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REPORT 02 OF THE BOARD OF TRUSTEES (I-23)
Opposing the Use of Vulnerable Incarcerated People in Response to Public Health Emergencies
(Reference Committee K)

EXECUTIVE SUMMARY

INTRODUCTION. At the 2022 Interim Meeting of the American Medical Association (AMA) House of Delegates, Resolution 901-I-22, "Opposing the Use of Vulnerable Incarcerated People in Response to Public Health Emergencies" was referred. This resolution called on the AMA to: (1) oppose the use of forced or coercive labor practices for incarcerated populations, (2) support that any labor performed by incarcerated individuals or other captive populations should include adequate workplace safety and fairness standards similar to those outside of carceral institutions and (3) support their reintegration into the workforce after incarceration.

DISCUSSION. Our nation incarcerates more than 1.2 million people in state and federal prisons, and two out of three of these incarcerated people are also workers. Reports note that individuals who are incarcerated are required to work or face additional punishment such as solitary confinement, denial of opportunities to reduce their sentence, and loss of family visitation. U.S. law explicitly excludes workers who are incarcerated from the most universally recognized workplace protections. Workers who are incarcerated are not covered by minimum wage laws or overtime protection, are not afforded the right to unionize, and are denied workplace safety guarantees. A majority of incarcerated workers surveyed say that they received no formal job training, and many also say they worry about their safety while working. Incarcerated workers with minimal experience or training are often assigned hazardous work in unsafe conditions and without standard protective gear, leading to preventable injuries and deaths.

Further, at least 30 states explicitly include incarcerated workers as a labor resource in their emergency operations plans for disasters and emergencies. Incarcerated workers were especially vulnerable to exploitation during the COVID-19 pandemic. Workers in at least 40 states were forced to produce masks, and other personal protective equipment during early pandemic lockdowns as COVID-19 tore through prisons, even as they often lacked access to these protective tools themselves.

This report discusses the impact of excluding individuals who are incarcerated from health and safety protections, the types of labor performed by individuals who are incarcerated, benefits and harms of incarcerated labor, and examines the incentives behind incarcerated labor. The report also provides a historical look at the root of incarcerated labor.

CONCLUSION. Individuals who are incarcerated face various inequities while performing labor in correctional facilities. The recommendations address these inequities and provide actions that can be taken by the AMA, by Congress, state legislatures, and correctional facilities to ensure that individuals who are incarcerated are provided appropriate rights and protections during labor.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 02-I-23

Subject: Opposing the Use of Vulnerable Incarcerated People in Response to Public Health Emergencies (Resolution 901-I-22)

Presented by: Willie Underwood III, MD, MSc, MPH, Chair

Referred to: Reference Committee K

INTRODUCTION

At the 2022 Interim Meeting of the American Medical Association (AMA) House of Delegates, Resolution 901-I-22, "Opposing the Use of Vulnerable Incarcerated People in Response to Public Health Emergencies," was referred. This resolution called on the AMA to oppose the use of forced or coercive labor practices for incarcerated populations, support that any labor performed by incarcerated individuals or other captive populations should include adequate workplace safety and fairness standards similar to those outside of carceral institutions, and support their reintegration into the workforce after incarceration.

BACKGROUND

The U.S. incarcerates over 1.2 million people in state and federal correctional facilities, and two out of three of these individuals who are incarcerated are also workers.[1] In most instances, the jobs of individuals who are incarcerated have looked similar to those of millions of people working on the outside. These jobs include working as cooks, dishwashers, janitors, groundskeepers, barbers, painters, and plumbers.[1] They manufacture products like office furniture, mattresses, license plates, dentures, glasses, traffic signs, athletic equipment, and uniforms.[1] They also cultivate and harvest crops, work as welders and carpenters, and work in meat and poultry processing plants.[1]

The incarcerated workforce provides vital public services such as repairing roads, fighting wildfires, or clearing debris after hurricanes.[1] This was especially evident during the COVID-19 pandemic where many individuals who were incarcerated were tasked with manufacturing masks, medical gowns, face shields, and other personal protective equipment that they were then prohibited from using to protect themselves.[2,3] Individuals who were incarcerated also worked in morgues, transported dead bodies, dug mass graves, and built coffins. They washed soiled hospital laundry, disinfected supplies, and cleaned medical units.[1,3]

HISTORY BEHIND INCARCERATED LABOR

Incarcerated labor has a long history in the United States and is rooted in racial oppression. The origins of incarcerated labor programs can be traced to the end of the Civil War and the passage of the 13th Amendment of the Constitution in 1865.[4] The 13th Amendment outlawed slavery and involuntary servitude, "except as a punishment for crime whereof the party shall have been duly convicted.[5]" What followed was a rise in practices designed to incarcerate and exploit Black people

and recently freed enslaved people.[6] One such practice was convict leasing. The system of convict leasing allowed correctional facilities to hire out or "lease" individuals who are incarcerated as laborers to private parties, such as railways, mines, or plantations.[6] Individuals who are incarcerated were not paid in this arrangement.[7]

The Convict Leasing System in the North and South

In the North, incarcerated people were often contracted out to private individuals and entities to perform labor in industrial factories.[8] Incarcerated laborers were often forced to work 14 to 16 hours a day and were brutally punished for many inhumane reasons.[8] These severe punishments allowed Northern states to produce in one year alone what, in today's dollars, amounts to over $30 billion worth of prison-made goods.[8] By the late 1800s, over 75 percent of the North's incarcerated population worked in these factories. This economic exploitation fell largely upon impoverished, immigrant, and African American communities who made up the majority of the incarcerated population in the North.[8]

In the South, conditions for people who were incarcerated were just as brutal, with workers who were incarcerated forced to labor for up to 17 hours each day, building factories, laying railroads, and mining coal.[8,9] Under the convict leasing system, private employers could bid on and "lease" individuals who are incarcerated for days, months, or years to work on plantations and at coal mines, turpentine farms, sawmills, phosphate pits, railways, and brickyards.[10] These private employers had unregulated control over unpaid, predominantly Black workers and subjected them to brutal punishments such as whipping and branding and, in many cases, worked people who were incarcerated to death.[11] For example, in Mississippi, not a single leased convict lived long enough to serve a 10-year sentence.[11]

Black Codes

Since the convict leasing system was so profitable, new laws known as "Black Codes" were passed which permitted sheriffs to arrest Black men on baseless charges and indirectly allowed states to expand their convict leasing programs.[12] Scholars note that these racist regulations emerged in 1865 as white-dominated Southern legislatures passed a series of laws that restricted the rights of newly freed Black citizens and allowed the state to maintain control over them.[6] The codes also limited Black people's ability to quit a job by criminalizing and imprisoning those who left a job for which they had a contract with the employer, which was often a requirement for employment.[13] Under the Black Codes and later the Jim Crow laws, the incarcerated population expanded, providing a large pool of unprotected and unpaid laborers for individuals or companies that wanted to profit off nonexistent labor costs.[13,14,15]

Shift From Convict Leasing System to Chain Gangs

By the 1890s, 35 states succumbed to rising union pressure to scale back incarcerated labor programs to reduce competition in the labor market. The result of this concession was the implementation of the "state-use system," in which the state became the only lawful purchaser of incarcerated labor and goods.[16] When Congress established the first federal correctional facilities in 1891, a similar system was adopted in which people who were incarcerated could be forced to work and produce certain commodities, provided that these workers were employed exclusively in the manufacture of such supplies for the government.[17] As state corrections systems expanded, the number of state-sponsored incarcerated labor programs expanded as well. Work crews, commonly known as chain gangs, were first established in the 1890s in Georgia and spread throughout the South as states began to phase out the convict lease system.[18] These chain gangs consisted of

individuals who are incarcerated, the vast majority of whom were Black men, who were forced to engage in unpaid labor in brutal conditions outside of the correctional facility, such as road construction, ditch digging, rock breaking, highway maintenance, and farming, under the supervision of correctional officers armed with shotguns and whips.[1,18] Chain gangs became more prevalent in the early 20th century as states gradually abolished the convict leasing system. By 1923 every state except for Rhode Island had used chain gangs to build and repair roads.[1,18]

Establishment of Work-Release Programs and Restitution Centers

In 1913, Wisconsin established the first work-release program in the United States.[19] This program allowed those convicted of misdemeanors to leave jail during the day for the limited purpose of attending work.[19] Since the workers' wages were collected directly by the jail, which also profited from reduced supervisions costs, the model proved to be quite cost-effective.[1,19] Several states were quick to adopt near-identical versions of the Wisconsin program, while others sought to further reduce the costs associated with incarcerating large groups by expanding the program to allow those convicted of minor felonies to participate as well.[1,19]

A similar growth in incarcerated labor programs occurred within the federal system as well. In 1934, four years after the Federal Bureau of Prisons was first established, Congress authorized the creation of the Federal Prison Industries program.[1,19] This program allowed federal correctional facilities to employ individuals who are incarcerated for manufacturing of supplies, the construction of public works, and the maintenance and care of the institutions of the state in which they are imprisoned.[20] The initial aim of this program, like many of those discussed above, was to offset the costs of incarceration by allowing state governments to profit from incarcerated labor.[12] Like the state-use system, this program drew intense criticism from union groups who were concerned that incarcerated labor would displace "free labor.[1,12]" In response, Congress passed several pieces of legislation that outlawed the use of incarcerated labor to maintain federal highways and prohibited the interstate sale of prison-made goods but allowed certain exceptions which allowed states and the federal government to continue benefiting from incarcerated labor.[1,12,21]

In the 1970s, Congress and individual states increasingly allowed private entities and state governments to benefit from incarcerated labor.[1,12] For example, in 1972, Minnesota established America's first "restitution centers" in which low-level offenders were "paroled" out of jail only to be sent to a lower-security confinement facility where they were required to secure employment to pay off any victim restitution which they owed, or otherwise participate in community service.[22] Similar to work release programs, these restitution centers proved incredibly cost-effective and, in the years that immediately followed, were rapidly adopted by other states.[23]

"War on Drugs" to Present Day

Scholars argue that the modern-day iteration of these same practices is the U.S. government's "War on Drugs," which has resulted in increased enforcement for low-level drug crimes and overly punitive sentencing schemes for drug offenses.[24] These practices are disproportionately enforced against communities of color and directly contribute to the drastic rise in carceral populations, which has tripled since 1980.[25] At present, approximately 55 percent of the U.S. carceral population works while serving their sentences.[26] Sometimes people who are incarcerated may "volunteer" to work for barely any payment as they have no other source of income while incarcerated.[27] In many other cases, labor is neither voluntary nor compensated and yet is still deemed acceptable under the punishment exception.[28] Certain states have codified requirements for participation in work programs and repercussions for anyone refusing to work when jobs are

available.[29] In the absence of formal statutes that regulate incarcerated labor, individuals who are incarcerated who refuse work also face threats from guards that they will be placed in solitary confinement, transferred to dangerous housing units, or lose some of their good-time credits.[30]

WORKPLACE SAFETY FOR INDIVIDUALS WHO ARE INCARCERATED

Occupational Health and Safety Administration (OSHA)

OSHA sets workplace safety standards and provides education and training to ensure that standards are met.[31,32] In addition to standard-setting, OSHA has enforcement powers to receive worker complaints, conduct inspections, and issue citations to employers for safety violations. Importantly, the Occupational Safety and Health (OSH) Act's remedial positioning does not require that an injury occur before the agency is authorized to promulgate health and safety standards and issue citations.[32,33] OSHA provides no private right of action for workers to bring suit against their employers in court.[32,34] The OSH Act allows employees to file complaints with the agency when they believe that their workplace is in violation of a health or safety standard, or that working conditions present an imminent danger.[31,32] If OSHA determines that there are reasonable grounds to believe that a violation or danger exists, the agency must initiate an inspection as soon as practicable, to determine if such violation or danger exists.[31,32]

Although the OSH Act federalized workplace safety and health regulations and offers broad coverage to employees across the country, state and local government employees are statutorily exempted from coverage under the federal act.[35] This exemption for state employees reflects the federal government's desire to avoid unnecessary interference with a state's public administration, and to allow states themselves to regulate the health and safety of their employees. This is supported by provisions in OSH Act that allow states to opt out of regulation by federal OSHA by designing their own state health and safety plans, as long as the state plan is at least as effective as the federal program.[36]

OSHA's Applicability to Individuals who are Incarcerated

The standards promulgated by OSHA and the enforcement mechanisms available under OSH Act only cover workers who are classified as "employees."[36] The term "employee" is defined by the Act as follows: an employee is "an employee of an employer who is employed in a business of his employer which affects commerce."[37] This definition, similar to definitions of employee in many other federal statutes, gives little guidance as to whom the statute is intended to cover. The question of which workers qualify as employees and therefore, who should receive protections is a controversial and important threshold question in most areas of employment and labor law.[38]

OSHA had long interpreted its authorizing statute to exclude most incarcerated workers from its protections, primarily through agency interpretations of the term "employee."[36] In 1995, OSHA issued an agency directive interpreting OSH Act to exclude federal individuals who are incarcerated from employee status.[39] OSHA advised that although no individuals who are incarcerated are statutorily protected as "employees," workers who are incarcerated and are required to perform work similar to that outside of prisons are entitled to the applicable protections open to anyone else in similar situations, including the right to file a report of hazards with appropriate safety and health officials.[39,40] This directive suggests that the agency's jurisdiction does not extend to the large number of workers who perform "prison housework," such as cooking, serving food, and janitorial duties. Furthermore, at least one court has found that OSHA safety standards in the federal correctional facility context are advisory, rather than mandatory.[41]

OSHA has interpreted the statute's exclusion of state employers and employees from OSHA's jurisdiction to include those who are incarcerated and detained in state facilities.[42] In its interpretation letter on this matter, OSHA appears to presume that workers who are incarcerated are covered under state health and safety regulations, to the extent that said regulations exist for state employees.[43] However, since 23 states do not fill the state and local government gap in OSHA's coverage with their own health and safety plan, individuals who are incarcerated and detainees in those states are presumably also not covered by any state-issued health and safety standards.[44] Correctional officers and staff are covered under state plans, but most state agencies do not appear to directly respond to complaints by incarcerated workers.[45,46]

Accreditation and Standards for Correctional Facilities

Currently the National Commission on Correctional Health Care (NCCHC) establishes rigorous standards for health services in correctional facilities. This done by operating a voluntary accreditation program for institutions that meet those standards, offering certification for correctional health professionals, conducting educational conferences and webinars, and producing industry-specific publications and other resources. [47,48] Established by health, mental health, legal, and corrections professionals, NCCHC's standards cover the areas of patient care and treatment, governance and administration, personnel and training, safety and disease prevention, special needs and services, and medical-legal issues.[49] Some state, federal, and private correctional facilities point to accreditation by outside, private organizations like the American Correction Association (ACA) to establish that their correctional facilities comply with health and safety standards.[49] This accreditation agency publishes authoritative standards for correctional operations and conducts triennial reaccreditations of state, federal, and privately-operated correctional and detention facilities.[50] For a facility to become ACA-accredited, it must comply (at the time of accreditation) with a certain percentage of mandatory and non-mandatory standards.[51] The accreditation system relies on self-evaluation, paper audits, and on-site inspections for which the facility is given three months' notice to prepare.[52] It should be noted that there is no mechanism for those who are incarcerated to raise health and safety concerns and file complaints about non-compliance with the accreditation standards.[49,50]

PRESENT DAY LOOK AT INCARCERATED LABOR

Types of Incarcerated Work

More than 80 percent of incarcerated workers in state and federal correctional facilities who were surveyed by the Bureau of Justice Statistics reported working in jobs that served to maintain the correctional facilities where they are incarcerated.[53] Approximately 30 percent of all incarcerated workers perform general janitorial duties, nearly 20 percent work in food preparation or carry out other kitchen duties, 8.5 percent provide grounds maintenance, 6.6 percent work in maintenance or repair, 4.5 percent work in laundry, and 14.1 percent perform essential services by working in correctional hospitals or infirmaries, libraries, stockrooms, stores, and barber shops.[1,52]

State correctional facilities, constitute a second type of incarcerated labor program that accounts for about 6.5 percent of incarcerated jobs.[1.52] The number of incarcerated workers employed in state correctional facility programs has been dropping in recent years, from 91,043 in 2008 to 51,569 in 2021.[1,52] These are jobs in state-owned corporations that produce goods, services, and commodities sold to other government agencies. Many states require all state agencies, political units, and public institutions to purchase manufactured goods, including furniture, cleaning supplies, printed materials, and uniforms, from their state correctional facilities.[54] States also rely on incarcerated

workers to provide a variety of services, such as data entry, repairing state-owned vehicles, and washing laundry for public hospitals and universities.[1]

A third category of incarcerated labor is public works assignments, sometimes referred to as "community work crews," for the benefit of state, municipal, and local government agencies and occasionally nonprofit organizations.[1] States and municipalities contract with state departments of corrections to use the labor of incarcerated workers for a variety of public works projects such as maintaining cemeteries, school grounds, fairgrounds, and public parks; construct buildings; clean government offices; clean up landfills and hazardous spills; undertake forestry work in state-owned forests; and treat sewage.[1] One study found that at least 41 state departments of correction have public works programs that employ incarcerated workers.[1] Through such programs, incarcerated workers also perform critical work preparing for and responding to natural disasters, including sandbagging, supporting evacuations, clearing debris, and assisting with recovery and reconstruction after hurricanes, tornadoes, mudslides, or floods.[1,55]

A fourth category of incarcerated labor is work for private industries through the Prison Industry Enhancement Certification Program (PIECP), which allows private companies to produce goods and services using incarcerated labor.[56] Some individuals who are incarcerated work directly for the private company while others are employed by the correctional facility and are contracted out to the company.[57] PIECP employs the smallest number, approximately 1 percent, of people who are incarcerated.[58] Some incarcerated workers engage in farming or ranching work for correctional facility programs or for private corporations through PIECP programs to produce livestock, crops, and other agricultural products for sale.[1,57] Some of this agricultural work occurs on penal plantations or prison farms, some of which are situated on land that was originally the site of slave plantations.[1]

Residential Reentry Centers (RRC)

The Federal Bureau of Prisons (BOP) contracts with RRC, also known as halfway houses, to provide assistance to incarcerated individuals who are nearing release.[59] Contrary to the belief that halfway houses are supportive service providers, the majority of halfway houses are an extension of the carceral experience, complete with surveillance, onerous restrictions, and intense scrutiny.[60] RRCs are meant to provide a safe, structured, supervised environment, as well as employment counseling, job placement, financial management assistance, and other programs and services.[60] RRCs are meant to help incarcerated individuals gradually rebuild their ties to the community and facilitate supervising ex-offenders' activities during this readjustment phase. RRC staff should assist incarcerated individuals in obtaining employment through a network of local employers, employment job fairs, and training classes in resume writing, interview techniques, etc.[60] Typically, incarcerated individuals are expected to be employed 40 hours/week within 15 calendar days after their arrival at the RRC.[60]

In federal RRCs, staff are expected to supervise and monitor individuals in their facilities, maintaining close data-sharing relationships with law enforcement.[61] Disciplinary procedure for violating rules can result in the loss of good conduct time credits, or being sent back to prison or jail, sometimes without a hearing. Most states do not release comprehensive policy on their contracted halfway houses.[61] Lack of publicly available data makes it difficult to hold facilities accountable. Basic information like how many facilities there are and what conditions are like is difficult for several reasons:

- No standard, transparent policies. There are few states that publicly release policies related to contracted halfway houses. In states like Minnesota, at least, there appear to be very loose guidelines for the maintenance of adequate conditions within these facilities.[61]
- Privatization. The majority of halfway houses in the United States are run by private entities, both nonprofit and for-profit. For example, the for-profit GEO Group recently acquired Community Education Centers, which operates 30 percent of all halfway houses nationwide.[62] Despite their large share of the industry, they release no publicly available data on their halfway house populations. The case is similar for other organizations that operate halfway houses.
- Poor federal data collection. The Bureau of Justice Statistics does periodically publish some basic data about halfway houses, but only in one collection (the Census of Adult State and Federal Correctional Facilities), which isn't used for any of the agency's regular reports about correctional facilities or populations.[63]
- Lack of oversight. The most comprehensive reporting on conditions in halfway houses are audits by oversight agencies from the federal government or state corrections departments. Since 2013, only 8 audits of federal RRCs have been released by the Office of the Inspector General.[64]

Benefits of Incarcerated Labor

One of the main advantages of using the incarcerated workforce is that it can decrease costs for companies.[65] By using individuals who are incarcerated for work, companies can save money on wages and benefits. Additionally, incarcerated labor can help reduce recidivism rates by providing individuals who are incarcerated with job skills and experience.[1,58] This can increase their chances of finding employment once they are released from correctional facilities. Another benefit is that it can help reduce overcrowding in correctional facilities.[58] When individuals who are incarcerated are engaged in work, they are less likely to engage in disruptive behavior, which can lead to disciplinary action and extended sentences.[1,58] This can ultimately lead to a reduction in the number of individuals who are incarcerated in correctional facilities. Further, companies that use incarcerated labor can contribute to the rehabilitation of individuals who are incarcerated. By providing them with meaningful work and skills training, companies can help individuals who are incarcerated develop a sense of purpose and self-worth. This can lead to improved mental health and a reduced likelihood of reoffending.[1,58]

Today, incarcerated labor is an integral part in the lives of individuals who are incarcerated and the economy. Incarcerated labor contributed to large productions of PPE during the COVID-19 pandemic.[2] In 2020 alone, a report revealed that over 4,100 corporations profited from the use of incarcerated labor.[66] According to the National Correctional Industries Association, the value of saleable goods and services produced by incarcerated workers in prison industries programs nationwide totaled $2.09 billion in 2021.[1,67]

Harms of Incarcerated Labor

Despite some of the advantages of using incarcerated labor, there are also many drawbacks. One of the main concerns is that incarcerated labor may be exploitative.[1,58] Individuals who are incarcerated are often paid low wages and do not have the same protections as other workers. For example, individuals who are incarcerated are only paid $0.23–$1.15 per hour, and portions of these wages are often garnished to cover court fees or other incarceration-related expenses.[68] In comparison, the federal minimum wage is currently $7.25 per hour, and many states impose higher minimum-wage requirements.[69] Using incarcerated labor may also perpetuate the cycle of poverty

and incarceration.[1,58] Individuals who are incarcerated who work for low wages may struggle to support themselves and their families after they are released from correctional facilities, leading them to turn to crime again.[1] Forced labor can also displace educational benefits like GED programs, college programs, and skills training. Further, the use of incarcerated labor can also lead to human rights abuses. In some cases, individuals who are incarcerated have been forced to work in dangerous or unhealthy conditions, without proper safety equipment or training.[1]

As noted above, individuals who are incarcerated sometimes work in dangerous industrial settings or other hazardous conditions that would be closely regulated by federal workplace health and safety regulations, if they were not incarcerated. Sixty-four percent of incarcerated workers surveyed in a study stated that they felt concerned about their safety while working.[1] The study also noted that incarcerated workers with minimal experience or training are assigned work in unsafe conditions and without protective gear that would be standard in workplaces outside correctional facilities.[1] As a result, incarcerated workers have been burned with chemicals, maimed, or killed on the job. Although lack of data related to workplace conditions and injuries in correctional facilities makes it difficult to know the full extent of injuries and deaths, injury logs generated by the California Prison Industry Authority show that incarcerated workers reported more than 600 injuries over a four-year period, including body parts strained, crushed, lacerated, or amputated.[70] Further, incarcerated workers report receiving inadequate training on how to handle hazardous chemicals, operate dangerous equipment with cutting blades, clean biohazardous materials like excrement and blood, and use dangerous kitchen equipment.[1]

Workers who are incarcerated are employed at dangerous meat, poultry, and egg processing plants, where lack of adequate training or safety procedures has led to dozens of documented injuries and at least one death of a worker who was incarcerated.[1] Workers who are incarcerated have also been severely injured—even paralyzed and killed— by falling trees and tree limbs while cutting down trees on community work crews and in forestry and firefighting jobs.[71] In California, where research has shown that workers who are incarcerated were more likely to be injured than professional firefighters, at least four incarcerated firefighters have been killed while fighting wildfires, and more than 1,000 required hospital care during a five-year period.[72] Further, workers who are incarcerated endure brutal temperatures with inadequate water or breaks, while working outdoors and inside facilities without air conditioning. Incarcerated firefighters have been sickened and killed by heat exposure during routine training exercises in California.[73]

Race and Gender Discrimination Play a Role in Job Assignments

Studies have found that correctional facilities allocate job assignments along racial lines, even when they have contrary policies in place.[74] Desirable jobs, such as more highly paid work in the call center or the fleet garage where police vehicles are serviced, were more often allocated to white incarcerated people. This can result from biased decisions made by correctional officers as well as systems that rely on peer referral for consideration. A 2016 study found that Black men have significantly higher odds of being assigned to maintenance and other facility services work than white men—41.2 percent of Black men and 35.3 percent of white men were assigned such jobs, which are typically paid the lowest wage, if at all.[75]

Discrimination also occurs along gender lines. A study noted that white male incarcerated workers are disproportionately more likely to be assigned to higher-paying, skilled, vocational labor assignments than their minority and female counterparts.[76] Numerous women incarcerated at the South Idaho Correctional Institute reported to the ACLU of Idaho that there is a lack of training opportunities as compared to men.[1] For example, men have an opportunity to obtain their commercial driver's license. That opportunity, however, is not available to incarcerated women. Further it was noted that the white incarcerated individuals get the plumbing, electrician, and

carpentry jobs; and the Black and Latino incarcerated individuals get the jobs like kitchen, yard gang, laundry, clothing, but none of the jobs that can train incarcerated individuals to get a good job once released.[1] Discrimination is even more prominent in incarcerated pregnant individuals who already have limited rights.[77] Further, pregnant incarcerated individuals oftentimes have to work to support their families but lack workplace protections.[78] Work inside correctional facilities provide limited medical care to incarcerated individuals and therefore their reproductive health and pregnancy needs are generally not being appropriately addressed.[79]

Reentry is another critical point at which women are too often left behind. Almost 2.5 million women and girls are released from prisons and jails every year, but few post-release programs are available to them — partly because so many women are confined to jails, which are not meant to be used for long-term incarceration.[79] Additionally, many women with criminal records face barriers to employment in female-dominated occupations, such as nursing and elder care.[78] Compounding issues, formerly incarcerated women — especially women of color — are also more likely to be unemployed and/or homeless than formerly incarcerated men, making reentry and compliance with probation or parole even more difficult.[78]

SHOULD OSHA COVER INDIVIDUALS WHO ARE INCARCERATED?

The statutory purpose of OSH Act—to protect working individuals—is a broad mandate. Despite the absence of a statutory exemption for individuals who are incarcerated, OSHA and its state counterparts have interpreted the Act to not cover most incarcerated correctional facility workers.[35-37,67] Even for the small number of incarcerated workers covered by federal OSHA standards, the enforcement mechanism is limited by restrictions on surprise inspections and a lack of protection from reprisals for submitting complaints.[35-37,67] This significant gap in coverage under the OSH Act leaves some of the most vulnerable workers—often working in dangerous settings with little agency—at high risk for workplace accidents, illness, and death. Scholars argue that safe and healthful working conditions should not hinge on whether that labor is voluntary or on where the labor is performed.[80] It is also important to note that there is no other effective mechanism for incarcerated workers to raise concerns about dangerous workplace conditions and hold correctional facility administrations accountable. The NCCHC and ACA accreditation standards that some states accept as a substitute for state health and safety inspections do not provide a mechanism for individuals who are incarcerated to raise complaints. Any grievances filed with the correctional facility must go through layers of bureaucracy and can result in unlawful retaliation against the complainant by staff.[81] Individuals who are incarcerated are excluded from most state workers' compensation statutes, and incarcerated worker injuries are often not found to reach the level of a constitutional violation.[82] Finally, sovereign immunity and other doctrinal hurdles preclude most tort claims against correctional facility administrators.[83]

Given this concerning gap in coverage, some note that OSHA's authorizing statute should be interpreted more broadly, to cover all incarcerated laborers, including those that work in institutional "housework" work assignments.[67] The regulatory interpretation exempting individuals who are incarcerated in state facilities should be reconsidered given states' failure to fill this large gap in coverage.[1,67] OSHA standards should be considered mandatory in the carceral context, with additional standards specific to incarcerated work. Importantly, a mechanism should be designed so incarcerated workers can file complaints directly with an outside agency and an anti-retaliation provision should be introduced to protect workers from internal prison discipline for filing complaints.[67]

This expansion in coverage could be achieved in part through administrative action as OSHA could issue new federal directives and interpretations that cover housework and make clear the

mandatory nature of the regulations. States that already operate state OSHA plans could incorporate detainees and individuals who are incarcerated explicitly into their regulations.[67] Both federal and state agencies should devise grievance mechanisms to make it easy for incarcerated workers to file complaints and requests for inspections directly with an outside body, without the correctional facilities' oversight. In addition, members of Congress have repeatedly introduced the Protecting America's Workers Act which would expand OSHA coverage to state and municipal employees; this bill could be amended to incorporate protections for workers incarcerated in state and local correctional facilities.[84]

EXISTING AMA POLICY

AMA policy D-430.992 "Reducing the Burden of Incarceration on Public Health" support efforts to reduce the negative health impacts of incarceration, through implementation and incentivization of adequate funding and resources towards indigent defense systems; implementation of practices that promote access to stable employment and laws that ensure employment non-discrimination for workers with previous non-felony criminal records; and housing support for formerly incarcerated people, including programs that facilitate access to immediate housing after release from carceral settings. This policy also calls on the AMA to partner with public health organizations and other interested parties to urge Congress, the Department of Justice, the Department of Health and Human Services, and state officials and agencies to minimize the negative health effects of incarceration by supporting programs that facilitate employment at a living wage, and safe, affordable housing opportunities for formerly incarcerated individuals, as well as research into alternatives to incarceration.

CONCLUSION

The roots of modern-day labor programs can be traced to the end of the Civil War and the passage of the 13th Amendment that abolished slavery "except as a punishment for crime."[5] States in the North and the South turned to incarcerated labor as a means of partially replacing chattel slavery and the free labor force slavery provided. As state corrections systems expanded, so too did the number of state-sponsored incarcerated labor programs.[7] The exception clause in the 13th Amendment disproportionately encouraged the criminalization and effective re-enslavement of Black people during the Jim Crow era, and the impacts of this systemic racism persist to this day in the disproportionate incarceration of Black and brown community members.[1,5,8] Under today's system of mass incarceration, nearly 2 million people are held in prisons and jails across the United States.[85] Almost all U.S. correctional facilities have work programs that employ incarcerated workers: Nearly 99 percent of public adult correctional facilities and nearly 90 percent of private adult correctional facilities have such programs.[86]

The current lack of remedies for incarcerated workers facing unsafe conditions or suffering from work-related injuries disincentivizes correctional facilities from investing resources into maintaining safe working conditions.[1,67] Expanding coverage under OSHA to include all workers inside correctional and detention facilities would allow incarcerated workers to file grievances with outside agencies, request inspections, and utilize the administrative appeals and mandamus procedures under the Act.[67] In addition, an increased OSHA presence in correctional facilities could assist individuals who are incarcerated in seeking damages or other judicial remedies for egregious health and safety violations. This expansion of coverage would not only provide access to important independent enforcement mechanisms but would also signal to correctional facility administrators that the government takes prisoner health and safety seriously.[67] This signaling, and the increased risk of fines and litigation, could improve correctional facilities' general

accountability for the health and safety of those they incarcerate, affirming the inherent dignity, value, and humanity of workers who are incarcerated.

The use of incarcerated labor for business purposes raises many ethical concerns. Many people argue that using individuals who are incarcerated for work is a form of exploitation and violates their human rights.[1,67,87] Additionally, the fact that individuals who are incarcerated are not entitled to the same protections as other workers raises questions about the fairness of using incarcerated labor for profit. However, proponents of incarcerated labor argue that it provides individuals who are incarcerated with valuable job skills and work experience that can help them successfully reintegrate into society upon release.[58] They also argue that it can be a cost-effective way for businesses to produce goods and services. Additionally, alternatives to using incarcerated labor should be explored to provide individuals who are incarcerated with a path to economic self-sufficiency that does not rely on their incarceration. One potential alternative to using incarcerated labor is to invest in education and job training programs for individuals who are incarcerated.[1,58] By providing individuals who are incarcerated with the skills and knowledge they need to succeed in the workforce, they can be better equipped to find employment upon release and avoid reincarceration. This approach not only benefits the individuals who are incarcerated themselves, but also the broader community by reducing recidivism rates and promoting economic growth.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 901-I-22, and the remainder of this report be filed.

1. Our AMA acknowledges that systemic racism is a root of incarcerated labor policies and practices.
2. Our AMA supports:
   (a) Efforts to ensure that all work done by individuals who are incarcerated in correctional facilities is fully voluntary.
   (b) Eliminating policies that require forced labor or impose adverse consequences on incarcerated workers who are unable to carry out their assigned jobs due to illness, injury, disability, or other physical or mental limitations.
   (c) Eliminating policies that negatively impact good time, other reductions of sentence, parole eligibility, or otherwise extend a person's incarceration for refusal to work when they are unable to carry out their assigned jobs due to illness, injury, disability, or other physical or mental limitations.
   (d) The authority of correctional health care professionals to determine when an individual who is incarcerated is unable to carry out assigned work duties.
3. Our AMA encourages:
   (a) Congress and state legislatures to clarify the meaning of "employee" to explicitly include incarcerated workers within that definition to ensure they are afforded the same workplace health and safety protections as other workers.
   (b) Congress to enact protections for incarcerated workers considering their vulnerabilities as a captive labor force, including anti-retaliation protections for workers who are incarcerated who report unsafe working conditions to relevant authorities.
   (c) Congress to amend the Occupational Safety and Health Act to include correctional institutions operated by state and local governments as employers under the law.
   (d) The U.S. Department of Labor to issue a regulation granting the Occupational Safety and Health Administration jurisdiction over the labor conditions of all workers incarcerated in federal, state, and local correctional facilities.
4. Our AMA encourages:

(a) Comprehensive safety training that includes mandatory safety standards, injury and illness prevention, job-specific training on identified hazards, and proper use of personal protective equipment and safety equipment for incarcerated workers.
(b) That safety training is delivered by competent professionals who treat incarcerated workers with respect for their dignity and rights.
(c) That all incarcerated workers receive adequate personal protective equipment and safety equipment to minimize risks and exposure to hazards that cause workplace injuries and illnesses.
(d) Correctional facilities to ensure that complaints regarding unsafe conditions and abusive staff treatment are processed and addressed by correctional administrators in a timely fashion.

5. Our AMA acknowledges that investing in valuable work and education programs designed to enhance incarcerated individuals' prospects of securing employment and becoming self-sufficient upon release is essential for successful integration into society.
6. Our AMA strongly supports programs for individuals who are incarcerated that provides opportunities for advancement, certifications of completed training, certifications of work performance achievements, and employment-based recommendation letters from supervisors.

Fiscal Note: Minimal - less than $1,000

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REPORT 05 OF THE BOARD OF TRUSTEES (I-23)
AMA Public Health Strategy: The Mental Health Crisis
(Reference Committee K)

EXECUTIVE SUMMARY

At the 2023 Annual Meeting of the House of Delegates (HOD), the policy, "Public Health Strategy", was adopted. The second directive of the policy directs the American Medical Association (AMA) to provide a status update of its initiatives to address the ongoing mental health crisis. The following informational Board Report provides this update and will be provided to the HOD for review at the 2023 Interim Meeting.

This report provides detailed information about the AMA's many efforts to address the mental health crisis. The AMA's work includes numerous activities in the following areas:

1. Adoption of multiple related AMA policies;
2. Advocacy for legislative changes, resources and research (e.g., state, national, congressional, legislative, regulatory and private sector);
3. Formation of collaborative partnerships with Federation members and other medical and professional societies;
4. Development of educational and interactive tools and resources;
5. Publication of reports and research;
6. AMA-sponsored conferences, as well as AMA presence at external conferences; and
7. Creation of a recognition program for health systems to promote physician wellness.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 05-I-23

Subject: AMA Public Health Strategy: The Mental Health Crisis

Presented by: Willie Underwood, III, MD, MSc, MPH, Chair

Referred to: Reference Committee K

INTRODUCTION

At the 2023 Annual Meeting of the House of Delegates (HOD), the policy, "Public Health Strategy", was adopted. The second directive of the policy directs the American Medical Association (AMA) to provide a status update of its initiatives to address the ongoing mental health crisis. The following informational Board Report provides this update for the HOD at the 2023 Interim Meeting.

BACKGROUND:

The United States is in the midst of a decades-long mental health crisis exacerbated by the COVID-19 pandemic.[1] The number of American adults reporting symptoms of anxiety and/or depressive disorder grew from one in ten in 2019 to four in ten by early 2021.[2,3] Deaths due to drug overdose are four times higher than in 1999.[2] The prevalence and severity of mental health conditions among children and teens have also increased sharply with the U.S. surgeon general urging action to address the mental health crisis among young people including increased suicidal behaviors.[4] Research shows a high incidence of co-occurring mental illness and substance use disorder, perceived stigma with both conditions, and the importance of privacy to those seeking care.[5,6,7,8,9]

Mental health is also a major concern for physicians and medical students. A recent survey showed that nearly a quarter of physicians report clinical depression and are more likely to have suicidal ideation compared to those in other professions.[10] For most physicians, seeking treatment for mental health sparks legitimate fear of resultant loss of licensure, loss of income and/or other meaningful career setbacks as a result of ongoing stigma. More than 40 percent of physicians do not seek help for depression (or burnout) for fear of disclosure to a state licensing board, leaving many to suffer in silence or worse.[11] The AMA is deeply committed to combating the ongoing mental health crisis and continues to strategically lead and support numerous initiatives to promote the mental wellbeing of physicians, their care teams and the patients they serve.

AMA POLICY

The AMA has numerous policies aimed at addressing mental health issues among the patient population, physicians and other health care professionals.

The AMA developed principles on mental health. They state:

a. Tremendous strides have already been made in improving the care and treatment of patients with psychiatric illness, but much remains to be done. The mental health field is vast and includes a network of factors involving the life of the individual, the community and the nation. Any program designed to combat psychiatric illness and promote mental health must, by the nature of the problems to be solved, be both ambitious and comprehensive.
b. The AMA recognizes the important stake every physician, regardless of type of practice, has in improving our mental health knowledge and resources. The physician participates in the mental health field on two levels, as an individual of science and as a citizen. The physician has much to gain from a knowledge of modern psychiatric principles and techniques and much to contribute to the prevention, handling and management of emotional disturbances. Furthermore, as a natural community leader, the physician is in an excellent position to work for and guide effective mental health programs.
c. The AMA will be more active in encouraging physicians to become leaders in community planning for mental health.
d. The AMA has a deep interest in fostering a general attitude within the profession and among the lay public more conducive to solving the many problems existing in the mental health field (Policy H-345.999, "Statement of Principles on Mental Health").

Additionally, the AMA supports working with all interested national medical organizations, national mental health organizations, and appropriate federal government entities to convene a federally-sponsored blue ribbon panel and develop a widely disseminated report on mental health treatment availability and suicide prevention to:

a. improve suicide prevention efforts, through support, payment and insurance coverage for mental and behavioral health and suicide prevention services including but not limited to the National Suicide Prevention Lifeline;
b. increase access to affordable and effective mental health care through expanding and diversifying the mental and behavioral health workforce;
c. expand research into the disparities in youth suicide prevention;
d. address inequities in suicide risk and rate through education, policies and development of suicide prevention programs that are culturally and linguistically appropriate;
e. develop and support resources and programs that foster and strengthen healthy mental health development; and
f. develop best practices for minimizing emergency department delays in obtaining appropriate mental health care for patients who are in mental health crisis.

Our AMA also supports physician acquisition of emergency mental health response skills by promoting education courses for physicians, fellows, residents, and medical students including but not limited to mental health first aid training (Policy D-345.972, "Mental Health Crisis").

The AMA advocates the following steps to remove barriers that keep Americans from seeking and obtaining treatment for mental illness:

a. reducing the stigma of mental illness by dispelling myths and providing accurate knowledge to ensure a more informed public;
b. improving public awareness of effective treatment for mental illness;
c. ensuring the supply of psychiatrists and other well trained mental health professionals, especially in rural areas and those serving children and adolescents;
d. tailoring diagnosis and treatment of mental illness to age, gender, race, culture and other characteristics that shape a person's identity;
e. facilitating entry into treatment by first-line contacts recognizing mental illness and making proper referrals and/or to addressing problems effectively themselves; and

f. reducing financial barriers to treatment (Policy H-345.981, "Access to Mental Health Services").

Further, our AMA encourages: (1) medical schools, primary care residencies and other training programs as appropriate to include the appropriate knowledge and skills to enable graduates to recognize, diagnose and treat depression and other mental illnesses, either as the chief complaint or with another general medical condition; (2) all physicians providing clinical care to acquire the same knowledge and skills; and (3) additional research into the course and outcomes of patients with depression and other mental illnesses who are seen in general medical settings and into the development of clinical and systems approaches designed to improve patient outcomes.

Furthermore, any approaches designed to manage care by reduction in the demand for services should be based on scientifically sound outcomes research findings.

The AMA will work with the National Institute on Mental Health and appropriate medical specialty and mental health advocacy groups to increase public awareness about depression and other mental illnesses, to reduce the stigma associated with depression and other mental illnesses and to increase patient access to quality care for depression and other mental illnesses.

Our AMA: (1) will advocate for the incorporation of integrated services for general medical care, mental health care and substance use disorder care into existing psychiatry, addiction medicine and primary care training programs' clinical settings; (2) encourages graduate medical education programs in primary care, psychiatry and addiction medicine to create and expand opportunities for residents and fellows to obtain clinical experience working in an integrated behavioral health and primary care model such as the collaborative care model; and (3) will advocate for appropriate reimbursement to support the practice of integrated physical and mental health care in clinical care settings.

Our AMA recognizes the impact of violence and social determinants on women's mental health (Policy H-345.984, "Awareness, Diagnosis and Treatment of Depression and Other Mental Illnesses").

Moreover, the AMA supports:

a. maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers and other state-supported psychiatric services;
b. state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment to avoid repeated psychiatric hospitalizations and interactions with the law primarily as a result of untreated mental conditions;
c. increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness; and
d. enforcement of the Mental Health Parity Act at the federal and state level.

AMA will take these resolves into consideration when developing policy on essential benefit services (Policy H-345.975, "Maintaining Mental Health Services by States").

The AMA will also: (1) utilize their existing communications channels to educate the physician community and the public on the new 9-8-8 National Suicide Prevention Lifeline program; (2) work with the Federation and other stakeholders to advocate for adequate federal and state funding for the 9-8-8 system including the development of model legislation; and (3) collaborate with the Substance Abuse and Mental Health Services Administration, the 9-8-8 partner community and

other interested stakeholders to strengthen suicide prevention and mental health crisis services that prioritize education and outreach to those populations at highest risk for suicide attempts, suicide completions and self-injurious behavior (Policy D-345.974, "Awareness Campaign for 988 National Suicide Prevention Lifeline").

The AMA also supports (1) mental health and faith community partnerships that foster improved education and understanding regarding culturally competent, medically accepted and scientifically proven methods of care for psychiatric and substance use disorders; (2) better understanding on the part of mental health providers of the role of faith in mental health and addiction recovery for some individuals; and (3) efforts of mental health providers to create respectful, collaborative relationships with local religious leaders to improve access to scientifically sound mental health services (Policy H-345.971, "Faith and Mental Health").

Additionally, the AMA: (1) continues to support jail diversion and community based treatment options for mental illness; (2) 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; (3) federal funding to encourage increased community and law enforcement participation in crisis intervention training programs; (4) 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; and (5) increased research on non-violent de-escalation tactics for law enforcement encounters with people who have mental illness and/or developmental disabilities and research of fatal encounters with law enforcement and the prevention thereof (Policy H-345.972, "Mental Health Crisis Interventions").

Also of importance, our AMA advocates for the repeal of laws that deny persons with mental illness the right to vote based on membership in a class based on illness (Policy H-65.971, "Mental Illness and the Right to Vote").

The AMA (1) recognizes the importance of, and supports the inclusion of, mental health (including substance use, abuse and addiction) screening in routine pediatric physicals; (2) will work with mental health organizations and relevant primary care organizations to disseminate recommended and validated tools for eliciting and addressing mental health (including substance use, abuse and addiction) concerns in primary care settings; and (3) recognizes the importance of developing and implementing school-based mental health programs that ensure at-risk children/adolescents access to appropriate mental health screening and treatment services and supports efforts to accomplish these objectives (Policy H-345.977, "Improving Pediatric Mental Health Screening").

Moreover, the AMA:

a. recognizes youth and young adult suicide as a serious health concern in the U.S.;
b. encourages the development and dissemination of educational resources and tools for physicians, especially those more likely to encounter youth or young adult patients, addressing effective suicide prevention including screening tools, methods to identify risk factors and acuity, safety planning and appropriate follow-up care including treatment and linkages to appropriate counseling resources;
c. supports collaboration with federal agencies, relevant state and specialty medical societies, schools, public health agencies, community organizations and other stakeholders to enhance awareness of the increase in youth and young adult suicide and to promote protective factors, raise awareness of risk factors, support evidence-based prevention strategies and interventions, encourage awareness of community mental health resources and improve care for youth and young adults at risk of suicide;

d. encourages efforts to provide youth and young adults better and more equitable access to treatment and care for depression, substance use disorder and other disorders that contribute to suicide risk;
e. encourages continued research to better understand suicide risk and effective prevention efforts in youth and young adults, especially in higher risk sub-populations such as Black, LGBTQ+, Hispanic/Latinx, Indigenous/Native Alaskan youth and young adult populations and among youth and young adults with disabilities;
f. supports the development of novel technologies and therapeutics, along with improved utilization of existing medications to address acute suicidality and underlying risk factors in youth and young adults;
g. supports research to identify evidence-based universal and targeted suicide prevention programs for implementation in middle schools and high schools;
h. will publicly call attention to the escalating crisis in children and adolescent mental health in this country in the wake of the COVID-19 pandemic;
i. will advocate at the state and national level for policies to prioritize children's mental, emotional and behavioral health;
j. will advocate for a comprehensive system of care including prevention, management and crisis care to address mental and behavioral health needs for infants, children and adolescents; and
k. will advocate for a comprehensive approach to the child and adolescent mental and behavioral health crisis when such initiatives and opportunities are consistent with AMA policy (Policy H-60.937, "Youth and Young Adult Suicide in the United States").

The AMA also advocates for (1) increased research funding to evaluate the validity, efficacy and implementation challenges of existing mental health screening tools for refugee and migrant populations and, if necessary, create brief, accessible, clinically-validated, culturally-sensitive and patient centered mental health screening tools for refugee and migrant populations; (2) increased funding for more research on evidence-based mental health services to refugees and migrant populations and the sex and gender factors that could increase the risk for mental disorders in refugee women and girls who experience sexual violence; and (3) increased mental health training support and service delivery funding to increase the number of trained mental health providers to carry out mental health screenings and treatment, as well as encourage culturally responsive mental health counseling (Policy D-345.982, "Increasing Mental Health Screenings by Refugee Resettlement Agencies and Improving Mental Health Outcomes for Refugee Women").

Our AMA supports (1) improvements in current mental health services for women during pregnancy and postpartum; (2) advocacy for inclusive insurance coverage of mental health services during gestation and extension of postpartum mental health services coverage to one year postpartum; and (3) appropriate organizations working to improve awareness and education among patients, families and providers of the risks of mental illness during gestation and postpartum; and will continue to advocate for funding programs that address perinatal and postpartum depression, anxiety and psychosis and substance use disorder through research, public awareness and support programs (Policy H-420.953, "Improving Mental Health Services for Pregnancy and Postpartum Mothers").

Further, our AMA is in support of adequate attention and funds being directed towards culturally and linguistically competent mental health direct services for the diverse, multi-ethnic communities at greatest risk, and encourages greater cultural and linguistic-competent outreach to ethnic communities including partnerships with ethnic community organizations, health care advocates and respected media outlets (Policy H-345.974, "Culturally, Linguistically Competent Mental Health Care and Outreach for At-Risk Communities").

The AMA also supports: (1) strategies that emphasize de-stigmatization and enable timely and affordable access to mental health services for undergraduate and graduate students in order to improve the provision of care and increase its use by those in need; (2) colleges and universities in emphasizing to undergraduate and graduate students and parents the importance, availability and efficacy of mental health resources; and (3) collaborations of university mental health specialists and local public or private practices and/or health centers in order to provide a larger pool of resources, such that any student is able to access care in a timely and affordable manner (Policy H-345.970, "Improving Mental Health Services for Undergraduate and Graduate Students").

Our AMA advocates for:

a. physicians, medical students and all members of the health care team (i) to maintain self-care, (ii) receive support from their institutions in their self-care efforts and (iii) in order to maintain the confidentiality of care, have access to affordable health care including mental and physical health care, outside of their place of work or education;
b. employers support access to mental and physical health care including but not limited to providing access to out-of-network in person and/or via telemedicine, thereby reducing stigma, eliminating discrimination and removing other barriers to treatment; and
c. for best practices to ensure physicians, medical students and all members of the health care teams have access to appropriate behavioral, mental, primary and specialty health care and addiction services (Policy D-405.978, "Access to Confidential Health Care Services for Physicians and Trainees").

Our AMA also supports requirements of all health insurance plans to implement a compliance program to demonstrate compliance with state and federal mental health parity laws (Policy H-185.916, "Expanding Parity Protections and Coverage of Mental Health and Substance Use Disorder Care").

Lastly, the AMA advocates that funding levels for public sector mental health and substance use disorder services not be decreased in the face of governmental budgetary pressures, especially because private sector payment systems are not in place to provide accessibility and affordability for mental health and substance use disorder services to our citizens (Policy H-345.980, "Advocating for Reform in Payment of Mental Health and Substance Use Disorder Services").

DISCUSSION

Federal and State Advocacy

Congressional

In 2021, the AMA successfully advocated for passage of the "Dr. Lorna Breen Health Care Provider Protection Act." The Act dedicated resources to support the mental health needs of physicians including funding for the National Suicide Prevention Lifeline. The AMA also successfully advocated for the addition of new Medicare-supported GME positions, at least 100 of which were reserved for psychiatric specialty residency positions, in the 2021 Consolidated Appropriations Act. This was the first increase of its kind in nearly 25 years. The AMA also supported additional funding for grants to establish or expand programs to grow and diversify the maternal mental health/substance use disorder treatment workforce and the Substance Abuse and Mental Health Services Administration (SAMHSA) Minority Fellowship Program.

In 2022, the AMA worked with pertinent national medical specialty societies to advocate for a number of measures to be included in a comprehensive mental health package as part of the

SAMHSA reauthorization process. AMA submitted comments to House Ways and Means Committee, House Energy and Commerce Committee, Senate HELP Committee and Senate Finance Committee as part of this work. Congress enacted significant new investments and policy changes to address the ongoing mental health crisis as part of H.R. 2471, Omnibus Appropriations for Fiscal Year 2022. AMA-supported measures that were in the final law included:

1. Funding for SAMHSA at $6.5 billion, a $530 million increase including $2 billion directed to mental health programs, an increase of $288 million over fiscal year (FY) 2021. This included $102 million in additional resources for the implementation of the 9-8-8 hotline number, $42 million set aside to help communities improve related crisis care response and services and a $10 million new pilot program to help communities create or enhance mobile crisis response teams consisting of mental health responders and avoiding unnecessary police response.
2. $17 million to promote and train culturally competent care via the SAMHSA Minority Fellowship Program.
3. $24 million for the Loan Repayment Program for Substance Use Disorder Treatment Workforce to provide as much as $250,000 in loan repayments to psychiatrists and other substance use disorder clinicians who agree to work full-time in a health professional shortage area or county with abnormally high overdose rates for up to six years.
4. An increase of $5 million for the Employee Benefits Security Administration, which is responsible for enforcing compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) for the 2.2 million employer-sponsored health plans regulated under the Federal Employee Retirement Income Security Act. Importantly, the package specifically directed the utilization of additional resources to fully fund the hiring and training of additional health investigators to focus exclusively on MHPAEA compliance.
5. New policy eliminating the parity opt-out for non-federal governmental health plans and providing funding for state insurance departments to enforce and ensure compliance with the mental health parity law.
6. New policy extending the current public health emergency Medicare telehealth flexibilities and delays the implementation of the in-person requirement for telehealth services for mental health until December 31, 2024.
7. Grants and technical assistance to primary care practices to implement the evidence-based Collaborative Care Model into their practices for early intervention and prevention of mental health and substance use disorders.
8. 200 new Medicare-supported graduate medical education slots in FY 2026 psychiatry and psychiatry subspecialties.

In 2023, the AMA endorsed the Parity Enforcement Act of 2023 (H.R.3752) to provide the Secretary of the Department of Labor authority to impose civil monetary penalties on federally regulated group health plans for violations of the federal mental health and substance use disorder parity law. Additionally, the AMA signed onto a letter in support of the Children's Hospitals Graduate Medical Education program asking for the provision of $738 million in FY 2024 funding for the program which is critical because of the ongoing youth mental health crisis. The AMA has also endorsed the Resident Physician Shortage Reduction Act of 2023 (H.R. 2389) to add 14,000 Medicare-supported residency slots over seven years to address the physician workforce shortage including psychiatry and psychiatry subspecialties.

<u>Legislative</u>

In the past two years, the AMA Advocacy Resource Center (ARC) has advocated for and supported new laws in multiple states including Arizona, Delaware, Georgia, Illinois, Kentucky, Mississippi and Virginia. These laws help protect physicians who seek care for mental health

conditions. Provisions range from providing "safe-haven" protections that shield records from disclosure to provisions requiring state licensing boards to remove stigmatizing questions from medical licensure applications.[12]

Regulatory

The ARC has worked closely with the Dr. Lorna Breen Heroes' Foundation and Federation of State Medical Boards (FSMB) to encourage all medical boards to remove stigmatizing, inappropriate questions that seek disclosure of past diagnosis of a mental illness or substance use disorder. In the past year, ARC efforts with the Foundation and FSMB have resulted in three state medical boards revising their questions and the ARC is working with eight additional state medical boards on proposed revisions.[13]

Private Sector

The ARC also is working directly with chief medical, wellness and compliance officers at more than 20 regional and multistate health systems to revise their credentialing applications to remove stigmatizing questions about past diagnosis or treatment of mental illness and substance use disorders. The efforts of the AMA and Dr. Lorna Breen Heroes' Foundation have led to nearly ten systems confirming and/or revising changes to be consistent with AMA policy and the Foundation's recommendations. Several additional health systems have approached the Foundation and AMA for technical assistance in revising their applications.

National

In partnership with the Dr. Lorna Breen Heroes' Foundation and the FSMB, the AMA has presented its wellness-focused advocacy efforts at multiple medical society and national organization meetings including the FSMB, American Academy of Family Physicians and the Federation of State Physician Health Programs. Additional efforts have focused on urging public support for wellness-focused initiatives in collaboration with the American Heart Association, Accreditation Council of Graduate Medical Education, National Committee of Quality Assurance, National Association Medical Staff Services and others.

Mental Health and Substance Use Disorder Parity

The AMA continues to urge state departments of insurance to meaningfully enforce state mental health and substance use disorder parity laws. AMA advocacy continues with the National Association of Insurance Commissioners to ensure that payers provide timely and accurate information as part of regular compliance reviews with parity laws. Notably, AMA efforts to increase regulators' focus on enforcement have resulted in strong, parity-focused network adequacy regulations in Colorado and enforcement actions in Illinois that highlighted payers' discriminatory actions with respect to medications for people with a mental illness or substance use disorder. The AMA continues to play an important role in urging regulators at the National Association of Insurance Commissioners to enforce state mental health and substance use disorder parity laws in partnership with the American Psychiatric Association and The Kennedy Forum. The AMA also is urging states to use opioid litigation settlement funds to increase resources for state departments of insurance to enforce parity laws.

Statements

AMA Immediate Past President, Dr. Jack Resneck Jr., released a statement to physicians and their care teams, health systems and policy makers calling for the expansion of the mental health workforce, acceleration of behavioral health integration (BHI) adoption within primary care, improvement and expansion of quality, timely patient access to equitable care through BHI and the advancement, support and increased patient access to quality telepsychiatry.[14]

Dr. Resneck also produced a statement that addressed the threat posed to physician wellbeing and the patient-physician relationship by physician burnout. He called for expanded access to mental and behavioral health resources for physicians, the streamlining of prior authorization, a major source of administrative burden, and the improvement of patient trust and health literacy to confront another significant burden experienced by physicians- misinformation and disinformation.[15]

Acceleration of Behavioral Health Integration (BHI)

In 2020, the AMA partnered with the RAND Corporation to publish a study in the Annals of Internal Medicine summarizing the key motivators, facilitators and barriers to BHI from those physician practices with firsthand experience.[16] That same year, the AMA partnered with seven other Federation members, the American Academy of Child and Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association and American Psychiatric Association, to create the BHI Collaborative which equips physicians and their practices with the necessary knowledge to overcome obstacles and sustain integrated care for their patients and families.[17] Additional research was conducted when the AMA partnered with Manatt Health to publish a report on the opportunities and limitations of incorporating technology to advance and enhance BHI adoption.[18]

Leadership from the BHI Collaborative published a call to action in Health Affairs calling on payers and policy makers to join forces with physicians to ensure primary care physicians and their care teams have the necessary support to provide equitable, whole-person care for their patients and families. It identified numerous practical solutions that health plans, employers and state/federal policy makers can pursue to effectively support the widespread, sustainable adoption of BHI by physician practices.[19] The AMA will be partnering with the Hawaii Medical Association, the University of Hawaii and the Physicians Foundation on a research pilot to examine the potential benefits of empowering rural-based primary care physicians and medical students to effectively implement and sustain digitally-enabled BHI in their practices.

In 2023, the Collaborative expanded beyond its initial primary care focus to include Federation members from specialties that provide longitudinal care to patients with chronic illnesses that are significantly impacted by comorbid mental health conditions. These members included the American Academy of Neurology, American College of Cardiology, American Gastroenterological Association and Association for Clinical Oncology.

The BHI Collaborative has yielded numerous free and open-source resources for physicians and others interested in integrated care. This includes the BHI Compendium, which provides an implementation framework to help guide practices through key steps and considerations of delivering effective and sustainable integrated behavioral health care, as well as educational and training opportunities through its Overcoming Obstacles series. This series provides actionable insights and real-world best practices including operational topics such as billing and coding, condition-specific topics such as suicidal ideation and patient population-specific topics such as pediatric and obstetric/gynecological care.[20,21] The Collaborative also offers, through its pilot BHI Immersion Program, free enhanced technical assistance on how to effectively implement BHI to a diverse cohort of 24 health care organizations from across the country.[22]

The AMA also developed six additional strategic behavioral health guides that provide physician practices with practical strategies, actionable steps and evidence-based resources on specific areas

of integrated care. Topics included guidance on pharmacological treatment, substance use/misuse disorder screening and treatment, suicide prevention and key CPT billing codes.[23]

Other Tools and Resources

To address the mental wellness and health of physicians, the AMA STEPS Forward® program has produced several resources including a playbook, toolkits (15), educational modules (15), webinars (5), podcasts (11) and practice success stories (32).[24] The topics of these resources include preventing physician suicide, stress first aid, physician peer support programs and Project ECHO.[25,26,27,28]

The AMA has also developed the Organizational Biopsy®, an assessment tool and set of services designed to support organizations in holistically measuring and acting to improve organizational wellbeing. The tool is shared with over 200 health systems and provides health systems with a comprehensive assessment across four domains: organizational culture, practice efficiency, self-care and retention.[29] The assessment includes a "Barriers to Mental Health" question to enhance leadership's understanding of barriers that may be preventing their physicians from accessing mental health services and support. Following an assessment, organizations receive an executive summary of their key findings and access to the Organizational Biopsy data through an online reporting platform that includes national comparison data. Building on this work, the Joy in Medicine team will present an abstract at the 2023 American Conference on Physician Health that examines the relationship between certain demographic groups and responses to the "Barriers to Mental Health" question. The abstract will also review the relationship between burnout and how people respond to the "Barriers to Mental Health" question.

The AMA Debunking Regulatory Myths series, which helps physicians and their care teams understand medical regulatory requirements to reduce guesswork and administrative burdens, covered the topic of licensing and credentialing bodies' inquiry into physician mental health.[30,31] The resource clarified that it is neither a Joint Commission, nor FSMB, requirement that licensing and credentialing organizations ask probing questions about clinicians' past mental health, addiction or substance use history on licensure and credentialing applications.[31]

The AMA's Accelerating Change in Medical Education Consortium published a book titled, *Educator Well-Being in Academic Medicine*, that was written and edited by experts from across the country who have studied, planned and implemented educator wellbeing programs in undergraduate and graduate medical education. The book provides concrete, systems-based solutions to better support the educational mission and educator wellbeing.[32]

The AMA Ed Hub™ online learning platform provides physicians and other medical professionals with education from the AMA and other trusted sources on a variety of topics of which include mental health. One such resource is the "Mental Health and Anxiety Disorders" CME course which features modules from trusted education providers such as the AMA Journal of Ethics™, AMA STEPS Forward, JAMA Network™, Stanford Medicine and The Fenway Institute.[33] It also has a dedicated "Psychiatry and Behavioral Health" topic page on the latest in psychiatry including recent guidelines and advances in management of specific conditions such as anxiety, depression and bipolar disease.[34]

Additionally, the JAMA Network includes JAMA Psychiatry- an international peer-reviewed journal for clinicians, scholars and researchers in the fields of psychiatry, mental health, behavioral science and allied fields. It has a journal impact factor of 25.8- among the highest of all psychiatry journals. The journal aims to inform and stimulate discussion around the nature, causes, treatment

and public health importance of mental illness, as well as promote equity and justice for those impacted.[35] Readers can also listen to podcasts where editors and authors discuss articles published in the journal.[36]

Reports, Conferences and Programs

Council on Medical Education Reports

The Council on Medical Education has developed several reports focused on the mental wellbeing of physicians and medical students. Topics included confidential access to mental health services for medical students and physicians, mental health disclosures on physician licensing applications and medical student, resident and physician suicide.[37,38,39]

AMA Substance Use and Pain Task Force Reports

In 2015, the AMA convened more than 25 national, state, specialty and other health care organizations to develop guidance for physicians to help combat and end the opioid epidemic, as well as address the needs of patients with pain. Such organizations included the American Academy of Addiction Psychiatry, American Academy of Pain Medicine, American Academy of Family Physicians and American Society of Addiction Medicine.[40,41] In 2019, the AMA Pain Care Task Force released a report that detailed efforts necessary to help patients with pain. Such recommendations included (1) support access to comprehensive, affordable and compassionate treatment, (2) put an end to stigma and (3) encourage safe storage and disposal of prescription medication.[40,41,42] In 2021, the 25 health care organizations and the AMA Pain Care Task Force united to form the AMA Substance Use and Pain Task Force. The collective group released a report in 2022 to better address the opioid epidemic, this time paying close attention to health inequities such as those surrounding race, gender and sexual orientation. These recommendations targeted physicians, policymakers and other relevant stakeholders and suggested they work to (1) improve data collection, (2) remove barriers to treatment, (3) support individualized patient care, (4) support public health and harm reduction strategies and (5) strengthen multi-sector= collaboration[40,41,43].

AMA-Sponsored Conferences

The AMA hosts two biannual scientific conferences- the American Conference on Physician Health, co-sponsored with Mayo Clinic and Stanford Medicine, and the International Conference on Physician Health™, co-sponsored with the British Medical Association and the Canadian Medical Association. These events promote scientific research and discourse on health system infrastructure and actionable steps organizations can take to improve physician wellbeing and publicly demonstrate the AMA's commitment to physician wellbeing and reducing burnout.[44,45]

Joy in Medicine™ Health System Recognition Program

The Joy in Medicine™ Health System Recognition Program is designed to guide organizations interested in, committed to, or currently engaged in improving physician satisfaction and reducing burnout.[46] The program is based on three levels of organizational achievement in prioritizing and investing in physician wellbeing. Each level, Bronze, Silver and Gold, is composed of six demonstrated competencies- assessment, commitment, efficiency of practice environment, leadership, teamwork and support. The 2024 iteration of the program will require health systems to review current credentialing applications and change all language that is invasive or stigmatizing around mental health and substance use disorders to qualify for the minimum level of recognition. The program also continues to have an ongoing relationship with the ALL IN campaign and the Dr. Lorna Breen Heroes' Foundation to advocate for updating credentialing and licensing applications.

Health Equity and Whole-Person Care

The AMA Center for Health Equity (CHE) produced two *Prioritizing Equity* spotlight videos focused on mental health and trauma-informed approaches concerning the COVID-19 pandemic. Additionally, CHE Vice President of Equitable Health Systems and appointed member of the American Psychiatric Association's Mental Health Services Conference Scientific Program Committee, Dr. Karthik Sivashanker, presented at Association's conference as a plenary speaker in 2022. There, he spoke about the role of the Association and the profession more broadly in addressing historical injustices and present inequities at the intersection of mental health and racism.[47]

CONCLUSION

The AMA has made substantial efforts to address the ongoing mental health crisis and continues to effectively promote the mental health and wellbeing of physicians, their care teams and the patients they serve. The AMA's efforts have included the adoption of a variety of policies, advocacy, partnerships with professional organizations, development and dissemination of tools, education and resources, research, conferences and a program for health systems to promote physician wellness.

RECOMMENDATIONS

The Board of Trustees recommends that the second directive of BOT Report 17 be rescinded as having been accomplished by this report. (Rescind HOD Policy)

Fiscal Note: Minimal

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 14-I-23

Subject: Funding for Physicians to Provide Safe Storage Devices to Patients with Unsecured Firearms in the Home (Res. 923-I-22)

Presented by: Willie Underwood, III, MD, MSc, MPH, Chair

Referred to: Reference Committee K

At the 2022 Interim Meeting, the House of Delegates (HOD) referred the third resolve clause of Resolution 923, "Physician Education and Intervention to Improve Patient Firearm Safety," to the Board of Trustees for a report back to the HOD. The third resolve of Resolution 923 asked "that our American Medical Association (AMA) and all interested medical societies advocate for policies that support the provision of funding for physicians to provide affordable rapid-access safe storage devices to patients with firearms in the home." The reference committee heard mixed testimony on whether to adopt this clause, with concerns raised about the approach outlined to achieve the sponsor's intended goals. Some speakers sought referral due to the complexity, cost, and concerns that, while well-intentioned, the implementation could lead to increased physician liability. Therefore, the reference committee recommended that the third resolve be referred to the Board for decision. However, following further debate on the HOD floor, the HOD voted instead to refer the third resolve clause to the Board for report back at the 2023 Interim Meeting. This report responds to this action.

BACKGROUND

Addressing firearm violence is a longtime priority for the AMA. In the 1980s the AMA recognized firearms as a serious threat to the public's health as the weapons are one of the main causes of intentional and unintentional injuries and deaths. At the 2016 Annual Meeting, following the Pulse nightclub shooting, policy was adopted declaring that "gun violence represents a public health crisis which requires a comprehensive public health response and solution." Since that time firearm injuries and deaths have increased and disparities have widened. The majority of AMA policy focuses on firearm safety and on preventing firearm injuries and deaths, including physician education, patient counseling about unsecured firearms in homes, and safe storage solutions.

On the advocacy front, the AMA continues to push lawmakers to adopt common-sense steps, broadly supported by the American public, to prevent avoidable deaths and injuries caused by firearm violence, including closing background check loopholes and urging Congress to earmark appropriations to the Centers for Disease Control and Prevention and the National Institutes of Health specifically for firearm violence research efforts. The AMA has also worked with the American Foundation for Firearm Injury Reduction in Medicine (AFFIRM), a physician-led, non-profit organization that aims to counter the past lack of federal funding for firearm violence research by sponsoring firearm violence research with privately raised funds.

In 2018, the AMA created a continuing medical education module to help physicians learn how to identify and counsel patients at high-risk of firearm injury and death. Case studies focus on patients at risk of suicide, victims of domestic violence, and parents of children with firearms in the home. The module is available for free on the AMA Ed Hub and is being revised to include updated data and scenarios. The updated module will be released in 2023. The module includes a handout that physicians can share with their patients on different firearm storage options, including average cost. The AMA is also developing an online tool that will be released in 2023 that contains state-specific information about legal topics related to firearms, such as laws governing physicians counseling patients about firearms, physicians' obligations to disclose confidential patient information, safe storage and child access prevention laws, laws governing the possession and transfer of firearms, and extreme risk protection orders.

Most recently, Policy D-145.992, "Further Action to Respond to the Gun Violence Public Health Crisis," adopted by the HOD at A-22, directed the AMA to "establish a task force to focus on gun violence prevention including gun-involved suicide." Following an initial meeting in February of 2023 of those Federation members who have been most highly engaged on the issue of firearm injury prevention, the AMA Board of Trustees approved the charter and membership of the task force in June of 2023. In addition, the AMA is actively participating in a coalition led by the American Academy of Pediatrics focused on maintaining and increasing federal funding for firearm violence research and looks forward to additional information regarding participating in a new coalition, the Healthcare Coalition for Firearm Injury Prevention, formed by the American College of Surgeons.

DISCUSSION

As firearm violence continues to be a public health crisis in the country with an increase in mass shootings and the unrelenting daily incidents of deaths and injuries from suicides, homicides, and accidental shootings, many physicians are frustrated at the ongoing death and violence and have urged the AMA and Congress to do more to prevent firearm-related injuries and deaths. This is especially so with respect to children: in 2020 and 2021, firearms were involved in the deaths of more children ages 1-19 than any other type of injury or illness, surpassing deaths due to motor vehicles, which had long been the number one factor in child deaths.

The Board understands and shares this frustration and agrees that firearm injury prevention continues to be of vital importance. We also recognize, however, that this a difficult and multi-faceted problem without a single solution. As stated above and summarized in more detail in recent reports BOT Rep. 2-I-22, "Further Action to Respond to the Gun Violence Public Health Crisis," and BOT Rep. 17-A-23, "AMA Public Health Strategy," the AMA has extensive existing policy covering prevention, safety, education, and research on firearm violence prevention, including safe storage of firearms in the home. Moreover, there are numerous national, state, and local organizations, many of which the AMA works with, including Brady, Giffords, the Johns Hopkins Center for Gun Violence Solutions, and Moms Demand Action, which focus on trying to prevent and reduce firearm violence. The AMA has met with the Ad Council and Brady around their End Family Fire campaign, which is a movement to promote responsible firearm ownership and encourage safe firearm storage in the home. The AMA has amplified the PSAs developed by this campaign on our social media channels. In addition to these national efforts, there are numerous local efforts underway with public health departments, police departments, hospitals, and local governments that are promoting safe storage or providing free gun locks (see, e.g., Oak Park, IL, and Anne Arundel County, MD).

While it is beyond the scope of this report to provide a comprehensive survey of the different types of safe storage devices and their effectiveness, the Board notes that in the recent past, safe storage, as with other firearm safety issues, has not been extensively studied, most likely due to the lack of federal funding until the last few years for such research. Some studies have raised questions about the effectiveness of promoting safe storage or how such promotion is done. For example, a 2017 report by the U.S. Government Accountability Office (GAO), "Programs that Promote Safe Storage and Research on Their Effectiveness," identified 16 public or nonprofit programs that promote the safe storage of firearms on the national and local levels primarily involving education efforts through media campaigns and partnerships in the community:

> GAO identified 12 studies that evaluated locking device distribution or physician counseling programs from GAO's literature review, as well as from discussions with researchers. These studies found that free lock distribution efforts influenced behavior to store firearms more safely, but these results were largely based on self-reports. Studies evaluating physician consultation presented mixed results. Some found that counseling in pediatric primary care visits did not change parents' storage behavior, but emergency care consultation following an adolescent psychiatric crisis did prompt parents to store firearms safely.

In another study released in 2023, "Firearm Owners' Preferences for Locking Devices: Results of a National Survey," it was noted that while secure home storage of firearms may reduce suicide and injury risk and that providing locking devices may increase secure firearm storage practices, questions remain about which devices motivate secure storage. The study concluded that current prevention efforts may not be aligned with firearm owners' preferences and that more rigorous research is needed on this issue to better inform health care and community-based programs to provide free or discounted devices.

While safe storage of firearms in the home can lower the risk of injuries and deaths from firearms, and the AMA remains committed to educating physicians and counseling patients about existing initiatives and programs, the Board is concerned that there may be research gaps in existing knowledge about the most effective approaches to providing safe storage devices to patients. The Board also agrees with the issues and questions raised during Reference Committee and HOD floor debate about Resolution 923, specifically about complexity, cost, and concerns that, while well intentioned, the implementation could lead to increased physician liability in providing any such devices. The Board notes that while the AMA supports educating patients about the importance of children wearing bicycle helmets and using car seats, as a general practice, pediatricians do not provide bike helmets and car seats but rather ask parents if they have and use helmets and car seats. Moreover, in light of the availability of safe storage devices from existing police department, hospital, and local government programs that already are providing free gun locks, the Board concludes that the AMA should encourage existing and new programs to work with physician offices, hospitals, and other health care entities to provide safe storage devices at low or no cost.

Recommendation

The Board of Trustees recommends that Alternate Resolution 923 be adopted in lieu of Resolution 923 and that the remainder of the report be filed:

> RESOLVED, That our AMA encourage health departments and local governments to partner with police departments, fire departments, and other public safety entities and organizations to make firearm safe storage devices accessible (available at low or no cost) in communities in

collaboration with schools, hospitals, clinics, physician offices, and through other interested stakeholders. (New HOD Policy)

Fiscal Note: Less than $500.

REPORT 1 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-23)
Drug Shortages: 2023 Update
(Reference Committee K)

EXECUTIVE SUMMARY

INTRODUCTION. American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue. Additionally, at the I-22 HOD meeting, Resolution 935, "Government Manufacturing of Generic Drugs to Address Market Failures," was referred to CSAPH for study. Due to the implications of government manufacturing efforts on alleviating drug shortages, the two reports have been combined.

DISCUSSION. Drug shortages remain an ongoing and complex public health concern in the United States and the AMA continues to monitor the situation and act when appropriate. Overall, new drug shortages are the highest they have been in a decade, including many instances of high-profile drug shortages with visibility in the public sphere, including amphetamine/dextroamphetamine salts (trade name Adderall or Mydayis), semaglutide (trade name Ozempic, Wegovy, or Rybelsus), and platinum-based chemotherapeutics such as cisplatin and carboplatin, amongst many others. This report examines three root causes for drug shortages: the evolving prescribing landscape, modern challenges of advertising and patient demand, and the economics and fragility of generic drug manufacturing. Potential solutions, including non-profit or government-owned generic drug manufacturing are explored.

CONCLUSION. Drug shortages continue to be a complicated, multi-factorial issue which directly impacts patient care in the United States. The AMA's policy regarding drug shortages is timely and comprehensive, and updates are proposed to align with the topics discussed. New policy is also recommended for non-profit and public generic drug manufacturing.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-23

Subject: Drug Shortages: 2023 Update

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

Additionally, Resolution 935-I-22, "Government Manufacturing of Generic Drugs to Address Market Failures", was referred to CSAPH for study. That resolution asked:

> that our American Medical Association support the formation of a non-profit government manufacturer of pharmaceuticals to produce small-market generic drugs.

Due to the implications of government manufacturing efforts on alleviating drug shortages, the two asks will be addressed in this report.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2020 to June 2023, using the text terms "drug shortages", "government drug manufacturing" and "non-profit drug manufacturing." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), and Duke Margolis Center for Health Policy, and contemporary media reporting.

BACKGROUND

CSAPH has issued thirteen reports on drug shortages, with the most recent published at the November 2022 Interim meeting. The remainder of this report will provide an update on drug shortages since the 2022 report was developed, including specific comments on issues associated with government or non-profit manufacturing.

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing and complex public health concern in the United States and the AMA continues to monitor the situation and act when appropriate. Overall, new drug shortages are the highest they have been in a decade, including many instances of high-profile drug shortages with visibility in the public sphere, including amphetamine/dextroamphetamine salts (trade name Adderall or Mydayis), semaglutide (trade name Ozempic, Wegovy, or Rybelsus), and platinum-based chemotherapeutics such as cisplatin and carboplatin, amongst many others.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service (see Box 1 for links to these resources). It should be noted that FDA resources also include guidance on drugs which have had their use dates extended while a known shortage is ongoing. Further, the ASHP shortages resources provides useful clinical mitigation strategies to minimize the impact of drug shortages, such as substitutions and alternative agents.

According to ASHP statistics (see Appendix 1), trends in drug shortages have gotten worse in the last year.[1] In the 2022 update of this report, the Council commented that while *new* drug shortages were decreasing year-after-year, the complexities of the supply chain were causing each individual shortage to last longer, which resulted in a net increase of shortages.[2] During the 2022 calendar year, however, there was a spike in new drug shortages, combined with the continuing problems of resolving ongoing shortages, resulting in the highest levels of drug shortages in the United States since 2014. For the first quarter of 2023, the five classes of drugs facing the largest number of shortages are: central nervous system therapies (52), antimicrobials (35), fluids/electrolytes (30), hormones (27), and chemotherapies (23).

In July 2023, ASHP conducted a survey of over 1000 of their members, with over 99 percent reporting challenges posed by drug shortages. Beyond the obvious disruptions to care, respondents also noted the increase in budget – both for purchasing alternative or scarce drugs and for the increasing cost of labor to manage the supply chain.[3] A link to their survey results has been included in Box 1 of this report. This highlights the disproportionate impact that drug shortages may have on smaller health facilities, such as solo practices or rural clinics, which may not have the staff or inventory to be able to rapidly adapt purchasing and procurement.

The Food and Drug Administration

The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs in shortage as well as notifications about new and resolved drug shortages. This mobile app also gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, a link to the mobile app, and additional information (Box 1).

The tenth annual report on drug shortages from the FDA to Congress published in early 2023 summarized the major actions the FDA took in calendar year 2022 related to drug shortages.[4] During the COVID-19 public health emergency, the FDA continued to closely monitor the medical product supply chain and as expected, the supply chain was impacted heavily, leading to supply disruptions or shortages of drug products in the United States. Appendix 2 includes a breakdown of the FDA's calendar year 2022 metrics, including the number of expedited reviews (204), expedited inspections (30), and prevented shortages (222). However, new challenges and complexities to shortages have emerged in the last year worth further evaluating for action.

CHALLENGES IN THE DRUG SUPPLY CHAIN

Drugs shortages are a multi-factorial problem, with seemingly small issues having large, cascading effects down the supply chain for years. In this year's survey of the drug shortages landscape, three key new challenges were identified: an evolving prescribing landscape, increased advertising for in-demand drugs, and the fragility of the drug manufacturing supply chain.

Challenge: An Evolving Prescribing Landscape

In our 2022 drug shortages report, the Council described the role of the Drug Enforcement Agency (DEA) and production quotas leading to drug shortages for medications such as opioids and mixed amphetamine salts (MAS). Since that report's publication, the shortage of MAS has continued and also received intense scrutiny from legislators and the media.[5,6] Used for the treatment of attention deficit hyperactivity disorder (ADHD), and colloquially referred to by its trade name Adderall, MAS has been classified as under shortage since August 2022.[7]

The root cause of MAS shortage is typically attributed to a surge in demand. Manufacturers are then unable to meet this new demand as supply has been capped due to their status as a Schedule II controlled substance under the Controlled Substances Act. Under this schedule, MAS are deemed to "have a high potential for abuse which may lead to severe psychological or physical dependence" and have significant restrictions on production, prescribing, and dispensing, including manufacturing quota allotments.[8]

Despite its status as a controlled substance, one study conducted in 2021, found that prescriptions for MAS increased by over 20 percent from 2019 to 2021 in patients aged 22-44. The increase was largely attributed to the expansion of telehealth services afforded during the COVID-19 pandemic, increasing access to these medications.[9] Prior to the 2020 COVID-19 public health emergency order, prescribing of MAS required an in-person visit and could not be performed via telehealth. Since the end of the public emergency order, the DEA has announced a temporary extension of prescribing policies until at least 2024.[10]

The DEA has not increased the aggregate production quota for amphetamine, indicating that "[a]ccording to DEA's data, manufacturers have not fully utilized the [aggregate production quota] for amphetamine in support of domestic manufacturing, reserve stocks, and export requirements for the past three calendar years 2020, 2021 and 2022."[11] In fact, in August 2023, the FDA and DEA issued a joint letter which called on manufacturers to increase production, stating "Based on DEA's internal analysis of inventory, manufacturing, and sales data submitted by manufacturers of amphetamine products, manufacturers only sold approximately 70 percent of their allotted quota for the year, and there were approximately 1 billion more doses that they could have produced but did not make or ship."[12] However, there were at least two manufacturers who have publicly indicated that they petitioned the DEA to have their amphetamine quota increased and it has contributed to their inability to meet demand or list their reason for shortage as "awaiting DEA quota review/approval".[7,13] Currently the market does not support incentivizing companies to meet their manufacturing allotment, even in cases of drug shortages, which can cause continued challenges.

Federal officials have raised concerns that expanded telehealth prescribing of MAS may lead to increased diversion and illicit use, although it is unclear what underlying data has been used to reach this conclusion.[14] While the appropriateness of telehealth in ADHD diagnosis and subsequent MAS prescriptions are beyond the scope of this report, it should be noted that studies suggest that

historically, ADHD has been under-diagnosed in vulnerable populations such as children of color and women.[15,16]

Challenge: Increased Advertising and PBM Formularies for In-Demand Drugs

Semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist used to treat type 2 diabetes, exploded in popularity in 2021 after a formulation was FDA-approved for weight loss and long-term weight management.[17] Nine months later, it was listed as under shortage by the FDA due to increased demand.[18] Unlike many other drugs under shortage, semaglutide's increase in popularity can largely be attributed to a massive advertising presence, particularly through social media. For example, one report suggests that by November 2022, one hashtag (#Ozempic) was viewed over 273 million times on the social media platform TikTok.[19] By June 2023, merely seven months later, that number has increased to 1.2 billion views – all while the drug was actively experiencing shortage.[20] It should be noted, however, that in today's modern social media landscape, drugs can see a surge in public interest without direct advertising from the manufacturer, and instead may be driven by public discourse or celebrity influencers. Per AMA policy H-105.988, our AMA supports a ban on all direct-to-consumer pharmaceutical advertising.

Like MAS described above, it is outside the scope of this report to comment on the appropriateness of semaglutide advertising and prescriptions, including for formulations which have not been FDA-approved for weight loss. However, it can be generally said that when it comes to accessing drugs under shortage, stabilizing supply to current patients using a medication for the management of chronic disease should be prioritized over attracting new patients to compete for the same limited resource. In response, manufacturers, and some (but not all) telehealth prescribing platforms have halted advertising campaigns for semaglutide while the drug is in shortage.[21] It should be noted that approximately 47 percent of patients receiving insurance coverage for GLP-1 agonists did not receive coverage for a corresponding clinical visit, with direct-to-consumer telehealth platforms likely being the source for a portion of these prescriptions.[22] Additionally, some social media platforms have begun banning or suspending accounts for posting content related to GLP-1 agonists, however this change in policy appears to be ineffective and inconsistently enforced.[23]

An additional concern around GLP-1 agonist shortages is the role that pharmacy benefit managers' (PBMs) formularies play in accessing classes of medication. Under the 2023 National Preferred Formulary from a major PBM, two of the "preferred alternatives" for GLP-1 agonists are currently in shortage, while the two "excluded medications" are not.[24] If a medication is excluded from the formulary, it will not be reimbursed by insurance and patients are explicitly recommended by the PBM to "please ask your doctor to consider writing you a new prescription for one of the […] preferred alternatives," thus pushing patients towards a medication already in short supply and potentially leaving a patient without their medication for a chronic condition.

Challenge: The Fragility of the Drug Supply Chain

Platinum-based drugs such as cisplatin and carboplatin are first-line chemotherapies for many cancers, including lung cancer.[25] The National Cancer Institute estimates that approximately 20 percent of all cancer patients receive a platinum-based therapy during their treatment.[26] In February 2023, a cisplatin shortage was reported, followed by a carboplatin shortage in April 2023 which resulted in physicians having to ration life-saving treatments or deviate from clinical guidelines. Additionally, these shortages stifle medical innovation as they restrict access to clinical trials which either iterate on, or compare against, the standard of care.[27]

In response to this shortage, the FDA temporarily allowed the importation of a non-approved formulation of cisplatin from a Chinese manufacturer that does not have an English-language label and does not have the US National Drug Code, a linear barcode that allow for the product to be scanned and tracked.[28]

One of the key factors in the platin shortage is the economics of generic drug manufacturing. According to one study, the leading risk factor for a chemotherapy experiencing a shortage is the age of the drug.[29] This may seem counterintuitive – the longer a drug has been on the market, the better understanding we should have of expected demand, and have had more time to improve manufacturing yields. However, when considering the impact age has on profit margins, it begins to make more sense. Since cisplatin and carboplatin are available as generic medications, the profit incentives for their manufacturing dramatically decreases. Per the FDA's National Drug Code Directory, there are currently only 8 manufacturers of cisplatin and 6 for carboplatin.[30] The unit price of cisplatin and carboplatin are estimated to be $15 and $23 USD, respectively.[31]

Due to the limited number of manufacturers of generic drugs, any disruption to the marketplace can result in a multi-month-long shortage. In the case of platins, a single overseas cisplatin manufacturing site was shut down due to quality concerns revealed during an FDA inspection.[32] Shutting down this facility decreased the supply of cisplatin, resulting in a worldwide shortage, which then cascaded into a carboplatin shortage when there was a surge in demand from patients switching drugs.

In July 2023, a Pfizer plant in Rocky Mount, North Carolina, was struck by a tornado, destroying the facility.[33] The impact of this tragic event is still being fully evaluated and will likely be felt for years to come. It is estimated that 25 percent of all sterile injectables used by U.S. hospitals were manufactured at this single site and will likely result in shortages for over 64 formulations of 30 different drugs, including lidocaine, a drug that has been in shortage in some capacity since 2015.[34] The Food and Drug Administration estimates that this plant was the sole U.S. supplier for "less than 10" drugs, however additional details, such as what drugs and what formulations, are not available due to disclosure laws.[35] In a pre-emptive response to potential spikes in demand due to the fear of oncoming shortages, Pfizer transitioned many of their products to a strict allocation model rather than being readily available for purchase. In a letter to customers dated August 3rd, 2023, Pfizer additionally disclosed emergency ordering procedures for 12 medications.[36] A link to the Pfizer injectables product availability list, as well as additional resources for locating potential alternatives developed by the United States Pharmacopeia, have been included in Box 1.

However, the story of the Pfizer plant is unfortunately not an uncommon one. For example, in May 2022, a surge of COVID-19 infections led to the shutdown of a single Shanghai-based facility, resulting in a worldwide shortage of iodinated contrast agents.[37] In 2017, Hurricane Maria destroyed a facility producing sterile saline, resulting in a shortage.[38] The ongoing war in Ukraine also threatens the world's supply of helium gas, which is used for a wide variety of medical devices.[39]

POTENTIAL SOLUTIONS

As described above, drug shortages can be the result of a variety of factors, ranging from decades-long policy choices to severe weather. As such, proposed solutions for mitigating drug shortages primarily aim to make the drug supply chain more resilient and adaptable.

Solution: Increased Transparency

As outlined above with MAS and GLP-1 agonists, one of the persistent struggles with managing the drug supply chain is poor visibility into drug demand. In the case of MAS, a change in prescribing rules caused a surge of demand; in the case of GLP-1 agonists, a new off-label usage and subsequent marketing campaign caused prescriptions to spike. In both cases, shortages were primarily driven by supply not matching this newfound demand.

FDA leadership has been publicly discussing the role of the agency regarding drug shortages, including multiple calls for manufacturers to improve reporting of data.[40] Specifically, the FDA claims that less than half of all drug manufacturers are complying with reporting requirements that would provide the agency with information regarding the quantity of active pharmaceutical ingredients (API) and drugs being manufactured. They have also requested that the agency be granted additional authority to request manufacturers provide the FDA with information whenever they observe spikes in demand, so that the FDA can better predict when shortages may occur. This policy was originally proposed for inclusion in the Pandemic and All-Hazards Preparedness Act (PAHPA). PAHPA, which oversees HHS's emergency response activities, requires Congressional reauthorization every five years, and is considered "must-pass" legislation.[41] It is expected to be re-authorized in September 2023, which is after this report has been finalized, but before its presentation to the HOD at the Interim meeting. As of writing, PAHPA negotiations are still ongoing, and it is unclear if FDA's proposals regarding new drug shortage authorities will be included in the final legislative package. Other legislative measures are also being considered – for example, the House Energy & Commerce Committee chair released a request for information and subsequent discussion draft for legislation addressing root causes of drug shortages.[42] Additionally, the White House convened a new task force to develop proposals for improving drug shortages earlier this year, although a timeline has not been made public.[43]

Solution: Pre-Emptive Purchasing

In recent months, the strategy of pre-emptive purchasing, or stockpiling of critical drugs has been proposed. For example, in a recent publication from the Brookings Institute, they propose a "first-in, first-out" buffer inventory to be maintained at a national level by an entity such as HHS, which would hopefully prevent surges in demand from overcoming the supply.[44] Other proposals, such as one put forth by the Centers for Medicare & Medicaid Services, would incentivize hospital systems to maintain their own buffer supply.[45]

However, both models have flaws which may require further study or thoughtful guardrails. For a model in which a national entity maintains the buffer supply, there may be lessons to be learned from the pain points observed around sourcing and purchasing personal protective equipment (PPE) during the COVID-19 pandemic. Specifically, when the federal government entered the market to purchase PPE for the Strategic National Stockpile (SNS), they often found themselves bidding against the same state entities that would likely be the final recipient of those supplies if routed through the SNS.[46] If the model were to price state or local purchasers out of the market and instead force them to go through the national buffer supply, this risks again placing the health of the drug supply chain with a single source of failure, which could increase the national vulnerability to political disputes, mismanagement, or a catastrophic weather event.

Similarly, if the task were given to more local entities, such as at the hospital-level, the concern would be around which hospitals would have the ability to obtain and manage a buffer supply. For example, the initial purchasing of a buffer supply and the subsequent administrative and storage

could be too costly for all but the most profitable hospitals, and would put smaller clinics, particularly in rural settings, at a significant disadvantage.

Solution: Government, Public, or Non-Profit Manufacturing of Drugs

One of the suggested solutions for protecting the pharmaceutical supply chain against market-driven shortages, such as those seen with platins, is to have the manufacturing of essential medicines not be driven by profit incentives. Publicly owned production of medications in capitalist societies is not a new concept and has been implemented in countries such as Sweden (Apotek Produktion & Laboratorier), Poland (Polfa Tarchomin), India (Rajasthan Drugs and Pharmaceuticals), and Thailand (Government Pharmaceutical Organization). Even within the United States, California's Department of Health Services developed, conducted clinical trials, and has been manufacturing intravenous botulism immune globulin (BIG-IV, or BabyBIG), the only treatment for infant botulism, since 1988.[47] Under state law, California may only charge what is required to cover operational costs of BIG-IV manufacturing.

In 2020, California also passed legislation requiring the government, through the CalRx initiative, to partner or contract with manufacturers for the explicit purpose of creating competition and lowering prices in the generic drugs market. In March 2023, CalRx announced it would begin manufacturing insulin, with generic naloxone as a potential future target.[48] While the CalRx program was conceived to introduce competition into markets where limited manufacturers have led to generic drug prices that are arbitrarily and egregiously high, a similar approach could conceivably be taken to enter markets where low profit margins drive manufacturers away.

While not state-owned, a non-profit manufacturing model to address drug shortages has already been developed in the United States. In 2018, a group of philanthropic organizations partnered with medical systems (such as Advocate Aurora Health, Kaiser Permanente, and the U.S. Department of Veterans Affairs) to develop CivicaRx, a non-profit manufacturer of generic drugs.[49] The first drug made by CivicaRx was vancomycin, an antibiotic that has been under shortage for the past 8 years.[50] CivicaRx currently uses a supply partner model but has also initiated construction of domestic manufacturing facilities in Virgina.[51] Of note, some members of CivicaRx are religious affiliated hospitals, which may impact their future willingness to manufacture generic contraceptives, abortifacients, or other drugs opposed by their religious doctrine.

Programs such as CalRx and CivicaRx are too new to fully appreciate the impact that they will have on alleviating drug shortages, but the appeal is clear. Beyond simply the market and supply stabilization by removing profit incentives, having manufacturing facilities located within the United States and responsive to government agencies alleviates many of the major hurdles described by the FDA when combating drug shortages: low visibility into the supply chain, the difficulties of overseas inspections, and poor communication regarding changes in demand. It should also be noted that while the majority of public or non-profit manufacturing is centered on generic drugs, a similar approach could be used for other vulnerable links in the supply chain, such as APIs or fill-finish services.

ONGOING AMA ACTIVITIES

AMA staff continue to remain engaged in drug shortage activities. Staff are involved in a multi-stakeholder effort to remain current on policies, drug shortage and supply chain issues, and to develop group recommendations on the topics, many of which are already contained within AMA policy. The effort includes our AMA, the ASHP, the American Hospital Association (AHA), the

United States Pharmacopeia, the American Society of Anesthesiologists, and the American Society of Clinical Oncology.

Additional advocacy efforts were made since the publication of the 2022 drug shortages update, including communication with the DEA regarding shortages driven by telehealth prescriptions, and how enforcement activities should focus on outlier practices rather than blanket restrictions on telehealth care.[52]

CONCLUSION

In conclusion, drug shortages continue to be a persistent and worsening crisis that endangers patients. In this annual update on drug shortages, three case studies were discussed, investigating the roles of the DEA and production quotas, advertising, PBMs and formularies, and the fragility of the generic drug market particularly when it relies on a small number of overseas manufacturers. Finally, the topic of non-profit or state-owned manufacturing was investigated as a potential tool in alleviating drug shortages. The AMA's policy regarding drug shortages is timely and comprehensive, and updates are proposed to align with the topics discussed. New policy is also recommended for non-profit and public generic drug manufacturing.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution I-22-935, and that the remainder of the report be filed:

A. That Policy H-100.956, "National Drug Shortages," be amended by addition to read as follows:

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations and pharmacy benefit managers on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing

Organization (GPO), pharmacy benefit managers, and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers, and supports efforts by the Federal Trade Commission to oversee and regulate such forces.

7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market or caused to stop production due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers and distributors to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, any unpredicted changes in product demand, and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.
13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of global reporting requirements for indicators of drug shortages.
14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing.
15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.
16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.
19. Our AMA urges the Drug Enforcement Agency and other federal agencies to regularly communicate and consult with the FDA regarding regulatory actions which may impact the manufacturing, sourcing, and distribution of drugs and their ingredients.
20. Our AMA supports innovative approaches for diversifying the generic drug manufacturing base to move away from single-site manufacturing, increasing redundancy, and maintaining a minimum number of manufacturers for essential medicines.

21. Our AMA supports the public availability of FDA facility inspection reports to allow purchasers to better assess supply chain risk.
22. Our AMA opposes the practice of preferring drugs experiencing a shortage on approved pharmacy formularies when other, similarly effective drugs are available in adequate supply but otherwise excluded from formularies or coverage plans.
23. Our AMA shall continue to monitor proposed methodologies for and the implications of a buffer supply model for the purposes of reducing drug shortages and will report its findings as necessary. (Amend HOD Policy)

B. That the following policy be adopted:

Non-Profit or Public Manufacturing of Drugs to Address Generic Drug Shortages

Our AMA:
(1) supports activities which may lead to the stabilization of the generic drug market by non-profit or public entities. Stabilization of the market may include, but is not limited to, activities such as government-operated manufacturing of generic drugs, the manufacturing or purchasing of the required active pharmaceutical ingredients, or fill-finish. Non-profit or public entities should prioritize instances of generic drugs that are actively, at-risk of, or have a history of being, in shortage, and for which these activities would decrease reliance on a small number of manufacturers outside the United States.

(2) encourages government entities to stabilize the generic drug supply market by piloting innovative incentive models for private companies which do not create artificial shortages for the purposes of obtaining said incentives. (New HOD Policy)

CITED POLICIES

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices H-105.988

1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines:
(a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
(b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing.
(c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
(d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended.
(e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.
(f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.
(g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.
(h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.
(i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
(j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.
(k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.
3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.

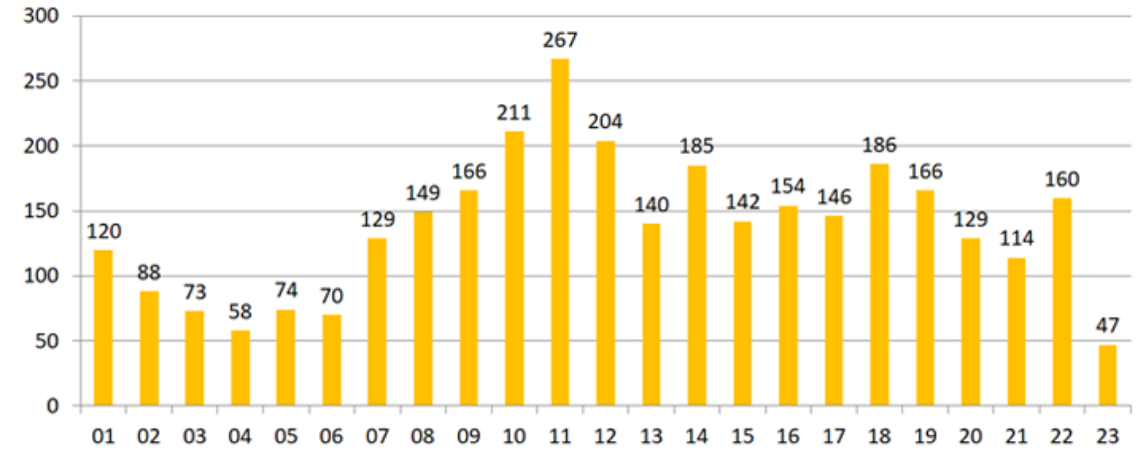
4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.
5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.
6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA.
7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion.
10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.
11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.
12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.
13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).
14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer’s suggested retail price of those drugs.

Box 1. Resources available to assist in mitigation of drug shortages.

1. ASHP Resource Center
2. ASHP list of current shortages
3. FDA Drug Shortages Page (includes current shortages list, extended use dates, mobile app, and additional information)
4. ASHP member survey on current drug shortages
5. Pfizer injectables availability report
6. USP resource on Pfizer Rocky Mount facility alternative products and market share data (note: may require providing name and email address to access)

APPENDIX 1

Figure 1. National Drug Shortages: New Shortages by Year: January 2001 to March 31, 2023

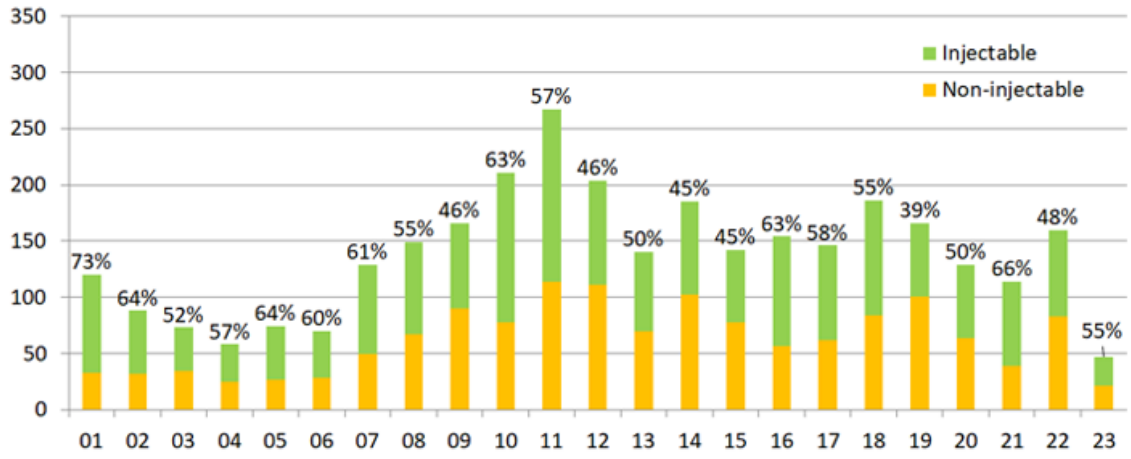


Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

Figure 2. National Drug Shortages: New Shortages by Year
Percent Injectable: January 2001 to March 31, 2023, % Injectable



Note: Each column represents the number of new shortages identified during that year.

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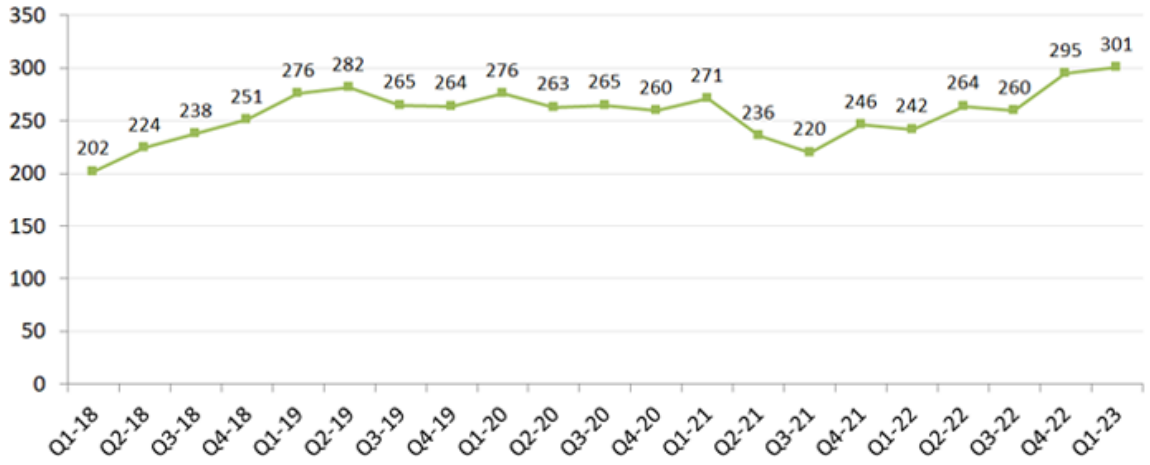
Figure 3. National Drug Shortages: Active Shortages by Quarter: 5 Year Trend



Note: Each point represents the number of active shortages at the end of each quarter.

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Figure 4. National Drug Shortages: Active Shortages Top 5 Drug Classes

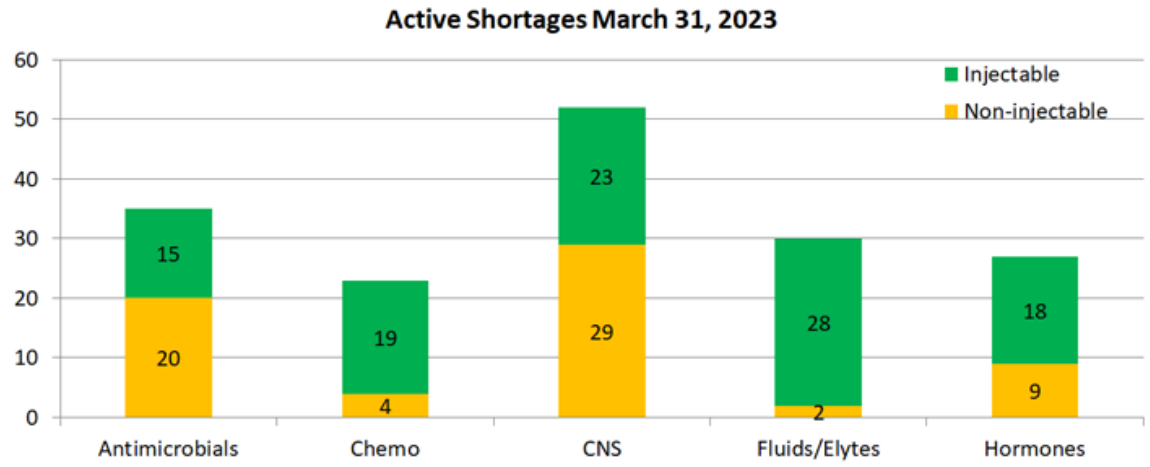

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Figure 5. National Drug Shortages: Common Drug Classes in Short Supply: 5 Year Trend

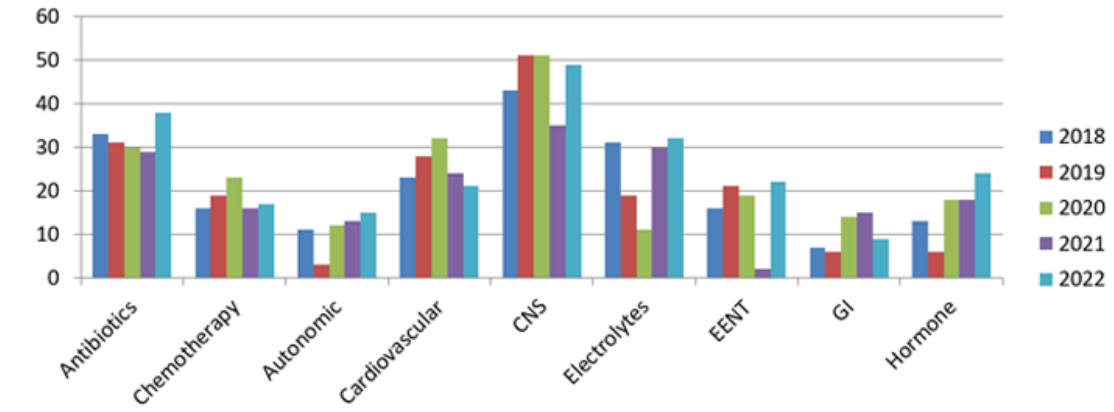

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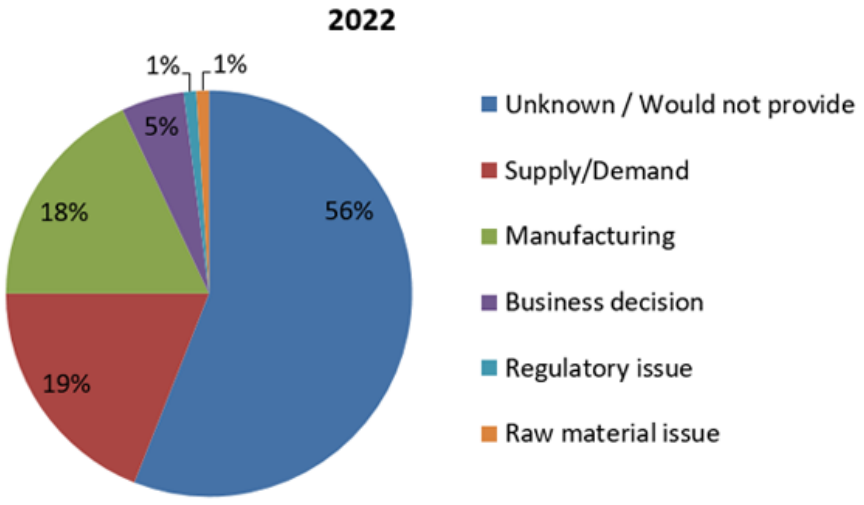
Figure 6. National Drug Shortages: Reasons for Shortages as Reported by Manufacturers During UUDIS Investigation — 2022



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APPENDIX 2

Table 1. Breakdown of statistics from the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER)

	CDER	CBER
NUMBER OF SHORTAGES		
New Shortages	48	1
Prevented Shortages	210	12
Ongoing Shortages	81	5
Notifications	1267	26
Number of Manufacturers Notifying	133	17
ACTIONS TAKEN TO MITIGATE SHORTAGES		
Regulatory Flexibility and Discretion	85	0
Expedited Reviews	193	11*
Expedited Inspections	30	0

* This number includes expedited reviews for six biologics license application (BLA)/BLA supplements and five lot-release submissions for CBER-regulated products.

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REPORT 2 OF THE COUNCIL OF SCIENCE AND PUBLIC HEALTH (I-23)
Precision Medicine and Health Equity
(Reference Committee K)

EXECUTIVE SUMMARY

INTRODUCTION. In continuance of the American Medical Association's (AMA) commitment to health equity, the Council on Science and Public Health has initiated this report, based on in-depth interviews conducted by the AMA and its Health, Science and Ethics team, on precision medicine and its intersections with health equity. Precision medicine, for the purposes of this report, will refer to the practice of utilizing genetics (the study of single genes) and genomics (the study of the whole genome) to personalize or tailor care to individual patients. To explore the past, present, and future landscape of genetics in medicine and to propose a path forward for equitable adoption of emerging technologies, a qualitative research study was performed by interviewing those with lived experiences and other experts. This report represents a summary of the interviews and presents policy recommendations based on the findings.

METHODS: One-hour, in-depth interviews were conducted virtually between November 2022 and February 2023 with 15 experts in one of five areas related to equitable precision medicine (community/patient advocates, social science research, genomics research, genetics clinicians, and industrial representatives). It should be noted that many of the interviewees had expertise or direct experience in several areas (i.e., a clinician may also participate in research). Interviewees were contacted by email and interviewed for 60 minutes, with the opportunity for written follow-up if required. Video recordings of interviews were converted to text-based transcripts by a third-party, and subsequently analyzed by a team of researchers. This project was categorized IRB-exempt through the University of Illinois Chicago (ID: STUDY2022-1388). Supplemental resources for this report were identified by manual screening of literature using Google Scholar or PubMed databases identified by interviewees.

DISCUSSION. Interviewees described many ways in which precision medicine intersects with health equity. For example, interviewees described the ways in which the troubling history of the American eugenics movement still reverberate in the health care setting, or the underlying datasets used to evaluate genetic conditions are predominantly based on samples of European ancestry. To help address these concerns, interviewees described promising practices which include the role of community members in designing and executing research, or the movement away from race- or ethnicity-based clinical guidelines and reimbursement. Other topics, such as research recruitment strategies, the role of law enforcement, ongoing practices of social exclusion, and the economic ties between clinical practitioners and genetic testing companies are also explored.

CONCLUSION. The goal of precision medicine has been to tailor care for the individual patient. In its idealized form, it would eliminate much of the unconscious biases from historical approaches and social constructs that may impact diagnosis and treatment. In its current form, precision medicine and its implementation continue to struggle with familiar issues of inequity, often stemming from an inability to demonstrate trustworthiness. Experts remain highly optimistic about the future of precision medicine and health equity, as long as it comes with the recognition that significant work must still be done to ensure that everyone benefits from these advancements.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-23

Subject: Precision Medicine and Health Equity

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

In continuance of the American Medical Association's (AMA) commitment to health equity, the Council on Science and Public Health has initiated this report, based on in-depth interviews conducted by the AMA focused on precision medicine and its intersections with health equity. The Council believes there is value in sharing these findings with the House of Delegates as there are important policy recommendations to consider. Precision medicine, for the purposes of this report, will refer to the practice of utilizing genetics (the study of single genes) and genomics (the study of the whole genome) to personalize or tailor care to individual patients. To explore the past, present, and future landscape of genetics in medicine and to propose a path forward for equitable adoption of emerging technologies, in-depth interviews were conducted with individuals who have had personal experiences with precision medicine as well as precision medicine experts. This report presents a summary and recommendations based on the findings from those interviews.

Emphasis for this report has been placed on areas in which genetic research and precision medicine offer unique challenges to equity and trustworthiness, such as eugenics, privacy, genetic essentialism, and social exclusion. Some facets, such as cost, access, workforce diversity, and other aspects of institutionalized racism and other inequities, are present in the adoption of precision medicine and discussed where appropriate but may ultimately be better addressed by other AMA efforts.

METHODS

One-hour, in-depth interviews were conducted virtually between November 2022 and February 2023 with 15 experts in one of five areas related to equitable precision medicine (community/patient advocates, social science research, genomics research, genetics clinicians, and industrial representatives). It should be noted that many of the interviewees had expertise or direct experience in several areas (i.e., a clinician may also participate in research). Interviewees were contacted by email and interviewed for 60 minutes, with the opportunity for written follow-up if required.

All interviewees were provided with two definitions prior to starting the interview: precision medicine ("the prevention and treatment of disease that takes into account individual variations in genes or using genetic and genomic testing to assist in the prevention, diagnosis and treatment of diseases") and health equity ("assurance of the conditions for optimal health for all people"). An interview guide was used in each interview, but conversation was permitted to develop naturally to allow potential unexpected themes and ideas to arise. The guide outlined five topics: (1) the concept of race, ethnicity, and ancestry in medicine, (2) earning and building trust, (3) social

drivers of health and precision medicine, (4) economics of access and benefits, and (5) challenges implementing precision medicine moving forward.

Interviewees were compensated $200 by Amazon gift card for their participation and will not be identified beyond general descriptions of their expertise and profession (ex: social science researcher). Video recordings of interviews were converted to text-based transcripts by a third-party, and subsequently analyzed by a team of researchers. This project was categorized IRB-exempt through the University of Illinois Chicago (ID: STUDY2022-1388). Supplemental resources for this report were identified by manual screening of literature using Google Scholar or PubMed databases identified by interviewees.

HISTORY OF GENETIC RESEARCH AND HEALTH EQUITY IN THE UNITED STATES

The United States has a deplorable history of eugenics. Dating back to at least the 20th century, leading eugenicists felt that the quality of the human race could be improved by selective breeding for certain traits, such as intelligence or physical ability.[1] This deeply flawed belief led directly to harm and abuses of marginalized and minoritized populations that were deemed "undesirable" and included abhorrent practices such as forced sterilization and restrictions on immigration, and are viewed today as a thinly veiled guise to reinforce segregation.[2] Through entities such as the Eugenics Record Office, propaganda and lobbying efforts resulted in forcible, state-endorsed sterilization of Black, Latinx, and Indigenous people, and those with disabilities.[3] This history of eugenics was heard throughout the interviews.

> *Black men, for example, or Latina women subjected to sterilization, that is exactly how communities have been viewed, for years, as subjects of experimentation, or treated for years as subjects of experimentation, rather than as patients deserving of the latest and greatest that science and medicine have to offer*. (Participant 3 – Community Representative)

While some may believe that the eugenics movement is a historical oddity, there are many still bearing the scars today. The Family Planning Services and Population Research Act of 1970 (later to be known as 'Title X'), subsidized the treatment of family planning services for those receiving Medicaid or through the Indian Health Service. Title X is a critical tool for funding contraceptive and family planning services in the United States – but under the same program, an estimated 25 percent of Indigenous women of child-bearing age in the United States were sterilized by their physicians over a 6-year period.[4] It is reported that many of these procedures were either performed coercively or without the individual's knowledge.[5]

Beyond eugenics, interviewees noted a long legacy of abuse and exploitation of marginalized and minoritized populations by genetic researchers. For example, interviewees described the experiences of the Havasupai tribe, in which researchers approached the community offering to investigate if there was a genetic cause of the elevated rates of Type 2 diabetes, but subsequently used those same DNA samples for stigmatizing schizophrenia research and human migration studies which were never consented to.[6] Similarly, the Nuu-chah-nulth of the Pacific Northwest were approached to study higher incidence of arthritis in their community, and subsequently were studied for human migration without their consent.[7] In the case of the Karitiana, an Indigenous population of Brazil, they were approached by a genetics research company which subsequently sold their samples for $85 per sample for two decades without compensating the tribe.[8] Now, interviewees noted, genetic testing companies often donate testing kits to Indigenous people but retain intellectual property rights rather than the individual or the community.

> *[Companies] have wanted to give out freely genetic tests to Indigenous patients as a means of service, but really it's a means of collecting information from Indigenous peoples to improve their own algorithms, which are patentable and also subject to intellectual property rules and trademarking and all those other types of restricted things.* (Participant 1 – Community Representative)

Interviewees also noted the parallels that many research projects and genetic databases share with the story of Henrietta Lacks. Lacks, a Black woman with cervical cancer, unknowingly had her tumor biopsied and subsequent cells immortalized and used for research without her consent.[9,10] These then-named HeLa cells, one of the most ubiquitously used cell lines for *in vitro* research, have been commercialized and used as the foundation for generating billions of dollars in profit from biomedical advances. Additionally, genetic researchers have published the genetic information of the HeLa cell line, thus exposing potentially sensitive information about not only Henrietta Lacks, but her direct and extended family as well.[11] In August 2023, it was announced that the Lacks family reached a settlement with Thermo Fisher Scientific for their commercialization of HeLa cells.[12]

Interviewees noted how Henrietta Lacks' story can seem all-too-familiar for marginalized and minoritized communities being asked to participate in genetic research – the companies making the request benefit greatly, while those same communities, who take on significant personal risk, will never benefit from the new technologies that are created.

> *Everything from the Tuskegee syphilis study to Henrietta Lacks, to the average everyday health disparity that many African-Americans experience in their medical care that leads to a situation of distrust for the average African-American with regard to the medical establishment. And that distrust breeds a lack of a desire to participate. It's like, 'I don't trust you, so why do I even want to associate with you?'* (Participant 2 – Community Representative)

ONGOING IMPACTS

Interviewees highlighted that many abusive or inequitable practices continue to impact the quality of care those groups receive today. Much genetic research is based on genome-wide association studies (GWAS), which find statistical correlations between populations with certain genetic mutations and their subsequent health outcomes. While sometimes these GWAS result in identifying underlying mechanisms of disease (for example, a rs6025 mutation results in deficient human factor V function, thus increasing risk of thrombosis and embolism), many genetic associations are correlations based on statistical analysis of patient samples held within large databases rather than an identification of a direct biological cause.[13]

If a patient receives a genetic test result that notes a genetic mutation that has not been sufficiently researched, it is marked as a variant of unknown significance (VUS), or functionally an unactionable result, which may sometimes be interpreted as a negative result.[14] When certain groups are poorly represented in genetic research databases, that means the underlying statistical certainty is weaker, resulting in higher rates of VUS, which manifests in fewer referrals to specialty care, and increased morbidity and mortality.[15-19] According to the GWAS Diversity Monitor, a tool which analyzes data from the National Human Genome Research Institute and European Bioinformatics Institute's GWAS Catalog, as of July 2023, approximately 95 percent of all GWAS

participants are of European ancestry.[20] Only 3 percent are of Asian ancestry, 0.15 percent are of African ancestry and 0.3 percent are of Hispanic or Latin American ancestry.

> *What I encounter on a day-to-day [basis] is just the lack of data. There's a lot more research and datasets available for European ancestry people than everybody else, […] And that kind of trickles down into how these European ancestry genetic datasets are used to make all of our genomic discoveries, then that trickles down into discoveries being more applicable to people of European ancestry than other populations.* (Participant 7 – Genetics Researcher)

Additionally, one statistician described how in much of genetic research, samples from individuals identifying as multiple races or ethnicities ('admixed race') are often excluded entirely from any correlative research, or simply defined as "other," as it adds additional complexity that most statistical models cannot adequately handle.

> *If you include mostly European individuals and then have also some admixed individuals in there, there's a concern that you can get false positive hits. […] So the easiest thing to get around that is to just not deal with it, and exclude anybody who's not cleanly fitting into whatever you think is a homogeneous category. […] Even when there is data for diverse people, it's getting thrown out.* (Participant 7 – Genetics Researcher)

The discrepancies in participation rates are multifactorial, but past research behavior has demonstrated to many underrepresented communities that the genetics ecosystem may not be trustworthy with their data. Interviewees noted that some groups, such as the Navajo Nation, have gone so far as to place a moratorium on members participating in genetics research due to the risk of abuse and exploitation.[21]

Other interviewees noted that past practices which resulted in these deep inequities have now placed individuals from marginalized and minoritized groups in a cycle with seemingly no correct decision – since precision medicine approaches have lower value for them, why would they ever agree to participate? For example, a practicing clinical geneticist described their struggles with communicating the realities of the system that has been created while trying to care for the patient in front of them.

> *Depending on where your ancestors came from and how much we know about genetic relevance of disease to specific variants, can I give you useful information? And at the end of the day, if I'm giving you a lot of gobbledygook that basically is just confusing and not medically useful to your doctors, then why did you waste your time?* (Participant 15 – Clinical Practitioner)

> *If the folks who are contributing the most important information to genetics research don't even have access to genomic medicine because of published data on just lower referral rates for genetic testing, lower rates of follow up, just lots of different assumptions being made about what insurance people have. Then you create a system where people are being asked to take a risk in offering up their DNA sample, potentially [to] not ever have the benefit from it or potentially have their descendants not have benefit from it*

> *if they don't have access to the medicine.* (Participant 8 – Genetics Researcher)

This raises an interesting conundrum for precision medicine – unlike many other forms of medical research, an individual's choice to participate will have direct impact on members of their community, and conversely, the community at large's willingness to participate will have direct impact on the value that an individual receives from a given test. Many interviewees noted that genetic research recruitment campaigns for underrepresented groups often focus on messaging that emphasizes something to the effect of "if you want your community to benefit from new medical research, you need to participate," which some interviewees responded positively to, while others noted how coercive this approach can be.

> *I have a scripture from the Book of Hosea that I frequently [use] that says that "my people perish for lack of knowledge". And I explain, for our community, particularly the African-American community, knowledge of our collective genomes is knowledge we can't afford to lack. It'll actually put us behind the eight-ball further with regard to our health outcomes because if we continue to not participate, we'll continue to not know about what genotypes are specific, what variants of significance are in our genomes that lead to disease and that lead to us understanding our risk of certain disease earlier and therefore, improving our health outcomes.* (Participant 2 – Community Representative)

> *One of the tendencies I'm noticing with precision medicine is that it's like, "Make sure you're getting involved and being included as research subjects in this, because you're going to miss the boat. And your communities are not going to benefit from these advances." It's sort of operating in a coercive manner in that way, and Indigenous people have experienced that coercive dynamic since the creation of these countries.* (Participant 4 – Social Science Researcher)

As a direct result of unrepresentative research databases, inequity has now been institutionalized in the way clinical guidelines and reimbursement are made for genetic testing – a clear example of ongoing, modern race-based medicine. For example, interviewees noted that people of Ashkenazi Jewish descent often have expanded carrier screening options, or that people of Asian ancestry are more likely to be offered, and have insurance reimburse, genetic testing for a highly toxic side effect when prescribing carbamazepine.[22,23] Interviewees described how these guidelines directly result in decreased access to genetic testing and precision medicine. Although these guidelines were put into place to specifically suggest genetic testing for patients whose ancestries present these genetic variations more frequently, interviewees described how these guidelines concurrently decrease access to genetic testing and precision medicine for populations that do not have an "insurance covered ancestry." Additionally, they noted that these guidelines reinforce the concept of racial essentialism by thinking of conditions such as cystic fibrosis as a "white" disease or sickle cell anemia as a "Black" disease.

> *There are more individuals now being born with Tay-Sachs disease that are non-Ashkenazi Jewish because of the effective carrier screening efforts that were directed at those populations. […] The people of Ashkenazi Jewish descent were aware of their risk and took advantage of reproductive technologies that could avoid the birth of a child that has a severe fatal*

> *disease. Whereas in populations where we don't think about this, there's that risk.* (Participant 9 – Clinical Practitioner)

Law Enforcement and Personal Privacy

In recent years, there have been several high-profile instances from which genetic databases have been leveraged by law enforcement entities for identifying suspects.[24,25] Given the discrepancies and inequity around law enforcement and race, many interviewees described how marginalized and minoritized communities view this as another significant barrier to participation. Interviewees, particularly those directly engaged with the health care system, pointed towards the data security provisions of the Health Insurance Portability and Accountability Act (HIPAA) and the Genetic Information Non-Discrimination Act (GINA). Some pointed out how many of these instances of genetic databases being used for law enforcement purposes were from direct-to-consumer companies which may not be bound by HIPAA and GINA, but others noted that it is very difficult to differentiate between clinical and consumer genetics in terms of public perception, and it is important to call out where abuses have occurred and rectify them before one can be perceived as trustworthy.

> *So we have a prison system, a policing system, an education system, a medical system that are all based on the idea that there are fundamental innate differences about people on the basis of some basic physical attributes like skin color and a couple facial features, skin and hair and eye color, texture, shape.* (Participant 8 – Genetics Researcher)

> *I think it really depends how the data is used. I mean, we've seen the risk of the direct-to-consumer model of testing where people all of a sudden find each other and there's a lot of social risks and genomics gets connected to [law enforcement databases] and criminal investigations and all of those things. Some people actually see that as a benefit. Some people see it as a risk. I think it depends on, again, people's level of knowledge about their family structures and concerns about policing.* (Participant 6 – Social Science Researcher)

Even if strides were made to improve the trustworthiness of direct-to-consumer genetic testing databases, there have also been instances in which clinical screening programs have been improperly leveraged for law enforcement purposes. For example, in New Jersey in 2022, police subpoenaed, without a warrant, heel prick blood samples from the state-run newborn screening program for the purposes of genetic identification of samples from a 1996 cold case.[26] A regulatory landscape analysis found that approximately one-third of states have laws which would allow law enforcement to access newborn screening blood samples for the purposes of genetic identification, while another quarter of states had no discernable policy barring it.[27] Parents that wish to protect their families from warrantless investigations from law enforcement are thus forced to sue the state to destroy blood samples, or opt-out entirely from their child receiving critical early-life disease screening.[28] It should be noted that state-run newborn screening programs are covered by HIPAA and GINA protections, however HIPAA has specific exemptions for law enforcement.

In the wake of the *Dobbs v. Jackson Women's Health Organization* Supreme Court decision and the subsequent restrictions on abortion, interviewees were asked if they were aware of any concerns regarding patient privacy, including carrier screening results and law enforcement action if the termination of a pregnancy were suspected. At the time the interviews were performed, no

interviewee described any known instances, but this will be an issue that is monitored closely moving forward.

GROUP CONSENT AND COMMUNITY-INVOLVED RESEARCH

Genetics research is unique in the impact that individual participation can have on the broader sub-populations they may belong to. As such, many interviewees described their desire to rethink what informed consent looks like in a genetics research context. Some described a concept of "group consent," in which leaders of a community explicitly consent to research. However, at the time of writing, it is not known if any successful models of group consent have been utilized in genetics research, and the concept may be more aspirational than obtainable. Others, instead, described a model where informed consent more explicitly outlines the impacts that individual participation can have on a community.

> *It could be something like a clause stating that your information could be used to make inferential statements about the group or community to which you belong to or to which you belong, and that could have unforeseen effects or impacts on your group or community's rights to resources, if any.* (Participant 1 – Community Representative)

Others noted that a simple approach for obtaining consent is to simply make sure that the impacted communities are the ones involved in, or calling for, the research itself.

> *I think that it works better when the people who are doing the work are the people who it's going to apply to. They are the ones who will decide whether something is a good idea and ethical and appropriate for their community.* (Participant 5 – Social Science Researcher)

> *[Indigenous communities] are not interested so much in questions of ancestry and population migrations. They're thinking about, "Our community's experiencing high levels of H. Pylori, and therefore stomach cancer. How can we address these kinds of real-life issues facing our community and our people?"* (Participant 4 – Social Science Researcher)

> *We asked, 'Why not use Indigenous samples to study conditions that affect Indigenous peoples? How is that for a concept?' [The companies] basically stated that we constitute 3 percent of the US's population and therefore we're not profit-generative for that type of approach.* (Participant 1 – Community Representative)

In addition to providing a more complete model of informed consent, interviewees described how community representation in the research design phase can be a step towards demonstrating trustworthiness.

> *The way that I am able to interact with marginalized communities is just so much more effective, because of that inherent trust. Because the face looks like your face. Or the face is speaking your language, and it makes a huge difference for patients.* (Participant 13 – Industry Representative)

As described above, one of the underlying concerns from historic and current behavior from the genetic research ecosystem is the failure to properly compensate communities for their research

participation, such as the experience of the Karitiana. Interviewees noted that when researchers come from the community itself, they are more likely to appropriately compensate participants. Others discussed how compensation is perhaps an appropriate vehicle for initiating meaningful discussions that build trust with a community. For example, one industry representative described how some companies are providing stock or establishing public benefit corporations to support the community and research participants, particularly when genetic-informed treatments can be very costly. Others described how the actions of researchers tell a lot about their level of commitment to the communities they are studying. For example, if a community is experiencing higher-than-average levels of preventable disease, pairing studies into potential genetic causes with investments in preventative care resources sends a clear signal that the researchers are genuinely interested in improving the well-being of a community, rather than just observing how different they are.

Further, some raised concerns around the unusual relationships that may occur between clinicians, researchers, and the pharmaceutical companies developing precision medicines. Typically borne from lower rates of reimbursement and coverage, health systems may be pushed to offer genetic testing and genomic sequencing through partnerships with for-profit biotechnology companies, which can increase access, but also raises questions about privacy and financial benefit. There is disagreement among genetics practitioners and researchers about the value and ethics of these relationships. Several genetics practitioners and industry representatives describe these partnerships as necessary, given the financial realities of genomic research. Some even see partnerships with biotechnology companies as advancing equity by working to ensure all populations are represented in drug developments.

> *We wanted to get genetic information for all of our patients and we want to sequence their genomes and we need a way of being able to fund this, and there are for-profit groups that would come in and say, 'yep, I would do that for you'. And the quid pro quo is you get the data, that's great. […] We get the data and we get some genetic data and some clinical information that goes with that. And of course we're using that information to develop drugs or to develop treatments. And so that's why we're willing to make the investment and you should want to have your patients represented because if you don't, we're going to develop the wrong drugs for the wrong people.* (Participant 15 – Clinical Practitioner)

Others believe partnerships reinforce perceptions that genomic research and development extracts valuable information from communities without providing benefits back.

> *The problem is we aren't allowed to see the memorandums of understanding between these companies and medical centers. So, we don't actually even know exactly what's been agreed to. […] [Company] will have access to the medical records for those individuals, and they'll be able to link it without identifying anybody because they have the genotype data, they have medical records linked to the genotype data, then they have the genome sequence which they can figure out which genome it is based on the genotypes, and then link to the medical records and nobody else has access to any phenotype data.* (Participant 8 – Genomics Researcher)

Social Exclusion

While community-involved research may initially start as an effort to build trust, it also is a critical opportunity to assess whether researching potential genetic causes is even appropriate in the first

place. Interviewees highlighted that while we may often think of the eugenics movement as long in the past, there are still concerning practices around the pathologizing of social identities, which advocates worry will lead to exclusion or erasure of their communities. Prestigious academic journals are still actively publishing research seeking to identify genetic variation that may be associated with sexual and gender identity..[29-31] While researchers state that their intent is to investigate things such as evolutionary pressure or human behavior, the resulting impact and message it sends to the described community is unmistakable. By implying that there may be an underlying genetic cause to a socially constructed identity, that then suggests that there may be attempts to "cure," or erase from existence, that same community.

> *The idea where someone's sociopolitical identity is strongly informed by or based on an element of variation in one's sex characteristics, in one's sexual orientation, in one's gender identity—that this can be traced back to the genome points in the direction of eugenics. The idea that if we could just get rid of these variations, we would have a "more perfect human race."* (Participant 3 – Community Representative)

> *There are entire populations that are still being abused and have recently experienced things like forced sterilization. […] And so we get to decide whether or not we have a kid. Whether or not we have a history of Huntington's in our past. If I give you that information, does that mean that you get to sterilize me? Right? Because we don't want that.* (Participant 11 – Clinical Practitioner)

Interviewees then went on to describe other areas of medical practice which are unfortunately too familiar for those wishing to escape from the history of eugenics, particularly around the perception of disability.[32] For example, there are varying opinions on the appropriateness of genetic research or screening for conditions such as loss of hearing or deafness (with a lowercase "d"). Members of the Deaf (with a capital "D") community frequently view genetic testing more critically than the hearing community – Deaf individuals often fear that those who poorly understand their culture will view their identity as less desirable, use genetic testing and/or treatments to select against it, and ultimately destroy a vibrant community with its own languages, customs, and traditions.[33] Others may argue that screening for deafness may be a critical step to allow expecting parents to connect with resources, learn sign language, or otherwise better prepare to support a Deaf child. These concerns, which span communities such as those with autism spectrum disorders, schizophrenia, Huntington's disease, or achondroplasia, only further highlight the importance of community involvement in designing appropriate research. Understanding when, where, and why to screen for these traits, and the critical need of acknowledging the medical community's historic role in eugenics, are key steps to demonstrating trustworthiness.[34]

GENETIC ESSENTIALISM AND MISCONCEPTIONS OF RACE

Finally, interviewees described how research and medical ecosystems often have a fundamentally flawed view of race, ethnicity, and genetic ancestry and how it impacts health. Current AMA policy, such as H-65.953, "Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice" and D-350.981, "Racial Essentialism in Medicine," clearly outline that race is a social construct and is inappropriate to use as a proxy for genetics.

> *There's history and momentum behind it, meaning there's this really long, deep-seated history of classifying humans into different groups that are not*

> *scientific, that was done specifically and explicitly for the purpose of justifying, capturing people from their homes and taking them to new continents, enslaving them, treating them as shadow property, and then pretending that never happened, that's what race categories are all about.* (Participant 8 – Genetics Researcher)

Despite growing awareness, researchers' and clinicians' misunderstandings of race, ethnicity, and genetic ancestry continue to provide barriers to individuals seeking care. One social scientist identified the problem that they describe broadly as 'race-based medicine.' In practicing 'race-based medicine,' social scientists say clinicians make assumptions about a patient's health or risk factors based on the patient's phenotypic appearance. The social scientist cited the pharmaceutical drug BiDil as an example of 'race-based medicine.' BiDil (isosorbide dinitrate/hydralazine HCl) was a drug indicated by the FDA exclusively for treatment of congestive heart failure for Black patients.[35] In this interviewee's view, approving a drug for a single racial group is not supported by science or an appropriate understanding of race as a social, and not biological, category.

> *We can't default to the idea of if you are of African descent that you have an increased risk for kidney disease. If you look at African populations at a country level or even more deeply at ancestral tribal levels, the range of risk is enormous.* (Participant 9 – Clinical Practitioner)

As described previously, current clinical guidelines and reimbursement around genetic testing can often be linked directly to certain racial, ethnic, or ancestry categories, despite how they may be based on non-representative cohorts found in genetic databases. Additionally, these guidelines may require patients to self-identify their background (or worse, rely on a clinician's perception of a patient's appearance), which can often not accurately capture the genetic variations associated with ancestry that is relevant for testing.

> *Many of my patients are Dominican. And if I were to look at the DNA from any of my patients, I would see that they come with some of their genetic roots from West Africa. […] But if I ask those people to fill out a form that says […] by race and ethnicity, many of them will say, I'm Latina. But they would never say that they're Black. […] And in some ways I don't care. It's what you, in terms of acculturation and the customs, [believe] and all of those end up being incredibly important because there are certain customs and certain values and traditions that come with being Latina. […] But yet there are certain genetic variants that absolutely trace their roots to West Africa.* (Participant 15 – Clinical Practitioner)

> *There's a lot of diversity within any given checkbox that is just not being captured. So how informative that is about somebody's genetic predisposition, it's hard to say. An individual who self-identifies as African American lives in the US for example, is obviously going to have a very different genetic makeup than somebody who lives in South Africa currently or something like that. You know what I mean? But if they're on the census form, they might both check the same box.* (Participant 7 – Genetics Researcher)

Distinguishing cultural and social labels from genetic labels is important to ensure clinicians and researchers know what information is genetically relevant for an individual and that the various

identities a patient holds are not mislabeled or debased. They emphasize that you simply cannot precisely assess an individual's genetic risk based on their phenotype, cultural, or racial identity.

CONCLUSION

The goal of precision medicine has been to better understand and tailor care for the individual patient. In its idealized form, it would eliminate much of the unconscious biases from historical approaches and social constructs that may impact diagnosis and treatment. In its current form, precision medicine and its implementation continues to struggle with familiar issues of inequity, often stemming from an inability to demonstrate trustworthiness. There is optimism about the future of precision medicine and health equity, as long as it comes with the somber recognition that significant work must still be done to allow everyone to benefit from these advancements.

RECOMMENDATIONS

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

1. That our AMA:

    A. recognizes past and ongoing practices in the field of genetics, including eugenics, have resulted in harm and decreased the quality of care available to minoritized and marginalized groups, and undermined their trust in the available care. Our AMA strongly supports efforts to counter the impact of these practices.

    B. supports efforts to increase the diversity of genetics research participants and for research participants and impacted communities to be appropriately compensated.

    C. strongly opposes the use of race, ethnicity, genetic ancestry, sexual orientation, or gender identity as the basis for genetic testing recommendations, or the insurance coverage of genetic tests.

    D. supports policies which restrict access to genetic databases, including newborn screening samples or carrier screening results, by law enforcement without a warrant. States should clearly outline procedures for law enforcement to obtain access to genetic databases when there are compelling public safety concerns, consistent with AMA patient privacy policy.

    E. supports an affirmative consent or "opt-in" approach to genetics research including samples stored within large databases and encourages those in stewardship of genetic data to regularly reaffirm consent when appropriate.

    F. recognizes that an individual's decision to participate in genetics research can impact others with shared genetic backgrounds and encourages researchers and funding agencies to collaborate with impacted community members to develop guidelines for obtaining and maintaining group consent, in addition to individual informed consent. Our AMA supports widespread use of a robust consent process which informs individuals about what measures are being taken to keep their information private, the difficulties in keeping genetic information fully anonymous and private, and the potential harms and benefits that may come from sharing their data.

G. strongly opposes research seeking to find genetic causes for protected traits, including gender identity, sexual orientation, and differences in ability, unless specifically requested by, or in direct collaboration with, the impacted community. (New HOD Policy)

2. That current AMA policies H-315.983, "Patient Privacy and Confidentiality," H-65.953 "Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice," and D-350.981 "Racial Essentialism in Medicine" be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: minimal less than $1,000

CITED AMA POLICIES

H-315.983. Patient Privacy and Confidentiality
1. Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure; and (e) That the Health Insurance Portability and Accountability Act of 1996 (HIPAA) be the minimal standard for protecting clinician-patient privilege, regardless of where care is received.
2. Our AMA affirms: (a) that physicians and medical students who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians and medical students should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.
3. Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients, physicians, and medical students should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure.
4. Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review.
5. The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.
6. Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained.
7. Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual.
8. When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.
9. Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures.
10. Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of

identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.
11. Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures
12. Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.
13. Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.
14. Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance.
15. In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands.
16. The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.
17. Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing.
18. Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.
19. Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.
20. Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes.
21. Our AMA will draft model state legislation requiring consent of all parties to the recording of a physician-patient conversation.
BOT Rep. 9, A-98. Reaffirmation I-98. Appended: Res. 4, and Reaffirmed: BOT Rep. 36, A-99. Appended: BOT Rep. 16 and Reaffirmed: CSA Rep. 13, I-99. Reaffirmation A-00. Reaffirmed: Res. 246 and 504 and Appended Res. 504 and 509, A-01. Reaffirmed: BOT Rep. 19, I-01. Appended: Res. 524, A-02. Reaffirmed: Sub. Res. 206, A-04. Reaffirmed: BOT Rep. 24, I-04. Reaffirmed: BOT Rep. 19, I-06. Reaffirmation A-07. Reaffirmed: BOT Rep. 19, A-07. Reaffirmed: CEJA Rep. 6, A-11. Reaffirmed in lieu of Res. 705, A-12. Reaffirmed: BOT Rep. 17, A-13. Modified: Res. 2, I-14. Reaffirmation: A-17. Modified: BOT Rep. 16, A-18. Appended: Res. 232, A-18. Reaffirmation: I-18. Reaffirmed: Res. 219, A-21. Reaffirmed: Res. 229, A-21. Reaffirmed: BOT Rep. 12, I-21. Reaffirmed: BOT Rep. 22, A-22. Reaffirmation: A-23.

H-65.953. Elimination of Race as a Proxy for Ancestry, Genetics, and Biology in Medical Education, Research and Clinical Practice
1. Our AMA recognizes that race is a social construct and is distinct from ethnicity, genetic ancestry, or biology.
2. Our AMA supports ending the practice of using race as a proxy for biology or genetics in medical education, research, and clinical practice.
3. Our AMA encourages undergraduate medical education, graduate medical education, and continuing medical education programs to recognize the harmful effects of presenting race as biology in medical education and that they work to mitigate these effects through curriculum change that: (a) demonstrates how

the category "race" can influence health outcomes; (b) that supports race as a social construct and not a biological determinant and (c) presents race within a socio-ecological model of individual, community and society to explain how racism and systemic oppression result in racial health disparities.
4. Our AMA recommends that clinicians and researchers focus on genetics and biology, the experience of racism, and social determinants of health, and not race, when describing risk factors for disease.
Res. 11, I-20.

D-350.981 Racial Essentialism in Medicine
1. Our AMA recognizes that the false conflation of race with inherent biological or genetic traits leads to inadequate examination of true underlying disease risk factors, which exacerbates existing health inequities.
2. Our AMA encourages characterizing race as a social construct, rather than an inherent biological trait, and recognizes that when race is described as a risk factor, it is more likely to be a proxy for influences including structural racism than a proxy for genetics.
3. Our AMA will collaborate with the AAMC, AACOM, NBME, NBOME, ACGME and other appropriate stakeholders, including minority physician organizations and content experts, to identify and address aspects of medical education and board examinations which may perpetuate teachings, assessments, and practices that reinforce institutional and structural racism.
4. Our AMA will collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors.
5. Our AMA will support research that promotes antiracist strategies to mitigate algorithmic bias in medicine.
Res. 10, I-20

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REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-23)
HPV-Associated Cancer Prevention
(Reference Committee K)

EXECUTIVE SUMMARY

BACKGROUND. American Medical Association (AMA) Policy H-440.872 "HPV-Associated Cancer Prevention," as adopted by the House of Delegates (HOD), asked that our AMA study requiring HPV vaccination for school attendance and report its findings to the AMA House of Delegates by the 2023 Interim Meeting.

METHODS. English language articles were selected from searches of PubMed and Google Scholar using the search terms "HPV vaccination", "HPV vaccine mandates," "mandated vaccines AND schools" and "school attendance AND HPV vaccine mandate". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies; applicable organizations were also reviewed for relevant information.

DISCUSSION. HPV vaccination remains the best method for preventing cancer-causing infections and precancers. HPV infections and cervical precancers have dropped since 2006, when HPV vaccines were first used in the United States. Among teen girls, infections with HPV types that cause most HPV cancers and genital warts have dropped 88 percent and among young adult women, they have dropped 81 percent. Among vaccinated women, the percentage of cervical precancers caused by the HPV types most often linked to cervical cancer have dropped by 40 percent. Routine HPV vaccination is widely recommended for age- and guideline-eligible male and female adolescents and young adults by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).

Few states mandate the HPV vaccine for school attendance in part because HPV is a sexually transmitted infection, and it is not likely to be transmitted in schools. Adding vaccines to the list required for attendance is viewed by some as putting up unnecessary roadblocks for school attendance. Opponents have also expressed moral objections related to a vaccination mandate for a sexually transmitted infection. However, proponents of the HPV vaccine mandates for school entry argue that it is important to promote immunization when the vaccine is most effective – before the initiation of sexual activity and exposure to HPV. Those already infected with HPV can also benefit from the vaccine because it can prevent infection against HPV strains that they may not have contracted. Additionally, the vaccine elicits a higher immune response in adolescents ages 11 to 12 than in older teens.

CONCLUSION. Current available evidence shows that without widespread public support, monitoring, sanctions for noncompliance, or changes to the method of vaccine administration, school-entry HPV vaccine mandates do little to encourage uptake. Stronger health care practices such as more in-depth discussions with hesitant parents and establishing vaccination as the default are strategies to improve vaccination coverage rates. This report is specifically focused on the history of vaccine mandates for school entry, the legality of vaccine mandates, public health ethical considerations, assessment on the effectiveness of HPV vaccine mandates on HPV vaccination rates, and other interventions to increase HPV vaccination rates.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-I-23

Subject: HPV-Associated Cancer Prevention

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

INTRODUCTION

American Medical Association (AMA) Policy H-440.872 "HPV-Associated Cancer Prevention," as adopted by the House of Delegates (HOD), asked that our AMA study requiring HPV vaccination for school attendance and report its findings to the AMA House of Delegates by the 2023 Interim Meeting.

BACKGROUND

Since licensure in the United States (U.S.) in 2006, the human papillomavirus (HPV) vaccine has been shown to be a safe, effective, and durable method for decreasing HPV-related infections and subsequent sequelae, including genital warts and cervical, vulvar, vaginal, penile and anal cancers and potentially oropharyngeal cancers.[1] Routine HPV vaccination is widely recommended for age- and guideline-eligible male and female adolescents and young adults by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP).[2] HPV vaccine is recommended for routine vaccination at age 11 or 12 years and for everyone through age 26 years if not adequately vaccinated when younger.[3] For adults ages 27 through 45 years, clinicians can consider discussing the HPV9 vaccination with people who are most likely to benefit.[4]

HPV vaccination remains the best method for preventing cancer-causing infections and precancers. HPV infections and cervical precancers have dropped since 2006, when HPV vaccines were first used in the U.S. For example, among teen girls, infections with HPV types that cause most HPV cancers and genital warts have dropped 88 percent and among young adult women they dropped 81 percent.[5] Among vaccinated women, the percentage of cervical precancers caused by the HPV types most often linked to cervical cancer has dropped by 40 percent.[3]

Although recommendations by ACIP provide clinical guidance, school vaccination requirements are generally determined by state legislatures or state health departments. Few states require the HPV vaccine for school attendance in part because HPV is considered a sexually transmitted infection (STI), and it is not likely to be transmitted in schools.[6] Adding vaccines to the list required for school is viewed by some as putting up unnecessary roadblocks for school attendance. For the HPV vaccine, some have expressed moral objections related to a vaccination mandate for a STI.[7] This report is specifically focused on the history of vaccine mandates for school entry, the legality of vaccine mandates, assessment on the effectiveness of HPV vaccine mandates on HPV vaccination rates, and other interventions to increase HPV vaccination rates.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "HPV vaccination", "HPV vaccine mandates," "mandated vaccines AND schools" and "school attendance AND HPV vaccine mandate". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

Background on HPV

HPV is a group of more than 200 related viruses, some of which are spread through vaginal, anal, or oral sex.[8] The majority of HPV infections are self-limited and are asymptomatic. Sexually transmitted HPV types fall into two groups, low and high risk.[6] Low-risk HPVs generally cause no disease.[6] However, a few low-risk HPV types can cause warts on or around the genitals, anus, mouth, or throat. High-risk HPVs can cause several types of cancer.[6] There are about 14 high-risk HPV types including HPV16 and HPV18, which are responsible for most HPV-related cancers.[6] Nearly all people are infected with HPV within months to a few years after becoming sexually active. Around half of these infections are with a high-risk HPV type.[6] HPV can infect anyone regardless of their sex, gender identity, or sexual orientation. HPV vaccination is the best method to prevent infection with disease-causing HPV types, preventing many HPV-related cancers and cases of genital warts. Before HPV vaccines were introduced, approximately 355,000 new cases of ano-genital warts occurred every year.[9]

Prevalence of HPV-associated cancers

Long-lasting infections with high-risk HPVs can cause cancer in parts of the body where HPV infects cells, such as in the cervix, oropharynx, anus, penis, vagina, and vulva.[6] HPV infects the squamous cells that line the inner surfaces of these organs. For this reason, most HPV-related cancers are squamous cell carcinomas. Some cervical cancers come from HPV infection of gland cells in the cervix and are adenocarcinomas.[6] Each year, there are about 45,000 new cases of cancers in parts of the body where HPV is often found, and HPV is estimated to cause about 36,000 of these.[6]

Background on HPV Vaccines and Recommendations for Vaccination

The FDA approved first-generation Gardasil®, produced by Merck, in 2006, which prevented infection of four strains of HPV – 6, 11, 16, and 18.[10] In December 2014, Gardasil®9 was approved by the FDA.[8] This vaccine protects against 9 strains of HPV: the four strains approved in the previous Gardasil vaccine, as well as 31, 33, 45, 52, and 58.[8] These strains are associated with the majority of cervical cancer, anal cancer, and throat cancer cases as well as most genital warts cases and some other HPV-associated ano-genital diseases.[11] The vaccine was initially approved for cervical cancer prevention, but in 2020 the FDA broadened its approval to include the prevention of oropharyngeal cancer and other head and neck cancers.[12]

With over 120 million doses of HPV vaccines distributed in the United States, robust data demonstrate that HPV vaccines are safe.[13] There have been relatively few adverse events reported after HPV vaccination. Commonly reported symptoms include injection-site reactions such as pain, redness and swelling, as well as dizziness, fainting, nausea, and headache.[14] Current research suggests the vaccine protection is long-lasting: more than 10 years of follow-up data indicate the

vaccines are still effective and there is no evidence of waning protection, although it is still unknown if recipients will need a booster.[15] Further, HPV vaccination has not been associated with initiation of sexual activity or sexual risk behaviors.[16] HPV vaccine is recommended for routine vaccination at age 11 or 12 years. Vaccination can be started at 9 years of age. ACIP also recommends vaccination for everyone through age 26 years if not adequately vaccinated when younger. HPV vaccination is given as a series of either two or three doses, depending on age at initial vaccination.[15] HPV vaccines are currently not recommended for use in pregnant persons.[15] HPV vaccines can also be administered regardless of history of ano-genital warts, abnormal Pap test or HPV test, or ano-genital precancer.[15]

VACCINE MANDATES

Legality of Vaccination Mandates

In the early 19th century, smallpox remained one of the largest threats to public health. Amid frequent smallpox outbreaks, Massachusetts passed the nation's first vaccine mandate in 1810. The Massachusetts law gave local health boards the authority to require vaccination when outbreaks occurred, imposing fines or quarantine for non-compliance.[17] In 1827, Boston enacted the first school vaccine mandate for smallpox; other cities and states soon followed.[18] Today, four common childhood vaccinations – DtaP, MMR, polio, and varicella – are required for children to enroll in kindergarten in every state,[1] with 44 states also requiring a hepatitis B vaccination before kindergarten and 30 states requiring a meningitis vaccination before entering later grades.[19] Until the COVID-19 pandemic, vaccine mandates in the United States have mostly been enacted by state and local governments in relation to public venues, schools, and health care facilities, with the military also requiring certain vaccines.[20] Vaccine mandates require that individuals be vaccinated against certain illnesses, usually as a condition of entry to or participation in certain activities. The most common vaccine mandates are applied to enrollment in schools. However, vaccine mandates are not absolute. School vaccine mandates in every state allow for exemptions.

The legal basis for vaccine mandates typically lies within the police powers of a state. Police powers encompass the broad power of a state to regulate matters affecting the health, safety, and general welfare of the public, housed within the Tenth Amendment of the Constitution.[2,21] While school vaccination requirements are framed as conditional, courts often view them as compulsory; however, these compulsory mandates have been widely accepted and judicially sanctioned.[18] The legitimacy of compulsory vaccination programs depends on both scientific factors and constitutional limits. Scientific factors include the prevalence, incidence, and severity of the contagious disease; the mode of transmission; the safety and effectiveness of any vaccine in preventing transmission; and the nature of any available treatment. Constitutional limits include protection against unjustified bodily intrusions, such as forcible vaccination of individuals at risk for adverse reactions, and physical restraints and unreasonable penalties for refusal.[22] Vaccination programs have been legally challenged as inconsistent with federal constitutional principles of individual liberty and due process, an unwarranted governmental interference with individual autonomy, and an infringement of personal religious beliefs under First Amendment principles.[2]

The U.S. Supreme Court has only officially addressed vaccine mandates in two cases. In 1905, the Court upheld the constitutionality of vaccine mandates in the seminal case *Jacobson v. Massachusetts*.[23] Jacobson challenged the Massachusetts law mentioned earlier that gave local health boards the authority to require vaccination when outbreaks occurred. The Court held that a vaccine mandate was valid so long as there was a danger to public health and safety and the

[1] With the exception of Iowa, which does not require a mumps vaccine.

mandate had a real or substantial relation to the goal of protecting public health. In 1922, the Court upheld vaccine mandates as a condition of school attendance in *Zucht v. King*.[24] In its brief, three paragraph opinion, the Court reaffirmed the broad discretion of the states to employ police powers and states' authority to delegate those powers to municipalities to determine under which conditions health regulations become operative.

The most frequently used arguments against compulsory vaccination are the religious clauses in the First Amendment. Supreme Court jurisprudence outside the realm of vaccination has clarified that the right of free exercise of religion does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability.[2] The majority of states grant religious exemptions to school vaccine mandates, but even laws that do not provide for religious exemptions have been deemed constitutional.[25] Arguments have also been made under the Equal Protection Clause of the Fourteenth Amendment, but courts have rejected arguments that school vaccine mandates discriminate against school children to the exclusion of other groups because school children are not a constitutionally protected class.[2]

Other constitutional arguments have had even less success. Constitutional rights are generally framed as the right to be free of some form of government intrusion or restriction. As such, courts have found that the Constitution does not guarantee any "positive" rights, e.g., any requirement that the government provide anything. This includes education, thus there is no limit on the sort of reasonable regulations that a state may choose to impose on the privilege of a public education.[2] Arguments that vaccine requirements are arbitrary, capricious, or unreasonable have also failed, as well as arguments that school vaccination laws constitute illegal searches and seizures that violate the Fourth Amendment.[2]

Vaccine Exemptions

Vaccine exemption laws vary by jurisdiction. All 50 states and Washington D.C. (D.C) allow for vaccine exemptions for medical reasons. There are 45 states and D.C. that grant religious exemptions.[26] Currently, 15 states allow philosophical exemptions for children whose parents object to immunizations because of personal, moral or other beliefs. How exemptions are enforced also varies among states. Examples of how states have addressed enforcement include: parental notarization or affidavit in the exemption process, and education about the benefits of vaccination and risk of being unvaccinated.[27] To reduce non-medical exemptions, the CDC recommends that states strengthen the rigor of the application process, frequency of submission, and enforcement as strategies to improve vaccination rates.[27]

There is a growing body of evidence regarding the impact of state vaccination requirements for school age children on vaccination coverage and the association of non-medical exemption rates with increased disease incidence. The use of philosophical exemptions and under immunization tend to cluster geographically, putting some communities at greater risk for outbreaks. This geographic clustering of exemptions is associated with increased local risk of vaccine-preventable diseases, such as pertussis and measles.[27]

Possibility of HPV Vaccine Mandates

When discussion surrounding an HPV vaccine mandate first began, it was riddled with controversy. Being initially recommended only for females aged 11-12 years,[28] parents were uncomfortable with the idea of giving a vaccine for a STI to young girls, especially as the manufacturer mounted an expensive lobbying campaign to get it mandated.[29] Though the idea that parents do not need to vaccinate their children against STIs at a young age remains prevalent, studies routinely show that

parents underestimate their children's sexual activity.[30] Moreover, communication about sexual activity before a child's sexual "debut" correlates with less risky sexual behavior for the child.[31,32] The traditional rationale of tying vaccination to school attendance, is to prevent the spread of a disease outbreak that would prevent large numbers of children from attending school. However, there are already precedents that do not meet those narrow conditions. The tetanus part of the Tdap vaccine protects against an illness that is not communicable between humans at all. The traditional justification for tying vaccination to school entry not only fails to comprehensively weigh the risks and benefits of HPV vaccination, it also does not reflect the realities of mandatory vaccination today. In *Boone v. Boozman*, an Arkansas court explained in the context of hepatitis B vaccines that the method of transmission is not the only factor by which a disease can be judged dangerous and thus require mandated vaccination.[33] The caveat to *Boone* is that the court noted that the longevity of the virus on fomites added to the danger warranting a vaccination requirement for the high-traffic environment of a school setting, which may not be said of HPV.

Equity Implications of HPV Vaccine Mandates

Studies have shown that awareness of HPV, and HPV vaccination rates, are lower among Black and Hispanic women as compared to non-Hispanic Whites.[34] For mandated vaccines, by contrast, there is no evidence of racial disparity in rates of vaccination.[34] Black and Hispanic children receive these vaccines at comparable rates to other children, suggesting that mandates would be an effective tool for reducing disparities in vaccination and cervical cancer.[34] Mandating vaccination is not a substitute for improved education, screening, and treatment in minority populations, but it can be an important means of achieving greater health equity with respect to HPV-associated disease.[34]

Among adolescents aged 13–17 years in 2021, HPV vaccination coverage (at least 1 dose and HPV vaccine up to date) increased to approximately 58.6 percent.[35] Despite overall progress in vaccination coverage among adolescents, coverage disparities remain, particularly by geographic area. HPV vaccination was lower among adolescents living in rural areas than among adolescents living in urban areas.[31] These geographic disparities were statistically significant only among adolescents living at or above poverty level.[31] Access to the Vaccines for Children (VFC) program might contribute to higher vaccination coverage and lack of a geographic disparity for adolescents living below the poverty level among those in rural and urban areas. **Error! Bookmark not defined.**,[31]

Cost is not likely to be a concern in the equitable distribution of the HPV vaccine, since payment for vaccines is covered by a variety of sources. Under the Patient Protection and Affordable Care Act, all health insurance plans in the insurance marketplace must cover the HPV vaccine without cost sharing as it is recommended by the ACIP. The Vaccines for Children (VFC) program also pays for ACIP-recommended vaccination for all children through age 18 who are Medicaid-eligible, uninsured, American Indian or Alaskan Native, or underinsured. The Children's Health Insurance Program (CHIP) must cover ACIP-recommended vaccines since beneficiaries are not covered under VFC. Merck, the manufacturer of one approved HPV vaccine, Gardasil, also provides vaccines free of charge to eligible individuals, primarily the uninsured who, without our assistance, could not afford needed Merck medicines.[36]

Barriers to Implementing Vaccine Mandates

The COVID-19 pandemic highlighted several barriers to vaccine mandates overall. There was speculation that rampant misinformation related to the COVID-19 vaccine would lead to a spillover of distrust into vaccination in general, potentially leading to a reduction in childhood vaccination rates in general.[35] Online public opinion polls show that there is no evidence of such spillover, in fact, trust in the safety of vaccines and the public health institutions that promote them increased

overall.[35] However, attitudes regarding school requirements for routine vaccinations became more negative, suggesting a spillover of anti-mandate sentiments more broadly.[37] Further, one study noted that during the 2020–21 school year, national coverage with state-required vaccines among kindergarten students declined from 95 percent to approximately 94 percent.[38] In the 2021–22 school year, coverage for all state-required vaccines among kindergarten students further decreased to approximately 93 percent.[39] Another study found that for the first time since 2013, the proportion of 13–17-year-olds who received their first doses of the HPV vaccine did not increase.[40] Instead, vaccination coverage decreased among Medicaid-insured teens and remained lowest among uninsured teens, two of the four groups eligible for the VFC program.[37] This highlights that despite widespread return to in-person learning, COVID-19–related disruptions continue to affect vaccination coverage, preventing a return to pre-pandemic coverage levels among kindergarten students and adolescents.

Public support for school requirements for routine childhood vaccination dropped by 10 to 12 percentage points between 2019 and 2023 (down to only 70-74 percent support three years into the pandemic).[37] This left about one-quarter of U.S. adults (25-28 percent) opposed to vaccine requirements in 2023, which is the highest level of opposition to routine childhood vaccination requirements in recent history.[37] Notable drops in support during this time occurred among Republicans and those leaning Republican, as well as among adults who are not vaccinated against COVID-19.[37]

Moreover, when those opposing routine childhood vaccine requirements for school were asked about potential reasons why, the top reason cited by approximately half of those in opposition was that "it should be the parents' choice to decide for their child" (49 percent).[37] Most of the public believes routine vaccines are very safe, and this attitude is distinct from support for government requirements to be vaccinated.[37]

LESSONS FROM STATES WITH HPV VACCINE MANDATES

Hawaii, Rhode Island, Virginia, and D.C. have laws that require HPV vaccination for school entry. D.C. and Virginia require the HPV vaccine for girls to enter the sixth grade but allow parents to opt out of the requirement due to medical, moral, or religious reasons.[41] Rhode Island requires all seventh-grade students to be vaccinated.[38] While girls must still access HPV vaccines via a health professional, these mandates encourage a standardized age of vaccine administration and require schools to distribute information about the benefits of HPV vaccination to all parents. Parents are expected to review this information before opting their daughters out of HPV vaccination. It was hypothesized that these mandates were expected to facilitate the equal distribution of basic knowledge about HPV vaccines across various groups, promote uniformity in health care provider recommendations, and as a result, lessen inequities in uptake.[42]

One study aimed to understand the effects of mandates on HPV vaccine uptake in Virginia and D.C. years after implementation.[39] The study showed that there were improved clinician vaccine recommendations for some racial-ethnic minority girls.[39] However, the study also showed that mandates did not influence vaccine completion. Unexpectedly, rates of initiation and completion were lower in mandated (vs. non-mandated) jurisdictions in the post- mandate period, and completion declined in mandated jurisdictions once mandates came into effect. This suggests low enforcement of—and adherence to—HPV vaccine mandates, which was surprising given school-entry mandates have been effective for achieving high uptake of other adolescent and childhood vaccines.[43,44] However, these findings complement other studies identifying no impact of school-entry HPV vaccine mandates on overall uptake.[45,46]

The study interestingly noted reverse disparities in vaccine initiation in mandated jurisdictions for adolescents with the least educated parents.[39] This is in part due to D.C. and Virginia's broad opt-out provisions, which allow parents to refuse HPV vaccination after reviewing educational materials.[47] Further, the study showed that health care professionals' failure to discuss HPV vaccination with patients contributes to non-vaccination—particularly for low-income and racial-ethnic minority adolescents.[39]

Overall, the findings show that school-entry HPV vaccination mandates may disperse health-enhancing knowledge more equally across the population; however, they did not significantly change the rates of individuals who were up to date on HPV vaccination.[39] Further, barriers to uptake (i.e., lack of health care access, time constraints) may persist and differences in clinician behaviors may continue to shape patterns of uptake.

INTERVENTIONS FOR INCREASING HPV VACCINATION RATES

Studies have demonstrated that the most effective intervention to increase vaccine uptake in individuals is strong recommendation for vaccination by their health care professional.[39,48] Research documenting HPV vaccination inequities suggests low-income and Black (vs. White) girls are less likely to receive a strong health care professional recommendation for vaccination and the racial gap in recommendations has waned, but not disappeared, over time.[49,50] School-entry HPV vaccination mandates may have provided the incentive for clinicians to discuss HPV vaccination with eligible individuals and their parents as part of routine care, mitigating inequities in recommendation receipt.[39] Other studies found that reminder-based interventions for health care professionals such as standing orders and social media campaigns have improved vaccination coverage.[51] Finally, studies have found that environmental interventions, particularly school-based and childcare center-based vaccination programs were most effective in increasing vaccination coverage.[52]

The Community Preventive Services Task Force (CPSTF) has also released the following findings on what works in public health to improve vaccination rates based on available evidence. The following interventions could be applied to increasing HPV vaccination rates:

- Home visits to increase vaccination rates.[53]
- Vaccination programs in schools and organized child-care centers.[54]
- Vaccination programs in WIC settings.[55]
- Immunization information systems set up to create or support effective interventions, such as client reminder and recall systems, provider assessment and feedback, and clinician reminders for vaccination or missed vaccination opportunities.[56]

EXISTING AMA POLICY

AMA policy H-440.872 "HPV-Associated Cancer Prevention" urges physicians to educate themselves and their patients about HPV and associated diseases, HPV vaccination, as well as routine HPV related cancer screening. This policy also states that the AMA will intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public. Further, it recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination and encourages interested parties to investigate means to increase HPV vaccination

rates by facilitating administration of HPV vaccinations in community-based settings including school settings.

AMA policy H-440.970, "Nonmedical Exemptions from Immunizations" states that the AMA believes that nonmedical (religious, philosophic, or personal belief) exemptions from immunizations endanger the health of the unvaccinated individual and the health of those in the community at large. It also supports the immunization recommendations of ACIP for all individuals without medical contraindications and recommends that states have in place an established mechanism, which includes the involvement of qualified public health physicians, of determining which vaccines will be mandatory for admission to school and other identified public venues based upon the recommendations of the ACIP and policies that permit immunization exemptions for medical reasons only.

The AMA also continues to develop material and publish new stories on how doctors can effectively communicate with patients to help build vaccine confidence.[57,58]

CONCLUSION

HPV is a common virus, some types of which spread through sexual contact.[59] Some sexually transmitted HPVs can cause genital warts, whereas others, called high-risk or oncogenic HPVs, can cause cancer.[54] High-risk HPVs cause virtually all cervical cancers, most anal cancers, and some vaginal, vulvar, penile, and oropharyngeal cancers.[6] Research has demonstrated that the HPV vaccine is a safe and effective way to decrease HPV-related cancers. However, the vaccination rate in the U.S. is suboptimal.

When first proposed, HPV school vaccine mandates were controversial. Some parents were uncomfortable with the idea of giving a vaccine for a STI to young girls age 11-12.[25] The United States is one of many countries with a long history of using school mandates to increase vaccination rates; these mandates have been consistently upheld by US courts against claims that they violate individual rights.[60] Currently, Hawaii, Rhode Island, Virginia, and D.C. have laws that require HPV vaccination for school entry. D.C. and Virginia require the HPV vaccine for girls to enter the sixth grade but allow parents to opt out of the requirement due to medical, moral, or religious reasons.[40]

Data studying jurisdictions with HPV vaccine mandates have shown that broad opt-out provisions, low enforcement of—and adherence to—HPV vaccine mandates, and no mechanism to ensure completion of the HPV vaccine series have limited the success of mandates. Further, other studies have shown that without widespread public support, monitoring, sanctions for noncompliance, or changes to the method of vaccine administration, school-entry HPV vaccine mandates do little to encourage uptake.[39] Rather, emphasis should be put on educating parents on the benefits of vaccination within the community and clinical settings.[61] Stronger health care practices such as more in-depth discussions with hesitant parents and establishing vaccination as the default are strategies that could help improve vaccination coverage rates.[55] Finally, other interventions such as strong recommendations from health care professionals, parent education, and school and childcare center-based vaccination programs are effective ways to increase initiation of HPV vaccination and ensure completion of the HPV vaccine series.[50-53]

RECOMMENDATIONS

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

1. That our AMA amend policy H-440.872, "HPV-Associated Cancer Prevention" by addition and deletion to read as follows:

HPV-Associated Cancer Prevention, H-440.872

1. Our AMA (a) strongly urges physicians and other health care professionals to educate themselves, appropriate patients, and patients' parents when applicable, about HPV and associated diseases, the importance of initiating and completing HPV vaccination, as well as routine HPV related cancer screening; and (b) encourages the development and funding of programs targeted at HPV vaccine introduction and HPV related cancer screening in countries without organized HPV related cancer screening programs.

2. Our AMA will work with interested parties to intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public.

3. Our AMA supports legislation and funding for research aimed towards discovering screening methodology and early detection methods for other non-cervical HPV associated cancers.

4. Our AMA:

(a) encourages the integration of HPV vaccination and ~~routine cervical~~ appropriate HPV-related cancer screening into all appropriate health care settings and visits,

(b) supports the availability of the HPV vaccine and routine cervical cancer screening to appropriate patient groups ~~that benefit most from preventive measures~~, including but not limited to low-income and pre-sexually active populations,

(c) recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination.

5. Our AMA encourages ~~will encourage~~ all efforts by interested parties ~~appropriate stakeholders to investigate means~~ to increase HPV vaccine availability, and HPV vaccination rates by facilitating administration of HPV vaccinations in community-based settings ~~including school settings~~ such as local health departments, schools, and organized childcare centers.

~~6. Our AMA will study requiring HPV vaccination for school attendance.~~

6~~7~~. Our AMA encourages collaboration with interested parties to make available human papillomavirus vaccination to people who are incarcerated for the prevention of HPV-associated cancers.

8. Our AMA will encourage continued research into (a) interventions that equitably increase initiation of HPV vaccination and completion of the HPV vaccine series; and (b) the impact of broad opt-out provisions on HPV vaccine uptake. (Amend Current HOD Policy)

2. That our AMA reaffirm Policy H-440.970, "Nonmedical Exemptions from Immunizations." (Reaffirm HOD Policy)

Fiscal Note: $5,000 - $10,000

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REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH
Supporting and Funding Sobering Centers (Resolution 913-I-22)
(Reference Committee K)

EXECUTIVE SUMMARY

BACKGROUND. The objective of this report is to provide a comprehensive overview of sobering centers and their role in addressing the needs of individuals who are acutely intoxicated. This report highlights the current landscape, research, and implementation barriers to establishing safe and effective sobering centers in the U.S.

METHODS. English language articles and grey literature were selected from searches of PubMed and Google Scholar using the search terms “sobering center,” “sober center,” “stabilization program,” “inebriate program,” “inebriate center,” and “diversion center.” Additional articles were identified by manual review of the reference lists of pertinent publications. Searches of selected medical specialty society, national, and local government agency websites were conducted to identify definitions, guidelines, statements, and reports.

RESULTS. Sobering centers may play a role in diverting individuals who are acutely intoxicated from emergency departments and jails, providing a supportive environment for sobering care. The lack of standardized guidelines and best practices poses challenges for these centers, impacting their ability to effectively serve diverse populations and address safety and health equity concerns. Funding and financial sustainability remain significant barriers, with limited options for reimbursement from traditional insurers. Additionally, gaining community acceptance for sobering centers in neighborhoods can be challenging due to stigma and misconceptions.

CONCLUSION. Sobering centers provide a supportive environment for individuals who are acutely intoxicated, effectively diverting them from emergency departments and jails. However, the evidence-based resources and peer-reviewed research for sobering centers are limited, with most reports being based on annual operating data or individual sites. As most sobering centers are funded and operated by local governments, there is limited cross-collaboration on the national level in researching cost effectiveness, health outcomes and standardizing data collection or best practices. Comprehensive external validation of sobering centers is necessary to establish their efficacy and impact on the individuals they serve.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-I-23

Subject: Supporting and Funding Sobering Centers

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

At the 2022 Interim Meeting of the American Medical Association (AMA), the House of Delegates Resolution 913 "Supporting and Funding Sobering Centers," was referred. Resolution 913 asked that our AMA recognize the utility, cost effectiveness, and racial justice impact of sobering centers; support the maintenance and expansion of sobering centers; support ongoing research of the sobering center public health model; and support the use of state and national funding for the development and maintenance of sobering centers.

This report investigates the various aspects of sobering centers, including available evidence, best practices, implementation challenges, access issues, and health equity considerations. Through an analysis of the current state of sobering centers, this report sheds light on their effectiveness and identifies areas for improvement and further research. This report serves as the Council on Science and Public Health's (CSAPH) findings and recommendations regarding sobering centers.

METHODS

English language articles and grey literature were selected from searches of PubMed and Google Scholar using the search terms "sobering center," "sober center," "stabilization program," "inebriate program2," "inebriate center," and "diversion center.". Additional articles were identified by manual review of the reference lists of pertinent publications. Searches of selected medical specialty society, national, and local government agency websites were conducted to identify definitions, guidelines, statements, and reports.

BACKGROUND

Sobering Centers (SCs), also known as stabilization programs, support and connection centers, and diversion centers, were established in The Uniform Alcoholism and Treatment Act of 1971 as an alternative to jail admission for public intoxication and the emergency department (ED) for individuals who are acutely intoxicated, non-violent, and do not present with acute medical conditions or co-existing medical complaints.[1,2] The act legally allows states to create treatment solutions to monitor, stabilize and coordinate care for individuals who are acutely intoxicated on alcohol.[3] Over time states and localities have broadened the scope of SCs to encompass intoxication from substances beyond alcohol.

SCs typically prioritize one of three main programmatic purposes: jail diversion, ED diversion and homeless/social welfare practices.[1] Prior to the establishment of SCs, the prevalent approach to dealing with public intoxication involved detaining individuals in jail cells, often referred to as "drunk tanks." During this process, individuals were charged with drunk and disorderly or public

intoxication offenses. These jail cells were commonly unmonitored, and individuals who are intoxicated often faced adverse consequences, including preventable fatalities resulting from overdose, suicide, or unidentified medical conditions such as head trauma.[3,4]

Public intoxication is addressed in a variety of ways by states across the U.S. As of 2016, 22 states had laws making public intoxication illegal, while 12 states specified that intoxication is not a crime, although municipalities within those states might still have laws against it.[5] In states where public intoxication is still considered a crime, individuals are typically charged with a misdemeanor, punishable by jail time and/or a fine.[6] Racial and ethnic disparities in ticket, arrest, and incarceration rates exist, as the people most frequently impacted are disproportionately Black, have a substance use disorder, and are unstably housed, though the overlap is unclear.[7] Despite similar substance use rates between racial groups, the arrest rates for Black, Latinx, and Indigenous peoples are exponentially higher when compared to Whites for substance use, public intoxication, and associated charges such as disorderly conduct.[8]

The criminalization of public drunkenness or intoxication has also resulted in class bias in law enforcement, without producing significant rehabilitative or deterrent effects.[9] A key policy change to avoid unnecessary removal of people from public spaces and prevent arrest and incarceration would be to repeal existing public intoxication laws. By decriminalizing public intoxication—defined as the elimination of criminal penalties so that individuals are not arrested or incarcerated solely for being intoxicated—we can shift the focus of law enforcement from penalizing a state of being. It is important to note that this policy change would not affect laws designed to prevent specific harmful actions to self or others while using a substance, such as driving under the influence (DUI).

There are approximately 52 known SCs located in approximately 23 states in both rural and urban settings, with 25 percent of the nation's known SCs located in California.[4,10] It is possible that additional SCs exist, but are not identified in available sources. In 2019, SCs had approximately 30,000 encounters in California alone, indicating a possible utility for the services in other jurisdictions across the US.[4] Currently, there is no collated national data on SCs and most are run at the local level by the city or county. This results in disjointed information regarding their use and creates barriers to assessing best practices, implementation, health outcomes, and societal impact. A study of 18 SCs found that a majority (56.6 percent) are located on the West coast and are concentrated in both small and large cities.[11] Additionally, 82 percent are a part of a non-profit organization, as opposed to stand-alone sites.[11]

In general, SCs are low-threshold, 24/7 short-term care facilities for individuals who are acutely intoxicated. However, there is no standard or consensus definition of a SC. According to Oregon statute, a SC is a facility that provides a safe and supervised environment for individuals who are acutely intoxicated until they are no longer intoxicated.[12] Under Oregon code, SCs are affiliated with an approved substance use disorder (SUD) treatment program and has comprehensive written policies for the safety of individuals who are intoxicated, staff, and volunteers. These policies include case consultation, training, advice, and a plan for making referrals to SUD treatment. While the majority are open 24/7, other SCs vary widely in their hours, capacity, accommodations, health services offered, staffing, and budgets. Some SCs have a co-located detoxification or withdrawal management facility, mental health counseling, and residential inpatient treatment located in the same building for easy triage, but there are many that are stand-alone and work within their community to refer people to local health and social services.

DISCUSSION

Sobering Center Context

The intersection of the criminal-legal system, housing insecurity, and ED utilization highlights a complex web of social, racial, and health disparities in the U.S. with relation to SCs. In 2019, the U.S arrested approximately 316,032 people for "drunkenness" or "public intoxication" and 1,558,862 people for drug violations with the vast majority of those arrested being Black or Latinx.[13] Racial disparities exist throughout the criminal-legal system and result in exacerbated negative health outcomes. Whereas 32 percent of the population in the U.S is Black or Latinx, they comprise of 56 percent of people incarcerated – with Blacks incarcerated at more than 5 times the rate of whites.[14]

Homelessness, frequently interconnected with substance use, exacerbates adverse health outcomes, and is influenced by various social drivers of health (e.g., health care access, employment, education, poverty). The association between homelessness and substance use is bidirectional. While substance use can be a factor that results in homelessness, people experiencing homelessness may use substances as a coping mechanism to deal with the safety risks and trauma of being unhoused.[15] LGBTQ+ youth and veterans experience higher rates of homelessness and substance use, largely attributable to psychological stressors including trauma and social and structural stressors including social marginalization, discrimination, and health care inequities.[16,17] Homelessness has also been associated with increased substance use disorder disease severity and poorer health outcomes[18–20] While substance use affects all socioeconomic categories, research indicates higher rates of ED use and recidivism for those with co-occurring homelessness and substance use disorders, exacerbating the need for comprehensive support and evidence-based interventions that support these populations.[21]

The ED serves as a critical point of contact for individuals who are unhoused and use substances. A Substance Abuse and Mental Health Services Administration (SAMHSA) conducted analysis of participating hospitals determined that the top ten drugs in drug-related ED visits in 2022 were related to alcohol (45 percent), opioids (12.7 percent), cannabis (11.9 percent), methamphetamine (8.2 percent), and cocaine (5.8 percent).[22] Alcohol was found as the most common additional substance involved in methamphetamine, cannabis, and cocaine related ED visits.[22] (See Table 1) Acute alcohol intoxication is a known risk factor for frequent utilization of the ED,[23] and while acute alcohol intoxication can require emergency medical intervention due to potential complications, such as respiratory depression or liver failure, studies have shown that fewer than 1 percent of individuals assessed with uncomplicated alcohol intoxication need emergency services.[24] However, there is a need for national-level research to quantify the number of individuals admitted to EDs for uncomplicated alcohol intoxication versus complicated cases. Such data would help evaluate the extent to which alternative services like SCs could benefit the population at large.

Limited resources and time in most EDs make it challenging to provide monitoring for individuals who do not have critical medical complications.[3,4] In response to the emerging needs of these populations, states and localities have instituted sobering centers (SCs) as an approach to stabilize individuals intoxicated on drugs (alcohol, opioids, methamphetamines, or cocaine).[4] While supportive services and referral to evidence-based treatment may be available on-site, SCs are not treatment facilities for people who use substances or have substance use disorders.[4]

Sobering Center Components

The most comprehensive survey conducted on SCs in the U.S. provides valuable insights into the diversity of clientele, practices, and staffing within these centers. The survey collected self-reported data from 11 sobering centers located in 14 states, offering a view of their operations.[1] Further research on sobering centers not included in the survey, provides a broader perspective on the practices and characteristics of these facilities. The collective data from the surveyed centers and additional research shed light on the various approaches and differences found among sobering centers across the country.

Referral and Admissions

Typically, SCs receive direct referrals from law enforcement with some centers solely receiving referrals from law enforcement.[1] Centers also accept referrals from EMS/ambulatory personnel and non-ambulance vans or outreach vans that respond to 911 calls that involve public intoxication.[1] While self-referral and walk-ins are an option at some SCs, referrals can also be made from EDs, social services, clinics, or community programs.[3,25] In a survey conducted of 18 SCs, 69 percent accepted referral from law enforcement, 62 percent from EDs, and 54 percent walk-in/self-referral.[11] (See Table 2 for referral flowchart)

All SC clients are admitted voluntarily.[1] The number of individuals able to receive services in SCs varies from 11 to 84 persons. Individuals are primarily referred to SCs for alcohol intoxication, but an undetermined amount of SCs have expanded to include people intoxicated from other substances such as opioids, methamphetamine, cannabis, and cocaine, in an effort to expand the scope of services given the evolving substance landscape.[4,26]

SCs in New York City accept individuals with active psychiatric disorders.[2] These centers are a part of a multi-agency effort to provide a health-centered alternative to emergency room visits and criminal-legal interventions, serving as a vital component in the city's broader strategy to address mental health and substance use as interconnected public health issues.[2] This strategy differs from other SCs that solely admit individuals who are intoxicated, and those presenting to a SC with active psychiatric disorders are triaged to a higher level of care, such as an ED. There is a wide variation in the number of clients a SC sees annually. From 2019-2020, one SC only admitted 10 clients while another admitted 13,325, with approximately 20 percent being repeat clients.[11] The agencies were deidentified in the report, so it is unclear whether location impacted admitted clients. The report lacked specificity regarding whether the estimated clients admitted were unique or if SCs served dual purposes, such as drop-in cooling centers during summer months.[11] However 67 percent of the SCs are co-located with other programs which could account for the varying client admittance. [11]

All SCs report having a triage process in place, although the specific procedures vary.[1] In terms of admitting clients, in centers where staff lacks medical training the assessment is informal and might involve a breathalyzer for alcohol, but does not include taking vital signs.[1] In Cambridge, the assessment revolves around determining if a client can walk safely when they arrive on their own or are brought in by the police.[1] Other centers use triage checklists completed by pre-hospital transport (EMS or outreach van), intake staff, or both.[25] (See Table 3 for sample inclusion criteria) These checklists typically focus on complaints and vital signs, with clients considered unsuitable for the center if they have medical issues or abnormal vital signs. However, none of the checklists used have been externally validated or recognized by a national organization as safe practices, but

many have input from local emergency medical staff, local public health officials, and other sobering centers.

Clients

The types of clients that are admitted into SCs usually fall into two categories. The first population consists of clients characterized by chronic use, cognitive impairment, or co-occurring homelessness, who face severe disorganization in their lives,[4] essentially, functioning as shelters that admit people who are intoxicated. The second population is comprised of individuals who may be housed or unhoused but can independently manage their daily activities.[4] This group primarily seeks a secure space to metabolize alcohol or other substances and does not require intensive services. The issue becomes complex when all available beds are consistently occupied, some by individuals with no other housing options and others who require only short-term sobering care. Both populations have acute needs, and the scarcity of beds suggests systemic limitations. Striking a balance between meeting the needs of both populations is essential to ensure effective and equitable utilization of SC resources.[4]

Length of Stay

The average length of stay for clients in SCs varies. In California, length of stays typically range from 7 to 12 hours.[4] However, some centers have a minimum stay requirement of 4 hours, while others may have no minimum length of stay.[1] The duration of stay in SCs is influenced by several factors, including the individual's level of intoxication, their ability to recover safely, and the center's specific protocols and resources. These timeframes aim to provide sufficient time for individuals to stabilize, ensure their safety, and potentially access additional support or services before being discharged.

Staffing

The credentials of the people who staff SCs varies widely. The majority of SCs fall across a spectrum of staffing non-physician providers such as licensed nurses, emergency medical technicians (EMTs), paramedics, and/or health care technicians.[4] For example, in San Francisco one SC has registered nurses (RNs), medical assistants, and non-medical personnel, while SCs located in Cambridge, MA and San Diego, CA have all non-medical personnel.[1] It should also be noted that many SCs are co-located within medical facilities and have access to behavioral health staff including physicians, even if they are not staffed as part of the SC, as opposed to stand-alone SCs.

Services

SCs offer a range of services and typically include hospitality, supportive care, wound care, and provision of essential daily living materials such as clothing, showers, and hygiene supplies. Additionally, SCs facilitate linkages to primary care, mental health services, and substance use disorder treatment. Peer support and counseling services are also commonly available, along with connections to social services and housing resources. It is important to note that while some centers may have a co-located medically supervised withdrawal program (ASAM level 3.7), this is not universally offered across all SCs. The scope of services provided by SCs can vary from one location to another while some are co-located with residential treatment, others only provide referral. For example, in Portland, Oregon, the SC operates as part of a centralized facility that

offers comprehensive services for people experiencing homelessness or with SUD. On the other hand, in Bethel, Alaska the SC is a stand-alone facility with no long-term services.[1] SCs report the majority of individuals who are intoxicated do not need a higher level of emergency care and greater than 90 percent of the clients were "appropriate" for the center.[1] However, 5 SCs (41.7 percent) reported experiencing a client fatality at some point in their operation. The circumstances around these deaths were not included in the report.[11]

SCs have different approaches to client monitoring and supervision. All programs typically have at least two members on staff at all times, and it is considered best practice to continuously check-in on clients, however it is unclear what interval is most appropriate especially when compared to monitoring practices in EDs.[1] According to a subject matter expert, an essential aspect of a sobering center is the strategic placement of medical staff, ensuring that they have a clear view of every individual in the room.[27] Alternatively, continuous bedside monitoring at intervals of 5 or 10 minutes may also be implemented.[27] At least one wrongful death lawsuit, *Ryder v. MFI Recovery Center*, has been filed against a SC alleging falsified observation logs concerning the frequency with which staff monitored a client, leading to a fatal overdose.[28] The SCs license has since been revoked by the California Department of Health Care Services.[29] Of note, in many cases, the safety and monitoring of clients surpasses the level of care provided in jails by law enforcement, which begs the question of if SCs are a more appropriate setting for people who are intoxicated than jail.

In terms of discharge policies, each SC has established its own protocols for discharge practices that typically include evaluating a client's ability for self-care, including ambulation, having a plan after leaving, and meeting hygiene needs.[1] Discharge assessments may involve screening vital signs, modified mini-mental status exams, resolution of signs and symptoms of intoxication as characterized in the DSM-4, as well as general well-being checks conducted by non-medical staff. While these specific signs and symptoms were not outlined in the report, it is important to note the potential for complications due to precipitated withdrawal by sudden cessation for those who have dependence or use disorder.[30] In two programs, a specific blood alcohol level, an estimated measurement through breathalyzer, is used as a clinical indication for discharge.[1]

Secondary transport of clients is uncommon. A study conducted at a SC in San Francisco revealed that the majority of visits to the center did not require ambulance discharge, and only 4.4 percent (506 individuals) needed to be transferred to the ED.[25] The main reasons for transfer included tachycardia (26 percent), alcohol withdrawal (19 percent), pain (19 percent), altered mental status (13 percent), and emesis (13 percent).[25] The study concludes that clients who were transferred to the sobering center after being medically cleared in the ED had slightly higher rates of discharge back to the ED. [25] This suggests the importance of having medically trained staff at sobering centers to monitor individuals and effectively triage and provide care for their needs. (See Table 4 for Clinical Indications & Table 5 for Reasons for Secondary Transfer)

National statistics on recidivism rates specific to SCs are not available. However, a study conducted in Houston, Texas, from 2013 to 2017 found that out of the 25,282 clients admitted, 77 percent (19,486 individuals) were admitted more than once, and 23 percent (5,814 individuals) were admitted three or more times.[26] Similarly, a SC in Iowa has reported instances of recidivism, where individuals are encouraged to return to the center multiple times as a step toward eventual treatment.[31] However, there may be limits on the number of times individuals can access the center within a specific time frame, such as per week, to ensure equal access for all individuals seeking services.

Cost-Effectiveness Analysis

Cost savings associated with the implementation of SCs are substantial and far-reaching. By diverting individuals from incarceration, SCs offer a cost-effective alternative to the high expenses of housing inmates. For instance, Harris County jail admission costs $286 per day, while a SC, operating at full capacity, would incur a significantly lower cost of $127 per admission.[26] SCs contribute to substantial savings by reducing unnecessary emergency care expenses. A cost analysis comparing the San Francisco SC with direct ED costs per encounter found that acute intoxication care at the SC resulted in savings of $243 per client with the SC care being less costly ($274) when compared to the ED ($518).[32] There is currently no research comparing the costs of SCs staffed with medical personnel to those staffed solely with non-medical personnel. SCs also alleviate the burden of unnecessary law enforcement processing. For example, the Santa Cruz Recovery Center demonstrated a 53 percent reduction in law enforcement processing, translating to $83,290 in savings in officer costs.[33]

The financial impact of SCs can extend to city and state levels as well. Houston reported a positive fiscal impact of $2.9 million in the first 20 months after opening its sobering center.[34] However there is still further data needed, as the study did not estimate or denote the cost of SC admission, which can vary greatly depending on physical location and number of clients admitted. In New York City, the government spent $51 million on establishing a SC in East Harlem, but in the first 6 months only admitted 45 people, which averages to $1.1 million per visit.[35] This highlights a significant need for enhanced cross-collaboration and open communication among stakeholders involved in the implementation of sobering centers. Effective dialogue among healthcare providers, law enforcement agencies, community organizations, and policymakers is essential for the successful establishment, maintenance, and optimal utilization of sobering centers.

Nationally, when considering the cost of ED visits, SC visits, and sobering center start-up costs, a budget analysis estimated annual cost savings ranging from $230 million to $1 billion, assuming a diversion rate of 50 percent based on previous studies.[36] A challenge to consider in implementation is the utilization of the centers when compared to the cost of long-term solutions such as an overdose prevention site or supportive housing. There is limited data available on the in-depth cost-effectiveness analysis of SCs. SCs may be cheaper than jail or ED stays but the appropriate comparison for people experiencing homelessness with substance use disorder is permanent supportive housing (PSH).

PSH with a housing first approach, is a competitive model for sobering care for people who are unhoused. PSH is defined as long-term and affordable housing with ongoing supportive services (e.g., counseling, treatment, conflict resolution, nutrition) by staff (e.g., case managers, social workers, and health care professionals) to assist people living with mental health and/or substance use disorders who have experienced housing insecurity or homelessness. The harm reduction and community housing model of PSH ensures that residents can be monitored for intoxication, if needed, while concurrently obtaining supportive services. However, this does not address the clients that would be admitted to a SC for short-term monitoring that already have permanent housing. Overall, the limited cost-effectiveness research suggests SCs are less expensive alternatives that can benefit individuals in crisis and yield potential economic advantages for communities and states.

Best Practices

Assessing standards and best practices among SCs is challenging due to the lack of uniformity across different centers. Members of the *American College of Emergency Physicians Public Health and Injury Prevention Committee on Sobering Centers* surveyed 11 SCs. The respondents shared best practices which include motivational interviewing, housing first philosophy, case management,

inter-organizational communication, peer support, and harm reduction.[37] The California Health Care Foundation identifies three foundational best practices for SCs.[4] First, a low-barrier and compassionate service model ensures easy access for individuals by minimizing paperwork, eligibility requirements, and complex intake processes.[4] Second, SCs play a central role in care coordination, with many offering around-the-clock staffing and services to provide immediate crisis response and facilitate communication with other service providers.[4] Lastly, programmatic flexibility is crucial, allowing SCs to meet the specific needs of individuals and the community, such as offering longer stays on a case-by-case basis, providing shelter during inclement weather, or caring for high-need individuals who may not meet standard eligibility criteria.[4]

Another example of a best practice observed at SCs is their commitment to accommodating individuals despite challenging behavior, with only rare instances of permanent restrictions from accessing services.[4] For instance, individuals who exhibit violent or threatening behavior may face short-term restrictions from sobering services, typically lasting a few weeks, or undergo regular risk assessments during each visit.[4] Some centers establish safety committees consisting of frontline and managerial staff who regularly review behavioral incidents and may establish permanent restrictions on SC visits for individuals with severe substance use disorder who experience substantial health and cognitive decline, necessitating higher levels of care.[4] While these best practices support accessible, coordinated, and adaptable care within SCs, there is still a need for the establishment of standardized and externally validated intake and discharge protocols, and internal clinical best practices that are publicly available to localities for implementation.

Law Enforcement and Criminal-Legal Implications

SCs can play a critical role in promoting health equity by providing a non-punitive approach and access to health services for individuals. However, there are concerns regarding the potential misuse of sobering centers as an alternate form of punishment by law enforcement. Around 75 percent of SCs have formal partnerships with law enforcement agencies, raising questions about the ongoing criminalization of people who are unhoused and use substances which can lead to dangerous behaviors, such as hurried substance use in public or isolated locations, increasing the risk of fatal overdose.[11,15] There are barriers and challenges to achieving equitable health outcomes. Expanding law enforcements' scope to triage and determine what is medically necessary or critical to send individuals to the ED, jail, or SCs, can impact health outcomes and create disparities in access to hospital-based and SC-based services.

In a survey of police agencies, 65 percent indicated they leave the decision to use a SC to the officers' discretion and use formal written policies and informal practices to provide guidance.[11] And while 80 percent of police agencies reported training officers on using SCs, 20 percent do not provide officers with any guidance regarding the use of SCs.[11] A major concern with any law enforcement interaction especially for communities of color, people with disabilities, LGBTQ+, people who use drugs, low-income, migrant, and unhoused individuals is inequitable exposure to law enforcement action, injuries, violence, and death – which can effect individuals likelihood to seek health services and treatment, achieve positive health outcomes, and lead to compounding structural and systematic existing health inequities.[38] For these reasons, many states and localities have begun using unarmed non-law enforcement officers to address nonviolent social and medical issues in an effort to limit the scope of police power and to prevent unnecessary arrests and police violence.[39]

SCs also have the potential to serve as a connection point to treatment and health services for minoritized and marginalized populations. They can act as a steppingstone towards more comprehensive care and treatment, promoting access to vital resources. The provision of free

services and triage based on need rather than ability to pay aligns with principles of health equity, ensuring that individuals receive the care they require without financial barriers.

The presence of SCs has shown promising results in decreasing jail admissions for public intoxication, with significant declines reported in some areas. For example in Houston, Texas after the opening of a SC, jail admissions for public intoxication decreased by 95 percent (from 15,387 to 835).[26] Similarly, the Santa Cruz County Sheriff's Office reported a 53 percent decline in public intoxication bookings after the opening of the SC.[33] Overall, SCs have the potential to advance health and racial equity, however there are challenges to address. It is crucial to develop clear policies and guidelines to ensure equitable access to SC services and mitigate potential biases in decision-making. Strong collaborative efforts between law enforcement, healthcare providers, and community stakeholders are essential in fostering a non-punitive, supportive, and equitable environment to accessing SCs, particularly for populations who have been historically marginalized or underserved.

Implementation Barriers

Implementation barriers for SCs encompass various factors. One significant barrier is the lack of specific certification or accreditation programs for sobering services. While organizations operating SCs may have accreditation for other programs such as detoxification or rehabilitation, there is currently no specialized accreditation for sobering centers themselves.[3] Pursuing satellite status under an existing Federally Qualified Health Center (FQHC) may be feasible if the center is associated with a community health center that offers additional clinical services.[3] However, achieving FQHC status as a standalone sobering center is challenging.[3] The implementation of SCs in a rural or suburban setting could also present additional challenges including the ability for the SC to triage effectively between hospitals, behavioral health centers, shelters, and law enforcement due to lack of funding and resources. However, there is no data or research that addresses the specific barriers that rural and suburban SCs have encountered when compared to SCs in cities.

Funding and financial sustainability present significant challenges, particularly for services in SCs that contribute to individual well-being but lack proper reimbursement mechanisms. These services may include hygiene resources like showers and nutritional support such as food. SCs typically operate as nonprofit organizations, and rely on diverse funding sources including public and private grants, fundraising, and state-based grants.[27] Billing through traditional insurers such as Medicaid or other third-party payers is not common practice.[1]

However, as of 2021, some states including California, have made progress in securing federal funding through the "in-lieu of services" (ILOS) mechanism under the Centers for Medicare and Medicaid Services (CMS) using the state's 1915(b) waiver.[40,41] California's Medi-Cal reform proposal, CalAIM, includes a "Whole Person Care" (WPC) pilot program that authorizes sobering centers as one of fourteen "community supports" that can substitute certain medical services covered by Medi-Cal, such as ED visits or inpatient hospital care.[40,41] Although collaborative models between health plans and sobering centers have not emerged, California encourages managed care plans to offer as many of the Community Supports as possible.[4,40] CMS and Medi-Cal financing of sobering centers offers a potential pathway for licensing of the programs through California's Department of Health Care Services with certification from Medi-Cal for both county and privately owned and operated SCs. Despite these advancements, there is still a lack of guidance on billing Medi-Cal for sobering services, posing ongoing challenges for financial sustainability.[13]

Other reported implementation challenges are regarding workflows with external partners. For example, issues with reimbursement coverage for EMS services have led to EMS dropping

individuals off in the ED instead of the SCs.[31] To effectively establish and run SCs, strong coordination and community collaboration are crucial. The development of protocols and Memorandums of Understanding (MOUs) between various stakeholders enable smoother operations. Another common consensus among SCs highlights the lack of available resources for clients seeking stabilization, including detoxification, residential treatment, housing, and long-term care leading to some clients rotating in and out of short-term services, resulting in potential challenges in achieving sustained recovery and stability.[4]

Overcoming stigma and gaining community acceptance for a SC in a neighborhood is a significant challenge, often referred to as NIMBYism (Not In My Backyard). Neighbors may express concerns about the potential impacts of having a SC in their community, leading to resistance and reluctance. Building community engagement, education, and buy-in becomes particularly challenging when addressing the stigma surrounding these services. It is essential to engage with the community openly, providing accurate information and dispelling misconceptions about SCs to foster understanding and acceptance. Effective communication and transparency can play a crucial role in gaining support and ensuring the successful integration of sobering centers into the communities they serve.

Future Research Needs

While the existing research provides valuable insights into the operations and impact of SCs, there remain significant gaps that require further investigation. Key areas for further research include exploring the short-term and long-term health outcomes of individuals who utilize these centers and conducting more rigorous cost effectiveness analysis studies comparing SCs to permanent supportive housing and overdose prevention sites for people experiencing homelessness who are also using substances. Understanding the effectiveness of substance use treatment referrals made by SCs, as well as the attendance and longevity of individuals in such programs, is crucial to evaluating the overall effectiveness of these interventions. Additionally, follow-up data and comprehensive studies are needed to gain a deeper understanding of the long-term effects and potential benefits of SCs on individuals' health and well-being. Further research in these areas is essential for developing evidence-based strategies, interventions, and best practices to optimize the impact of SCs on the health and recovery of the populations they serve.

EXISTING AMA POLICY

AMA currently has policies related to substance use, substance use disorders (SUD) and community-based programs. Policy D-95.987, “Prevention of Drug-Related Overdose,” notes AMA’s support for compassionate treatment of patients with SUD and people who use drugs, urges that community-based programs offering naloxone, opioid overdose, drug safety, and prevention services continue to be implemented in order to further develop best practices, and encourages the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose. Policy D-95.962, “Enhanced Funding for and Access to Outpatient Addiction Rehabilitation,” advocates for sustained funding to states in support of evidence-based treatment for patients with SUD and/or co-occurring mental disorder.

CONCLUSION

SCs provide a supportive environment for individuals who are acutely intoxicated, effectively diverting them from emergency departments and jails. However, the evidence-based resources and peer-reviewed research for sobering centers are limited, with most reports being based on annual operating data or individual sites. It's important to note that different centers may have varying

resources and offer diverse levels of support, reflecting the distinct community needs they aim to address. As most SCs are funded and operated by local governments, there is limited cross-collaboration on the national level in researching cost effectiveness, health outcomes and standardizing data collection or best practices. Comprehensive external validation of SCs is necessary to establish their efficacy and impact on the individuals they serve. While the research on SCs is limited, there is a considerable level of interest and support for their development.[37]

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 913-I-22, and the remainder of the report be filed:

1. That our AMA will:
   A. Monitor the scientific evidence and encourage further research of sobering centers and similar entities for best practices including:
      (1) Health outcomes from sobering center utilization;
      (2) Partnerships with medical personnel and health care entities for policies, protocols and procedures that improve patient outcomes, such as transitions of care and safety measures;
      (3) The appropriate level of medical collaboration, evaluation, support, and training of staff in sobering centers;
      (4) Health economic analyses for sobering care models in comparison to existing health care, criminal-legal, and community-based systems; and
      (5) Best practices for sobering centers based on location (e.g., urban, suburban, and rural).

   B. Support state and local efforts to decriminalize public intoxication.

   C. Support federal and state-based regulation of sobering centers.

   D. Encourage and support local, state, and federal efforts (e.g., funding, policy, regulations) to establish safe havens for sobering care, as an alternative to criminalization, with harm reduction services and linkage to evidence-based treatment in place of EDs or jails/prisons for medically uncomplicated intoxicated persons. (New HOD Policy)

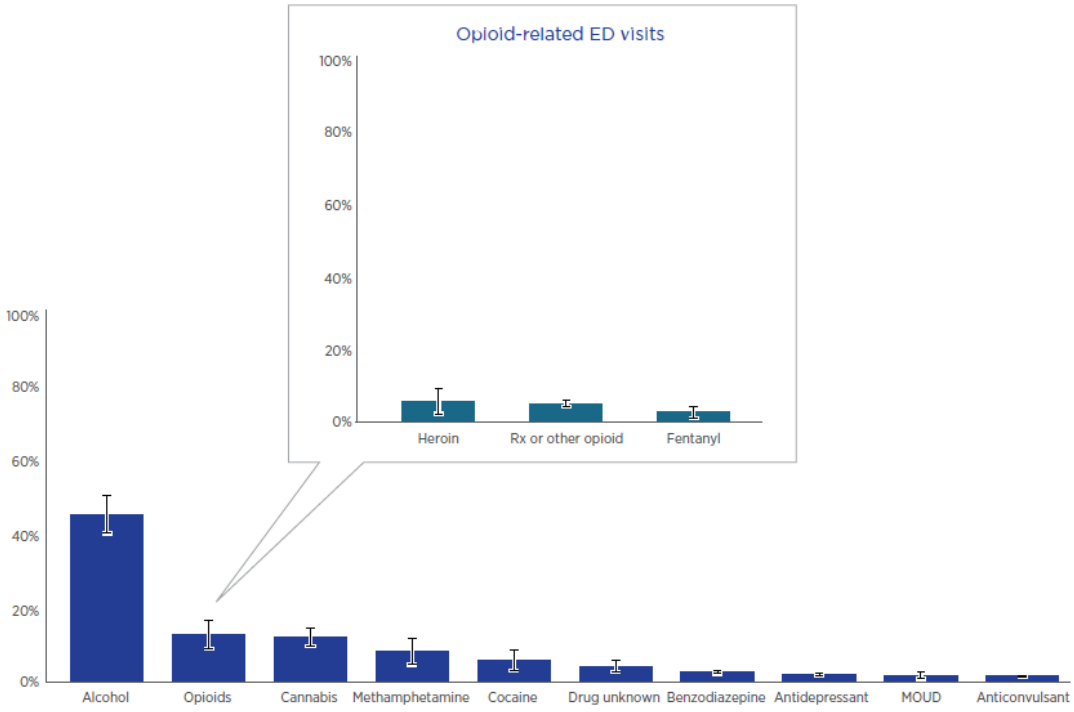
2. That our AMA reaffirm the following policies HOD policies:
   - H-345.995, "Prevention of Unnecessary Hospitalization and Jail Confinement of the Mentally Ill,"
   - H-95.912, "Involuntary Civic Commitment for Substance Use Disorder,"
   - H-95.931, "AMA Support for Justice Reinvestment Initiatives,"
   - H-515.955, "Research the Effects of Physical or Verbal Violence Between Law Enforcement Officers and Public Citizens on Public Health Outcomes," and
   - D-430.993, "Study of Best Practices for Acute Care of Patients in the Custody of Law Enforcement or Corrections." (Reaffirm HOD Policies)

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

TABLE 1: SAMHSA TOP 10 SUBSTANCES INOLVED IN DRUG-RELATED ED VISITS, 2022

Substance Abuse and Mental Health Services Administration. *Findings from Drug-Related Emergency Department Visits 2022,* Drug Abuse Warning Network. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; 2022. Accessed July 14, 2023. https://store.samhsa.gov/sites/default/files/pep23-07-03-001.pdf

Figure 4.A Top ten substances involved in drug-related ED visits, 2022



Note: Opioid includes heroin, fentanyl, and other prescription opioids. See Appendix B for other drug definitions. Multiple substances can be reported in a single ED visit, so percentages can add up to more than 100 percent.

In 2022, alcohol was the substance most reported (45.0%) in drug-related ED visits, followed by opioids (12.7%) and cannabis (12.0%). Among 4.2 percent of drug-related ED visits, an unknown drug was reported as at least one of the substances involved. Within opioids, heroin (5.6%) and Rx or other opioids (5.0%) were reported significantly more often than fentanyl (2.7%).

TABLE 2: Referral Flowchart from Sobering Center in Houston, TX

Jarvis SV, Kincaid L, Weltge AF, Lee M, Basinger SF. Public Intoxication: Sobering Centers as an Alternative to Incarceration, Houston, 2010–2017. *Am J Public Health*. 2019;109(4):597-599. doi:10.2105/AJPH.2018.304907

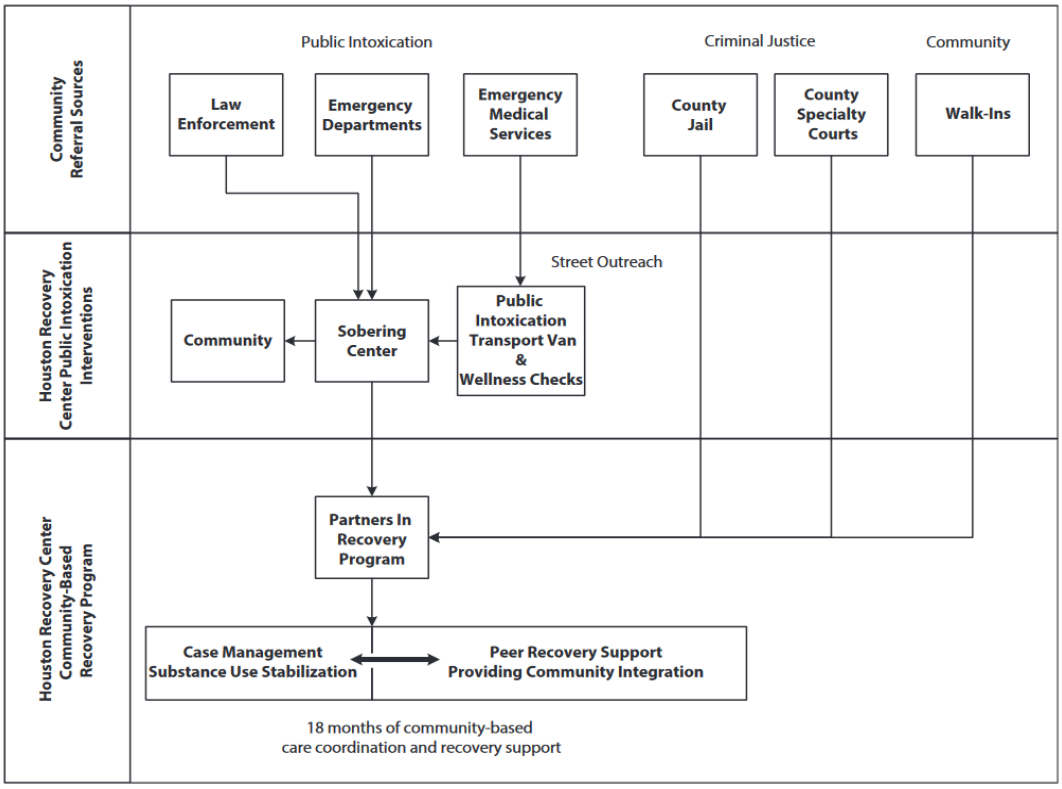


FIGURE 1—Houston Recovery Center Current Proactive Intervention for Public Intoxication and Substance Use: Houston, TX

TABLE 3: Destination Inclusion Criteria from Sobering Center in San Francisco, CA

Smith-Bernardin SM, Kennel M, Yeh C. EMS Can Safely Transport Intoxicated Patients to a Sobering Center as an Alternate Destination. *Annals of Emergency Medicine*. 2019;74(1):112-118. doi:10.1016/j.annemergmed.2019.02.004

1. DESTINATION INCLUSION CRITERIA
    a. Sobering Services: Intoxicated patients with no acute medical condition(s) or co-existing medical complaints may be transported to the San Francisco Sobering Center, if the patient meets the following criteria:
        i. Be at least 18 years or older;
        ii. Found on street / in a shelter or in Police Department custody;
    b. Voluntarily consent or have presumed consent (when not oriented enough to give verbal consent) to go to the Sobering Center;
    c. Not be on the San Francisco Sobering Center "Exclusion List."*
    d. Be medically appropriate by meeting ALL of the following criteria:
        i. Indication of alcohol intoxication (odor of alcoholic beverages on breath, bottle found on person);
        ii. Glasgow Coma Score of 13 or greater;
        iii. Pulse rate greater than 60 and less than 120;
        iv. Systolic blood pressure greater than 90;
        v. Diastolic blood pressure less than 110;
        vi. Respiratory rate greater than 12 and less than 24;
        vii. Oxygen saturation greater than 89%;
        viii. Blood glucose level greater than 60 and less than 250;
        ix. No active bleeding;
        x. No bruising or hematoma above clavicles;
        xi. No active seizure; and,
        xii. No laceration that has not been treated.

**Exclusion List: Periodically, a client may be deemed inappropriate by sobering center staff for use of the sobering center for a fixed amount of time. The client is then placed temporarily on an exclusion list. The most common reasons for placement on the exclusion list are physical violence against staff or other clients and repeated inability to care for basic needs and activities of daily living once sober. There are typically 3 to 8 persons on this list at any one time.*

Figure 1. Criteria for paramedic triage to the San Francisco Sobering Center.

TABLE 4: Clinical Indications for Secondary Transfer for Sobering Center in San Francisco, CA

Smith-Bernardin SM, Kennel M, Yeh C. EMS Can Safely Transport Intoxicated Patients to a Sobering Center as an Alternate Destination. *Annals of Emergency Medicine*. 2019;74(1):112-118. doi:10.1016/j.annemergmed.2019.02.004

Table 1. Clinical indications for secondary transfer from the San Francisco Sobering Center to an ED.

Clinical Indicator	Range
Pulse, unstable, beats/min	>100 (high); <60 (low)
Blood pressure, unstable, mm Hg	>160 systolic or >100 diastolic (high); <100 systolic (low)
Temperature, °F/°C	>100/37.8 (high); <95/35 (low)
Respiration, breaths/min	>20 (high); <7 (low)
SpO_2, %	<90 (low)
Blood glucose level, mg/dL (finger stick)	>250 (high); <50 (low)
Alcohol withdrawal, suspected	Clinical note may include tremors, hallucinations/delusions, headache, nausea, Clinical Institute Withdrawal Assessment score. Excludes seizure activity.
Injury	Clinical note includes reference to physical signs of trauma, laceration, abrasion, swelling, or incidence of or client statement of injury. Injuries may have occurred on site or before admission to sobering center.
Fall	Clinical note indicates client fall on site with or without injury, including fall from standing or out of bed
Patient complaint of pain	Complaint of acute pain, excluding chest pain
Chest pain	Indicates specific complaint of chest pain or discomfort
Seizure activity	Includes both witnessed seizures and suspected seizure followed by sudden change in mental status, difficult arousal, incontinence, bleeding
Altered mental status	Includes either a decrease in mental status after admission or a persistent altered state that has not improved with time
Drugs, other	Includes client statement of ingestion of other drugs, or corresponding symptoms with or without the presence of paraphernalia or other drugs
Suicidal ideations or attempt	Includes client statement of intent to harm self, inability to contract for safety, signs of injury, and witnessed attempts at self-harm
Emesis	Indicates active vomiting as opposed to nausea
Client request	Client request not accompanied with signs of need for higher level of care

TABLE 5: Clinical Reasons for Transfer for sobering center in San Francisco, CA

Smith-Bernardin SM, Kennel M, Yeh C. EMS Can Safely Transport Intoxicated Patients to a Sobering Center as an Alternate Destination. *Annals of Emergency Medicine*. 2019;74(1):112-118. doi:10.1016/j.annemergmed.2019.02.004

Table 2. Clinical reason for transfer to the ED.

Clinical Reason for Discharge	EMS and ED Combined (n=213, 168 Unduplicated Clients), No., % (95% CI)	EMS Referrals (n=151), No., % (95% CI)	ED Referrals (n=62) No., % (95% CI)
Pulse high, >100 beats/min	56, 26 (21–33)	27, 18 (13–25)	29, 47 (34–59)
Alcohol withdrawal, suspected	41, 19 (13–28)	19, 13 (8–23)	22, 36 (22–58)
Complaint of pain	40, 19 (14–25)	26, 17 (12–24)	14, 23 (14–35)
Emesis	28, 13 (9–18)	18, 12 (8–18)	10, 16 (9–28)
Altered mental status	28, 13 (9–18)	27, 18 (13–25)	1, 2 (0–11)
Blood pressure high, >160 systolic, >100 diastolic, mm Hg	25, 12 (8–17)	12, 8 (5–14)	13, 21 (12–33)
Client request (no obvious need)	25, 12 (8–17)	16, 11 (7–17)	9, 15 (8–26)
Chest pain	18, 8 (5–13)	6, 4 (2–9)	12, 19 (11–31)
Seizure	16, 8 (5–12)	9, 6 (3–11)	7, 11 (5–22)
Fall	15, 7 (4–11)	14, 9 (6–15)	1, 2 (0–11)

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REPORT 5 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-23)
Promoting the Use of Multi-Use Devices and Sustainable Practices in the Operating Room
(Reference Committee K)

EXECUTIVE SUMMARY

BACKGROUND. At the 2022 Interim Meeting of the House of Delegates, Resolution 936 was referred for study. That resolution asked that our American Medical Association advocate for research into and development of intended multi-use operating room equipment and attire over devices, equipment and attire labeled for "single-use" with verified similar safety and efficacy profiles.

METHODS. English language articles were selected from searches of PubMed and Google Scholar using the search terms "sustainability AND operating room," "single-use devices AND operating room," "surgical drapes AND reusable," and "pharmaceutical waste AND surgery." Additional articles were identified by manual review of the reference lists of relevant publications. Web sites managed by government agencies, particularly the U.S. Centers for Disease Control and Prevention (CDC), were also reviewed for relevant information.

DISCUSSION. The health care industry is a major contributor of both plastics waste and GHG emissions. The U.S. health sector is estimated to produce 6 billion tons of waste annually and to be responsible for 8.5 percent of U.S. GHG emissions.[4,5] Operating rooms (OR) are generally one of the most resource intensive areas within hospitals themselves, contributing roughly 20-33 percent of total health care waste and are a major driver of hospital GHG emissions.[4] Lastly, waste generation is costly to health care systems. It was estimated that the U.S. health care system spent 3.2 billion U.S. dollars in medical waste costs in 2017.[4] Thus, finding ways to reduce overall waste generation has been found to be an important cost savings strategy while also improving environmental impacts.[1]

CONCLUSION. To improve sustainability in OR and reduce overall waste, hospitals can choose from a number of strategies. The easiest, most cost-effective, and risk-neutral strategies are improving existing recycling programs for paper, glass, and plastics within the hospital and reducing the amount of equipment that is unpackaged but not used and thrown away. While improved recycling programs may help decrease waste generation, it may not have the largest ecological benefit. The second strategy involves modifying and improving surgical kits to reduce unnecessary items. This would require surgical teams to audit their current practices, identify the equipment needed, and work with kit manufacturers to make necessary updates.

Reusing and reprocessing medical equipment as well as switching to reusable textiles are also strategies for reducing waste in the OR which can result in large cost savings and overall waste reduction benefits. However, reusable and reprocessed equipment should be considered on a case-by-case basis and be informed on the risk level of the surgery. A decision to switch to a reusable device or piece of equipment should be preceded by a life-cycle assessment to ascertain whether it has a positive environmental impact (in comparison to a single use device). More studies are needed to understand whether there is an increased risk of infectious disease transmission from reusable equipment and textiles but there is little existing evidence to suggest that they are inherently riskier. Regardless of strategy, future sustainability efforts must be approached with leadership support and across departments to enact meaningful change.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-I-23

Subject:	Promoting the Use of Multi-Use Devices and Sustainable Practices in the Operating Room
Presented by:	David J. Welsh, MD, MBA, Chair
Referred to:	Reference Committee K

At the 2022 Interim Meeting of the House of Delegates, Resolution 936 was referred for study. That resolution asked that our American Medical Association (AMA) advocate for research into and development of intended multi-use operating room equipment and attire over devices, equipment and attire labeled for "single-use" with verified similar safety and efficacy profiles.

BACKGROUND

The development and growing use of single-use plastics has created a global crisis, as the production of these products increase greenhouse gas (GHG) emissions and the disposal of plastics has led to over 2 million tons of plastic pollution in oceans globally.[1,2] Increased GHG emissions from human activities over the last two centuries are well understood to be a major contributor to climate change.[3] The health care industry is a major contributor of both plastics waste and GHG emissions. The U.S. health sector is estimated to produce 6 billion tons of waste annually and to be responsible for 8.5 percent of U.S. GHG emissions.[4,5] Operating rooms (OR) are generally one of the most resource intensive areas within hospitals themselves, contributing roughly 20-33 percent of total health care waste and are a major driver of hospital GHG emissions.[4] Lastly, waste generation is costly to health care systems. It was estimated that the U.S. health care system spent 3.2 billion U.S. dollars in medical waste costs in 2017.[4] Thus, finding ways to reduce overall waste generation has been found to be an important cost savings strategy while also improving environmental impacts.[1]

The following report outlines the types of waste associated with ORs, with particular attention to single-use equipment and textiles, potential alternatives aimed at improving sustainability, and the benefits and downsides of those alternatives, relative to disposable products. This report focuses primarily on sustainability from the perspective of waste reduction, but there are other sustainability challenges in the OR that could be addressed in future resolutions or reports. These include the reduction of GHG emissions from anesthesia drugs[5] and overall energy consumption in the OR attributed to lighting, ventilation, etc.[6] These issues are outside of the scope of this report.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "sustainability AND operating room," "single-use devices AND operating room", "surgical drapes AND reusable," and "pharmaceutical waste AND surgery." Additional articles were identified by manual review of the reference lists of relevant publications. Web sites managed

by government agencies, particularly the U.S. Centers for Disease Control and Prevention (CDC), were also reviewed for relevant information.

DISCUSSION

Unnecessary waste generation in the OR comes from several sources. In many medical settings, the use of single-use devices and products generate a huge portion of hospital waste. Plastics from the packaging of sterile medical devices is also largely thrown away as opposed to being recycled. Additionally, there are often components of surgical kits or pieces of equipment that are laid out in preparation for surgery but are not used and then thrown away. This significantly contributes to overall waste generation and is very costly to hospitals.[5] It has also been documented that pharmaceutical waste is another critical issue, particularly with anesthetic drugs.[5,7] Lastly, there is evidence that at least a third of the materials going into the red bag waste stream[a] are not biohazardous and could be recycled or be disposed of in a less costly or GHG-emitting manner.[7] The potential solutions for reducing OR waste fall into the well-known three R's of sustainability: reduce, reuse, and recycle.

Reducing Unnecessary Waste

There are several potential solutions to reduce overall waste production that occurs with instruments and devices that are taken out of their packaging, not used, but still thrown away. Prior to surgery, devices or instruments perceived to be necessary for the procedure are taken out of their packaging and placed on a sterile tray. In many cases, not all these items are used but are disposed of as they are no longer sterile. Pre-packaged surgical kits may contain multiple devices to be used during a specific surgery. However, not all those devices are always used. In one study of unused surgical supplies in hand surgeries, researchers recorded surgical and dressing items disposed of and not used in 85 consecutive cases in a single surgeon's practice and found that, on average, 11.5 items were wasted per case.[8]

One potential solution is simply not retrieving and opening packages until they become necessary during the surgery, assuming the extra time it would take to retrieve and open the instruments would not pose a significant threat to the patient. Another potential solution is evaluating which disposable OR supplies generally remain unused during procedures and revising the surgical supply packs based on the evaluation results. An evaluation of such intervention was found to significantly reduce waste and hospital costs.[1]

One potential challenge with both solutions proffered above is the historical precedent of how pre-operation procedures have been dictated by the surgical team. As pointed out in one study, a major barrier to enacting any policy to improve sustainability is "related to behavioral inertia or reluctance to change current practice simply because changing it requires more effort."[9] Nurses and other staff responsible for preparing the OR are told by surgical staff what they want opened and available prior to surgery. Either solution mentioned above would most likely require working with the larger surgical team to assess which devices are necessary, working with surgical kit manufacturers, educating staff about the changes, and retraining.

Reducing pharmaceutical waste

[a] Red bag waste is considered biohazardous waste, or items that have been contaminated with blood or other infectious materials. Additionally, some evidence suggests close to 90% of red-bag waste does not meet red-bag waste criteria.[7]

As mentioned earlier, in addition to the unnecessary physical waste generation (i.e., trash), another component of unnecessary waste in the OR is pharmaceutical or medication waste. In the OR setting, anesthesia medication waste is well documented; propofol is the most wasted medication by volume whereas emergency medications, such as atropine, epinephrine, or phenylephrine, have the highest percentage of being opened but not used, and therefore must be thrown away.[5,10] Not only is pharmaceutical waste costly to hospitals, but it also has adverse environmental impacts, particularly in terms of surface, ground, and drinking water contamination.[5,7] Recommended strategies for reducing pharmaceutical waste in the OR include: using prefilled syringes for emergency medications, splitting vials for pediatric anesthesia to accommodate smaller dose volumes, and avoiding drawing up medications that may not be used.[5]

Reusing Equipment and Textiles

For the purposes of this report, it is important to define what is meant by reusable devices, single-use devices, and equipment reprocessing:

- Reusable medical devices are those devices that health care professionals can reprocess and reuse on multiple patients. These are generally made of materials that are designed and manufactured to withstand multiple rounds of sterilization, with chemicals and/or extreme heat.
- Single-use devices, also known as disposable devices, are those "intended for use on one patient during a single procedure . . . and is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient."
- Equipment Reprocessing is defined as the disinfecting, cleaning, sterilizing, packaging, labeling, and storing a used or opened package of a medical device, *that was intended as a single-use item*, to be placed into service again (as opposed to reprocessing items that were intended to be reusable).[11]

History of single-use devices in medicine

Prior to the 1970s, most medical devices were considered reusable. While the first single-use device was developed in 1948, the proliferation of single-use devices in medicine started in the 1970s (as well as the reuse of these products through sterilization and reprocessing) due to an increase in demand and complexity of equipment being used.[11, 12,13] There were also several high profile incidents in the 1970s that occurred with reused medical equipment that helped spur the move towards single-use devices.[12] In the United Kingdom, the increased use of disposable, single-use medical devices grew even more in the early 2000s resulting from the Creutzfeldt Jakob disease epidemic in the 1990s. Studies showing the persistence of proteins from the disease on reusable devices, even after sterilization, led to calls for single-use surgical instruments to prevent transmission of the disease, even though no cases were found to be a result of transmission through reusable medical devices.[12] Single-use equipment has now become the norm in medical settings and has increased the overall waste generation in health care settings.

Multi-use Equipment

Several studies have utilized life cycle assessment (LCA) to evaluate the environmental impacts of various OR reusable equipment in comparison to single-use equipment. Reusable equipment has been found in some circumstances to reduce costs, water consumption, energy consumption, waste, and GHG emissions.[14] However, the ecological benefits of multiple-use equipment over single-use equipment are not always clear. It depends on the complexity of the equipment and the sterilization method used[6] as well as where the study is being conducted (e.g., different countries have varying energy production portfolios, which can influence the LCA).

Reprocessed single-use devices

Reprocessing of single-use devices has been happening for almost 40 years. However, the Federal Drug Administration (FDA) only developed guidance for third-party businesses to reprocess single-use equipment in 2000. Currently, companies that reprocess medical devices are regulated by the FDA and are held to the same standards as manufacturers of medical devices. Reprocessing equipment represents significant cost savings for hospitals and can have ecological benefits. The Association of Medical Device Reprocessors (AMDR) estimates that hospitals can lower their costs for medical devices by 25-40 percent by using reprocessed equipment[15] and divert tens of millions of pounds of medical waste from landfills every year.[16]

Infectious disease risk with reused devices

It is important to note that there always exists a risk of infection for any reusable product or during any type of surgery. A major concern over reusable equipment or the reprocessing of single-use items is whether it is inherently riskier than a new single-use item. However, the benefits of single-use objects over reusable or reprocessed objects for infectious risk reduction is based on weak evidence and few studies have been done to compare the risk of infection.[11,14] A narrative review of the literature was published in 2021 on whether there was a difference between single-use devices versus reusable devices in terms of their environmental impact and risk of infectious/bacterial contamination, within anesthesia equipment specifically. Based on the review, the authors found the greatest risk of pathogen transmission came from improper hand hygiene and washing among the anesthesia team, not the equipment itself.[14] In another example, researchers studying the outcomes of cataract surgery in Avarind Eye Care System in southern India found lower rates of postoperative endophthalmitis than in the U.S., despite Avarind's reuse of as many of their surgical and pharmaceutical supplies as possible.[17] Additionally, a U.S. Government Accountability Office report published in 2008 found no increased health risk to consumers from using reprocessed single-use devices.[18]

According to the FDA, there are certain design features of medical products that make them easier and safer to reprocess for reuse, which include:

- Smooth surfaces, including smooth inner surfaces of the long, narrow interior channels;
- The ability to disassemble devices with multiple components;
- Non-interchangeable connectors for critical connections;
- Clear identification of connecting accessories, such as drainage tubing;
- Clear indication and identification of components that must be discarded after patient use and cannot be reprocessed or reused;
- Disposable components for the hardest to clean areas;
- Designs that address how fluid flows through the device, and areas of debris build-up within devices.[19]

Additionally, there are a number of devices that have been identified as being amenable to reprocessing, including cardiac catheters, trocars, laparoscopic staplers/vessel sealers, and external fixation devices.[6] However, there are still concerns over their safety and efficacy as "many single-use devices are reused without being adequately evaluated" for whether they sufficiently reduce infectious materials.[11] Also, the safety of reused equipment is highly dependent on making sure the process of sterilization and cleaning is done properly. There are important differences between third party and in-hospital reprocessing. Sterilization processes need to be followed exactly, which may not always happen in a hospital setting since they are not regulated or overseen by the FDA.

Third party reprocessing businesses must be registered with the FDA and meet similar safety standards as device manufacturers, and therefore operate under much more stringent regulations than hospitals.

Reusable versus disposable textiles

The use of sterilized surgical gowns and drapes has a long history in medicine. The first credited use of a sterilized surgical gown was in 1883 by German surgeon, Gustav Neuber of Kiel, and the first painting of a surgeon wearing a gown dates to 1889.[20] Beginning in the 19th century and for the first half of the 20th century, surgical gowns and drapes were made of reusable textiles, first cotton fabric and then later muslin, with the introduction of disposable drapes in the 1960s.[20] When it was found that muslin fabric was not an effective barrier to bacteria, research was conducted to find improved materials that were impervious to bacterial penetration. New paper-based garments were then introduced and "manufacturers of non-woven disposable surgical gowns and drapes launched a vigorous promotional and advertising campaign to the surgical community, claiming the advantages of their products for use in surgery," for both comfortability and safety.[20] Despite advances in woven and reusable textiles to improve safety and permeability since the mid-20th century, there has been a large increase in the use of disposable textiles in health care. As of an article published in 2021, approximately 80 percent of US hospitals use disposable surgical gowns.[6]

In terms of the evidence on the ecological impacts of reusable textiles in comparison to disposables, studies have largely shown that reusable textiles have ecological benefits on almost all accounts, except in some cases water usage due to the laundering required. In a review article of six LCA studies on reusable versus disposable gowns, the results showed that reusable gowns outperformed disposable on all four environmental indicators categories considered (i.e., energy consumption, greenhouse gas emissions, water consumption, and solid waste generation).[21] In another recent article, an LCA was conducted on reusable versus disposal surgical head covers. Reusable head covers were found to have a 56 to 61 percent lower carbon footprint than disposable head covers and, for 16 out of 17 secondary outcomes, reusable head covers had a lower environmental impact.[22]

While the ecological benefits of reusable textiles are well documented, the evidence comparing surgical site infection risks between reusable and disposable textiles is less well developed and the results are mixed. Earlier studies comparing reusable versus disposable textiles, which largely pushed hospitals to move towards disposable products, found disposables to have better infection control. However, many of these earlier studies are outdated due to updates in materials used to produce reusable gowns and drapes.[23] Additionally, many of these early studies were funded by disposable gown manufacturers and their objectivity has been called into question. Both the World Health Organization and CDC guidance documents have reported no meaningful evidence to support differences in the occurrences of surgical site infections between disposable and reusable materials.[24] However, similar to single-use devices, few studies have compared infection rates from reusable versus disposable textiles and the evidence is mixed.[25,26]

Benefits and challenges of reusable and reprocessed products

Beyond their cost savings and ecological benefits, another potential benefit of reusable and reprocessed products is improved system resiliency. The COVID-19 pandemic highlighted supply-chain issues that can occur when hospital systems rely primarily on single-use medical devices and disposable textiles produced in other countries and/or in areas affected by supply-chain disruptions.

The use of reusable products and reprocessed devices helps create resilience within the hospital system during times of device shortages.[27]

On the other hand, there are also additional challenges for the adoption of multi-use and reprocessed devices and attire. Different surgeons may have their own instrument requirements, even for the same surgery, which can complicate the development of a unified standard for reusable or reprocessed equipment in certain settings. Surgical teams would need to unify their instrument preferences around specific reusable products or ones that could be safely reprocessed to make meaningful change. Additionally, patient specific risk factors, such as age, whether they are immunocompromised, length of stay in the hospital, and medication allergies are just a few examples that may impact the risk of infection from reusable or reprocessed devices and attire.[20]

Recycling Programs

There are several barriers within hospital systems to recycling materials in the OR, which include a lack of knowledge about what can be recycled, proper separation of materials, concern for infectious diseases, limitations on space in the OR, and lack of time.[4,9] Several studies have shown that there is a lot of room for improvement in recycling programs and have demonstrated the effectiveness of recycling improvement programs in health care settings. A study in Australia of waste from the intensive care unit found that nearly 60 percent of the waste generated could be recycled and there was minimal infectious waste cross contamination.[28] Pilot studies have also shown that interventions to improve recycling of OR waste can have a positive impact in terms of reduced waste going into the landfill, particularly when the intervention is accompanied by staff education and training on proper recycling technique.[4] Lastly, an evaluation of 13 sustainability actions at a French hospital focused on the OR, which included seven waste reduction actions, five waste sorting actions, and one eco-responsible purchasing action, found significant ecological benefits as well as economic benefits for the hospital.[29]

While improving recycling programs may be one of the easier changes to implement within a hospital setting, it may be the least effective in terms of global ecological benefit and truly reducing waste generation, particularly since so much of the waste generated is plastic. Plastic recycling represents a very small percentage of overall materials recycled in the U.S. According to the EPA, plastics made up less than 5 percent of all recycled materials in 2018.[30] The primary issues of recycling plastics are that most plastics cannot be recycled at all or cannot be repeatedly recycled (like aluminum or paper) without quickly degrading in quality.[31,32]

Available Resources for Sustainable Purchasing

Sustainable purchasing practices has been highlighted as a critical step in the healthcare setting when establishing a sustainable or green agenda.[7] Several organizations have already developed best practices for reducing waste in the OR and/or guides for implementing more sustainable purchasing processes in health care, which are provided below.

- Practice Greenhealth
    - Sustainable Procurement in Healthcare Guide[33]
    - Greening the Operating Room™ Checklist[34]
- Healthcare without Harm
    - Purchasing Resources[35]

Joint Commission Standards

In March of 2023, the Joint Commission announced they were developing new requirements to address environmental sustainability for the Hospital (HAP) and Critical Access Hospital (CAH) accreditation programs.[36] The announcement noted that health care organizations can no longer ignore their contributions to GHG emissions.[36] Hospitals consume energy (such as electricity and natural gas) and use materials (such as disposables) that contribute to increased waste and GHG emissions. The proposed new standard, LD.05.01.01, would have required both hospitals and critical access hospitals to appoint an individual to oversee the reduction of greenhouse gas emissions in coordination with clinical and facility representatives.

Hospitals would be asked to measure three or more of the following:

- Energy use
- Purchased energy (electricity and steam)
- Anesthetic gas use
- Pressurized metered dose inhaler use
- Fleet vehicle gasoline consumption
- Solid waste disposal to landfills or through incineration

The hospital would then have to use the measures to reduce GHG emissions in a written plan. After receiving industry feedback, on the new proposed standards on sustainability, the Joint Commission noted their plans to roll them out as optional.[37]

EXISTING AMA POLICY

Policy H-480.959, “Reprocessing of Single-Use Medical Devices” notes that our AMA supports (1) the FDA guidance on "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,” and (2) the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry. This policy also encourages increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices and supports the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved. The policy also notes that the AMA strongly opposes any rules or regulations regarding the repair or refurbishment of medical tools, equipment, and instruments that are not based on objective scientific data.

Under Policy H-135.973, “Stewardship of the Environment,” 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 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.

CONCLUSION

To improve sustainability in OR and reduce overall waste, hospitals can choose from a number of strategies. The easiest, most cost-effective, and risk-neutral strategies are improving existing recycling programs for paper, glass, and plastics within the hospital and reducing the amount of equipment that is unpackaged but not used and thrown away. While improved recycling programs may help decrease waste generation, it may not have the largest ecological benefit. The second strategy involves modifying and improving surgical kits to reduce unnecessary items. This would require surgical teams to audit their current practices, identify the equipment needed, and work with kit manufacturers to make necessary updates. Another strategy is donating supplies that are not being used and are not expired to nonprofit organizations that repurpose surplus medical supplies and equipment, such as Medwish International.

Reusing and reprocessing medical equipment as well as switching to reusable textiles are also strategies for reducing waste in the OR which can result in large cost savings and overall waste reduction benefits. However, reusable and reprocessed equipment should be considered on a case-by-case basis and be informed on the risk level of the surgery. Even modifying existing drapes to be shorter by removing unnecessary length at the ends could reduce overall waste generation. A decision to switch to a reusable device or piece of equipment should be preceded by a life-cycle assessment to ascertain whether it has a positive environmental impact (in comparison to a single use device). More studies are needed to understand whether there is an increased risk of infectious disease transmission from reusable equipment and textiles but there is little existing evidence to suggest that they are inherently riskier.

While not discussed in the peer-reviewed literature, manufacturers of medical devices and textiles could also take a more holistic and total life cycle approach to product creation, which would incorporate sustainability considerations at the design phase and at each component of the product's life. This would require considering sustainable options of material selection (e.g., choosing a bio-based material versus petroleum based product), product design (e.g., can the product be smaller or more amenable to reprocessing safely), manufacturing process (e.g., how can you reduce energy and water usage), packaging (e.g., can compostable packaging materials be used), distribution (e.g., how do you minimize transportation distances), and disposal (e.g., will this produce be reusable or recyclable).[38]

Regardless of strategy, future sustainability efforts must be approached with leadership support and across departments to enact meaningful change.

RECOMMENDATIONS

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

1. That Resolution 936-I-22, which asks for our AMA to advocate for research into and development of intended multi-use operating room equipment and attire over devices, equipment and attire labeled for "single-use" with verified similar safety and efficacy profiles be adopted. (New HOD Policy)

2. That Policy H-480.959, "Reprocessing of Single-Use Medical Devices," be reaffirmed. (Reaffirm Existing Policy)

3.That our AMA work with interested parties to establish best practices for safe reuse of equipment and improved surgical kits used in the operating room, and to disseminate best practices for reducing waste in the operating room as well as guides for implementing more sustainable purchasing processes in health care. (New HOD Policy)

Fiscal Note: $5,000 - $10,000

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REPORT 6 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH
Marketing Guardrails for the "Over-Medicalization" of Cannabis Use (Resolution 501-A-22)
(Reference Committee K)

EXECUTIVE SUMMARY

BACKGROUND. American Medical Association Policy D-95.958, “Marketing Guardrails for the "Over-Medicalization" of Cannabis Use,” adopted by the House of Delegates (HOD) at the 2022 Interim Meeting, directed the Council on Science and Public Health (CSAPH) to study marketing practices of cannabis, cannabis products and cannabis paraphernalia that influence vulnerable populations, such as children and pregnant people. CSAPH has issued seven previous reports on cannabis.

METHODS. English language articles were selected from searches of PubMed and Google Scholar using the search terms “cannabis”, “marijuana”, “marketing”, and “advertising”. Additional articles were identified by manual review of the reference lists of pertinent publications. Searches of selected stakeholders, national, and local government agency websites were conducted to identify definitions, guidelines, regulations, and reports.

RESULTS. States have diverse regulations regarding cannabis marketing, with some completely prohibiting it, while others have established guidelines through state-based regulatory bodies. Research indicates advertising can normalize substance use and disproportionately targets youth, reflected in studies on alcohol and tobacco industries. The U.S. cannabis industry's rapid growth has seen increasing advertising expenditure, yet knowledge gaps persist in understanding and regulating these practices, particularly on platforms accessible to minors like social media. States’ advertising, marketing, packaging restrictions and national public health campaigns aim to safeguard consumers, especially children, and promote safe behaviors.

CONCLUSION. Research on cannabis marketing regulation and enforcement is sparse, especially concerning its efficacy in safeguarding vulnerable groups, notably youth. While federal regulatory agencies oversee the marketing and advertising of hemp (including CBD), the regulation of cannabis and cannabis-derived products varies by state. The challenges in the field of cannabis products are accentuated by the lack of research and guidance on dosing and adverse effects, leading consumers to rely on potentially inaccurate marketing sources like dispensary staff or online sites, emphasizing the need to ensure accurate and consistent information in marketing despite the known harms posed by cannabis. A closer look at the marketing regulatory frameworks established for substances such as alcohol and tobacco could offer valuable insights into marketing and advertising practices for cannabis and its derived products.

REPORT 6 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 6-I-23

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

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

BACKGROUND

American Medical Association (AMA) Policy D-95.958, "Marketing Guardrails for the "Over-Medicalization" of Cannabis Use," adopted by the House of Delegates (HOD) at the 2022 Interim Meeting, directed the Council on Science and Public Health (CSAPH) to study marketing practices of cannabis, cannabis products and cannabis paraphernalia that influence vulnerable populations, such as children and pregnant people. CSAPH has issued seven previous reports on cannabis. The most recent report, presented at the November 2020 HOD meeting, summarizes current state legislation legalizing adult cannabis and cannabinoid use, and reviews other pertinent information and developments in these jurisdictions to evaluate the public health impacts of legalization. This report investigates the marketing practices of cannabis products and serves as the Council on Science and Public Health's (CSAPH) findings and recommendations.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "cannabis", "marijuana", "marketing", and "advertising". Additional articles were identified by manual review of the reference lists of pertinent publications. Searches of selected stakeholders, national, and local government agency websites were conducted to identify definitions, guidelines, regulations, and reports.

INTRODUCTION

As of April 24, 2023, 38 states, the District of Columbia (D.C.), Guam, Puerto Rico, and the U.S. Virgin Islands have legalized the use of cannabis for medical purposes through either a legislative process or ballot measure.[1] As described in Council Report 5-I-17, these laws vary greatly by jurisdiction from how patients access the product (home cultivated or dispensary), to qualifying conditions, product safety and testing requirements, packaging and labeling requirements, the retail marketplace, and consumption method. In 2012, Colorado and Washington were the first U.S. jurisdictions to legalize the adult use of cannabis.[2] As of June 1, 2023, a total of 23 states, D.C., Guam, and the Northern Mariana Islands have legalized cannabis for adult use, 15 through the ballot measure process, and 11 via legislation, with three more states expected to include ballot measures in upcoming elections (Ohio, Florida, and Nebraska).[1]

In 2021, cannabis was consumed by an estimated 52.5 million people, or 18.7 percent of the U.S. population aged 12 or older.[3] Cannabis is a psychoactive substance consisting of distinctive compounds known as cannabinoids that include Cannabidiol (CBD) and Tetrahydrocannabinol (THC). Cannabis products containing THC remain Schedule I Controlled Substances, while CBD

products are regulated as an agriculture commodity. THC is the primary psychoactive compound in cannabis that produces the "high" sensation, along with altering perception, mood, and cognition. CBD (cannabidiol), on the other hand, is non-psychoactive and does not cause a “high” that is associated with THC. Each state that has legalized cannabis for medical or adult-use has its own unique requirements for marketing, advertising, and sale, with the main standardized requirement being that purchasers must be 21 years of age or older. There are challenges in developing marketing regulations due to scientific uncertainty (due to lack of research because of scheduling) regarding benefits and risks associated with the use of cannabis.[6] While millions of people in the U.S. use cannabis each month, evidence is mounting of harmful physical and mental health effects associated with heavy or long-term cannabis use and the negative impacts, particularly for vulnerable populations such as children, young adults, people with psychiatric disorders, and pregnant people.[7–9]

AMA policy separates cannabis legalization for medicinal (D-95.969) or adult use (H-95.924) also known as non-medical, or recreational use. AMA policy opposes state-based legalization of cannabis for medical use (whether via legislative, ballot, or referendum processes) and supports the traditional federal drug approval process for assessing the safety and efficacy of cannabis-based products for medical use. Medical use is defined as the use of cannabis or its derivatives to treat medical conditions or symptoms under the supervision of a health care provider. Additionally, AMA policy notes that cannabis products that have not been approved by the FDA (but are marketed for human ingestion in many states) should carry the following warning label: “[Cannabis] has a high potential for abuse. This product has not been approved by the FDA for preventing or treating any disease process” (D-95.969).

Marketing is categorized as “any commercial communication or other activity, including advertising, promotion, and sponsorship, that is designed to increase the recognition, appeal and/or consumption” of the product being marketed.[10] While the oversight of alcohol advertising and marketing falls under the jurisdiction of the Federal Trade Commission (FTC), a significant portion of alcohol advertisers voluntarily adheres to self-imposed codes and standards.[11] These standards are primarily aimed at limiting the marketing exposure to vulnerable groups. Although the FTC oversees the adherence to these codes to pinpoint violations, the general public can lodge complaints about non-compliant advertising or marketing to industry-specific organizations, including the Distilled Spirits Council, Beer Institute, or Wine Institute.

In the realm of tobacco, the landscape of marketing and advertising standards was largely shaped by the 1998 Master Settlement Agreement, where cigarette companies agreed to self-regulation. Currently, the marketing of tobacco is under federal jurisdiction, with the Federal Drug Administration (FDA) and FTC responsible for monitoring compliance. Contrastingly, the oversight of cannabis marketing predominantly falls to individual states, each governed by its respective regulatory body. This decentralized approach is largely due to cannabis's Schedule I status, which offers limited scope for federal regulatory bodies to provide consistent guidelines or oversight.

DISCUSSION

Controlled Substances Act Federal Implications

The U.S. Controlled Substances Act (CSA) of 1970 continues to categorize cannabis as a Schedule I controlled substance, citing its high potential for abuse, lack of currently accepted medical use, and unproven safety under medical supervision. The CSA bans “written advertisements that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled

substance."[12] Despite federal law prohibiting the advertising of cannabis, most states have legalized cannabis advertising and marketing within their jurisdiction. Historically, the CSA exclusively prohibited written advertisements (e.g., magazines, newspapers, and publications). However more recently, the legislation was amended to prohibit advertising via the internet, resulting in conceptually stringent federal restrictions on cannabis marketing, particularly those activities extending beyond state lines, leaving significant potential conflicts with state-level marketing practices, though thus far enforcement of such restrictions has been limited.[13]

Federal Marketing Regulations

Both the FDA and FTC play crucial roles in regulating marketing and advertising practices in the U.S. and have specific areas of oversight. However, their roles often intersect, especially when it comes to consumer protection. The FDA is responsible for protecting public health by ensuring the safety and efficacy of drugs, food, supplements, and other products. As part of this mandate, it oversees advertising and promotion. As an example of FDA's enforcement of marketing, in 2021 they issued warning letters to companies for illegally selling over-the-counter CBD products for pain relief stating that the drugs had not gone through the FDA approval process to determine efficacy, safety, side-effects, or how they can interact with other drugs or products.[14] Similarly, the FDA issued warning letters to companies for selling products containing CBD with claims that they can treat medical conditions, including opioid use disorder or as an alternative to opioids.[15] Companies that are issued warning letters for their violation of the Federal Food, Drug and Cosmetic Act are subject to legal action, product seizure, and/or injunction if they fail to remedy the violations listed in warning letters.

In tandem, the FTC oversees consumer protection matters by ensuring that advertisements are not deceptive or misleading to the general public. As part of this, they oversee the use of endorsements and testimonials in advertising. While the FTC stipulates that advertising must adhere to standards of truthfulness, evidence-based support, and non-misleading content, with any limitations or disclosures being clearly articulated, FTC enforcement for marketing in the context of state-legalized cannabis products has been complex.[16,17] The FDA ensures that prescription drug advertisements provide a balanced presentation of both the risks and benefits of the drug and that the ads are not misleading. The FTC typically regulates over-the-counter (OTC) drug advertising, yet the FDA still plays a role, especially concerning labeling and ensuring claims are substantiated. Both the FDA and FTC have the authority to impose penalties on companies that breach marketing and advertising regulations. Due to the overlap in their regulatory domains, the two agencies frequently collaborate to maintain consistent and thorough oversight.

FDA approved cannabinoid products

The FDA has approved several synthetic cannabinoid products for medical purposes, reflecting a growing recognition of their therapeutic potential. Specifically, the synthetic THC analogs dronabinol (Marinol® and Syndros®) and nabilone (Cesamet®) are approved for treating nausea and vomiting associated with chemotherapy, with dronabinol also approved for anorexia in patients with AIDS.[18] The agency has also approved one cannabis-derived drug product cannabidiol (CBD) oral solution (Epidiolex®) for specific rare and severe forms of epilepsy.[18,19] Because these products have received FDA approval, their marketing and advertising activities are subject to federal regulations, just like other pharmaceutical drugs. Both the FDA and FTC oversee and enforce these regulations to ensure consumer safety and accurate information dissemination.

The Farm Bill: Impact on Cannabis and Hemp Marketing

The 2018 Farm Bill amended the CSA by exempting hemp and hemp-based products, a variant of cannabis with low THC content, from CSA jurisdiction, thereby recognizing it as an "agricultural commodity" and effectively legalizing the marketing of hemp by licensed growers.[18,20] Research analyzing hemp marketing is limited, but there have been significant regional variations in state-based marketing channels.[21] One study found that while Colorado hemp producers primarily market online (24 percent), Kentucky producers primarily use word of mouth (44 percent).[21] (See Table 1) However, it remains unclear whether the approach to cannabis marketing influences sales-related variables, such as buyer profiles, age groups, or demographics.

The Farm Bill legalized hemp and hemp-derived CBD on the federal level, it did not address other cannabis-derived products, such as delta-8 THC and delta-10 THC products.[16,22] Nonetheless, there have been cases where both the FDA and FTC have taken regulatory action. On July 5, 2023, they sent warning letters to six firms for the unauthorized sale of imitation food items containing delta-8 THC.[23] Such products, which closely resemble conventional foods like chips, cookies, candy, and gummies, have raised FDA concerns about the potential for inadvertent consumption, especially by children, or ingestion of higher doses than intended.[23]

The Farm Bill mandates that hemp cultivation needs to be licensed and regulated under "state plans." However, the legalization and regulation of hemp and hemp-derived products, including CBD, brought these products under the authority of both the FDA and the Department of Agriculture, adding another layer of complexity.[24] This has led to the FDA using its authority over drug regulation to prevent unsubstantiated claims about the therapeutic efficacy of CBD-containing products.[5]

Despite FDA warning letters to companies illegally selling products with CBD, marketers have found ways to adapt their messaging within the FDA regulatory framework.[25] Strategies include reliance on consumer reviews to support marketing rather than direct seller claims, referring to websites that promote but do not sell CBD, and conflating research on THC or whole cannabis with effects of CBD alone.[5] Additional challenges have emerged leading to issues such as inaccurate labeling, inconsistent CBD formulation concentration, and unintentional product contamination from pesticides or insufficient purification processes.[5]

In January 2023, the FDA determined that the existing regulatory structures for foods and supplements are not suitable for CBD because they do not comprehensively cover the safety concerns that have been noted with CBD.[26] To address this, they plan to collaborate with Congress to develop a new regulatory pathway enhancing industry oversight of CBD, especially in marketing and advertising.[26] This new regulatory pathway would provide “safeguards and oversight to manage and minimize risks related to CBD products.”[26] These risk mitigation strategies include among others clear labeling, content limitations, and minimum purchase age.[26]

Cannabis Marketing

States have varying approaches to the marketing of cannabis and THC-containing products. While some states have completely banned marketing and advertising, other states have developed guidelines and regulatory bodies. In the majority of states where adult-use or medical use is legal, states have established regulatory bodies, officers, and/or programs that provide licensing and industry oversight to ensure compliance of existing cannabis laws, the development of marketing and advertising guidelines, and the enforcement of violation penalties. However, there are no federal standardized regulations, guidelines, or laws.

The marketing and advertising landscape has changed over time as states have implemented legislation granting state-based regulatory bodies the authority to enforce cannabis marketing guardrails. Given the scarcity of research dedicated to cannabis-specific marketing, many researchers have relied on studies conducted in the alcohol and tobacco industries for guidance.[28] Evidence from these industries suggests that advertising can contribute to the normalization and increased likelihood of substance use, with adolescents and youth often being disproportionately targeted.[29–31]

The U.S. cannabis industry registered a record $21.1 billion in sales in 2022, with expected annual sales of $37 billion by 2026.[32] Marketing and advertising have grown with the legalization of cannabis. However, there is currently no data available detailing the extent of this increase. As a proxy for evaluation, the cannabis industry spent approximately $661 million on advertising in 2018 and is projected to spend $2 billion in 2023 with a projected increase to $4.5 billion by the year 2030.[33] Even though cannabis legalization is implemented across states, there is still a scarcity of knowledge about marketing and advertising practices, potentially leaving gaps in regulation that could expose vulnerable populations to substantial harm. As the legal adult-use cannabis market expands, an extensive retail landscape has evolved to meet consumer demand for various types of cannabis and THC-containing products including edibles, beverages, and concentrates.

State Approaches to Regulating Cannabis Marketing and Advertising

State-based regulations primarily focus on the content and placement of marketing to safeguard consumers, with special emphasis on protecting minors. Similar to the voluntary self-regulatory code followed by the alcohol industry, many states have adopted policies prohibiting cannabis advertising in media where it is expected that over 30 percent of the audience will be under 21 years old.[10,36,37] However, research from the alcohol industry suggests that such policies are not particularly effective in preventing youth from exposure or interaction with alcohol-related content, indicating potential analogous issues with cannabis.[10,29,38]

Certain states, such as Colorado, Washington, and New York, explicitly forbid direct cannabis marketing towards children, but this has not deterred the rise of online and social media advertisements easily accessible to underage individuals.[23] With dispensaries offering convenience features such as online pre-ordering and home delivery, there are growing concerns regarding the lack of consistent state guidance on online cannabis marketing and social media promotions.[10,23,29] This concern is amplified by prior studies suggesting that minors have been able to successfully purchase other regulated products online such as cigarettes.[23,39]

The Network for Public Health Law conducted an extensive comparison of advertising and marketing regulations of adult-use cannabis in various states.[40] This comparison includes advertising limitations across 17 distinctive jurisdictions, with some jurisdictions excluded due to the lack of developed advertising regulations or other specific variables. The analysis highlights the considerable variance between states in marketing and advertising standards and regulation, categorizing policy measures into three main areas: medium restrictions, content restrictions, and physical restrictions.[40] Despite the existence of laws regulating cannabis marketing and advertising practices in many states, the actual enforcement of these laws has remained relatively unexplored. (See Table 3 for a companion to the State Regulation of Adult-Use Cannabis Advertising Table)

Medium Restrictions: Medium restrictions on cannabis advertising vary across states and are specific to certain advertising media, such as broadcast, print, or internet. The majority of states surveyed have restrictions on broadcasting advertising, print-media advertising, and internet advertising for cannabis in order to limit exposure to minors.[40] To a lesser extent, a few states have

laws restricting cannabis event sponsorship and location-based marketing which leverages the geographic location of a mobile device to push notifications about products offered at a nearby establishment.[40]

Content Restrictions: Content restrictions address the specifications and limitations placed on the content within cannabis advertisements. The majority of states surveyed regulate therapeutic claims in cannabis advertising, but they all regulate it to varying degrees. While some ban therapeutic claims altogether, others list numerous conditions on their states' approved lists. For instance, hepatitis C, Crohn's disease, Parkinson's disease, and Tourette's syndrome are qualifying medical conditions by state law for the use of cannabis[41], but the efficacy is supported only by low-quality evidence.[42] Nevertheless, some dispensaries may be financially motivated to increase customer sales by citing these cases.[23,43] Only six jurisdictions regulate safety claims in cannabis advertising, ranging from complete prohibition on safety claims to requirements for scientific evidence supporting the claims.[40]

All states except one surveyed explicitly outlaw false and/or misleading statements in advertisements.[40] Some states go further by defining what constitutes a misleading statement such as ambiguity and omission.[40] All jurisdictions ban ads that target children; however the extent of these prohibitions varies by state. For example, while Michigan bans ads for individuals under the age of 21, New Jersey specifically bans the inclusion of elements such as toys or cartoon characters that might appeal to individuals under 21 (See Table 4).[40] Along the same lines, the majority of states require a product warning on cannabis advertisements, while the warning required vary they generally inform about potential health risks, age requirements, and lack of FDA approval.[40] Similar to warnings on cigarette packages, the discrepancies in cannabis labeling across states can create challenges for consumers in reading and identifying health warnings, particularly for first time users or people with vision impairment. (See Table 5) The warning label signs size, text, and color vary from state to state.[34] (See Table 6) Lastly, more than half of the jurisdictions have varying regulations against offering gifts, prizes, or other inducements related to cannabis sales.[40]

Physical Restrictions: Physical restrictions focus on the physical characteristics and placement of cannabis outdoor advertising. The majority of states have exclusion zones around schools and other child-centric places (e.g., playgrounds, public parks) for advertising varying from 200 feet to 1,500 feet.[40] However, less states have restrictions regarding advertising on public property, public transportation, or in general visibility zones such as on signs or billboards.[40] One study that included a small sample (N=172) of adolescents in 6 states that have legalized adult-use cannabis found that the prevalence of billboard or storefront advertisements influences adolescents' usage patterns.[35] These billboards may lead to increased likelihood of frequent use and symptoms of cannabis use disorder.[35] (See Table 7) The marketing strategies employed by cannabis companies, particularly their branding techniques, could influence the frequency and manner of cannabis use among minors.[35]

Packaging Restrictions: The design of cannabis product packaging is at the forefront of these regulatory measures, as it plays a pivotal role in minimizing the appeal of cannabis items, especially edibles, to children. With legalization, states have reported a surge in accidental cannabis ingestion by children.[36] Many states have implemented packaging guidelines to mitigate such risks. For instance, nine states mandate opaque packaging and three states mandate plain packaging, with each having its unique definition.[37] Furthermore, every state demands child-resistant packaging, often based on standards from the Poison Prevention Packing Act of 1970, albeit implemented differently across states.[37] Some states, like California, have detailed child-resistant packaging systems with specific requirements for various types of cannabis products.[37]

Tamper-evident packaging, which showcases visible signs if meddled with, is required in three states.[37]

Most states, with a few exceptions, have a general directive prohibiting cannabis packaging that could entice children.[37] Some, such as Illinois, have explicit bans on packaging showcasing images appealing to minors, like cartoons or toys. Furthermore, 14 states strictly forbid packaging that imitates commercially available foods to minimize accidental ingestion by children.[37] Beyond general prohibitions, some states specify particular imagery or wording that cannot be used due to their potential allure to children. For instance, Maine prohibits the depiction of humans, animals, or fruit on the packaging.[37] A notable safety measure, the inclusion of the poison control number on cannabis packaging, is mandatory in four states.[37] The overarching objective across all these regulations is to safeguard children from the risks of accidental cannabis consumption and ensure public safety.

Marketing Through Social Media

The prominence of social media as a conduit for accurate information, disinformation. and misinformation about cannabis[38], coupled with social media-based cannabis promotion[10,31,39,40], poses a public health concern. The widespread engagement with these platforms among underage populations[41], and the established associations between exposure to cannabis marketing and subsequent intentions, initiation, and frequency of use among both adolescents[10,42] and adults[43,44], underscores the need for marketing regulations.[16]

In a study that investigated the correlation between adolescents' exposure to cannabis marketing in states where cannabis is legal, and their cannabis use in the past year found that exposure to cannabis marketing on social media platforms significantly increased the likelihood of the teens using cannabis. [20] Specifically, exposure increased the odds by 96 percent for Facebook, 88 percent for Twitter, and 129 percent for Instagram.[20] With each additional social media platform where exposure was reported, the odds rose by 48 percent.[20] Despite existing restrictions on cannabis advertising via social media platforms, teens are still encountering this marketing, leading to cannabis use. The study suggests that states should further regulate and enforce regulations of cannabis marketing on these platforms.

In a similar study, 11 social media companies that are the most popular amongst youth in the U.S. (e.g., TikTok, SnapChat, Instagram, and Facebook) were analyzed based on their cannabis marketing policies. While all social media platforms prohibit cannabis sales, they had varying policies on advertising and promotion.[16] (See Table 2) Paid advertising on social media for cannabis and cannabis products were prohibited by nine of the 11 platforms, the remaining two companies allow paid advertising within jurisdictions where cannabis is legal.[16] In addition, four out of the 11 platforms have ambiguous policies prohibiting unpaid cannabis promotion, with seven of the platforms allowing varying degrees of promotion by proxy such as through a link in their biography or allowing cannabis content and discussion but not promotion.[16]

Every social media platform mentioned limitations on cannabis-related content access for minors or underage individuals including age restrictions (thresholds set to either 18 or 21 years of age) or general age restrictions not specific to cannabis. However, researchers have highlighted concerns regarding age verification methods on social media platforms, noting their ambiguous effectiveness.[16] While one platform may set a threshold age of 21 years for exposure to cannabis, alcohol, and tobacco content, aligning with the legal age, other platforms may not, suggesting a need to adjust access based on legal ages, and improve age verification processes.

Another issue is the exposure to cannabis promotions in regions where cannabis is not legalized on the state-level. Regulating paid cannabis-related content on social media is challenging due to its vast volume and the difficulty in pinpointing the source's location. Additionally, the increasing prevalence of sponsored posts by influencers, indirect political promotions, and often undisclosed financial relationships make these posts hard to spatially identify and regulate.[16] Given the challenges of monitoring marketing on social media, there is a pressing need for both social media platforms and regulatory agencies to devise advanced strategies to automatically detect cannabis-related content. Implementing concrete advertising and marketing regulations on social media-based platforms and across the internet could serve to protect the health of vulnerable populations.[29,45]

Public Health Campaigns

When states legalize adult-use cannabis, they often implement policies that earmark tax revenue from cannabis sales for health and social initiatives, including educational public health campaigns that highlight the health risks associated with cannabis use.[46,47] This funding approach, in which counter-marketing resources became available only after significant sales had taken place, often leaves governments and public health offices in a reactive position, attempting to counter pre-established industry marketing and associated narratives. Although counter-marketing has shown some efficacy in reducing harmful tobacco and alcohol consumption, its effectiveness in reducing cannabis use has yet to be extensively studied in the U.S.[48]

The National Highway Traffic Safety Administration (NHTSA), in collaboration with the Ad Council, has launched a comprehensive campaign to raise awareness about the hazards of drug-impaired driving and encourage safer decisions. This campaign employs a multi-channel approach encompassing television, radio, banners, print media, out-of-home advertisements, and online videos.[49] (See Table 8) The primary focus is to deter individuals from operating vehicles while under the influence of drugs, specifically cannabis. Scientific studies indicate that cannabis can adversely impact several critical driving skills, such as reaction time, distance judgment, and overall coordination.[50–52] Given these risks, the campaign specifically targets young men between the ages of 18 and 34.[49] The campaign's core message is that alterations in perception after cannabis consumption can drastically change driving capabilities.[49]

NHTSA is one of the many stakeholders that is continually researching the correlation between cannabis impairment and crash risks. Findings from their Drug and Alcohol Crash Risk Study have shown that cannabis users have a higher likelihood of being involved in accidents.[53,54] This elevated risk might be attributable, in part, to the demographic skew towards young men, who inherently have a higher crash risk.[53] Recent studies by NHTSA in 2020 have highlighted a rising prevalence of drug use, especially alcohol, cannabinoids, and opioids, among seriously injured or fatally wounded road users during public health emergencies compared to previous times.[53,55]

EXISTING AMA POLICY

AMA currently has policy related to cannabis, research, and marketing. Policy H-95.924, "Cannabis Legalization for Adult Use" notes that states that have legalized cannabis should be required to take steps to regulate the product effectively in order to protect public health and safety including in marketing and promotion intended to encourage use, requiring legible and child-resistant packaging with messaging about the hazards about unintentional ingestion in children and youth. Policy H-95.952, "Cannabis and Cannabinoid Research" calls for more cannabis and cannabinoid research including into the long-term cannabis use among youth, adolescents, pregnant women, and women who are breastfeeding. Policy H-95.936, "Cannabis Warnings for Pregnant

and Breastfeeding Women" advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed. Policy H-95.911, "CBD Oil Use and the Marketing of CBD Oil" supports banning the advertising of cannabidiol as a component of marijuana in places that children frequent, and supports legislation that prohibits companies from selling CBD products if they make any unproven health and therapeutic claims. In addition, our AMA's advocacy team has been active in encouraging the FDA to regulate inappropriate medical claims and direct-to-consumer advertising.

CONCLUSION

Research on cannabis marketing regulation and enforcement is sparse, especially concerning its efficacy in safeguarding vulnerable groups, notably youth. While federal regulatory agencies oversee the marketing and advertising of hemp (including CBD), the regulation of cannabis and cannabis-derived products varies by state. The challenges in the field of cannabis products are accentuated by the lack of research and guidance on dosing and adverse effects, leading consumers to rely on potentially inaccurate marketing sources like dispensary staff or online sites, emphasizing the need to ensure accurate and consistent information in marketing. A closer look at the marketing regulatory frameworks established for substances such as alcohol and tobacco could offer valuable insights into optimal marketing and advertising practices for cannabis and its derived products.

RECOMMENDATIONS

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

A. Our AMA supports and encourages:

1. research on the effects of cannabis marketing to identify best practices in protecting vulnerable populations, as well as the benefits of public health campaigns such as preventing impaired driving or dangerous use.
2. state regulatory bodies to enforce cannabis-related marketing laws and to publicize and make publicly available the results of such enforcement activities.
3. social media platforms to set a threshold age of 21 years for exposure to cannabis advertising and marketing and improve age verification practices on social media platforms.
4. regulatory agencies to research how marketing best practices learned from tobacco and alcohol policies can be adopted or applied to cannabis marketing. (New HOD Policy)

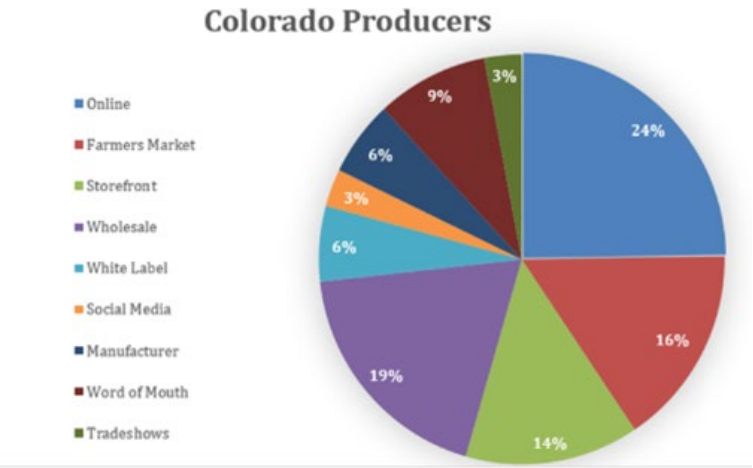
B. That our AMA reaffirm policies:

- H-95.952, "Cannabis and Cannabinoid Research," that calls for further funding for adequate and well-controlled studies of cannabis and cannabis derived products and support of the rescheduling of cannabis, and
- H-95.923, "Taxes on Cannabis Products," that notes our AMA's encouragement of states and territories to allocate a substantial portion of their cannabis tax revenue for public health purposes, including substance [use] prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts. (Reaffirm HOD Policy)

Fiscal Note: Minimal – less than $1,000

TABLE 1. Colorado and Kentucky Hemp Grower Marketing Channels

Hill R, Jablonski BBR, Van L, et al. Producers marketing a novel crop: a field-level view of hemp market channels. *Renewable Agriculture and Food Systems*. 2023;38. doi:10.1017/S1742170523000145



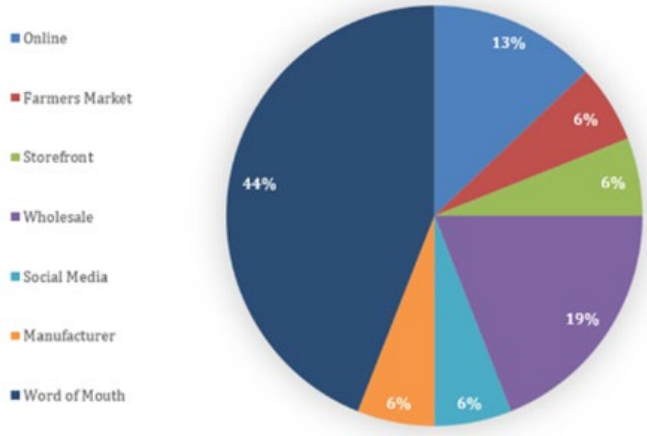


TABLE 2. Summary of Social Media Platform Policies Regarding Cannabis Promotion, as of October-November 2022

Berg CJ, LoParco CR, Cui Y, et al. A review of social media platform policies that address cannabis promotion, marketing and sales. *Subst Abuse Treat Prev Policy*. 2023;18(1):35. doi:10.1186/s13011-023-00546-x

	Specifies cannabis	Recognizes jurisdictional differences	Paid advertising		Unpaid promotion		Cannabis sales		Underage restrictions			
			Completely prohibited	Allowed but restricted	Completely prohibited	Allowed but restricted	Completely prohibited	Allowed but restricted	Age unspecified	< 18 years old	< 21 years old	Addresses cannabis
Discord	X	-	X	-	X	-	X	-	-	X	-	-
Facebook	X*	-	X	-	-	X	X	-	-	X	-	-
Instagram	X	-	X	-	-	X	X	-	X	-	-	-
Pinterest	X*	-	X	-	-	X	X	-	-	X	-	-
Reddit	X*	X	X	-	X	-	X	-	-	X	-	-
Snapchat	X*	X	-	X	X	-	X	-	X	-	-	-
TikTok	-	X	X	-	X	-	X	-	-	X	-	X
Tumblr	X*	X	-	X	-	X	X	-	-	-	X	X
Twitch	X*	-	X	-	-	X	X	-	X	-	-	-
Twitter	X*	X	X	-	-	X	X	-	-	X	-	X
YouTube	X	-	X	-	-	X	X	-	-	X	-	X

Notes: See also Supplementary Table 1 for more details. * Differentiates CBD from cannabis containing THC.

TABLE 3: State Regulation of Adult-Use Cannabis Legal Research Table

The Network for Public Health Law. State Regulation of Adult-Use Cannabis Advertising.; 2022. Accessed July 18, 2023. https://www.networkforphl.org/wp-content/uploads/2022/11/State-Regulation-of-Adult-Use-Cannabis-Advertising.pdf

STATE	SOURCE	REQUIRING COMMISSION APPROVAL	Medium Restrictions					CONTENT RESTRICTIONS						PHYSICAL RESTRICTIONS				
			Radio/Television (restriction- audience share over min. age)	Print (restriction- audience share over min. age)	Internet (restriction- audience share over min. age)	Event Sponsorship (restriction- audience share over min. age)	Location-Based Marketing Restrictions	Curative/Therapeutic Claims	Safety Claims	Content Targeting Children	Validity of Statements	Gifts/Prizes/Other Inducements	Product Warnings	Signs within Close Proximity to Schools	Signs on Public Property/Transp ortation	Signs Visible to General Public	Size/Other Features	Illuminated Signs
Alaska	Alaska Admin. Code tit. 3 § 306.770	N	N	N	Y	Y (70%)	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N
Arizona	Ariz. Rev. Stat. Ann. § 36-2859	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
California	Cal. Bus. & Prof. Code § 26150-26156 (2017)	N	Y (71.6%)	Y (71.6%)	Y (71.6%)	Y (71.6%)	Y	Y	N	Y	Y	Y	N	Y	N	N	N	N
Colorado	Colo. Code Regs §212-3-3 R.700 Series	N	Y (71.6%)	Y (71.6%)	Y (71.6%)	Y (71.6%)	N	N	Y	Y	Y	N	N	Y	N	N	Y	N
Connecticut	Conn. Gen. Stat. §21a-421bb (Public Act No. 22-103) (2022)	N	Y (90%)	Y (90%)	Y (90%)	Y (90%)	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N	Y
District of Columbia	No Advertising Provisions	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Illinois	410 Ill. Comp. Stat. 705/55-20 (2019)	N	N	N	N	N	N	Y	N	Y	Y	Y	N	Y	Y	N	N	N
Maine	18-691-1 Me. Code R. § 52	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N
Maryland	Md. Code Ann.,Health-Gen. § 13-3313.1 (2019)	N	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	N
Massachusetts	935 Mass. Code Regs. 500.105(4)	N	Y (85%)	Y (85%)	Y (85%)	Y	N	Y	Y	Y	Y	Y	Y	N	Y	N	N	Y
Michigan	Mich. Admin. Code r. 420.507 (2020)	N	Y (70%)	Y (70%)	Y (70%)	Y	N	Y	N	Y	Y	N	N	N	N	N	N	N
Montana	Mont. Admin. R. 42.39.123 (2021)	N	Y	Y	Y	N	Y	N	Y	Y	N	N	N	N	N	N	N	N
Nevada	Nev. Rev. Stat. § 678B.520 (2021)	N	Y (70%)	Y (70%)	Y (70%)	Y (70%)	N	N	N	Y	Y	Y	Y	Y	Y	N	N	N
New Jersey	N.J. Admin. Code § 17:30-14.2	N	Y (71.6%)	Y (71.6%)	Y* (71.6%)	Y (80.6%)	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N
New Mexico	N.M. Code R. § 16.8.3.8 (2022)	N	Y	Y (70%)	Y (70%)	N	Y	Y	N	Y	Y	N	Y	Y	Y	N	N	N
New York	N.Y. Can. § 86 (2022)	N	Y	Y	Y	N	N	Y	N	Y	Y	Y	N	Y	Y	Y	N	N
Oregon	Or. Admin. R. 845-025-8040 to 845-025-8060	N	Y (70%)	Y (70%)	Y (70%)	N	Y	Y	Y	Y	Y	N	Y	N	Y	N	N	N
Rhode Island	Rhode Island Gen.Laws § 21-28.11-5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Vt. Stat. Ann. Tit. 7 § 864 (2021)																	

Vermont	25-002 Vt. Code R. § 2.2.11 (2022)	Y	Y (85%)	Y (85%)	Y (85%)	Y (85%)	N	Y	N	Y	Y	Y	Y	N	N	N	N	N
Virginia	No Advertising Provisions	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Washington	Wash Admin. Code § 314-55-155 (2013)	N	N	N	N	N	N	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
1	RCW 69.50.369																		

TABLE 4: Cannabis Products that Appeal to Youth[56]

Fair L. THC edibles that look like snacks popular with kids? FTC and FDA have something to say about that. Federal Trade Commission. Published July 3, 2023. Accessed August 7, 2023. https://www.ftc.gov/business-guidance/blog/2023/07/thc-edibles-look-snacks-popular-kids-ftc-fda-have-something-say-about

Some of the products cited in FDA-FTC cease and desist letters to companies selling THC products copying the look of snacks popular with children

TABLE 5. Massachussets Cannabis Warning Label[57]

Line Packaging Supplies. Warning Label Massachusetts. Line Packaging Supplies. Accessed August 30, 2023. https://www.linepackagingsupplies.com/warning-label-massachusetts/

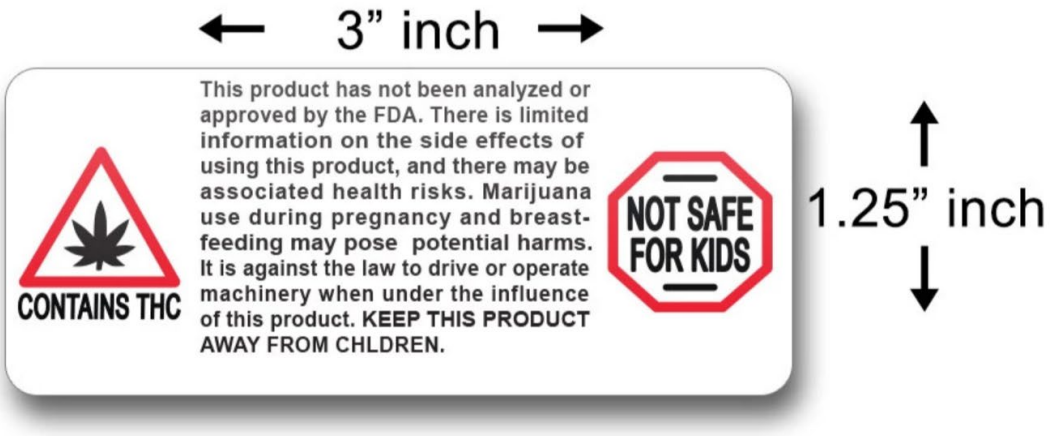


TABLE 6. Current Usage of the International Intoxicating Cannabis Products Symbol (IICPS) and Other Symbols

Doctors for Cannabis Regulation. Universal Cannabis Symbol. Accessed August 30, 2023. https://www.dfcr.org/universal-cannabis-symbol

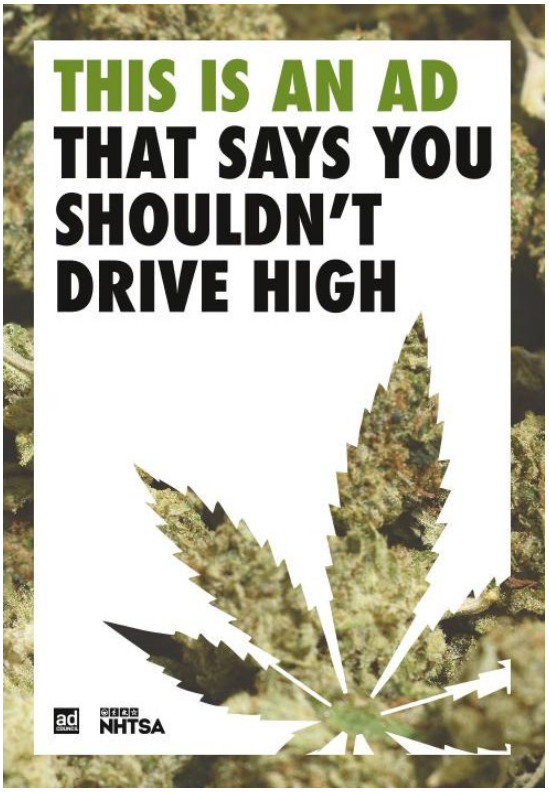
Symbol design	Authorities having jurisdiction (AHJs) using the symbol	Shape of outline (conventional meaning)	Emphasized color (conventional meaning)	Number of colors (including white)	Graphical element (cannabis leaf)	Large graphical element for the visually impaired	Text excluded from interior of symbol	ISO & ANSI compliant
	**IICPS:** MT, NJ, SD, & VT	Triangle (warning)	Yellow (caution)	2	Yes	Yes	Yes	Yes
	AR	None	None	2	No	No	No	No
	AZ, CO, FL, & OH	Diamond (none)	Red (prohibition)	2	No	No	No	No
	CA	Triangle (warning)	None	2	Yes	No	No	No
	CT, MA, ME, & RI	Triangle (warning)	Red (prohibition)	3	Yes	Yes	Yes	No
	MD	Triangle (warning)	Red (prohibition)	2	Yes	No	No	No
	MI	Inverted triangle (none)	Green (safe condition)	2	Yes	Yes	No	No
	NM	Diamond (none)	Red (prohibition)	2	No	No	No	No
	NV	Triangle (warning)	None	2	No	No	No	No
	NY	Square (none)	Yellow, red (caution, prohibition)	4	Yes	No	No	No
	OK	Rectangle (none)	Red (prohibition)	3	Yes	No	No	No
	OR	Rectangle (none)	Red (prohibition)	3	Yes	Yes	No	No
	WA	Diamond (none)	Yellow, green (caution, safe condition)	4	Yes	Yes	No	No
	Canada	Octagon (stop)	Red (prohibition)	3	Yes	Yes	No	No

TABLE 7. Cannabis Billboards[58]

Stanford University. Marijuana Billboards. Research into the Impact of Tobacco Advertising. Accessed August 30, 2023. https://tobacco.stanford.edu/marijuanas/billboards/

TABLE 8. Ad Council Drug-Impaired Driving Print Assets

Ad Council. Drug-Impaired Driving Campaign & Media Assets. Drug-Impaired Driving Prevention. Accessed August 21, 2023. https://www.adcouncil.org/campaign/drug-impaired-driving-prevention#print



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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 7-I-23

Subject: Efficacy of Requirements for Metal Detection/Weapons Interdiction Systems in Health Care Facilities

Presented by: David J. Welsh, MD, MBA, Chair

Referred to: Reference Committee K

Resolution 938-I-22, asked that our American Medical Association Council on Science and Public Health study the issues of (1) workplace violence as it impacts health care workers, patients, and visitors, and (2) anticipated positive impacts of weapons detection and interdiction systems toward reduction of workplace violence, so that our AMA can develop learned and data-based recommendations and accompanying advocacy regarding proposed new requirements for the deployment of these systems in health care settings, and share these recommendations with accrediting bodies such as The Joint Commission, Liaison Committee on Medical Education, Accreditation Council for Graduate Medical Education, and other relevant stakeholders, including the American Hospital Association.

This report updates information contained in CSAPH 2-I-10, "Violence in the Emergency Department," and Board of Trustees Report 2-I-12, "Surveying Violence in the Non-hospital Work Environment," and CSAPH 7-A-16, "Preventing Violent Acts Against Health Care Providers." There is a significant amount of background information on this issue contained within these previous reports, including information on the types of workplace violence, prevalence of workplace violence in health care settings, risk factors, high-risk practice areas, hospital-based shootings, reporting of workplace violence, the current requirements to prevent violence against health care workers, and a review of interventions and evidence on their effectiveness. Our intention with this report is not to repeat that information, but to share relevant updates. We also recognize that the threat of violence against health care professionals does not only exist within health care facilities, but threats of violence outside of health care facilities is beyond the scope of this report.

METHODS

English language reports were selected from a search of the PubMed and Google Scholar databases using the search terms "health care" and "violence," "workplace violence" and "prevention," and "firearms" and "hospitals," "weapon" and "health care," and "metal detector" and "health care." Searches were time-limited to articles published since the last report on this topic in 2016. Additional articles were identified by manual review of the references cited in these publications. Further information was gathered from internet sites managed by relevant federal agencies and health care organizations.

BACKGROUND

The health care and social service industries experience the highest rates of injuries caused by workplace violence.[1] Workers in these industries are 5 times as likely to suffer a workplace violence injury than workers overall.[1] Health care workers accounted for 73 percent of all nonfatal workplace injuries and illnesses due to violence in 2018.[1] From 2011 to 2018, there were 156 workplace homicides to private health care workers, averaging about 20 each year. The most common assailant in workplace homicides to health care workers was a relative or domestic partner of the injured worker.[1]

The COVID-19 pandemic seemingly worsened violence against health care professionals. A survey by the International Council of Nurses, the International Committee of the Red Cross, the International Hospital Federation, and the World Medical Association conducted from May to July 2021 sought to understand the perceptions of violence against health care professionals during the first year of the COVID-19 pandemic.[2] The report found that of those organizations that had received reports of violence, 58 percent of the respondents perceived an increase and 9 percent of those who reported violence said it had not occurred before the pandemic.[3] All respondents reported verbal aggression; 82 percent mentioned threats and physical aggression while 27 percent reported staff being threatened by weapons.[4] Twenty-one percent reported the death or severe wounding of a health-care worker or patient.[4]

While fatal shootings, such as those at Legacy Good Samaritan Medical Center in Portland, Methodist Dallas Medical Center, Northside Medical building in Atlanta, and on the campus of Saint Francis Health System in Tulsa, Oklahoma receive media attention, there are many other non-fatal acts of violence in health care workplaces that are either not reported or get little attention.[5] Evidence indicates that workplace violence might lead to various negative impacts on health care professionals' psychological and physical health, such as increase in stress and anxiety levels and feelings of anger, guilt, insecurity, and burnout.[6] Furthermore, the general sentiment of health care professionals attacked in the workplace is that hospital administrators and the judicial system accept this violence occurs and do not do enough to protect health care professionals.[7]

DISCUSSION

Emergency departments, mental health, and long-term care providers are among the most frequent victims of patient and visitor attacks. Perpetrator characteristics or circumstances that influence this pattern of violent events include altered mental status, dementia and behavioral issues, substance use disorders, pain/medication withdrawal, and dissatisfaction with care.[8,9] Regulatory agencies have taken the following actions since 2016 to address violence in health care facilities.

Occupational Safety and Health Administration (OSHA)

In the Council's 2016 report, it was noted that OSHA does not have specific standards for workplace violence.[22] However, the courts have interpreted Section 5(a)(1) of the Occupational Safety and Health Act of 1970 (the General Duty Clause), to mean that:

> an employer has a legal obligation to provide a workplace free of conditions or activities that either the employer or industry recognizes as hazardous and that cause, or are likely to cause, death or serious physical harm to employees when there is a feasible method to abate the hazard.[22]

This means that workplace violence must have taken place, or the employer must be aware of threats or other signs that the potential for violence exists, to be held accountable under the General Duty Clause.

In 2017, OSHA published an updated compliance directive to provide OSHA compliance officers with guidance on responding to complaints of workplace violence in the health care setting.[10] In 2019, the Occupational Safety and Health Review Commission (OSHRC) upheld a citation issued to a health care employer after an employee was fatally stabbed by a mentally ill patient.[11] OSHRC held that incidents of workplace violence fall within an employer's obligation under the General Duty Clause.

In March of 2023, OSHA announced that it is in the early stages of developing a potential standard, Prevention of Workplace Violence in Healthcare and Social Assistance. OSHA convened a Small Business Advocacy Review (SBAR) Panel and heard from representatives from small businesses and who served as small entity representatives who could potentially be affected by the draft rule.[12]

The Joint Commission

Effective January 1, 2022, revised workplace violence prevention standards apply to the Joint Commission-accredited hospitals and critical access hospitals.[13] The Joint Commission cited the high incidence of workplace violence and the rationale for the creation of new accreditation requirements. The revised standards provide a framework to guide hospitals in developing effective workplace violence prevention systems, including leadership oversight, policies and procedures, reporting systems, data collection and analysis, post-incident strategies, training, and education to decrease workplace violence.[13] Effective workplace violence prevention programs require a worksite analysis with environmental modifications implemented based on findings from the analysis. Best practices and applicable laws and regulations are constantly evolving, so hospitals are required to review the program's policies and procedures, training, and education for consistency with the latest recommendations.[13]

FGI Guidelines

FGI is an independent, not-for-profit organization dedicated to developing guidance for the planning, design, and construction of hospitals, outpatient facilities, and residential health, care, and support facilities. FGI's "Draft Guidelines for Emergency Conditions in Health and Residential Care Facilities," provides that emergency departments shall be designed to ensure that access control can be maintained at all times.[14] Furthermore, the draft guidelines note that the exterior perimeter of the emergency department should have the capability to be secured to control access and provide safety in the event of a disaster or situations requiring a higher level of security.[14] Means to detect weapons, such as a metal detector, shall be provided at each point of entry to the emergency department.[5] A video surveillance system shall be provided for each emergency department entrance and where entrances may be locked, a visible duress alarm system shall be provided.[14] At the time of this report, the final guidelines were not yet available.

MAGNETOMETERS IN HEALTH CARE SETTINGS

Most studies on workplace violence have been designed to quantify the problem, but few have described methods to prevent such violence.[15] At the time of our last report, it was noted that some hospitals have installed magnetometers (metal detectors) at their entrances to prevent individuals from bringing weapons into facilities. Henry Ford Hospital in Detroit confiscated 33 handguns, 1,324 knives, and 97 chemical sprays within the first six months of screening. Other hospitals, including Johns Hopkins Hospital in Baltimore, suggested that widespread use of magnetometers is impractical given the many entrances most hospitals have. There were also concerns that armed

guards manning magnetometers could be the source of weapons used in hospital-based shootings. Since that time, there have been limited studies evaluating the effectiveness of magnetometers in reducing violence in health care facilities.

Perceptions of magnetometers in health care

Surveys have examined patient and employee attitudes towards the use of metal detectors specific to emergency departments. A survey of patrons in pediatric emergency departments found that the public has a strong perception that a metal detector protects both patrons and employees.[16] This finding is consistent with a prior survey of 176 patrons and 95 employees in an urban emergency department, which found that most patrons and staff liked the metal detector and said it created a safer environment.[17] Eighty-nine percent of the patrons and 73 percent of the employees said the metal detector made them feel safer.[17] Only 12 percent of the patrons and 10 percent of the employees said the metal detector invaded their privacy or the privacy of others.[17]

The International Association for Healthcare Security and Safety's 2020 Healthcare Crime Survey, asked participants if they used walk-through metal detectors to screen visitors and patients as they entered the hospital 24 hours a day, 7 days a week.[18] Eight percent (n = 19) of participant hospitals used walk-through metal detectors 24/7 in 2019. Three hospitals reported no impact on crime, security incidents, or workplace violence.[18] The remaining hospitals reported a positive impact on crime, security incidents, and workplace violence.[18]

Weapons retrieved after initiation of magnetometers

A 2021 cross-sectional survey of hospital security directors found that using a metal detector facilitates the discovery and awareness of weapons entering the health care facility.[19] Hospitals with metal detectors were more than 5 times as likely to frequently confiscate weapons.[19] The study also found that hospitals with psychiatric units were more likely to have frequent confiscation of weapons, likely due to the standard procedure of searching patients before admission.[19]

These findings are consistent with a previous study that found a metal detector installed at the entrance of an urban, high-volume teaching hospital emergency department resulted in the retrieval of firearms, knives, chemical sprays, and other weapons. A total of 5877 weapons were retrieved, an average of 218 per month: 268 firearms, 4842 knives, 512 chemical sprays, and 275 other weapons, such as brass knuckles, stun guns, and box cutters.[20]

However, it cannot be determined from data related to confiscation of weapons whether metal detectors reduce workplace violence in health care facilities.

Costs of magnetometers in health care facilities

One article notes that adding metal detectors is not as easy as it sounds. In addition to the cost of the equipment and personnel (at least two per metal detector), space is needed for the machine and for patients and visitors to wait in line.[21] Private search rooms may also be needed "for more intensive searching of people who set off the metal detector even after removing items most likely to cause problems."[21] X-ray machinery may also be needed to scan bags, requiring additional budget and space. Emergency departments may also station security guards at ambulance entrances to "wand" patients as they arrive to detect weapons.[21]
The process of going through the detectors can be time-consuming and frustrating when patients are seeking care. There may be the need for a nurse or paramedic to help with patient queuing so clinical staff have visibility of patients.[21] There have been instances, though not specific to

magnetometers, of patients going to the emergency department for treatment who have been unable to get in quickly enough for treatment. For example, Massachusetts passed "Laura's Law" after Laura Levis, who died in 2016 at the age of 34 outside CHA Somerville Hospital.[22] Having gone to the emergency department for an asthma attack, she found a well-lit entrance door to the emergency department locked. She called 911 for help, but by the time firefighters located her, she had suffered a cardiac arrest and died several days later.

There is little information in the published literature on equity considerations around the use of metal detectors in health care facilities, though we know they may interfere with implantable cardioverter defibrillators and pacemakers as well as pose challenges for those with limited mobility.

EXISTING AMA POLICY

Policy D-515.983, "Preventing Violent Acts Against Health Care Providers," notes that our AMA will continue to work with other appropriate organizations to prevent acts of violence against health care providers and improve the safety and security of providers while engaged in caring for patients, as well as widely disseminate information on effective workplace violence prevention interventions in the health care setting.

Policy H-515.966, "Violence and Abuse Prevention in the Health Care Workplace," encourages all health care facilities to: adopt policies to reduce and prevent all forms of workplace violence and abuse; develop a reporting tool that is easy for workers to find and complete; develop policies to assess and manage reported occurrences of workplace violence and abuse; make training courses on workplace violence prevention available to employees and consultants; and include physicians in safety and health committees.

H-515.957, "Preventing Violent Acts Against Health Care Providers," encourages OSHA to develop and enforce a standard addressing workplace violence prevention in health care and social service industries; encourages Congress to provide additional funding to the National Institute for Occupational Safety and Health (NIOSH) to further evaluate programs and policies to prevent violence against health care workers; and encourages NIOSH to adapt the content of their online continuing education course on workplace violence for nurses into a continuing medical education course for physicians.

Policy H-215.977, "Guns in Hospitals," encourage hospitals to incorporate, within their security policies, specific provisions on the presence of firearms in the hospital. Given that security needs stem from local conditions, firearm policies must be developed with the cooperation and collaboration of the medical staff, the hospital security staff, the hospital administration, other hospital staff representatives, legal counsel, and local law enforcement officials. Consultation with outside experts, including state and federal law enforcement agencies, or patient advocates may be warranted. The development of these policies should begin with a careful needs assessment that addresses past issues as well as future needs. Policies should, at minimum, address the following issues: a means of identification for all staff and visitors; restrictions on access to the hospital or units within the hospital, including the means of ingress and egress; changes in the physical layout of the facility that would improve security; the possible use of metal detectors; the use of monitoring equipment such as closed circuit television; the development of an emergency signaling system; signage for the facility regarding the possession of weapons; procedures to be followed when a weapon is discovered; and the means for securing or controlling weapons that may be brought into the facility, particularly those considered contraband but also those carried in by law enforcement personnel.

CONCLUSION

Health care personnel represent a significant portion of the victims of workplace violence and workplace violence can result in negative outcomes for health care personnel. In addition to physical injuries, it can result in low morale, decreased productivity, increased stress, and turnover. Citing the high incidence of workplace violence, the Joint Commission has revised workplace violence prevention standards for hospitals and critical access hospitals. The revised standards provide a framework to guide hospitals in developing effective workplace violence prevention systems. OSHA has also signaled that they are in the early stages of developing a potential standard on the Prevention of Workplace Violence in Healthcare and Social Assistance.

However, more research is needed regarding the effectiveness of interventions to prevent workplace violence in the health care setting, including the use of magnetometers and other weapons interdiction systems. While data suggests that magnetometers make patients and staff feel safer and they are effective in retrieving weapons, it is not clear to what extent they reduce workplace violence in health care settings and if the benefits outweigh the costs. As exiting AMA policy notes, security needs stem from local conditions and the development of health facility security policies should begin with a careful needs assessment that addresses past issues as well as future needs.

RECOMMENDATIONS

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

1. That existing AMA policies on preventing violence against health care professionals be reaffirmed:

   D-515.983, "Preventing Violent Acts Against Health Care Providers," H-515.966, "Violence and Abuse Prevention in the Health Care Workplace," H-515.957, "Preventing Violent Acts Against Health Care Providers," H-215.977, "Guns in Hospitals," and H-515.950, "Protecting Physicians and Other Healthcare Workers in Society." (Reaffirm Existing Policy)

2. That our AMA encourages: (1) additional funding and research to evaluate effective interventions to prevent workplace violence against physicians and other health care professionals, including the effectiveness of magnetometers and other weapons interdiction systems in health care facilities; (2) health care facilities that have implemented magnetometers and other weapons interdiction systems to evaluate the impact on workplace violence and share best practices, including equity considerations; (3) the dissemination and awareness of guidance by OSHA and other organizations on the prevention of violence in health care facilities, including hospitals, ambulatory centers, and other clinical settings. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 901
(I-23)

Introduced by: Arizona Medical Association, American College of Occupational and Environmental Medicine, Aerospace Medicine Association

Subject: Silicosis from Work with Engineered Stone

Referred to: Reference Committee K

Whereas, Exposure to silica dust is a health hazard for workers who manufacture, finish, and install natural and engineered stone countertop products, causing silicosis, which is a progressive, debilitating, incurable, and sometimes fatal occupational disease[1]; and

Whereas, Close to 100,000 workers are employed in the manufacture, finishing, and installation of natural and engineered stone countertop products in the United States[2]; and

Whereas, Clusters of silicosis cases have been reported nationally and internationally among stone countertop fabrication workers, including cases in California[3] and Texas; and

Whereas, Silicosis is a disease related to long-term exposure, usually appearing after many years of exposure, unlike workplace injuries; and

Whereas, Implementing effective exposure controls is integral to the business of operating an engineered stone fabrication shop[5]; and

Whereas, The State of California has developed silica safety resources for stone fabricators and physicians that can guide other states in developing local resources[6]; therefore be it

RESOLVED, That our American Medical Association should encourage physicians, including occupational health physicians, pulmonologists, radiologists, pathologists, and other health-care professionals, to report all diagnosed or suspected cases of silicosis in accordance with National Institute for Occupational Safety and Health (NIOSH) guidance (New HOD Policy); and be it further

RESOLVED, That our AMA should advocate for the establishment of preventive measures to reduce exposure of workers to silica levels above the OSHA permissible exposure level (PEL) for respirable crystalline silica, which is a time-weighted average (TWA) of 50 micrograms per cubic meter ($\mu g/m^3$) of air (Directive to Take Action); and be it further

RESOLVED, That our AMA should advocate for the establishment of a registry of cases of silicosis to be maintained for workers diagnosed with silicosis resulting from engineered stonework or from other causes, either by state Departments of Public Health or their Division of Occupational Safety and Health (Directive to Take Action); and be it further

RESOLVED, That our AMA should advocate for the establishment of state funds to compensate workers who have been diagnosed with silicosis resulting from their work with silica, to recognize the progression and the need for increasing levels of compensation over time (Directive to Take Action); and be it further

RESOLVED, That our AMA recommends that State Medical Associations should take action with respect to the prevention of silicosis and to the recognition and compensation of affected workers in their states. (New HOD Policy)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 9/18/2023

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 902
(I-23)

Introduced by: Integrated Physician Practice Section

Subject: Post Market Research Trials

Referred to: Reference Committee K

Whereas, patient safety necessitates that physicians have access to sound, unbiased information about the safety and effectiveness of drugs; and

Whereas, physicians rely on data and evidence provided by the Food and Drug Administration (FDA) to guide patients in sound clinical decision-making; and

Whereas, recent trends in FDA approvals have resulted in pharmaceuticals coming to market and gaining FDA approval faster and with less evidence of their efficacy; and

Whereas, clinical trial data for new pharmaceuticals increasingly relies on surrogate endpoints rather than direct measure of clinical benefit, as seen by an increase from 44 percent of pivotal trials based on surrogate endpoints between 2005 and 2012, to 60 percent based on surrogate endpoints between 2015 and 2017; and

Whereas, medications such as the FDA-approved Aducanumab demonstrate that surrogate endpoints that are “reasonably likely” to predict clinical benefit do not always result in actual clinical efficacy; and

Whereas, approximately three quarters of all new drugs in recent years were approved using an expedited regulatory pathway, making it more challenging to assess longer-term benefits and risks; and

Whereas, lack of sufficient data has significant implications for patients, medical professional, and health care spending; and

Whereas, Researchers have found that over half of post-market commitment studies and post-market requirement studies have produced novel information for clinical practice or have led to regulatory action, such as confirmation of benefit or a labeling change; and

Whereas, insufficient data can lead to concerns regarding patient safety and potential negative side effects; and

Whereas, drug manufacturers sometimes fail to complete “post-marketing” follow up trials in a timely manner, if at all; and

Whereas, studies have found that among more than 600 post-marketing studies imposed in 2009 and 2010, 20 percent were never started after five to six years, while others were significantly delayed; and

Whereas, the FDA Amendments Act of 2007 gave the FDA more authority to ensure timely completion of post-marketing requirements, however the FDA has yet to impose a civil monetary penalty for a delay; therefore be it

RESOLVED, that our American Medical Association advocate that the Food and Drug Administration use its authority to require and enforce timely completion of post-marketing trials or studies whenever sponsors rely on surrogate endpoints to support approval (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate that the Food and Drug Administration use its authority to require that pharmaceuticals that received approval using surrogate endpoints demonstrate direct clinical benefit in post-market trials as a condition of continued approval (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate that the Food and Drug Administration require drug manufacturers to make the findings of their post-market trials publicly available. (Directive to Take Action)

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

Received: 8/31/23

RELEVANT AMA POLICY

Reforming the FDA Accelerated Approval Process H-100.944
Our AMA supports: (1) mechanisms to address issues in the Food and Drug Administration (FDA)'s Accelerated Approval process, including but not limited to: efforts to ameliorate delays in post-marketing confirmatory study timelines and protocols for the withdrawal of approvals when post-marketing studies fail; and (2) specific solutions to issues in the FDA's Accelerated Approval process if backed by evidence that such solutions would not adversely impact the likelihood of investment in novel drug development.
Citation: Res. 525, A-22

Real-World Data and Real-World Evidence in Medical Product Decision Making H-480.938
1. Our AMA supports the generation and use of real-world data (RWD) and real-world evidence (RWE) fit for regulatory purpose to: (a) evaluate effectiveness and safety of medical products, while assuring patient privacy and confidentiality; (b) improve regulatory decision-making; (c) decrease medical product costs; (d) increase research efficiency; (e) advance innovative and new models of drug development; and (f) improve clinical care and patient outcomes.
2. Our AMA supports the aim of the U.S. Food and Drug Administration (FDA) to expand and clarify the use RWD and RWE in regulatory decision-making including in: (a) understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations; (b) pursuing the integration of RWE into medical product development and regulatory review; and (c) utilizing RWE to support new indications for approved medical products, and its ability to satisfy post-approval study requirements.
3. Our AMA supports that there be adequate funding of data infrastructure to allow for transparent data management capabilities, improved access to data by clinicians, especially physicians, as well as researchers and other stakeholders, and improved reliability and relevance of data.
4. Our AMA supports cooperation and collaboration of stakeholders to facilitate the collection and use of RWD and RWE that is deemed fit for regulatory purpose.
5. Our AMA will evaluate and develop a response to the educational needs of physicians seeking to understand the use of fit for purpose RWD and RWE in clinical practice.
Citation: CSAPH Rep. 2, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 903)
(I-23)

Introduced by: Medical Student Section

Subject: Supporting Emergency Anti-Seizure Interventions

Referred to: Reference Committee K

Whereas, over 3 million Americans live with active epilepsy, placing them at risk for status epilepticus and sequelae such as cognitive and psychiatric impairment or even death[1-2]; and

Whereas, lack of recognition of and rapid intervention for status epilepticus as a neurological emergency outside the hospital delays treatment and increases morbidity and mortality[2-6]; and

Whereas, the Food and Drug Administration approved intranasal midazolam and intranasal diazepam in 2019 and 2020 as effective emergency interventions for status epilepticus, which may improve care due to their easy administration by nonmedical caregivers (especially when patients cannot swallow or when rectal administration is difficult in public), rapid onset compared to oral medication, high bioavailability, safety, and reduction of stigma[7-8]; therefore be it

RESOLVED, that our American Medical Association support efforts in the recognition of status epilepticus and bystander intervention trainings (New HOD Policy); and be it further

RESOLVED, that our AMA encourage physicians to educate patients and families affected by epilepsy on status epilepticus and work with patients and families to develop an individualized action plan for possible status epilepticus, which may include distribution of home pharmacotherapy for status epilepticus, in accordance with the physician's best clinical judgment. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 09/11/2023

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RELEVANT AMA POLICY

H-130.938 Cardiopulmonary Resuscitation (CPR) and Defibrillators
Our AMA: (1) supports publicizing the importance of teaching CPR, including the use of automated external defibrillation; (2) strongly recommends the incorporation of CPR classes as a voluntary part of secondary school programs; (3) encourages the American public to become trained in CPR and the use of automated external defibrillators; (4) advocates the widespread placement of automated external defibrillators, including on all grade K-12 school campuses and locations at which school events are held; (5) encourages all grade K-12 schools to develop an emergency action plan for sudden cardiac events; (6) supports increasing government and industry funding for the purchase of automated external defibrillator devices; (7) endorses increased funding for cardiopulmonary resuscitation and defibrillation training of community organization and school personnel; (8) supports the development and use of universal connectivity for all defibrillators; (9) supports legislation that would encourage high school students be trained in cardiopulmonary resuscitation and automated external defibrillator use; (10) will update its policy on cardiopulmonary resuscitation and automated external defibrillators (AEDs) by endorsing efforts to promote the importance of AED use and public awareness of AED locations, by using solutions such as integrating AED sites into widely accessible mobile maps and applications; (11) urges AED vendors to remove labeling from AED stations that stipulate that only trained medical professionals can use the defibrillators; and (12) supports consistent and uniform legislation across states for the legal protection of those who use AEDs in the course of attempting to aid a sudden cardiac arrest victim. [CCB/CLRPD Rep. 3, A-14; Appended: Res. 211, I-14; Modified: Res. 919, I-15; Appended: Res. 211, I-18; Modified: Res. 418, A-23]

D-60.976 Childhood Anaphylactic Reactions
Our AMA will: (1) urge all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans (MERP); (b) practice these plans in order to identify potential barriers and strategies for improvement; (c) ensure that school campuses have a direct communication link with an emergency medical system (EMS); (d) identify students at risk for life-threatening emergencies and ensure these children have an individual emergency care plan that is formulated with input by a physician; (e) designate roles and responsibilities among school staff for handling potential life-threatening emergencies, including administering medications, working with EMS and local emergency departments, and contacting families; (f) train school personnel in cardiopulmonary resuscitation; (g) adopt the School Guidelines for Managing Students with Food Allergies distributed by FARE (Food Allergy Research & Education); and (h) ensure that appropriate emergency equipment to deal with anaphylaxis and acute asthmatic reactions is available and that assigned staff are familiar with using this equipment; (2) work to expand to all states laws permitting students to carry prescribed epinephrine or other medications prescribed by their physician for asthma or anaphylaxis; (3) support increased research to better understand the causes, epidemiology, and effective treatment of anaphylaxis; (4) urge the Centers for Disease Control and Prevention to study the adequacy of school personnel and services to address asthma and anaphylactic emergencies; (5) urge physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan; and (6) work to allow all first responders to carry and administer epinephrine in suspected cases of anaphylaxis. [CSAPH Rep. 1, A-07; Modified: CCB/CLRPD Rep. 2, A-14]

H-440.884 Food Allergic Reactions in Schools and Airplanes
Our AMA recommends that all: (1) schools provide increased student and teacher education on the danger of food allergies; (2) schools have a set of emergency food allergy guidelines and emergency anaphylaxis kits on the premises, and that at least one member of the school administration be trained and certified in the indications for and techniques of their use; and (3) commercial airlines have a set of emergency food allergy guidelines and emergency anaphylaxis kits on the premises, and that at least one member of the flight staff, such as the head flight attendant, be trained and certified in the indications for and techniques of their use. [Res. 415, A-04; Reaffirmed: CSAPH Rep. 1, A-14]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 904
(I-23)

Introduced by: Medical Student Section

Subject: Universal Return-to-Play Protocols

Referred to: Reference Committee K

Whereas, sports injuries, including concussions and musculoskeletal injuries, are associated with various sequelae, including cognitive impairment, decreased physical activity, impaired mobility, obesity, cardiovascular disease, post-traumatic arthritis, depression, and anxiety[1-4]; and

Whereas, previous injury is a significant risk factor for subsequent injury, due to altered proprioception and range of motion and scar tissue[5]; and

Whereas, women athletes experience overuse injuries more often than men athletes[6]; and

Whereas, inconsistencies in return-to-play criteria lead to a wide range of rehabilitation programs of different timelines, including both accelerated and 9-12 month protocols[7-8]; and

Whereas, for athletes with concussions, only 45% of athletes recommended to return to play after 10 to 14 days actually experienced significant recovery, but this number rose to 96% after 8 weeks post-injury, indicating that wide discrepancies in timelines affect recovery rates[9]; and

Whereas, uniform return-to-play criteria has demonstrated efficacy for athletes with posterior cruciate ligament injury, resulting in 92% returning to baseline performance 2 years after injury and 70% continuing to perform at the same level 5 years after injury[10]; therefore be it

RESOLVED, that our American Medical Association encourage interested parties to: (a) establish a standard, universal protocol for return-to-play recovery for collegiate and professional athletes; (b) promote additional evidence-based studies on the effectiveness of a universal protocol for evaluation and post-injury management course at the collegiate and professional level; (c) support national and state efforts to minimize the consequences of inadequate recovery windows for collegiate and professional athletes. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

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RELEVANT AMA POLICY

H-470.971 Athletic Preparticipation Examinations for Adolescents
To promote the health and safety of adolescents, our AMA recommends that state medical societies work with appropriate state and local agencies to promote the following:
(1) The development of standards for preparticipation athletic examinations that are consistent with consensus recommendations of the American Academy of Family Physicians, American Academy of Pediatrics, American Medical Society for Sports Medicine, American Orthopedic Society for Sports Medicine, and the American Osteopathic Academy of Sports Medicine.
(2) Only licensed MDs, DOs, and licensed physician extenders practicing under the supervision of licensed MDs and DOs perform preparticipation examinations.
(3) The decision of whether or not an adolescent is healthy and physically mature enough to participate in a particular sport is made by a qualified physician.
(4) The decision of when an injured athlete resumes participation is made by a qualified physician.
(5) The most current guidelines established by the American Academy of Pediatrics, American College of Cardiology, American College of Sports Medicine, and other appropriate medical specialty societies are used to determine eligibility for sports participation. [BOT Rep. R, A-90; Amended: CSA Rep. 5, I-99; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: BOT Rep. 9, A-14; Reaffirmed: CSAPH Rep. 3, A-15]

H-470.954 Reduction of Sports-Related Injury and Concussion
1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences.
2. Our AMA supports the adoption of evidence-based, age-specific guidelines on the evaluation and management of concussion in all athletes for use by physicians, other health professionals, and athletic organizations.
3. Our AMA will work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the ability of physicians to prevent, diagnose, and manage concussions and other sports-related injuries.
4. Our AMA urges appropriate agencies and organizations to support research to: (a) assess the short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span; (b) identify determinants of concussion and other sports-related injuries in pediatric and adult athletes, including how injury thresholds are modified by the number of and time interval between head impacts and concussions; (c) develop and evaluate effective risk reduction measures to prevent or reduce sports-related injuries and concussions and their sequelae across the lifespan; and (d) develop objective biomarkers to improve the identification, management, and prognosis of athletes suffering from concussion to reduce the dependence on self-reporting and inform evidence-based, age-specific guidelines for these patients.
5. Our AMA supports research into the detection, causes, and prevention of injuries along the continuum from subconcussive head impacts to conditions such as chronic traumatic encephalopathy (CTE). [CSAPH Rep. 3, A-15; Appended: Res. 905, I-16]

H-470.959 Reducing Risk of Concussion and Other Injuries in Youth Sports
1. Our American Medical Association promotes the adoption of requirements that athletes participating in school or other organized youth sports and who are suspected by a coach, trainer, administrator, or other individual responsible for the health and well-being of athletes of having sustained a concussion be removed immediately from the activity in which they are engaged and not return to competitive play,

practice, or other sports-related activity without the written approval of a physician (MD or DO) or a designated member of the physician-led care team who has been properly trained in the evaluation and management of concussion. When evaluating individuals for return-to-play, physicians (MD or DO) or the designated member of the physician-led care team should be mindful of the potential for other occult injuries.

2. Our AMA encourages physicians to: (a) assess the developmental readiness and medical suitability of children and adolescents to participate in organized sports and assist in matching a child's physical, social, and cognitive maturity with appropriate sports activities; (b) counsel young patients and their parents or caregivers about the risks and potential consequences of sports-related injuries, including concussion and recurrent concussions; (c) assist in state and local efforts to evaluate, implement, and promote measures to prevent or reduce the consequences of concussions, repetitive head impacts, and other injuries in youth sports; and (d) support preseason testing to collect baseline data for each individual.

3. Our AMA will work with interested agencies and organizations to: (a) identify harmful practices in the sports training of children and adolescents; (b) support the establishment of appropriate health standards for sports training of children and adolescents; (c) promote evidenced-based educational efforts to improve knowledge and understanding of concussion and other sport injuries among youth athletes, their parents, coaches, sports officials, school personnel, health professionals, and athletic trainers; and (d) encourage further research to determine the most effective educational tools for the prevention and management of pediatric/adolescent concussions.

4. Our AMA supports (a) requiring states to develop and revise as necessary, evidenced-based concussion information sheets that include the following information: (1) current best practices in the prevention of concussions, (2) the signs and symptoms of concussions, (3) the short-and long-term impact of mild, moderate, and severe head injuries, and (4) the procedures for allowing a student athlete to return to athletic activity; and (b) requiring parents/guardians and students to sign concussion information sheets on an annual basis as a condition of their participation in sports. [Res. 910, I-10; Reaffirmed: BOT Rep. 9, A-14; Modified: CSAPH Rep. 3, A-15; Modified: BOT Action in response to referred for decision: Res. 409, A-17]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution:905
(I-23)

Introduced by: Medical Student Section

Subject: Support for Research on the Relationship Between Estrogen and Migraine

Referred to: Reference Committee K

Whereas, migraine is a leading cause of disability, lost productivity, and medical expenses for patients, with frequent late diagnosis and subsequent financial burden[1]; and

Whereas, migraine affects about 1 in 6 individuals, with women affected at 2 to 3 times the rate as men, and 25% of patients with migraine experience aura[2-6]; and

Whereas, migraine's effect on cerebral blood vessels can increase stroke risk, but migraine with aura is associated with double the stroke risk compared to migraine without aura[7-11]; and

Whereas, oral contraceptives (OCPs) are used by 25% of women of reproductive age, with the most common OCPs being combined estrogen-progestin OCPs[12-13]; and

Whereas, due to estrogen's association with cardiovascular risk, patients with migraine may avoid combined OCPs, but data on stroke risk for these patients is not always clearly delineated by presence of aura, impacting the use of individualized risk assessment[7-11]; and

Whereas, lack of specificity in data on the relationship between migraine with and without aura and combined OCPs may result in many patients being unable to use these medications for contraception, menstrual regulation, menstrual migraines, uterine bleeding, cancer prevention, acne, hirsutism, osteoporosis, menopausal symptoms, hormone replacement therapy (such as gender-affirming care), and various other hormonal indications[13-15]; and

Whereas, studies suggest that cardiovascular risk due to estrogen may vary based on dose, administration route, age, menstrual and menopausal status, and presence of aura[7-11,16-33]; and

RESOLVED, that our American Medical Association support further research regarding the role of estrogen as a risk factor for stroke and cardiovascular events at the dosages and routes found in, inclusive of but not limited to combined oral contraceptive pills, vaginal rings, transdermal patches, hormone replacement therapy, and gender affirming hormone therapy in individuals with migraine and migraine with aura (New HOD Policy); and be it further

RESOLVED, that our AMA work with relevant stakeholders to advocate for increased resources to allow for appropriate education and assessment, when indicated, of migraine and migraine with aura consistent with current diagnostic guidelines in medical practice sites inclusive of but not limited to primary care, obstetrics and gynecology, endocrinology, neurology, and cardiology clinics. (Directive to Take Action)

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

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RELEVANT AMA POLICY

H-75.990 Development and Approval of New Contraceptives
Our AMA: (1) supports efforts to increase public funding of contraception and fertility research; (2) urges the FDA to consider the special health care needs of Americans who are not adequately served by existing contraceptive products when considering the safety, effectiveness, risk and benefits of new contraception drugs and devices; and (3) encourages contraceptive manufacturers to conduct post-marketing surveillance studies of contraceptive products to document the latter's long-term safety, effectiveness and acceptance, and to share that information with the FDA. [BOT Rep. O, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11; Modified: CSAPH Rep. 1, A-21]

H-75.995 Contraceptive Advertising
Our AMA supports the concept of providing accurate and balanced information on the effectiveness, safety and risks/benefits of contraception in all public media and urges that such advertisements include appropriate information on the effectiveness, safety and risk/benefits of various methods. [Res. 4, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17]

D-75.995 Over-the-Counter Access to Oral Contraceptives
Our AMA: (1) encourages the US Food and Drug Administration to approve a switch in status from prescription to over-the-counter for oral contraceptives, without age restriction; (2) encourages the continued study of issues relevant to over-the-counter access for oral contraceptives; and (3) will work with expert stakeholders to advocate for the availability of hormonal contraception as an over-the-counter medication. [Sub. Res. 507, A-13; Modified: BOT Rep. 10, A-18; Modified: Res. 518, A-22]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 906
(I-23)

Introduced by: Medical Student Section

Subject: Online Content Promoting LGBTQ+ Inclusive Safe Sex Practices

Referred to: Reference Committee K

Whereas, 80% of young adults and adolescents learn about sexual health and safe sex from television, with LGBTQ+ individuals especially turning to television to receive information that may otherwise be difficult to access depending on their community[1,2-3]; and

Whereas, a 2015 content analysis showed that 56% of visual cues and dialogues and 26% of major and minor storylines focused on sexual health, and while 8% of visual cues and dialogues and 20% of major and minor storylines focused on sexual orientation and gender identity, none presented information on sexual health and safe sex[1]; and

Whereas, a growing majority of young adults use online streaming services to consume television and media[4-5]; and

Whereas, stigma perpetuates harmful information in sexual education curricula, with many states negatively describing sex between LGBTQ+ individuals[6]; and

Whereas, online and social media education on safe sex (inclusive of LGBTQ+ individuals) can be an inexpensive and effective way to reach the LGBTQ+ community, including youth[7-8]; and

Whereas, existing AMA policy already urges television broadcasters, producers, and sponsors to encourage education about safe sex practices; therefore be it

RESOLVED, that our American Medical Association amend policy H-485.994, "Television Broadcast of Sexual Encounters and Public Health Awareness" by addition and deletion, to read as follows:

> Television Broadcast and Online Streaming of Sexual Encounters and Public Health Awareness on Social Media Platforms, H-485.994
> The AMA urges television broadcasters and online streaming services, producers, ~~and~~ sponsors, and any associated social media outlets to encourage education about heterosexual and LGBTQ+ inclusive safe sexual practices, including but not limited to condom use and abstinence, in television or online programming of sexual encounters, and to accurately represent the consequences of unsafe sex. (Modify Current HOD Policy)

Fiscal Note: Minimal – less than $1,000

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RELEVANT AMA POLICY

H-485.994 Television Broadcast of Sexual Encounters and Public Health Awareness

The AMA urges television broadcasters, producers, and sponsors to encourage education about safe sexual practices, including but not limited to condom use and abstinence, in television programming of sexual encounters, and to accurately represent the consequences of unsafe sex. [Res. 421, I-91; Reaffirmed: CSA Rep. 3, A-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15]

H-170.968 Sexuality Education, Sexual Violence Prevention, Abstinence, and Distribution of Condoms in Schools

(1) Supports the concept of sexuality education in the home, when possible, as well as developmentally appropriate sexuality education programming in the schools at all levels, at local option and direction;
(2) Urges schools at all education levels to implement comprehensive, developmentally appropriate sexuality education programs that: (a) are based on rigorous, peer reviewed science; (b) incorporate sexual violence prevention; (c) show promise for delaying the onset of sexual activity and a reduction in sexual behavior that puts adolescents at risk for contracting human immunodeficiency virus (HIV) and other sexually transmitted diseases and for becoming pregnant; (d) include an integrated strategy for making condoms and other effective barrier protection methods available to students and for providing both factual information and skill-building related to reproductive biology, sexual abstinence, sexual responsibility, contraceptives including condoms, alternatives in birth control, and other issues aimed at prevention of pregnancy and sexual transmission of diseases; (e) utilize classroom teachers and other professionals who have shown an aptitude for working with young people and who have received special training that includes addressing the needs of LGBTQ+ youth; (f) appropriately and comprehensively address the sexual behavior of all people, inclusive of sexual and gender minorities; (g) include ample involvement of parents, health professionals, and other concerned members of the community in the development of the program; (h) are part of an overall health education program; and (i) include culturally competent materials that are language-appropriate for Limited English Proficiency (LEP) pupils;
(3) Continues to monitor future research findings related to emerging initiatives that include abstinence-only, school-based sexuality education, and consent communication to prevent dating violence while promoting healthy relationships, and school-based condom availability programs that address sexually transmitted diseases and pregnancy prevention for young people and report back to the House of Delegates as appropriate;
(4) Will work with the United States Surgeon General to design programs that address communities of color and youth in high risk situations within the context of a comprehensive school health education program;

(5) Opposes the sole use of abstinence-only education, as defined by the 1996 Temporary Assistance to Needy Families Act (P.L. 104-193), within school systems;
(6) Endorses comprehensive family life education in lieu of abstinence-only education, unless research shows abstinence-only education to be superior in preventing negative health outcomes;
(7) Supports federal funding of comprehensive sex education programs that stress the importance of preventing unwanted teenage pregnancy and sexually transmitted infections via comprehensive education, including contraceptive choices, abstinence, and safer sex, and opposes federal funding of community-based programs that do not show evidence-based benefits; and
(8) Extends its support of comprehensive family-life education to community-based programs promoting abstinence as the best method to prevent teenage pregnancy and sexually-transmitted diseases while also discussing the roles of condoms and birth control, as endorsed for school systems in this policy;
(9) Supports the development of sexual education curriculum that integrates dating violence prevention through lessons on healthy relationships, sexual health, and conversations about consent; and
(10) Encourages physicians and all interested parties to develop best-practice, evidence-based, guidelines for sexual education curricula that are developmentally appropriate as well as medically, factually, and technically accurate. [CSA Rep. 7 and Reaffirmation I-99; Reaffirmed: Res. 403, A-01; Modified Res. 441, A-03; Appended: Res. 834, I-04; Reaffirmed: CSAPH Rep. 7, A-09; Modified: Res. 405, A-16; Appended: Res. 401, A-16; Appended: Res. 414, A-18; Appended: Res. 428, A-18; Modified: Res. 413, A-22]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 909
(I-23)

Introduced by: Medical Student Section

Subject: High Risk HPV Subtypes in Minoritized Populations

Referred to: Reference Committee K

Whereas, American Indian/Alaska Native (AI/AN) people continue to disproportionately suffer the highest rates of HPV-associated cervical cancer and are twice as likely to develop and four times as likely to die from cervical cancer as non-Hispanic whites[1,2]; and

Whereas, compared to other groups, AI/AN women are less likely to be screened for HPV, leading to inadequate high-risk HPV typing and surveillance in this population[3-4]; and

Whereas, despite greater HPV vaccine initiation, AI/AN patients were found to have higher rates of high-risk HPV (34.8%) compared to the national average (20.7%), including strains not included in the 9-valent HPV vaccine, such as HPV-51 in the Great Plains region[3]; and

Whereas, data is insufficient to account for significant variations in high-risk cervical cancer strains in AI/AN patients by geographic region (Northern Plains, Alaska, Southwest)[3,5-7]; and

Whereas, a study evaluating the number of racial and ethnic minoritized groups participating in clinical cancer trials found that only 0.048% of participants identified as AI/AN, despite comprising 2.9% of the US population[8-9]; and

Whereas, factors resulting in low research participation by members of minoritized groups include fear of discrimination by medical professionals, inability to access specialty care centers, a history of unethical medical testing, and insufficient time or financial resources[10]; and

Whereas, historical wrongs against AI/AN people, such as the unethical distribution of research samples of Havasupai tribal members and forced sterilization of AI/AN people across the nation, contribute to decreased participation by AI/AN people in research trials[11]; and

Whereas, AI/AN patients were insufficiently sampled for strains of high-risk HPV for vaccine development and vaccine impact studies, consistent with the overall underrepresentation of AI/AN individuals in vaccine clinical trials[3,6,12]; therefore be it

RESOLVED, that our American Medical Association amend H-440.872, “HPV Vaccine and Cervical and Oropharyngeal Cancer Prevention Worldwide,” by addition as follows:

> HPV Vaccine and Cervical and Oropharyngeal Cancer Prevention Worldwide H-440.872
> 1. Our AMA (a) urges physicians and other health care professionals to educate themselves and their patients about HPV and associated diseases, HPV vaccination, as well as routine HPV related cancer screening; and (b) encourages the development and funding of programs

targeted at HPV vaccine introduction and HPV related cancer screening in countries without organized HPV related cancer screening programs.

2. Our AMA will intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public.

3. Our AMA (a) encourages the integration of HPV vaccination and routine cervical cancer screening into all appropriate health care settings and visits; (b) supports the availability of the HPV vaccine and routine cervical cancer screening to appropriate patient groups that benefit most from preventive measures, including but not limited to low-income and pre-sexually active populations; and (c) recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination.

4. Our AMA encourages appropriate parties to investigate means to increase HPV vaccination rates by facilitating administration of HPV vaccinations in community-based settings including school settings.

5. Our AMA will study requiring HPV vaccination for school attendance.

6. Our AMA encourages collaboration with interested parties to make available human papillomavirus vaccination to people who are incarcerated for the prevention of HPV-associated cancers.

7. Our AMA supports further research by relevant parties of HPV self-sampling in the United States to determine whether it can decrease health care disparities in cervical cancer screening.

8. Our AMA advocate that racial, ethnic, socioeconomic, and geographic differences in high-risk HPV subtype prevalence be taken into account during the development, clinical testing, and strategic distribution of next-generation HPV vaccines. (Modify Current HOD Policy)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 09/27/2023

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RELEVANT AMA POLICY

H-440.872 HPV Vaccine and Cervical and Oropharyngeal Cancer Prevention Worldwide
1. Our AMA (a) urges physicians and other health care professionals to educate themselves and their patients about HPV and associated diseases, HPV vaccination, as well as routine HPV related cancer screening; and (b) encourages the development and funding of programs targeted at HPV vaccine introduction and HPV related cancer screening in countries without organized HPV related cancer screening programs.
2. Our AMA will intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public.
3. Our AMA (a) encourages the integration of HPV vaccination and routine cervical cancer screening into all appropriate health care settings and visits; (b) supports the availability of the HPV vaccine and routine cervical cancer screening to appropriate patient groups that benefit most from preventive measures, including but not limited to low-income and pre-sexually active populations; and (c) recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination.
4. Our AMA encourages appropriate parties to investigate means to increase HPV vaccination rates by facilitating administration of HPV vaccinations in community-based settings including school settings.
5. Our AMA will study requiring HPV vaccination for school attendance.
6. Our AMA encourages collaboration with interested parties to make available human papillomavirus vaccination to people who are incarcerated for the prevention of HPV-associated cancers.
7. Our AMA supports further research by relevant parties of HPV self-sampling in the United States to determine whether it can decrease health care disparities in cervical cancer screening.
[Res. 503, A-07; Appended: Res. 6, A-12; Reaffirmed: CSAPH Rep. 1, A-22; Reaffirmation: A-22; Modified: Res. 916, I-22; Modified: Res. 404, A-23; Appended: Res. 404, A-23]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 910
(I-23)

Introduced by: Medical Student Section

Subject: Sickle Cell Disease Workforce

Referred to: Reference Committee K

Whereas, patients with sickle cell disease (SCD) face barriers such as lack of specialized care, transportation issues, and geographic limitations[1-18]; and

Whereas, interdisciplinary services for patients with SCD may include primary care, specialty care (hematologists and physicians who specialize in SCD, cardiologists, pulmonologists, nephrologists, vascular neurologists, and surgeons), behavioral healthcare to help manage acute and chronic pain and psychiatric comorbidities, and educational and employment services to support patients whose school or work is often interrupted[19–21]; and

Whereas, comprehensive interdisciplinary care models for SCD gain direct expertise working with the multifaceted issues of SCD and demonstrated improved outcomes in symptom control, fewer acute hospitalizations, decreased overall costs, and reduced rates of life-threatening complications such as acute chest syndrome[19-26]; and

Whereas, increased access to specialized and interdisciplinary care can also reduce medical mistrust and reports of discrimination among patients with SCD, improve adherence to treatment plans, and increase patient satisfaction scores[27–36]; and

Whereas, multiple Congressional bills, including the Sickle Cell Disease Comprehensive Care Act and the Sickle Cell Disease Treatment Centers Act of 2022, aim to improve care for patients with SCD[37]; therefore be it

RESOLVED, that our American Medical Association amend H-350.973, “Sickle Cell Disease,” by addition to read as follows:

> Sickle Cell Disease H-350.973
> Our AMA:
> (1) recognizes sickle cell disease (SCD) as a chronic illness;
> (2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD;
> (3) supports the inclusion of SCD in newborn screening programs and encourages genetic counseling for parents of SCD patients and for young adults who are affected, carriers, or at risk of being carriers;
> (4) supports ongoing and new research designed to speed the clinical implementation of new SCD treatments;
> (5) recommends that SCD research programs have input in the planning stage from the local African American community, SCD patient advocacy

groups, and others affected by SCD;
(6) supports the development of an individualized sickle cell emergency care plan by physicians for in-school use, especially during sickle cell crises;
(7) supports the education of teachers and school officials on policies and protocols, encouraging best practices for children with sickle cell disease, such as adequate access to the restroom and water, physical education modifications, seat accommodations during extreme temperature conditions, access to medications, and policies to support continuity of education during prolonged absences from school, in order to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections; ~~and~~
(8) encourages the development of model school policy for best in-school care for children with sickle cell disease.
(9) supports expanding the health care and research workforce taking care of patients with sickle cell disease; and
(10) collaborates with relevant parties to advocate for improving access to comprehensive, quality, and preventive care for individuals with sickle cell disease, to address crucial care gaps that patients with sickle cell disease face and improve both the quality of care and life for patients affected by sickle cell disease. (Modify Current HOD Policy)

Fiscal Note: Moderate - between $5,000 - $10,000

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RELEVANT AMA POLICY

H-350.973 Sickle Cell Disease

(1) recognizes sickle cell disease (SCD) as a chronic illness;
(2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD;
(3) supports the inclusion of SCD in newborn screening programs and encourages genetic counseling for

parents of SCD patients and for young adults who are affected, carriers, or at risk of being carriers;
(4) supports ongoing and new research designed to speed the clinical implementation of new SCD treatments;
(5) recommends that SCD research programs have input in the planning stage from the local African American community, SCD patient advocacy groups, and others affected by SCD;
(6) supports the development of an individualized sickle cell emergency care plan by physicians for in-school use, especially during sickle cell crises;
(7) supports the education of teachers and school officials on policies and protocols, encouraging best practices for children with sickle cell disease, such as adequate access to the restroom and water, physical education modifications, seat accommodations during extreme temperature conditions, access to medications, and policies to support continuity of education during prolonged absences from school, in order to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections; and
(8) encourages the development of model school policy for best in-school care for children with sickle cell disease. [CLRPD Rep. 3, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Modified: BOT Rep. 12, A-11; Appended: Res. 906, I-19]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 913
(I-23)

Introduced by: Medical Student Section

Subject: Public Health Impacts of Industrialized Farms

Referred to: Reference Committee K

Whereas, an industrialized farm, also known as Concentrated Animal Feeding Operation (CAFO), refers to a facility that keeps a large number of animals confined for more than 45 days in any 12-month period[1]; and

Whereas, CAFOs are well-known sources of water and air pollution and are associated with numerous environmental and population health risks[2-7]; and

Whereas, residing in proximity to CAFOs is associated with increased transmission of zoonotic pathogens, development of antibiotic resistance, and increased risk of respiratory disease, acute gastrointestinal illness, urinary tract infections, autoimmune disease, adverse birth outcomes, anemia, kidney disease, and cardiovascular mortality[8-17]; and

Whereas, the adverse health effects of CAFOs tend to disproportionately affect communities of color, low-income communities, and rural communities[18-20]; and

Whereas, pollution from CAFOs is regulated by the Environmental Protection Agency (EPA) under the 1972 Clean Water Act and Clean Air Act[1]; and

Whereas, in 2019, the EPA signed an amendment stating CAFOs are exempt from the Emergency Planning and Community Right to Know Act (EPCRA) and the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA), which are statutes requiring industries to report when high levels toxic chemicals are released into the environment[21]; and

Whereas, in 2022, the EPA denied two petitions from groups asking it to revise its CAFO regulations and instead announced it will undertake a comprehensive evaluation of its guidelines and will incorporate feedback from stakeholders to inform its regulatory revisions[22]; therefore be it

RESOLVED, that our American Medical Association recognize Concentrated Animal Feeding Operations (CAFOs) as a public health hazard (New HOD Policy); and be it further

RESOLVED, that our AMA encourage the Environmental Protection Agency and appropriate parties to remove the regulatory exemptions for CAFOs under the Emergency Planning and Community Right-to-Know Act and the Comprehensive Environmental Response, Compensation, and Liability Act and tighten restrictions on pollution from CAFOs. (New HOD Policy)

Fiscal Note: Moderate - between $5,000 - $10,000

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22. US EPA O. Animal Agriculture Water Quality Subcommittee. Published August 14, 2023. Accessed September 16, 2023. https://www.epa.gov/npdes/animal-agriculture-water-quality-subcommittee

RELEVANT AMA POLICY

H-135.911 Environmental Health Equity in Federally Subsidized Housing

1. Our American Medical Association acknowledges the potential adverse health impacts of living in close proximity to Superfund sites or other contaminated lands.
2. Our AMA advocates for mandated disclosure of Superfund sites or other contaminated lands proximity to those purchasing, leasing, or currently residing in housing in close proximity to Superfund sites or other contaminated lands.

3. Our AMA supports efforts of public agencies to study the safety of proposed public housing expansions with respect to pollutant exposure and to expand construction of new public and publicly subsidized housing properties on lands without demonstrated unsafe levels of hazardous pollutants. [Res. 415, A-23]

H-135.998 AMA Position on Air Pollution
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. [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-14; Reaffirmation A-16; Reaffirmed: BOT Rep. 29, A-19]

H-135.996 Pollution Control and Environmental Health
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. [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]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 914
(I-23)

Introduced by: American Academy of Pediatrics
American Academy of Child & Adolescent Psychiatry

Subject: Adverse Childhood Experiences

Referred to: Reference Committee K

Whereas, Adverse Childhood Experiences (ACEs) are currently defined by a 1998 Kaiser Permanente and CDC study as stressful, traumatic events that occur during childhood which currently include episodes of physical, sexual or emotional abuse, physical and emotional neglect, familial mental illness, incarceration, substance use, having separated parents, and witnessing violence against the child's mother; and

Whereas, Current evidence shows 63.9% of adults in the US have experienced one or more ACEs; and

Whereas, Experiencing four or more ACEs significantly increases the risk of morbidity and mortality from chronic diseases including cardiovascular disease, depression, cancer, diabetes, obesity, and suicide; and

Whereas, Current research demonstrates preventing ACEs can reduce heart disease by 1.9 million cases and depression by 21 million cases; and

Whereas, Research on interventions aimed at children who experience ACEs can diminish the impact of these events on child behavioral and mental health problems by lowering metabolic, immunologic, neuroendocrine, and inflammatory activation while also enhancing the parent-child relationship, trust in clinicians, and utilization of healthcare; and

Whereas, The expanded categories of ACEs identified in The Philadelphia ACE Project are: witnessed violence, felt discrimination, unsafe neighborhood, experienced bullying, lived in foster care; and

Whereas, The World Health Organization's ACE International Questionnaire (ACE-IQ) recognizes additional ACEs including migration trauma; and

Whereas, The expanded categories of ACEs are more inclusive of historically marginalized communities better identifying at risk groups for chronic morbidity and mortality; and

Whereas, Studies have shown more than 50% of Black and Hispanic children have experienced at least one ACE; and

Whereas, The current limited definition of ACEs does not allow expansion based upon more current research identifying poverty, food insecurity, migration, foster care and bullying as additional ACEs; and

Whereas, Recent bicameral, bipartisan legislation was introduced in Congress to establish a national ACEs response team grant dedicating $40 million in federal resources towards prevention and early intervention efforts aimed at diminishing the impacts ACEs have upon the developing child; and

Whereas, The Mental Health Liaison Group, comprised by over 70 national organizations including the American Academy of Pediatrics, and American Psychiatric Association, and the American Academy of Child and Adolescent Psychiatry, wrote letters of support for the filed legislation while our AMA had not done so at the time of this resolution; and

Whereas, Preventing damage to the developing brain of a child, or at a minimum ameliorating the toxic stress which occurs during these Adverse Childhood Experiences saves lives and money; therefore be it

RESOLVED, That our American Medical Association collaborate with the Centers for Disease Control and Prevention (CDC) and other relevant interested parties to advocate for the addition of witnessing violence, experiencing discrimination, living in an unsafe neighborhood, experiencing bullying, placement in foster care, migration-related trauma, and living in poverty, and any additional categories as needed and justified by scientific evidence to the currently existing Adverse Childhood Experiences (ACEs) categories for the purposes of continuing to improve research into the health impacts of ACEs and how to mitigate them (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the CDC and other relevant interested parties to advocate for resources to expand research into ACEs and efforts to operationalize those findings into effective and evidence-based clinical and public health interventions (Directive to Take Action); and be it further

RESOLVED, that our AMA support the establishment of a national ACEs response team grant to dedicate federal resources towards supporting prevention and early intervention efforts aimed at diminishing the impacts ACEs have on the developing child. (New HOD Policy)

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

Received: 9/27/23

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915
(I-23)

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

Subject: Social Media Impact on Youth Mental Health

Referred to: Reference Committee K

Whereas, over the past decade, there has been a substantial increase in social media engagement among children and adolescents; and

Whereas, this trend has been further amplified during the COVID-19 pandemic, as digital connection became the default method of socialization for many across the country; and

Whereas, social media use is nearly universal among young people with up to 95% of teenagers are active online; and

Whereas, despite a minimum age requirement of 13 years on most U.S. platforms, nearly 40% of children aged 8-12 are on social media as well; and

Whereas, concurrently, rates of depression and anxiety among youth have surged; and

Whereas, data has shown that those who spend more than 3 hours per day on social media have double the risk of poor mental health and that the average teenager spends about 3.5 hours per day using social media platforms; and

Whereas, 46% of teens reported that social media contributes to negative feelings about their body image; and

Whereas, there is currently not enough evidence to conclude that social media use is sufficiently safe in this population; and

Whereas, the adolescent brain is at a vulnerable stage of development that can make adolescents and young adults prone to experiencing adverse effects from social media use, including disruptions in sleep patterns, fostering unrealistic self-comparisons, adopting avoidant coping strategies, engaging in cyberbullying, and encountering predatory behaviors; and

Whereas, our American Medical Association advocates that children’s mental health and barriers to mental health care access for children represent a national emergency that requires urgent attention from all interested parties; therefore be it

RESOLVED, that our American Medical Association work with relevant parties to develop guidelines for age-appropriate content and access and to develop age-appropriate digital literacy training to precede social media engagement among children and adolescents (Directive to Take Action); and be it further

RESOLVED, that our AMA amend policy D-478.965 by insertion as follows: (4) advocates for and support media and social networking services addressing and developing safeguards for users, including protections for youth online privacy, effective controls allowing youth and caregivers to manage screentime content and access, and to develop age-appropriate digital literacy training (Modify Current HOD Policy); and be it further

RESOLVED, that our AMA advocate that the federal government requires social media companies to share relevant data for further independent research on social media's effect on youth mental health and fund future federal research on the potential benefits and harms of social media use on youth mental health. (Directive to Take Action)

Fiscal Note: $251,462 Convene expert panel, develop & disseminate educational materials

Received: 9/27/23

Currently under study by CSAPH with a report due at the June 2024 HOD Annual Meeting.

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RELEVANT AMA POLICY

D-345.972 Mental Health Crisis
1. Our AMA will work expediently with all interested national medical organizations, national mental health organizations, and appropriate federal government entities to convene a federally-sponsored blue ribbon panel and develop a widely disseminated report on mental health treatment availability and suicide prevention in order to:
a) Improve suicide prevention efforts, through support, payment and insurance coverage for mental and behavioral health and suicide prevention services, including, but not limited to, the National Suicide Prevention Lifeline;
b) Increase access to affordable and effective mental health care through expanding and diversifying the mental and behavioral health workforce;
c) Expand research into the disparities in youth suicide prevention;
d) Address inequities in suicide risk and rate through education, policies and development of suicide prevention programs that are culturally and linguistically appropriate;
e) Develop and support resources and programs that foster and strengthen healthy mental health development; and
f) Develop best practices for minimizing emergency department delays in obtaining appropriate mental health care for patients who are in mental health crisis.
2. Our AMA supports physician acquisition of emergency mental health response skills by promoting education courses for physicians, fellows, residents, and medical students including, but not limited to, mental health first aid training.
3. Our AMA along with other interested parties will advocate that children's mental health and barriers to mental health care access for children represent a national emergency that requires urgent attention from all interested parties.
4. Our AMA will join with other interested parties to advocate for efforts to increase the mental health workforce to address the increasing shortfall in access to appropriate mental health care for children. [Res. 425, A-22; Appended: Res. 422, A-23]

D-478.965 Addressing Social Media and Social Networking Usage and its Impacts on Mental Health
Our AMA: (1) will collaborate with relevant professional organizations to: (a) support the development of continuing education programs to enhance physicians' knowledge of the health impacts of social media and social networking usage; and (b) support the development of effective clinical tools and protocols for the identification, treatment, and referral of children, adolescents, and adults at risk for and experiencing health sequelae of social media and social networking usage; (2) advocates for schools to provide safe and effective educational programs by which students can learn to identify and mitigate the onset of mental health sequelae of social media and social networking usage; (3) affirms that use of social media and social networking has the potential to positively or negatively impact the physical and mental health of individuals, especially adolescents and those with preexisting psychosocial conditions; (4) advocates for and support media and social networking services addressing and developing safeguards for users; and (5) advocates for the study of the positive and negative biological, psychological, and social effects of social media and social networking services use. [Res. 905, I-17; Modified: Res. 420, A-21; Reaffirmation: A-23]

H-478.976 Teens and Social Media
Our American Medical Association will study and make recommendations for teenage use of social media, including proposing model state and federal legislation as needed, with a report back at the 2024 Annual Meeting. [Res. 430, A-23]

H-60.934 Internet Pornography: Protecting Children and Youth Who Use the Internet and Social Media
Our AMA: (1) Recognizes the positive role of the Internet in providing health information to children and youth. (2) Recognizes the negative role of the Internet in connecting children and youth to predators and exposing them to pornography. (3) Supports federal legislation that restricts Internet access to pornographic materials in designated public institutions where children and youth may use the Internet. (4) Encourages physicians to continue efforts to raise parent/guardian awareness about the importance of educating their children about safe Internet and social media use. (5) Supports school-based media literacy programs that teach effective thinking, learning, and safety skills related to Internet and social media use. (6) Actively support legislation that would strengthen child-centric content protection by internet service providers and/or search engines in order to limit the access of pornography to minors on the internet and mobile applications. [BOT Rep. 10, I-06; Modified: CSAPH Rep. 01, A-16; Appended: Rep. 926, I-22]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 916
(I-23)

Introduced by: Washington, American Association of Public Health Physicians

Subject: Elimination of Buprenorphine Dose Limits

Referred to: Reference Committee K

Whereas, Washington state lost 2,910 citizens to death from drug overdoses, primarily fentanyl, in the year ending February 2023, a 23.9% increase over the previous year, far more than any other state[1]; and

Whereas, buprenorphine use reduces risk of opioid overdose death by at least 50%,[2] making it one of the two most effective treatments available for opioid use disorder (OUD); and

Whereas, keeping patients in treatment requires an effective dose that protects them from withdrawal symptoms and craving; and

Whereas, patients and prescribers encounter strict dose limits set by clinics, health systems, pharmacies and insurers based on guidelines set by the United States Food and Drug Administration (FDA) in 2021; and

Whereas, fentanyl currently in widespread use is 100 times more potent and far more lethal than the prescription pain medications that were the prevalent illicit opioids when the FDA's dosing guideline was set; and

Whereas, extensive research published over decades[4] shows that 1) buprenorphine's life-saving benefits are dose-dependent well above the FDA's guideline and 2) individualized dosing is most effective for keeping patients in treatment; therefore be it

RESOLVED, that our American Medical Association support flexibility in dosing of buprenorphine by elimination of non-evidence-based dose limits imposed by clinics, health systems, pharmacies and insurance carriers (New HOD Policy); and be it further

RESOLVED, that our AMA advocate for the elimination of non-evidence-based buprenorphine dose limits imposed by the United States Food and Drug Administration, clinics, health systems, pharmacies, and insurance carriers. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 9/27/23

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RELEVANT AMA POLICY

D-95.972 Expanding Access to Buprenorphine for the Treatment of Opioid Use Disorder
1. Our AMA's Opioid Task Force will publicize existing resources that provide advice on overcoming barriers and implementing solutions for prescribing buprenorphine for treatment of Opioid Use Disorder.

2. Our AMA supports eliminating the requirement for obtaining a waiver to prescribe buprenorphine for the treatment of opioid use disorder.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 917
(I-23)

Introduced by: New England

Subject: Advocating for Education and Action Regarding the Health Hazards of PFAS Chemicals

Referred to: Reference Committee K

Whereas, in 2019 the American Medical Association resolved to support research and policy to address the effects of PFAS exposure[1] and supported legislation and regulation seeking to address contamination, exposure, classification, and clean-up of per- and polyfluoroalkyl substances as follows:[2] “our AMA: (1) supports continued research on the impact of perfluoroalkyl and polyfluoroalkyl chemicals on human health; (2) supports legislation and regulation seeking to address contamination, exposure, classification, and clean-up of PFAS substances; and (3) will advocate for states, at minimum, to follow guidelines presented in the Environmental Protection Agency’s Drinking Water Health Advisories for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), with consideration of the appropriate use of Minimal Risk Levels (MRLs) presented in the CDC/ATSDR Toxicological Profile for PFAS”; and

Whereas, Per- and polyfluoroalkyl substances (PFAS), are a large class of chemicals with at least one aliphatic perfluorocarbon moiety; this carbon - fluorine bond is exceptionally strong and therefore highly resistant to degradation; thus the moniker “forever chemicals” because these chemicals persist, have the potential to bioaccumulate and become more concentrated in the environment with the passage of time;[3] and

Whereas, PFAS are ubiquitous: they are found in “non-stick” products that resist stains, oil, grease, and water including cookware,[4] artificial turf, clothing, leather, carpets, food packaging, firefighting foam, cosmetics, shampoos, sunscreens, pesticides; medical equipment such as PPE, masks, gowns, IV tubing, and medications;[5] and petroleum extraction (“fracking”) fluids;[6] the latter are sometimes repurposed as road salt or as “biosolids” that are then spread on crops[7]; and

Whereas, the PFAS chemicals PFOA and PFOS have recently been designated by the US EPA as hazardous substances that can be responded to via Superfund;[8] and while the EPA has set health advisory levels at between 0.002 and 0.004 ng/L, health effects, according to the EPA, can occur at any level;[9] and

Whereas, PFAS exposure has been associated with endocrine disruption, immune suppression, impaired organogenesis, damage to reproductive organs, and hepatotoxicity; low infant birth weight, preeclampsia,[10] impaired fertility, obesity, Type 2 diabetes, harms to neurocognitive and behavioral development in children, and malignancies, including prostate, kidney, and testicular cancer;[11] and

Whereas, PFAS exposure occurs via food, air, and water, including drinking water and rain;[12] water can become contaminated when PFAS leaches into water supplies from plastic containers, landfills, industrial and agricultural runoff, or following pesticide spraying (PFOS has been detected in 6/10 tested pesticides at levels between 3.92 to 19.2 mg/kg);[13] other common

sources of exposure include: ingestion of contaminated dust (from carpets, upholstery, etc.) as well as migration into food or beverages from boxes/packaging/plastic bottles); in infants, toddlers, and children, hand-to-mouth behavior is a significant source of exposure; and

Whereas, PFAS has direct impacts on the practice of medicine since they are used extensively in medical products, including medications, IV tubing, and PPE;[14] pharmaceuticals often include a fluorine molecule to increase cell permeability to Increase uptake;[15] and persons with high PFAS levels may be less responsive to certain medications, like vaccines;[16] and

Whereas, like lead, exposure to PFAS is widespread, but like lead, mitigating exposure and focusing on children and adults who are highly exposed is helpful since these persons can then be identified and helped (ie, parents can be cautioned to use a different, PFAS-free water source to use to make up baby formula, etc); like lead, limiting length and extent of high exposure could potentially improve health outcomes; and

Whereas, PFAS chemicals disproportionately pose challenges to low income and minority communities: some of the highest levels found across the country exist in lower income communities, even when the exposure hazard is not disproportionate between low and high income communities, the ability to respond with adequate filtration and monitoring efforts is unequal; and

Whereas, the National Academy of Science, Engineering and Medicine has recommended[17] that individuals with significant exposure to PFAS (including those who live near commercial airports, military bases and farms where sewage sludge may have been used) be tested and receive ongoing medical monitoring; PFAS blood testing in the population based C8 Dupont study in 69,030 participants was essential in determining associated health conditions with PFAS chemicals;[18,19] and PFAS blood tests are currently available through Quest and other providers;[20] and

Whereas, 99% of United States residents have various PFAS detectable in their blood[21]; and

Whereas, Newly developed educational resources on PFAS are available and include a free CME course on PFAS and comprehensive medical information and guidance on PFAS-REACH project's website (funded by the NIH's National Institute of Environmental Health Sciences (NIEHS))[22] and the July 2022 National Academy of Science, Engineering and Medicine report on PFAS;[23] therefore be it

RESOLVED, that our American Medical Association improve physician and public education around the adverse health effects of PFAS and potential mitigation and prevention efforts. (Directive to Take Action)

Fiscal Note: $51,420 Develop continuing medical education module

Received: 10/3/23

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RELEVANT AMA POLICY

Per- and Polyfluoroalkyl Substances (PFAS) and Human Health H-135.916

Our AMA: (1) supports continued research on the impact of perfluoroalkyl and polyfluoroalkyl chemicals on human health; (2) supports legislation and regulation seeking to address contamination, exposure, classification, and clean-up of (PFAS) substances; and (3) will advocate for states, at minimum, to follow guidelines presented in the Environmental Protection Agencys Drinking Water Health Advisories for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), with consideration of the appropriate use of Minimal Risk Levels (MRLs) presented in the CDC/ATSDR Toxicological Profile for (PFAS).

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 918
(I-23)

Introduced by: New England

Subject: Condemning the Universal Shackling of Every Incarcerated Patient in Hospitals

Referred to: Reference Committee K

Whereas, as of February 1, 2022, there are 6,033 total male individuals, of whom 5,440 are criminally sentenced, 24 are pre-trial detainees, and 569 face civil commitments, and 199 total female individuals, of whom 155 are criminally sentenced, 40 are pre-trial detainees, and 4 face civil commitments, who are in the jurisdiction of the Massachusetts Department of Corrections;[i] and

Whereas, in 2021, the average male justice-involved individual was 44 years old and the average female justice-involved individual was 42 years old in Massachusetts, with 951 individuals 60 years of age and over as of January 1, 2021,[ii] and average age of individuals who are incarcerated rising concurrently with their health needs;[iii] and

Whereas, in 2016, about 43% of federal justice-involved individuals reported ever having a chronic condition, 33% reported currently having a chronic condition, and 31% had medical visits outside of carceral facilities;[iv] and

Whereas, people of color are overrepresented in prisons and jails in Massachusetts, with Whites accounting for 76% of the state population but 49% of prison or jail population, Blacks accounting for 7% of the state population but 26% of prison or jail population, and Latinos accounting for 10% of the state population but 24% of prison or jail population;[v] and

Whereas, US carceral facilities provide health care for justice-involved individuals in both on-site and off-site facilities depending on the type of service, with emergency, obstetrics, gynecology, and cardiology procedural services more commonly provided at non-carceral hospital facilities;[vi] and

Whereas, universal shackling in a hospital refers to the placement of metal restraints around the legs, wrists, or waist of justice-involved patients, regardless of age, illness, mobility, or criminal record disposition,[vii] with the recent exception of perinatal patients in Massachusetts; and

Whereas, Massachusetts enacted legislation in 2014 to prevent perinatal shackling, or the use of shackles for patients who are incarcerated and pregnant, in labor, or in postpartum recovery, by correction officers while the attending physician or nurse treating the perinatal patient may request immediate removal of restraints;[viii] and

Whereas, our American Medical Association has model state legislation to prohibit the practice of shackling pregnant prisoners;[ix] and

Whereas, US Senators Elizabeth Warren and Corey Booker introduced the Dignity for Incarcerated Women Act in 2017,[x] and the First Step Act of 2018 placed a federal prohibition on

the use of restraints on individuals who are pregnant and in the custody of the federal Bureau of Prisons or the US Marshals Service;[xi,xii] and Whereas, Thirty-two states have implemented some form of restriction on perinatal shackling, with 13 states banning shackling throughout pregnancy, labor, postpartum, and during transport between carceral and health care facilities;[xiii] and

Whereas, physicians and nurses in hospitals routinely assess the necessity of physical or pharmacological restraints on non justice–involved patients who may harm themselves or others, as well as document their use in the electronic medical record with descriptions of the reason for restraint, form of restraint, and periodic re-evaluations of continued need for restraint and any consequence on patient health;[xiv,xv] and

Whereas, the use of restraints on non justice–involved patients in the hospital setting is regulated by the Centers for Medicare and Medicaid Services, which mandate that the least restrictive form of restraint that protects the safety of the patient, health care staff, and others is used;[xvi,xvii] and

Whereas, shackling patients under special circumstances including, but not limited to, old age, loss of consciousness, terminal illness, or limited mobility, is unnecessary and excessive restraint, thus cruel, inhuman, and degrading as defined by the Universal Declaration of Human Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, and the International Covenant on Civil and Political Rights [xviii,xix,xx] and in violation of the medical ethics principle of nonmaleficence; and

Whereas, physical restraint use on patients is associated with delays in necessary emergency operations, increased falls and deliriums, as well as elevated risks of in-hospital deaths and venous thrombosis;[xxi,xxii] and

Whereas, in psychiatric settings, restraints have led to inappropriate actions by staff, invoking a fear response in patients and a loss of trust in the psychiatric staff,[xxiii] ultimately causing patients to be less likely to follow their treatment plan, use medical care, or consent to a surgical procedure;[xxiv] and

Whereas, formerly justice-involved individuals of color who experienced discrimination in healthcare settings due to their criminal records are less likely to use primary care resources upon release,[xxv] report worse mental and physical health following their release,[xxvi] and are more likely to report increased psychological distress;[xxvii] and

Whereas, physicians have written about the moral injury and contribution to physician burnout due to practicing in hospitals that routinely shackle every justice-involved patient;[xxviii,xxix] and

Whereas, violence against health care workers is of critical importance that should be addressed through effective hospital security protocols and staff training;[xxx] and

Whereas, current hospital policies for shackling in Massachusetts align with policies governing the shackling of non-justice-involved patients only in regard to justice-involved pregnant individuals, yet permit the universal shackling of all non-pregnant justice-involved patients, regardless of other special circumstances including, but not limited to, old age, loss of consciousness, terminal illness, or limited mobility; therefore be it

RESOLVED, that our American Medical Association condemns the practice of universally shackling every patient who is involved with the justice system while they receive care in

hospitals and outpatient health care settings (New HOD Policy); and be it further

RESOLVED, that our AMA advocate for the universal assessment of every individual who is involved with the justice system who presents for care, by medical and security staff in collaboration with correctional officers, to determine whether shackles are necessary or may be harmful, and, if restraint is deemed necessary, that the least restrictive alternative to shackling with metal cuffs is used when appropriate (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate nationally for the end of universal shackling, to protect human and patient rights, improve patient health outcomes, and reduce moral injury among physicians. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/3/23

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RELEVANT AMA POLICY

Shackling of Pregnant Women in Labor H-420.957

1. Our AMA supports language recently adopted by the New Mexico legislature that "an adult or juvenile correctional facility, detention center or local jail shall use the least restrictive restraints necessary when the facility has actual or constructive knowledge that an inmate is in the 2nd or 3rd trimester of pregnancy. No restraints of any kind shall be used on an inmate who is in labor, delivering her baby or recuperating from the delivery unless there are compelling grounds to believe that the inmate presents:

- An immediate and serious threat of harm to herself, staff or others; or
- A substantial flight risk and cannot be reasonably contained by other means.

If an inmate who is in labor or who is delivering her baby is restrained, only the least restrictive restraints necessary to ensure safety and security shall be used."

2. Our AMA will develop model state legislation prohibiting the use of shackles on pregnant women unless flight or safety concerns exist.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 919
(I-23)

Introduced by: Indiana

Subject: Lithium Battery Safety

Referred to: Reference Committee K

Whereas, more pieces of equipment utilize lithium batteries; and

Whereas, lithium batteries have limited useful lifetime use; and

Whereas, disposal and recycling of lithium batteries is not a well-established system; and

Whereas, improper storage of lithium batteries can lead to fires; and

Whereas, putting out lithium battery fires can be difficult and requires robust resources; and

Whereas, rural communities' fire department coverage resources can be less robust and less able to handle lithium battery fires; and

Whereas, local agencies often are not aware of lithium battery storage in their area; therefore be it

RESOLVED, that our American Medical Association seek legislation to increase environmental and public safety oversight of lithium batteries and businesses that store and dispose of lithium batteries. (Directive to Take Action)

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

Received: 10/4/23

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 920
(I-23)

Introduced by: Indiana

Subject: Antipsychotic Medication Use for Hospice Patients

Referred to: Reference Committee K

Whereas, antipsychotic medications are associated with increased morbidity and mortality in the geriatric population; and

Whereas, antipsychotic medication use is often prohibited in skilled facilities, so many hospice patients do not experience relief of their distress with the use of medications that are acceptable at nursing facilities; and

Whereas, hospice patients are a unique population that often remain in their current living environment during their end-of-life journey, particularly in patients with dementia who often struggle with behavioral issues; and

Whereas, hospice patients have different goals for their care than other residents of skilled facilities, and one common goal of caring for hospice patients is to allow them to remain in their preferred environment to avoid further distress; and

Whereas, hospice patients develop behaviors that are often difficult to manage in response to their terminal state, but they do respond to anti-psychotic medications; therefore be it

RESOLVED, that our American Medical Association seek legislation or regulatory changes that exempt hospice patients from limitations on the use of antipsychotic medications for behavioral changes. (Directive to Take Action)

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

Received: 10/4/23

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 921
(I-23)

Introduced by: Women Physicians Section

Subject: Addressing Disparities and Lack of Research for Endometriosis

Referred to: Reference Committee K

Whereas, endometriosis is defined as a medical condition in which endometrial-like tissue from the uterus grows in a location outside of the uterus[1]; and

Whereas, an estimated 11% of women in the United States have endometriosis, though this was noted to be a conservative estimate, as the actual percentage of patients with this condition would likely increase when considering individuals with symptoms below the clinical threshold or a patient population containing of all individuals with uteruses[2]; and

Whereas, endometriosis is the third most common cause of gynecological-related hospitalization and when patient populations are stratified by diagnostic indicators, the incidence of endometriosis were found to be as high as 71.4%[4,3]; and

Whereas, endometriosis is one of the most common reproductive conditions among women compared to 11% of women of reproductive age experience infertility, 5-10% experiencing Polycystic Ovarian Syndrome (PCOS), and 0.7% experiencing cervical cancer[5-7]; and

Whereas, although novel mechanisms contributing to the development of endometriosis have been suggested, there is currently no single, widely accepted etiology for endometriosis[8-10]; and

Whereas, symptoms of endometriosis vary from asymptomatic to severe pelvic pain, and bleeding, many symptoms of endometriosis can have multiple causes, making endometriosis difficult to diagnose[11]; and

Whereas, the most common classification system of endometriosis, the revised American Society of Reproductive Medicine (rASRM) classification system, was created in 1968 and considers endometriosis involvement of the peritoneum, fallopian tubes, ovaries, and cul-de-sac, but has been found to have numerous disadvantages, indicating the need for additional research to improve this system[12,13]; and

Whereas, the length of time for a patient to receive an endometriosis diagnosis appears to have decreased in recent years, a diagnosis of endometriosis typically takes an average of 4-11 years, and the amount of time for diagnosis in Black and Hispanic women is considerably higher [14,15, 31]; and

Whereas, multiple studies have suggested that diet may play an important role in alleviating endometriosis symptoms, however, the studies are limited with small sample sizes, which further points to the growing need for additional endometriosis research and awareness[16-18]; and

Whereas, in the current endometriosis research that does exist, small sample sizes are common, which prevents the creation of evidence-based guidelines for practitioners[16-18]; and

Whereas, endometriosis has been found to have a significant negative impact on the quality of life of those diagnosed, including increased cost of healthcare, higher healthcare resource utilization, and decreased productivity at both home and workplace[19-21]; and

Whereas, black and Hispanic patients are less likely to receive a diagnosis of endometriosis than their White or Asian counterparts, further contributing to a delay in diagnosis and placing a disproportionate healthcare burden on these patients[22]; and

Whereas, the American Journal of Obstetrics and Gynecology has previously noted the prolonged period between presentation of endometriosis symptoms and treatment for or diagnosis of endometriosis, as well as the health disparities this may cause[15]; and

Whereas, a majority of recommendations for practice regarding endometriosis from the American Academy of Family Physicians are based on consensus, expert opinion, and disease-oriented evidence rather than research, indicating the need for additional endometriosis research to improve endometriosis guidelines for physician practice[23]; and

Whereas, the American College of Obstetricians and Gynecologists has multiple practice guidelines based on scientific evidence that outline different combinations of medication and surgical intervention as treatment options for endometriosis, but many are dependent on a prior diagnosis of endometriosis[24]; and

Whereas, the American Society of Reproductive Medicine has multiple fact sheets on endometriosis available for patients, but no practice documents for practitioners specifically dedicated to endometriosis[25]; and

Whereas, it is clear that additional research is needed to understand symptoms, causes, and treatment of endometriosis, however the National Institute of Health (NIH) dedicates only 0.038% of the overall NIH budget to endometriosis research[26]; and

Whereas, endometriosis research continues to remain an extremely underfunded area of women's health research, even after recent legislation increased endometriosis research funding from $13 million to $26 million in 2020[27]; and

Whereas, in 2022, endometriosis, a condition affecting approximately 11% of women, is allocated only $27 million of the $45 billion NIH research budget, while inflammatory bowel disease, a condition affecting 1.3% of all patients, is allocated $195 million dollars for research[28-30]; and

Whereas, current AMA Policy H-525.988 currently supports increased funding for women's health research, but fails to specifically highlight the dire need for endometriosis research and does not take measurable action or advocacy to achieve these increases in research; and

Whereas, endometriosis research continues to remain significantly underfunded since the passage of this H-525.988 and its subsequent modification in 2010, indicating a persistent policy gap and the need for an additional resolution to specifically address this gap for patients with endometriosis; therefore be it

RESOLVED, that our American Medical Association collaborate with stakeholders to recognize endometriosis as an area for health disparities research that continues to remain critically

underfunded, resulting in a lack of evidence-based guidelines for diagnosis and treatment of this condition amongst people of color (Directive to Take Action); and be it further

RESOLVED, that our AMA collaborate with stakeholders to promote awareness of the negative effects of a delayed diagnosis of endometriosis and the healthcare burden this places on patients, including health disparities among patients from communities of color who have been historically marginalized (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate for increased endometriosis research addressing health disparities in the diagnosis, evaluation, and management of endometriosis (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate for increased funding allocation to endometriosis-related research for patients of color, especially from federal organizations such as the National Institutes of Health. (Directive to Take Action)

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

Received: 10/5/23

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RELEVANT AMA POLICY

Sex and Gender Differences in Medical Research H-525.988
Our AMA:
(1) reaffirms that gender exclusion in broad medical studies questions the validity of the studies' impact on the health care of society at large;
(2) affirms the need to include all genders in studies that involve the health of society at large and publicize its policies;
(3) supports increased funding into areas of women's health and sexual and gender minority health research;
(4) supports increased research on women's health and sexual and gender minority health and the participation of women and sexual and gender minorities in clinical trials, the results of which will permit development of evidence-based prevention and treatment strategies for all women and sexual and gender minorities from diverse cultural and ethnic groups, geographic locations, and socioeconomic status;
(5) recommends that all medical/scientific journal editors require, where appropriate, a sex-based and gender-based analysis of data, even if such comparisons are negative; and
(6) recommends that medical and scientific journals diversify their review processes to better represent women and sexual and gender minorities. [Res. 80, A-91; Appended: CSA Rep. 4, I-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 05, A-16; Modified: Res. 004, A-23]

An Expanded Definition of Women's Health H-525.976
Our AMA recognizes the term "women's health" as inclusive of all health conditions for which there is evidence that women's risks, presentations, and/or responses to treatments are different from those of men, and encourages that evidence-based information regarding the impact of sex and gender be incorporated into medical practice, research, and training. [CSAPH Rep. 05, A-16]

Racial and Ethnic Disparities in Health Care H-350.974
1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The

elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.
2. The AMA emphasizes three approaches that it believes should be given high priority:
A. Greater access - the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.
B. Greater awareness - racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.
C. Practice parameters - the racial disparities in access to treatment indicate that inappropriate considerations may enter the decision making process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities
3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.
4. Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations. [CLRPD Rep. 3, I-98; Appended and Reaffirmed: CSA Rep.1, I-02; Reaffirmed: BOT Rep. 4, A-03; Reaffirmed in lieu of Res. 106, A-12; Appended: Res. 952, I-17; Reaffirmed: CMS Rep. 10, A-19; Reaffirmed: CMS Rep. 3, A-21; Reaffirmed: Joint CMS/CSAPH Rep. 1, I-21]

Reducing Racial and Ethnic Disparities in Health Care D-350.995
Our AMA's initiative on reducing racial and ethnic disparities in health care will include the following recommendations:
(1) Studying health system opportunities and barriers to eliminating racial and ethnic disparities in health care.
(2) Working with public health and other appropriate agencies to increase medical student, resident physician, and practicing physician awareness of racial and ethnic disparities in health care and the role of professionalism and professional obligations in efforts to reduce health care disparities.
(3) Promoting diversity within the profession by encouraging publication of successful outreach programs that increase minority applicants to medical schools, and take appropriate action to support such programs, for example, by expanding the "Doctors Back to School" program into secondary schools in minority communities. [BOT Rep. 4, A-03; Reaffirmation A-11; Reaffirmation: A-16; Reaffirmed: CMS Rep. 10, A-19]

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

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

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

(a) Provide care that meets patient needs and respects patient preferences.

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

The medical profession has an ethical responsibility to:

(g) Help increase awareness of health care disparities.
(h) Strive to increase the diversity of the physician workforce as a step toward reducing health care disparities.
(i) Support research that examines health care disparities, including research on the unique health needs of all genders, ethnic groups, and medically disadvantaged populations, and the development of quality measures and resources to help reduce disparities.

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

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law. [Issued: 2016]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 922
(I-23)

Introduced by: American Association of Neurological Surgeons, Congress of Neurological Surgeons, California

Subject: Prescription Drug Shortages and Pharmacy Inventories

Referred to: Reference Committee K

Whereas, opioid and other drug shortages have become common; and

Whereas, physicians cannot know or predict inventories at any given pharmacy; and

Whereas, physicians are often asked to write new prescriptions to allow medications to be filled at an alternate pharmacy; and

Whereas, requests for new prescriptions often come days later when the original prescriber may not be available; and

Whereas, many states no longer accept paper prescriptions, which allowed prescriptions to be presented to more than one pharmacy when necessary; and

Whereas, requiring a new prescription can delay the availability of critical medications or critical prescription medications; therefore be it

RESOLVED, that our American Medical Association work with the pharmacy industry to develop and implement a mechanism to transfer prescriptions without requiring a new prescription (Directive to Take Action); and be it further

RESOLVED, that our AMA advocate for legislation and/or regulations permitting pharmacies to transfer prescriptions to other pharmacies when prescription medications are unavailable at the original pharmacy or the patient requests the prescription be transferred. (Directive to Take Action)

Fiscal Note: Moderate - between $5,000 - $10,000

Received: 10/11/23

RELEVANT AMA POLICY

Access to Medication H-120.920
Our AMA will advocate against pharmacy practices that interfere with patient access to medications by refusing or discouraging legitimate requests to transfer prescriptions to a new pharmacy, to include transfer of prescriptions from mail-order to local retail pharmacies.

Legalization of Interpharmacy Transfer of Electronic Controlled Substance Prescriptions H-120.923
Our AMA will advocate for the removal of state, federal and other barriers that impede interpharmacy transfers of valid electronic prescriptions for Schedule II-V medications.