or "excited delirium syndrome" as a medical diagnosis and opposes the use of the terms until a clear set of 11 12 diagnostic criteria are validated; 13 14 2. Is concerned about law enforcement officer use of force accompanying "excited 15 delirium" that leads to disproportionately high mortality among communities of color, particularly among Black men, and denounces "excited delirium" solely as a 16 17 justification for the use of force by law enforcement officers. 18 19 3. Opposes the use of sedative/hypnotic agents, including ketamine, to chemically 20 restrain an individual solely for a law enforcement purpose; 21 22 4. Recognizes that drugs for chemical restraint used outside of a hospital setting by non-23 physicians have significant risks intrinsically, in the context of underlying medical conditions, and also related to potential drug-drug interactions with agents the 24 25 individual may have taken; 26 27 5. Calls for comprehensive reviews, performed by independent investigators including 28 appropriate medical and behavioral health professionals, of law enforcement agencies 29 and emergency medical service agencies to: 30 a. Investigate any cases labeled as "excited delirium" for disproportionate 31 application of the term, including prevalence of its use by race, ethnicity, gender, age, and other demographic factors; 32 b. Evaluate the prevalence of ketamine use in the field in unmonitored 33 34 individuals; 35 c. Assess that training and guidelines have been properly established by 36 supervising medical and behavioral health specialists, are appropriate, and 37 include de-escalation training; and 38 d. Assess, on an ongoing basis, that personnel are conducting themselves 39 according to guidelines and training to ensure patient safety; and 40 41 6. Urges law enforcement and emergency medical service personnel to participate in appropriate training that minimally includes de-escalation techniques and the 42 43 appropriate use of drugs used to restrain individuals; and 44 7. Urges medical and behavioral health specialists, not law enforcement, to serve as first 45 responders and decision makers in medical and mental health emergencies in local 46 47 communities and that administration of any pharmacological treatments in a non-48 hospital setting be done equitably, in an evidence-based, anti-racist, and stigma-free

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(New HOD Policy)

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2. That Policy H-65.954, "Policing Reform," which recognizes police brutality as a manifestation of structural racism which disproportionately impacts Black, Indigenous, and other people of color, notes AMA's willingness to work with interested national, state, and local medical societies in a public health effort to support the elimination of excessive use of force by law enforcement officers, states that AMA will advocate against the utilization of racial and discriminatory profiling by law enforcement through appropriate anti-bias training, individual monitoring, and other measures, and will advocate for legislation and regulations which promote trauma-informed, community-based safety practices, be reaffirmed. (Reaffirm Current AMA Policy)

3. That Policy H-345.972, "Mental Health Crisis Interventions," which supports jail diversion and community based treatment options for mental illness, implementation of law enforcement-based crisis intervention training programs for assisting those individuals with a mental illness, such as the Crisis Intervention Team model programs, federal funding to encourage increased community and law enforcement participation in crisis intervention training programs, and legislation and federal funding for evidence-based training programs by qualified mental health professionals aimed at educating corrections officers in effectively interacting with people with mental health and other behavioral issues in all detention and correction facilities, be reaffirmed. (Reaffirm Current AMA Policy)

Fiscal Note: Less than \$1000

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501 (JUN-21)

Introduced by: New York

Subject: Ensuring Correct Drug Dispensing

Referred to: Reference Committee E

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

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

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

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

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

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

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

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

Received: 03/31/21

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AUTHOR'S STATEMENT OF PRIORITY

Providing a color photo of a dispensed pharmaceutical would reduce the number of drug dispensing errors made by pharmacies and hospital dispensaries. It would also help patients to be sure what they are taking is the correct drug. Providing as much information as possible at each step in the dispensing process would reduce the number of errors made each year. More information about a patient's medications can only help everyone in the chain of medication use. The sooner this is implemented the sooner mistakes are eliminated.

RELEVANT AMA POLICY

Epidemiology of Drug Errors H-120.963

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

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

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

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

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

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502 (JUN-21)

Introduced by: New York

Subject: Scientific Studies which Support Legislative Agendas

Reference Committee E Referred to:

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

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

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

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

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

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

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21 22 Whereas. The recent debate before Congress to address surprise medical bills often found physician organizations at odds with the perspectives of not only the insurance industry, but also the business, labor, and patient advocacy organizations as well as numerous think thanks; and

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

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

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

Received: 03/31/21

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AUTHOR'S STATEMENT OF PRIORITY

AMA works with many groups toward shared goals, this resolution seeks to expand that network to ensure that medicine, and healthcare for patients is seen as a top priority for all stakeholders. Always important, alliances within healthcare have taken on increased urgency as outside influences, groups and government erode physician autonomy, practice income, and patient care. During the past year, the value of scientifically accurate information has been brought to the forefront of the public eye through the media and agencies such as the CDC. AMA needs to strengthen and expand its network of allies and contacts so that undisputed scientific information can be provided/utilized to support AMA advocacy goals, physicians, patients and continued excellence in US healthcare.

RELEVANT AMA POLICY

Statement of Collaborative Intent G-620.030

- (1) The AMA House of Delegates endorses the following preamble of a Statement of Collaborative Intent: The Federation of Medicine is a collaborative partnership in medicine. This partnership is comprised of the independent and autonomous medical associations in the AMA House of Delegates and their component and related societies. As the assemblage of the Federation of Medicine, the AMA House of Delegates is the framework for this partnership. The goals of the Federation of Medicine are to: (a) achieve a unified voice for organized medicine;
- (b) work for the common good of all patients and physicians;
- (c) promote trust and cooperation among members of the Federation; and
- (d) advance the image of the medical profession; and (e) increase overall efficiency of organized medicine for the benefit of our member physicians.
- (2) The AMA House of Delegates endorses the following principles of a Statement of Collaborative Intent: (a) Organizations in the Federation will collaborate in the development of joint programs and services that benefit patients and member physicians.
- (b) Organizations in the Federation will be supportive of membership at all levels of the Federation.
- (c) Organizations in the Federation will seek ways to enhance communications among physicians, between physicians and medical associations, and among organizations in the Federation.
- (d) Each organization in the Federation of Medicine will actively participate in the policy development process of the House of Delegates.
- (e) Organizations in the Federation have a right to express their policy positions.
- (f) Organizations in the Federation will support, whenever possible, the policies, advocacy positions, and strategies established by the Federation of Medicine.
- (g) Organizations in the Federation will support an environment of mutual trust and respect.
- (h) Organizations in the Federation will inform other organizations in the Federation in a timely manner whenever their major policies, positions, strategies, or public statements may be in conflict.
- (i) Organizations in the Federation will support the development and use of a mechanism to resolve disputes among member organizations.
- (j) Organizations in the Federation will actively work toward identification of ways in which participation in the Federation could benefit them.
- (CLRPD/CEJA/C&B Report, A-97; Consolidated: CLRPD Rep. 3, I-01; Modified: BOT Rep. 23, A-02; Modified: CCB/CLRPD Rep. 3, A-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503 (JUN-21)

Introduced by: American Society of Addiction Medicine

Subject: Access to Evidence-Based Addiction Treatment in Correctional Facilities

Referred to: Reference Committee E

Whereas, Provisional data indicate drug overdose deaths exceeded 90,000 during the 12 months ending in September 2020,¹ the highest number of overdose deaths ever recorded during a 12-month period; and

Whereas, Opioid overdose death rates are increasing more rapidly among Black Americans than white Americans;² and

Whereas, Experts attribute the acceleration in drug overdose deaths to the disruption to daily life due to the COVID-19 pandemic;³ and

Whereas, Scholars have noted early indicators that the pandemic is increasing racial inequities in overdose deaths;⁴ and

Whereas, Incarcerated individuals are 129 times more likely to die from overdose within the first two weeks after release when compared to the general U.S. population⁵ and nearly five percent of all deaths from illicit opioids occurs among people who were released from jail or prison in the past month;⁶ and

Whereas, Black adults are 5.9 times as likely to be incarcerated than whites and Hispanics are 3.1 times as likely to be incarcerated as whites;⁷ and

Whereas, Effective substance use disorder treatment, including medications, is key to preventing relapse, overdose and death;⁸ and

 Whereas, Individuals who are receiving medications for the treatment of opioid use disorder (OUD) prior to incarceration may be forced to discontinue such treatment, and those with untreated OUD are often not offered evidence-based and life-saving treatment upon entering iail⁹ or prison;¹⁰ and

 Whereas, Federal Medicaid funds are prohibited by law from being used for health care in jails and prisons ("the inmate exclusion clause" of the 1965 Social Security Act), and law generally prevents payment for medical care furnished to a Medicare beneficiary who is incarcerated or in custody at the time the services are delivered; and

Whereas, Our AMA has endorsed the use of medications for OUD in prisons, encouraged public funding for such programs, and supported the establishment of post-incarceration programs to continue OUD; therefore be it

Page 2 of 5

1 RESOLVED, That our American Medical Association amend policy H-430.987, "Opiate 2 Replacement Therapy Programs in Correctional Facilities," by addition and deletion to read as 3 follows:

Opiate Replacement Therapy Programs Medications for Opioid Use Disorder in Correctional Facilities H-430.987

- 1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) medications for opioid use disorder (OUD) as an effective therapy in treating opiate addicted the standard of care for persons with OUD who are incarcerated; and (b) ORT for opiate addicted medications for persons with OUD who are incarcerated, an endorsement in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.
- 2. Our AMA advocates for legislation, standards, policies and funding that encourage require correctional facilities to increase access to evidence-based treatment of OUD epicid use disorder, including initiation and continuation of epicid replacement therapy medications for OUD, in conjunction with counseling psychosocial treatment when available and desired by the person with OUD, in correctional facilities within the United States and that this apply to all incarcerated individuals who are incarcerated, including pregnant women individuals who are pregnant, postpartum, or parenting.
 3. Our AMA supports advocates for legislation, standards, policies, and funding that encourage
 - 3. Our AMA supports advocates for legislation, standards, policies, and funding that encourage 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 pregnant women individuals who are pregnant, postpartum, or parenting, are released to offer post-incarceration treatment plans for OUD epioid use disorder, 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, including medications for addiction treatment medication assisted therapy.
- 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. (Modify Current HOD Policy); and be it further

Resolution: 503 (JUN-21) Page 3 of 5

1 RESOLVED, That our AMA amend policy H-430.986, "Health Care While Incarcerated," by 2 addition and deletion to read as follows:

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- 1. Our AMA advocates for adequate payment to health care providers, including primary care and mental health, and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.
- 2. Our AMA supports partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of
- 10 health care services for juveniles and adults in the correctional system.
- 11 3. Our AMA encourages state Medicaid agencies to accept and process Medicaid applications 12 from juveniles and adults who are incarcerated.
- 13 4. That our AMA encourage state Medicaid agencies to work with their local departments of
- 14 corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have
- 15 been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility 16 determination for Medicaid.
- 17 5. Our AMA encourages advocates for states to suspend rather than terminate Medicaid 18 eligibility of juveniles and adults upon intake into the criminal justice legal system and
- 19 throughout the incarceration process, and to reinstate coverage when the individual transitions 20 back into the community.
 - 6. Our AMA urges advocates for Congress to repeal the "inmate exclusion" of the 1965 Social Security Act that bars the use of federal Medicaid matching funds from covering healthcare
- 22 23 services in jails and prisons., the Centers for Medicare & Medicaid Services (CMS), and state
- 24 Medicaid agencies to provide Medicaid coverage for health care, care coordination activities
- and linkages to care delivered to patients up to 30 days before the anticipated release from 25
- 26 adult and juvenile correctional facilities in order to help establish coverage effective upon
- 27 release, assist with transition to care in the community, and help reduce recidivism.
- 28 7. Our AMA advocates for Congress and the Centers for Medicare & Medicaid Services (CMS)
- 29 to revise the Medicare statute and rescind related regulations that prevent payment for medical
- 30 care furnished to a Medicare beneficiary who is incarcerated or in custody at the time the 31 services are delivered.
- 32 8.7. Our AMA advocates for necessary programs and staff training to address the distinctive
- 33 health care needs of incarcerated women and adolescent females who are incarcerated,
- 34 including gynecological care and obstetrics care for pregnant and postpartum women 35 individuals who are pregnant or postpartum.
- 36 9.8. Our AMA will collaborate with state medical societies, relevant medical specialty societies,
- and federal regulators to emphasize the importance of hygiene and health literacy information 37
- 38 sessions, as well as information sessions on the science of addiction, evidence-based addiction
- 39 treatment including medications, and related stigma reduction, for both inmates individuals who
- 40 are incarcerated and staff in correctional facilities.
- 41 10.9. Our AMA supports: (a) linkage of those incarcerated to community clinics upon release in
- 42 order to accelerate access to comprehensive health care, including mental health and
- 43 substance abuse disorder services, and improve health outcomes among this vulnerable patient
- 44 population, as well as adequate funding; and (b) the collaboration of correctional health workers
- 45 and community health care providers for those transitioning from a correctional institution to the
- 46 community. (Modify Current HOD Policy)

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

Received: 05/04/21

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AUTHORS STATEMENT OF PRIORITY

The COVID-19 pandemic has highlighted and exacerbated the stark racial health disparities that exist in the United States, with Black and Latinx Americans experiencing worse health outcomes than white Americans. At the same time, the pandemic has accelerated the epidemic of drug overdose deaths. Record numbers of drug overdose deaths are being projected for 2020, with overdose death rates increasing more rapidly among Black Americans than whites.

Patients' involvement with the criminal legal system complicates the medical community's efforts to treat addiction, prevent overdose deaths, and reduce health disparities related to substance use. For decades, America has tried to arrest and incarcerate away problems with drug use and addiction rather than treat addiction as a medical disease. As a result, millions of individuals with a preventable and treatable medical disease – many of them Black and Latinx Americans, who are incarcerated at much higher rates than whites despite similar rates of drug use – have been locked up where they have not been offered evidence-based treatment for their disease. Upon their release, they are 129 times more likely to die from overdose than the general population.

Access to opioid use disorder (OUD) treatment, including all FDA-approved medications for OUD, in jails and prisons is a critical public health and ethical issue. Our AMA must take a leadership role in calling for evidence-based, medical treatment for the nearly 20 percent of individuals who are incarcerated who meet criteria for OUD.

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- 2. Furr-Holden D, Milam AJ, Wang L, Sadler R. African Americans now outpace whites in opioid-involved overdose deaths: a comparison of temporal trends from 1999 to 2018. *Addiction*. 2021;116(3):677-683. doi:10.1111/add.15233
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RELEVANT AMA POLICY

Opiate Replacement Therapy Programs in Correctional Facilities H-430.987

- 1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (b) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.
- 2. Our AMA advocates for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy in conjunction with

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counseling, in correctional facilities within the United States and that this apply to all incarcerated individuals including pregnant women.

3. Our AMA supports legislation, standards, policies, and funding that encourage 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 pregnant women, are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths and help ensure post-incarceration medical coverage and accessibility to medication assisted therapy.

Citation: Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17

Health Care While Incarcerated H-430.986

- 1. Our AMA advocates for adequate payment to health care providers, including primary care and mental health, and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.
- 2. Our AMA supports partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of health care services for juveniles and adults in the correctional system.
- 3. Our AMA encourages state Medicaid agencies to accept and process Medicaid applications from juveniles and adults who are incarcerated.
- 4. That our AMA encourage state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid.
- 5. Our AMA encourages states to suspend rather than terminate Medicaid eligibility of juveniles and adults upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community.
- 6. Our AMA urges Congress, the Centers for Medicare & Medicaid Services (CMS), and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from adult and juvenile correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism.
- 7. Our AMA advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum women.
- 8. Our AMA will collaborate with state medical societies and federal regulators to emphasize the importance of hygiene and health literacy information sessions for both inmates and staff in correctional facilities.
- 9. Our AMA supports: (a) linkage of those incarcerated to community clinics upon release in order to accelerate access to comprehensive health care, including mental health and substance abuse disorder services, and improve health outcomes among this vulnerable patient population, as well as adequate funding; and (b) the collaboration of correctional health workers and community health care providers for those transitioning from a correctional institution to the community.

Citation: CMS Rep. 02, I-16; Appended: Res. 417, A-19; Appended: Res. 420, A-19; Modified: Res. 216, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504 (JUN-21)

Introduced by: Delaware

Subject: Healthy Air Quality

Referred to: Reference Committee E

Whereas, Particulate matter (PM) or particle pollution is a mixture of solid particles and liquid droplets found in the air that come in many sizes and shapes and can be made up of hundreds of different chemicals¹; and

Whereas, Particulate matter inhaled can get deep into the lungs and even into the bloodstream¹; and

Whereas, Particles less than 2.5 micrometers in diameter, also known as fine particles or PM 2.5, pose the greatest risk to health¹; and

Whereas, In 2016-2018, more cities had high days of ozone and short-term particle pollution compared to 2015-2017 and many cities measured increased levels of year-round particle pollution²; and

Whereas, Harmful revisions and setbacks to key protections currently in place or required under the Clean Air Act of 1970 threaten to make air quality even worse in parts of the US²; and

Whereas, Atmospheric pollutants have been linked to a host of chronic and acute illnesses, and contribute to the risk of COVID-19 complications, with preventable health, social, and economic impacts³⁻⁸; and

Whereas, Evidence that both prenatal and postnatal exposures to PM 2.5 are associated with later development of allergic rhinitis, a precursor to pediatric asthma, the vulnerable time window may be within late gestation and the first year of life⁸; and

Whereas, Poor air and water quality disproportionately affect the economically disadvantaged as well as communities of color^{3-5,7-9}; and

Whereas, Statistics for 2020 show the nation's electricity was generated from 60% of fossil fuels, 20% from nuclear supplies and another 20% from renewable sources¹⁰; and

Whereas, Current technology is capable of replacing fossil fuel-generated power with renewable sources^{7,11}; therefore be it

RESOLVED, That our American Medical Association champion legislation and policies at the federal level to shift our energy generation away from polluting sources like fossil fuels and toward less polluting renewables in order to drive down the generation of PM 2.5 and other pollutants. (Directive to Take Action)

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Fiscal Note: Modest - between \$1.000 - \$5.000

Received: 05/11/21

AUTHOR'S STATEMENT OF PRIORITY

Air pollution is the leading environmental health risk humans face. The combined effects of outdoor and household air pollution cause around seven million (one in eight) premature deaths every year, largely as a result of increased mortality from stroke, heart disease, lung disease, and cancers.

According to data from the World Health Organization (WHO), air quality in most cities fails to meet WHO guidelines for safe levels, putting people at additional risk of respiratory disease and other health problems. Without action, air pollution in many cities will continue to get worse.

Emerging research is shedding light on the links between air pollution and severe illness from COVID-19, underscoring the critical need to ensure healthy air for all. Researchers SUNY College of Environmental Science and Forestry found that an increase in exposure to hazardous air pollutants is associated with a 9% increase in death among patients with COVID-19, after accounting for differences in wealth and other health issues. Another study from the Harvard T.H. Chan School of Public Health and the Dana-Farber Cancer Institute looked at the impact of long-term exposure to fine particle pollution on COVID-19 death rates. Researchers found that just a small increase (1 microgram per cubic meter) in long-term average exposure to fine particle pollution is associated with an 11% increase in the COVID-19 death rate. Adding to the evidence on the connection between racial disparities, air pollution, and COVID-19, the researchers found a 49% increase in the COVID-19 death rate in counties with elevated fine particle pollution and that had a higher Black population.

While the COVID-19 pandemic is understandably treated as an imminent danger, the climate crisis is thought of as a consequence yet to come and that will be dealt with in the future.

The Medical Society of Delaware requests that our resolution, "Healthy Air Quality," be considered an urgent priority resolution for the upcoming Special Meeting of the AMA House of Delegates in June 2021 for these reasons. There is support from the Biden Administration to confront the climate crisis, to include protecting the air from harmful pollution. The time is now to make important changes for the health of our patients.

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RELEVANT AMA POLICY

Preventing Death and Disability Due to Particulate Matter Produced by Automobiles H-135.915

Our AMA will: (1) promote policies at all levels of society and government that educate and encourage policy makers to limit or eliminate disease causing contamination of the environment by gasoline and diesel combustion-powered automobiles, advocating for the development of alternative means for automobile propulsion and public transportation; and (2) support individual states' legal efforts to retain authority to set vehicle tailpipe emission standards that are more stringent than federal standards. Citation: Res. 915, I-19

AMA to Protect Human Health from the Effects of Climate Change by Ending its Investments in Fossil Fuel Companies H-135.921

- 1. Our AMA will choose for its commercial relationships, when fiscally responsible, vendors, suppliers, and corporations that have demonstrated environmental sustainability practices that seek to minimize their fossil fuels consumption.
- 2. Our AMA will support efforts of physicians and other health professional associations to proceed with divestment, including to create policy analyses, support continuing medical education, and to inform our patients, the public, legislators, and government policy makers.

 Citation: BOT Rep. 34, A-18

AMA Advocacy for Environmental Sustainability and Climate H-135.923

Our AMA (1) supports initiatives to promote environmental sustainability and other efforts to halt global climate change; (2) will incorporate principles of environmental sustainability within its business operations; and (3) supports physicians in adopting programs for environmental sustainability in their practices and help physicians to share these concepts with their patients and with their communities. Citation: Res. 924, I-16; Reaffirmation: I-19

EPA and Green House Gas Regulation H-135.934

- 1. Our AMA supports the Environmental Protection Agency's authority to promulgate rules to regulate and control green house gas emissions in the United States.
- 2.Our AMA: (a) strongly supports evidence-based environmental statutes and regulations intended to regulate air and water pollution and to reduce greenhouse gas emissions; and (b) will advocate that environmental health regulations should only be modified or rescinded with scientific justification. Citation: Res. 925, I-10; Reaffirmed in lieu of Res. 526, A-12; Reaffirmed: Res. 421, A-14; Appended: Res. 523, A-17

Global Climate Change and Human Health H-135.938

- 1. Supports the findings of the Intergovernmental Panel on Climate Change's fourth assessment report and concurs with the scientific consensus that the Earth is undergoing adverse global climate change and that anthropogenic contributions are significant. These climate changes will create conditions that affect public health, with disproportionate impacts on vulnerable populations, including children, the elderly, and the poor.
- 2. Supports educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
- 3. (a) Recognizes the importance of physician involvement in policymaking at the state, national, and global level and supports efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and (b) recognizes that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
- 4. Encourages physicians to assist in educating patients and the public on environmentally sustainable practices, and to serve as role models for promoting environmental sustainability.

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5. Encourages physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently, and that the AMA's Center for Public Health Preparedness and Disaster Response assist in this effort.

6. Supports epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment.

Citation: CSAPH Rep. 3, I-08; Reaffirmation A-14; Reaffirmed: CSAPH Rep. 04, A-19; Reaffirmation: I-19

Protective NAAQS Standard for Fine Particulate Matter (PM 2.5) H-135.946

Our AMA supports more stringent air quality standards for particulate matter. We specifically request a NAAQS that provides improved protection for our patients which includes:

- 12 μg/m3 for the average annual standard
- 25 µg/m3 for the 24-hour standard
- 99th percentile used for compliance determination.

Citation: BOT Action in response to referred for decision Res. 720, I-05; Reaffirmed in lieu of Res. 507, A-09; Modified: CSAPH Rep. 01, A-19

Protective NAAQS Standard for Particulate Matter (PM 2.5 & PM 10) D-135.978

At such time as a new EPA Proposed Rule on National Ambient Air Quality Standards for Particulate Matter is published, our AMA will review the proposal and be prepared to offer its support for comments developed by the American Thoracic Society and its sister organizations.

Citation: BOT action in response to referred for decision Res. 926, I-10; Reaffirmed: Res. 915, I-19;

Support the Health Based Provisions of the Clean Air Act H-135.950

Our AMA (1) opposes changes to the New Source Review program of the Clean Air Act; (2) urges the Administration, through the Environmental Protection Agency, to withdraw the proposed New Source Review regulations promulgated on December 31, 2002; and (3) opposes further legislation to weaken the existing provisions of the Clean Air Act.

Citation: (Res. 417, A-03; Reaffirmation A-05; Reaffirmation I-11)

Environmental Preservation H-135.972

It is the policy of the AMA to support state society environmental activities by:

- (1) identifying areas of concern and encouraging productive research designed to provide authoritative data regarding health risks of environmental pollutants;
- (2) encouraging continued efforts by the CSAPH to prepare focused environmental studies, where these studies can be decisive in the public consideration of such problems;
- (3) maintaining a global perspective on environmental problems;
- (4) considering preparation of public service announcements or other materials appropriate for public/patient education; and
- (5) encouraging state and component societies that have not already done so to create environmental committees.

Citation: Res. 52, A-90; Reaffirmed: Sunset Report, I-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

Clean Air H-135.979

Our AMA supports cooperative efforts with the Administration, Congress, national, state and local medical societies, and other organizations to achieve a comprehensive national policy and program to address the adverse health effects from environmental pollution factors, including air and water pollution, toxic substances, the "greenhouse effect," stratospheric ozone depletion and other contaminants.

Citation: Sub. Res. 43, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmation I-06; Reaffirmation I-07; Reaffirmed in lieu of Res. 507, A-09; Reaffirmed in lieu of Res. 509, A-09; Reaffirmed: CSAPH Rep. 01, A-19

Stewardship of the Environment H-135.973

The AMA: (1) encourages physicians to be spokespersons for environmental stewardship, including the discussion of these issues when appropriate with patients; (2) encourages the medical community to cooperate in reducing or recycling waste; (3) encourages physicians and the rest of the medical community to dispose of its medical waste in a safe and properly prescribed manner; (4) supports

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enhancing the role of physicians and other scientists in environmental education: (5) endorses legislation such as the National Environmental Education Act to increase public understanding of environmental degradation and its prevention; (6) encourages research efforts at ascertaining the physiological and psychological effects of abrupt as well as chronic environmental changes; (7) encourages international exchange of information relating to environmental degradation and the adverse human health effects resulting from environmental degradation; (8) encourages and helps support physicians who participate actively in international planning and development conventions associated with improving the environment; (9) encourages educational programs for worldwide family planning and control of population growth; (10) encourages research and development programs for safer, more effective, and less expensive means of preventing unwanted pregnancy; (11) encourages programs to prevent or reduce the human and environmental health impact from global climate change and environmental degradation.(12) encourages economic development programs for all nations that will be sustainable and yet nondestructive to the environment; (13) encourages physicians and environmental scientists in the United States to continue to incorporate concerns for human health into current environmental research and public policy initiatives; (14) encourages physician educators in medical schools, residency programs, and continuing medical education sessions to devote more attention to environmental health issues;

(15) will strengthen its liaison with appropriate environmental health agencies, including the National Institute of Environmental Health Sciences (NIEHS); (16) encourages expanded funding for environmental research by the federal government; and (17) encourages family planning through national and international support.

Citation: CSA Rep. G, I-89; Amended: CLRPD Rep. D, I-92; Amended: CSA Rep. 8, A-03; Reaffirmed in lieu of Res. 417, A-04; Reaffirmed in lieu of Res. 402, A-10; Reaffirmation I-16

Global Climate Change - The "Greenhouse Effect" H-135.977

Our AMA: (1) endorses the need for additional research on atmospheric monitoring and climate simulation models as a means of reducing some of the present uncertainties in climate forecasting; (2) urges Congress to adopt a comprehensive, integrated natural resource and energy utilization policy that will promote more efficient fuel use and energy production;

- (3) endorses increased recognition of the importance of nuclear energy's role in the production of electricity;
- (4) encourages research and development programs for improving the utilization efficiency and reducing the pollution of fossil fuels; and
- (5) encourages humanitarian measures to limit the burgeoning increase in world population. Citation: (CSA Rep. E, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-12; Reaffirmed in lieu of Res. 408, A-14)

Federal Clean Air Legislation H-135.984

- 1. Our AMA urges the enactment of comprehensive clear ambient air legislation which will lessen risks to human health.
- 2. Our AMA will: (a) oppose legislative or regulatory changes that would allow power plants to avoid complying with new source review requirements to install air pollution control equipment when annual pollution emissions increase; and (b) work with other organizations to promote a public relations campaign, strongly expressing our opposition to EPA's Affordable Clean Energy rule and its proposed amendments of the New Source Review requirements under the Clean Air Act.

 Citation: Res. 142, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation I-07; Reaffirmed in lieu of Res. 507, A-09; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation A-13; Reaffirmation A-14; Appended: Res. 917, I-18

Clean Air H-135.991

- (1) The AMA supports setting the national primary and secondary ambient air quality standards at the level necessary to protect the public health. Establishing such standards at the level necessary to protect the public health. Establishing such standards at a level "allowing an adequate margin of safety," as provided in current law, should be maintained, but more scientific research should be conducted on the health effects of the standards currently set by the EPA.
- (2) The AMA supports continued protection of certain geographic areas (i.e., those with air quality better than the national standards) from significant quality deterioration by requiring strict, but reasonable, emission limitations for new sources.

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(3) The AMA endorses a more effective hazardous pollutant program to allow for efficient control of serious health hazards posed by airborne toxic pollutants.

- (4) The AMA believes that more research is needed on the causes and effects of acid rain, and that the procedures to control pollution from another state need to be improved.
- (5) The AMA believes that attaining the national ambient air quality standards for nitrogen oxides and carbon monoxide is necessary for the long-term benefit of the public health. Emission limitations for motor vehicles should be supported as a long-term goal until appropriate peer-reviewed scientific data demonstrate that the limitations are not required to protect the public health.

Citation: (BOT Rep. R, A-82; Reaffirmed: CLRPD Rep. A, I-92; Amended: CSA Rep. 8, A-03; Reaffirmation I-06; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation I-09; Reaffirmation A-14)

Pollution Control and Environmental Health H-135.996

Our AMA supports (1) efforts to alert the American people to health hazards of environmental pollution and the need for research and control measures in this area; and (2) its present activities in pollution control and improvement of environmental health.

Citation: Sub. Res. 40, A-70; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

Reducing Sources of Diesel Exhaust D-135.996

Our AMA will: (1) encourage the US Environmental Protection Agency (EPA) to set and enforce the most stringent feasible standards to control pollutant emissions from both large and small non-road engines including construction equipment, farm equipment, boats and trains; (2) encourage all states to continue to pursue opportunities to reduce diesel exhaust pollution, including reducing harmful emissions from glider trucks and existing diesel engines; (3) call for all trucks traveling within the United States, regardless of country of origin, to be in compliance with the most stringent and current diesel emissions standards promulgated by US EPA; and (4) send a letter to US EPA Administrator opposing the EPAs proposal to roll back the glider Kit Rulewhich would effectively allow the unlimited sale of re-conditioned diesel truck engines that do not meet current EPA new diesel engine emission standards.

Citation: Res. 428, A-04; Reaffirmed in lieu of Res. 507, A-09; Reaffirmation A-11; Reaffirmation A-14; Modified: Res. 521, A-18

Research into the Environmental Contributors to Disease D-135.997

Our AMA will (1) advocate for greater public and private funding for research into the environmental causes of disease, and urge the National Academy of Sciences to undertake an authoritative analysis of environmental causes of disease; (2) ask the steering committee of the Medicine and Public Health Initiative Coalition to consider environmental contributors to disease as a priority public health issue; and (3) lobby Congress to support ongoing initiatives that include reproductive health outcomes and development particularly in minority populations in Environmental Protection Agency Environmental Justice policies.

Citation: Res. 402, A-03; Appended: Res. 927, I-11; Reaffirmed in lieu of: Res. 505, A-19;

AMA Position on Air Pollution H-135.998

Our AMA urges that: (1) Maximum feasible reduction of all forms of air pollution, including particulates, gases, toxicants, irritants, smog formers, and other biologically and chemically active pollutants, should be sought by all responsible parties.

- (2) Community control programs should be implemented wherever air pollution produces widespread environmental effects or physiological responses, particularly if these are accompanied by a significant incidence of chronic respiratory diseases in the affected community.
- (3) Prevention programs should be implemented in areas where the above conditions can be predicted from population and industrial trends.
- (4) Governmental control programs should be implemented primarily at those local, regional, or state levels which have jurisdiction over the respective sources of air pollution and the population and areas immediately affected, and which possess the resources to bring about equitable and effective control. Citation: BOT Rep. L, A-65; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation I-06; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation A-11; Reaffirmation A-12; Reaffirmation A-16; Reaffirmed: BOT Rep. 29, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505 (JUN-21)

Introduced by: Pennsylvania

Subject: Personal Care Products Safety

Referred to: Reference Committee E

Whereas, The Federal Food, Drug, and Cosmetic (FD&C) Act that is designed to ensure the safety of personal care products, referred to as "cosmetics" – including makeup, fragrance, lotion, toothpaste, body wash, shampoo, deodorant and more – has remained largely unchanged since the law was enacted in 1938: ¹ and

Whereas, FDA can pursue enforcement action against products on the market that are "adulterated" or "misbranded" and against firms or individuals who violate the law, manufacturers are not required to register in the Voluntary Cosmetic Registration Program and FDA estimates that only one-third of firms file cosmetic product ingredient statements; ² and

Whereas, Although companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products, and the Cosmetic Ingredient Review (CIR) Expert Panel that includes dermatologists, pathologists, toxicologists, and chemists set standards for components of cosmetics, there are currently no legal requirements for cosmetic manufacturers who market products to American consumers to test their products for safety; ^{1, 3} and

Whereas, FDA lacks authority to issue mandatory recalls of products based on safety concerns and can only warn consumers about contaminated products; and cosmetic firms are not required to initiate recalls when FDA becomes aware of adulterated or misbranded cosmetic products on the market; ² and

Whereas, Cosmetic firms are not required to provide any safety information to FDA even if requested by FDA during an inspection; ² and

Whereas, States may have more extensive requirements for cosmetic manufacturers, distributors, and packagers than exist federally, ⁴ while a nationwide standard would enable more uniform regulatory oversight; and

Whereas, FDA regulatory oversight authority is limited and FDA faces challenges in identifying and analyzing safety signals due to its lack of reliable and complete serious adverse event report data; ² and

Whereas, Firms are not required to follow FDA draft guidance on good manufacturing practices (GMPs) for cosmetics products; 2 and

Whereas, The program for cosmetics at the Center for Food Safety and Applied Nutrition, FDA's lead Center for the regulation of cosmetics, was approximately \$10 million or about three percent of the Center's budget, despite 2,727,847 lines of cosmetics products imported into the

Resolution: 505 (JUN-21) Page 2 of 4

United States from 177 countries in FY 2018, an increase of more than one million lines of annual cosmetic imports since one decade prior; ² and

Whereas, Based on different regulatory frameworks, there are few restrictions on materials that a cosmetic manufacturer may use as a cosmetic ingredient without premarket approval from FDA, ^{2, 5, 6} where the United States prohibits or restricts 11 types of harmful ingredients from cosmetics, while the European Union has banned or restricted more than 1,300 chemicals ⁷ often due to absence of safety data rather than data that shows harm; ⁸ and

 Whereas, Decisions should be evidence-based; 595 cosmetic manufacturers have reported using 88 chemicals that have been linked to cancer, birth defects or reproductive harm in more than 73,000 products since 2009, ^{4, 9} however, FDA has testified that most cosmetics on the market in the United States are safe and in rare cases when safety issues arise many firms work with FDA to address them; ² in addition a causative relationship between endocrine disruption and cancer and the concentration of certain ingredients in cosmetic products "has not been proven scientifically;" ^{10, 11} and

Whereas, Chemical use and concentration should be considered; researchers found that permanent hair dye and straighteners were associated with an increased risk for breast cancer ^{12, 13} and formaldehyde found in hair products can expose salon workers to health risks, ^{14,} however, parabens and formaldehyde releasers prevent severe infections and complications such as the *Pseudomonas*-induced corneal ulcers from inadequately preserved mascara; ^{15, 16} and

 Whereas, FDA confirmed the presence of asbestos in makeup products sold by two different retail stores, ^{17, 18, 19, 20} and asbestos exposure is associated with mesothelioma and cancers of the lung, larynx, and ovary; and linked to increased risks of cancers of the stomach, pharynx, and colorectum; ²¹ and

Whereas, FDA discovered elevated lead levels in a bentonite clay product sold online and in retail outlets, and lead poisoning can lead to anemia, weakness, kidney and brain damage, and death; and pregnant women who are exposed to lead will also expose their unborn child, which can cause potentially serious health complications; ^{22, 23} and

 Whereas, Restrictions should be evidence based; for example, propyl paraben is used in a wide range of products, a finding of questionable significance in a topically applied personal care product since parabens are poorly absorbed percutaneously, ¹⁰ studies have shown that some parabens injected in very high doses were found to be thousands to millions of times weaker than estradiol in rats and yeast cells, ^{11, 24} a study that claimed to find parabens in human breast tumors lacked a control group and parabens were found in blank samples, ^{11, 25} and the CIR extensively reviewed the scientific literature on paraben safety and concluded that the parabens as currently used in personal care products in the United States are safe; ¹⁰ and

Whereas, AMA policy H-440.855 supports that FDA should be able to recall cosmetic products that it deems to be harmful and supports creation of a publicly available registry, however, the registry remains voluntary with limited participation by manufacturers; therefore be it

Resolution: 505 (JUN-21)
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1 RESOLVED, That our American Medical Association advocate that the Food and Drug

- 2 Administration (FDA) be given the appropriate resources and authority to effectively regulate
- 3 and enforce standards for personal care products, including being authorized to mandate
- 4 registration and reporting by manufacturers, conduct appropriate inspections of manufacturing
- 5 facilities, ensure robust review of product safety, and require adherence with Good
- 6 Manufacturing Practices while allowing flexibility for small business to comply; and reaffirm
- 7 support for providing the FDA with sufficient authority to recall cosmetic products that it deems
- 8 to be harmful. (Directive to Take Action)

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

Received: 05/11/21

AUTHOR'S STATEMENT OF PRIORITY

The Pennsylvania Delegation would appreciate the committee considering its Resolution A-20, "Personal Care Products Safety," to be "High Priority" for the upcoming June HOD. Safety concerning products in personal cosmetics sold to American consumers is of utmost importance to both those who use them, and their physicians, who are responsible for the health and safety to some degree of all patients. Federal law designed to make sure laws are safe in this regard have not changed since 1938. Over time, only 11 chemicals identified in American cosmetics have been banned, as opposed to more than 1,300 in Europe. Clearly, we are way behind in providing safe cosmetics for American citizens. The personal care products needing safety scrutiny include hair, lotion, makeup, toothpaste, shampoo, deodorant, body wash and fragrance – all staples of use by millions of people in our country. Known carcinogenic chemicals previously identified in cosmetics include asbestos, hair dye and hair straighteners; lead, propyl paraben and formaldehyde are others with known adverse health effects that have been identified. Clearly, this is a public health hazard of extreme proportions that can be begun to be addressed by introducing new bipartisan legislation that requires the FDA to evaluate a minimum of 5 ingredients found in personal care products sold in the U.S. It behooves the AMA to take the lead in investigating the scope and extent of possible harm and injury of personal care safety products to U.S. consumers, who are all our patients.

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- $^{5} \underline{\text{https://www.fda.gov/cosmetics/resources-consumers-cosmetics/cosmetics-safety-qa-prohibited-ingredients}}$
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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506 (JUN-21)

Introduced by: Pennsylvania

Subject: Wireless Devices and Cell Tower Health and Safety

Referred to: Reference Committee E

Whereas, Industry propaganda is masking and mitigating the scientific evidence showing concerning biological effect to pulsated microwave and millimeter wave electromagnetic fields (EMF), the type of radiation emitted from all of our wireless devises (cell phones, cell phone towers, WiFi, computers, smart TV, smart meters, bluetooth, etc); and

Whereas, Most citizens are under the false impression that there are bonafide safety guidelines set forth by the FCC. The safety guidelines, established in 1996 under the leadership of telecommunications lobbyist Tom Wheeler, are ONLY based on an erroneous assumption that microwaves are dangerous when they heat liquids up (so-called "thermal" EMF), much like a microwave oven; and

Whereas, Now there is overwhelming scientific evidence that non-thermal EMFs can cause significant health effects at levels that are orders of magnitudes lower than those allowed by these FCC guidelines; and

Whereas, The data shows that fetuses and children are far more vulnerable to these effects, as they have higher surface to volume ratios, high densities of stem cells, a developing brain, and tissue with greater extracellular water leading to deeper penetration effects; and

Whereas, Based on the 1996 Telecommunications Act, local jurisdictions do not have the right to approve or disapprove the placement of cell tower based on safety or health reasons. In the last two years, Verizon and AT&T have tried twice to convince the PA General Assembly to approve a bill that further preempts municipal rights for managing 5G cell towers in the public rights-of-way; therefore be it

RESOLVED, That our American Medical Association oppose legislation that blocks the public's right to guard its own safety and health regarding cell tower placement (Directive to Take Action); and be it further

RESOLVED, That our AMA promote ways to reduce radiation exposure from wireless devices, especially for pregnant women and children (wired devices preferable to wireless, shielding, etc.). (Directive to Take Action)

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

Received: 05/11/21

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AUTHOR'S STATEMENT OF PRIORITY

With the pervasiveness of wireless communication in our present-day society, the resolution is concerned with the possible effects of EMF (electromagnetic field) on humans, particularly the more vulnerable such as children and fetuses.

It is felt that the standards for such safety, established in 1996, were biased by lobbyist, and exclusive of other scientific criteria. Furthermore, the telecommunications act of 1996 usurps local jurisdiction on the placement of telecommunication towers.

It is therefore requested that our AMA oppose legislation that may block the public's "access to know" in these matters and foster shielding of EMF effects from wireless devices.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507 (JUN-21)

Introduced by: Colorado, American Academy of Ophthalmology, GLMA: Health

Professionals Advancing LGBTQ Equality, American Society

of Cataract and Refractive Surgery

Subject: Evidence-Based Deferral Periods for MSM Donors of Blood, Corneas and

Other Tissues

Referred to: Reference Committee E

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

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

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

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

Whereas, Corneas are an avascular tissue and are not a major reservoir of HIV12; and

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

Whereas, MSM blood donors are only ineligible for 3 months after last sexual contact, despite the known risk of HIV transmission through blood transfusions¹³; and there is no deferral period whatsoever for MSM donors of solid organs (such as hearts, lungs, kidneys, etc.)^{14,15}; and

Whereas, Many peer nations have no deferral period for MSM corneal donors whatsoever (e.g. Spain, ¹⁶ Italy, ¹⁷ Mexico, ¹⁸ Chile, ¹⁹ Argentina, ²⁰ Germany, ²¹ Denmark, ²² South Africa²³); and

Whereas, Many other peer nations have deferral periods for MSM corneal donors far shorter than 5 years (e.g. 3 months in the United Kingdom,²⁴ 4 months in the Netherlands,²⁵ 4 months in France,²⁶ 12 months in Canada²⁷); and

Whereas, AMA Policy H-50.973, "Blood Donor Deferral Criteria," states that AMA supports blood donor deferral criteria that are "representative of current HIV testing technology" but does not address the FDA's even stricter deferral criteria for MSM donors of corneas and other tissues²⁸; and

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Whereas, A recent *JAMA Ophthalmology* study estimated that between 1558 and 3217 potential corneal donations were disqualified in 2018 alone in the United States and Canada due to the two countries' bans on MSM corneal donors³; and

Whereas, An estimated 12.7 million visually impaired patients are in need of corneal transplant surgery worldwide, with only 1 cornea donated for every 70 corneal transplants needed²⁹; therefore be it

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

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

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

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

Received: 05/12/21

AUTHOR'S STATEMENT OF PRIORITY

We believe this resolution meets all the criteria to be classified as "High Priority." Corneal transplantation is the most commonly performed transplant surgery in the United States, yet there is only 1 cornea donated for every 70 corneal transplants needed worldwide. A recent *JAMA Ophthalmology* study estimated that up to 3217 blind patients a year are deprived of vision-restoring surgery due to outdated FDA policy banning corneal donation by men who have had sex with another man in the preceding 5 years, even if all infectious disease testing is negative.

AMA has spoken clearly and repeatedly to advocate for evidence-based guidelines for MSM *blood* donation, yet AMA has never previously advocated for changes to the FDA's separate policies preventing MSM donation of corneas and other tissues. This represents a substantial gap in AMA policy. Arguing for evidence-based health policy and for equitable treatment of the LGBTQ community is consistent with AMA's mission and existing policy.

Since the FDA's policy for MSM corneal donors is classified as *regulatory guidance* and not as an official regulation, the FDA could change its stance on this issue through a simple press release, without requiring an act of Congress or a formal "notice and comment" process. The relative bureaucratic ease of this change means that there is a realistic chance that AMA advocacy could convince the FDA to act. Any further delay would continue to deprive thousands of blind patients of vision-restoring surgery, while allowing an inequitable health policy against the LGBTQ community to endure.

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